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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

FINLAND

Helsinki, Finland

15 to 26 October 2012

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
REPORT TO
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Mission date:	*15 to 26 October 2012*
Regulatory body:	*Finnish Radiation and Nuclear Safety Authority (STUK)*
Location:	*Helsinki, Finland*
Regulated facilities and activities in the scope:	*Nuclear Power Plants, Waste Management Facilities, Industrial and Medical Facilities.*
Organized by:	*International Atomic Energy Agency (IAEA)*

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IAEA-2012

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.

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EXECUTIVE SUMMARY

At the request of the Government of Finland, an international team of senior safety experts met representatives of the Radiation and Nuclear Safety Authority of Finland (STUK) from 15 to 26 October 2012 to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place at STUK Headquarters in Helsinki. The purpose of the peer review was to review the Finnish regulatory framework for nuclear and radiation safety. As recommended by the IAEA Nuclear Safety Action Plan, special attention was given to regulatory implications in the Finnish framework for safety of the lessons learned from the TEPCO-Fukushima Dai-ichi nuclear power plant accident.

The review compared the Finnish 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 Finnish counterparts in the areas covered by the IRRS.

The IRRS review team consisted of 18 senior regulatory experts from 17 IAEA Member States, five IAEA staff members and one IAEA administrative assistant. The IRRS review team carried out the review in the following areas: responsibilities and functions of the Government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, public and environmental exposure control, transport, waste management and decommissioning, as well as lessons learned from the TEPCO-Fukushima Dai-ichi accident.

In addition, policy issues were discussed, including: uranium mining and milling, NORM and associated waste; interface between nuclear safety and nuclear security; and the possible conflicts of interest in the advisory bodies concerned with STUK.

The IRRS review addressed all facilities and activities regulated by STUK, with the exception of the research reactor FiR 1, which STUK decided to exclude because the operator has made a decision to shut down the operation of the reactor.

The mission included observations of regulatory activities and interviews and discussions with STUK staff, representatives from the Ministry of Employment and the Economy, the Ministry of Social Affairs and Health, the Ministry of the Interior and other organizations to help assess the effectiveness of the regulatory system. Visits were also performed to: Olkiluoto nuclear power plant, Porvoo Energy thermal power station, Posiva Onkalo, Loviisa nuclear power plant and Turku University Hospital. The IRRS team members observed the working practices during inspections carried out by STUK, including discussions with the licensee personnel and management. In addition the IRRS team observed a STUK emergency exercise, which involved several organizations (NPP, Regional Rescue Department, National Meteorological Institute and STUK's Emergency Response Centre).

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

The IRRS review team made the following general observations:

- The Finnish regulatory system is comprehensive and allows STUK to operate in practice as an independent regulatory body;

- STUK benefits from a committed, technically competent and well-motivated staff;
- STUK has several areas of excellence such as safety assessment of nuclear power plants and spent fuel repositories, as well as regulatory oversight in the area of medical exposures;
- STUK is an open organization, sharing experience and views at the national and international levels;
- STUK is perceived as a credible regulatory body by stakeholders.

The actions taken by STUK immediately after the TEPCO Fukushima Dai-ichi accident were timely and effective in requesting the licensees to summarize the prompt and longer term actions related to the safety of the power plants. The assessments have not identified any safety issue that would necessitate short term actions. Nevertheless a number of safety enhancements have been initiated while others are still under investigation. It was exemplary how STUK took the responsibility of providing adequate, professional and effective information to all interested parties.

In response to Finland's nuclear programme, STUK faces challenges over the next several years, which include regulatory oversight of:

- Existing facilities and activities;
- Construction of a new nuclear power plant and consideration of its operating licence;
- Construction licence applications for two future nuclear power plants;
- Construction licence application for the spent fuel waste repository; and

Necessary human resources and competences in STUK will have to be developed and secured, with sustained governmental support.

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

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

- STUK's excellent record of active contribution to the global improvement of radiation and nuclear safety through its participation in relevant international activities and its commitment to continue these activities in the future;
- The long standing political commitment to plan a geological repository, the associated regulatory process and the actual implementation of this plan at the Onkalo facility;
- STUK's effective safety assessment of new nuclear power plants, including the independent regulatory verification of novel design solutions using analytical tools, experimental results and relevant research outcomes;
- The organization and conduct of emergency exercises by STUK, as well as the coordination with stakeholders, supported by outstanding tools and programmes of the STUK emergency centre; and
- STUK's training of inspectors for medical exposures and STUK's role in quality assurance in radiation therapy and diagnostic radiology.

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:

- Although STUK operates, in practice, as an independent regulatory body, the Government should strengthen the legislative framework by embedding, in law, STUK as a body separated from other entities having responsibilities or interests that could unduly influence its decision-making;
- Recognizing that Finland has successfully implemented many strategic decisions related to radioactive waste management, in particular the disposal options for low and intermediate level waste and spent fuel, the Government should incorporate these and strategies for other radioactive waste into a comprehensive radioactive waste policy and strategy;
- STUK should further enhance the effectiveness of its inspection activities by developing a formal qualification programme for inspectors, making more use of and clarifying the processes for unannounced and reactive inspections, and extending the use of the graded approach for planning and conducting inspections across all regulated facilities and activities; and
- STUK should withdraw from the current practice of conducting the environmental radiation monitoring programmes in the vicinity of the nuclear facilities based on commercial contracts with the licensees. Furthermore, STUK should implement an independent monitoring programme for the environment, to verify the results of the off-site environmental monitoring programmes submitted by the licensees.

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

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

I. INTRODUCTION

At the request of the Government of Finland, an international team of senior safety experts met representatives of the Radiation and Nuclear Safety Authority of Finland (STUK) from 15 to 26 October 2012 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the peer review was to review the Finnish regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Finland in October 2010. A preparatory mission was conducted 28 to 29 February 2012 at STUK Headquarters in Helsinki to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the facilities regulated by STUK and selected safety aspects.

The IRRS review team consisted of 18 senior regulatory experts from 17 IAEA Member States, five IAEA staff members and one IAEA administrative assistant. The IRRS review team carried out the review in the following areas: responsibilities and functions of the Government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, public and environmental exposure control, transport, waste management and decommissioning. As recommended by the IAEA Nuclear Safety Action Plan, special attention was given to regulatory implications in the Finnish framework for safety of the TEPCO-Fukushima Dai-ichi accident.

In addition, policy issues were discussed, including: uranium mining and milling, NORM and associated waste; interface between nuclear safety and nuclear security; and possible conflicts of interest in the advisory bodies concerned with STUK.

STUK conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of STUK's self-assessment and supporting documentation were provided to the team as advance reference material for the mission. During the mission the IRRS review team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and staff from STUK and performed direct observation of STUK working practices during inspections. Meetings with the Ministry of Employment and the Economy, the Ministry of Social Affairs and Health, the Ministry of the Interior, the Advisory Commission on Nuclear Safety and STUK's Advisory Commission were also organized.

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of the Finnish radiation and nuclear safety regulatory framework and activities to review its effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities regulated by STUK with the exception of the research reactor. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS mission will facilitate regulatory improvements in Finland and other Member States from the knowledge gained and experiences shared STUK and IRRS reviewers and through the evaluation of the effectiveness of the Finnish regulatory framework for nuclear safety and its good practices.

The key objectives of this mission were to enhance nuclear and radiation safety, as well as emergency preparedness and response:

- Providing Finland and STUK, through completion of the IRRS questionnaire, with an opportunity for self-assessment of its activities against IAEA safety standards;
- Providing Finland and STUK with a review of its regulatory programme and policy issues relating to nuclear and radiation safety, and emergency preparedness;
- Providing Finland and STUK with an objective evaluation of its nuclear and radiation safety, as well as emergency preparedness and response regulatory activities with respect to IAEA 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 fields;
- Providing key STUK staff with an opportunity to discuss their practices with reviewers who have experience with different practices in the same field;
- Providing Finland and STUK with recommendations and suggestions for improvement; and
- Providing other States with information regarding good practices identified in the course of the review.

II. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Finland, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 28to 29 February 2012. The preparatory meeting was carried out by the appointed Team Leader Mr Philippe Jamet, Deputy Team Leader Mr John Loy and the IRRS IAEA team representatives, Ms Adriana Nicic, Mr Ahmad Al Khatibeh, Mr Hilaire Mansoux and Mr Peter Zombori.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of STUK represented by Mr Tero Varjoranta, STUK Director General, other senior management and staff. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS mission:

- Nuclear power plants;
- Fuel cycle facilities;
- Waste facilities;
- Radiation sources facilities;
- Decommissioning;
- Transport;
- Patient protection;
- Occupational radiation protection;
- Public and environmental exposure control;
- Waste management (policy and strategy, predisposal and disposal);
- Regulatory implications of the TEPCO Fukushima Dai-ichi accident; and
- Selected policy issues.

At the time of the preparatory meeting, it was discussed that the research reactor FiR 1 may be included in the scope of the review, but STUK informed IAEA that a decision related to the end of its operation might be taken in the course of the year. The decision to stop the operation of Fir 1 was taken by the operator in the summer of 2012, and as a consequence, STUK decided not to include it in the scope of the IRRS mission. As a result, and according to the IRRS Guidelines, the IRRS mission to Finland is therefore a limited scope mission.

Mr Varjoranta made presentations on the national context, the current status of STUK and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Finland in October 2012.

