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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

SWITZERLAND

Brugg, Switzerland

20 November to 2 December 2011

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
REPORT TO
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Mission date: *20 November to 2 December 2011*
Regulatory body: *ENSI*
Location: *ENSI HQ in Brugg, SWITZERLAND*
Regulated facilities and practices: *Nuclear power plants, Research Reactors, Waste Management Facilities, Decommissioning, Radiation Protection', Transport*
Organized by: *International Atomic Energy Agency (IAEA)*

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

CONTENT

I. 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 20 November to 02 December 2011, in order to conduct an Integrated Regulatory Review Service (IRRS) Mission. The mission took place at the headquarters of ENSI in Brugg.

The purpose of this IRRS mission was to review the effectiveness of the Swiss framework for safety within the competence of ENSI. This IRRS mission was the fifth to be conducted after the occurrence of the TEPCO-Fukushima Dai-ichi accident. Accordingly, special attention was given to the regulatory implications of the TEPCO-Fukushima Dai-ichi accident in the Swiss framework for safety, as part of a newly developed core IRRS module.

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

The IRRS review team consisted of 18 senior regulatory experts from 14 IAEA Member States, one observer, 4 staff members from the IAEA and an IAEA administrative assistant. The IRRS review team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; regulations and guides; emergency preparedness and response; interfaces with nuclear security; occupational radiation protection, environmental monitoring; control of radioactive discharges and materials for clearance; waste management; and transport.

The IRRS mission also included the following Regulatory Policy Issues for discussion: response to the TEPCO-Fukushima Dai-ichi accident; long term operation of nuclear power plants, interfaces with other authorities and openness, transparency and stakeholders' involvement. The IRRS review addressed all facilities and activities regulated by ENSI: five nuclear power plants, three research reactors and spent fuel and waste management facilities. Radiation sources in non-nuclear facilities, which are not regulated by ENSI were not included in the scope.

The mission included observations of regulatory activities and a series of interviews and discussions with ENSI staff and other organizations to help assess the effectiveness of the regulatory system. These activities included visits to: Beznau, Leibstadt and Mühleberg nuclear power plants, External Storage Facility for emergency equipment, ENSI Emergency Response Centre, ZWILAG, Central Interim Storage Facility and National Cooperative for the Disposal of Radioactive Waste. Throughout the review of the various areas and policy issues, special consideration was given to the implications of the TEPCO-Fukushima Dai-ichi accident for the Swiss Regulatory System. The IRRS team members observed the working practices during inspections carried out by ENSI, including discussions with the licensee personnel and management. In addition the IRRS team observed one of the NPPs annual emergency exercises, which was conducted simultaneously at three locations (NPP Gösgen, National Emergency Operation Centre (NEOC) in Zurich and ENSI's Emergency Response Centre).

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

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

The Swiss government recently established a new regulatory framework for the oversight of nuclear safety. The Act establishing ENSI as the national regulatory authority with responsibility for the nuclear safety and security of Swiss nuclear facilities became effective in 2009. ENSI works within a complex framework that includes the Federal Council, responsible for issuing regulations and the general licence as well as the Department of the Environment, Transport, Energy and Communications, responsible for issuing the construction and operating licences.

The main observations of the IRRS review team were the following:

- ENSI operates as an independent regulator and does that in an open and transparent manner and its regulatory processes are well organized and integrated in a strong management system.
- ENSI benefits from having mature, competent staff with a wide range of specialists.
- To continuously evaluate the safety of the nuclear power plants, ENSI uses a systematic safety assessment process which integrates inspection findings based on their safety significance, plant performance indicators and operating experience in its comprehensive regulatory oversight of nuclear safety and security.
- ENSI ordered operators to promptly implement first measures in response to the TEPCO Fukushima Dai-ichi accident and developed an action plan based on a comprehensive analysis of the accident to improve the Swiss NPP's robustness to external events.

Among the good practices identified by the IRRS review team are the following:

- ENSI ensures that licensees' practices for back-fitting continuously improve safety and stay current with technology. Back-fitting rules have clear criteria on the safety goals that must be fulfilled, and back-fitting must be considered in the implementation of lessons learned from operational events.
- ENSI's management system is properly established, is process-oriented, comprehensive, user friendly and contributes to staff efficiency and effectiveness in conducting regulatory oversight.
- There is good coordination and cooperation between federal and cantonal organizations as well as with the neighbouring countries in the field of national nuclear emergency preparedness and response.
- The sectorial plan for the national radioactive waste disposal repositories is safety based and is an open and transparent process.

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

- ENSI should have the authority to issue regulatory requirements and to formulate binding conditions to be fully reflected in various authorizations, whenever it is necessary, to assure public health safety and security.
- The relevant authorities, commissions and committees involved in nuclear safety matters should provide their recommendations and advice directly to ENSI before it issues its final decisions. This should be done in an open and transparent manner.
- ENSI needs to continue its efforts to mature and develop its regulatory framework with respect to defining its graded approach to safety, furthering its inspection program in all areas, but especially in waste, decommissioning and transport and to collaborate with other inspection bodies.

The IRRS review team findings are summarized in Appendix V and VI.

A joint IAEA and ENSI press conference took place at the end of the mission during which an IAEA press release was issued.

II. INTRODUCTION

At the request of the Government of Switzerland, an international team of 19 senior safety experts met representatives of the Swiss Federal Nuclear Safety Inspectorate (ENSI), from 20 November to 02 December 2011, in order to conduct an Integrated Regulatory Review Service (IRRS) Mission to review the Swiss regulatory framework for nuclear and radiation safety within the competence of ENSI and its effectiveness.

There was a preparatory mission in May 2011 carried out at ENSI Headquarters to discuss the objective, purpose and consequently the preparations of the review as well as its scope in connection with the areas regulated by ENSI and selected safety aspects.
The IRRS review team consisted of 18 senior regulatory experts from 14 IAEA Member States, one observer, 4 staff members from the IAEA and an IAEA administrative assistant. The IRRS review team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; regulations and guides; emergency preparedness and response; occupational radiation protection, environmental monitoring; control of radioactive discharges and materials for clearance; waste management; and transport.

This IRRS mission was the fifth to be conducted after the occurrence of the TEPCO-Fukushima Dai-ichi accident. Accordingly, special attention was given to the regulatory implications of the TEPCO-Fukushima Dai-ichi accident in the Swiss framework for safety, as part of a newly developed core IRRS module.

In addition, policy issues were addressed, including: response to the TEPCO-Fukushima Dai-ichi accident; long term operation of nuclear power plant, interfaces with other authorities and openness, transparency and stakeholders' involvement. The additional areas added to the core modules of the IRRS were: occupational radiation protection, environmental monitoring; control of radioactive discharges and materials for clearance; waste management; and transport.

ENSI prepared substantial documentation as advance reference material and a well prepared self-assessment. During the mission the IRRS review team performed a systematic review of all topics using the advance reference material, conducted interviews with management and staff from ENSI, ENSI Board and performed direct observation of the working practices during inspections. Meetings with other administrations involved in the national regulatory infrastructure for safety were also organized, with the Federal Office of Energy (SFOE), Federal Office of Public Health (FOPH), and Swiss Accident Insurance Fund (SUVA), authorities responsible for emergency preparedness (representatives of Federal Authorities, Cantons and Germany).

Meetings were also organized with the Secretary General of the Federal Department of the Environment, Transport, Energy and Communications (DETEC), Swiss Federal Nuclear Safety Commission (NSC), Swiss Association for Technical Inspections (SVTI), Commission for Nuclear Waste Disposal (KNE), Federal Commission for Radiation Protection and Radioactivity Monitoring (KSR), National Cooperative for the Disposal of Radioactive Waste (Nagra) and Paul Scherrer Institute (PSI).

All through the mission the IRRS team received excellent and open co-operation from ENSI, questions from the IRRS team members were fully answered, documents requested were presented and explained and additional discussion sessions were organized.

III. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of the Swiss nuclear regulatory framework and regulatory activities to review its regulatory effectiveness and to exchange information and experience in the areas covered by IRRS. The facilities and activities addressed by the review were all facilities and activities regulated by ENSI, namely the five nuclear power plants (Beznau I and II, Mühleberg, Gösgen and Leibstadt) three research reactors, spent fuel and waste management facilities. The review was carried out by comparison against IAEA safety standards as the international benchmark for safety.

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

The key objectives of this mission were to enhance nuclear safety and emergency preparedness:

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

IV. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Swiss Government authorities, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 23 to 24 May 2011. The preparatory meeting was carried out by the appointed Team Leader Mr Jean-Christophe Niel, Deputy Team Leader Mr Eric Leeds, and the IRRS IAEA Team representatives, Mr Gustavo Caruso, Mr Ahmad Al Khatibeh and Mr Peter Zombori.

The IRRS mission preparatory team had extensive discussions regarding regulatory programmes and policy issues with the senior management of ENSI represented by Mr Hans Wanner, Director and Mr Georg Schwarz, Deputy Director, representatives of ENSI Board and other members of ENSI senior management and staff. The discussions resulted in the following areas to be covered by the IRRS mission:

- Nuclear Power Plants
- Research Reactors
- Waste Facilities
- Decommissioning
- Occupational Radiation Protection
- Control of Radioactive Discharges and Materials for Clearance
- Environmental Monitoring
- Waste Management (policy and strategy, predisposal and disposal)
- Transport
- Selected policy issues

Mr Wanner, Mr Schwarz and ENSI staff made comprehensive presentations on the current status of ENSI, the self-assessment results to date. IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the work plan for the implementation of the IRRS in Switzerland in November 2011.

The proposed IRRS review team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS review team was confirmed. Logistics including meeting and work space, counterpart identification, lodging and transportation to accommodate site visits and observations were also addressed. In September 2011, ENSI provided IAEA with the advance reference material for the review, including the self-assessment results, through an external webpage dedicated to IRRS mission. The IRRS review team members conducted a review of the advance reference material and provided their inputs to the IAEA Coordinator prior to the commencement of the IRRS mission.

The Liaison Officer for the preparatory meeting and the IRRS mission were Mr Georg Schwarz and Mr Andreas Schefer.

B) REFERENCE FOR THE REVIEW

The most relevant IAEA safety standards used as review criteria are: GSR Part 1, Safety Requirements on Governmental, Legal and Regulatory Framework for Safety, GS-R-2, Preparedness and Response for a Nuclear or Radiological emergency and GS-R-3, Safety Requirements on The Management System for Facilities and Activities. The complete list of IAEA publications used as the reference for this mission is given in Appendix VIII.

C) CONDUCT OF THE REVIEW

An opening IRRS review team meeting was conducted on Sunday, 20th November 2011 in Baden by the IRRS Team Leader and the IRRS IAEA Team Coordinator to discuss the general overview, the focus

areas and specific issues of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers.

In addition, IAEA Team Coordinator presented the new module on the IRRS "Regulatory implications from TEPCO-Fukushima Dai-ichi Accident" to be applied.

The Liaison Officer was present at the opening IRRS review team meeting, in accordance with the IRRS guidelines, and presented the agenda for the mission. The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 21st November 2011, with the participation of ENSI senior management and staff. Opening remarks were made by Mr J.-C. Niel, the IRRS Team Leader. Mr H. Wanner, Director of ENSI gave an overview of ENSI status and activities.

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

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

The IRRS exit meeting was held on Friday, 2nd December 2011. The opening remarks at the exit meeting were presented by Mr H. Wanner, Director of ENSI. The results of the IRRS mission were presented by Mr J.-C. Niel. The closing remarks were made by Mr Jim Lyons, IAEA Director, Division of Nuclear Installation Safety.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY

Switzerland has a well-defined legislative and regulatory framework for the peaceful use of nuclear energy and the protection against ionizing radiation. The subject matter and purpose of the legislation enacted by the Swiss Confederation is to protect humans and the environment against the risks of ionizing radiation. The basic strategy is licensing of both facilities and activities and their regulatory oversight. The objective is to verify continuing compliance with safety regulations and that licensees are meeting their obligation to continuously improve safety.

The policy and strategy are codified in major statutes which establish the regulatory framework for the safety of facilities and sources, radiation protection, safe transport of radioactive material, safe management of waste, decommissioning and emergency planning.

- The Nuclear Energy Act of 2003 applies to nuclear goods, nuclear installations and radioactive waste that is generated in nuclear installations or that is surrendered to the federal collection centre. It states the basic principles of nuclear safety, including the precautionary principle, the protection of the people and the environment and measures to prevent sabotage and the proliferation of nuclear material. It also defines the licensing procedure, general responsibilities of the licensee, regulations on decommissioning and disposal of radioactive waste and criminal sanctions. In addition, the Nuclear Energy Act designates the Swiss Federal Nuclear Safety Inspectorate (ENSI) as the supervisory authority for nuclear safety and security and defines its powers and funding.
- The Radiological Protection Act of 1991 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 persons in the general population, for permanently monitoring the environment and for protecting the population in the event of increased radioactivity.
- The ENSI Act, passed in 2007 and enacted in 2009, establishes ENSI as an independent institution under public law with its own legal status. The most important provisions of the act refer to organisational principles, tasks and responsibilities of ENSI, financing and budget, independence of ENSI and accountability of the ENSI Board to the Federal Council.

The national policy and strategy align with the IAEA Safety Fundamentals. The Swiss national policy aligns directly with 10 IAEA fundamental safety principles.

In addition, Art. 4 of the Nuclear Energy Act states that precautionary measures must be taken that contribute towards an additional reduction of risk insofar as they are appropriate. This principle includes an 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 Nuclear Energy Act) (see chapter 2.1).

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The competence for nuclear energy and radiation protection rests with the Confederation. This competence encompasses legislation and implementation.

The basic provisions of the legislation governing nuclear energy and radiation protection are set out in ordinances and guidelines. Regulations are formally enacted by the parliament (acts), the Federal Council (ordinances) or a Department (ordinances). According to Art. 2 para. 2 of the ENSI Act, ENSI participates in the preparation of regulations affecting its area of responsibility. In addition, ENSI issues guidelines either in its capacity as regulatory authority or based on a mandate in an ordinance. Guidelines are "semi mandatory" support documents. They formalise the implementation of legal requirements and facilitate uniformity of implementation practices (for details, see chapter 9.2).

The competent authorities are designated by the federal legislation. Implementing authorities of the Nuclear Energy Act are mainly:

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

For nuclear installations 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 report to the attention of the licensing authority). Once the licence is granted, ENSI supervises the licence holder and issues permits. Permits are always granted in the frame of an existing licence. Permits enable the supervisory authorities to verify that conditions specified in the licence and relevant legal and regulatory requirements are met during the construction and commissioning process (cf. Art. 75 of the Nuclear Energy Ordinance). 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 Nuclear Energy Act). In addition, ENSI is responsible for inspection and enforcement to ensure the nuclear power plants' operators fulfil their requirements to operate their facilities safely. ENSI has also the power to issue orders on necessary and reasonable measures aimed at preserving nuclear safety and security.

In order to ensure coordination and mutual assistance between the Federal authorities and efficiency in the processes, the Nuclear Energy Act provides "concentrated decision procedures". They apply to licences for construction of nuclear facilities as well as permits issued by ENSI to modify existing facilities. In those procedures, the authority whose responsibility is primarily affected acts as a "lead authority" and decides on all relevant aspects. The other involved authorities of the Confederation and the Cantons submit their opinion to the lead authority that has to duly consider them and to resolve conflicts. The procedure to resolve conflicts between the involved authorities is transparent to the public.

As noted previously, the licensing system in Switzerland is based upon a licensing authority (i.e. Federal Council and DETEC) entitled to issue various licences and the decommissioning order. It is also based upon an independent safety authority (ENSI), performing review and assessments as well as supervision activities and entitled to formulate opinions and conditions in the licensing process.

The Federal Council and DETEC are governmental organizations with interests and competences in fields other than nuclear safety, security and radiation protection and also potentially involved in the promotion of nuclear activities. ENSI is one of the two governmental organizations whose primary and sole mission is to ensure nuclear safety. ENSI should therefore be clearly provided by in laws with the proper authority to formulate binding licence conditions and regulatory requirements.

The framework for safety provides for a graded approach, most clearly manifested in the Nuclear Energy Act. Nevertheless, the IRRS team considers that the application of the graded approach should be assessed to ensure that an adequate regulatory framework including guidelines and an oversight programme exist where necessary for instance for research reactors, transport and decommissioning. As an example, ENSI is planning to regulate the decommissioning of five large power reactors, starting in 2020 but it is still in the early stages of developing the decommissioning regulatory program (see chapter 13.3). Nevertheless, it is noted that high level requirements for decommissioning are in the Nuclear Energy Act and in the Nuclear Energy Ordinance. It should also be checked whether all activities on a nuclear facility related to transport packages are subjected to a formal process of approval based upon a graded approach (see chapter 10.7).

Irrespective of this, the IRRS team considers the implementation of the graded approach to nuclear safety should be transparent and publically available. This could be important in particular in the area of research reactors where the IRRS team notes that there has been one previous research reactor accident and one safety event at a research reactor and yet no specific regulation or regulatory requirement exists.

The Nuclear Energy Act is related to the Radiological Protection Act, which regulates radiation protection in a broad and general sense. The Radiological Protection Act applies to the use of nuclear energy insofar as the Nuclear Energy Act does not contain any specific provisions.

Implementing authorities of the Radiological Protection Act are:

- the above mentioned authorities in the field of nuclear energy (licences under of the Nuclear Energy Act also cover radiation protection, ENSI supervises nuclear facilities with respect to radiation protection),
- for other (i.e. "non-nuclear") situations, activities and facilities that may involve an ionizing radiation hazard, the regulatory body is the Federal Office of Public Health and the Swiss National Accident Insurance Fund (SUVA). The Federal Office of Public Health supervises those enterprises where the primary need is the protection of the public (especially medical enterprises and research institutions). SUVA supervises those enterprises where the primary need is the protection of employees, in particular industrial and commercial enterprises. In principle, all licences (i.e. also in the supervisory area of SUVA) are granted by the Federal Office of Public Health. As far as activities closely related to nuclear facilities are concerned, licences are also granted by ENSI (e.g. activities involving radioactive substances at nuclear facilities or transport of radioactive substances to and from nuclear facilities).

With respect to other legislative areas relevant to nuclear energy and radiation protection the following applies:

- The competence for the implementation of the environmental legislation rests with the Federal Office for the Environment and the Cantonal authorities.
- The legislation on land use, planning and construction is implemented by the Federal Office for Spatial Development and the Cantonal authorities.
- The (industrial) safety of workers is regulated in the Labour Act (including the relevant ordinances); the competence for the implementation rests with the Cantonal Labour Inspectorates, the State Secretariat for Economic Affairs (SECO) and the Swiss National Accident Insurance Fund (SUVA).
- Oversight on fire protection in nuclear facilities is a joint responsibility of ENSI and the Cantons. The competence for the adoption and implementation of the relevant regulations primarily rests

with the authorities of the Cantons. The cantonal regulations also apply to nuclear facilities. In addition, ENSI has set out specific requirements to be met by nuclear facilities (regulatory guideline HSK-R-50, IAEA Safety Guide NS-G-2.1 "Fire Safety in the Operation of Nuclear Power Plants").

- The competence for the implementation of the legislation on civil protection rests primarily with the Federal Office for Civil Protection. The National Emergency Operations Centre (attached to the Federal Office for Civil Protection) is responsible for alerting, instructing and informing the public and for the initiation of early countermeasures in all cases of radiological emergencies.
- The State Secretariat for Economic Affairs is responsible for the implementation of the legislation concerning the control of dual use goods (Goods Control Act and Safeguards Ordinance).

The IRRS team has not noticed any gap in the regulatory framework. On the other hand, overlaps or potential conflicts exist, to some degree, with respect to radiation protection and transport (see chapters 10 and 12).

The IRRS team also discussed the oversight and inspections on conventional safety. ENSI does not have the authority to inspect and oversee conventional safety. The oversight and conventional safety inspections are the responsibility of other authorised bodies, some of whom perform only to a very limited extent conventional safety inspections in the nuclear facilities. The government should authorize ENSI, or agreement of the appropriate Swiss authority should be sought to extend the authority of ENSI to inspect conventional safety at nuclear facilities. Alternatively the government should require the authority responsible for conventional safety to meet their legal obligations (see Policy Discussion on interfaces with others authorities).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 – Requirement 2 paragraph 2.5 (9) states that** *"The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of) regulations and preparing guidance for their implementation."*
R1	**Recommendation: The government should consider providing ENSI with the authority to issue regulatory requirements.**
(1)	**BASIS: GSR Part 1 para. 4.39 – Requirement 26 states that** *"Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 1 para. 4.60 – Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based".*
(3)	**BASIS: NS-R-4 para. 3.2 states that** *"The government shall ensure that an adequate legal infrastructure and regulatory basis for assessing the safety of the research reactor is available."*
R2	**Recommendation: ENSI should formalize and implement its graded approach for regulatory oversight of nuclear safety including as example research reactors, transport and decommissioning.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 para. 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization…"*
(2)	**BASIS: WS-R-5 para. 3.6 states that** *"The responsibilities of the regulatory body include: Establishing safety and environmental criteria for the decommissioning of facilities, including criteria for the clearance of material during decommissioning and conditions on the end state of decommissioning and on the removal of controls."*
(3)	**BASIS: RS-G-1.1 para. 5.37 states that** *"Written procedures should be used as part of the work planning process as appropriate. Elements to be considered include:…* *(j) Conventional safety*."
(4)	**BASIS: GSR Part 1, Requirement 2 states that** *"The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated."*
R3	**Recommendation: The government should take appropriate measures to ensure conventional safety requirements are being supervised and complied with at all nuclear facilities and that there are effective interfaces between conventional, radiation and nuclear safety.**

1.3. ESTABLISHMENT OF A REGULATORY BODY

The legislator (parliament) directly designated ENSI as the supervisory authority for nuclear safety, security and radiation protection for nuclear facilities. In addition, the legislation stipulates the duties and powers of the supervisory 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 financed through fees charged to the applicants and licence holders. Should licensees stop their activities, ENSI would be financed by the funds that are being supplied for decommissioning and whose consistency is assessed every 10 years. As a result, sufficient funding of ENSI is ensured independently of the Confederation. This enables ENSI to make available the necessary competences and resources to fulfil its statutory activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1, Requirement 3 states that** *"The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities."*
GP1	**Good Practice: The system in place to finance ENSI enables it to adjust its effective funding to its workload and then to obtain the resources necessary to fulfil its statutory obligation, without interference from government authorities.**

1.4. INDEPENDENCE OF THE REGULATORY BODY

The team recognized the effective independence of ENSI is established in the legislation and has been experienced in practice. The following apply:

- ENSI is an institution under the public law that is legally, institutionally, politically and financially independent.
- The ENSI act established ENSI as an independent institution under public law with its own legal status.
- State responsibilities for the use of nuclear energy and the protection from its hazards are separated.
- ENSI performs its supervisory work autonomously and independently as specified in Article 18 of the ENSI Act. This prevents the Federal Council or any other administrative authority from interfering in the supervisory activities of ENSI.

While ENSI is an independent regulator, it does not possess decision-making authority for issuing a licence for a nuclear facility. This authority rests with the Federal Council or the Department of Environment, Transport, Energy and Communications. These two authorities grant licences based on the technical expertise of ENSI, along with considerations involving other factors, including land use and resource use. These authorities are not required to follow the technical advice from ENSI, however, the process is transparent to the public and the decision-making authority must justify the non-consideration of ENSI's advice (see chapter 5).

A modification of the ENSI ordinance issued in November 2011 provides detailed provisions on the financial and administrative links the members of ENSI Board are allowed to have with authorized parties. These provisions seem to be supportive of preserving ENSI's independence, however due to the size of the country; it may prove difficult to identify people having good knowledge of nuclear safety who comply with all these provisions. Therefore, these strict provisions may prevent the Federal Council from appointing appropriate people to fulfil ENSI Board's duties.

1.5. PRIME RESPONSIBILITY FOR SAFETY

Art. 22 of the Nuclear Energy Act states that the licence holder is responsible for the safety of the installation and its operation. Art. 72 of the same Act defines the duties and powers of supervisory authorities. In particular, it states that supervisory authorities shall order all necessary and reasonable measures aimed at preserving nuclear safety and security. It also specifies that in the event of an immediate threat, they may impose immediate measures that deviate from the issued licence or ruling and may call on the intervention of the relevant federal police authority if there is evidence that offences against the provisions of Nuclear Energy Act may have been committed.

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

1.6. COMPLIANCE AND RESPONSIBILITY FOR SAFETY

As mentioned in chapter 1.5, the Nuclear Energy Act states that the licence holder is responsible for the safety of the installation and its operation, which implies that having an authorization does not affect the licence holder's prime responsibility for safety. Nevertheless, the law does not stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.

In order to strengthen the licensee's prime responsibility for safety, the Swiss regulations and guidelines mainly fix the safety goals to be achieved but not the ways to achieve them.

The responsibility for safety remains with the operator, even if he chooses to call upon third parties. The operator can delegate tasks, but not his prime responsibility for safety. Art. 30 para. 1 of the Nuclear Energy Ordinance states that the organisation of the installation must be structured in such a manner that it ensures internal responsibility for the various domains of operation and that quality assurance must be implemented for services provided by contractors.

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

The federal legislation clearly defines the duties and responsibilities of the various authorities having responsibilities for safety.

In addition, according to Art. 14 of the Ordinance on the Organisation of the government and the administration (SR 172.010.1), the authorities are obliged to collaborate. They shall inform and support each other and coordinate their activities. Similar provisions apply to relations between the Cantons and the Confederation. Art. 44 of the Federal Constitution explicitly includes the provision of administrative assistance (para. 2).

According to Art. 8 and 9 of the Administrative Procedure Act, if an authority regards its jurisdiction as doubtful, it shall immediately enter into an exchange of views with the authority it considers may have jurisdiction. Jurisdictional conflicts between authorities shall be decided by the joint supervisory authority, or in the absence of such, the Federal Council.

As mentioned in paragraph 1.2., the "concentrated decision procedures" are used to help coordinating the different authorities involved in issuing licences and permits.

Moreover, all authorities concerned are involved in the drafting of new regulations and guides and amendments thereof through a "consultation procedure".

ENSI has also close interactions with DETEC in answering parliament's motions.

ENSI has regular exchanges with DETEC, SFOE and other federal authorities regarding the quality of their cooperation through regular and formalized meetings and written exchanges.

1.8. COMPETENCE FOR SAFETY

At present time, 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 relating to the promotion of research; education and training (especially Art. 86 of the Nuclear Energy Act and Art. 77 of the Nuclear Energy Ordinance) are only discretionary.

In addition, the recent decision not to build new NPPs and to phase out nuclear energy will not help in developing competence in nuclear safety or in attracting new people into this area. Building and maintaining competence in nuclear safety is then a real concern for Switzerland.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 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."*
(2)	**BASIS: GSR Part 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."*
R4	**Recommendation: The government should evaluate the needs for building and maintaining competence of the parties that have responsibilities in relation to safety in the near, mid-term and long-term future. It should then adopt the appropriate strategy to fulfil those needs.**

1.9. PROVISION OF TECHNICAL SERVICES

Swiss federal offices are mainly in charge of providing technical services relating to safety. For instance, the Federal Office of Public Health maintains the Central Dose Registry (Art. 53 of the Radiological Protection Ordinance) and monitors ionizing radiation and radioactivity in the environment throughout Switzerland. In addition, ENSI monitors ionizing radiation and radioactivity in the vicinity of nuclear facilities and the Paul Scherrer Institut (PSI). In monitoring radioactivity in foodstuffs, the Federal Office of Public Health cooperates with the Cantons (Art. 104 of the Radiological Protection Ordinance). The Federal Office of Public Health prepares a sampling and measurement program in cooperation with ENSI, the Swiss National Accident Insurance Fund (SUVA), the National Emergency Operations Centre and the Cantons. Regarding calibration of equipment, the Federal Office of Metrology (METAS) has approved three verification laboratories for the verification of radio-diagnostic dosimeters, surface contamination monitors, local dose rate measuring instruments and medical radionuclide calibrators.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR COOPERATION

Switzerland participates in more than 70 international commissions on the OECD, IAEA, WENRA, the Network of Regulators of Countries with Small Nuclear Programmes (NERS), and other institutions. Switzerland is part of all IAEA conventions and has signed bilateral treaties with all neighbouring countries and with 8 more countries to cooperate on nuclear matters and for emergency preparedness.

As ENSI's staff is only composed of 140 people, Switzerland is represented by ENSI's experts and also by PSI's experts. Nonetheless, ENSI board members have few contacts with the international experts.

All Swiss plants undergo regularly WANO missions. From 1994 to 2000 the plants have undergone OSART missions. Whereas ENSI has access to OSART mission results, it does not have access to WANO mission results. Switzerland promotes the idea that the use of IAEA requirements should be strengthened for regular peer review missions on the assessment of the regulatory framework and activities, on NPP design and on NPP operation. Therefore, Switzerland actively contributed to the establishment of the IAEA Action Plan on Nuclear Safety. ENSI intends to have all the NPPs carry out new OSART missions.

Switzerland underwent an IRRT mission in 1998 and its follow-up mission in 2003 and has provided experts to participate in various IRRT and IRRS missions in the past. ENSI undergoing an IRRS mission periodically is stated in the ENSI ordinance.

The IAEA safety standards as well as the WENRA safety reference levels are duly considered in the Swiss regulatory framework.

In addition, the Swiss nuclear safety legislation demands that operators monitor the state of the art in science and technology, monitor operational experience and back-fit the installations to the necessary extent that it is in keeping with operational experience and the current state of back-fitting technology.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 para. 3.2 states that** *"The features of the global safety regime include international peer reviews of the regulatory control and safety of facilities and activities, and mutual learning by participating States".*
GP2	**Good Practice: The ENSI ordinance requires ENSI to undergo an IRRS mission periodically.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The Nuclear Energy Act, the Nuclear Energy Ordinance and regulatory guidelines include requirements on the notification of events. The Ordinance also requires each plant to form a group that investigates events, defines corrective actions and follows through their implementation to prevent recurrence. The insights from these events, as well as from international events, must be reported to ENSI at least every three months. In addition, operators are legally obligated to review their NPP design after every INES 1 event in their own plant or after any INES 2 event in another NPP in Switzerland or abroad.

As the regulator, ENSI has established a group of specialists to review domestic and international operating experience and to use the insights to improve the regulatory process in Switzerland. This has

included the use of operating experience in the yearly assessment of the safety situation at each NPP in Switzerland. This systematic safety assessment, which also includes inspection findings and performance indicators, as well as event investigation, is used to focus its inspections for the following year, representing a true feedback of operational experience into the regulatory framework.

ENSI actively participates in the Nuclear Energy Agency's Committee's on operational and regulatory experience feedback; the Working Group on Operating Experience and the Working Group on Inspection Practices. ENSI also shares operational experience with the IAEA, with the EU Clearinghouse and through bilateral contacts with other regulators, specifically the German and French Regulators.

ENSI issues an annual report compiling all new information about the regulation basis, regulatory safety research, lessons learnt from events in foreign NPPs, international cooperation and current changes and developments in the basics of the nuclear regulatory process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 – Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities."*
GP3	**Good Practice: The Art. 2 of DETEC Ordinance n°732.114.5 issued in 2008 requires operators to review the design of their plant after every INES 1 event in their own plant or after any INES 2 event in another NPP in Switzerland or abroad without any additional request from ENSI.**
GP4	**Good Practice: In order to share and to record the research results and experience accumulated during the year, ENSI publishes an additional report, on regulatory safety research, lessons learnt from events in foreign NPPs, international cooperation and current changes and developments in the basics of the nuclear regulatory process.**

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

ENSI is institutionally, financially and politically independent. It is subordinate to the Federal Council and is supervised by a board whose members are elected by the Council. While the Board provides a focus on the ENSI strategies, organization and financing, it does not provide an input to ENSI's technical decision making process. The ENSI Board defines the strategic objectives of ENSI for a four-year term.