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 tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The STUK Liaison Officer for the preparatory meeting and the IRRS mission was Mr Hannu Koponen.

STUK provided the IAEA (and the review team) with the advance reference material for the review at the end of August 2012, including the self-assessment results. In preparation for the mission, the IAEA review team members conducted a review of the advance reference material and provided their initial review comments to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCE FOR THE REVIEW

The most relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources were used as review criteria. A more complete list of IAEA publications used as 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, 14 October 2012, in Helsinki 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. They also presented the agenda for the mission.

In addition, the IAEA Team Coordinator and Review Area Facilitator presented the expectations regarding the module on the "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 logistical arrangements planned for the mission.

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

The IRRS entrance meeting was held on Monday, 15th October 2012, with the participation of STUK senior management and staff. Opening remarks were made by Mr Varjoranta, Director General of STUK, Mr Herkko Plit, Deputy Director General from the Ministry of Employment and Economy, Mr Jari Keinanen, Director from the Ministry of Social Affairs and Health, Mr Philippe Jamet, IRRS Team Leader and Ms Adriana Nicic, IRRS Team Coordinator. Mr Varjoranta gave an overview of the Finnish context, STUK activities and the action plan prepared as a result of the self-assessment.

During the mission, a review was conducted for all the review areas with the objective of providing Finland and STUK with recommendations and suggestions for improvement 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 26th October 2012. The opening remarks at the exit meeting were presented by Mr Tero Varjoranta and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Philippe Jamet. Closing remarks were made by Ms Adriana Nicic on behalf of Mr Jim Lyons, IAEA, Director, Division of Nuclear Installation Safety.

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

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

In Finland the policies and strategies for nuclear safety and radiation safety are mainly expressed through legislation. The Finnish Constitution stipulates how and by whom the acts and decrees, as well as delegation of legislative powers, can be issued. The relevant pieces of legislation in these fields are the Nuclear Energy Act and the Radiation Act.

The Nuclear Energy Act states that the use of nuclear energy shall be in line with the overall good of society, and in particular shall ensure that the use of nuclear energy is safe for man and the environment and does not promote the proliferation of nuclear weapons. Basic safety principles are also set out, for example that safety should be as high as reasonably achievable (SAHARA). The Act also lays down general principles for the use of nuclear energy, the implementation of nuclear waste management, the licensing and control of the use of nuclear energy, and those for the competent authorities.

The Radiation Act states that its fundamental legal purpose is to prevent and limit health hazards and other detrimental effects of radiation. The Act covers the use of radiation and other practices that involve or may involve exposure to radiation hazardous to human health. Basic safety principles are also provided, such as justification, optimisation and limitation. The Act lays down the general principles for the use of radiation and other practices, including the licensing processes and regulatory functions.

The graded approach commensurate with the radiation risks associated with the facilities and activities is reflected in the radiation and nuclear energy legislation. However STUK has stated that the principle of the graded approach is not explicitly expressed and will be included in revisions of the two Acts.

Nevertheless, there are differences in the licensing processes for different facilities based on the graded approach. For example, according to the Nuclear Energy Act, the construction of a nuclear facility, "of considerable general significance", requires a governmental Decision-in-Principle. Furthermore all nuclear facilities require both construction and operating licences. The graded approach is also taken in to account specifically in STUK regulatory guides (see Section 9).

The IRRS team is satisfied that Finland has a clear national policy and strategy for safety and that it meets the Requirements of GSR Part 1 Requirement 1. The fact that this policy and strategy is set out at the level of law demonstrates Finland's long-term commitment to the fundamental safety principles.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

As described earlier, current nuclear energy legislation is based on the Nuclear Energy Act and radiation safety is based on the Radiation Act. The Nuclear Energy Act clearly sets out those facilities and activities that are covered. The Radiation Act applies to ionizing and non-ionizing radiation and covers radiation appliances and radioactive materials, radioactive waste, radiation practices and radiation work. (However, STUK's Action Plan has identified that this Act does not specify sources and circumstances that are out of scope.) These Acts are supported by Government decrees that include legally binding regulations. The Acts also clearly identify that the legal responsibility for safety lies with the operator.

STUK is the independent governmental organization for the regulatory control of the use of radiation and nuclear energy, and is described in the next section. It is the body that undertakes review and assessment, inspection, preparation of regulations and guides, and enforcement. It is responsible for regulating both safety and security matters.

The Ministry of Employment and the Economy (MEE) in law has overall authority in the field of nuclear energy. It is responsible for the legislation in the nuclear energy field, and also prepares licensing decisions for the Government.

The authorisation process for a nuclear facility includes the following phases: Decision-in-Principle, Construction licence, and Operating licence. These are granted by the Government (Cabinet of Ministers). However, a safety review by STUK is needed before the Decision-in-Principle is given and the Construction and Operating licences are granted.

The Decision-in-Principle is mainly a political one, where the Government decides whether the project is in line with the overall good of society. The local municipality has a veto and the Parliament has the choice of ratifying or not the Government's decision. Nevertheless this is also the first stage of STUK's appraisal of safety. The Environmental Impact assessment is also required at this stage. But the more detailed steps from a regulatory point of view are the issuing of the Construction and Operating licences.

The Ministry of Social Affairs and Health (MSAH) in law has overall authority in the field of the use of radiation and other radiation practices. It has responsibility for the legislation in the radiation safety area. However, under this Act it is for STUK to issue licences.

The Ministry of the Interior is the overall authority in the areas of rescue services and security. It also sets the requirements by decree for off-site plans and activities in radiation emergencies.

The law also clearly stipulates that the licensee whose operations generate or have generated nuclear waste shall be responsible for all nuclear waste measures and their appropriate preparation, as well as their costs. MEE oversees the Nuclear Waste Management Fund to ensure this is the case.

This IRRS team believes that the Government has established a clear framework for safety and satisfies GSR Part 1 Requirement 2. Particular matters relating to this framework and associated conclusions are given in subsequent sections below.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

STUK is the independent governmental organization for the regulatory control of the use of radiation and nuclear energy. Its responsibilities are clearly set down in law and decrees and are listed in Section 3.1 of the report.

STUK is administratively under the Ministry of Social Affairs and Health. The Ministry agrees the overall strategic direction of STUK's activities and administers the governmental budget. As described earlier this Ministry has overall authority in the field of radiation safety. During discussions with the IRRS team both the Ministry and STUK emphasised that the regulatory control of the safe use of radiation and nuclear energy is independently carried out by STUK. The IRRS team found no evidence to suggest otherwise.

STUK's overall resources are obtained through three sources:

a) Direct State Funding

b) Charges on the licensees

c) Services

In the nuclear energy field, about 90% of the cost of STUK's resources is recovered directly through charges to the licensees. These resources cover STUK's direct regulatory activities. The other 10% is used for activities such as international cooperation. The Ministry for Social Affairs and Health has an interest in ensuring this is managed responsibly, but the team found no evidence that STUK would be unable to

obtain sufficient resources through this route to undertake its direct regulatory activities. The IRRS team was therefore satisfied that this source of funding was secure.

In the radiation safety field about 60% of the resources is obtained through charges to the licensees, which also cover STUK's direct regulatory activities. Similarly the team found no evidence that STUK would be unable to obtain sufficient resources through this route to undertake its direct regulatory activities.

However, unsurprisingly in the current global financial climate, the State Funding budget is under pressure. Across Finland, public sector funding is facing budget reductions of the order of 2-5% per annum. STUK's budget is not immune from this. Therefore, the remaining 40% of state funding under radiation safety, and approximately 90% state funding of the research and other related activities, will be affected. The IRRS team recognised that there would be some challenges for STUK arising from these reductions. However, in the limited time available, the team found no evidence to suggest that, apart from the particular areas relating to environmental monitoring (see section 1.8), these reductions would undermine STUK's ability to discharge properly its assigned responsibilities.

As described in Section 1.2 above, in accordance with national legislation, construction and operating licences under the Nuclear Energy Act are granted by the Government following a decision by the Cabinet of Ministers. MEE prepares the text of the licence, including conditions, based on the opinions of different governmental authorities, including those of STUK.

IAEA Requirements allow for authorisations to be granted by the regulatory body or another governmental body. The IRRS team noted that the licences in Finland are granted by the Government, rather than the Ministry (namely MEE) that has overall authority for the nuclear energy field. However the team did note that MEE prepares the licence for the governmental decision. The IRRS team in particular examined the role and authority of STUK in defining conditions relevant to safety in this licensing process. It found that the current practice of the licensing process in Finland is in practice (de facto) in line with IAEA requirements and guidance. But the team considers that in law (de jure) the role of the nuclear safety regulator in the process is not secured completely and unambiguously. In discussions with the IRRS team this was accepted by MEE.

The IRRS team also examined whether there were any other areas where STUK's role "de jure" was not secure. As discussed later in section 9.1 of the report, the team similarly identified that the specification of legally binding regulations is "de facto" in line with IAEA guidance, but not "de jure".

The team believes that in order to ensure the independence of the regulatory body is clear and transparent, the Government should strengthen the legislative framework by embedding, in law, STUK as a regulatory body separated from entities having responsibilities or interests that could unduly influence its decision making.

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 … to fulfil its statutory obligations for the regulatory control of facilities and activities."*
(2)	**BASIS: GSR Part 1 Requirement 4 states that** *"The Government shall ensure that the regulatory body is effectively independent it its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R1	**Recommendation: The Government should embed, in law, STUK as an independent regulatory body separated from other entities having responsibilities or interests that could unduly influence its decision making.**

The IRRS team recognises that this recommendation may take some time to implement. Therefore, in the meantime, it believes that some first steps are needed to rectify the matters identified above. The team understands that the detailed content of the Nuclear Energy Act is currently under review. It would therefore be timely to take the opportunity to address them in the forthcoming revision.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirements 23 states** *"Authorisation by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite .."* **and 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."*
R2	**Recommendation: The Government should seek to modify the Nuclear Energy Act so that the law clearly and unambiguously stipulates STUK's legal authorities in the authorisation process for safety. In particular, the changes should ensure that STUK has the legal authority to both:** **- specify any licence conditions necessary for safety; and** **- specify all regulations necessary for safety.**

The IRRS team identified that the Ministry of Employment and the Economy, which is responsible for energy policy, takes an active interest in the nuclear energy regulatory system. The team recognises that the Government has a duty to ensure that Finland has an effective regulatory body that is accountable to Finnish Society on Nuclear and Radiation Safety. However, the team noted that it is vital that ways of ensuring that accountability should not unintentionally undermine the independence of the regulatory body.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 4 Para 2.8 states that** *"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 from Government departments and governmental bodies on matters relating to the safety of facilities and activities."*
S1	**Suggestion: The relevant Ministries and STUK should develop Memoranda of Understanding for implementing their roles, responsibilities and cooperation with a view to ensuring that STUK is accountable while clearly maintaining its regulatory independence.**

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

Both the Nuclear Energy Act and the Radiation Act clearly set out the legal responsibilities for safety. The Acts stipulate that a licence is required for all facilities and activities governed by the Acts. The licensee has the prime responsibility for safety; that its responsibility covers all stages in the lifetime of the facility or activity; and its responsibility cannot be delegated or transferred without the approval of STUK, and in some cases, also the Ministry of Employment and the Economy.

The IRRS team is satisfied that from its assessment of the Advance Reference Material, and through the team's examination of relevant parts of legislation, that the Government has assured full compliance with relevant IAEA Requirements.

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

As described earlier, STUK is responsible for the regulatory control of safe use of nuclear energy. In addition, STUK is responsible for attending to the regulatory control of physical protection and emergency planning, and for the necessary control of the use of nuclear energy to prevent proliferation of nuclear weapons.

However, there are a significant number of other regulatory authorities that have responsibilities regarding the use of nuclear energy and radiation, some national and some at the municipal level. STUK listed many of these in its Advance Reference Material and in its Action Plan it has identified that it should produce a report setting out the responsibilities and functions of these authorities. Based on this work STUK will consider whether there need to be written agreements with some of them. The IRRS team welcomes this but also believes that STUK should further consider how to better coordinate its activities with these bodies.

The team therefore believes that STUK should identify the responsibilities and functions of all relevant governmental authorities that regulate practices other than nuclear or radiation safety, and develop appropriate working arrangements with them. In particular, coordination of some common activities, such as inspections, could help avoid conflicting requirements being placed on the authorised parties.

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

The Nuclear Energy Act mandates that nuclear waste generated in Finland shall be handled, stored and permanently disposed of in Finland. The principles of the nuclear waste management were originally set in the Finnish Government's policy decision of 1983 and later in the decisions by the Ministry of Employment and the Economy. These decisions set a long-term schedule for the implementation of nuclear waste management including a spent fuel disposal facility.

According to the Nuclear Energy Act licensees generating nuclear waste are responsible for all nuclear waste management measures including spent fuel, which in Finland is considered as nuclear waste. In this respect, it was noted that while Finland had previously considered reprocessing of spent fuel the current Government policy is that spent fuel will be directly disposed in a repository (open fuel cycle).

The Nuclear Energy Act addresses financial provision for nuclear waste management. Funds for future waste management and decommissioning are collected to ensure that assets are available even in case of insolvency of the licensee.

The Radiation Act provides that the organization engaged in radiation practice is required to take any measures to render harmless radioactive wastes arising from its operation. Rendering radioactive waste

harmless means any measures needed to treat, isolate or dispose of the waste, or to restrict its use so that it does not endanger human health or the environment. The State has the secondary responsibility in case that a producer of radioactive waste is incapable of fulfilling its management obligation (Radiation Act, Section 51).

An inventory of nuclear waste is updated every year by utilities while STUK holds a data base for all the nuclear waste produced in the country. A national inventory of radioactive sources is also realized. Unused radioactive sources from industrial and medical use are either returned to the manufacture or delivered to a recognized installation handling radioactive waste. Waste is stored in a long-term storage situated at Olkiluoto NPP site. A private company has been approved by STUK to collect unused radioactive sources and transport them to Olkiluoto where they are stored by STUK on behalf of the Government before final disposal.

Finland has identified and implemented management routes for the nuclear waste and the essential part of the radioactive waste produced in the country, according to their categories:

- Cleared waste: waste can be cleared according to levels that are set by STUK (cf. YVL 8.2). The regulations provide for both conditional and unconditional clearance.
- Low and intermediate level waste (LILW): The main stream is produced during operation and maintenance of NPP's. The waste is segregated into two streams (low level and intermediate level). In both Loviisa and Olkiluoto, the low level waste is compacted or cut (metal pieces). The intermediate level waste (mostly resins) is however conditioned differently depending on the utility: at Olkiluoto the intermediate level waste is immobilized/solidified using a bituminization process; at Loviisa the planned immobilization process will involve cementation. At present the cementation plant is in process of being commissioned.
- Institutional radioactive waste: At present radiation sources that are not returned to the supplier are collected and stored by STUK on behalf of the Government. The disposal route for these wastes has not been finalised.
- Spent Fuel: The planned waste management for spent fuel involves –
    - In pool interim storage at the reactor site for a period of approximately 40 years to allow cooling.
    - Thereafter the fuel elements will be encapsulated in cast-iron/copper canisters prior to being emplaced in a repository.
    - The repository concept entails geological disposal at depth of approximately 400m in crystalline bedrock.
    - The spent fuel from the current Loviisa reactors and Olkiluoto reactors (current plus planned future reactors for which a decision in principle for disposal of spent nuclear fuel has been issued) will all be disposed in the repository at Onkalo. While it has been agreed that spent fuel from other planned reactors (Fennovoima operations) will be disposed in geological repositories the plans and sites for such repositories are at present not finalized.
- NORM wastes:

  While there have been past practices of uranium mining in the country there is currently no active mining of uranium. It is however noted that there are some plans for future uranium extraction activities. Some such activities may be co-located at existing mines that exploit copper, gold, nickel, lead, etc. In line with this STUK has recognized the need to review and update the existing regulation on mining activities and associated waste management. In doing so STUK needs to

ensure that there is consistent and clear regulation in stances where the uranium is exploited as well as in instance where the uranium may be associated with the waste arising but not exploited for its radioactive properties.

The national arrangements for management of nuclear waste are well advanced and Finland has established pragmatic cradle to grave solutions for safe management of all nuclear waste arising from the authorized NPPs. Finland is recognised as being a world leader in establishment of a geological repository for spent fuel disposal. The repository preparation started more than 30 years ago and the repository is expected to be ready for waste disposal around 2020. A decision in principle for the repository was initially issued in 2000 and has been updated in 2002 and again in 2010. The construction licence application is planned to be submitted, by Posiva OY, to the Government at the end of 2012.

The remarkable stability of the process must be underlined as well as the fact that Finland is commended for the advanced preparations for management of spent fuel from the Olkiluoto and Loviisa NPPs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: SF-1 Para 3.9 states that** *"Government authorities have to ensure that arrangements are made for preparing programmes of actions to reduce radiation risks, including actions in emergencies, for monitoring releases of radioactive substances to the environment and for disposing of radioactive waste. Government authorities have to provide for control over sources of radiation for which no other organization has responsibility, such as some natural sources, 'orphan sources' and radioactive residues from some past facilities and activities."*
GP1	**Good Practice: In Finland the political commitment to implement a geological repository and the regulatory process for implementing the geological disposal is well defined and has been in place for a long period of time (since 1983).**

In addition, a plan for the management of the radioactive waste is required to be submitted to MEE every three years. This plan, assembled by Posiva OY on behalf of the utilities (Loviisa and Olkiluoto), gives a precise description of the waste management practices to be implemented during the next three years of operation of the plants and provides a 6 year perspective. STUK reviews this plan and prepares statement of adequacy to MEE.

The waste management policy in Finland has therefore allowed management of the essential amount of waste produced in Finland, the exception being a few high-activity disused spent sealed sources, the institutional waste that could not be returned to the supplier and representing a small quantity of waste.

However, Finland has recognised that in terms of legal obligations related to the EU Directive 2011/70 Euratom, a national programme for the management of all kinds of waste is mandated and that currently "no specific comprehensive policy and strategy exists".

Establishment of a national programme for radioactive and nuclear waste management would facilitate:

- a consolidation and coverage of all waste streams in Finland including management of
    - future spent fuel not currently planned to be disposed at Onkalo,
    - NORM wastes and
    - disused and spent sealed sources.