ENSI has grown substantially over the past four years (40%) in anticipation of a nuclear renaissance. Since the Parliament has suspended work on establishing new NPPs, that additional workforce is being used to evaluate lessons learned from Fukushima to further improve safety of the Swiss NPPs.

ENSI is funded mostly by fees that are paid by the industry (see chapter 1.3). A modest amount of money is provided by the Federation to pay for expenses from answering questions from the public, parliamentary inquiries and to fund regulatory research activities.

ENSI measures the fulfilment of its statutory obligations through a broad set of performance indicators, covering the four fields of activity: management, assessment of facilities, surveillance of operations and support. The executive board provides a semi-annual review and report of its findings to the staff and the ENSI Board. The allocation of staff and financial resources is reassessed and revised if necessary during this process. In general, about 80% of the technical staff works on the safety of the NPPs and the rest for the radioactive waste facilities, transport activities and research reactors. In this way, ENSI provides a graded approach in its use of resources commensurate with safety.

3.2. EFFECTIVE INDEPENDENCE DURING CONDUCT OF REGULATORY ACTIVITIES

The ENSI Act became effective on January 1, 2009, establishing ENSI as a new organization, separate from any other Government organization, and financially and politically independent. Control of the ENSI staff to ensure that it remains independent is accomplished in several ways included through oversight by the appointed ENSI Board, by the ENSI Ordinance requiring quality assurance mechanisms be used, periodic audits by outside organizations, such as the IRRS Mission conducted through the IAEA, and the certification of the quality management system. However, ENSI has retained its independence with regard to its technical decisions related to safety and has retained the authority to shut down a nuclear installation in case of an immediate threat, without political interference.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

ENSI differentiates between human resources management for the development of the skills needed to comply with the job profiles and knowledge management for the development and maintenance of the knowledge needed for daily work.

The ENSI executive board evaluates the ENSI staffing situation twice a year as part of its management review. The current staffing levels and competencies were based on a projection of new build, which has since been altered by the suspension of any new build following the accident at Fukushima. ENSI staff had grown by approximately 40% over the past four years and ENSI management will need to re-evaluate its staffing plans in light of the new environment. In particular, the IRRS team is concerned about the staff resources allocated in areas such as decommissioning, waste management and emergency preparedness

regarding its duties in these areas (see chapters 11 and 13).

This past year ENSI instituted a new human resources practice establishing a competence portfolio for ENSI staff. The competence portfolio is a catalogue of the competencies required for ENSI's different expert positions as well as an evaluation of the further education needed according to these requirements. The education programme for the individual staff member is defined and agreed between the staff member and the supervisor and is also used for staff advancement and also partly to staff compensation. The IRRS team found the human resources management system developed by ENSI very valuable but considers it should ensure the system is uniformly implemented and encourages ENSI to continue its development.

In 2008, a new knowledge management strategy was issued. It is based on the following areas:

- plant documentation,
- law and regulation,
- research results.

The system boundaries, the processes for updating and maintenance of information and the electronic platform to distribute it have been defined and lead to a clear organization. The project has been recently completed and is already integrated into ENSI's management system. The IRRS team was informed that ENSI's staff members are highly motivated and involved in keeping the system alive and up-to-date.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
S1	**Suggestion: ENSI should ensure there is sufficient competent staff to complete the development of the decommissioning program, to fulfil its duties regarding the safety of radioactive waste management and to further develop ENSI's emergency preparedness.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The Nuclear Energy Act allows ENSI to establish contracts with external experts as necessary to support ENSI staff. A long term established relationship with the Swiss Association for Technical Inspections (SVTI) provides for the assistance in inspecting pressurized systems. Other contracts have been established with engineering, research and academic institutions to provide assistance with specific specialties such as civil engineering, seismic hazard analysis, deterministic safety analysis, probabilistic safety analysis and accident management.

Among others, ENSI has a multiple-year contract of expertise with the Paul Scherrer Institute (PSI) in the areas of deterministic safety analysis, radiation protection and research projects. PSI is also an authorized party beside ENSI as it operates the research reactor PROTEUS and the central collection centre of waste. The IRRS team then underlined two possible conflicts of interest. One of the conflicts lies in the fact that PSI can also provide NPP's 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 analyse would not be independent. But the multiple-year contract between ENSI and PSI requires PSI to ask permission from ENSI before contracting with NPP's operators in order to avoid a conflict of interest. The second potential conflict lies in the nature of the relationship existing between ENSI and PSI: supervision authority-authorised party and client-supplier. Regarding the size of the country, this

issue seems difficult to avoid and as the different departments of PSI are clearly separated, there is no conflict evident at the present time. Nevertheless, ENSI should remain vigilant on this issue.

ENSI has recently established an expert group on reactor safety mostly composed by foreign experts to provide an input on safety decisions before ENSI management decides on an action. This was an internal ENSI initiative, taken so that the regulator could have access to an independent opinion on safety issues.

The Federal Government also established three Federal Commissions to provide second opinions for nuclear safety issues: the Swiss Federal Nuclear Safety Commission (NSC), the Commission for Radiological Protection and Monitoring of Radioactivity (KSR), and the Commission for Nuclear Waste Disposal (KNE). All three Commissions provide information and opinions to ENSI, but are not authorized to give instructions to ENSI.

The KSR's mission is to provide insights of international recommendations in the field of radiation protection, the development of sound principles for the application of radiation protection regulations and to interpret environmental radioactivity monitoring results. The KSR advises several federal departments, including DETEC and the Federal Council. The KNE provides expert advice to ENSI on important scientific, long-term safety and construction issues associated with the disposal of radioactive waste.

The NSC acts as a second opinion on nuclear matters to DETEC and the Federal Council that have already been decided by ENSI. While providing a second opinion is extremely valuable, and is highly regarded by the IRRS Team, the structure of the relationship of NSC within the federal government could present a number of problems and inefficiencies and could result in confusion with regard to important nuclear safety matters within the government. For example, if the NSC and ENSI provide conflicting advice to DETEC with regard to a licensing matter, DETEC does not have the technical expertise to evaluate the differences. This could be very inefficient and confusing for the public. With regard to a current issue, ENSI has already produced a Fukushima lessons learned document and has begun enhancing safety at the Swiss NPPs based on its assessment. However, the NSC will not begin examining the Fukushima event for another year. If the NSC's findings conflict with ENSI, it could lead to confusion and unnecessary delays in safety enhancements. In many countries, such advisory bodies provide its recommendations directly to the management of the regulatory body so that it can be considered before matters of safety are decided. This should be done in an open and transparent manner such that all decisions and the judgement used to evaluate them are available to all interested parties. This should be consistent for any stakeholder, authority, commission or committee involved in significant nuclear safety matters.

In addition, as an independent entity, NSC can define their own scope of work and priority for further investigations without having to communicate transparently on them. NSC also reports sometimes directly to the parliament members without having made public its conclusions before. It is important that the role of ENSI as the independent regulatory authority for nuclear safety with responsibility for ensuring public health and safety and protecting the environment is maintained and not undermined both within the regulatory framework and in the perception of the public.

The IRRS team therefore suggests that the government consider reviewing the process of involvement of the NSC and the other commissions, by reviewing their mandates and/or revising their operational model so that they provide their advice directly to ENSI before it issues its final decision.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1, Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."
(2)	**BASIS: GSR Part 1 para. 4.28. states that** *"There shall be consistency in the decision making process of the regulatory body and in the regulatory requirements themselves, to build confidence among interested parties."*
R5	**Recommendation: Government should ensure that relevant authorities, commissions and committees, for example the NSC, involved in nuclear safety matters, provide its recommendations and advice directly to ENSI before it issues its final decision. This should be done in an open and transparent manner, in order to allow ENSI to make an informed decision.**

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

Besides the meetings on the exchange of operating experience, meetings are also regular organized between the management of ENSI and the management of each nuclear installation where current nuclear safety issues are addressed. In these discussions possible problems in the relationship can be addressed and eliminated at an early stage. Furthermore, expert discussions on specific topics like safety culture are organized regularly by ENSI to the attention of the four operators.

The formal mechanisms of communication include consultation with the operators in the preparation of guidelines, the notification of regulatory decisions regarding the review of submitted projects and reports (assessment of facilities) and the supervision of the operator's compliance with the legal and regulatory requirements (surveillance of operations) (see chapter 9.3). These mechanisms are regulated in detail in ENSI's procedures. In addition, ENSI's comprehensive safety evaluation is reported annually to the operators and the public.

Relations between ENSI and the operators seem to be open and frank; they apparently work together in a professional and respectful way. Nevertheless, since the new detailed legal framework entered into force, relations are said to have become more formal and assessments very detailed. The ambitious recruiting of new staff may also contribute to more formal relations, as junior inspectors generally rely more on standardized procedures. ENSI faces the challenge to train a significant number of new staff and to maintain their focus on the safety significance of the issue they are pursuing.

In addition to the feedback received through the meetings, ENSI distributes a feedback form after having issued permits. This is an open way to improve the efficiency and the effectiveness of the regulatory process as well as the professional relationship between ENSI and the authorized parties. Unfortunately, the answers provided by the operators bring out very few suggestions.

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 has implemented an electronic management control system that includes all of its processes and is available to its entire staff. The system is ISO-certified. The ENSI executive board also conducts twice yearly reviews of the system for staff performance and to reflect changes in the system. ENSI also relies on regulatory guidelines that reflect the international state of science and technology, the IAEA safety standards and the WENRA safety reference levels. The ENSI Board annually provides its judgement on the ENSI performance to the Federal Council.

To ensure consistency and fidelity in its decision-making, ENSI has implemented a rule where no individual worker can decide a safety matter on their own. All decisions must be reviewed and receive at least a dual signature with a manager. The management system defines signature authority according to the importance and consequences of the decision. These processes provide a level of consistency to the decision making process that should build confidence among all interested parties.

While the Swiss system has provided for the independence and autonomy of ENSI, it has also retained the important principles of scrutiny and accountability of the regulator. ENSI is required to justify its decisions in an open and transparent way. While ENSI's technical decisions can be made without undue political interference, ENSI is accountable for its decisions to the Federal Council, the Parliament and ultimately, to the Swiss people. In addition, ENSI's decisions can be reviewed in a court of law. The Swiss system has also established a completely separate entity, the Swiss Federal Nuclear Safety Commission, to provide a second technical opinion (see para. 3.4). These myriad of processes and oversight help ensure the stability and consistency of regulatory control.

3.7. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

New legislation concerning ENSI or its activities is subjected to public consultation in which interested parties can comment on the proposed additions or changes. New or amended guidelines are subjected to stakeholders' consultation. These guidelines are also posted on the ENSI web site for public consultation enabling the public to comment on the proposed regulatory changes before they are enacted.

ENSI provides the public with general information by means of press releases, annual reports, electronic newsletters, brochures on specific topics and its web site www.ensi.ch. The German version of the website is comprehensive and clear. However, some important documents are missing or are not up to date on the English and French version and no reference to their presence on the German page is made. This can prevent foreign interested parties from having access to important information.

ENSI representatives participate in public discussions on current topics such as deep geological repositories for radioactive waste. Furthermore, ENSI answers enquiries from the public received by telephone, email or ordinary mail. The way how inquiries have to be treated and answered are documented in the management system.

ENSI monitors how it is perceived by the public by reviewing the press and the Internet. Meetings with different stakeholders on nuclear safety related topics also enable ENSI to collect opinions. Every four years, ENSI carries out a survey to determine how the regulatory authority is perceived by the public; these measures are outlined in the communication concept.

It is recognized as a Good Practice that ENSI participates in the sectorial plan and is described further in chapter 13.

POLICY DISCUSSION: Openness, Transparency and Stakeholders Involvement

ENSI receives more and more requests for access to detailed technical documents like safety reports. These result from the Freedom of Information Act, the Nuclear Energy Act (which requires ENSI to inform the general public regularly on the condition of nuclear installations and any matters pertaining to nuclear goods and radioactive waste), and the TEPCO Fukushima Dai-ichi accident.

The issues raised by this situation are twofold:

- How to be as open and as transparent as the legislation requests and, at the same time, to deal with security issues?

- How are balanced the responsibility to inform the public between ENSI and the operators?

The policy issue discussion was attended by the ENSI board and the executive board.

It was introduced by some slides on the legal basis (Freedom of an Information Act and Ordinance, Information Security Ordinance) and on ENSI's communication concept regarding openness, transparency and stakeholder involvement.

The discussion gave the opportunity for the team members to present their national experience.

The team were informed of the involvement of ENSI to deal with this issue, notably specialist information to the public was hired recently.

Several conclusions could be drawn from the exchanges:

- Transparency and openness implies a professional attitude requiring competence, staffing and procedure;
- Transparency and openness can be a powerful tool for the nuclear regulatory body to perform its duties and mission for the benefit of the public, the former may create public trust, the latter may contribute to the protection of the public;
- Transparency must primarily rely on the operators;
- Transparency may conflict with security. The two issues must be clearly identified and dealt with rigorously. The conflicting requirements of these two fields need to be managed by the regulatory body;
- International exchanges on those issues would be most valuable.
- ENSI should consider establishing regular trainings for journalists to help understanding and avoid misinterpretations.
- Switzerland should consider an amendment of the freedom for information requirements in order to enhance the responsibility of the licensees in the security of information.

POLICY DISCUSSION: Interfaces with others authorities

During the preparatory meeting, the overall organisation of the control of radiation protection and nuclear safety was presented to the members of the team. It appeared that licensing and supervisory missions were shared by several authorities. Clear allocation of responsibility and well defined interfaces are conditions for an effective regulatory system. Hence, it was initially proposed that the IRRS mission scope covers these authorities (mainly DETEC, SFOE, FOPH, SUVA...). As a result of the IRRS preparatory mission, it was decided that these aspects would not be included in the scope of the mission. Nevertheless, interfaces with other authorities were considered as a policy to be discussed during the mission. The following paragraph does not deal with other bodies having an important role on these issues, such as the NSC which is treated in chapter 3.4 of the report.

There are interfaces with:

Radiation protection

Three authorities are involved in radiation protection:

- Federal Nuclear Safety Inspectorate ENSI
- Federal Office of Public Health FOPH
- Swiss National Accident Insurance Fund (SUVA)

ENSI is the licensing and supervisory authority for activities at nuclear facilities, FOPH for activities in medicine, research and military and Suva is the supervisory authority for activities at the non-nuclear industry.

Emergency preparedness

Switzerland has a rather complex organization for the management of nuclear/radiological, biological, chemical or natural emergency events. The Federal NBCN Crisis Management Board coordinates civil and military support at federal and regional levels. In this Board the most important federal offices including ENSI are represented. The Federal NBCN Crisis Management Board runs a stand-by emergency service, the National Emergency Operations Centre (NEOC), which is responsible for alerting and informing the public and for initiating early countermeasures.

In case of an emergency at a nuclear facility, ENSI assesses the appropriateness of the measures taken by the plant operator, elaborates forecasts regarding the evolution of the accident at the site and the possible dispersion of radioactivity in the environment and its consequences. It also advises the Federal Office for Civil Protection (FOCP) and the Federal NBCN Crisis Management Board on the measures to be implemented for the protection of the population.

Following Fukushima, an inter-departmental working group (IDA NOMEX) was set up related to emergency preparedness and response to a nuclear accident. Improvements were identified in the responsibility for the organisation of measurements in normal and emergency situation. This is dealt with in chapter 15.2.

Transport

Responsibilities are shared between FOPH/Suva (Radiation Protection legislation) and ENSI (Nuclear Energy legislation). This includes inspections and transport licensing. The responsibilities are defined, but it appears to be complex operationally because the regulatory oversight organisation in charge is defined by the destination of the transport (NPP or not) while the package approval organization may not.

Safety / Security / Safeguards

ENSI is the supervisory authority with regard to nuclear safety and security, whereas the SFOE is responsible for other areas of the nuclear energy legislation e.g. safeguards. The information exchange between ENSI and SFOE are limited.

Conventional Safety of Workers

In its function as supervisory authority for nuclear safety and security, ENSI regularly performs inspections within the facilities while Suva and the Work-Inspectorate of the Canton (“kantonales Arbeitsinspektorat”), responsible for all measures on conventional safety of workers, are very rarely on site. ENSI considers that enforcement following information on deficiencies in worker’s safety delivered to Suva and the Work-Inspectorate of the Canton should be enhanced.

The policy discussion gathered the ENSI board and executive board and a large part of the review team. As a conclusion of the presentation and of the discussions, it appears that (except for potential improvements in conventional work safety and safeguards – see at other parts of the report) no evidence was given that would support a necessity to change the allocations of responsibilities. Nevertheless, coordination processes should be formalised and as far as possible enhanced. It should be taken into account in the revision of the radiation protection ordinance which is going on or the IDA NOMEX

working group set up after Fukushima. This concern should also apply to transport where the operator relies on other organisations (this point is treated in chapter 10) or to conventional safety of workers (see chapter 1.2).

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

Introduction

The IAEA General Safety Requirements publication GSR Part1 Requirement 19, issued 2010, and GS-R-3, issued 2006, define the requirements for establishing, implementing, assessing and continually improving a Management System that integrates safety, health, environmental, security, quality and economic elements. The management system shall assure that:

- The responsibilities assigned to the regulatory body are properly discharged;
- The performance of the regulatory body is maintained and improved;
- The safety culture in the regulatory body is fostered and supported.

The Swiss Federal Nuclear Safety Inspectorate has an integrated management system that covers activities including quality management, environmental management, safety at work, risk management and emergency preparedness.

The development of the Management System started in the year 2000. Based on legal requirements the system has to be certified. For the first time it was certified according to ISO 9001 in 2001. Nowadays it is certified in accordance with ISO 9001 and ISO 14001. The certification according to OHSAS 18001 should be achieved in 2012. It is aligned with the goals of ENSI and contributes to the fulfilment of these goals. The management system properly reflects requirements established by national legislation as well as those in the IAEA safety standards requirements publications.

The current system is process-oriented and consists of 25 main processes arranged in 4 process groups that can also be considered as products:

- Management Processes,
- Assessment of Facilities,
- Surveillance of Operations,
- Supporting Processes.

The core processes are part of either Assessment of Facilities or Surveillance of Operations and represent the main activities of the inspectorate to fulfil the mandate given by the legislation.

The documentation of the system is process oriented and hierarchically structured. The whole system is computerized, easily understandable and user's friendly.

The entire documentation consists of around 800 single documents. They are located on a central server and every document is available to all staff members. Access to the system documentation is provided by an electronic tool called "Squirrel", which is available on every workstation within ENSI. This tool was introduced in 2004 and became essential for the acceptance of the management system. Squirrel helps to find any document very quickly with a few mouse clicks. The documents can be found through the process structure, by the document type or simply by searching for keywords. Frequently used templates can be found very quickly in a separate list, ensuring everybody is working with the current version. Furthermore, Squirrel provides some additional useful functions for process owners, like replacing a document by a new version while moving the old document to the archive or automatically creating hyperlinks to other system documents.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1, Requirement 19 states that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."*
GP 5	**Good Practice: The ENSI management system is properly established and supported by software applications, which provide a comprehensive platform to ensure that the system works properly, is user friendly and allows interconnection among various management system processes.**

Safety Culture

There is evidence that safety plays a paramount role at ENSI even though all features of safety culture are not directly addressed in the management system. ENSI also started a project related to safety culture – "Safety culture in nuclear power operation and regulation in Switzerland". To ensure that all staff pays appropriate attention to all safety culture aspects in their roles and tasks ENSI should address safety culture in their Management system. This will ensure a common understanding of the key aspects of "safety culture" within the organization, support individuals and teams in conducting their tasks successfully taking into account all possible interaction, and reinforce a learning and questioning attitude.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-3 para. 2.5 states that** *"The management system shall be used to promote and support a strong safety culture by:* • *Ensuring a common understanding of the key aspects of safety culture within the organization;* • *Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;* • *Reinforcing a learning and questioning attitude at all levels of the organization;* • *Providing the means by which the organization continually seeks to develop and improve its safety culture."*
S2	**Suggestion: ENSI should explicitly address safety culture in its management system to achieve a common understanding of the key safety culture aspects within the organization.**

Graded approach

The ENSI applies a graded approach to assure that surveillance is balanced. This is reflected in AAU1606 – "Priorities and level of processing" where the process describes how to establish both sound priorities and the level of processing required for each business activity.

Management commitment

The commitment of the management to the implementation, assessment and continual improvement of the management system is visible and influencing the work of ENSI. The procedures for assessment and proposals for improvement are established and easily accessible through the existing software tool. All proposals are duly assessed and where appropriate implemented. Management at all levels follows the

evaluation of the management system based on semi-annual reports and reports from internal and external audits.

Satisfaction of interested parties

Taking into account ENSI the mandate given to ENSI by law, the communication concept has been prepared to address expectation of various parties. ENSI prepares various reports - for official as well as for public purposes, participates in public hearings, and organizes meetings with members of the parliament to discuss specific nuclear safety issues which are currently on the political agenda. For communication purposes ENSI web page is also used.

Stakeholder requirements are discussed by the executive board and the inspectorate tries to satisfy the expectations as long as they do not have any negative impact on safety. The final decision, especially if safety is concerned, is taken by the inspectorate without any influence of the stakeholders.

Organizational policies, planning and responsibility and authority for the management system

The organizational policies are properly established and are based on the mandate given to ENSI by law. They are subject to periodical review by the executive board.

The policies are a part of the management system and accessible to all employees. The policies are also communicated through reports which are issued quarterly and are publicly available.

The ENSI Board is responsible for establishment of the business plan. There is set up process for preparing the plan. Based on the business plan goals the indicators are defined and the results are reviewed by the executive board at least every quarter. If there are deviations identified the Board of Directors defines corrective measures and then follows the results. In order to minimize the operational risk the special "Risk management" process was implemented. The process allows the systematic recording, assessment, management, reporting and monitoring of business risks throughout the organization.

Resource management

The process for allocation of appropriate human and financial resources is in place. Human resources are addressed in the process HPB0060 – Human Resources and two specific working documents – AAU1600 – ENSI Staff Executive Regulation and AAU1090 – Personnel Development Concept.

Attention is given to the development of staff competence as well as to the transfer of knowledge (see chapter 3.3).

Process implementation

The ENSI Management system has been developed in the years 2000 and 2001. Once the system was fully established, the responsibility for continuous improvement was passed to the process owners. Each process is regularly evaluated to ensure that it remains effective. The process indicators used for effectiveness measuring are available to all staff members through software Pteromy.

Control of records is established and maintained for documents and products (e.g. review reports).

There exists evidence that the organization pays attention to organizational changes nevertheless organizational change should be addressed in the management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-3 para. 5.28 states that** *"Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified."*
(2)	**BASIS: GS-R-3 para. 5.29 states that** *"The implementation of such changes shall be planned, controlled, communicated, monitored, tracked and recorded to ensure that safety is not compromised."*
S3	**Suggestion: ENSI should establish an appropriate approach in the management system to address organizational changes.**

Measurement, assessment and improvement

The overall process to monitor and measure the effectiveness of the management system is established. Various tools are used – self-evaluation, internal and external audits, among them IRRS. Senior managers of ENSI regularly evaluate the results (at least quarterly) and if necessary corrective action are implemented.

All non-conformances are duly recorded and reported and necessary actions are taken.

Opportunities for management system improvement are identified. All staff is encouraged to submit their comments and proposals. This is also supported by the software tool – Chinchilla.

5. AUTHORIZATION

5.1. GENERAL

This section reviews authorizations for nuclear facilities and activities using the requirements of GSR Part 1 and the associated guides as the basis. The review focuses on those authorization aspects that are part of ENSI's responsibilities.

5.2. LEGAL BASIS

Nuclear energy and radiation protection is regulated in Switzerland by the Nuclear Energy Act – NEA (of 21 March 2003) and the Radiological Protection Act - RPA (of 22 March 1991).

Art. 6 of the NEA establishes that anyone who handles nuclear materials is obliged to obtain a licence from the authority designated by the Federal Council. The Federal Council may impose a licensing obligation for:

a. handling or using any materials or equipment intended for, or required for the use of nuclear energy;
b. the export or brokerage of technology.

The licensing procedure is regulated by the Federal Council.

Authorizations are issued by several federal authorities, namely the *Federal Council*, the *Federal Department of Environment, Transport, Energy and Communications* (DETEC), the *Swiss Federal Office of Energy*, the *Swiss Federal Nuclear Safety Inspectorate* (ENSI), the *Federal Office of Public Health* the *Swiss Accident Insurance Fund*. In particular, authorizations cover all nuclear installations and activities, unless exempted by the law, and all phases of the installations life (i.e. siting, construction, operation, decommissioning and closure). In the case of nuclear facilities and radioactive waste, as well as ionizing radiation sources associated with them, authorizations are granted by the Federal Council, the Federal Department of Environment, Transport, Energy and Communications (DETEC), and the Swiss Federal Nuclear Safety Inspectorate (ENSI). In the case of activities of industrial, medical and research field involving ionizing radiation, authorizations are granted by the Federal Office of Public Health and the Swiss Accident Insurance Fund. These last activities are however outside the scope of the IRRS mission.

The second level of legislation consists of ordinances, the most important of which are the *Nuclear Energy Ordinance* (of 10 December 2004) and the *Radiological Protection Ordinance* (of 22 June 1994).

5.3. TYPES OF AUTHORIZATION

There are four types of authorizations: licence, orders, permits and operator licences.

According to the Nuclear Energy Act a licence is requested for the siting, the construction and operation of a nuclear installation (a NPP, a research reactor, a waste and/or fuel storage or disposal facility). According to Art. 12 of the NEA, anyone intending to construct or operate a nuclear installation must first obtain a *"General licence"* by the Federal Council (the only exception being facilities with low hazard potential, Art. 12 Para. 3 of the NEA). Specific licences have subsequently to be obtained for the construction and operation. The Construction and Operation licences are granted by the Federal Department of Environment, Transport, Energy and Communications (DETEC).

Licences granted under the Nuclear Energy Act covers nuclear safety, security and radiation protection aspects.

In case of a change in the purpose or scope of a nuclear facility or of a comprehensive upgrading of a nuclear power plant, for instance in order to extend its service life, an amendment of the General Licence issued by the Federal Council is requested.

In case of modifications that significantly affect the original construction licence or the operating licence amendments issued by DETEC have to be granted.

According to the Nuclear Energy Act (NEA), geological investigations to be carried out in order to closely examine potential sites for a deep geological repository and activities that affect a designated protection zone in which interventions could interfere with the safety of a deep geological repository are subject to a licence granted by DETEC.

The authorization system in Switzerland envisages Orders, which oblige the licence holder to perform certain specific activities. In particular, they are issued by DETEC for the Decommissioning of nuclear facilities and by the Federal Council for closure of deep geological repositories.

As a second level type of authorizations there are the Permits, which are granted by the Supervisory authority (ENSI) in the context of the general framework defined by a licence (Construction or Operation licence) or by an order (Decommissioning Order).

Another type of authorization attains to the personnel of a nuclear facility performing key safety relevant operations and activities in a NPP or Research Reactor (i.e. reactor operators, shift supervisors, and stand-by safety engineers in NPPs). These personnel are authorized by the Licence holder with the formal agreement of ENSI.

5.4. LICENCES

The General Licence is granted by the Federal Council and to a large extent it is the result of the combination of a technical evaluation and a political decision. Consequently, the procedure adopted to grant the licence provides for a wide participation of the public (public vote is possible), the cantons and neighbouring states and involves a broad political discussion on the risks and benefits associated with a nuclear facility.

As stated in the Nuclear Energy Act no legal entitlement exists with respect to the granting of a general licence.

According to Art. 14 of the NEA, the general licence specifies the licence holder, the location and the purpose of the installation, a brief outline of the project and the maximum permissible exposure to radiation for people in the vicinity of the installation. In the case of deep geological repositories the licence specifies criteria which, if not fully met, lead to the exclusion of a planned disposal zone due to a lack of suitability.

As specified in Art. 23 of the Nuclear Energy Ordinance applications for a general licence must be accompanied by a safety analysis report and security report (including information on site characteristics), purpose and outline of project, anticipated exposure to radiation in the vicinity of the installation, important information regarding organisation and personnel, and, in case of geological disposal, indication of long-term safety), a concept for decommissioning or for the monitoring period and closure, an environmental impact report and a report on compliance with spatial planning requirements.

The procedure established in Art. 42 of the NEA states that the application has to be submitted to the Swiss Federal Office of Energy (the Federal Office), together with all necessary documentation. The Federal Office asks for advisory opinion from governmental expert bodies according to their competences (in particular, ENSI to review and assess the safety and security reports and the decommissioning concept, the Federal office of environment for the Environmental Impact report and the Federal office of Spatial development for the report on compliance with spatial requirements). As reported to the IRRS team the regulatory review and assessment by ENSI is documented in a Safety Evaluation Report, which may include licence conditions to be attached to the licence. The licensing procedure coordination follows a concentration model according to which a single authorization is issued by the leading authority (namely the Federal Council or DETEC) that contains the conditions of all competent authorities.

The licensing process involves also the cantons and neighbouring countries. A consultation according to the ESPOO convention, to which Switzerland is a signing party, is performed too. The application and the corresponding reviews by the federal and cantonal authorities are published as official documents and are subject to a 3-month consultation period during which anyone can raise an objection. The process ends with a decision of the Federal Council which has to be ratified by the Parliament. Eventually the decision is subject to a country-wide popular vote, a so-called (optional) referendum.

The Construction licence - which is granted by DETEC - according to Art. 17 of the NEA specifies the licence holder, the location of the installation, the planned reactor thermal power output or capacity of installation, the main elements of technical implementation, a brief outline of emergency protection measures, a list identifying all structures, systems and components of the installation that may only be constructed or installed after a permit has been issued by the relevant supervisory authorities.

Art. 24 of the NEO with associated Annex 4 specifies the type of demonstrations and documentation to be submitted by the applicant. The application for a construction licence shall contain a Safety Analysis Report, an environmental impact report, a report on compliance with spatial planning requirements, a quality management programme for the planning and construction phase, an emergency preparedness concept and a decommissioning plan or, in case of deep geological repositories, a project for the monitoring period and a plan for the closure of the installation. It must include a report on compliance of the project with the general licence conditions.

The procedure specified in Art. 50 of NEA states that applications must be submitted to the Federal Office, together with all necessary documentation.

Even if not explicitly stated in the Act it has been clarified to the IRRS mission experts that the various federal authorities are involved in evaluating the application documents according to their specific responsibilities. The ENSI Safety Evaluation Report for a construction licence application covers all the areas mentioned above (except those related to environmental impact evaluation and spatial planning requirements).

The licensing process also involves the canton where the facility is to be constructed and the public. The application and the assessment reports are made public and those entitled may file an objection. The construction licence is drafted by the Federal Office of Energy and eventually issued by DETEC. It can be challenged in court and there are two appeal stages that can be invoked before it is legally binding.

The Operating Licence is granted by DETEC providing specific conditions listed in Art. 20 of NEA are met such as the demonstration of compliance with all provisions established in general licence and in the construction licence and with relevant nuclear safety and security requirements, insurance of protection of population and environment, compliance with requirements on personnel and organization.

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, the levels of start-up that require a permit from the relevant supervisory authority prior to commencement of operation of the installation.

The application for an Operating licence shall contain the Final Safety Analysis Report, various technical documentation necessary for operation (as defined in Annex 3 and 4 of the Nuclear Energy Ordinance, e.g. security report, actual plant specific PSA, technical specifications, in-service inspection program, ageing monitoring program).

The procedure for granting an Operating licence is essentially the same as for granting a construction licence. The ENSI Safety Evaluation Report resulting from the performed review and assessment addresses all areas mentioned above.