- Foster exchange between waste generators to identify best practices in terms of safety and waste minimisations and the visibility and communication of strategies for all waste management in Finland and public confidence in relation to the subject of radioactive waste management

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 5 Requirement 2 Para 3.5 states that** *"National policy and strategy on radioactive waste management states that "To ensure the effective management and control of radioactive waste, the Government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State, shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles [2] and with international instruments, conventions and codes that have been ratified by the State. The national policy 9 and strategy shall form the basis for decision making with respect to the management of radioactive waste."*
R3	**Recommendation: Recognising that Finland has successfully implemented many strategic decisions related to radioactive waste management, in particular the disposal options for low and intermediate level waste and spent fuel, the Government should incorporate these and strategies for other radioactive waste into a comprehensive policy and strategy.**

1.7. COMPETENCE FOR SAFETY

Recognising the importance of having a high level of competence and a robust safety culture in Finland, MEE set up a wide-ranging committee of all interested parties in Finland, including operators, educational and research institutes, and the regulator, to examine the long term competence needs of the nuclear energy sector, including those for nuclear safety. This Committee published a report in May 2012. MEE recognises that this is just the start of a process to secure this long term competence. Nevertheless, the IRRS team believes that this initial work is commendable and recognised it as a good practice. The IRRS team encourages the Government to continue to progress the actions arising from this report to ensure that the country has a comprehensive and sustainable high national competence at all levels.

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"*
GP2	**Good Practice: The Government report on Nuclear Energy Competence in Finland is commendable and the IRRS team encourages the Government to continue to progress the actions arising from this work.**

Within this overall framework it is vital that STUK has sufficient number of competent staff to deliver its regulatory functions. This is addressed in Section 3.3 of the report.

1.8. PROVISION OF TECHNICAL SERVICES

Under GSR Part 1 Requirement 13 the Government shall make provision, where necessary, for technical services in relation to safety. For example, STUK is responsible under law for environmental surveillance of radiation in Finland and of undertaking the necessary measurements. To undertake this responsibility STUK needs to obtain and maintain appropriate equipment. The IRRS team found evidence to suggest that the existing equipment may not be of the appropriate standard, and may need upgrading in future years, to fully meet its responsibilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 13 states that** *"The Government shall make provision, where necessary, for technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment".*
(2)	**BASIS: GSR Part 1 Requirement 8 states that** *"The Government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency".*
R4	**Recommendation: The Government should ensure that STUK has sufficient resources to fulfil the responsibilities placed on it by the Government to provide technical services.**

1.9. INTERFACE OF SAFETY WITH NUCLEAR SECURITY

This section reports on an area that STUK identified would benefit from a policy discussion with the IRRS team. The discussion session was attended by STUK management and staff members, and seven members of the IRRS team.

A STUK senior manager presented a policy paper produced in preparation for the IRRS mission. This was followed by a discussion that gave team members the opportunity to present some of their national experiences and raise related challenges.

The team was informed of the latest development of STUK framework related to security, including the development of the relevant YVL guides and the closure, in May 2012, of the IPPAS recommendation on the need to combine safety and security events in the emergency exercises. STUK's emergency plan now covers both security and safety events and the exercises are conducted accordingly.

Several conclusions could be drawn from the exchanges:

- In some countries, safety and security regulatory bodies were recently combined and integration of their work needed to address matters such as the different nature of the legislative systems, (e.g. goal-setting for safety and more prescriptive for security) as well as differences in culture and inspectors' background.
- In contrast STUK has regulated both these areas from the start. Furthermore, STUK operates, in these areas, within governmental decrees on safety and security, which are comparable in type and details. The decree on security is supported by security YVL guides for nuclear installations, which are under final stages of development.
- In some countries, regulatory requirements for security may vary in the level of detail between nuclear facilities and radiation practices.

- In discussion it was suggested that STUK may need to develop additional regulatory guidance for assessing safety and security cases in an integrated way, both using the graded approach.
- In some countries, licensees are expected to protect against design basis threats (DBT), but during integrated exercises they are expected to respond to beyond DBT.
- Regulatory frameworks may include performance-based regulations, open and public, supported by guides, some of which may not be publicly available.
- There are various practices for identification of the target sets used during exercises and these may differ among countries.
- STUK had found it helpful that its security staff/ inspectors typically had a safety background and had a good knowledge of safety vulnerabilities. However, other regulators noted that having staff with other backgrounds more closely related to security was also helpful for some matters.
- STUK conducts some joint safety-security inspections for nuclear facilities.
- Arrangements are planned for effective implementation of joint inspection for radiation practices, including training for inspectors, involvement of local police, etc.
- In the area of security issues related to transport, a joint guide will be prepared by STUK and the Ministry of Transport and Communications.

The closing remarks were made by STUK's Director General, who highlighted the importance of the security of the grid, especially after the TEPCO Fukushima Dai-ichi accident, the challenge of cyber security and indicated the need of close collaboration at an international level.

1.10. SUMMARY

Finland has a clear national policy and strategy for safety, mainly set out in law, supported by a clear framework for safety. STUK operates, in practice, as an independent regulatory body but the IRRS team recommends that the Government should strengthen the legislative framework by establishing STUK as a body separate in law from other arm of Government. In the meantime, the team gives a further recommendation and suggestion to improve both the legal position of STUK and ways of working with the Government.

The political commitment and the regulatory process to implement a geological repository are identified as a good practice, and it is now recommended that a comprehensive strategy and policy for waste management is developed.

The development of national long-term competence for the nuclear energy sector, including nuclear safety is identified as a further good practice.

Finally the Government is recommended to ensure that STUK has sufficient resources to fulfil the responsibilities placed on it by the Government to provide technical services.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The principle of continuous safety enhancement was adopted in Finland in the 1970's when nuclear power plant operation was started. Responsibilities and activities related to the safe use of nuclear energy in Finland are shared between several Ministries and authorities, are consistent with commitments to international arrangements and are intended to keep the use of nuclear energy in line with the overall good of society, to ensure that the use of nuclear energy is safe for man and the environment and does not promote the proliferation of nuclear weapons.

The Government of Finland, Ministries involved in the use of nuclear energy for peaceful purposes and STUK actively use substantial resources in promoting the global safety regime on the international, regional and bilateral levels. STUK´s duties, as defined in the decree on STUK, include responsibility for contributing to international cooperation in its field of activity, and for taking care of international control, contact and reporting activities, as enacted or prescribed.

Finland is a contracting party to international treaties and conventions for ensuring safety in the utilization of nuclear energy and radioactive waste management; it fulfils its respective international obligations, participates in the relevant international arrangements and promotes international cooperation to enhance safety globally. Finland has made a political commitment to follow the guidance of the Code of Conduct on the Safety and Security of Radioactive Sources.

In line with governmental policy STUK contributes to global safety enhancement through active participation, in international cooperation in the field of nuclear and radiation safety and security as well as in the safety of waste management. STUK is represented in IAEA technical cooperation programmes, commissions and committees, in UNSCEAR, WENRA, ENSREG, HERCA, OECD/NEA, IRPA, ICRP and other international fora. STUK participates in the coordinated actions at EU, IAEA and OECD level to identify potential further improvements of NPP safety following the accident at the Fukushima NPP in Japan. The Finnish reports on stress tests and follow-up undertaken in accordance with protocols agreed at the European level have been reviewed by the peer review teams set up by ENSREG. Fukushima related activities in Finland are consistent with the IAEA and ENSREG action plans.

Representatives of STUK actively participate in the development of IAEA safety standards. STUK uses the IAEA safety fundamentals, requirements and guides as a basis for updating its national guides. These guides are benchmarked against the IAEA safety requirements. STUK plans revision of the radiation safety in the light of the revised international basic safety standards (GSR Part 3).

The Finnish Government has requested several international peer reviews related to the use of nuclear energy and radiation sources. These peer reviews have been focused on regulatory activities (IRRT), waste management (EU Peer Review), nuclear power plants (OSART), research reactors (IAEA) and physical protection (IPPAS) as well as on Finland's environmental surveillance programme (EC). In addition STUK's research activities have been evaluated by international teams. The results of these international peer reviews have been published.

Finland is proactive in making Finnish experts available to participate as team members in international peer reviews. STUK experts have participated in several IRRT/IRRS missions, and also experts have been nominated to the EU IRRS mission expert pool.

The IRRS team is satisfied that Finland is fulfilling international obligations and supporting international cooperation in line with clear national policy and strategy for safety and that it meets the requirements of GSR Part 1 Requirement 14. The fact that these activities are set out transparently in the reporting system demonstrates Finland's commitment to the global safety regime on international, regional and bilateral levels.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 14 states that** *"The Government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally."*
GP3	**Good practice: STUK has an excellent record of active contribution to the global improvement of radiation and nuclear safety through its participation in relevant international activities. STUK has devoted high quality expertise to this activity and intends to continue in the future.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

STUK has established and developed an Operating Experience Feedback (OEF) process that includes review and assessment of operating events. In addition, all the findings of STUK's inspections are taken into account when analysing operational experiences. STUK has been a member of the Information System on Occupational Exposure (ISOE) since its establishment in 1992.

All incidents at nuclear facilities or involving radiation practices are analysed by the licensees and reported to STUK. The reports are assessed by STUK, following which the corrective actions are planned and implemented by the licensees.

Several of the corrective measures at operating Finnish NPPs have been identified through international reporting systems (IRS, WANO).

The most important source of international operating experience used by the Finnish utilities is the World Association of Nuclear Operators (WANO), which provides a global Operational Experience Feedback network for all operating organizations.