Based on Art. 73 of the NEO ENSI is responsible to review submitted applications. Chapter 6 of NEA – Procedures and Supervision do not explicitly mention that the licences are granted by fully incorporating ENSI opinion and conditions. In reality, the implemented procedure, as also made clear by a decision of DETEC dated September 30 2011, envisage that ENSI opinion and conditions are normally taken on board in the granted authorization because DETEC does not have the technical competences to perform review and assessment and therefore regularly depends on obtaining the necessary expert reports from the safety authority for this purpose. Additional observations on the authority to formulate binding conditions to be incorporated in the authorizations or in their amendments that should be given to ENSI by legal provisions are given in section 1.2. of this report.

In addition, according to Art. 71 of NEA, the NSC may report to Federal Council or DETEC on ENSI's expert opinions. Additional information on the role of federal commissions providing second opinions to DETEC for nuclear safety issues is given in section 3.4 of this report.

5.5. ORDERS

Decommissioning of nuclear facilities and closure of deep geological repositories are not authorized with a licensing procedure, but require an authorization order**.**

The decommissioning order is issued on the basis of the decommissioning project which must be submitted by the licence holder upon termination of operation. It defines in particular the timetable and the steps of decontamination, dismantling and demolition, and the management of the arising radioactive waste. The order is issued by DETEC. After successful and complete decommissioning, DETEC declares that the former nuclear facility is no longer subject to the nuclear energy legislation.

The oversight of decommissioning activities is regulated through hold points which must be cleared with the corresponding permits issued by ENSI.

The closure for a repository is issued on the basis of the project for closure which must be submitted by the licence holder for the repository. It is issued by the Federal Council upon expiry of the monitoring period after emplacement of the waste packages is completed. After closure the Federal Council may order further surface monitoring for a limited period of time, after which it will declare that the disposal facility is no longer subject to the nuclear energy legislation.

5.6. PERMITS

Permits are requested in the case defined in the nuclear legislation, or may be prescribed in the conditions attached to a licence and are issued by the Swiss Federal Nuclear Safety Inspectorate.

In particular, according to Art. 17 of the NEA the construction licence specifies a list of structures, systems and components of the installation that may only be constructed or installed after a permit has been issued by the relevant supervisory authority. In a similar manner specific steps for the start-up of a plant are identified in the Operating Licence (Art. 21 of the NEA) and specific decommissioning activities are identified in the decommissioning order (Art. 28 of the NEA).

Art. 65, paragraph 3, of the NEA states that in the event there is the need to introduce amendments to the licence that do not deviate significantly from the respective licence or order as cited in paragraph 2, but which may have an influence on nuclear safety or security, the holder is required to obtain a permit from the supervisory authorities.

The NEO, Art. 40, specifies the modifications that do not deviate significantly from the respective licence but which require a permit in accordance with above mentioned Article 65, of the Nuclear Energy Act (e.g. modifications to structures, systems and components subject to safety or security classification and to equipment relevant to safety or security, providing the existing safety or security functions are maintained or improved, certain modifications in the reactor core, etc.).

A substantial part of the daily business of the Swiss Federal Nuclear Safety Inspectorate is related to issuing permits for amendments that do not deviate significantly from the relevant licence, but which may have an influence on nuclear safety or security. The range of plant modifications that do not deviate significantly from a licence but need a permit by the Swiss Federal Nuclear Safety Inspectorate is large. In principle, any modification of a safety classified system, structure or component requires a permit (the same applies to safety-relevant plant documentation such as the Technical Specifications). In the case of a minor modification of a single component, the extent of the ENSI review and assessment is normally limited, whereas in the case of complex modifications of systems and the construction of additional safety classified buildings, the evaluation can be extensive.

5.7. OPERATOR LICENCE

Based on Art. 25 of the Ordinance on Personnel Requirements, (known by the acronym VAPK) a licence is required for a reactor operator, shift supervisor or a stand-by engineer in a nuclear power plant. A licence is also required for working as a reactor operator, reactor technician or reactor physicist in a research reactor. Such licence is granted by the licence holder of the nuclear installation if the candidate has passed the examination of fundamental knowledge of nuclear engineering as it is stated in the VAPK ordinance as well as the corresponding licensing examination. The candidate has to fulfil also other requirements defined by the VAPK ordinance. Each licensing requires the written consent of ENSI. The exam is assessed by the examination board, to which ENSI nominates its representatives. The examination board consists of the plan, training centre, and ENSI representatives. It is only possible for the candidate to pass the exam when all members of the examination board approve this exam. The details of exam are determined in the ENSI-B10 guideline which was prepared by ENSI based on provision in the VAPK ordinance. Validity of the licence is also specified in the VAPK ordinance. In Art. 33 of the VAPK ordinance the withdrawal of the licence is codified and the ordinance also establishes requalification requirements.

All parts of training and retraining are under supervision of ENSI.

Based on the evidence the authorization/licensing process of personnel is in compliance with the IAEA requirements and guides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 para. 2.6 states that** *"Where several authorities are involved, the government shall specify clearly the responsibilities and functions of each authority within the governmental, legal and regulatory framework for safety."*
(2)	**BASIS: GSR Part 1 para. 2.8 states that** *"To be effectively independent, the regulatory body shall have sufficient authority and sufficient staffing and shall have access to sufficient financial resources for the proper discharge of its assigned responsibilities. The regulatory body shall be able to make independent regulatory judgements and decisions, free from any undue influences that might compromise safety, such as pressures associated with changing political circumstances or economic conditions, or pressures from government departments or from other organizations. Furthermore, the regulatory body shall be able to give independent advice to government departments and governmental bodies on matters relating to the safety of facilities and activities."*
R6	**Recommendation: The government should revise relevant legislation in order to provide ENSI with the authority to formulate binding conditions on nuclear safety, security and radiation protection. This should be fully reflected in various licences, orders or in their amendments whenever it is necessary before or after the issuance of the authorization.**

6. REVIEW AND ASSESSMENT

6.1. GENERAL

The objective of the review and assessment of relevant information is to determine whether facilities and activities comply with regulatory safety requirements and the conditions specified in the authorization. The specific objectives of the review and assessment will depend on the stage of the lifetime of the facility. Management within the regulatory body of the review and assessment process is an important part of the process.

Items reviewed and discussed during the mission are as follows:

- Management of review and assessment,
- Organization and technical resources for review and assessment,
- Performance of the review and assessment,
- Monitoring of the review and assessment.

6.2. NUCLEAR POWER PLANTS

6.2.1. LEGAL BASIS AND GUIDANCE DOCUMENTS

The Nuclear Energy Act (NEA, 732.1) defines the overall goals, scope, and principles which govern safety analyses and verifications to be performed by the licensee over the lifetime of a nuclear facility. This Act together with the principles of nuclear safety and security are defined in more detail in the accompanying Nuclear Energy Ordinance (NEO, 732.11) and in particular in the DETEC (Swiss Federal Department of Environment, Transport, Energy and Communication) Ordinance on Hazard Assumptions and the Assessment of the Protection against Accidents in Nuclear Installations (732.112.2).

International Regulation

IAEA regulation and the WENRA reference levels form an important basis for ENSI's guidelines. However, as indicated in ENSI's Advanced Reference Material, the laws, ordinances and regulations in Switzerland are in some areas less detailed than in some other countries, therefore it is part of the law that the corresponding regulations of vendor countries (US and Germany) are taken into consideration whenever there are no Swiss specific regulations.

6.2.2. REGULATORY REVIEW AND ASSESSMENT

Independent verification by operating organization

The purpose of the independent safety verification is to establish that the safety assessment satisfies the applicable safety requirements.

In IAEA GSR Part 4 (Req. 21), the operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body. In addition, the regulatory body has to carry out a separate independent verification to satisfy itself that the safety assessment is acceptable and to determine whether it provides an adequate demonstration that the legal and regulatory requirements are met. The Team noted that ENSI had discussed this requirement but not yet systematically implemented it. However, some examples within the fuel area (new fuel codes) were provided in which ENSI requires an independent evaluation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 4, Requirement 21 states that** *"That the operating organisation shall carry out an independent verification of the safety assessment before it is used by the organisation or submitted to the regulatory body."*
(2)	**BASIS: NS-R-1 para. 3.13 states that** *"The operating organization shall ensure that an independent verification of the safety assessment is performed by individuals or groups separate from those carrying out the design, before the design is submitted to the regulatory body."*
(3)	**BASIS: NS-G-1.2 para. 5.2 states that** *"Independent verifications are performed separately both by the plant owner-operator, who generally conducts an independent review of the design organization, and by the regulatory body."*
(4)	**BASIS: GS-G-1.2 para. 4.2 states that** *"The regulatory body should have a system to audit, review and monitor all aspects of review and assessment process so as to ensure that it is being carried out in a suitable and efficient manner…."*
R7	**Recommendation: ENSI and other relevant authorities should establish a regulatory requirement for licensees to independently verify all safety information internal or coming from its contractors notably design organizations and vendors, prior to its submittal to the regulatory body.**

Internal Guidance

In para. 3.2 of IAEA GS-G-1.2, it is stated that the regulatory body should provide internal guidance on the procedures to be followed in the review and assessment process and guidance on the safety objectives to be met. Detailed guidance on specific topics for review and assessment should also be provided, as necessary. Consideration should be given to the extent to which the regulatory body's internal guidance may be available to operators and the public.

As stated in IAEA GS-G-1.2 para. 3.6, in carrying out a review and assessment of an operator's submission, the regulatory body should employ a systematic plan to provide assurance that all the topics significant to safety will be covered and that operators of similar facilities will be treated equally. This plan should include a series of procedures that the regulatory body will follow for all aspects and topics covered by the submission in order to identify those items for which applicable safety objectives and requirements have been met and those for which they have not. An outline of such a plan might be as i) definition of scope, ii) purpose, technical basis, iii) identification of the additional information, iv) performance of step by step review and assessment, v) decisions on the acceptability of the operator's safety arguments or the need for further submissions.

The principal purpose of this systematic plan is to assure the quality and uniformity of staff safety reviews and is also to make information about regulatory matters widely available and to improve communication between regulator, interested members of the public, and operating organization, thereby increasing understanding of the regulator's review process.

The procedure and process of the review and assessment are well described in the ENSI management system and the safety objectives are specified in ENSI Guidelines.

Back-fitting

The regulation requests that the safety of SWISS NPPs has to be continuously improved by back-fitting measures (NEA 732.1 Art. 22, NEO 732.11 Art. 12 and DETEC Ord. 732.114.5 and ENSI-G07). All NPPs have implemented programmes to improve their safety records.

ENSI review and assessment of back-fitted or modified safety systems, safety-related systems and their components covers at least i) quality assurance of manufacturing, assembling and commissioning, ii) impact on safety concepts and on results of safety analyses as appropriate, iii) operating experience with the same or similar system/component from NPPs and other nuclear installations in Switzerland and abroad (see Guidelines HSK-R-23, HSK-R-31, HSK-R-35, HSK-R-46, HSK-R-51, ENSI-G07, ENSI-G11, ENSI-B06 and ENSI-B10).

The IRRS team found that the back-fitting rule is very clear. It is clearly stated that an INES-2 worldwide (INES-1 at the plant itself) shall be analysed and might lead to back-fitting. If the analysis shows that the design basis is violated (e.g. dose criteria cannot be met), the plant has to shut down immediately until the corresponding back-fit is complete. Fukushima is such an example leading to measures which have to be implemented. However, no immediate shutdown was needed as none of the criteria of the DETEC Ordinance 732.114.5 on the Methodology and the General Conditions for Checking the Criteria for the Provisional Taking out of Service of Nuclear Power Plants have been met. Based on the back-fitting rule, numerous plant improvements have been initiated.

Examples of back-fitting and replacement are:

- additional shutdown and residual heat removal systems for the Mühleberg and Beznau plants (SUSAN and NANO projects) that are both installed in bunkered flood-proof buildings;
- to mitigate flooding effects, special equipment has been installed in various NPPs. For instance, at Beznau NPP there are special diesel generators and auxiliary feed-water pumps in flood-proof areas;
- BWRs can be manually connected to a hilltop reservoir to flood the core;
- to mitigate the radiological effect on the environment in the event of a severe accident, a filtered containment venting system was back-fitted to all Swiss NPPs in the early 1990s at the request of the regulatory body;
- replacement of the existing reactor protection and control systems with a computer-based system at both units of Beznau NPP;
- replacement of source and intermediate-range nuclear instrumentation with a digital wide range monitor system at Beznau and Mühleberg NPPs;
- implementation of a motorized safety/relief valves at one PWR to manually depressurize the RPV (reactor pressure level) (AM measure).

Many of the listed modifications were derived from safety analyses (in particular from the PSA).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: NS-R-1 para. 3.9 states that** *"The design shall take into account of relevant operational experience that has been gained in operating plants and of the results of relevant research programmes."*
GP6	**Good practice: The rules for back-fitting have clear initiation points, criteria on what safety goals must be fulfilled and the measures that may be needed for their implementation.**

Power uprating

In the event of reactor power uprating, important modifications or equipment replacement, the operating organization should identify and justify possible associated changes in process conditions (e.g. flow pattern, velocity, vibration) that could cause accelerated or premature ageing and failure of some components. ENSI has reviewed and approved the reactor power uprating in accordance with the proper Guideline.

Maintenance of the Safety Assessment - Update of the Safety Analysis Report (SAR)

GSR Part 4, para. 5.2 states that the safety assessment in itself cannot achieve safety. Safety can only be achieved if the input assumptions are valid, the derived limits and conditions are implemented and maintained, and the assessment reflects the facility or activity as it actually is at any point in time. Updating of the safety assessment is also important in order to provide a baseline for the future evaluation of monitoring data and performance indicators and, for facilities for the storage and disposal of radioactive waste, to provide an appropriate record for reference with regard to future use of the site.

In GSR part 4 para. 5.10 it is stated, the safety assessment has to be periodically reviewed and updated at predefined intervals in accordance with regulatory requirements. Periodic review may need to be carried out more frequently to take into account any changes that may significantly affect the safety of the facility and activity etc.

The operating organizations in Switzerland should update the Safety Analysis Report in accordance with NEO Art. 41, Annex 3. However there is no formal process for periodic review of the updated safety analysis report by ENSI to confirm that information in the current SAR is most updated. The only process to review the safety assessment at ENSI seems applying only after relevant plant modifications (including modifications of relevant technical documentation such as the Technical Specifications) and for PSR reviews.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 4 para. 5.2. states that** *"The safety assessment in itself cannot achieve safety. Safety can only be achieved if the input assumptions are valid, the derived limits and conditions are implemented and maintained, and the assessment reflects the facility or activity as it actually is at any point in time. Facilities and activities change and evolve over their lifetimes (e.g. through construction, commissioning, operation, and decommissioning and dismantling or closure) and with modifications, improvements and effects of ageing. Knowledge and understanding also advance with time and experience. The safety assessment has to be updated to reflect such changes and to remain valid. Updating of the safety assessment is also important in order to provide a baseline for the future evaluation of monitoring data and performance indicators and, for facilities for the storage and disposal of radioactive waste, to provide an appropriate record for reference with regard to future use of the site."*
(2)	**BASIS: GSR Part 4 para. 5.10. states that** *"The safety assessment has to be periodically reviewed and updated at predefined intervals in accordance with regulatory requirements. Periodic review may need to be carried out more frequently to take into account any changes that may significantly affect the safety of the facility and activity etc."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S4	**Suggestion: ENSI should develop a formal process for conducting regulatory reviews of safety analysis reports of nuclear facilities.**

Assessment of human factor and organizational changes

Human interactions at the facility in different activities should be addressed in the safety assessment. ENSI has a section ("Human and Organisational Factors") which reviews NPP staff qualification and training, safety culture, organizational management system and user friendly human system interface (HSI). Examples of the assessment of HSIs were introduced and discussed. Those are human and organization factor, operation experience, systematic and integrated treatment and analysis, impact analysis, and iterative development. Some of HSI projects were also introduced such as symptom oriented emergency operating procedures and the upgrade of a Main Control Room (screen controlled). ENSI has developed the guideline G-07 "Organization of nuclear installations" and provided requirements on availability of human resources, on organizational changes, and on recruitment.

Digital I&C alarm system computerized procedures

Modernization of NPP and consideration of common cause failure (CCF) was presented by the electrical engineering section. Reasons for retrofitting of existing I&C systems were discussed. There are appropriate guidelines for the I&C area developed by ENSI such as HSK-R-46 and G-05.

The 'PRESSURE' project of Beznau NPP was introduced to illustrate the approval and assessment process, (i.e. CCF, I&C replacement, diversity and NANO (bunkered emergency system)). As another example, CPU based safety control systems such as secondary independent control system to avoid CCF in safety system, were also discussed. It was confirmed that the regulation, licensing procedure, safety assessment are well performed in accordance with ENSI Guidelines.

6.2.3. SAFETY ANALYSIS

Deterministic safety analysis

In Switzerland the DBA is a step-wise process. The first step is to define a list of design basis accidents (based on an established list and experience and events occurring worldwide). The second step is to categorize these accidents, based on the frequency of DBA. The categories are specified in RPO §94. The third step is the performance of Deterministic Safety Analysis (DSA). The results are compared with technical criteria given in DETEC Hazard Assumption Ordinance 732.112.2 and shutdown criteria given in DETEC Shutdown criteria Ordinance 732.114.5. The fourth step is offsite dose consequences analysis according to ENSI-G08 and G14. The calculated offsite dose is compared with the dose limits given in RPO 814.501.1 §94.

The whole process performed by ENSI is in conformance with international practice and is in accordance with IAEA NS-R-1, SS2-G and NS-G-1.2. The categorization assigned to accidents based on frequency and application of single failure criterion in the safety analysis in Switzerland is not a common international practice, however, it is concluded that it does fulfil the relevant requirements and guidance of IAEA. It should be noted that the dose limit of 1 mSv in the accident category 2 (frequency between 10^{-2} and 10^{-4} per year) is low compared to international standards.

For the operator actions and the use of mobile equipment in DBA, IAEA NS-R-1, para. 5.28 states that in cases "where prompt action is not necessary, manual initiation of systems or other operator actions may be permitted, provided that the need for the action be revealed in sufficient time and that adequate procedures (such as administrative, operational and emergency procedures) be defined to ensure the reliability of such actions". This recommendation is appropriately implemented into ENSI Guideline A01 Art. 4.4.4.

Different options for performing deterministic safety analysis are suggested by the IAEA No. SSG-2. ENSI guideline allows to use of best estimate codes with conservative initial and boundary conditions and conservative input data and assumptions in the safety analysis with sensitivity studies including LOCA (loss of coolant accident) calculation. In general, IAEA recommends use of a best estimate code with realistic initial and boundary conditions.

External natural hazards assumptions

In Switzerland the following initiating events and effects of external events of natural origin have to be taken into account (DETEC Hazard Assumptions Ordinance 732.112.2):

- Earthquake,
- Flooding,
- Extreme weather conditions,
- Fires (e.g. forest fire)
- Lightening.

The external hazards of earthquake, flooding and severe weather conditions have to be determined with the help of probabilistic hazard analysis, considering up to date scientific knowledge. In the deterministic safety analysis external natural events with a frequency greater or equal to 10^{-4}/yrs (mean value) have to be analysed. For earthquakes this is in compliance with IAEA Safety Standards NS-G 1.6 and SSG-9. According to IAEA Safety Standards two levels of ground motion hazard are evaluated for each plant. The seismic level SL-2 is the bounding earthquake, which is in the order of 10^{-3} and 10^{-4} per year (mean value).

Flooding hazards are described in IAEA NS-G-3.5, chapter 2.27 discusses both deterministic and probabilistic cases. All flooding scenarios with frequencies greater than 10^{-4} per year have to be analysed in the DSA.

The IAEA Safety Guide NS-G-3.4 for extreme weather conditions are described and are in conformity of the other two guides mentioned above. In IAEA Guide SSG-2 (Table 2) accidents with a frequency between 10^{-4} and 10^{-6} per year are treated as beyond design basis accident whereas in Switzerland these accidents are DBA belonging to accident category 3.

PSA

Legal and technical basis as well as application of PSA were presented and discussed. Discussion was focused on the use of PSA in the integrated regulatory safety oversight. It is concluded that ENSI makes an extensive use of PSA in the regulation and is well advanced in the application of PSA leading to numerous plant improvements.

ENSI requirements on how the PSA should be executed are rather prescriptive and have to some extent harmonised PSA from the utilities. Furthermore, the licensees have to maintain the PSA up-to-date

("living PSA"). ENSI has requirements on how the licensee shall use PSA to enhance the safety of the plant. Furthermore, criteria are defined for specific PSA applications in the regulatory guideline ENSI-A06.

During the visit to PSI, research activities and tasks in support of ENSI ("on-call task") were discussed with Risk and Human Reliability Group. The scopes and types of regulatory support, formal process with contractors and highlights of general assessment were discussed. Internal discussion only with the PSI staff was done to confirm the technical competency of ENSI staff in the area of PSA. The team confirmed that ENSI has a close cooperation with PSI, especially in the area of safety analysis including PSA. PSI has provided a strong support as a contractor to work with regulatory issues. The process how task are initiated, defined, carried out and finalized in the contract is very transparent and systematically checked. It is a good practice that ENSI formally produces the review results of the report submitted by the contractor. Current regulatory activities on the human reliability analysis were presented by PSI and discussed.

PSA is systematically integrated in the regulation. Based on PSA, numerous plant improvements have been initiated.

Examples of good practices are:

- PEGASOS (Reassessment of seismic hazards),
- Level 2 PSA for low power and shutdown states,
- Human reliability analysis,
- Comprehensive review process and update of PSA,
- Probabilistic assessment of operating experience.

The applicability and effectiveness of ENSI's re-evaluation process are illustrated by the probabilistic reassessment of seismic hazards at Swiss NPP sites (the PEGASOS project and the PEGASOS Refinement Project). The large-scale project (SSHAC Level 4) PEGASOS – a German acronym for "Probabilistic Assessment of Seismic Hazards for Swiss Nuclear Power Plant Sites" – was carried out (this was before the Fukushima accident) by Swiss licensees in response to a requirement that came out of ENSI's PSA review process. Based on the PEGASOS outputs, ENSI increased the level of seismic hazards which was then used in the PSA studies. Higher hazard assumptions are also used for the design of new safety-related structures and components. Furthermore, in the context of the continuous back-fitting process undertaken by Swiss NPPs, ENSI places particular emphasis on seismic safety. Commendable is the work and application by ENSI of PSA results together with review and assessment activity of applications in order to grade the relevance of safety measures design and back-fitting.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 4 Requirement 15 states that** *"Both deterministic and probabilistic approach shall be included in the safety analysis. Also No.SSG-3 (Level1 PSA) and No. SSG-4 (Level 2 PSA)."*
GP7	**Good Practice: ENSI is using PSA in different areas of its regulatory activity in an advanced and comprehensive manner.**

Validation and verification of computer codes used in the Safety Analysis Report

Any methods of calculation and computer codes used in the safety analysis shall undergo verification and validation to a sufficient degree (GSR Part 4 Req. 18). The methods used in the computer code for the calculation should be adequate for the purpose and the controlling physical and logical equations should be correctly implemented into computer code.

Computer codes used in the safety analysis of NPPs in Switzerland and their validation/verification process were discussed. ENSI performed the verification and validation process of the computer codes used in the safety analysis in accordance with ENSI A01 in an appropriate manner. Independent audit calculations are performed by ENSI and the PSI e.g. for the codes TRACE and FALCON. An example of the code validation process of the fuel performance code CARO-E3 for KKB by ENSI was presented and discussed. The validation discussed was performed in the context of a formal application of the plant to use the code in the future. After an initial screening if documents were missing, ENSI used PSI as a consultant to verify that the code was adequate for its purpose. After ENSI had obtained and reviewed the corresponding report from PSI, ENSI could give the approval to the licensee (in this particular case not done yet). The team judges that this procedure is properly performed.

Severe Accident Management Program

For beyond design basis accident (BDBA) no dose limits are defined and it cannot be excluded that a perilous amount of radioactive substances can be released. According to Art. 24 para. 1 Let. b and Art. 28 para. 1 Let. d of the Nuclear Energy Ordinance, for the construction permit and the operation permit of a new nuclear power plant, it shall be demonstrated that the mean core damage frequency (CDF) of the plant is less than 10^{-5} per year. For existing NPPs, requirements are defined according to the Ordinance on Hazard Assumptions and Evaluation of Protection Measures against Accidents in Nuclear Installations (SR 732.112.2) and the guideline ENSI-A06.

The development program of severe accident management (SAM) has been considered by ENSI from 1998 and is required according to Ordinance 732.11. All NPPs in Switzerland have developed the plant specific SAM procedures well in accordance with the IAEA guidance. The SAM program consists of identification of plant vulnerabilities/capabilities, strategies and related accident management measures, strategies, hardware provisions and supporting analysis.

As part of the SAM program severe accident management guidelines (SAMG) have been developed as required by ENSI guidelines B12. Verification of the SAMG have been carried out to check the correctness of a written procedure or guideline and to ensure that the technical and human factors have been properly incorporated. All procedures and guidelines have been reviewed.

Exercises and drills should be based on an appropriate scenario that will require the application of a substantial number of procedures and guidelines. The team confirmed that ENSI has monitored and evaluated the exercises and drills of the operating organizations.

6.2.4 PERIODIC SAFETY REVIEW

It is mandatory to submit a PSR report once every 10 years by the NEO Art. 34. HSK-R-48 is ENSI guideline for PSR. The guideline was developed in 2000 and describes contents of the PSR only for safety concepts, assessment of operation management and behaviour, deterministic/probabilistic safety analysis and overall assessment of the safety status. The team identified that the current guideline HSK-R-48 has not systematically considered 14 safety factors recommended by the IAEA NS-G-2.10. The safety factors

include equipment qualification, ageing, safety performance, human factors and organization/administration, etc. The team did not identify any missing safety factors in the scope of the PSR performed in Switzerland. ENSI provided its plan for updating PSR guideline in 2012.

Policy Issue: Long Term Operation

To maintain plant safety it is very important to detect ageing effects of systems, structures and components, to address associated reductions in safety margins and to take corrective actions before loss of integrity or of functional capability occurs. Effective ageing management is in practice accomplished by coordinating existing programmes, including maintenance, in-service inspection and surveillance, as well as operations, technical support programmes (including analysis of any ageing mechanisms) and external programmes such as research and development.

With the aid of a programme for managing ageing effects, the licence holder must systematically monitor ageing of all systems, structures and components, the function and integrity of which are important with regard to safety and security (Art. 35 NEO). ENSI Guideline B-01, which is based on the IAEA Standards Series NS-G-2.12, specifies the requirements for implementing and documenting the ageing surveillance programmes. The ageing surveillance programme is in place for all NPPs and is a pre-requisite for long term operation in Switzerland.

Requirements for long term operation are as follows:

1) Ageing surveillance programme (ASP)
   - Systematic ASP for classified SSC in the mechanical, civil and electric engineering areas
2) Verification of the shutdown criteria
   - Compliance with the shutdown criteria for ageing over the expected operation time (primary circuit, containment)
3) Deterministic and probabilistic safety analysis
   - Compliance with the dose limits for DBA and the CDF limit for existing plants
4) Technological ageing
   - Assessment of realized and planned back-fitting projects

ENSI was prompted to give in-depth consideration to the issues related to long term operation in 2004. As part of the conversion of what was then a fixed-term operating licence for KKB2 (Beznau NPP2) into an unlimited operating licence, ENSI developed the current procedure for demonstrating the reliability of long term operation.

The team had a discussion regarding the requirements that ENSI has concerning ageing management. Ageing management has evolved during the years due to the older reactors are reaching a mature age, the first reactor started its operation in 1969. With the implementation of ENSI-B01, the licensees have to provide a yearly report of the ageing management program; this report also includes the results of all ageing-relevant findings (ISIs).

The relevant ordinance of DETEC SR 732.114.5 considers that taking out of service must take place on account of design errors, or due to physical ageing damage. If ageing damage is ascertained, the licence-holder must immediately take the nuclear power plant out of service on a provisional basis if the following criteria are met:

- Embrittlement of the reactor pressure vessel (RPV): adjusted reference temperature for a depth of one quarter of the RPV wall thickness is greater than 93°C, or the upper shelf energy from Charpy impact tests is less than 68 joules;
- Integrity of the primary circuit: occurrence of cracks which penetrate the walls, or wall thick-ness less than the minimum wall thickness at design pressure (without allowances, safety factor equal to 1.0);
- Integrity of the primary containment: wall thickness is less than the minimum wall thickness at design pressure (without increments, safety factor equal to 1.0);
- Integrity of the secondary containment: damage to more than 20% of the concrete surface (10% in the area of pre-stressed components) due to cracks with a width of over 0.5 mm or due to scabbing.

The IRRS team considered that a defined closure criteria to shut down an NPP based on the status of the reactor vessel and the containment is an example of an effective ageing management.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: IAEA NS-G-2.12 para. 7.10 states that** *"The operating organization assesses the effects of ageing on nuclear power plant safety, the effectiveness of the ageing management programme and the need for improvements to the ageing management programme."*
GP8	**Good Practise: ENSI has clear closure criteria to shut down NPP based on the status of the reactor vessel and the containment is an example for an effective ageing management.**

6.3. RESEARCH REACTORS

PSI has decided that the research reactor PROTEUS (1 kW_{th}) will be decommissioned while former research reactor DIORIT and SAPHIR are already in the state of decommissioning. Two small research reactors ($P < 2\ kW_{th}$) exist at the University of Basel (Uni BS) and at the Swiss Federal Institute of Technology Lausanne (EPFL), which are used mainly for teaching purposes. Due to its graded approach ENSI has no specific regulation and regulatory requirement to the research reactors. There is a general recommendation referring to this issue in chapter 1.2.

7. INSPECTION

7.1. GENERAL

According to the Nuclear Energy Act (SR 732.1), Art. 72 para. 1, the supervisory authorities shall ensure that licence holders meet their obligations in accordance with the provisions of the Act. To monitor the compliance with legislation and regulatory requirements, ENSI uses inspections as one of the most important instruments. ENSI is empowered by the Nuclear Energy Act to perform these inspections. The Act gives ENSI inspectors the right to enter all sites of nuclear facilities, buildings and installations without prior notification and inspect all relevant documentation. Inspections can and are conducted in all nuclear facilities with a graded approach and in different phases of the lifetime of a nuclear facility. ENSI inspections cover also the transport of nuclear materials. The inspections on the safeguards of nuclear materials are under the responsibility of the Federal Office of Energy.

7.2. NUCLEAR POWER PLANTS

For nuclear power plants, ENSI established a Basic Inspection Programme (BIP) in 2001. The BIP includes inspection areas, inspection topics and the intervals between inspections (from 1 to 10 years). The BIP identifies generic inspections common to all nuclear power plants as well as plant specific inspections. The structure of the BIP reflects the organizational structure of ENSI. Topics are assigned to the different sections according to their field of competence and responsibility. With the BIP as a basis, plant specific annual inspection programmes are established by ENSI. The annual inspection programme includes inspections focused on construction of systems, structures and components (including modifications), maintenance, periodic testing, radiological protection, management system and competencies of operational staff. The annual inspection programme is complemented and adjusted with additional inspections based on the results of the annual systematic safety assessment and activities at the plant during the year. These adjustments and additions are related to e.g. plant modifications or specific outage activities planned to be performed at the site. In addition to planned inspections, ENSI conducts also reactive inspections usually in response to events.

Inspection methods applied by ENSI include examination and evaluation of the nuclear power plant, procedures, records and documentation, surveillance and interviewing of personnel, as well as the possibility to take samples and perform measurements. 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.

The results of ENSI’s inspections are used as an input to the systematic safety assessment process. Findings of the inspections are rated according to their safety significance and recorded continuously to the system. The categorization of the rated findings in the system is based on the one hand on requirements for the design, operation, state and behaviour of the plant or man and organization, and on the other hand on the different levels of defence in depth as well as on the fulfilment of safety functions. With the system the personnel of ENSI and ENSI’s management is able to maintain an up to date status of the safety of the plant.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 27 states that** *"The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."*
GP9	**Good Practice: The integration of rated inspection results with the safety assessment system provides a useful and systematic tool for ENSI to continuously evaluate the safety of the nuclear power plants.**

The current BIP was established in 2001 and it resulted from the expert judgment of the section heads reflecting also requirements from the regulatory guidelines (e.g. periodicity of system tests). The inspection areas in the BIP were updated in 2011. However, the description of the inspection process in the management system does not explicitly describe the evaluation and development of the process or BIP and annual inspection programmes. See recommendation in paragraph 7.7.

The safety assessment system that uses the results of the inspections as an input was established in 2005 and it is an essential part of ENSI's integrated oversight process. In the systematic safety assessment the performance of the plant as well as the organisation is assessed within the framework of defence in depth. Since the same framework of defence in depth was not used as a basis when basic inspection programme was developed in 2001, it could be useful to perform an evaluation if the inspections defined in the BIP adequately and in a balanced way also cover the different levels of defence in depth. When performing the evaluation also risk insights could be utilized to ensure completeness as well as implementation of graded approach in the inspection programmes.

The inspection process is described and governed by the ENSI management system. It includes planning and preparations of the inspections, conduct and reporting of inspections together with responsibilities for the inspection process. Inspections are done by inspectors with special competence. ENSI has also nominated site inspectors. Site inspectors are generalists and their inspections, which are usually unannounced, are focused on the normal operation of the plant and safety related outage activities. All inspectors are trained to do inspections and inspectors recruited to ENSI after beginning of 2009 have gone through a formal qualification. ENSI's management system does not give detailed guidance for inspectors on the topics to be covered in the inspections. The topics of the inspection are defined and decided during inspection preparation. To ensure that also individual inspections cover all areas of regulatory responsibility, a more detailed guidance on the contents of the inspections could be provided to inspectors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 para. 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization…"*
(2)	**BASIS: GSR Part 1 para. 4.52 states that** *"Regulatory inspections shall cover all areas of responsibility of the regulatory body…"*
(3)	**BASIS: GS-G-1.3 para. 3.14 states that** *"Inspections by the regulatory body should be concentrated on areas of safety significance. These are those SSCs and activities affecting safety or processes important to safety which are identified as such in the safety*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	documentation submitted by the operator or in the findings of the regulatory body's review and assessment, or which are stipulated in the conditions attached to the licence."
(4)	**BASIS: GS-G-1.3 para. 4.1 states that** *"To ensure that all nuclear facilities in a State are inspected to a common standard and that their level of safety is consistent, the regulatory body should provide its inspectors with written guidelines in sufficient detail. […]* *(d) implementation of the inspection programme, including:* - *areas to be subject to inspection,* - *method of inspection to be used,* - *methods for selection of inspection samples,* - *relevant technical information and questionnaires;* *(e) reporting requirements and practices for inspectors;* *(f) policies of the regulatory body as they may affect inspection;"*
S5	**Suggestion: ENSI should consider reassessing its current inspection programme for nuclear power plants to determine if it covers adequately all levels of defence in depth which is the basis used in ENSI's systematic safety assessment. ENSI should also consider issuing more detailed guidance on the contents of the inspections conducted within the Basic Inspection Programme to ensure that inspections cover all areas of the responsibility of the regulatory body.**

Related to the oversight of safety culture, ENSI has been preparing a concept paper. The paper will include ENSI's definition of safety culture, and expectations for how it will oversee the safety culture of the licensee as part of the integrated oversight. ENSI has also discussed the subject with the licensees. These discussions have been conducted twice with all licensees and will be continued in the future. ENSI inspectors have been trained to make observations on safety culture and there is a possibility to address observations in the inspection reports.

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. ENSI collaborates also with cantonal organizations responsible for fire protection. Inspections on fire protection are normally conducted in co-operation. On the area of safeguards the responsible authority is the Federal Office of Energy, which also conducts inspections in the area.

7.3. RESEARCH REACTORS

ENSI establishes annual inspection programmes also for research reactors. The same process as described above for nuclear power plants is implemented to the applicable extent to research reactors for planning, execution and reporting of inspections. Facility inspectors have been nominated for research reactors. The number of inspections and other oversight activities on research reactors is lower than that of the nuclear power plants due to very low potential risk of radioactive products release to environment from Swiss research reactors. Results of the inspections are utilised in the annual safety assessment. Improvements for this process are still possible and are under development.

7.4. WASTE FACILITIES

ENSI establishes annual inspection programmes for waste facilities. The same process as described above for nuclear power plants is implemented to the applicable extent to waste facilities for planning, execution and reporting of inspections. Facility inspectors have been nominated for waste facilities. The number of inspections and other oversight activities on waste facilities is lower than that of the nuclear power plants due to lower potential risk of radioactive products release to environment from Swiss waste facilities. Results of the inspections are utilised in the annual safety assessment. Improvements for this process should be considered to ensure that inspection process covers adequately safety significant issues and activities at the waste facilities. See recommendation in paragraph 7.7.

7.5. INSPECTION OF RADIOACTIVE SOURCES AND X-RAY EQUIPMENT AT NUCLEAR FACILITIES

Although ENSI is the competent authority for inspection of radioactive sources and X-ray equipment within the nuclear facilities, there is no inspection programme to cover this area of responsibility. There is no systematic process to confirm compliance of radioactive sources and X-ray equipment with regulatory requirements. ENSI only performs some ad hoc inspections on NDT-activities (Non Destructive Testing with industrial radiography) during NPP outages and some reactive inspections after an event. See recommendation in paragraph 7.7.

7.6 TRANSPORT

Inspection programmes for transport at each nuclear facility consist of one inspection for nuclear material and one for radioactive material (for example contaminated tools after outage activities). The scope of the inspections can vary and are determined based upon previous findings and the annual meeting held with other Authorities. If the scope includes leak testing of the transport package this is sub-contracted to SVTI. ENSI have 3 full time SVTI staff supporting transport inspections, with the majority of this resource being allocated to the surveillance of manufacture of the storage casks.

The results of the inspections are subjected to a systematic evaluation process for transport to determine the scope of the next inspection to be carried out and on what timescale.

7.7. SCOPE AND EFFECTIVENESS OF THE INSPECTION PROCESS

The IRRS team considers that the inspection process as described in the ENSI management system is followed for NPPs. ENSI also evaluates the effectiveness of this process for NPPs.

Taking into account the findings mentioned above related to the inspections of waste facilities, decommissioning, the use of radioactive sources and X-ray equipment at the nuclear facilities, the IRRS team recommends ENSI perform a holistic evaluation on the effectiveness of its inspection process and on the coverage of inspection programmes. The objective of this evaluation should be to conclude whether the inspection process applied to NPPs is effective for other nuclear facilities, sources and X-ray equipment and to ensure that all areas of responsibility of the regulatory body are covered by the inspection programmes.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-3 para. 6.1. states that** *"The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement."*
(2)	**BASIS: GSR Part 1 para. 4.50. states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
R8	**Recommendation: ENSI should evaluate the effectiveness of the inspection process and coverage of the inspection programmes to ensure that also all other nuclear facilities (e.g. waste facilities, decommissioning, X-ray equipment and radioactive sources at the nuclear facilities) are adequately addressed.**

8. ENFORCEMENT

8.1. GENERAL

The legal basis for enforcement is described in the Nuclear Energy Act Art. 72 and 73. The Act gives extensive and well defined powers to the supervisory authorities. Art. 72 para. 2 states *"They shall order any necessary and reasonable measures aimed at preserving nuclear safety and security"*. In case of an immediate threat, NEA Art. 72 gives both duty and authority to supervisory authorities to take immediate actions to eliminate threat in case the licensee does not fulfil its responsibility for safety. This applies also to nuclear goods, radioactive waste and other sources. The Act also enables supervisory authorities to ask assistance of police authorities or customs administration (including border control). Supervisory authorities are authorized to take measures to eliminate risks that are not addressed in the regulatory requirements or in the authorization.

For nuclear power plants ENSI has established criteria for shutting down the plant in case safety of the public or the environment is endangered. Each ENSI inspector is empowered to impose the immediate shut-down of a NPP or to forbid a re-start after shutdown. ENSI's regulatory enforcement policy is specified as a process in the Management System (see process descriptions for enforcement HPB0340, corrective action SPB0341, prosecution SPB0342). ENSI's enforcement process is well structured and defined.

During recent years ENSI has faced situations where prosecution had to be initiated in cases where nuclear or radiation safety was not challenged. This is due to the fact that Swiss legislation is detailed and as such - when violated - has a low threshold to initiate prosecution without assessment of the level of wilfulness or safety significance of the issue. Even minor non-compliances, listed in Art. 93 of the Nuclear Energy Act, can result in prosecution. Examples of such minor non-compliances are a failure to comply with either a reporting obligation or an obligation to keep adequate records. If there is a reasonable suspicion such an offence has occurred, supervisory authorities are obligated to notify the Federal Office of Energy, which will decide upon subsequent prosecution.

Art. 44 of the Radiation Protection Act also lists minor non-compliances in the field of radiological protection. Such offences in nuclear installations will be prosecuted by the supervisory authorities (ENSI for nuclear installations). Prosecution is governed by the Federal Act on Administrative Criminal Law.

Penalties imposed on the licence holder are not an instrument of enforcement in the Swiss legal framework. The Nuclear Energy Act defines explicit fines to individuals (fine up to 500 000 Swiss francs) or imprisonment e.g. in a case where a safety system is made inoperable either wilfully or by mistake. This kind of legislation can have negative impact on safety since it may result in a non-reporting of safety significant issues, and blame for the person making or reporting the mistake. This in turn results in lack of openness and transparency, and prevents organizational and individual learning from events increasing the possibility in repetition of events and therefore safety risks. The Nuclear Energy Act and the Radiation Protection Act should be changed in such a way that a blame free safety culture can be established and supported in the nuclear facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 para. 4.54 states that** *"The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 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."*
(3)	**BASIS: GS-R-3 para. 2.5. states that** *"The management system shall be used to promote and support a strong safety culture by:* - *Ensuring a common understanding of the key aspects of safety culture within the organization;* - *Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;* - *Reinforcing a learning and questioning attitude at all levels of the organization."*
R9	**Recommendation: The Government should change the legal framework in such a way that the threshold for prosecution should be commensurate with safety significance, in accordance with a graded approach. The legal framework should also - given the importance of openness and transparency for nuclear safety - allow prosecution of a licensee in order to avoid the detrimental effects of blame on an individual.**

ENSI has a process of systematic follow-up of requested actions/orders. In its management system ENSI has performance indicators to measure the effectiveness of the enforcement process. For example, ENSI has a process indicator to measure how well licensees respond to all ENSI orders and demands and how the deadlines set by ENSI are respected. Results of these indicators are discussed with the licensee management. At the end of the process, after the fulfilment of the actions, ENSI "closes" the process by writing a confirmation letter to the authorized party.

9. REGULATIONS AND GUIDES

9.1. GENERAL

The Swiss legislation and regulation system on nuclear and radiation safety is structured as a four level framework:

- Federal Constitution of the Swiss Confederation,
- Nuclear Safety related Acts,
- Nuclear Safety related Ordinances,
- Guidelines.

An overview is given in **Figure 1**.

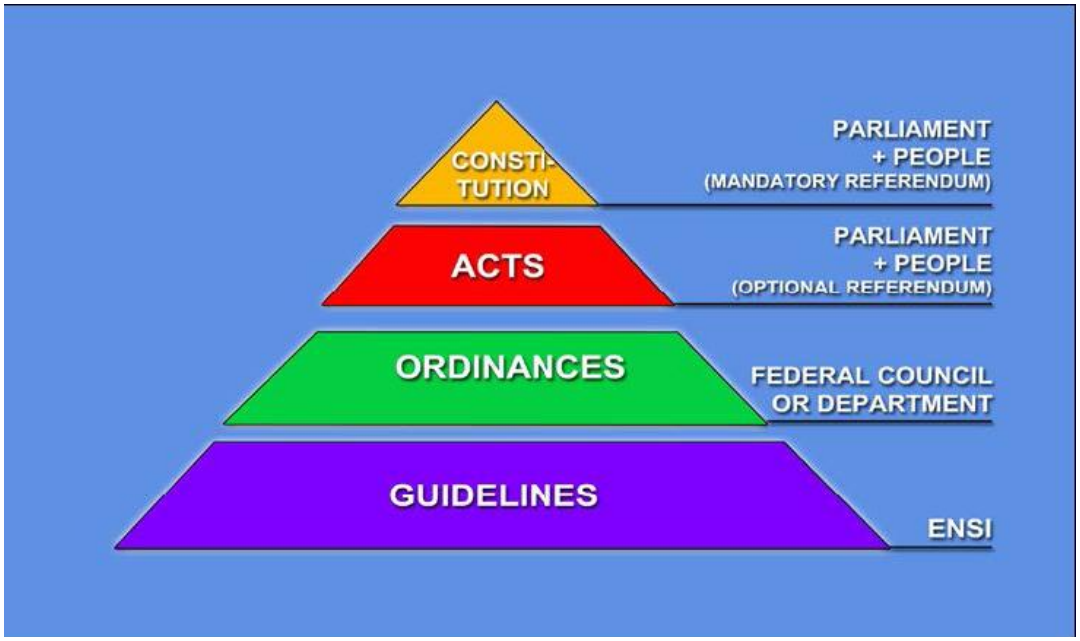

Figure 1: Regulatory Pyramid

Industry consensus standards related to the nuclear and radiation safety can also be made a part of the regulations by endorsing them in the Federal Regulations or Guidelines or by including them into the licensing basis of a facility. In addition ENSI has prepared a list of standards and norms for the use in the regulatory process (AAU1130). The documents in the list are approved by ENSI. If a proposed solution is in compliance with the documents within the list ENSI will accept the proposed solution (if it does not violate requirements in a higher-level document).

The Federal Council (the Swiss government) has established a new basis for regulations in the Nuclear Energy Act (NEA 732.1, 2003) and in the Nuclear Energy Ordinance (NEO 732.11, 2004). The Federal Constitution states in general that the Confederation is responsible for legislation in the field of nuclear Energy and protection against ionizing radiation (Art. 90 and 118 of the Constitution). The Federal Act on the Swiss Federal Nuclear Safety Inspectorate (ENSIG 732.2, 2007) defines the role of ENSI in the regulatory process and authorizes ENSI to issue Guidelines. Every Guideline contains a special section listing acts and ordinances according to which it is developed.

The hierarchy and structure of the Swiss nuclear and radiation safety regulations and guidelines is generally consistent with international practices.

9.2. EXISTING REGULATIONS AND GUIDES

General

The fundamental laws governing regulation of civilian uses of nuclear materials and facilities are the Nuclear Energy Act (NEA 732.1, 2003), the Nuclear Energy Ordinance (NEO 732.11, 2004), the Radiological Protection Act (RPA 814.50, 1991) and the Radiological Protection Ordinance (RPO 814.501, 1994).

The Nuclear Energy Act establishes the basic principles for nuclear safety and security, licensing process for nuclear related facilities and activities, the regulatory apparatus and financial and governmental aspects. The Radiological Protection Act establishes the basic principles for radiation safety related to all activities, installations, events and situations that may involve an ionizing radiation hazard and establishes an emergency response organization for incidents that could endanger the public as a result of increased radioactivity.

The Nuclear Energy Ordinance establishes more detailed principles for nuclear safety and security for nuclear facilities, e.g. detailed requirements for licensing documents, requirements for the organization of a nuclear facility, requirements for assessment of safety and security analysis. The Radiological Protection Ordinance applies to substances, articles and waste whose activity, concentration, contamination, dose rate or mass exceeds certain values (as given in Annex 2 of the same ordinance). This Ordinance also applies limitations for ionizing radiation generators, equipment and installations.

A complete list of all acts and ordinances is available on the website of the Swiss Federal Administration (http://www.admin.ch/ch/d/sr/sr.html). The regulations within acts and ordinances are mandatory.

In addition there are guidelines e.g. to substantiate the implementation of legal requirements and to ensure uniform implementation in practice. The guidelines are issued by ENSI. Guidelines are “semi mandatory” which means that ENSI may allow deviations in individual cases. In such a case the proposed solution has to ensure at least an equivalent level of nuclear safety or security. This equivalent level of safety or security has to be accepted by ENSI. ENSI stated that deviations from Guidelines are very seldom. The process to deal with these deviations seems to be appropriate. The IRRS Team verified the procedure on the basis of one example.

Following the new Nuclear Energy Act and Nuclear Energy Ordinance ENSI designed a new framework for its guidelines. The guidelines were divided into three categories:

Series A: Guidelines covering the assessment of facilities
Series B: Guidelines covering the surveillance of operations
Series G: Guidelines with general requirements

In addition there was a project to ensure that the guidelines were complete and cover all relevant activities. The previously issued guidelines had adopted the design principles from the country of origin of the Swiss nuclear power plants (namely USA and Germany). ENSI identified gaps within its guidelines and started a comprehensive program to close these gaps. This process is still on-going. For example in stage of current development are 19 guidelines. ENSI presented the IRRS Team with the concept and the implementation plan of this project. On the basis of the consultation and the presented papers the IRRS

Team considers that there is a clear and comprehensive approach taken by ENSI and that the implementation process is in place and works.

A complete list of all guidelines is available on the website of ENSI (http://www.ensi.ch).

ENSI has a comprehensive program to complete its new regulatory framework. With respect to the new boundary conditions (phase-out decision on the political level) it seems to be appropriate to give a suggestion on this topic.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
S6	**Suggestion: ENSI should follow its comprehensive program to complete the regulatory framework in the future. The regulatory framework should be completed in a timely manner.**

NPP and Research Reactors

ENSI has shown a good covering by the Swiss regulation framework of all requirements aspects of NPPs designing and operation. It is demonstrated in the following tables.

Requirements	Act	Ordinance	Guideline
NPPs design			
Safety objectives	NEA, RPA	NEO, RPO, SR732.112.2	-
The concept of defence in depth	NEA	NEO	
Responsibilities in management	NEA	NEO	G07
Management of design	NEA	NEO, SR732.112.2	G07, A01, A05, G11
Proven engineering practices	NEA	NEO, VBRK	G02, G11
Operational experience and safety research	NEA	NEO	G02, G07
Safety assessment	NEA	NEO, VBRK	G07, G11
Independent verification of the safety assessment	-	-	G07
Quality assurance	-	NEO	G07
Requirements for defence in depth	NEA	NEO, SR732.112.2	R101, G02
Safety functions	NEA	NEO, SR732.112.2	A06, G01, G02
Accident prevention and plant safety characteristics	NEA	NEO	G02
Radiation protection and acceptance criteria	RPA	RPO, NEO	A01, A08, B09, G14, G15, R39
Safety classification	NEA	NEO	A06, G01
General design basis	NEA	NEO, SR732.112.2, VBRK	A01, A05, A08, B12, G01, G02, G09, G11, G14, R50, R101
Design for reliability of structures, systems and components	-	NEO	A01, A05, G01, G02, G11, R101
Provision for in-service testing, maintenance, repair, inspection and monitoring	-	VBRK	G11, R31, R46
Equipment qualification	NEA	VBRK	G11, R31, R46
Ageing	-	NEO, VBRK	G11

Human factors	NEA	NEO	G07
Other design considerations	NEA	NEO, SR732.112.1, VBRK	A01, A05, A10-A12, G01, G02, G11, G17, G18, R04, R07
Safety analysis	-	NEO, RPO, SR732.112.2	A01, A05, A06, A08, G14
Reactor core and associated features	-	NEO, VBRK	R61, G02, G11, R101
Reactor coolant system	-	NEO, VBRK, RPO	A05, B06, B12, G02, G09, G11, NE14, R101, R103
Containment system	-	NEO, VBRK	B06, B12, G02, G11, R40, R101, R103
Instrumentation and control	NEA	NEO	G02, B12, R46, R101
Emergency control centre	-	-	B12
Emergency power supply	-	-	G02, R101
Waste treatment and control systems	-	NEO, RPO	B05, G04, R07
Fuel handling and storage systems	-	-	G02, G04, R61
Radiation protection	NEO, RPA	RPO, NEO	G13, R07
NPPs operation			
General requirements	NEA	NEO, RPO, VAPK	G07, G09, B10, B12,
Interface with the regulatory body	NEA	NEO	A04, B02, B03, G07, G09
Quality assurance		NEO	G07, G09
Feedback of operating experience	NEA	NEO	B02, B03, G07
Physical protection	NEA	NEO, SR732.112.1	A09-A13, R49
Fire safety	-	-	R50
Emergency preparedness	NEA	NEO, VAPK	B11, B12, G09
Qualification and training of personnel	-	NEO, RPO, VAPK, SR814.501.261	B07, B10, B13, G07
Commissioning programme	NEA	NEO	A15, G07, G09
Operational limits and conditions	-	NEO, SR732.114.5	A04, A06, B03, B10, G07, G09
Operating instructions and procedures	-	NEO, VAPK	B10, B12, G07, G09
Core management and fuel handling	NEA, RPA	NEO, VBRK	B05, G02, G07, G09, R60, R61
Maintenance, testing, surveillance and inspection of structures, systems and components important to safety	-	NEO, VBRK	B03, B06, B14, G07
Plant modifications	NEA	NEO	A04, B06, B14,G07, G11
Radiation protection and radioactive waste management	NEA, RPA	NEO, RPO, UVG	A08, B02, B05, B09, B10, B13, G04, G09, G13, G14, G15, R07
Records and reports	-	NEO	B02, G06, G07, G09
Periodic safety review	NEA	NEO	A03, G07, G08, R48
Decommissioning	NEA	NEO, RPO	G07, G17

It was established in discussions with ENSI counterparts that special nuclear research reactors guidelines have not been developed. This is based on a decision taken by ENSI. According to the Nuclear Energy Act the research reactors are nuclear installations. Therefore all the regulatory guidelines applicable to the Swiss nuclear installations can be used for the research reactors. There are only two small research reactors in operation in Switzerland with power capacity under 2000 W_{th}. According to chapter 1.14 of IAEA Safety Requirements NS-R-4 the following factors are to be considered in deciding whether to waive IAEA requirements by applying a graded approach: small reactor power < 2 kW; small source term; absence of spent fuel elements, high pressure systems and heating systems. ENSI performs its supervisory functions of the research reactors by inspections (at least one per year for each research reactor), setting requirements, issuing enforcement orders and granting execution permits within the terms of the issued licence.

Guidelines for other equipment like ionizing radiation generators, medical and industrial equipment are

not developed by ENSI because it has no responsibility for these facilities.

Decommissioning

The Swiss Federal Nuclear Safety Inspectorate (ENSI) does not have a formalized program to safely regulate decommissioning activities at nuclear facilities under its charge. High level requirements for decommissioning are in the Nuclear Energy Act (2003, revised 2009) and the Nuclear Energy Ordinance (2003). To date, decommissioning of one research reactors (LUCENS) has been completed using very restrictive release criteria to define non-radioactivity material. Two research reactors are in decommissioning status under the old energy act. One (SAPHIR) has been dismantled and building remains in use for other licenced activities. The other (DOIRIT) suffered a work stop due to a conventional (industrial) safety event involving asbestos, but work was authorized to restart with expected completion in 2012. ENSI approval to authorize the start of decommissioning of the research reactor facility was issued inconsistent with IAEA requirements because an all hazards assessment including conventional safety was not performed by the safety authority. Prior to issuing future authorizations to allow the operator to start decommissioning, ENSI should ensure that all safety requirements are completed.

ENSI is planning to regulate the decommissioning of five large power reactors starting in 2020 and is in the early stages of developing the decommissioning regulatory program. ENSI management has a plan for addressing decommissioning program issues. ENSI is a member of the Western European Nuclear Regulator's Association (WENRA) and informed the IRRS Team that ENSI will be drafting the decommissioning regulatory guidelines consistent with the WENRA Decommissioning Safety Reference Levels Report (WGWD 2.0). The WENRA report provides a cross reference to IAEA decommissioning safety requirements for licensees. It does not specify the regulators requirements such as the criteria for terminating a licence. Priority should be given to research reactors since there are two facilities are being decommissioned.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 10 states that** *"Provision for the decommissioning of facilities and the management of radioactive decommissioning and of spent fuel. The government shall make provision for the safe management and disposal of radioactive Decommissioning arising from facilities and activities, and the safe management of spent fuel."*
(2)	**BASIS: GSR Part 1 Section 2.28. states that** *"Decommissioning of facilities and the safe management and disposal of radioactive Decommissioning shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities…. The government shall enforce continuity of responsibility between successive authorized parties."*
(3)	**BASIS: GSR Part 1 Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
S7	**Suggestion: ENSI should continue to develop a decommissioning regulatory program that integrates all hazards assessments. Special attention should be given to conventional safety prior to issuing new permits for decommissioning.**

9.3. PROCESS FOR THE DEVELOPMENT OF REGULATIONS AND GUIDES

Acts and ordinances are developed with respect to the legal System of the Swiss Confederation. Acts can be initiated by members of the parliament, sections of the administration, cantons or the federal council.

Ordinances can be issued due to a provision in an act or due to an assignment of the superior administrative authority. The leading role is with the federal department. Acts and ordinances are developed in four steps:

- Draft by the administration,
- Consultation process,
- Parliamentary debate (for acts mandatory, for ordinances optional) and final version,
- Referendum (optional, only for acts).

Where ENSI has regular responsibility it takes part in the first three steps. ENSI's role is to ensure that the expert knowledge is taken into account in each step of the process. It is the task of the federal departments to ensure that ENSI is properly involved in the development process for acts and ordinances regarding nuclear energy.

The IRRS Team had discussions with ENSI and a representative of SFOE. The IRRS Team was convinced that there was a clear understanding of the role of both authorities within the regulatory process. According to SFOE there is no example up to now where SFOE has refused to implement a statement of ENSI regarding nuclear safety. The process of the involvement of ENSI is transparent.

ENSI itself develops Guidelines through a process known as "Regulatory Basis Process." The process contains several steps. An overview is shown in **Figure 2**.

Figure 2: Process of Issuance Guidelines

The Regulatory Basis Process includes an internal and external consultation process and ensures that the intent of a guideline is fully understood by all stakeholders and its impact is adequately evaluated before the rule is enacted. The procedures are explained in the Management System of ENSI (HPB140). The IRRS team considered this to be a good practice.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
GP10	**Good Practice: During the process of developing a guideline there is an extensive process of consultation of stakeholders. It is an open and transparent process.**

The initiative for rulemaking can come from many different sources. Within ENSI there is a standing Committee dealing on a regular basis with the regulatory framework. International standards (IAEA and WENRA) covered by a guideline are mentioned in the specification and the explanatory report of the guideline.

Coordination and consistency inside ENSI is ensured in particular by:

- the composition of the working group formed for a specific rulemaking action;
- the Committee for the Regulatory Basis. It is the task of the Committee to review the draft guidelines to ensure their consistency with the regulatory framework;
- the requirement for a detailed specification at the beginning of the regulatory process.

In addition staff of ENSI actively participates in a large amount in international activities (OECD, IAEA, WENRA) to promote nuclear safety. Therefore ENSI could use all inputs from these activities within the process of developing and reviewing the regulatory framework.

ENSI presents the following issues for future regulatory framework development:

- Criminal sanctions for negligence. Conducting of criminal prosecutions. Liability of individuals (see also chapter 8).
- Developing of guidelines for the post-operational phase and decommissioning (to be drafted 2011-2012).
- Review of ENSI guidelines in the light of the events at Fukushima (in process now). It is necessary to wait for the outcome of the different projects that deal with the implications in Switzerland of the lessons learned from Fukushima.
- Review of regulatory framework due to Swiss government and parliament decision to phase-out from nuclear energy (should start in 2012).

The IRRS Team confirms that there are clear structured processes in place for developing of regulations and guidelines. The IRRS Team also confirms that the Regulatory Basis Process used by ENSI is an appropriate tool to ensure that the regulatory framework is up to date.

9.4. REVIEW OF REGULATIONS AND GUIDES

ENSI has a general policy to periodically review and revise the guidelines. The review of guidelines is part of the process "Regulatory Basis". The process is described in the Management System of ENSI (HPB140). There it is stated that the Committee for the Regulatory Basis reviews the guidelines on a regular basis and at least every ten years. ENSI stated that most of the guidelines are reviewed earlier.

The IRRS Team looked for examples and it can be confirmed that many guidelines are reviewed in a shorter timescale.

ENSI takes initiatives to make revisions if new information is identified, or where relevant safety and security experiences occur repeatedly, or when technology has advanced. In addition all international activities ENSI takes part in are considered too. To enhance this process further a special section was created to analyse national and international events and operating experience in a more complete and consistent way. With this new section the impact of such events to the guidelines can be managed in a timely manner. The IRRS Team consulted with the Head of this new section. The IRRS Team considers that ENSI therewith adopted an appropriate approach to optimize the existing procedures.

In 2005 ENSI started its comprehensive project to design a new regulatory framework. Within this project ENSI did a review of all guidelines and came up with a detailed action plan. ENSI is continuing this effort to ensure that appropriate guidance is updated, and anticipates completion of this process by the end of 2014.

Up to now there are 46 guidelines for the NPPs in use, 19 guidelines are in preparation.

9.5. RULES FOR BACK-FITTING

Switzerland has a good legislation and regulation for a back-fitting framework with detailed criteria for nuclear installations.

Back-fitting must take account of operational experience and the current state of back-fitting technology in order to further reduce the risk to humans and the environment as ordered in Art. 22, para. 2, letter g of Nuclear Energy Act.

Art. 44 of the Nuclear Energy Ordinance defines criteria for provisional taking out of service and back-fitting of nuclear reactors. This Art. says: "The holder of an operating licence must take the nuclear reactor out of service and back-fit it if one or more of the following technical criteria are fulfilled:

a. Events or findings indicate that core cooling in the event of an accident in accordance with Article 8 can no longer be assured;
b. Events or findings indicate that the integrity of the primary coolant system can no longer be assured;
c. Events or findings indicate that the integrity of the containment can no longer be assured.

In Art. 44 it is also defined that the Department should specify the methodology and boundary conditions governing the review of the mentioned criteria in an ordinance. More detailed information about the criteria for back-fitting is presented in the DETEC Ordinance on the Methodology and the General Conditions for Checking the Criteria for the Provisional Taking out of Service of Nuclear Power Plants (732.114.5, 2008).

In addition, the guideline ENSI-A06 requires that back-fitting options have to be evaluated if the core damage frequency of a NPP is in between 10^{-4} and 10^{-5} per year.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 para. 1, Requirement 1 states that** *"The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
GP11	**Good Practice: The licensees are required by law to back-fit their installations to the extent that is necessary, based on worldwide operating experience and the state of current back-fitting technology.**

ENSI decided that there is no need for detailed criteria for research reactors with respect to their very low potential risk of radioactive products release to environment. The IRRS Team considers that this approach is appropriate.

9.6. RELATION TO IAEA STANDARDS

ENSI is in the process of updating its regulatory framework, mainly the ENSI guidelines. The update became necessary to be compliant with the new nuclear legislation in Switzerland. According to Art. 5 para. 1 of the Nuclear Energy Act ENSI considers that the IAEA Safety Standards Series are internationally accepted principles, may be used as a basis for the Swiss regulations.

The regulations stipulated in the existing and planned Swiss regulatory framework (acts, ordinances and guidelines), have been compared to the IAEA safety requirements for NPPs design (NS-R-1). In total, all of the 219 requirements as stipulated in Section 2 through 6 of NS-R-1 have been compared to the regulations given in the existing and planned Swiss regulatory framework.

The same has been done for the IAEA safety requirements for NPPs operation (NS-R-2). In total, all of the 134 requirements as stipulated in chapters 2 through 11 of NS-R-2 have been compared to the regulations given in the existing and planned Swiss regulatory framework.