STUK disseminates lessons learned from operational experiences in Finland to the international community through the IRS reports on incidents and operational events and annual reports on the regulatory activities and related findings. Reported events are selected according to IAEA/NEA IRS Reporting guidelines. STUK has established an internal IRS Group comprising a co-coordinator and sixteen technical experts covering various areas of expertise. The implementation of measures to improve safety is further discussed in relevant international meetings. STUK delivers all the relevant received information on operational experiences that it receives from international counterparts to the Finnish licensees.

STUK takes an active part in the planning and steering of the European coordination centre for nuclear power plants' operational experience feedback network (EU Clearinghouse on NPP OEF).

The IRS country coordinators have annual meetings where "good practices" are discussed. In addition, STUK has reported "good practices" at the NRC's Regulatory Information Conferences (RIC).

STUK organizes annually several radiation safety related meetings, where information is disseminated on abnormal incidents, lessons learned and progress in developing regulations. The largest of these are the Radiation Safety Meeting for Industrial Users and the Radiation Safety Conference organized jointly with Radiological Society of Finland. Meetings are also organized to inform Radiation Safety Officers of new requirements related to radiation protection and to share experience. Feedback is also presented in an annual report of radiation practices which is distributed to all licensees and is available on STUK's website. STUK's representatives act in meetings to promote good practices in radiation safety on the basis of their experience in research and regulatory work.

One area of focus should be that STUK consider improving its processes for sharing information with all relevant stakeholders (including public) in a timely manner, particularly in relation to events, that may have generic implications. For example, medical events at a licensee facility may have generic implications to other licensees and the public. As well, for nuclear installations an event at one site may be evaluated to have generic implications. Therefore, STUK should consider improving its processes for sharing information on matters that have generic implications with all relevant stakeholders (including the public) in a timely manner.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 requirement 36, Para 4.66 states that** *"The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communications, and it shall hold meetings to inform interested parties and the public and for informing the decision making process."*
(2)	**BASIS: RS-G-1.5, Para 2.22 states that** *"The Regulatory Authority should develop mechanisms for the periodic dissemination of information to relevant users, manufacturers, suppliers and other appropriate persons about radiation protection, safety, incidents and related findings, and licensing and inspection experience. This flow of information should keep those who might be affected by these incidents alert to problems they may encounter and to their consequences if these problems are not properly addressed. Information should be exchanged through the publication of newsletters and the periodic mailing of notices, by presentations at scientific and professional association meetings, by establishing a web site, or by co-sponsoring educational seminars and workshops with universities, technical schools, and professional and scientific associations. More rapid actions should be considered in response to real or potential problems that may result in significant consequences. In this case it is recommended that the Regulatory Authority promptly disseminates the information to and requests a relevant action from those registrants and licensees with a similar practice."*
S2	**Suggestion: STUK should consider improving its processes for sharing information on matters that have generic implications with all relevant stakeholders (including the public) in a timely manner.**

2.3. SUMMARY

Finland fulfils its international obligations in line with international agreements and cooperation, as well as the IAEA standards.

STUK successfully develops the principle of continuous safety improvement using operating and regulatory experience feedback. This system includes the use of experience from other states to enhance the safety of facilities and activities globally.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

STUK's Director General has the authority to decide STUK's organizational structure and manage STUK's resources without any consent from outside STUK. The current Director General was appointed by the Government for a period of 7 years.

STUK´s duties are defined in the decree on STUK, and according to the decree STUK has the following duties:

- regulatory control of safety of the use of nuclear energy, emergency preparedness, physical security and nuclear materials;
- regulatory control of the use of radiation and other radiation practices;
- monitoring the radiation situation in Finland, and maintaining of preparedness for abnormal radiation situations;
- maintaining of national metrological standards in the field;
- research and development work for enhancing radiation and nuclear safety;
- informing on radiation and nuclear safety issues, and participating in training activities in the field;
- producing expert services in the field;
- making proposals for developing the legislation in the field, and issuing general guides concerning radiation and nuclear safety; and
- participating in international cooperation in the field, and taking care of international control, contact or reporting activities as enacted or defined.

The core values for STUK are: competence (actions, statements, and decisions are based on professional knowledge and factual information), openness (operations are open and honest, both with stakeholders and general public as well as internally), cooperation (within STUK based on good co-worker relations, teamwork, and mutual respect and stakeholders involvement in the preparation of new operations and issues), and courage (observed problems and personal views are brought up boldly, responsibility for decision is assumed, and mistakes are acknowledged and corrected).

The organization of STUK is prescribed by its Director General and described in the management system of STUK (STUK 2.1 and 2.2). The tasks and duties of the different organizational units are described in more detail in the management system and in the organizational chart in appendix IX.

The review team noted that the emergency preparedness group comprised only 4 people but it was clarified that the emergency preparedness group is supported by other departments, not only for exercises but also for the development of procedures.

STUK is currently working on a new strategy for the next 5 year period. This work may result in a need to reorganize STUK. Organizational structure and resources are periodically evaluated. However, there are no concrete plans yet on any major STUK level reorganization. The management system should include a process for any potential major organizational change (see chapter 4).

STUK receives about one third of its financial resources through the Government budget. However, the costs of regulatory oversight are charged in full to the licensees. The model of financing the regulatory

work is called a net-budgeting model and it has been applied since 2000. In this model the licensees pay the regulatory oversight fees directly to STUK. The net-budgeting model makes it possible to increase, for example, personnel resources for regulatory oversight based on changing needs.

The expertise of STUK covers all the essential areas needed in the oversight of the use of radiation and nuclear energy. As needed, STUK orders independent analyses, review and assessment from technical support organizations to complement its own review and assessment work. The main technical support organization of STUK is the Technical Research Centre of Finland (VTT), but Aalto University (former Helsinki University of Technology) and Lappeenranta University of Technology (LUT) are used to some degree. Also international technical support organizations and experts have been used. If this support is needed for decision making related to the regulated activities, the costs of this work is charged to the licensee.

To support current and future regulatory needs there are also national research programmes for nuclear safety and waste management in Finland. These research programmes are implemented in cooperation with all Finnish stakeholders including the utilities. STUK has the leading role to steer the programmes and ensure that the programmes result in outcomes that support the regulator in anticipating future safety issues by providing information for proactive decision making. SAFIR is the name of the Finnish Research Programme on Nuclear Power Plant Safety http://virtual.vtt.fi/virtual/safir2014/ and KYT is the name of Finnish Research Programme on Nuclear Waste Management http://kyt2014.vtt.fi/eng/index.htm related to the safety of nuclear power plants and waste management. STUK and the Government should be commended for developing a national and international nuclear safety and waste management programmes. STUK demonstrated a systematic and efficient way to identify, prioritize and perform their nuclear safety and waste management research.

The advice and assistance from external organizations does not relieve STUK of its assigned responsibilities. The independence as well as possibilities to conflicting interests are addressed in the course of contracting. The final responsibility with regard to decision making rests with the regulatory body.

STUK's management system addresses implementation of a graded approach in all regulatory activities (discussed further in chapter 4).

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

The foundation for independence of STUK is given in the legislation. Legislation describes STUK's governmental position, regulatory duties as well as regulatory powers and financial arrangements to ensure conduct of regulatory activities. STUK is a governmental organization for the regulatory control of the use of radiation and nuclear energy. The legislation defines no other responsibilities or duties which would be in conflict with regulatory control (see chapter 1 of the report for further discussion and recommendation).

Control of the STUK staff to ensure that it remains independent is accomplished as follow:

- Day to day management activities between the staff and management ensures that there is adequate communication to identify if personal views may have an impact on oversight or decision making. In addition, decision making process is such that STUK's final decisions are always signed with two names and the second has to be a section head or higher depending on the issue.

- Every new employee of STUK has to go through a training programme. This training programme addresses independence by providing training on the role and responsibilities of STUK, principles of good regulation, safety culture, role and responsibilities of a public official working for STUK (including the Civil Service Act).
- In-depth training is described in STUK's management system which provides general guidance for the work. Management system guidance highlights the importance of independence as a one key principle of good regulation at all levels of regulatory activities. It also requires that persons in charge are independent of the issue being handled. The persons must make themselves disqualified when handling an issue which concerns organizations or persons connected with their personal circle of interests.
- There is also specific guidance on STUK's staff on receiving hospitality to avoid conflicting situations with the regulated licensees.

The one area that needs more attention should be the inspectors, particularly the resident inspectors at the nuclear facilities. When the resident inspectors are hired, they spend three to six months at STUK, and then go to the site where they can remain for an indeterminate time. Care should be taken that all resident inspectors have sufficient time at STUK and understand the roles and responsibilities of a public official working for STUK (see chapters 4 and 7 of the report for further discussion).

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The number of staff at STUK at the end of 2011 was 354. The majority of the professional staff of STUK work on regulatory functions related to the nuclear safety and waste management, which to some extent reflect the nature and safety significance of regulated activities. The number of people in this area has been increasing significantly over the past ten years. The increase is due to on-going construction activities (Olkiluoto 3 and the ONKALO facility) and plans for new construction (Olkiluoto 4 and Hanhikivi 1). Also the retirement of experienced staff has required increased recruitment.

To ensure that STUK has the appropriate number of people with relevant competencies, the following general process is applied. STUK establishes a strategy normally for a five year period. The strategy is implemented by core processes where specific operating programmes for the same period are updated annually. These plans reflect as accurately as possible the regulatory duties and work of STUK. STUK's competence and human resource needs are evaluated in each step mentioned above (strategy, operating plans) from organizational level to an individual level. Resource needs identified in the planning are documented in human resource plans and associated competencies influence the training programme.