For every requirement in NS-R-1 and NS-R-2 the cross references to the corresponding acts, ordinances or guidelines were given by ENSI the IRRS team.

Three requirements (3.7, 5.19, 5.59) of NS-R-1 were found not to be explicitly covered by the Swiss regulatory framework, as well as requirement 5.16 of NS-R-2. All other requirements are found to be covered by the existing and planned Swiss regulatory framework. The current coverage of NS-R-1 requirements is 88% and NS-R-2 requirements is 84%.

Similar comparisons of WENRA requirements for NPPs and other nuclear facilities with the Swiss regulatory framework have been done. It has been determined that 80% of WENRA requirements were covered by 2010.

The IRRS Team has recognized that ENSI is highly involved in IAEA activities concerning regulations and guides. The Swiss regulatory framework is mainly based on the IAEA Standard Series. ENSI takes appropriate efforts to follow the development of the IAEA regulatory framework and to manage the transfer to the Swiss regulatory framework in a timely manner.

10. TRANSPORT OF RADIOACTIVE MATERIAL

10.1. SWISS TRANSPORT LEGISLATION

The transport requirements of IAEA (TS-R-1) are revised biannually and fully implemented in the Swiss legislation.

TS-R-1 updates are used to update the UN model regulations for the classification and safe transport of dangerous goods (the so-called "orange book"), which are subsequently carried over into the specific regulations for all modes of transport by international organisations such as:

- for air transport, ICAO (International Civil aviation Organisation);
- for road transport, the United Nations working party 15, the ADR (French acronym for European Agreement concerning the international carriage of Dangerous goods by Road) working group;
- for rail transport, the OTIF (French acronym for intergovernmental Organisation for International Carriage by Rail) governed by the RID regulations (French acronym for Regulations concerning the International carriage of Dangerous goods by rail);
- for sea transport, the IMO (International Maritime Organization) operating under the IMDG code (International Maritime code for Dangerous Goods);
- for transport of dangerous goods on in-land waterways, the UN-ECE (United Nations Economic Commission for Europe) in cooperation with the CCNR (French acronym for Central Commission for Navigation on the Rhine) is responsible for the ADN regulation (French acronym for *European Agreement concerning* the i*nternational carriage* of *Dangerous goods* by i*nland*. Waterways).

Since Switzerland is an ADR and RID member, the relevant international requirements are implemented in Swiss national legislation for all transport of dangerous goods including class 7 (radioactive material):

- IATA regulations are implemented in the Swiss Air Transport Ordinance (ATO) reference SR 748.411;
- ADR is implemented in the Ordinance SDR reference 741.621 on the transport of dangerous goods by road;
- RID is implemented in the Ordinance of the DETEC RSD reference 742.401.6 on transport of dangerous goods by rail and cableway installations.

The Federal Office of Civil Aviation, under special circumstances, may grant exemptions from licence requirements for particular transportation, valid for a limited period. The applicant has to seek for international flights and for an approval from all countries whose airspace will be used.

ENSI is responsible for approval of package designs as well as for transportation of radioactive materials as described in Art. 1 of the Swiss ATO.

10.2. ACTS AND ORDINANCES

- Nuclear Energy Act (NEA)
- Nuclear Energy Ordinances (NEO)
- Radiological Protection Act (RPA)
- Radiological Protection Ordinances (RPO)

10.3. REGULATOR FRAMEWORKS

To aide understanding of the IRRS team, radioactive material has been categorised by ENSI for purposes of explaining the regulatory control as follows:

- Group 1 – fissile material (approximately 30 shipments per year)
  - Regulated by NEA and NEO, Licences issued by SFOE, Inspection and control by ENSI
- Group 2 – non-fissile material from nuclear facilities (30 – 100 shipments per year)
  - Regulated by NEA and NEO (radioactive waste), Licences issued by SFOE, ENSI issues technical advice to support SFOE (evidence of compliance with transport regulations), Inspection and control by ENSI
  - Regulated by RPA and RPO (radioactive material excluding waste), Licences issued by ENSI, Inspection and control by ENSI
- Group 3 – all other radioactive material from the medical, industrial and military sectors
  - Regulated by RPA and RPO, Licences issued by SFOPH, Inspection and control by SUVA

10.4. LICENSING OBLIGATIONS

Anyone who 'handles' nuclear materials is required to obtain a licence from the SFOE (NEA Art. 6 and NEO Art. 13). 'Handling' is defined as research, development, production, storage, transport, import, export, transit and brokerage (NEA Art. 3(j)).

Each of the aforementioned groups 1, 2 and 3 are regulated, issued licences and subjected to regulatory oversight (inspection and control). Technical assessment of transport packages is undertaken by ENSI for all three groups.

10.5. OVERVIEW

The Swiss legislation and regulatory structure is comprehensive but complex, nonetheless there is a clear understanding regarding scope of responsibilities in each authority regarding transport.

Assessment of package designs follow processes depending upon the origin of the transport package. For packages arriving from an ADR country, ENSI follow a package validation process that focuses on the ADR requirements for road transports. For packages arriving from outside the ADR zone, additional assessment takes place.

Compliance inspections are programmed and the outcomes are recorded in a systematic way. The services of SVTI are used to witness/inspect leak testing of transport packages as part of the annual inspection programme or as required by previous inspection findings.

The process is well documented in the ENSI management system.

10.6. INTERFACE BETWEEN REGULATORY AUTHORITIES

An annual meeting involving all regulatory authorities, including the Police, is held to discuss experiences and agree tactics for the following year. Nonetheless, there is a lack of formal sharing of information between regulatory authorities that are mandated to issue transport permits/licences or to carry out compliance inspections or enforcement in timeframes that would provide coordinated and effective regulatory oversight of transport activities for radioactive material. For example, in the context of regulatory oversight of Group 3 materials for which both ENSI and SUVA have responsibilities to issue permits depending if the material is to be transported onto a nuclear licence site.

An operator who transports a radioactive source in Switzerland will need to apply for a permit from SUVA while an operator who transports a radioactive source onto a nuclear licenced site will need to apply for a permit from ENSI.

The information submitted for both permits is the same and the content of the permit will be identical, however the title of the permits is different.

ENSI copies all permits it issues (valid for 10 years) to SUVA, whereas SUVA does not copy permits it issues (valid for 10 years) to ENSI.

Applicants to ENSI are asked if they also require a SUVA permit.

The existing arrangements do not prevent one Regulator refusing or withdrawing a permit whilst the other may issue a permit to the same operator.

The effective sharing of information would enable Regulators to be informed on intervention (inspection and enforcement) strategies and tactics of their counterparts.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR, Part 1 Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
R10	**Recommendation: The government should ensure that the Swiss Authorities responsible for the transport of radioactive material operate a collaborative process for the timely exchange of information regarding authorisations, inspections and enforcement actions to provide coordinated and effective regulatory oversight.**
S8	**Suggestion: ENSI should use the process recommended above for the exchange of information as a basis to collaborate with SUVA on compliance inspection programmes for companies subject to licences under RPA as well as NEA.**

10.7. REGULATORY CONTROL OF TRANSPORT RELATED ACTIVITIES ON A NUCLEAR FACILITY

ENSI has not defined all activities relating to the transport of radioactive material in the context of activities that require their authorisation on a nuclear facility.

For example, ENSI received formal notification by the ZWILAG operator of its intention to permit TNI to carry out maintenance of the TNI owned TN9/4 spent fuel transport cask at the ZWILAG facility. The TN9/4 is used to transport spent fuel from Mühleberg NPP to the ZWILAG facility.

Meetings took place between ENSI and the operators but no formal approval/authorization, which referred to the Quality Programme to be used, was issued, as it was not considered to be a change of scope for the facility, even though this was the first time this activity had taken place in the facility. ENSI should review its management processes to ensure that all activities on a nuclear facility related to transport packages are subjected to a formal process of approval based upon a graded approach.

It is important that the regulatory oversight and enforcement of industry not regulated under the RPA involves close collaboration with ENSI when new or used packagings' released from regulatory control under the NEA, are repaired, modified or maintained in an industrial facility.

10.8. ADOPTION OF GRADED APPROACH FOR TRANSPORT PACKAGES BY ENSI

ENSI developed a regulatory guide for safety classification of systems/components but it only relates to transport/storage casks. ENSI Regulatory Guide G05 section 7 states that repairs, modifications and replacement of safety-relevant parts have to be handled according to the requirements of equipment of safety class 2 for transport/storage casks. G05 does not relate to transport casks or other types of waste packages. A graded approach for transport packages should be adopted and guidance issued accordingly.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 23, para. 4.30 states that** *"Authorization for a facility shall include authorization of the activities taking place at the facility (e.g. operation, maintenance and engineering activities). The regulatory body shall verify, by appropriate means, the competence of individuals having responsibilities for the safety of authorized facilities and activities."*
(2)	**BASIS: GSR Part 1 Requirement 23, para. 4.31 states that** *"In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party's subsequent activities."*
(3)	**BASIS: GSR Part 1 Requirement 23, para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
(4)	**BASIS: TS-G-1.4, Appendix, para. A.6 (1) – (3) states that** *"(1) Identification of the package type according to the Transport Regulations [TS-R-1]; (2) Classification of the package by the development of a list of the packaging components and software to be used in its design, fabrication, use, inspection or testing, and assignment of a quality category (grade) to each (Table 2); (3) Specification of the management controls required and assignment of a quality category (grade) to each (Table 3)."*
(5)	**BASIS: TS-G-1.4 Appendix, para. A.16 states that** "*Type B packages (non-fissile and fissile). In all aspects contributing to the integrity of shielding and containment, together with criticality safety (where applicable), Grade 1 management controls are appropriate. All other aspects should be subjected to Grade 2 management controls, except where there is a minimal effect on safety, in which case Grade 3 management controls are appropriate.*"
(6)	**BASIS: TS-G-1.1 para. 311.7 states that** "*The competent authority should perform audits and inspections as part of its compliance assurance programme in order to confirm that the users are meeting all applicable requirements of the Regulations and are applying their quality assurance programs. Inspections are also necessary to identify instances of non-compliance which may necessitate either corrective action by the user or enforcement action by the competent authority. The primary purpose of an enforcement programme is not to carry out punitive action but to foster compliance with the Regulations."*
(7)	**BASIS: GRS Part 1 Requirement 32 states that** "*The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria*

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	for safety upon which its regulatory judgements, decisions and actions are based."
R11	**Recommendation: The government should ensure that there is appropriate and effective regulatory oversight and enforcement authority for all activities relating to packages that are used to transport radioactive material when such activities are undertaken on a facility that is not regulated under NEA.**
S9	**Suggestion: ENSI should issue a guidance document to specify the requirements for transport casks and other types of transport packages for radioactive material, including details of applying a graded approach to package components and management controls (activities).**

11. EMERGENCY PREPAREDNESS AND RESPONSE

11.1. GENERAL REQUIREMENTS

The legislative and statutory framework established at the national level in order to prepare for and manage any consequences of a nuclear or radiological emergency is set by:

a) Nuclear Energy Act (NEA) and Ordinance (NEO);
b) Radiation Protection Act (RPA) and Ordinance (RPO);
c) Ordinance on the Organisation of Operations in Connection with Nuclear, Biological, Chemical (NBC) and Natural Events;
d) Ordinance on the Protection in the Case of an Emergency;
e) Ordinance on the National Emergency Operation Centre (NEOC Ordinance);
f) Ordinance on Alerting and Alarming (Alarming Ordinance);
g) Ordinance on the Supply of the Population with Iodine Tablets (Iodine Tablets Ordinance);
h) Ordinance on Dangerous Substances and Food Contaminants;
i) Ordinance on Emergency Preparedness in the Vicinity of Nuclear Installations;
j) Concept for the Emergency Preparedness in the Vicinity of Nuclear Power Plants (ComNBC, 2006);
k) IAEA Convention on Nuclear Safety;
l) IAEA Convention on Early Notification of a Nuclear Accident;
m) IAEA Convention on Assistance in case of a Nuclear Accident or Radiological Emergency;
n) Bilateral agreements with neighbour countries (France, Germany, Italy, Austria and Liechtenstein).

The Regulatory Body (ENSI) is responsible for verifying that the licence holder fulfils its responsibilities according to the legislation, e.g. Nuclear Energy Act, articles 4, 5, 20, 22, and Nuclear Energy Ordinance articles 24, 30, 33, 38, 40. However, emergency preparedness is not fully included as part of the regular inspections (although the observation of the annual emergency exercises in NPPs is considered as an element of the inspection regime).

According to articles 8 and 9 of the Ordinance on the Protection in the Case of an Emergency, ENSI should have capability on emergency response.

With regard to emergency response, ENSI is responsible for the evaluation of the measures taken by the plant operator/licensee for the protection of personnel and the environment and to monitor their implementation. In this respect, the Regulatory Body may make recommendations and, if necessary, also issue orders. It prepares forecasts concerning the evolution of the emergency on-site, the dispersion of radioactivity in the environment and its consequences. For this purpose, ENSI uses among others its atmospheric dispersion calculation system (ADPIC), measurement data forwarded by the plant (ANPA) and its network of dose rate monitors (MADUK) in the vicinity of the nuclear facilities.

Being part of the Federal NBCN Crisis Management Board, the Regulatory Body has the duties and responsibilities set forth for members of the Federal NBCN Crisis Management Board. It also advises the cantons, regions and communities on planning and preparation of their tasks.

The Regulatory Body has to specify the type, the presentation and number of application documents to be submitted for an operating licence to be granted. This includes detailed requirements for the organization which are to be specified by the ENSI in guidelines. Requirements for Emergency Preparedness and Response at the site are set in the guideline ENSI-B12 and ENSI-G07 (stand-by engineer on duty). Topics addressed in these guidelines encompass emergency procedures and criteria for alert (RABE), the emergency organization, accident management (SAMG), infrastructure, accident instrumentation, safety

parameter display system (SPDS), transmittal of plant parameters to the Regulatory Body and tasks of the stand-by engineer on duty. In application of NEO and RPO, the Regulatory Body is entitled to set the requirements for the execution of emergency exercises. These requirements are laid down in the guideline ENSI-B11. The radiation protection ordinance (RPO, article 101) assigns the Regulatory Body the authority to specify the extent to which licensees are required to participate in the preparation and implementation of emergency protection measures in the vicinity of the site or to adopt such measures themselves.

The threat assessment does not use the methodology proposed by the GS-R-2.

11.2. FUNCTIONAL REQUIREMENTS

11.2.1. Establishing emergency management and operations

Emergency plans are available at the national, local and international level. At the national level, the "Concept for the Emergency Protection in the Vicinity of Nuclear Power Plants" (2006) has been adopted. A national strategy for NBC protection has been set up (2007) with the participation of the cantons. Bilateral agreements concerning the information exchange exist with neighbouring countries and international institutions.

The Federal NBCN Crisis Management Board is mobilized by the NEOC. The responsibilities are set down in the Ordinance on the Organization of Operations in Connection with NBC and Natural Events, the Ordinance on Protection in case of an Emergency and the Ordinance on the NEOC.

In case of a nuclear accident, ENSI is responsible for assessing the situation of the plant independently of the licensees' own evaluation. The NEOC has the duty to take the necessary measures until the Federal NBCN Crisis Management Board has achieved its operational readiness and to order immediate measures for the protection of the population in case of an imminent danger. The Federal Office for Civil Protection is further responsible for alerting the authorities and the public.

The NEOC is the specialist agency of the Confederation for exceptional events, including events with increased radioactivity. It is responsible for the assessment of the radiological hazard. It coordinates the civil and military resources until the Federal NBCN Crisis Management Board takes over the lead. If necessary, it forwards warning messages and alert orders, informs the population during the pre- and cloud phase and orders immediate measures. With its sampling and measurement organization, it manages the radiation measurements in all of Switzerland, determines the radiological danger, and forwards the corresponding assessment to the Federal NBCN Crisis Management Board. The Federal NBCN Crisis Management Board assesses the overall situation and proposes necessary measures to the Federal Council. The Federal Council decides on possible measures, which are either announced to the cantons via the Information Centre of the Federal Chancellery or directly to the population via broadcasting. Within their respective territories, the cantons are responsible for forwarding warning messages of the NEOC to the communities, for coordinating protective and rescue measures at the local level and for performing them.

11.2.2. Identifying, notifying and activating

According to NEA, article 22, the licensee shall notify incidents, without delay, to the Regulatory Body, in particular incidents that qualify as emergencies according to the emergency preparedness regulations. In an accident situation, the plant operator is responsible for timely alerting the Regulatory Body as well as the NEOC. The alert criteria are written down in the emergency preparedness regulations of the plant. The emergency preparedness regulations must be approved by ENSI according to Nuclear Energy

Ordinance, article 28 (Appendix 3) and article 40. Further incident reporting criteria are set down in the guideline ENSI-B03.

The Regulatory Body maintains a group of stand-by engineers on duty (24/7). All messages sent by ENSI following an incident notification show the classification of the incident based on the INES scale. For incidents of public relevance according to ENSI-B03 occurring at NPP or ZZL and for incidents rated level 2 on INES, a message is sent by fax to the nuclear facility, the General Secretariat (GS) of the Federal Department of the Environment, Transport, Energy and Communications (DETEC), the NEOC, the Federal Office of Public Health (FOPH) and the authorities of the canton where the NPP is located. In case of the NPP of Beznau and Leibstadt, information is faxed to the authorities of the community immediately across the German border and to the authorities of Baden-Württemberg. For incidents rated ≥ 3 on INES, which are considered as emergencies in the Regulatory Body's terminology, the plant and the NEOC are informed by fax. In all cases where the emergency organization of ENSI is engaged, immediate contact by phone is taken by the stand-by engineer on duty of the Regulatory Body with the stand-by engineer on duty of the NEOC.

The Regulatory Body advises the NEOC to notify the IAEA through USIE (Unified System for Information during Emergencies) in case of incidents rated ≥2 on INES or events attracting international public interest. The notification of the international organizations and the neighbouring countries lies within the responsibility of the NEOC.

The plant operator will notify directly both the Regulatory Body and the NEOC if the criteria for warning or alarming defined in the emergency preparedness regulations are met. In case of fast evolving accidents (release larger than 1 annual release limit within an hour), the plant operator will contact directly the authorities of the canton which will both activate the sirens in the Zone 1 and issue instructions to the population by radio-broadcast.

Art. 1 of the Ordinance on the NEOC specifies that the NEOC is the competent authority at the federal level for extraordinary circumstances in case of threats associated with increased levels of radioactivity. It is further specified that the NEOC is responsible for the notification of the foreign countries and the international contact points.

11.2.3. Taking mitigatory action

The Regulatory Body does not have the legal responsibility for the purposes described in GS-R-2, paragraphs 4.35 and 4.36. However, ENSI is responsible for radiological forecasts in the vicinity of the plant, according to article 9 of the EPO. These forecasts are based on measured and calculated 3D wind fields from the Federal Office of Meteorology and Climatology and constitute the basis for NEOC for supporting the decision making process on the implementation of countermeasures to protect the population.

The NPP provides expertise and services in radiation protection for all responders on site. Further radiation protection support is provided to the intervening operational units by specialists from the cantons. These units are provided and maintained by the cantons and are assisted in an emergency case by the Federal NBCN Crisis Management Board, namely the NEOC, which can rapidly provide the expertise and additional resources as needed through the measurement and sampling organization.

11.2.4. Taking urgent protective action

By the Radiological Protection Act, the Federal Council sets the reasonable doses for exceptional situations. Intervention levels for measures for the protection of the population are set in the Ordinance on

the Organization of Operations in Connection with NBC and Natural Events. The Federal NBCN Crisis Management Board has the coordinating function at the planning stage for the management of NBCN events. It thus also sets the intervention levels under the lead of the NEOC. ENSI, as the supervising authority for the safety and security of nuclear facilities in Switzerland, and as part of the Federal NBCN Crisis Management Board, contributes to the process of setting these intervention levels.

After mobilisation of its emergency organization, ENSI will formulate recommendations for urgent protective actions within the framework defined by article 9 of the EPO.

If the accident poses a threat to the public and the environment, a three stage warning and alert procedure is set in motion: warning, general alert for the preparation of the emergency measures and general alert for the implementation of the prepared measures. For reasons of efficiency, protective measures for the public should be ideally implemented before radioactivity is actually released from the plant. Therefore, the criteria for warning and alert are primarily based on the situation in the NPP.

The decision to trigger a warning to authorities or a general alert is taken by the NEOC during a telephone conference at which the NPP, the canton in which the NPP is located, and ENSI participate. Within this telephone conference, the Regulatory Body issues recommendations on the urgent protective actions that should be implemented for the protection of the population.

11.2.5. Protecting emergency workers

Acceptable doses in exceptional situations are set by the Federal Council according to the Radiological Protection Act. The licensee is required by Radiological Protection Ordinance to take preventive, adequate measures to ensure that the personnel mobilized for the accident management is not exposed to doses above 50 mSv in the year following the accident.

ENSI is the supervising authority for the protection of workers and the environment in nuclear installations according to RPA. Through the Federal Act on the Nuclear Safety Inspectorate, ENSI participates in the preparation of decrees, laws and ordinances and correspondingly sets dose intervention levels for emergency workers.

Any dose received by emergency workers exceeding dose limits is to be reported immediately to ENSI. The RPO requires that any person who, in the course of a year, has received an effective dose of more than 250 mSv, an equivalent dose to the skin or bone surface of more than 2500 mSv, or an equivalent dose to any other organ of more than 1000 mSv is to be placed under medical surveillance. The Regulatory Body is informed on the results of the medical checks carried out and is required to keep this data as long as the person is occupationally exposed to radiation.

11.2.6. Assessing the initial phase

In an emergency situation, ENSI has the duties to assess the situation at the plant continuously and to provide a basis on which NEOC is adopting measures for the protection of the population. The recommendations of the Regulatory Body are based upon dose limits set in the Ordinance on the Organization of Operations in Connection with NBC and Natural Events.

If a revision of any Operational Intervention Level (OIL) is to be considered in the course of the events, the Federal NBCN Crisis Management Board and the offices represented therein will issue recommendations for the Federal Council, which sets the adequate doses in exceptional situations.

11.2.7. Keeping the public informed

Article 74 of the Nuclear Energy Act states that the relevant authorities shall regularly inform the general public about the condition of nuclear installations and any matters pertaining to nuclear goods and

radioactive waste and that the relevant authorities shall inform the general public of any special occurrences.

The information in an emergency situation is addressed in the "Communication-Concept in a Crisis" (ENSI-AN-7102) and in an agreement among the DETEC, the cantons of Solothurn, Aargau, Bern and the nuclear utilities (NNP, ZWILAG and PSI). In case of emergency, ENSI provides information to the public on technical matters concerning the plant, the assessment of the conditions on-site, the probable evolution of the conditions and radiological forecasts for the event.

11.2.8. Taking long term protective actions

It is not a legal responsibility for the Regulatory Body.

The preparation of long term protective actions lies within the responsibility of the Federal NBCN Crisis Management Board and the federal offices represented therein. The main offices involved will be the Federal Office of Public Health, the Federal Office for Agriculture and the Federal Office of Civil Protection along with the NEOC and the sampling and measurement organization. Being part of the Federal NBCN Crisis Management Board, the Regulatory Body may contribute to the formulation process of long term protective actions. It may contribute by setting up the technical basis for long term actions.

11.2.9. Conducting recovery operations

ENSI supports local and national officials in the longer term phase. However, the Regulatory Body's duties focus on the preparedness and early response phase of the accident.

11.3. INFRASTRUCTURAL ELEMENTS

11.3.1. Organization

The emergency organization of the Regulatory Body, its structure and duties of its constituting elements are described in the Electronic Management System of ENSI (NAU 7100), and it consists of:

- one director of operations,
- one chief of staff,
- one stand-by engineer on duty,
- one 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".

These Task Forces are complemented by "NPP Task Forces" in the areas of radiation protection and reactor safety. Liaison officers are sent to the Federal NBCN Crisis Management Board. In case of incidents involving transport of radioactive goods or in the case of a plant security issue, additional specialists are mobilized.

Every employee of the Regulatory Body is considered part of the emergency organization and carries out the tasks and functions assigned. The assignment to a particular function in the emergency organization takes into account as much as possible the actual duties in the Regulatory Body and the experience accumulated (electronic management system, chap. 1 of NAU-7100). The emergency organization draws its human resources from a pool of currently about 120 people and is subdivided in two teams (A and B) and a Support-Team.

It was identified that ENSI had limited human resources dedicated to emergency preparedness with regard to education, inspection on site and assessment of exercises to provide resilience for this function. The IRRS Team suggests that ENSI should consider increasing the number of people involved in emergency preparedness.

11.3.2. Plans and Procedures

The emergency organization of the Regulatory Body is described in detail in the emergency procedure documentation of the electronic management system (NAU). A subset of these NAU's is distributed to all members of the teams A and B of the emergency organization as a "Quick reference". In particular, the allocation of responsibilities is set forth in the NAU 7100, the procedure to identify conditions which could lead to the engagement of the ENSI's emergency organization is addressed in the NAU 7003. Intervention levels for the recommendation of protective actions are part of the Ordinance on the Organization of Operations in Connection with NBC and Natural Events and are also an integral part of documents of engagement of the NEOC. Procedures for alarming are sent via pager. Messages sent from the Regulatory Body to its partners at the Canton and Federal levels are part of the emergency documentation. Up to date telephone directories are included in the procedures.

The emergency plan of ENSI has a satisfactory compliance with the requirements of the GS-R-2.

11.3.3. Logistical support and facilities

The Emergency Response Centre is located in the basement of the Regulatory Body's headquarters at Brugg. The Response Centre includes dedicated rooms for the task forces, overnight accommodations and facilities for an autonomous operation of several days, including for example emergency diesel generator, plans and procedures, maps and information on all NPP.

In addition to the tools and procedures mentioned above, dedicated telephone and fax lines are installed between the NPP's, the Regulatory Body and the NEOC.

The task force "Infrastructure" of ENSI is responsible for maintaining the infrastructure elements in proper condition in case of emergency. This includes computer systems, electronic tools, communication lines, the emergency diesel and the organization of food supplies for the staff.

The proper operation of ENSI's own Emergency Response Centre, as well as the functioning of the whole national emergency management system, is heavily dependent on the reliability of communication between the different participants situated in various geographical locations. This situation makes the communication system vulnerable to natural disasters (e.g. earthquakes) and inadvertent or malicious human activities (land line cutting, sabotage etc.). To cope with the consequences of losing the contact alternative communication technologies would be needed. Although the recently conducted investigations of IDA NOMEX identified this vulnerability the establishment of the alternative communication system is expected to take long time. It is proposed to adopt a graded approach, aiming first at reaching interim solutions (based on currently available technologies) within the shortest reasonably achievable terms until the general new system is completed.

11.3.4. Training, drills and exercises

Training and exercise of the Regulatory Body is part of the ENSI Management System. All members of the Regulatory Body are part of the ENSI emergency organization. About 45 persons can be reached 24/7 by a pager system. The instruction and exercising of this body are as follows:

- for new members: 4 lessons with background information;
- refreshing for all members: 2 times a year (with additional instructions for the staff 2 times per year). The emergency organization takes part in one of the NPP exercises each year and takes part in all federal level exercises (bi-annually).

In addition to taking part in exercises, the ENSI emergency organization is mobilized several times a year (typically 5 times a year) following incidents reported by the licensees. The response of the emergency organization to a test pager alarm is also tested once a year.

The Regulatory Body has set the framework for exercises at the nuclear installation's site in the ENSI guideline ENSI-B11.

The following types of exercises are defined and are inspected by ENSI:

- Alarm Emergency Exercises,
- Staff Emergency Exercises,
- Plant Emergency Exercises,
- General Emergency Exercises.

Besides these types of exercises by the Regulatory Body, the NPPs carry out additional exercises focusing on single aspects of their emergency preparedness.

The Regulatory Body's emergency organization is participating in the national General Emergency Exercises which involve at least the plant operator, the NEOC and the canton in which the NPP is located. Counterparts from Germany participate in general emergency exercises at the plants of Beznau and Leibstadt.

ENSI made arrangements to assure that one of the NPP's annual emergency exercise coincided with the mission dates. The mission team could observe the exercise on three different locations: NPP Gösgen, NEOC (Zurich), and ENSI Emergency Response Centre (Brugg). It was concluded that the emergency management system is well developed and suitably functioning.

11.3.5. Quality Assurance Programme

The emergency documentation of the Regulatory Body is part of the ENSI Management System and thus subject to the quality assurance programme of the Regulatory Body. "Emergency Preparedness" is a process within this management system encompassing the sub-processes "organization", "procedures" and "facilities & documentation".

Communication systems are tested once a month, telephone directories are checked on a regular basis. The ADPIC-, MADUK- and ADAM-systems are maintained and monitored in the process "Remote Monitoring and Forecasting". The emergency response organisation coordinator of the Regulatory Body is responsible for checking the emergency documentation on a yearly basis. The ENSI Working group "Protection in the case of an Emergency" meets twice a year for a follow-up and discussion of issues identified in the area of emergency preparedness.

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(1)	**BASIS: GS-R-2 para. 4.20 states that** *"The emergency classification system for facilities or practices in threat category I, II, III or IV shall take into account all postulated nuclear and radiological24, 25, 26 emergencies. The criteria for classification shall be predefined*

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	emergency action levels (EALs) that relate to abnormal conditions for the facility or practice concerned, security related concerns, releases of radioactive material, environmental measurements and other observable indications (see para. 4.70). The classification system shall be established with the aim of initiating a response prompt enough to allow for effective management and the implementation of emergency operations, including mitigation by the operator, urgent protective action and the emergency protection of workers. It shall be ensured that the process of rating the event on the joint IAEA and OECD/NEA International Nuclear Event Scale (INES)[27] does not delay classification or other response actions."
(2)	**BASIS: GS-R-2 para. 4.20, Footnote 27 states that** *"The emergency response classification system is not to be confused with the INES. The INES is used for communicating to the public the severity or estimated severity of an event and cannot be used as the basis for emergency response actions."*
R12	**Recommendation: ENSI should make the emergency classification consistent with GS-R-2.**
(1)	**BASIS: GS-R-2 para. 3.2 states that** *"…The arrangements for emergency response actions both within and outside facilities, if applicable, or elsewhere under the control of the operator, are dealt with through the regulatory process. [The State] shall ensure that [the regulatory body and response organizations] have the necessary resources and that they make preparations and arrangements to deal with any consequences of [a nuclear or radiological emergency] in the public domain, whether the [nuclear or radiological emergency] occurs within or beyond national [borders]. These preparations shall include the actions to be taken both in and after an emergency."*
(2)	**BASIS: GS-R-2 para. 3.8 states that** *"The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention. For a facility in threat category I, II or III "Appropriate emergency [preparedness and response] arrangements shall be established from the time that nuclear fuel [or significant amounts of radioactive or fissile material] is brought to the site, and complete emergency preparedness as described here shall be ensured before the commencement of operation…"*
S10	**Suggestion: ENSI should fully integrate the emergency preparedness and response into the scope of the regular inspection (e.g. the proper status and functioning of emergency equipment, emergency dosimetry, personal protective equipment, evacuation routes, control room conditions for emergency situation, etc.).**
(1)	**BASIS: GS-R-2 para. 5.25 states that** *" Adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation (such as procedures, checklists, telephone numbers and manuals) shall be provided for performing the functions specified in Section 4. These items and facilities shall be selected or designed to be operational under the postulated conditions (such as the radiological, working and environmental conditions) that may be encountered in the emergency response, and to be compatible with other procedures and equipment for the response (such as the communication frequencies of other response organizations), as appropriate. These support items shall be located or provided in a*

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	manner that allows their effective use under postulated emergency conditions."
S11	**Suggestion: ENSI is suggested to work towards the improvement of communication redundancy to provide alternative communication means to the land-based lines in case of natural disasters.**
(1)	**BASIS: GS-R-2 para. 5.13 states that** *"Plans or other arrangements shall be made for co-ordinating the national response to the range of potential nuclear and radiological emergencies. These arrangements for a co-ordinated national response shall specify the organization responsible for the development and maintenance of the arrangements; shall describe the responsibilities of the operators and other response organizations; and shall describe the co-ordination effected between these arrangements and the arrangements for response to a conventional emergency. The arrangements should include provisions that can be used to formulate in detail a response to situations such as: a serious exposure or contamination resulting from contact with a source by a member of the public; the notification of a potential transboundary release of radioactive material; the discovery of a shipment containing a dangerous source that is not under control; the notification of the potential re-entry of a satellite; public concern or rumors about a threat; and other unanticipated situations warranting a response."*
S12	**Suggestion: The government should consider the development of a comprehensive national radiation emergency response plan based on the existing "Consensus Paper" on national cooperation in case of a nuclear accident.**
(1)	**BASIS: GS-R-2 para. 5.31 states that** *"The operator and the response organizations shall identify the knowledge, skills and abilities necessary to be able to perform the functions specified in Section 4. The operator and the response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel have the requisite knowledge, skills, abilities, equipment, and procedures and other arrangements to perform their assigned response functions. The arrangements shall include ongoing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities for emergency response undergo the specified training."*
S13	**Suggestion: ENSI is encouraged to initiate having longer exercises than the current few-hour long drills for testing the procedures over several shift changes.**
(1)	**BASIS: GS-R-2 para. 5.25. states that** *"Adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation (such as procedures, checklists, telephone numbers and manuals) shall be provided for performing the functions specified in Section 4…"*
GP12	**Good Practice: Excellent tools, both electronic and paper-based, have been developed and are available for radiological monitoring and consequence assessment as well as for public information.**
(1)	**BASIS: GS-R-2 para. 4.11 states that** *"For facilities in threat category I or II arrangements shall be made for coordinating the response to a nuclear or radiological*

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	emergency between the response organizations and jurisdictions (including other States) that fall within the precautionary action zone or the urgent protective action planning zone."
GP13	**Good Practice: Good coordination and cooperation between federal and cantonal organizations involved in the national nuclear emergency preparedness and response system as well as with the neighbouring countries.**

12. OCCUPATIONAL, PUBLIC AND ENVIRONMENTAL EXPOSURE CONTROL

GENERAL OVERVIEW OF RADIATION PROTECTION

The Swiss Constitution sets the competence for nuclear energy (Article 90) and for health protection, protection against ionizing radiation (Article 118). As a consequence its regulatory framework for the use of radioactive material and nuclear energy are based on two statutory provisions:

- the Radiological Protection Act which set the basic principles and recommendations of radiation protection;
- the Nuclear Energy Act which set principles and objectives governing the use of nuclear energy.