STUK has an on-going training programme for its personnel. General training programmes are established on organizational as well as on individual level reflecting the tasks and responsibilities of the individual. Individual needs for training are identified in the course of work and annual planning. A specific self-assessment tool (OSKAR) is used to explore the level of knowledge, skills and abilities available and necessary for regulatory functions. Inspectors working for the control of the use of radiation are required to have a formal qualification as a radiation safety officer (see chapter 7 of the report).

Until now STUK has not required formal qualifications for inspectors in other regulatory areas. However, the suggestion has been made that STUK should consider development of a formal qualification programme of inspectors for nuclear safety and waste management. One reason for this is the wider use of inspection organization in the future on this particular area. Formal qualification would ensure consistent inspection process between STUK and inspection organizations (see chapter 7 of the report for more discussion).

In addition to competence and resources of STUK's own staff, STUK uses technical support organizations as well as other consultants to support regulatory activities. However, also in these areas STUK's expertise has to be wide and deep enough to enable STUK to make good regulatory decisions. As an example, the current staff complement in the section for nuclear waste safety is 17 and this has been increased in anticipation of the construction licence application that is due in December 2012. The competence and preparation of the staff for the licence application is viewed by the IRRS team to be of a high standard.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

Legislation provides possibilities to STUK to liaise with stakeholders, contract expert organizations (Section 4 of the Act on STUK,) and to have advisory bodies (Section 56 of the Nuclear Energy Act (990/1987) and Section 7 of the Radiation Act (952/1991)) to support STUK in its regulatory functions. Process for contracting as well as conditions for the use of external organizations are described in STUK's management system.

The issues below were identified by meeting with the advisory commissions, meetings with STUK staff, and also a policy discussion of potential conflicts of interest.

There are 3 advisory bodies that may address safety as follows:

- The Advisory Commission for Nuclear Safety (YTN);
- The Advisory Commission on Radiation Safety;
- STUK´s Advisory Commission.

The members of the Advisory Commission for Nuclear Safety are nominated by the Government but they work in conjunction with STUK and report to STUK. There are seven members including nominees from the Ministry of the Environment as well as representatives from STUK and other technical experts. The members of the advisory commission have to conform to the Administrative Procedure Act (434/2003) which specifies the principles of independency and grounds for disqualification. The tasks of the advisory commission are to: 1) follow developments pertaining to the safe use of nuclear energy and to research in the field and make suggestions for the necessary measures, 2) give statements about licence applications pertaining to the construction and operation of nuclear facilities as well as about other significant applications regarding the use of nuclear energy; 3) give statements about questions that are significant from the viewpoint of the control of the safe use of nuclear energy; 4) give statements and make suggestions pertaining to the development of legislation concerning safety control pertaining to the use of nuclear energy; 5) review and assess rules, regulations and guides about the safety of the use of nuclear energy prepared by the Radiation and Nuclear Safety Authority (STUK) and other authorities; and 6) for its part, help maintain and promote cooperation between authorities and associations dealing with questions relating to the safety of the use of nuclear energy.

The Advisory Commission on Radiation Safety, which is established in the Ministry of Social Affairs and Health, has a different reporting line. The members of the Commission are again nominated by the Government at the request of the Ministry of Social Affairs and Health. They are to serve as a coordinating and expert body to consider issues of principle and matters of far-reaching consequences in the field of radiation safety. Section 30 of the Radiation Decree assigns this body to 1) address issues of principle concerning radiation safety; 2) monitor general developments in radiation safety; 3) make proposal and suggestions in matters concerning radiation safety; 4) issue opinions concerning radiation safety; and 5) perform other tasks assigned thereto by the Ministry of Social Affairs and Health. Therefore, they report to both STUK and the Ministry whereas the Advisory Commission on Nuclear

Safety reports directly to STUK. The Advisory Commission on Radiation Safety has nine members including nominees from Ministry of Employment and the Economy; Ministry of the Environment; and the Military. Other members are mainly medical physicists (often RSOs in hospitals) and the Secretariat from STUK. STUK requests the Commission to review such things as ST Guides but the Ministry may suggest consideration of other issues of importance to it. This Commission does not have the same structure, role and administrative procedures as the Advisory Commission on Nuclear Safety. The administrative procedures do not apply for members of this advisory commission.

STUK´s Advisory Commission provides policy advice to STUK in various areas, including strategies, as well as general advice in some specific topics of interest to society and for the organization. For example, the Commission has recently advised STUK in relation to commercialization of its services in technical areas, in order to allow the organization to maintain and enhance its expertise and provide for additional funding. Both the Commission and STUK may raise issues to be addressed during the Commission meetings. The members of the Commission are nominated by STUK and currently the Commission has a Chairperson and seven members, including four members of the Parliament. The Director General of STUK and another STUK staff member are also members of the Commission. One of the members of the Commission is a former senior manager from TVO. The IRRS team was informed that potential conflict of interest was taken into account when choosing the members of the Commission and it was concluded that, in order to provide sound advice, including various points of view, it was agreed that the Commission could include persons who had worked for a licensee, if the person is not anymore employed by the licensee. In addition, the members of the Commission are persons who are very well respected in their area of expertise. This approach has worked well to date and, if there is a specific issue that may create a potential conflict of interest for a member of the Commission the member will not provide his/her advice on that issue.

Some of the members in the Advisory Commission on Nuclear Security and the Advisory Commission for Radiation Safety may work for the authorized parties (as well as potentially future STUK advisory commissions). This is perceived as a potential conflict of interest that may have an impact on the advice given to the regulatory body. STUK should consider whether further changes or clarifications are warranted to ensure independent advice such as formalizing the process in the Administrative Procedure Act.

In addition, the IRRS team and STUK management discussed the issues of a more transparent process for the advisory commissions in the policy discussion on this topic. The discussion focused on possibly having a more formal process to address the perceptions of conflicts of interest including for example: specific selection criteria for members, openness and transparency, detailed meeting minutes, access for public to possibly include opponents of radiation as part of the advisory commission and a clear position on conflict of interest (to include financial).

In addition, there is an Advisory Commission on Nuclear Security which is not discussed further because it is outside the scope of this IRRS mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 20 Para 4.18 states that** *"The regulatory body may decide to give formal status to the processes by which it is provided with expert opinion and advice. If the establishment of advisory bodies, whether on a temporary or a permanent basis, is considered necessary, it is essential that such bodies provide independent advice, whether technical or non-technical in nature."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 1 Requirement 20 Para 4.21 states that** *"If the necessary advice or assistance can be obtained only from organizations whose interests potentially conflict with those of the regulatory body, the seeking of advice or assistance shall be monitored, and the advice given shall be carefully assessed for conflicts of interest."*
S3	**Suggestion: STUK and the Government should consider reviewing all the advisory commissions to evaluate consistency of roles, functions and reporting lines. STUK should also propose a formal mechanism to address potential conflicts of interest for advisory commissions.**

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

STUK has established both formal and informal mechanisms for communication between STUK and authorized parties to ensure possibilities for professional and constructive liaison. Based on the experience and stakeholder feedback, liaison and communication work very well between STUK and the authorized parties.

Formal and most frequently used mechanisms are through correspondence between STUK and authorized parties, and inspections on the authorized activities and organizations. It is also possible for STUK to invite authorized parties to a formal meeting. Formal mechanisms are described in detail in STUK's management system.

The informal mechanisms consist of informal meetings as well as discussions between individuals at different levels of the organizations. Both mechanisms allow possibilities for frank and open discussions to foster mutual understanding on safety related issues. Authorized parties are also given the possibility to be heard when regulatory decisions are made prior to issuance and to participate in the regulations update process prior they are set in force. Stakeholder feedback is also collected via questionnaires and surveys.

STUK's decisions and requirements have a sound legal basis and the requirements set have to be commensurate with safety. The basis for the decision, evaluation criteria, and scope of the review as well as basis for possible requirements set to the authorized parties is included in the decision or presented in a separate justification memorandum, which is to be attached to the decision and is submitted to the authorized parties.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

STUK's regulatory activities and decisions have to be based on legislation. They are outlined in the Acts and decrees for both Nuclear Safety and Radiation Safety. Regulatory activities and core processes are detailed in the management system and when decisions are made the legislative justification has to be provided to a decision maker as well as to the authorized party in question.

Changing regulatory requirements presented in the legislation and regulatory guides is possible following a process. The process includes active participation of the involved stakeholders as well as advisory groups. Although the regulatory guides are not legally binding, the licensee has to come with a proposal to meet the intent of the regulations and it must be approved by STUK. There is a four step process when modifying guidance documents including stakeholder as well as the respective advisory commission comment. This is an additional step to assure transparency when changing regulatory requirements.

Consistency in decision making process is ensured to some extent with a scope of and procedures for the review and assessment process and decision making. Regulatory decisions are made with two signatures to decrease the possibility for subjectivity. However, to improve consistency in decision making over time a tool should be developed and established within the management system to aid with regulatory decision making and also to be in a better position to capture previous regulatory decisions at all levels. As an example, the number of applications for Nuclear Installations that require review and approval by STUK is very large. Control of the documentation and assessment process is done through the electronic document management system SAHA, which covers, for example selection of a coordinator, recording and archiving submissions, task distribution, specification of intermediate actions, on-line monitoring of the review status, recording the STUK review/inspection reports, justification of the decisions taken.