Based on both acts, the Federal Council or the Department of Environment, Transport, Energy and Communication (DETEC), develops ordinances or regulations to be complied with by activities and facilities; general requirements for radiation protection are developed by the Office of Public Health, FOPH, and specific for nuclear energy are developed by the Office of Energy. These two Offices lead the development of both Ordinances but all other regulators binding to these ordinances are consulted.

Changes or amendments to the Ordinance on Radiation Protection is done by the Federal Council, through the Office of Public Health; however there is a rule avoiding any changes without the interested regulators take note and approve them by consensus. Therefore an interoffice consultation is put in place. This is a very important philosophy and process to maintain the consistency among all regulators in terms of radiation protection in the country to all types of facilities and activities. In general the Ordinances follow the ICRP and IAEA BSS recommendations and standards and soon will incorporate the new recommendations (ICRP 103, 2007) and the IAEA BSS (2011).

Regarding the Radiation Protection Ordinance (RPO) three regulators are legally empowered, the Federal Office of Public Health (FOPH), the Swiss National Accident Insurance Company (SUVA), and the Swiss Federal Nuclear Safety Inspectorate (ENSI). Therefore, although ENSI is designated by the parliament as the regulator responsible to supervise nuclear facilities, including radiation protection, the development of guidelines related to occupational exposure, discharge to the environment and control of the environment are jointly approved by the three regulators. This is positive delivering harmonization in radiation protection criteria and basic procedures for all facilities and activities in the country.

ENSI is required by the Nuclear Energy Act to regulate through guidelines, however these are not legally binding, although they may be seen by the facilities as being so. There is an agreement that any deviation from the guidelines has to be justified and written how safety will be also assured. Moreover ENSI has the respect and the necessary recognition as the safety authority for nuclear facilities. In addition, if operators do not follow the ENSI guidelines and do not propose an alternative safe solution agreed by ENSI, then ENSI can send an order to the operator, although this can be challenged in the Court.

ENSI has regular meetings with the radiation protection staff of facilities to evaluate needs for improvements in processes, equipment and practices. Every end of the year a joint meeting is conducted with responsible radiation protection staff of ENSI and operators to assess the overall performance. This has created an open environment of exchange of information and mutual respect and commitment with safety. In addition ENSI has also a guideline for safety culture.

There is also the Commission on Radiation Protection, KSR, where experts from different areas assess relevant matters related to radiation protection to advise and suggest the three Departments (DETEC, Department of Defence Civil Protection and Sports, Department of Home Affairs) involved in radiation protection regulations.

In general, it may be said that although the guidelines of ENSI are not legally binding there is an environment of safety culture created by an open and collaborative atmosphere among regulators and between regulators and operators, as mentioned in the following sub-paragraphs. As has been mentioned earlier in the report the collegiate approach to safety regulation and oversight is impressive.

The general impression of the IRRS team was that radiation protection in the area of ENSI competence was of a high standard in the regulator level and this was demonstrated by its positive effect on operators. There are areas of work in ENSI that contribute to this high level and although they are not identified as good practices in this report they are the practices of a good regulatory system that are worthy of noting. Such items included the effective co-operation between radiation regulators, the in-house accredited laboratory and the single dose registry for the whole country. Such items assist in building public confidence in the effectiveness of the regulator.

12.1. OCCUPATIONAL RADIATION PROTECTION

The implementation of the regulatory framework is done under the supervision of ENSI but a joint follow up is done involving the other radiation protection regulators regarding compliance with legally binding dose limits.

Dose measurements are provided by services approved by the regulator (in case of nuclear workers by ENSI), based on a Personal Dosimetry Ordinance and using recognized external experts, including from the primary metrology laboratory (METAS). Operators and ENSI receive information about the monthly doses. Any violation of the dose limits for workers is reported also to SUVA and together they take the necessary measures. If an accident occurs and there is a need for reconstruction of doses, ENSI is obliged to contract an external expert. In issues such as this the IRRS experts were impressed with the Swiss system. In addition there is a central register at the FOPH which receives information from all dosimetry services and from ENSI after being assessed. This central register makes available data from all occupational workers in the country allowing epidemiological studies and identification of activities which need more attention. This process of control reflects credibility in the control of occupational exposure, while maintaining the supervision of ENSI since all processes concerning worker doses are done through its coordination**.**

All these procedures and practices are responsible for safe working conditions where optimization of protection is a continuous process observed in the planning of activities at the facilities and reflected in collective dose pattern since the first nuclear power plant started the operation.

It is also important to mention that ENSI staff (radiation protection and all other inspectors) are submitted to a formalized training which is in the management system and are occupationally controlled within the ENSI radiation protection program.

Although the provisions of the IAEA BSS are generally expressed well in clear ordinance there are some requirements that are not as easy to link. For example:

- SS-115 I.10(c) requires workers to cooperate with the employer, registrant or licensee with respect to protection and safety and the operation of radiological health surveillance and dose assessment programmes. The RPO addresses this in a different manner, placing obligations rather than requiring cooperation. However the Radiation Protection Act (article 9) requires the support of the workers for safety.
- SS-115 I.29 requires licensees to minimize the need for relying on administrative controls and personal protective equipment for protection and safety during normal operations. This is not explicitly included in the RPO, but is rather found in the general safety legislation promulgated by SUVA, which requires state of the art engineering before the use of protective measures.

Many "items" are minor in nature, but some areas where significant benefit would be achieved through clarity are highlighted as suggestions.

Nevertheless there still exist some variations between the IAEA BSS and the current Swiss legislation. One specific area is dose values, for example in emergencies and for protection of pregnant women. In some areas limits are stricter than IAEA and in other areas more relaxed. Overall the effect is small, and could be related to societal principles of obligation and pragmatism. A review of the RPO is already on-going, and this offers the opportunity to clarify the values. As an example Article 121 of the RPO contains two principles under one requirement, and this leads to some confusion. Simply separating the two principles would assist understanding.

Other areas involve inconsistency with international standards. This is particularly important as far as Switzerland is concerned because of the reliance on an international workforce. And as mentioned earlier in this report there are issues more appropriately dealt with in binding regulations that are included in guidance.

There are a number of related findings that are incorporated into a single suggestion.

It was observed by the IRRS team that several dose "values" (limits or guides) varied slightly from those used in the IAEA requirements. For example:

- **Art. 121 of the RPO states that** *"The persons with special obligations may only be deployed for tasks …, or more than 250 mSv for life-saving actions."*
- **Art. 6 of the RPO states that** *"The principle of optimisation is deemed to be satisfied where activities do not lead in any cases to an effective dose of more than 100 μSv per year for occupationally exposed persons."*

In other words there are specific items in the RPO that require updating to match international requirements.

In addition, although there is a very good description of radiation zones in guidance there is no mention of supervised areas in the ordinance. In other words there are specific areas where there are items in guidance which have no clear link in the RPO.

The review and monitoring of the workplace requirements are set out in guidelines, but are covered in Guideline HSK R-07, draft Guideline ENSI-G09 and ENSI guideline ENSI-G-13. In other words there are issues that currently exist in ordinances that may belong in guidelines and vice versa.

There are areas where there are requirements from the BSS that are or may be implemented in other ordinances applicable to worker or personal safety. In such cases it is not always clear to what extent these ordinances apply.

The protection of female workers in consideration of pregnancy is applied by the ordinance on protection of motherhood (SR 822.11) whereas the ordinance on the prevention on the accidents and the occupational diseases is not applicable to Nuclear Facilities with regard to nuclear safety, security and the technical aspects of radiation protection (VUV SR 832.20, article 2).

In addition it appears that the Swiss system rather than requiring provision of alternative employment simply offers insurance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1; Requirement 2 states that** *"The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated."*
(2)	**BASIS: SS 115; V.28 states that** *"Workers who undertake actions in which the dose may exceed the maximum single year dose limit shall be volunteers."*
(3)	**BASIS: SS-115; I.4 (b) states that** *"Occupational protection and safety be optimized in accordance with the relevant principal requirements of the Standards."*
(4)	**BASIS: SS-115; I.24 states that** "*Registrants and licensees shall designate as a supervised area any area not already designated as a controlled area but where occupational exposure conditions need to be kept under review even though specific protection measures and safety provisions are not normally needed.*"
(5)	**BASIS: SS-115; I.37 states that** *"Registrants and licensees, in co-operation with employers if appropriate, shall establish, maintain and keep under review a programme for the monitoring of the workplace under the supervision, if so required by a Regulatory Authority, of a qualified expert and a radiation protection officer."*
(6)	**BASIS: SS-115; I.16 states that** *"A female worker should, on becoming aware that she is pregnant, notify the employer in order that her working conditions may be modified if necessary."*
(7)	**BASIS: SS-115; I.29 states that** "*Registrants and licensees shall minimize the need for relying on administrative controls and personal protective equipment for protection and safety during normal operations by providing appropriate protective measures and safety provisions, including well engineered controls and satisfactory working conditions."*
(8)	**BASIS: SS-115; I.18 states that** "*Employers shall make every reasonable effort to provide workers with suitable alternative employment … the worker, for health reasons, may no longer continue in employment involving occupational exposure."*
S14	**Suggestion: ENSI, FOPH and SUVA, in the planned review of the RPO, should ensure that the RPO is harmonized with international requirements, especially concerning worker protection, particularly in terms of dose values. In addition, there should be an adequate balance between ordinances and guidelines, a clear link established in ordinances for any necessary guidelines and clarity provided as to which worker protection ordinances apply to nuclear facilities.**

12.2. CONTROL OF RADIOACTIVE DISCARGES, MATERIALS FOR CLEARANCE AND ENVIRONMENTAL MONITORING

In this item again guidelines are approved by all responsible regulators, but it is important to highlight that for the clearance of material there is a joint guideline publication for release of inactive materials and zones from controlled areas, based on the request for minimization of waste set by the Radiation Protection and Nuclear Energy Act. However nothing is mentioned by any radiation protection regulator for site remediation after decommissioning or environmental remediation after an accident or any other event leading to land contamination.

Again, discharges limits are derived based on dose constraints set in the Guideline ENSI-G-15, according to ICRP recommendations and IAEA BSS. However, although the derivation of discharges limits are done based on dose constraints, the limits may be set below this value not because of optimization of protection but to comply with several other more restrictive ordinances such as the ordinances on Foreign Substances and Food Contaminants; and on Water Conservation.

The implementation of the regulatory framework is also done under the supervision of ENSI but a joint follow up is done by both ENSI and FOPH, regarding compliance with legally binding dose limits. The operator, ENSI and FOPH conduct routine emission control programs and cross-checked measurements. The results are published by ENSI and FOPH together.

As the discharges limits are legally binding, when violated ENSI must immediately take over the situation to the prosecutor. However any need to discharge above 10% of the limits has to be reported to ENSI beforehand. Nevertheless fluctuations far below the limits are evaluated. The mean values are showing a decreasing tendency over the years due to optimization of protection.

The FOPH is responsible for the environmental monitoring in the country and ENSI for the surroundings of nuclear facilities. Results are published together after being assessed by both relevant authorities. Additionally ENSI reports the data to OSPAR. The measurements are done by their own accredited laboratories (ISO/IEC 17025) and for some analysis by the Paul Scherrer Institut, by the Institut de Radiophysique, and other specialized laboratories. The Swiss law allows regulators to request the operator to conduct an environmental monitoring program. However, both ENSI and FOPH consider it more credible when this program is performed by the competent authorities.

ENSI also has an on line monitoring network, MADUK, for continuous evaluation of the dose rate in the vicinity of each nuclear facility. Every two years measurements by helicopter are made by NEOC as an emergency exercise and also characterizing the background dose rate in the region of the nuclear facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 7: states that** *"Coordination of different authorities with responsibilities for safety within the regulatory framework for safety Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
GP14	**Good Practice: Jointly developed Guideline by ENSI, FOPH and SUVA (ENSI-B04, Release of Material and areas from controlled zones) has led to consistent results at the**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	facilities regulated by the different regulators.
(1)	**BASIS: SF-1 Principle 10 states that** *"Protective actions to reduce existing or unregulated radiation risks must be justified and optimized."*
S15	**Suggestion: ENSI and FOPH should develop a similar joint document on strategies of site and environmental remediation based on WS-R-3.**

13. WASTE MANAGEMENT (POLICY AND STRATEGY, PREDISPOSAL AND DISPOSAL), DECOMMISSIONING

13.1. WASTE MANAGEMENT (POLICY AND STRATEGY, PREDISPOSAL AND DISPOSAL)

The legislation and regulatory framework for nuclear installations is well established in Switzerland. It provides the formal basis for the supervision and the continuous improvement of nuclear installations. The main legal provisions for authorizations and regulation, supervision and inspection are regulated in the Nuclear Energy Act, the Nuclear Energy Ordinance, the Radiological Protection Act and the Radiological Protection Ordinance. The Nuclear Energy Act and its ordinance were implemented in 2005. Safety requirements and regulations are detailed in more than 40 regulatory guidelines of ENSI. These cover all aspects of NPP construction, operation and decommissioning, of nuclear waste transport and disposal as well as radiation protection and emergency preparedness. The Nuclear Energy Act also provides for inspections and safety assessments to be performed by ENSI, and for the enforcement of the applicable regulations and of the terms of the licence.

The IRRS Team visited ZWILAG, the Central Storage Facility for radioactive waste. The facility has been in operation for a decade and appears to be very well maintained. It was noted that the facility is currently operating at approximately 60 % capacity for drummed waste. Currently the plasma incinerator of low-level waste operates 50 % of the year in two campaigns; one campaign corresponds to roughly the annual production of incinerable raw waste from all Swiss nuclear installations, the second campaign being used to reduce the stockpile, which was accumulated after shutdown of the old pilot incinerator at PSI and the operational availability of the new ZWILAG incinerator. Transfer of spent fuel and high-level reprocessing waste to ZWILAG in dual purpose casks varies between 2 and 6 cask shipments per year.

The volume of material will increase significantly when decommissioning of the power reactors may start in the 2020s.

The disposal of high level and long-lived intermediate level waste is focussed around the feasibility studies for a repository in Switzerland. The project "Gewähr" submitted by Nagra in 1985 was a feasibility study based on a repository in the crystalline basement of Northern Switzerland. This project did not succeed in providing the required demonstration. The Federal Council then ordered that research should be continued and extended to sedimentary rocks. As a result of a broad selection process, Nagra chose the Opalinus clay formation in the north of the Canton of Zurich for further geological investigations. The results of these investigations formed the basis of a feasibility demonstration, which was submitted for review to the federal authorities in December 2002. The technical review by the competent Swiss authorities was concluded in August 2005 after a broad public consultation. The Federal Council approved the feasibility demonstration in 2006.

A comprehensive site selection process (Sectorial Plan) for a repository for high level waste and one for low and intermediate level waste has been started under the guidance and supervision of the federal authorities. The aim of a sustainable waste management policy should include preparation for and implementation of safe, long-term disposal of waste arising from the operation of the nuclear power plants and from medicine, industry and research by the generations enjoying the benefits of these activities. Based on the applicable legislation, the federal government has assumed its role in the planning and implementation of waste management measures and ensures that the necessary financial means are available. The decision on whether to grant a general licence is subject to a national referendum.

Observation and conclusions

The site selection for disposal of radioactive waste is very complex and involves a broad spectrum of issues engaging stakeholders in Switzerland. The public consultation process and involvement of all stakeholders are recognized as important parts of the decision making process. The Sectorial Plan for Deep Geological Repositories defines the selection process for sites for geological repositories and opens the way to discussing key aspects of sustainable regional development. The Sectorial Plan provides an opportunity for all stakeholders to be involved and to address all possible aspects connected to the siting of disposal facilities. The Sectorial Plan is being used as the instrument for coordination between cantons of land use on a national basis. This approaches the siting of disposal for radioactive waste in very structured way. It establishes the process to achieve the goal, which is to select a suitable disposal site, and has high level of public and stakeholder involvement. This extensive process allowed implementing agreement and support of all stakeholders of that process. It is very good mechanism and instrument for a decision making process for site selection based on safety, but at the same time including wide consultation of all stakeholders in this process. Since the decision to grant a general licence is subject to a national referendum this could leave the policy for disposal l incomplete and more or less indefinite, and could creating continuing security and other hazards which disposal would eliminate.

There are the waste management program and the well-established funds for decommissioning and for disposal. The technical basis for both funds and for the waste management program is required to be updated every 5 years. Changes are thus addressed and documented at that point. A financial update is required on an annual basis.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-1 para. 2.28 states that** *"Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and radioactive sources and for the duration of activities. The strategy shall include appropriate interim targets and end states. Radioactive waste generated in facilities and activities necessitates special consideration because of the different organizations concerned and the long timescales that may be involved. The government shall enforce continuity of responsibility between successive authorized parties."*
(2)	**BASIS: WS-R-5 para. 3.4. states that** *"The responsibilities of the government include:* - *Defining the national policy for decommissioning and for management of the resulting radioactive waste;* - *Defining the legal, technical and financial responsibilities of organizations to be involved in decommissioning;* - *Ensuring that the necessary scientific and technical expertise remains available both for the operating organization and for the support of independent regulatory and other national review functions;* - *Establishing a mechanism to provide and ensure adequate financial resources for safe and timely decommissioning."*
(3)	**BASIS: GS-R-3 para. 5.1. states that** *"The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(4)	**BASIS: GS-R-3 para. 5.4. states that** *"The development of each process shall ensure that the following are achieved:* - *Process requirements, such as applicable regulatory, statutory, legal, safety, health, environmental, security, quality and economic requirements, are specified and addressed.* - *Hazards and risks are identified, together with any necessary mitigatory actions.* - *Interactions with interfacing processes are identified.* - *Process inputs are identified.* - *The process flow is described.* - *Process outputs (products) are identified.* - *Process measurement criteria are established."*
GP15	**Good practice: The use of the Sectorial Plan as the instrument for the repository site selection is an open and transparent process that involves stakeholders.**

Observations and conclusions

The Swiss have a very complicated licensing system, with several regulatory bodies with cross-cutting responsibilities. Switzerland has a strategically important nuclear power industry, and has a significant waste disposal issue requiring stakeholder involvement. The government has the obligation to ensure that ENSI, as the independent regulatory body, has sufficient qualified staff to manage the nuclear safety program. The ENSI scope of work includes performing independent regulatory reviews and assessments and participating in the Sectorial Plan for the radioactive waste disposal sites. As the independent regulatory authority for nuclear safety, ENSI should be more visible to the public. ENSI does engage with other authorities, committees and organisations through active participation and communication in the Sectorial Plan. However, the IRRS team suggests that ENSI develops its engagement plan with the Cantons and the public to increase public awareness and acceptance of ENSI as an independent regulator.

The IRRS Team has noted that ENSI became independent from SFOE in 2009. However, because of the perception of SFOE, it does not appear that much has changed in the way ENSI is perceived as an independent regulator. This could be an issue for the broader public perception and provides support for different commissions like NSC and KNE. The IRRS Team has understood that it is the routine practise in Switzerland to have independent second opinions. The issue the IRRS team has with this is *when* the independent reviews are conducted. It is recommended that the commissions input be part of the decision making process and not a second opinion that may undermine ENSI as the independent regulator and authority for nuclear safety. This was also highlighted in chapter 3. ENSI should invite all stakeholders to discuss assessments and reviews to develop a consensus. After ENSI issues the safety based approval for the repository site locations, all stakeholders and parties should support the approval decision for the implementation of this decision. The decision process related to nuclear safety of a future repository should not be jeopardized by having stakeholder organizations issuing opinions outside of the coherent sequential and logical process. By implementing the recommendation, the government will improve the efficiency of the siting process and strengthen ENSI as the independent nuclear safety authority. This issue is addressed by recommendation in chapter 3.4.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1, Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
(2)	**BASIS: GS-R-1 para. 4. states that** *"To maintain the effective independence of the regulatory body, special consideration shall be given when new staff members are recruited from authorized parties, and the independence of the regulatory body, regulatory aspects and safety considerations shall be emphasized in their training. The regulatory body shall ensure that its staff operate professionally and within its remit in relation to safety."*
(3)	**BASIS: GS-R-1 para. 4.11. states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
(4)	**BASIS: GS-R-1 para. 5.10. states that** *"The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny. The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout."*
(5)	**BASIS: GS-R-3 para. 5.6. states that** *"For each process a designated individual shall be given the authority and responsibility for:* - *Developing and documenting the process and maintaining the necessary supporting documentation;* - *Ensuring that there is effective interaction between interfacing processes;* - *Ensuring that process documentation is consistent with any existing documents;* - *Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation;* - *Monitoring and reporting on the performance of the process;* - *Promoting improvement in the process;* - *Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organization."*
GP16	**Good Practice: Sectorial Plan provides very good process for confidence building among all stakeholders. ENSI is leading the Technical Forum Safety meetings with all stakeholders, but also international experts and interested community are involved in the review process.**

13.2. DECOMMISSIONING REGULATOR RESOURCES

ENSI resources appear to be focused on obtaining the two geological radioactive waste repositories and the regulatory program for decommissioning has limited attention and resources. The ENSI decommissioning regulatory program is the process of being developed. The decommissioning regulatory staff needs to be trained and qualified to ensure personnel have appropriate training and experience in decommissioning safety. ENSI should continue to participate in international forums to gain experience

and ensure lessons learned from research and power reactors decommissioning projects are incorporated into the ENSI regulatory program. Also, ENSI should consider assigning a project manager to each decommissioning site to ensure there is a single point of contact for all decommissioning plan review and revisions, licensing amendments, permitting and radiological information to determine site termination criteria have been achieved.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 10 states that** *"Provision for the decommissioning of facilities and the management of radioactive decommissioning and of spent fuel. The government shall make provision for the safe management and disposal of radioactive Decommissioning arising from facilities and activities, and the safe management of spent fuel."*
(2)	**BASIS: WS-R-3, Section 4.11., states that** *"To ensure an adequate level of safety, the responsible parties shall perform safety assessments and environmental impact assessments; shall apply prepare and implement appropriate safety procedures; shall apply good engineering practices; shall ensure staff are well trained, qualified and competent; shall establish and implement a quality assurance programme; and shall keep records as required by the regulatory body."*
S16	**Suggestion: ENSI should continue to be an active participant in the IAEA and other international decommissioning forums to gain valuable regulatory experience for the decommissioning of the Swiss research and power reactors.**
S17	**Suggestion: ENSI should develop a human resources plan for providing inspectors and other technical specialists required to regulate reactor decommissioning projects and to ensure end point criteria are met for terminating the licences.**

14. INTERFACES WITH NUCLEAR SECURITY

14.1. LEGAL BASIS

The Nuclear Energy Act, which came into force in 2005, introduced in Switzerland the basis for a comprehensive regulation that covers both nuclear safety and security. In particular, there are several provisions in the Nuclear Energy Act and in the Nuclear Energy Ordinance which testifies that safety and security issues have to be jointly addressed.

In this regard the following articles of the NEA can be mentioned as examples:

- Art. 5, which states that security measures must be taken in order to prevent any interference with the safety of nuclear installations and nuclear materials through unauthorized acts or theft of nuclear materials;
- Art. 7, which mentions that one condition to be met to grant a licence is the proper assurance of safety and security;
- Art. 11, which defines reporting requirements for both safety and security events;
- Art. 16, which defines that the construction licence can be granted providing that the project meets the principles governing nuclear safety and security;
- Art. 20, which states that the operating licence can be granted providing that the installation and planned type of operation meet the relevant nuclear safety and security requirements;
- Art. 21, which specifies the safety, security, and emergency measures to be taken by the licence holder during operation of the installation;
- Art. 65, which states that in the event of amendments that do not deviate significantly from the respective licence or order, but which may have an influence on nuclear safety or security, the holder is required to obtain a permit from the supervisory authorities;
- Art. 70, which states that ENSI is the supervisory authority for safety and security;
- Art. 72, which requires the supervisory authorities to order all necessary and reasonable measures aimed at preserving nuclear safety and security;
- Art. 88, related to criminal provisions applicable to potential violations of safety and security requirements.

Also the Nuclear Energy Ordinance covers safety and security in an integrated manner. Examples of that are:

- Chapter 2, related to Principles of Nuclear Safety and Security, establishes in Art. 7 requirements for nuclear safety, in Art. 8 requirements to prevent accidents and in Art. 9 requirements for security;
- Art. 21, which defines events and findings related on security to be reported to the authority;
- Art. 23, related to the general licence application documents which include together the safety analysis report and the security report;
- Art. 26, which states that the installation of security equipment should receive a permit from ENSI;
- Art. 31, related to quality management of operation, which states that tasks of relevance to safety and security must be defined in a management cycle and must be systematically planned, executed, controlled, documented, internally and externally audited on a periodical basis, and adjusted as necessary;
- Art. 33, which establishes requirements for the licence holder on systematic safety and security assessment;

- Art. 38 and 39, which establish detailed reporting requirements for the licensee respectively in relation to safety and security.

In the field of nuclear security there are other ordinances issued by the Swiss Federal Council (Personal Security Background Checks in the Area of Nuclear Installations (PSPVK) - Ordinance 732.143.3, Ordinance on the Security Guards of Nuclear Installations (VBWK) - 732.143.2) and by DETEC (Ordinance on the Threat Assumptions and Security Measures for Nuclear Installations and Nuclear Materials-732.112.1).

According to Art. 70 of NEA, in 2009 ENSI was separated from the Swiss Federal Office of Energy and entitled of performing both nuclear safety and security supervision.

Legislation in force assigns the supervision of the operators system of accounting for, and control of, nuclear material to a part of the Swiss Federal Office of Energy. Not many interactions seem to be in place so far with ENSI to optimize the existing interface with security aspects.

14.2. ENSI SUPERVISION ACTIVITY

According to duties assigned by the legislation in force, ENSI issues permits on relevant safety and security changes to nuclear installations within the scope of the current licence; supervises their implementation; performs inspections on the sites; supervises the safety and security of transports of nuclear materials to and from nuclear installations and assesses the safety of proposed solutions for the geological disposal of nuclear waste.

Most of routine activities performed in the field of security relates to the implementation of upgrading modifications on the physical protection systems in the sites. In the past years, mainly from the 9/11 event, they have in particular been addressed with the installation of vehicle barriers, new perimeter detection systems, strengthening of existing structural barriers, upgrading of access control systems etc.

As established by the NEA and more in detail defined in the NEO security related modification can be implemented by the operator only on the basis of a permit granted by ENSI. Permits in the security field are granted, according to the relevance of the modification, in four steps, which implies the security concept, specifications for structures, systems, components, implementation documents for security installations, operating documents (for start-up).

The review and assessment process associated to the release of such security permits is conducted with the involvement of safety experts, by adopting a project management approach depending on the case. In a similar manner, the proper exploitation of interfaces between safety and security is ensured in the review and assessment process for granting permits related to plant modifications of safety related systems and components. The Probabilistic safety assessment performed for the NPPs in operation in Switzerland has offered the opportunity to prioritize the level of physical protection to be ensured by structures, systems and components relevant to safety.

Joint inspection designed to verify safety and security aspects are also periodically conducted by ENSI.

A similar approach is followed for transport activities for which ENSI is entitled to grant approval or validation of package certificates as well as provide opinions and conditions to the Swiss Federal Office of Energy (SFOE), who grants licences for transport activities, both in matters of safety and security.

Difficulties currently exist in implementing this approach in a more integrated manner including the accountancy and control of nuclear materials, due to the fact that these responsibilities have remained in the SFOE when the security ones where transferred by the SFOE to ENSI in 2009.

It has to be mentioned that ENSI is also quite active in international activities. It is member of INSRA; an IPPAS mission took place in 2008. Amendments to the Convention on Nuclear Materials and Installations were ratified in 2008.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 para. 2.39 states that** *"Specific responsibilities within the governmental and legal framework shall include:* a) Assessment of the configuration of facilities and activities for the optimization of safety, with factors relating to nuclear security and to the system of accounting for, and control of, nuclear material being taken into account; b) Oversight and enforcement to maintain arrangements for safety, nuclear security and the system of accounting for, and control of, nuclear material; c) Liaison with law enforcement agencies, as appropriate; d) Integration of emergency response arrangements for safety related and nuclear security related incidents."
S18	**Suggestion: The Government should consider complementing the responsibilities assigned to ENSI for nuclear safety and security with the responsibility in the supervision of accounting for and control of nuclear material, so as to enhance the efficiency of the supervision system and the effectiveness of related activities by implementing a completely integrated approach.**
(1)	**BASIS: GSR Part 1 para. 2.4 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."*
GP17	**Good practice: The integrated approach adopted by ENSI in the review and assessment as well as supervision of plant modifications, which always involve in a systematic manner safety and security experts, promote a very effective management of the existing interfaces so as to optimize mutual benefits on nuclear safety and security measures and to avoid possible mutual detrimental effects.**

14.3. INTERFACE WITH OTHER AUTHORITIES

The IRRS team had the opportunity to appreciate that continuous interaction are in progress with other authorities of the Federation having competences in the field of security (i.e. Intelligence Services, Cantonal Police, Office for Civil Aviation), in particular for the definition of the Design Basis Threat (DBT) and its updating, the performance of exercises connected to contingency and emergency plans, flight restriction on nuclear installations sites.

In particular it is worth note that cooperation is in place with other authorities involved in security matters in other sectors. In particular, commendable is the cooperation in place with Federal Office of Civil Aviation to perform joint inspections on access control aspects so as to exchange practices.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: INSAG24 - Part 29 states that** *"Because of the close relationship between safety and security, many countries see advantages in having a single regulator responsible for both. This authority may, in turn, be dependent on other government entities for assistance on security matters. That is, a regulator with responsibility for safety and security might be dependent on intelligence information from a specialized agency or agencies. It may also turn to police or military entities for fighting capability to augment the operator's security forces..."*
GP18	**Good Practice: In order to exchange technical experience, ENSI interaction with authorities competent for security matters in other sectors is quite positive.**

15. REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

This module brings together the information accumulated by the Team on Fukushima implications during the course of the mission and contains the views and conclusions of the team for each of the standard modules of the IRRS.

In particular, this module includes discussions on the following policy issues:

- Policy issue 0: Report of the Swiss Government, Response to the TEPCO Fukushima Dai-ichi Nuclear Accident.

15.1. ACTIONS TAKEN BY THE REGULATORY BODY IN THE AFTERMATH OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

A. IMMEDIATE ACTIONS TAKEN BY THE REGULATORY BODY

For almost two weeks from the day after the accident the ENSI emergency preparedness organization was in continuous activation on a two shift basis. Its task was the interpretation of the information available on the accident and the presentation of the facts to the public. Following the deactivation of the emergency preparedness organization a specific task force (called ENSI Japan Team) was set up for the initiation and performance of analyses deemed necessary and urgent.

ENSI has issued a number of orders in which it summarized the actions to be taken by the licensees in reply to the TEPCO Fukushima Dai-ichi event (for more details see Module 8 below).

In the immediate analysis of the events and of their local consequences ENSI followed the legally binding graded process in which the consequences of any event that may potentially affect the public are to be examined through three steps in consecutively broader contexts. In the first step it is to be investigated whether the event represents an immediate threat on the Swiss population from any of the Swiss nuclear plants. A positive answer to that would mean immediate shutdown of the plant affected. The analysis has not revealed any immediate threat and, on the other hand, reaffirmed that the hazard analyses as well as the probabilistic safety analysis results applied for the Swiss plants are conforming to the relevant international requirements.

The second question to be investigated is whether the circumstances necessitate the provisional shutdown of any of the plants. Provisional shutdown is to be ordered if certain criteria are met. In order to obtain answer to this question ENSI ordered the operators of the Swiss nuclear power plants to reassess their design in the light of the immediate consequences of the TEPCO Fukushima Dai-ichi accident. Specifically, the design of the plants had to be reassessed in view of the consequences of floods and/or excessive earthquakes with new (stricter) hazard assumptions from the point of view of flooding threat, seismic capacity of structures and components and seismic threat. In addition the reassessment of the failure of a dam nearby the Mühleberg NPP due to seismic effects was also initiated. Reassessment of the design did not substantiate to date the need for provisional shutdown of any of the Swiss power plants.

The graded investigating process finally has to determine whether measures are needed to improve safety of any of the plants as a consequence of the event. To obtain answer to this question screening analysis focused on spent fuel pools and water supply were required. Review of the design documentation of the plants identified specific inadequacies in some of the plants (e.g. related to cooling capacity or diversity) remediation of which was requested by ENSI in short term (c.f. below). In this context ENSI also ordered certain activities to be performed in short notice (establishment of an external storage facility for spare emergency equipment within two months, see also below) and in medium term (e.g. providing external connection means for emergency preparedness equipment by the end of 2012).

As part of the immediate reactions to the TEPCO Fukushima Dai-ichi events ENSI has initiated a series of inspections on various topics (spent fuel pool, mobile equipment to be used in case of flooding, filtered containment venting systems, see at Module 7 below).

B. TECHNICAL ISSUES CONSIDERED IN THE LIGHT OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

In the framework of the graded investigation process a number of technical issues have been considered. The first phenomenon investigated for all Swiss plants was the potential threat from flooding. It has been concluded flooding threat does not necessitate the provisional shutdown of any of the power plants. On the other hand, design reassessment of the Mühleberg NPP revealed certain need for back-fitting of the water intake in order to avoid blockage of the coolant inlet in the presence of debris resulted by a flood. The back-fittings were authorized by ENSI and performed by the licensee in summer 2011.

The second important issue is related to the protection of the plants against seismic hazards. The seismic hazard curves for the Swiss sites have been recently updated with a comprehensive probabilistic seismic hazard analysis according to state-of-the-art methods. The results of this study were approved and published by ENSI (HSK at that time) in 2007. Subsequently a refinement project on seismic hazards has started and is expected to deliver its final results by the end of 2012. The newly required safety demonstration by the operators of the NPPs (due by the end of March 2012) shall be based on the most updated seismic results available. Should the final seismic hazard analysis results at the end of 2012 differ from those used for the March demonstration, a final demonstration shall be performed.

Further issues considered were the spent fuel pools and the availability of ultimate heat sink in case of accidents. On the basis of the analysis submitted by the licensees in the short term, ENSI ordered to perform a number of modifications in the spent fuel cooling system (improvement of the cooling system in the older plants and modification of the instrumentation in every plant) and measures were requested related to the diversity of the ultimate heat sink (diverse water sources designed to withstand earthquakes are available in all plants except Mühleberg, see above). High level concepts on the elimination of deficiencies identified have been elaborated and submitted by the end of August 2011.

Further tasks by the operators are due by March 2012, which are related to accident analysis and management, like analysis of the hydrogen threat and detailed analysis of spent fuel pools.

Finally, the targeted safety reassessment performed in the framework of the EU stress tests covers every important technical issue related to safety margins, external initiating events, loss of ultimate heat sink, extended station blackout, and severe accident management. The analyses have been performed by the operators; at the time of the IRRS review the results are being evaluated by ENSI. The peer review process of the national EU stress test reports shall be concluded by mid-2012.

A pioneer solution is to be mentioned here in more details. Probably for the first time in the nuclear industry an external storage facility for emergency devices has been established by the Swiss NPPs making use of a former military storage basis. The external storage facility is meant to provide any of the NPPs with emergency diesel generators, pumps, electric cables, boric acid and installation tools and materials by means of helicopter transport should a natural disaster or other emergency make it necessary. The external storage should be reached by the first helicopter within one hour and is intended to satisfy the needs of a power plant within a few hours. The storage is equipped with the devices and goods in multiple quantities. The inventory is packed in such a way that it can be transported by the helicopters that have a maximum loading capacity of 2000 kg. The storage is almost fully equipped; its full capacity shall be tested in early 2012. The Team acknowledges the opportunity of visiting this facility.

C. OTHER ISSUES CONSIDERED IN THE LIGHT OF THE FUKUSHIMA ACCIDENT

ENSI has initiated an extensive investigation and analysis process in order to identify those lessons that can be learned from the accident in order to increase nuclear safety in Switzerland. The results have been summarized in three reports, a fourth on the radiological aspects of the TEPCO Fukushima Dai-ichi accident is in preparation. In the first report the detailed event sequence of the TEPCO Fukushima Dai-ichi accident has been reconstructed and commented unit by unit for both the Fukushima Dai-ni and Dai-ichi plants. Commenting annotations raise questions concerning the activity of the operator or give hints on how the progress of the accident could have been better mitigated or managed.

In the second report the accident events and actions have been analysed from organizational and human factors point of view. The analysis also includes a number of tentative conclusions (called hypotheses) on the presumed deficiencies and their possible causes in handling the accident.

The third report has identified the lessons learned and the action to be done in a well-structured and highly conceptual form. Altogether 39 lessons learned are identified related to organizational and human questions, leadership and decision-making issues, design, operational and safety problems. Based on and related to the lessons learned a number of so called Checkpoints are determined. A Checkpoint includes the task to be performed, its substantiation and the way of implementation. Checkpoints are distributed among so called focus areas, i.e. areas having had particular importance in the accident (design, emergency management, experience feedback, supervision, radiation protection, safety culture). Furthermore, Checkpoints are categorized according to their role in the defence in depth (accident prevention, accident management, consequence mitigation). 37 Checkpoints and the respective task have been defined. Full implementation of the Checkpoints is foreseen by 2015. For more details see the module-wise discussion below.

CONCLUSION [1]
The Team considers that ENSI has reacted on the TEPCO Fukushima Dai-ichi accident in an exemplarily well-organized and effective way. It had initiated those immediate measures which became necessary in the light of the lessons learned from the accident in a timely manner and at the same time has started a long term analysis and planning work to take advantage as much as possible of the conclusion that can be drawn from the TEPCO Fukushima Dai-ichi event at this time.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities."*
GP19	**Good Practice: ENSI should be commended for their prompt implementation of first measures and the development of a comprehensive action plan based on an analysis of the TEPCO Fukushima Dai-ichi accident.**

15.2. PLANS FOR UP-COMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

The document on lessons and Checkpoints as described above defines implementation activities to all the 37 Checkpoints. 21 out of them have been completed, initiated, or taken into account by ENSI supervision, the implementation of 16 Checkpoints is to be initiated later on. Most of them shall be related to the work of an interdepartmental working group set up by the Swiss Federal Council to examine the need of further actions in emergency preparedness on extreme events and in the measures to be taken.

Typical Checkpoints to be covered by the interdepartmental working group (called IDA NOMEX) are related to reliability and workability of the emergency preparedness monitoring network in flooding or earthquake circumstances; to adequate redundancy and diversity of the emergency communication facilities and data transmission; and to the organization and operation of the emergency preparedness system. In this latter issue particular attention is paid on the decision making process, on the qualification, competence and availability of the personnel, on working in harsh conditions and on the interface and coordination between the participating organizations.

Further issues to be reviewed by the interdepartmental working group relate to the timely availability and transfer of radiation exposure as well as of meteorological data; to the public information; and to arrangements for handling radioactive contaminations. On the other hand the issue of emergency exercises specific to circumstances similar to those in TEPCO Fukushima Dai-ichi (although mentioned) does not seem to be raised with sufficient emphasis.

CONCLUSION [2]

The Team concludes that taking advantage of lessons learned from the TEPCO Fukushima Dai-ichi accident in the long term is based on the joint work of a working group encompassing all the stakeholders that may have role in such an activity. The scope of the further investigations and actions is sufficiently broad, although, the Team suggests placing larger emphasis on planning and conducting complex, extended in time nuclear and radiological emergency exercises.

15.3. SIGNIFICANCE OF REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA ACCIDENT ACROSS REVIEWED AREAS

Note: ***The significance of Fukushima implications was considered as part of the review of each IRRS module. The review conclusions below and the plans presented by Switzerland to further address TEPCO Fukushima Dai-ichi issues in the coming years should be included in the scope of the follow-up IRRS mission to be invited by Switzerland.***

Module 1: Responsibilities and Functions of the Government

With respect to the responsibilities and functions of the Government, ENSI exercised its responsibilities as the Federal lead for the safety of the operating NPPs in Switzerland, as well as its role in Emergency Preparedness. With regard to the first issue, ENSI performed an independent review of the TEPCO Fukushima Dai-ichi accident to determine lessons learned and required a number of actions to be taken by the Swiss NPPs with regard to the most safety significant issues learned from the event, such as the ability of the NPPs to withstand a design basis earthquake or flooding scenario.

In responding to Fukushima, the Team observed that ENSI's role and responsibilities as well as its interfaces and co-operation with its Federal partners were exercised as appropriate. ENSI maintained its independence as a nuclear regulator and has already ensured that actions have been taken to improve the safety of the Swiss NPPs.

The emergency preparedness aspects of governmental functions and responsibilities are discussed in the part related to Module 10 below.

CONCLUSION [3]
The Team concludes that ENSI has exercised its national responsibilities with regard to the TEPCO Fukushima Dai-ichi event and continues to take actions to ensure the safety of the Swiss NPPs. It is also noted that ENSI is committed to address any relevant implications and lessons learned from the TEPCO Fukushima Dai-ichi accident for further improvement of its regulatory process.

Module 2: Global Nuclear Safety Regime

Switzerland is a contracting party to the Convention on Nuclear Safety, one of the major international conventions currently focused on evaluating and sharing lessons learned from the TEPCO Fukushima Dai-ichi accident. ENSI is very active internationally, participating on commissions in the OECD, IAEA, WENRA, the Network of Regulators of Countries with Small Nuclear Programmes (NERS), and other institutions. These activities allow ENSI to stay abreast of current international thinking with regard to safety improvements that should be considered in relation to the TEPCO Fukushima Dai-ichi accident, and also allows ENSI to share its findings and initiatives with regard to improving safety with the global community.

With regard to operating experience feedback, ENSI has published three separate documents on its evaluation of the Fukushima accident as described in the introduction to this module and has already required actions of its NPP operators to address the initial lessons learned.

CONCLUSION [4]
The Team recognises that ENSI is actively involved in international activities with regard to the TEPCO Fukushima Dai-ichi accident, including the EU Stress Tests, and has already taken initial actions to improve the safety of Swiss NPPs.

Module 3: Responsibilities and Functions of the Regulatory Body

The Team found that ENSI has taken appropriate actions with regard to the TEPCO Fukushima Dai-ichi accident within its responsibilities in the Swiss government and without interference. ENSI's actions have been timely and its decision-making has been conducted in an open, transparent manner. It has liaised appropriately with its governmental and non-governmental stakeholders and the Swiss NPPs.

The Team also found that ENSI has not delayed its actions waiting for a second opinion from the NSC, which is appropriate course of action for an independent and safety-conscious regulator. Communications between ENSI and the Swiss NPPs have been effective as evidenced by modifications already taken at some NPPs that will improve safety.

CONCLUSION [5]
The Team concludes that ENSI has taken appropriate actions with regard to the TEPCO Fukushima Dai-ichi accident in accordance with its roles and responsibilities as an independent regulator. The Team also recognises ENSI is committed to fostering improvement of the safety of the Swiss NPPs as well as the regulatory process as a result of lessons learned from the TEPCO Fukushima Dai-ichi event.

Module 4: Management System

After the TEPCO Fukushima Dai-ichi accident ENSI has performed an extraordinary management review in order to identify any gaps and opportunities for further improvement. Based on the analyses opportunities for improvement of ENSI were identified. Thus in order to establish safety requirements to prevent the recurrence of similar events, developments are needed in the fields of event analyses and of identification of root-causes. A new division named "Systems" has been created including a section for operational experience which is aimed to deal with these topics.

In addition to this the existing procedure of the ENSI Management System - the Occurrence Processing Process – is being modified to strengthen the focus on international occurrences.

CONCLUSION [6]
The Team recognizes that ENSI is actively involved in international activities. The ENSI Management System has been modified to strengthen the focus on international operational experience. The team concluded that this course of actions was appropriate.

Module 5: Authorization

According to the current legal basis, the authorization process of a nuclear installation in Switzerland is quite articulate and envisages three different licences to be granted before the plant enters into operation, namely the General Licence, the Construction Licence and the Operating Licence as indicated in Section 5.4 of this report.

According to the licensing procedure in Switzerland plant modifications are authorized by permits issued by ENSI (only substantial changes affecting the licence conditions require an amendment of the licence itself).

International safety reference levels are explicitly considered whenever guidelines are amended or new ones are drafted (according to the process 'Regulatory basis' in the ENSI MS). The regulatory documents on which ENSI position is based are listed in the safety evaluation report related to a licence application or in the official ENSI permit related to a proposed change.

Due to the political decision of phasing-out from nuclear energy (no new builds in Switzerland) the issuance of guidelines with further details on the content of submittal documents for construction and operation licence of NPPs is clearly no more a priority.

In the aftermath of the TEPCO Fukushima Dai-ichi accident ENSI issued orders to the licensees to assess their plants, to identify improvements in the light of the already known lessons derived from the accident, to implement any back-fitting measures according to a defined and strict time table.

All the modifications resulting from the back-fitting measures will be authorized according to the standard permits licensing procedure of ENSI.

CONCLUSION [7]
The IRRS Team considers that the regulatory process including orders and permits issued by ENSI is capable of dealing with authorization activities created in relation to the TEPCO Fukushima Dai-ichi accident without change.

Module 6: Review and Assessment

After the TEPCO Fukushima Dai-ichi accident ENSI reacted actively requesting short-term new assessments in the light of the experience from Fukushima, resulting in a few cases in back-fitting. In the medium-term actions ENSI also participates in the European Union stress tests. These analyses are on-going according to the schedule given for the stress tests.

According to the "Ordinance on the Methodology and the General Conditions for Checking the Criteria for the Provisional Taking out of Service of Nuclear Power Plants" , the Swiss NPPs are obliged to reassess their safety after an accident of INES level 2 or above in a foreign nuclear installation.

After the TEPCO Fukushima Dai-ichi accident, ENSI immediately released orders requiring a reassessment of the earthquake and flooding protection of the NPPs. For these (deterministic) safety analyses more restrictive boundary conditions/conservative assumptions (as compared to the requirements given by the guideline ENSI-A01) have to be applied:

- Frequency of the hazard: 10^{-4}/yr; dose limit 100 mSv to be demonstrated;
- Latest flooding hazards from the general licence applications for new NPPs (2008);
- Latest seismic hazard from the current PEGASOS Refinement Project (SSHAC Level 4);
- Loss of offsite power for 3 days;
- Deterministic demonstration that water intakes are available after flooding;
- For earthquake:
    - Option 1: deterministic demonstration that dams withstand the earthquake,
    - Option 2: dams & water intakes guaranteed failure;
- Safe shutdown for 3 days – no external support.

The evaluation of the flooding risk resulted in a back-fit (improved water intake) in one of the Swiss plants, because intake plugging could not be completely ruled out and there is no secondary Ultimate Heat Sink (just the river). The results for the seismic analyses will be available in March 2012.

In addition, ENSI required a safety re-evaluation of the spent fuel pools, in particular with regard to seismic and flooding events and the protection against hydrogen explosions during a severe accident. As an outcome of this re-evaluation, several potential improvements for the spent fuel pools have been identified so far (e.g. piping for water supply from outside the building, instrumentation for the level and temperature measurement including corresponding indications in the emergency control room, improvements for the spent fuel pool cooling systems).

CONCLUSION [8]
The Team considers that the immediate actions by ENSI after the TEPCO Fukushima Dai-ichi accident were adequate and commensurate with the risk posed. ENSI required new assessments of the nuclear plants, including the spent fuel pools. The extent of the assessment was clearly defined and criteria must be met according to the guideline ENSI-A01. These assessments resulted in back-fit for one plant and additional measures for spent fuel pool have been required. Furthermore ENSI required prepared accident measures. Besides these actions ENSI also decided to participate in the EU stress tests. The Team concludes that ENSI has fully complied with what can be expected from a regulatory body.

Module 7: Inspection

In response to the TEPCO Fukushima Dai-ichi accident, ENSI has conducted more than ten inspections on four areas. Inspected areas were the external storage for accident management equipment established

in May as a response to accident, preventive measures for the cooling of the fuel pools in design basis and beyond design basis accidents, thematic inspections on design reassessment of flooding and containment filtered venting systems. ENSI is not planning to conduct any additional inspections in 2011 unless there is a specific need to e.g. verify the information submitted by the licensees for the EU Stress Tests.

If safety improvements at the plants will be implemented due to Fukushima accident (or due to any other reason), ENSI will review and assess the design modification prior to their implementation. ENSI can also decide to perform inspections on the modifications during and after implementation if considered necessary.

Inspections have been performed according to the inspection process defined in the ENSI's management system. ENSI's inspection process enables reactive inspections and additional inspections to be conducted by ENSI on a case by case need. Inspections that have been carried out due to accident are so called focal point inspections. Inspections have been reported and documented.

In general, ENSI's inspection process and programme includes all nuclear facilities with a graded approach to safety. Facilities with a higher risk to public and to environment are inspected in more detail and more frequently. ENSI's inspection findings are rated according to their safety significance and utilized in systematic safety assessment. With the results of systematic safety assessment system ENSI is able to assess and trend the performance of organizations as well as the plant condition enabling ENSI to detect and react to declining performance.

CONCLUSION [9]
The Team considers the inspections performed by the regulatory body in response to the TEPCO Fukushima Dai-ichi accident were prompt and well-focused. Inspection process enables ENSI to conduct additional inspections if needed.

Module 8: Enforcement

With regard to enforcement after the TEPCO Fukushima Dai-ichi accident, ENSI has followed its process for enforcement in a consistent manner and in accordance with the legislation and ENSI's Management System. Since there was no immediate threat to public and environment according to ENSI's judgment, there was no reason to shut down a NPP or another nuclear facility. In response to the accident in TEPCO Fukushima Dai-ichi, ENSI issued four formal orders to Swiss NPPs and requested measures to assess and to further improve safety of the NPPs.

On 18 March 2011, ENSI ordered all Swiss NPPs:

- to do a design reassessment regarding earthquake and flooding;
- to get access to externally stored accident management equipment;
- to install connections for mobile accident management equipment that are accessible from outside of the buildings;
- to install connections for cooling fuel pools that are accessible from outside of the buildings;
- to do a screening analysis and report on design issues: 1. with regard to diversity of cooling water intakes and protection against earthquake, flooding and plugging; 2. with regard to the protection of fuel pools; 3. with regard to the cooling of fuel pools.

- On 1 April 2011, ENSI issued a formal order to all Swiss NPPs with specific requirements for the design reassessment regarding earthquake and flooding. The requirement concerned hazard assumptions on earthquakes, flooding, and the combination of earthquake and flooding.

- On 5 May 2011, ENSI issued plant specific requests in response to the licensees' reports regarding main cooling water and spent fuel pools (see order of the 18 March 2011).
- On 1 June 2011, ENSI ordered the Swiss NPPs to do a reassessment of their safety margins by participating in the European Union stress tests, although Switzerland is not a member of the EU.

Moreover, ENSI has an existing and clear process with well-defined criteria that will be implemented in the case the requested analysis and reassessments would lead to the identification of unforeseen radiation risks. This means for example that if the requested analysis will result in the fact that an earthquake or a flood with a return period of 10.000 year would lead to a maximum individual dose of more than 100 mSv, the NPP should be shut down until back-fitting measures are implemented.

Last but not least, the systematic follow-up of the requested actions/orders (to ensure that all the corrective actions after TEPCO Fukushima Dai-ichi are implemented as appropriate by the authorized party) is also done by ENSI. At the end of the process, after the fulfilment of all the actions, ENSI will "close" the process by writing a confirmation letter to the authorized party.

The other Swiss nuclear facilities were not addressed after TEPCO Fukushima Dai-ichi due to low or negligible risks caused by these facilities to the environment or people.

CONCLUSION [10]
The Swiss regulatory body demonstrated the independent implementation of a graded enforcement policy in response to the TEPCO Fukushima Dai-ichi accident. The actions taken by ENSI seem to be timely and commensurate with the safety importance of the issues raised by the accident. The ENSI enforcement process is capable of dealing with the enforcement activities created in relation to the TEPCO Fukushima Dai-ichi accident without change.

Module 9: Regulations and Guides

In the ENSI report on Fukushima Lessons it was recognized the impact of the TEPCO Fukushima Dai-ichi accident on regulations and guidelines needs further analysis. This is addressed in Checkpoint 30 (Category II) of the report: "*Review of regulatory documents (in particular the ENSI guidelines) to determine whether they cover all the relevant lessons from the accident at Fukushima*".

Review of ENSI guidelines in the light of the events in TEPCO Fukushima Dai-ichi is in progress. ENSI stated that it intends to wait for the outcome of the various projects that deal with the implications of the lessons learned from TEPCO Fukushima Dai-ichi in Switzerland (e.g. by the IDA NOMEX Working Group).

Furthermore, as the Swiss government and parliament have decided on the phase-out of nuclear energy, modification of the law (Nuclear Energy Act) should start in 2012 to reflect this decision. ENSI participates in the drafting and consultation process of the new act. After the modified law has been enacted, a further check of the implications on the rest of the regulatory framework should be conducted, i.e. ENSI guidelines will be scrutinized for their compatibility with the new act.

CONCLUSION [11]
The Team noted the commitment of ENSI to include lessons learned from TEPCO Fukushima Dai-ichi accident in revision of Swiss nuclear safety regulations. The team considers this response as adequate in the area of regulation and guides.

Module 10: Emergency Preparedness and Response

Regarding the EPR implications of the TEPCO Fukushima Dai-ichi nuclear emergency ENSI promptly acted on two important terms. On the shorter term ENSI addressed the following questions to be answered immediately or within the shortest period of time:

1. Is there an immediate threat for the Swiss population?
2. Are the criteria for provisional plant shutdown in Switzerland fulfilled?
3. Which measures are necessary to improve safety?

ENSI's systematic review and analysis of the events in the TEPCO Fukushima Dai-ichi NPP has led to the publication of the "Lessons Fukushima" report, with a number of lessons identified about the shortcomings in the area of preparedness and management of the emergency (inadequate preparation of emergency measures, unavailability of monitoring data, inadequate information to the public, etc.).

The longer term issues were the subject of the large scale national effort of IDA NOMEX (the interdepartmental working group with the participation of ENSI) concluding, among others, that:

- Tasks and responsibilities of the Federal NBCN Crisis Management Board must be better clarified;
- The concept of measures as a function of radiation dose must be verified;
- The interfaces between cantons and confederation should be better defined;
- The capacity of dealing with long lasting emergencies at the federal level must be addressed.

The need for providing redundancy in essential services (communication technologies, logistical supplies) for the emergency response operations was also identified.

CONCLUSION [12]
The Team concludes that ENSI responded promptly and properly to the urgent Emergency Preparedness and Response-related challenges in Switzerland due to the TEPCO Fukushima Dai-ichi accident and the longer term upgrading proposals of IDA NOMEX provide a sound basis for the improvement of the nuclear emergency preparedness capabilities of the country.

IRRS REVIEW TEAM

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APPENDIX II – MISSION PROGRAMME

Date and Time	Activity	Team Members
Sunday, 2011-11-20		
14:00-18:00	Opening Team Meeting	All
Monday, 2011-11-21		
09:00-12:30	Entrance Meeting − Welcome and Opening Remarks (H. Wanner, A. Eckhardt) − Introduction (H. Wanner) − Integrated Oversight (G. Schwarz) − ENSI's Electronic Management System (J.-C. Veyre)	All J.-C. Niel
13:30-15:00	Regulatory implications of the Fukushima accident (R. Sardella)	All
15:30-17:00	Module Discussion/Interviews (Lead Counterparts) Modules 1,2,3,12 (A. Schefer, M. Straub, G. Schwarz) Module 4 (J.-C. Veyre) Module 5 (R. Sardella) Module 6 (R. Schulz) Modules 7,8 (P. Flury) Module 9 (R. Sardella) Module 10 (G. Piller) Modules 11a,b,c (J. Hammer) Module 11d (F. Altorfer) Module 11e (S. Theis)	E. Leeds, A. Lorin-Wawresky, L. Matteocci M. Ziakova L. Matteocci, M. Ziakova G. Lowenhielm, S. Lee P. Tiippana, M. Jakes, A. Wertelaers G. Samokhin, T. Wildermann R. Dos Santos E. Amaral, V. Jurina M. Sneve, B. Watson S. Whittingham
17:00	Team Meeting	All
Tuesday, 2011-11-22		
09:00-17:00	Module Discussion/Interviews (arrangement see page 1)	(See page 1)
14:00-15:00	*Modules 1-3: Special Meeting with Members of the ENSI Board* A. Eckhardt, H.-J. Pfeiffer, H.-M- Prasser, J. Schmid, P. Steiner	J.C. Niel, E. Leeds, A. Lorin-Wawresky
17:00	Team Meeting, Report Drafting	All
Wednesday, 2011-11-23		
09:00-17:00	Module Discussion/Interviews (arrangement see page 1)	(See page 1)
07:30-13:30	*Module 11a/b/c ("Radiation Protection"):* *Inspection Beznau NPP*	E. Amaral, V. Jurina

09:00-13:30	*Module 11d ("Waste Management"): Visit Central Interim Storage Facility*	M. Sneve, B. Watson
09:00-13:30	*Module 6 ("Review & Assessment"): Visit to PSI (Human Reliability Analysis)*	G. Lowenhielm, S. Lee
12:30-17:00	*Modules 1-3: Meeting with (1) the Secretary General of the Federal Department of the Environment, Transport, Energy and Communications (Ministry) and (2) a representative of the Legal Services and Safety Division of the Federal Office of Energy (SFOE)*	J.-C. Niel, E. Leeds
13:00	*Module 10 ("Emergency Preparedness"): Observation of an Emergency Exercise*	R. Dos Santos
17:00	Team Meeting, Report Drafting	All
Thursday, 2011-11-24		
09:00-15:00	Module Discussion/Interviews (arrangement see page 1)	(See page 1)
07:30-17:00	*Module 7 ("Inspection"):* *Visit/Inspection Leibstadt NPP (Containment Venting)*	P. Tiippana, M. Jakes, A. Wertelaers
09:00-12:00	*Module 10 ("Emergency Preparedness"):* *Meeting with authorities responsible for emergency preparedness (representatives of Federal Authorities, Cantons and Germany)*	R. Dos Santos
09:00-11:00	*Module 5 ("Authorization"):* *Meeting with a representative of the Federal Office of Energy (SFOE)*	L. Matteocci, M. Ziakova
09:00-10:30	*Modules 1-3 and Module 11d ("Waste Management"):* *Meeting with the Swiss Federal Nuclear Safety Commission (NSC)*	E. Leeds, M. Sneve, B. Watson
10:30-11:30	*Module 11e ("Transports"):* *Meeting with a representative of the Federal Office of Energy (SFOE)*	S. Whittingham
11:00-12:00	*Module 11d ("Waste Management"):* *Meeting with the Commission for Nuclear Waste Disposal (KNE)*	M. Sneve, B. Watson
13:30-15:30	*Module 9 ("Regulations & Guides"): Meeting with a representative of the Federal Office of Energy (SFOE, process of issuing ordinances)*	G. Samokhin, T. Wildermann
13:30-15:00	*Module 11e ("Transports"):* *Discussion with authorities responsible for transports (FOPH, SUVA)*	S. Whittingham

13:30-15:00	*Module 11a/b/c ("Radiation Protection"):* *Meeting with the Federal Commission for Radiation Protection and Radioactivity Monitoring (KSR)*	E. Amaral, V. Jurina
15:30-17:00	*Module 11a/b/c ("Radiation Protection"): Meeting with authorities responsible for Radiation Protection in medicine, research and industry (FOPH, SUVA)*	E. Amaral, V. Jurina
17:00	Team Meeting, Report Drafting	All
Friday, 2011-11-25		
09:00-15:00	Module Discussion/Interviews (arrangement see page 1)	(See page 1)
07:30-16:30	*Optional Visit to the External Storage Facility and the Mühleberg NPP*	
09:00-13:30	*Module 11 d ("Waste Management"):* *Meeting with the National Cooperative for the Disposal of Radioactive Waste (Nagra)*	M. Sneve, B. Watson
10:00-11:30	*Module 7 ("Inspection"):* *Meeting with representatives of the Swiss Association for Technical Inspections (SVTI)*	P. Tiippana, M. Jakes, A. Wertelaers
14:00-15:30	*Module 11d ("Waste Management"): Meeting with representatives of the Radioactive Waste Disposal Section of the Federal Office of Energy*	M. Sneve, B. Watson
17:00	Team Meeting, Report Drafting	All
Saturday, 2011-11-26		
08:30-18:00	Team Meeting, Report Drafting	All
Sunday, 2011-11-27		
09:00-12:00	Team Meeting, Report Drafting	All
13:30	Social Event – Visit to Lucerne	All
Monday, 2011-11-28		
09:00-12:00	Policies Discussion (Lead Counterparts): − Openness, Transparency and Stakeholder Involvement (M. Straub) − Interfaces with other Authorities (G. Piller)	All
13:00-17:00	Report Drafting/Module Discussion	All
17:00	Team Meeting, Report Drafting	All
Tuesday, 2011-11-29		
09:00-12:00	Policies Discussion (Lead Counterparts)	All