The large number of submissions, and the necessary coherence in decision making between different experts makes it necessary to have a system in place whereby the decisions made are readily available. The team suggest that STUK enhancement the IT system, linking requirements from previous decisions of the similar category in the review and approval process for Nuclear Installation, in order to utilize experience feedback from previous submission and consistence of decision making.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 22 Para 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body. The regulatory body shall be able to justify its decision if they are challenged. In connection with its review and assessment and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements."*
S4	**Suggestion: In order to ensure that previous regulatory positions are captured and support consistency in decision-making over time STUK should consider developing further processes and tools to manage requirements.**

3.7. SAFETY RELATED RECORDS

Provisions for establishing and maintaining adequate and retrievable records relating to the safety of facilities and activities are set out in the legislation and regulatory guides. For the use of nuclear energy information related to the safety of the facilities and activities has to be submitted to STUK for information or for review and assessment in different stages of the lifetime of the facility.

Information produced and submitted in different steps of the lifetime (design, construction and operation) is stored over the lifetime of the plant and can be utilised before and during the decommissioning of the facility. Information is archived and maintained in STUK registers following the regulations and guidance for information management. In addition, the licensees must retain the information as well during the lifetime of the facility.

STUK has established and maintains registers for sealed radioactive sources and radiation generators (VASARA), for occupational doses (Dose register), for maintaining information related to the safety of facilities and activities and their decommissioning (SAHA and VASARA), for accidents and non-routine releases (SAHA and VASARA), for waste and spent fuel inventories (SAHA). In addition to registers at

STUK, it is required also that licensees maintain the data in their own registers. In particular, STUK is commended for maintaining the safety records of all radiation practices and the regulatory activities implemented by them in a Regulatory Data Management System, VASARA. The database includes all the regulatory information related to the licensee.

STUK publishes annual reports on the results of the oversight on the use of nuclear energy and use of radiation. The annual report on "Regulatory Oversight of Nuclear Safety in Finland" is required by the legislation to be submitted once a year to the Ministry of Employment and the Economy and it is also delivered to the Ministry of Environment, the Finnish Environment Institute, and the regional authorities of the localities in which a nuclear facility is located. An annual report on "Radiation Practices" is also prepared. When compiling the reports, information in the registers is used. The same information is also used in the periodic safety reviews conducted for nuclear power plants.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The decree on STUK defines STUK's tasks. One of the tasks is to inform about radiation and nuclear safety matters and participate on training activities in the area (Section 1 of the Decree on STUK). STUK's management system (Guide STUK 1.1) describes STUK's values, and one of the values is openness. In addition, Guide STUK 1.1 provides STUK's communication policy highlighting the following principles:

- STUK's communication is open, prompt and starts on STUK's own initiative
- STUK's experts and expertise are made available also outside office hours
- Good cooperation with the media to make STUK available and known to the public
- STUK's website is up to date and easy to use and contains good information on radiation and nuclear safety.

STUK utilizes the website to inform the public and interested stakeholders about nuclear and radiation safety in general, risks related to radiation and use of nuclear energy, safety requirements, roles and responsibilities of STUK, STUK's organization, current activities and operating experience, significant regulatory decisions taken, events and publications and safety research. STUK web pages can be found (www.stuk.fi) in Finnish, Swedish and in English. STUK has also made itself available in social media (Facebook and Twitter).

In addition to the website STUK utilizes different means to communicate with public and interested stakeholders:

- Communication with the authorized parties is conducted via correspondence, meetings and seminars and personal contacts
- STUK organizes and participates in training courses on nuclear and radiation safety for interested parties (e.g. training to media people, training on radiation protection, training on customs officers, training on regulatory requirements for licensees, vendors and subcontractors etc.)
- Press releases are published on safety significant events at nuclear facilities or in the use of radiation.
- Regular reports on radiation and nuclear safety are published quarterly and annually.

- STUK has also organized meetings and seminars with the public of the municipalities living in the vicinity of the nuclear power plants. The purpose of these meetings has mainly been to interact with the public and present the results of annual oversight results and safety assessments of the nuclear power plants.

For communication during emergencies STUK has established lists of contact points to relevant licensees, authorities and ministries in Finland and abroad. Communication is practiced in the annual emergency exercises.

STUK consults interested parties (public, advisory bodies, licensees, ministries, other authorities etc.) in licensing steps (when issuing safety assessments), when drafting new regulations and in the areas related to other authorities (e.g. security, emergency preparedness).

One area of focus should be that STUK may want to consider improving its processes for sharing information, particularly in relation to matters that have generic implications with all relevant stakeholders in a timely manner. This is discussed further in chapter 2 of the report.

3.9. SUMMARY

Overall, the responsibilities and functions of the regulatory body comply with the IAEA safety standards. The competence and preparation of the staff for a licence application is viewed by the IRRS team to be of a high standard. The team has made suggestions to improve their current programme: one suggestion related to advisory committees which had two parts, one to develop a formal mechanism for monitoring potential conflict of interest and another to review the basis of the Advisory committees, in particular those providing technical advice to evaluate for consistency; another suggestion is to improve consistency in decision-making by enhancing tools for regulatory activities.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

STUK has established and implemented a management system which is assessed and continually improved. The main standards forming the basis for the management system are the international standards ISO 9001, ISO/IEC 17025 and IAEA GS-R-3 safety standards (Guide STUK 1.2).

The regulatory safety goals of STUK are stated in the quality policy of STUK (Guide STUK 1.1), where the requirements for STUK´s regulatory activities are also listed. The quality policy of STUK defines the priority to safety culture. The STUK department directors have committed themselves to follow the quality policy requirements and request every STUK employee to do the same.

The regulatory procedures documented in the STUK management system are derived from the legislation and the STUK quality policy. The requirements are identified and documented in the different quality manuals and guides. However, it may be useful for STUK to review all their requirements for managing the organization, to ensure that the relevant requirements are addressed in a coherent manner.

The documents of the management system consist of about 300 separate quality manuals and guides arranged in a hierarchical manner: on top, there is the quality policy of STUK, then the STUK level quality manuals addressing the whole of STUK, then the manuals and guides for the different departments of STUK. In an annex to the STUK level quality manual there is an overall process map, describing the main processes.

Because of the number of documents and the fact that many of the management system manuals are handled at the departmental level there is a risk of duplications and inconsistencies in the documentation. Also there is a risk that the right document will not be found when needed. An action should be taken for ensuring that the quality manuals are streamlined, kept logical, not overlapping and up-to-date all the time.

Even though the quality policy and other internal guides recognizes the significance of maintaining a high-grade safety culture, the team formed the view that the safety culture issues should be more explicitly addressed in different ways so that to ensure a common understanding and a learning and questioning attitude in all levels of STUK. The importance of continually developing, assessing and improving safety culture should also be addressed as part of the quality manuals. To avoid regulatory capture, STUK should consider, in the development, assessment and improvement of the safety culture, the implications on safety in relation to independence to be addressed in the performance of regulatory functions.

STUK’s management system addresses implementation of a graded approach in all regulatory activities. In the oversight of nuclear facilities this is largely based on the application of safety classification also in regulatory activities (review and assessment) as well as on the use and information provided by both deterministic and probabilistic tools. The guidance related to graded approach given in the management system is on a fairly general level and could be made more explicit (e.g. in the area of periodic inspection programmes). For the oversight of use of radiation the basis for graded approach in regulatory control is laid down in the Radiation Act which enables minor-risk activities to be exempted from licensing and on the other hand sets more stringent requirements for high-risk activities. See further chapter 7 of the report, Recommendation 6.

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."*
S5	**Suggestion: STUK should consider explicitly addressing safety culture in its management system in order to ensure a common understanding of key safety culture characteristics to support individuals and groups to:** • **Reinforce a learning and questioning attitude at all levels of the organization;** • **Continuously develop, assess and improve the safety culture; and** • **Prevent regulatory capture.**

4.2. MANAGEMENT RESPONSIBILITY

The Director General has taken the responsibility for oversight of the management system and its continual improvement. The responsibilities of directors are established according to Guide STUK 2.1 (Rules of Administration) and among these responsibilities is accountability for implementation and development of the management system at departmental level. The Director General appoints the Quality Manager, who reports directly to him, to coordinate and develop the methods in the management system.

The Director General has established a permanent working group called the Quality Group, responsible for coordinating across all the departments. Members of the Quality Group are nominated by directors and they represent the departments of STUK. These persons are also responsible for management system issues on departmental level. The Quality Manager of STUK acts as a chairperson of the group.

Each director and section head is obliged to supervise the fulfilment of the management system in his or her sector. Every STUK employee is responsible for the quality of his/her work (Guide STUK 1.2).

STUK has established an integrated planning system. STUK's strategy is updated every fifth year and presents the most important goals and priority activities. Action plans and programmes for all core processes are derived on the basis of STUK's strategy. More detailed annual plans needed for its implementation are prepared for all of the organizational units and individuals.

The expectations of stakeholders are taken into account when STUK's strategy, action programmes for core processes and annual plans are prepared. STUK actively collects feedback through meetings, surveys and interviews from all interested parties. The preparation process of the guides for regulation of the radiation practice and the use of nuclear energy includes hearing from licensees and operators. Representatives of the licensees participate in the working groups established for the on-going revision project of YVL Guides. All drafts of the new regulatory guides under preparation or revision and published regulatory guides are available on STUK's website.