	− Long-term Operation (G. Schwarz) − Fukushima (R. Sardella)	
13:00-17:00	Report Drafting/Module Discussion	All
17:00	Team Meeting, Report Drafting	All
Wednesday, 2011-11-30		
09:00-12:00	Report Drafting	All
12:00	Draft Report “Modules” to Counterparts	All
13:00-18:00	Report Drafting	All
18:00	Draft Report “Fukushima” to Counterparts	All
Thursday, 2011-12-01		
09:00-18:00	Team Meeting, Plenary Discussion	All
Friday, 2011-12-02		
09:00-12:00	Exit Meeting, followed by Press Conference	All

APPENDIX III – SITE VISITS

SITE VISITS	
1.	Site Visit to BEZNAU NPP
2.	Site Visit to LEIBSTADT NPP
3.	Site Visit to MÜHLEBERG NPP
4.	Site Visit to EXTERNAL STORAGE FACILITY FOR EMERGENCY EQUIPMENT
5.	Site Visit to ENSI-EMERGENCY RESPONSE CENTRE
6.	Site Visit to ZWILAG-CENTRAL INTERIM STORAGE FACILITY
7.	Site Visit to NATIONAL COOPERATIVE FOR THE DISPOSAL OF RADIOACTIVE WASTE

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	ENSI Lead Counterpart	ENSI Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	Eric Leeds Aurelie Lorin-Wawresky Eliana Amaral	Andreas Schefer	Georg Schwarz Markus Straub
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	Eric Leeds Aurelie Lorin-Wawresky	Markus Straub	Georg Schwarz Albert Frischknecht
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Eric Leeds Aurelie Lorin-Wawresky	Markus Straub	Georg Schwarz Jean-Claude Veyre
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	Marta Ziakova	Jean-Claude Veyre	Georg Schwarz
5.	**AUTHORIZATION**		
	Marta Ziakova Lamberto Matteocci Bruce Watson Vladimir Jurina Malgorzata Sneve	Rosa Sardella	Dietmar Kalkhof Joachim Lucht Andreas Schefer Ulrich Schmocker
6.	**REVIEW AND ASSESSMENT**		
	Gustaf Loewenhielm Suk Ho Lee Bruce Watson Vladimir Jurina Malgorzata Sneve	Ralph Schulz	Gerhard Schoen Torsten Krietsch
7.	**INSPECTION**		

	IRRS EXPERTS	ENSI Lead Counterpart	ENSI Support Staff
	Bruce Watson Vladimir Jurina Malgorzata Sneve Petteri Tiippana Miroslav Jakes An Wertelaers	Peter Flury	Daniel Billeter Günter Prohaska
8.	**ENFORCEMENT**		
	Bruce Watson Vladimir Jurina Malgorzata Sneve Petteri Tiippana Miroslav Jakes An Wertelaers	Peter Flury	Daniel Billeter
9.	**REGULATIONS AND GUIDES**		
	Bruce Watson Vladimir Jurina Malgorzata Sneve Gennadiy Samokhin Thomas Wildermann	Rosa Sardella	Andreas Schefer Nathalie Studer Ulrich Schmocker
10.	**TRANSPORT OF RADIOACTIVE MATERIAL**		
	Steve Whittingham	Stefan Theis	Frank Koch
11.	**EMERGENCY PREPAREDNESS AND RESPONSE**		
	Raul Dos Santos Peter Zombori	Georges Piller	Ronald Rusch Ernst Blust
12.	**OCCUPATIONAL, PUBLIC AND ENVIRONMENTAL EXPOSURE CONTROL**		
	Eliana Amaral Vladimir Jurina Malgorzata Sneve	Felix Altorfer Johannes Hammer	Meinert Rahn Ann-Kathrin Leuz Stefan Theis Roland Scheidegger Franz Cartier

	IRRS EXPERTS	ENSI Lead Counterpart	ENSI Support Staff
			Andreas Leupin
13.	**WASTE MANAGEMENT (POLICY AND STRATEGY, PREDISPOSAL AND DISPOSAL), DECOMMISSIONING**		
	Eliana Amaral Vladimir Jurina Malgorzata Sneve	Felix Altorfer Johannes Hammer	Meinert Rahn Ann-Kathrin Leuz Stefan Theis Roland Scheidegger Franz Cartier Andreas Leupin
14.	**INTERFACES WITH NUCLEAR SECURITY**		
	Lamberto Matteocci	Georg Schwarz	Hans Mattli
15.	**REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT**		
	Ivan Lux	Rosa Sardella	-

POLICY ISSUE DISCUSSIONS		
PI 1 – Fukushima Regulatory Issues		
Ivan Lux	Rosa Sardella	**-**
PI 2 – Long Term Operation		
Suk Ho Lee **Gustaf Loewenhielm**	Georg Schwarz	Klaus Germerdonk
PI 3 – Interfaces with Other Authorities		
Jean-Christophe Niel	Georges Piller	Dietmar Kalkhof Hans Mattli
PI 4 – Openness, Transparency and Stakeholders Involvement (incl. public communication)		
Jean-Christophe Niel	Markus Straub	Sebastian Hueber Hans Mattli

APPENDIX V – RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	R1	**Recommendation:** The government should consider providing ENSI with the authority to issue regulatory requirements.
	R2	**Recommendation**: ENSI should formalize and implement its graded approach for regulatory oversight of nuclear safety including as example research reactors, transport and decommissioning.
	R3	**Recommendation:** The government should take appropriate measures to ensure conventional safety requirements are being supervised and complied with at all nuclear facilities and that there are effective interfaces between conventional, radiation and nuclear safety.
	GP1	**Good Practice:** The system in place to finance ENSI enables it to adjust its effective funding to its workload and then to obtain the resources necessary to fulfil its statutory obligation, without interference from government authorities.
	R4	**Recommendation:** The government should evaluate the needs for building and maintaining competence of the parties that have responsibilities in relation to safety in the near, mid-term and long-term future. It should then adopt the appropriate strategy to fulfil those needs.
2. GLOBAL NUCLEAR SAFETY REGIME	GP2	**Good Practice:** The ENSI ordinance requires ENSI to undergo an IRRS mission periodically.
	GP3	**Good Practice:** The Art. 2 of DETEC Ordinance n°732.114.5 issued in 2008 requires operators to review the design of their plant after every INES 1 event in their own plant or after any INES 2 event in another

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		NPP in Switzerland or abroad without any additional request from ENSI.
	GP4	Good Practice: In order to share and to record the research results and experience accumulated during the year, ENSI publishes an additional report, on regulatory safety research, lessons learnt from events in foreign NPPs, international cooperation and current changes and developments in the basics of the nuclear regulatory process.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	S1	Suggestion: ENSI should ensure there is sufficient competent staff to complete the development of the decommissioning program, to fulfil its duties regarding the safety of radioactive waste management and to further develop ENSI's emergency preparedness.
	R5	Recommendation: Government should ensure that relevant authorities, commissions and committees, for example the NSC, involved in nuclear safety matters, provide its recommendations and advice directly to ENSI before it issues its final decision. This should be done in an open and transparent manner, in order to allow ENSI to make an informed decision.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	GP5	Good Practice: The ENSI management system is properly established and supported by software applications, which provide a comprehensive platform to ensure that the system works properly, is user friendly and allows interconnection among various management system processes.
	S2	Suggestion: ENSI should explicitly address safety culture in its management system to achieve a common understanding of the key safety culture aspects within the organization.
	S3	Suggestion: ENSI should establish an appropriate approach in the management system to address organizational changes.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
5. AUTHORIZATION	R6	**Recommendation: The government should revise relevant legislation in order to provide ENSI with the authority to formulate binding conditions on nuclear safety, security and radiation protection. This should be fully reflected in various licences, orders or in their amendments whenever it is necessary before or after the issuance of the authorization.**
6. REVIEW AND ASSESSMENT	R7	**Recommendation: ENSI and other relevant authorities should establish a regulatory requirement for licensees to independently verify all safety information internal or coming from its contractors notably design organizations and vendors, prior to its submittal to the regulatory body.**
	GP6	**Good practice: The rules for back-fitting have clear initiation points, criteria on what safety goals must be fulfilled and the measures that may be needed for their implementation.**
	S4	**Suggestion: ENSI should develop a formal process for conducting regulatory reviews of safety analysis reports of nuclear facilities.**
	GP7	**Good Practice: ENSI is using PSA in different areas of its regulatory activity in an advanced and comprehensive manner.**
	GP8	**Good Practise: ENSI has clear closure criteria to shut down NPP based on the status of the reactor vessel and the containment is an example for an effective ageing management.**
7. INSPECTION	GP9	**Good Practice: The integration of rated inspection results with the safety assessment system provides a useful and systematic tool for ENSI to continuously evaluate the safety of the nuclear power plants.**
	S5	**Suggestion: ENSI should consider reassessing its current inspection programme for nuclear power plants to determine if it covers adequately all levels of defence in depth which is the basis used in ENSI's systematic**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		safety assessment. ENSI should also consider issuing more detailed guidance on the contents of the inspections conducted within the Basic Inspection Programme to ensure that inspections cover all areas of the responsibility of the regulatory body.
	R8	**Recommendation: ENSI should evaluate the effectiveness of the inspection process and coverage of the inspection programmes to ensure that also all other nuclear facilities (e.g. waste facilities, decommissioning, X-ray equipment and radioactive sources at the nuclear facilities) are adequately addressed.**
8. ENFORCEMENT	**R9**	**Recommendation: The Government should change the legal framework in such a way that the threshold for prosecution should be commensurate with safety significance, in accordance with a graded approach. The legal framework should also - given the importance of openness and transparency for nuclear safety - allow prosecution of a licensee in order to avoid the detrimental effects of blame on an individual.**
9. REGULATIONS AND GUIDES	**S6**	**Suggestion: ENSI should follow its comprehensive program to complete the regulatory framework in the future. The regulatory framework should be completed in a timely manner.**
	S7	**Suggestion: ENSI should continue to develop a decommissioning regulatory program that integrates all hazards assessments. Special attention should be given to conventional safety prior to issuing new permits for decommissioning.**
	GP10	**Good Practice: During the process of developing a guideline there is an extensive process of consultation of stakeholders. It is an open and transparent process.**
	GP11	**Good Practice: The licensees are required by law to back-fit their**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		installations to the extent that is necessary, based on worldwide operating experience and the state of current back-fitting technology.
10. TRANSPORT OF RADIOACTIVE MATERIAL	**R10**	**Recommendation: The government should ensure that the Swiss Authorities responsible for the transport of radioactive material operate a collaborative process for the timely exchange of information regarding authorisations, inspections and enforcement actions to provide coordinated and effective regulatory oversight.**
	S8	**Suggestion: ENSI should use the process recommended above for the exchange of information as a basis to collaborate with SUVA on compliance inspection programmes for companies subject to licences under RPA as well as NEA.**
	R11	**Recommendation: The government should ensure that there is appropriate and effective regulatory oversight and enforcement authority for all activities relating to packages that are used to transport radioactive material when such activities are undertaken on a facility that is not regulated under NEA.**
	S9	**Suggestion: ENSI should issue a guidance document to specify the requirements for transport casks and other types of transport packages for radioactive material, including details of applying a graded approach to package components and management controls (activities).**
11. EMERGENCY PREPAREDNESS AND RESPONSE	**R12**	**Recommendation: ENSI should make the emergency classification consistent with GS-R-2.**
	S10	**Suggestion: ENSI should fully integrate the emergency preparedness and response into the scope of the regular inspection (e.g. the proper status and functioning of emergency equipment, emergency dosimetry, personal protective equipment, evacuation routes, control room conditions for emergency situation, etc.).**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S11	**Suggestion:** ENSI is suggested to work towards the improvement of communication redundancy to provide alternative communication means to the land-based lines in case of natural disasters.
	S12	**Suggestion:** The government should consider the development of a comprehensive national radiation emergency response plan based on the existing "Consensus Paper" on national cooperation in case of a nuclear accident.
	S13	**Suggestion:** ENSI is encouraged to initiate having longer exercises than the current few-hour long drills for testing the procedures over several shift changes.
	GP12	**Good Practice:** Excellent tools, both electronic and paper-based, have been developed and are available for radiological monitoring and consequence assessment as well as for public information.
	GP13	**Good Practice:** Good coordination and cooperation between federal and cantonal organizations involved in the national nuclear emergency preparedness and response system as well as with the neighbouring countries.
12. OCCUPATIONAL, PUBLIC AND ENVIRONMENTAL EXPOSURE CONTROL	S14	**Suggestion:** ENSI, FOPH and SUVA, in the planned review of the RPO, should ensure that the RPO is harmonized with international requirements, especially concerning worker protection, particularly in terms of dose values. In addition, there should be an adequate balance between ordinances and guidelines, a clear link established in ordinances for any necessary guidelines and clarity provided as to which worker protection ordinances apply to nuclear facilities.
	GP14	**Good Practice:** Jointly developed Guideline by ENSI, FOPH and SUVA (ENSI-B04, Release of Material and areas from controlled zones) has led

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		to consistent results at the facilities regulated by the different regulators.
	S15	Suggestion: ENSI and FOPH should develop a similar joint document on strategies of site and environmental remediation based on WS-R-3.
13. WASTE MANAGEMENT (POLICY AND STRATEGY, PREDISPOSAL AND DISPOSAL), DECOMMISSIONING	GP15	Good practice: The use of the Sectorial Plan as the instrument for the repository site selection is an open and transparent process that involves stakeholders.
	GP16	Good Practice: Sectorial Plan provides very good process for confidence building among all stakeholders. ENSI is leading the Technical Forum Safety meetings with all stakeholders, but also international experts and interested community are involved in the review process.
	S16	Suggestion: ENSI should continue to be an active participant in the IAEA and other international decommissioning forums to gain valuable regulatory experience for the decommissioning of the Swiss research and power reactors.
	S17	Suggestion: ENSI should develop a human resources plan for providing inspectors and other technical specialists required to regulate reactor decommissioning projects and to ensure end point criteria are met for terminating the licences.
14. INTERFACES WITH NUCLEAR SECURITY	S18	Suggestion: The Government should consider complementing the responsibilities assigned to ENSI for nuclear safety and security with the responsibility in the supervision of accounting for and control of nuclear material, so as to enhance the efficiency of the supervision system and the effectiveness of related activities by implementing a completely integrated approach.
	GP17	Good practice: The integrated approach adopted by ENSI in the review and assessment as well as supervision of plant modifications, which

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		always involve in a systematic manner safety and security experts, promote a very effective management of the existing interfaces so as to optimize mutual benefits on nuclear safety and security measures and to avoid possible mutual detrimental effects.
	G18	Good Practice: In order to exchange technical experience, ENSI interaction with authorities competent for security matters in other sectors is quite positive.
15. REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT	GP19	Good Practice: ENSI should be commended for their prompt implementation of first measures and the development of a comprehensive action plan based on an analysis of the TEPCO Fukushima Dai-ichi accident.

APPENDIX VI – CONCLUSIONS ON THE REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

AREA	NO.	CONCLUSION
REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT	**C 1**	**The Team considers that ENSI has reacted on the TEPCO Fukushima Dai-ichi accident in an exemplarily well-organized and effective way. It had initiated those immediate measures which became necessary in the light of the lessons learned from the accident in a timely manner and at the same time has started a long term analysis and planning work to take advantage as much as possible of the conclusion that can be drawn from the TEPCO Fukushima Dai-ichi event at this time.**
PLANS FOR UP-COMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT	**C 2**	**The Team concludes that taking advantage of lessons learned from the TEPCO Fukushima Dai-ichi accident in the long term is based on the joint work of a working group encompassing all the stakeholders that may have role in such an activity. The scope of the further investigations and actions is sufficiently broad, although, the Team suggests placing larger emphasis on planning and conducting complex, extended in time nuclear and radiological emergency exercises.**
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	**C 3**	**The Team concludes that ENSI has exercised its national responsibilities with regard to the TEPCO Fukushima Dai-ichi event and continues to take actions to ensure the safety of the Swiss NPPs. It is also noted that ENSI is committed to address any relevant implications and lessons learned from the TEPCO Fukushima Dai-ichi accident for further improvement of its regulatory process.**
2. GLOBAL NUCLEAR SAFETY REGIME	**C 4**	**The Team recognises that ENSI is actively involved in international activities with regard to the TEPCO Fukushima Dai-ichi accident, including the EU Stress Tests, and has already taken initial actions to improve the safety of Swiss NPPs.**

AREA	NO.	CONCLUSION
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	C 5	The Team concludes that ENSI has taken appropriate actions with regard to the TEPCO Fukushima Dai-ichi accident in accordance with its roles and responsibilities as an independent regulator. The Team also recognises ENSI is committed to fostering improvement of the safety of the Swiss NPPs as well as the regulatory process as a result of lessons learned from the TEPCO Fukushima Dai-ichi event.
4. MANAGMENT SYSTEM OF THE REGULATRY BODY	C 6	The Team recognizes that ENSI is actively involved in international activities. The ENSI Management System has been modified to strengthen the focus on international operational experience. The team concluded that this course of actions was appropriate.
5. AUTHORIZATION	C 7	The IRRS Team considers that the regulatory process including orders and permits issued by ENSI is capable of dealing with authorization activities created in relation to the TEPCO Fukushima Dai-ichi accident without change.
6. REVIEW AND ASSESSMENT	C 8	The Team considers that the immediate actions by ENSI after the TEPCO Fukushima Dai-ichi accident were adequate and commensurate with the risk posed. ENSI required new assessments of the nuclear plants, including the spent fuel pools. The extent of the assessment was clearly defined and criteria must be met according to the guideline ENSI-A01. These assessments resulted in back-fit for one plant and additional measures for spent fuel pool have been required. Furthermore ENSI required prepared accident measures. Besides these actions ENSI also decided to participate in the EU stress tests. The Team concludes that ENSI has fully complied with what can be expected from a regulatory body.

AREA	NO.	CONCLUSION
7. INSPECTION	C 9	The Team considers the inspections performed by the regulatory body in response to the TEPCO Fukushima Dai-ichi accident were prompt and well-focused. Inspection process enables ENSI to conduct additional inspections if needed.
8. ENFORCEMENT	C 10	The Swiss regulatory body demonstrated the independent implementation of a graded enforcement policy in response to the TEPCO Fukushima Dai-ichi accident. The actions taken by ENSI seem to be timely and commensurate with the safety importance of the issues raised by the accident. The ENSI enforcement process is capable of dealing with the enforcement activities created in relation to the TEPCO Fukushima Dai-ichi accident without change.
9. REGULATIONS AND GUIDES	C 11	The Team noted the commitment of ENSI to include lessons learned from TEPCO Fukushima Dai-ichi accident in revision of Swiss nuclear safety regulations. The team considers this response as adequate in the area of regulation and guides.
10. EMERGENCY PREPAREDNESS AND RESPONSE	C 12	The Team concludes that ENSI responded promptly and properly to the urgent Emergency Preparedness and Response-related challenges in Switzerland due to the TEPCO Fukushima Dai-ichi accident and the longer term upgrading proposals of IDA NOMEX provide a sound basis for the improvement of the nuclear emergency preparedness capabilities of the country.

APPENDIX VII – ENSI REFERENCE MATERIAL USED FOR THE REVIEW

[1] IRRS Questions and Answers

- *Module 1: Responsibilities and Functions of the Government*
- *Module 2: Global Nuclear Safety Regime*
- *Module 3: Responsibilities and functions of the Regulatory Body*
- *Module 4: Management System of the Regulatory Body*
- *Module 5: Authorization*
- *Module 6: Review and Assessment*
- *Module 7: Inspection*
- *Module 8: Enforcement*
- *Module 9: Regulations and Guides*
- *Module 10: Emergency Preparedness and Response*
- *Module 11a: Occupational Radiation Protection*
- *Module 11b: Control of Radioactive Discharges and Materials for Clearance*
- *Module 11c: Environmental Monitoring*
- *Module 11d: Waste Management (policy and strategy, predisposal and disposal)*
- *Module 12: Interfaces with Nuclear Security*
- *Action Plan*

[2] Legislation

Nuclear Energy:

1. *Nuclear Energy Act (NEA,732.1)*
2. *Federal Act on the Swiss Federal Nuclear Safety Inspectorate (ENSIG,732.2)*
3. *Nuclear Energy Ordinance (NEO, 732.11)*
4. *Safeguards Ordinance (732.12)*
5. *Ordinance on Vessels and Piping classified as important to safety in Nuclear Installations (OVPN, 732.13)*
6. *Ordinance on the Swiss Federal Nuclear Safety Commission (NSC Ordinance, 732.16)*
7. *Ordinance on the Swiss Federal Nuclear Safety Inspectorate (ENSIV, 732.21)*
8. *Swiss Federal Nuclear Energy Liability Act (732.44)*
9. *DETEC Ordinance on the Threat Assumptions and Security Measures for Nuclear Installations and Nuclear Materials (732.112.1)*
10. *DETEC Ordinance on the Hazard Assumptions and the Assessment of the Protection against Accidents in Nuclear Installations (SR 732.112.2)*
11. *DETEC Ordinance on the Methodology and the General Conditions for Checking the Criteria for the Provisional Taking out of Service of Nuclear Power Plants (732.114.5)*
12. *Ordinance on the Requirements for the Personnel of Nuclear Installations (VAPK, 732.143.1)*
13. *Ordinance on the Security Guards of Nuclear Installations (VBWK, 732.143.2)*
14. *Ordinance on Personal Security Background Checks in the Area of Nuclear Installations (PSPVK, 732.143.3)*
15. *Personnel Rules of the Swiss Federal Nuclear Safety Inspectorate (ENSI Personnel Rules, 732.221)*
16. *Ordinance on Fees of the Swiss Federal Nuclear Safety Inspectorate(ENSI Fee Ordinance, 732.222)*

Radiation Protection:

1. *Radiological Protection Act (RPA, 814.50)*
2. *Radiological Protection Ordinance(RPO, 814.501)*

3. *Ordinance on Personal Dosimetry (Dosimetry Ordinance, 814.501.43)*
4. *Ordinance on the Handling of Unsealed Radioactive Sources (814.554)*

Emergency Preparedness:

1. *Ordinance on Alerting and Alarming (Alarming Ordinance, AV, 520.12)*
2. *Ordinance on the Organisation of Operations in Connection with NBC and Natural Events (NBCN Operations Ordinance, 520.17)*
3. *Ordinanceon Emergency Preparedness in the Vicinity of Nuclear Installations (732.33)*
4. *Ordinance on the Supply of the Population with Iodine Tablets (Iodine Tablets Ordinance, 814.52)*

Miscellaneous:

1. *Federal Constitution of the Swiss Confederation (101)*
2. *Federal Act on Freedom of Information in the Administration (Freedom of Information Act, FoIA, 152.3)*
3. *Ordinance on Freedom of Information in the Administration (Freedom of Information Ordinance, FoIO, 152.31)*
4. *Federal Act on Administrative Procedure(Administrative Procedure Act, APA, 172.021)*
5. *Federal Act on the Consultation Procedure(Consultation Procedure Act, CPA, 172.061)*
6. *Federal Act on the Protection of the Environment(Environmental Protection Act, EPA, 814.01)*

[3] ENSI

Guidelines:

1. *A01 Requirements for deterministic accident analysis for nuclear installations: Scope, methodology and boundary conditions of the technical accident analysis*
2. *A04 Application documents for modifications to nuclear installations requiring a permit*
3. *A05 Probabilistic Safety Analysis (PSA): Quality and Scope*
4. *A06 Probabilistic Safety Analysis (PSA): Applications*
5. *B01 Ageing management*
6. *B02 Periodical reporting for nuclear installations*
7. *B03 Reports for nuclear installations*
8. *B04 Clearance measurement of materials and areas from controlled zones*
9. *B05 Requirements for the conditioning of radioactive waste*
10. *B06 Vessels and piping classified as important to safety: Maintenance*
11. *B07 Vessels and piping classified as important to safety: Qualification of non-destructive testing*
12. *B09 Collecting and reporting of doses of persons exposed to radiation*
13. *B10 Initial training, recurrent training and continuing education of personnel*
14. *B11 Emergency exercises*
15. *B12 Emergency preparedness in nuclear installations*
16. *B13 Training and continuing education of the radiation protection personnel*
17. *B14 Maintenance of electrical and instrumentation and control equipment classified as important to safety*
18. *G01 Safety classification for existing nuclear power plants*
19. *G03 Specific design principles for deep geological repositories and re-quirements for the safety case*
20. *G04 Design and operation of storage facilities for radioactive waste and spent fuel assemblies*
21. *G05 Transport and storage casks for interim storage*
22. *G07 Organisation of nuclear Installations*
23. *G11 Vessels and piping classified as important to safety: Engineering, manufacture and installation*
24. *G13 Radiation protection measuring devices in nuclear installations: Concepts, requirements and testing*
25. *G14 Calculation of radiation exposure in the vicinity due to emission of radioactive substances from*

nuclear installations

26. *G15 Radiation protection objectives for nuclear installations*
27. *R-07 Guideline for the radiological monitored area of the nuclear installa-tions and the Paul Scherrer Institute*
28. *R-46 Requirements for the application of computer-based instrumentation and control important to safety in nuclear power plants*
29. *R-48 Periodic safety review of nuclear power plants*
30. *R-50 Requirements important to safety for fire protection in nuclear installations*
31. *R-101 Design criteria for safety systems of nuclear power plants with light-water reactors*

Processes:

MANAGEMENT PROCESSES:

1. *HPB0000 Introduction*
2. *HPB0020 Management*
3. *Performance Mandate 2009 - 2011*
4. *Organizational Bylaws*
5. *HPB0040 Finance and Controlling*
6. *HPB0060 Human Resources*
7. *AAU1090 Personnel Development Concept*
8. *AAU1600 ENSI Staff Executive Regulations*
9. *HPB0070 Risk Management*
10. *HPB0080 Improvement*
11. *HPB0100 Topical Issue and Project Management*
12. *AAU1606 Priorities and level of processing*

ASSESSMENT OF FACILITIES:

1. *HPB0140 Regulatory Basis*
2. *AAU1192 Specification: Guidelines*
3. *SPB0142 Guidelines*
4. *SPB0143 Designation of new principles*
5. HPB0160 Expert Reports
6. HPB0180 Permits

SURVEILLANCE OF OPERATIONS:

1. *HPB0220 Emergency Preparedness*
2. *HPB0260 Inspection and Licensing*
3. *HPB0280 Occurrence Processing*
4. *HPB0320 Planned Maintenance Outage*
5. *HPB0340 Enforcement*
6. *HPB0350 Systematic Safety Evaluation*
7. *HPB0360 Radiation Measurements*
8. *HPB0380 Remote Monitoring & Forecasting*

SUPPORTING PROCESSES:

1. *HPB0400 System Management*
2. *HPB0420 Information Technology*
3. *HPB0430 Environmental Management*
4. *HPB0440 Health and Safety*
5. *HPB0460 Purchasing*
6. *HPB0480 Administration and Archiving*

7. *HPB0490 Infrastructure and Operations*

[4] Reports

International Conventions:

1. *Convention on Nuclear Safety, Fifth Swiss Report, 2010*
2. *Joint Convention, Third Swiss Report, 2008*
3. *Joint Convention, Fourth Swiss Report, 2011*

ENSI-Reports and Concepts:

1. *Business Plan HSK (ENSI)*
2. *Report on Integrated Oversight*
3. *Report on Oversight on the Safety Culture in Nuclear Facilities*
4. *Report on the Use of the PSA in the Integrated Regulatory Safety Oversight*
5. *Communication Concept*
6. *Crisis Communication Concept*
7. *Decommissioning of Nuclear Facilities*

IRRT Mission to Switzerland:

1. *IRRT Report 1998*
2. *IRRT Report 2003 (Follow-up Mission)*

Miscellaneous:

1. *Report by the Federal Council on outsourcing and management of Confederation tasks (the corporate governance report)*
2. *Sectoral Plan for Deep Geological Repositories (Conceptual Part)*
3. *The Swiss Confederation a Brief Guide 2011*

Policy Issue 1: Fukushima Regulatory Issues

ENSI REPORTS:

1. *Fukushima Event Sequences*
2. *Fukushima Analysis*
3. *Fukushima Lessons*

FUKUSHIMA AREAS OF ATTENTION:

1. *Policy Issue (report modules 1-10)*
2. *Areas of Attention (modules 5-9)*

Policy Issue 2: Long Term Operation

1. *Basis for discussion (document)*

Policy Issue 3: Interfaces with Other Authorities

1. -

Policy Issue 4: Openness, Transparency and Stakeholders Involvement (incl. public communication)

1. *Basis for discussion (document)*

APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	**IAEA SAFETY STANDARDS SERIES No. SF-1 -** Fundamental Safety Principles
2.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 1 -** Governmental, Legal and Regulatory Framework for Safety
3.	**IAEA SAFETY STANDARDS SERIES No. GS-R-2 -** Preparedness and Response for a Nuclear or Radiological Emergency
4.	**IAEA SAFETY STANDARDS SERIES No. GS-R-3 -** The Management System for Facilities and Activities
5.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 4 -** Safety Assessment for Facilities and Activities
6.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 5 -** Predisposal Management of Radioactive Waste
7.	**IAEA SAFETY STANDARDS SERIES No. GS-R-1 -** Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety
8.	**IAEA SAFETY STANDARDS SERIES No. GS-R-2 -** Preparedness and Response for a Nuclear or Radiological Emergency
9.	**IAEA SAFETY STANDARDS SERIES No. GS-R-3 -** The Management System for Facilities and Activities
10.	**IAEA SAFETY STANDARDS SERIES No. SSR 2/1 -** Safety of Nuclear Power Plants: Design
11.	**IAEA SAFETY STANDARDS SERIES No. SSR 2/2 -** Safety of Nuclear Power Plants: Commissioning and Operation
12.	**IAEA SAFETY STANDARDS SERIES No. NS-R-4 -** Safety of Research Reactors
13.	**IAEA SAFETY STANDARDS SERIES No. TS-R-1 -** Regulations for the Safe Transport of Radioactive Material
14.	**IAEA SAFETY STANDARDS SERIES No. WS-R-3 –** Remediation of Areas Contaminated by Past Activities and Accidents
15.	**IAEA SAFETY STANDARDS SERIES No. WS-R-5 –** Decommissioning of Facilities Using Radioactive Material
16.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.1 -** Organization and Staffing of the Regulatory Body for Nuclear Facilities
17.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.2 -** Review and Assessment of Nuclear Facilities by the Regulatory Body
18.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.3 -** Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body

19. **IAEA SAFETY STANDARDS SERIES No. GS-G-1.4 -** Documentation for Use in Regulatory Nuclear Facilities

20. **IAEA SAFETY STANDARDS SERIES No. GS-G-2.1 -** Arrangements for Preparedness for a Nuclear or Radiological Emergency

21. **IAEA SAFETY STANDARDS SERIES No. GS-G-3.1 -** Application of the Management System for Facilities and Activities

22. **IAEA SAFETY STANDARDS SERIES No. GS-G-3.2 -** The Management System for Technical Services in Radiation Safety

23. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.3 -** Assessment of Occupational Exposure Due to External Sources of Radiation

24. **IAEA SAFETY STANDARDS SERIES No. RS-G-1.4 -** Building Competence in Radiation Protection and the Safe Use of Radiation Sources

25. **IAEA SAFETY STANDARDS SERIES No. NS-G-2.10 -** Periodic Safety Review of Nuclear Power Plants Safety Guide

26. **IAEA SAFETY STANDARDS SERIES No. NS-G-211 -** A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide

27. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).

28. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Generic Assessment Procedures for Determining Protective Actions during a Reactor Accident, IAEA-TECDOC-955, IAEA, Vienna (1997).

APPENDIX IX – ORGANIZATIONAL CHART

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