STUK has established measurable objectives for implementing strategies and plans. These are presented in the STUK's annual result plan. The implementation of the plans is regularly reviewed on all organization levels. At each level the implementation status is evaluated at least annually.

4.3. RESOURCE MANAGEMENT

Necessary factors for success of STUK are adequate human resources and professional competence in all areas relevant for radiation and nuclear safety.

In the annual plans resources are allocated to different areas of regulatory activities as well as to administration and to development activities. These plans are approved by the Director General.

Maintaining and developing human capital is supported by charts on competence needs and actual available competencies within each organizational unit. When evaluating the competence needs the safety significance of the regulated activities is also considered. According to the STUK management system the competence charts are reviewed annually and used for making personal development plans, succession planning and recruitment of new staff and planning the development of human capital in the long term.

STUK has internal training available, and also outside training facilities are used as appropriate. The training needs of each employee are discussed annually in the development plan. The personal performance targets for each employee are agreed upon in, at least, an annual discussion with the manager.

Infrastructure and working environment are subjects in the surveys on the staff wellbeing. Survey results show that members of the staff are satisfied to a high degree. Infrastructure and working environment are discussed also in annual discussions with each staff member and in management reviews.

4.4. PROCESS IMPLEMENTATION

STUK has identified and established 11 core processes (Guide STUK 1.2). All these core processes have sub-processes. In addition, there are several support processes. The requirements and working procedures are described in the Quality Manual of STUK.

Directors of the departments allocate resources for implementing, assessing and improving the management system on the departmental level in the annual planning.

Directors nominate process owners for all sub-processes (Guide STUK 1.2). The duty of the process owner is to:

- Follow up and analyse the functioning of the process.
- Develop the process and methods and indicators used to measure the process.
- Take care that the guides concerning the process are updated.

The IRRS team views the core processes as being a description of the duties of the different departments. However, the sequence, interactions and interdependencies of the processes and sub-processes are not shown in a clear manner. Flow charts of the different sub-processes could be developed in order to enhance the understanding of the regulatory activities. According to STUK's internal study some staff members have found it difficult to locate the appropriate guides. Some improvement actions have already been taken.

STUK uses both formal and informal communication concerning the implementation and effectiveness of the management system. All reports related to the management system are available for staff in SAHA and most on STUK's intranet (SANTRA) as well. Also all registers are available to staff.

Official records are maintained in paper and are recorded in IT systems. Some large documents from licensees are maintained in paper only, other documents are kept electronically and in paper. STUK's management system includes guidance to ensure prevent of loss, deterioration and inadvertent use of products. STUK's document management system SAHA has procedures for user management. The IT unit is responsible for taking back-ups of all available data in STUK's systems.

STUK's annual report includes a chapter on the management system and improvement actions. In addition information on improvements on management system is given in Regulatory Oversight on Nuclear Safety in Finland report. Both of these reports are published annually and are made available for interested parties on STUK's website. STUK's Director General reports on significant improvements and findings on the management system in his informative meetings for staff.

The Department of Nuclear Reactor Regulation carried out an organizational change in the beginning of the year 2008 and the plan for the change was evaluated before it was implemented. The new organization was also assessed afterwards. However, STUK's management system does not include a documented process for managing major organizational change. The team therefore thinks that STUK should consider establishing a documented approach in its management system to address organizational change. This is addressed in STUK´s preliminary action plan and will be taken into consideration in the implementation of STUK´s next strategic plan.

Further justification of the suggestion is provided above in Section 4.1 of the report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-3 Para 2.1 states that** *"The management system shall be established, implemented and assessed and continually improved and shall contribute to their achievement. The main aim of the management system be to achieve and enhance safety by:* - *Bringing together in a coherent manner all the requirements for managing the organization;* - *Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;* - *Ensuring that health, environment, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety."*
(2)	**BASIS: GS-R-3 Para 5.2 states that** *"The sequence and interactions of the processes shall be determined."*
(3)	**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.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	- *Process inputs are identified.* - *The process flow is described.* - *Process outputs (products) are identified.* - *Process measurement criteria are established."*
(4)	**BASIS: GS-R-3 Para 5.5 states that** *"The activities of and interfaces between different individuals or groups involved in a single process shall be planned, controlled and managed in a manner that ensures effective communication and the clear assignment of responsibilities."*
S6	**Suggestion: STUK should consider further improving its management system with respect to the following aspects:** • **Reviewing the requirements for managing the organization to ensure that the relevant requirements are addressed in a coherent manner;** • **Reviewing and revising the existing quality manuals and guidance documents for consistency and elimination of potential duplications;** • **Improving overall descriptions of the processes including sub-processes and their interdependency; and** • **Ensuring the easy identification of relevant procedures and documents.**

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

STUK has implemented systems for monitoring, measurement, assessment and review of activities. These include use of performance indicators, self-assessments, internal audits, external audits and management reviews. The self-assessments, audits, management reviews at all levels and external evaluations provide information for improving the management system. However, the IRRS team could not see a long-term systematic approach in the planning of the assessments. Moreover there seems to be no systematic evaluation of the effectiveness of the processes.

STUK has an annual plan for internal and external audits. This plan is based on the needs of the Director General and on the departmental level. The Quality Manager could also suggest additional internal audits.

Self-assessment is done annually at all organizational levels, the scope is determined by the needs of the organization as identified by the Director General.

Independent assessments are occasionally done by external (international and third party) evaluation groups.

The management system review is performed annually at STUK level but also at each departmental or other organizational level. In the Management review, the directors present among other issues listed in the internal guide the resultant actions taken due to the present internal and external audits performed at their respective departments.

STUK has a pool of personnel that have undertaken courses on internal audits (according to ISO 9001). The internal auditors are appointed on a case by case basis. The internal auditors are not conducting any audits in their own area of responsibility.

Non-conformances revealed during external and internal audits are recorded in a database together with the audit results and required corrective actions. However, the team has concluded that the up-date of actions were not always recorded and followed-up in a timely manner. The team has concluded that development of a more comprehensive programme could be done in a systematic way, applying a graded approach. Moreover, STUK should consider relating the items reviewed under this programme to the strategic plan that currently is under revision. Resources for implementing the required corrective actions are included in the annual plans.

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: GS-R-3 Para 6.2 states that** *"Senior management and management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture."*
(3)	**BASIS: GS-R-3 Para 6.3 states that "***Independent assessments shall be conducted regularly on behalf of senior management.* *-To evaluate the effectiveness of processes …"*
S7	**Suggestion: STUK should consider developing further a systematic long-term programme for self-assessments, internal and external audits, including follow-on actions and evaluations of the effectiveness of the processes. The programme should be monitored, recorded and reflect STUK's strategic plan.**

4.6. SUMMARY

STUK has established and implemented a management system which is assessed and continually improved. There is a strong commitment to the management system from senior management including the Director General. The regulatory safety goals of STUK are stated in the quality policy. The safety culture issues should be addressed more explicitly to ensure a common understanding and a learning and questioning attitude in all levels of the authority. The importance of continually developing, assessing and improving safety culture should also be addressed as part of the quality manuals.

STUK's management system addresses implementation of a graded approach in all regulatory activities. However, the guidance given in the management system is on a fairly general level and could be made more explicit.

The requirements are identified and documented in the different quality manuals and guides. However, the requirements for managing the organization are not brought together in a coherent manner.

STUK has identified and established core processes, sub-processes and support processes. However, the sequence, interactions and interdependencies of the processes and sub-processes are not shown in a clear manner. Flow charts in the different sub-processes could also enhance the understanding of the regulatory activities.

Directors of the departments allocate resources for implementing, assessing and improving the management system on the departmental level in the annual planning.

Non-conformances revealed during external and internal audits are recorded in a database together with the audit results and required corrective actions. However, the team concluded that the up-date of actions were not always recorded and followed-up in a timely manner.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The use of nuclear energy without a licence is prohibited under Section 8 of the Nuclear Energy Act (990/1987). The use of nuclear energy includes construction and operation of nuclear facilities, mining and milling operations aimed at producing uranium or thorium, possession, fabrication, production, transfer, handling, use, storage, transport and import of nuclear material and nuclear waste, export of nuclear waste as well as the export and import of ores containing uranium or thorium.

It is the licensee's obligation to assure safe use of nuclear energy. Therefore the licence applicant shall submit detailed demonstration of safety to STUK's review and assessment according to regulations as the Nuclear Energy Act, Nuclear Energy Decree, Government decrees and YVL Guides.

According to Section 16 of the Radiation Act licensing is a prerequisite for facilities and activities not explicitly exempted from the regulatory control. Exemptions are prescribed in Section 17 of the same act. The Authorization of all radiation practices is by licensing only.

The STUK Decree provides for the main responsibilities of STUK and its designation as a Regulatory Authority having the responsibilities of licensing all facilities involving ionising radiation.

Section 75 of the Nuclear Energy Act and Section 65 of the Radiation Act provide the appealing procedures for decisions made by the licensing body (the Government in the case of nuclear facilities and STUK in the case of radiation practices). The appellate authority for STUK's decision is Administrative Court of Helsinki.

The overall regulatory framework (legislative infrastructure and STUK regulations) addresses in a comprehensive way the issues of waste management and clearly defines the responsibilities. STUK has been given by law appropriate means for regulating waste management facilities and implementing corrective actions.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

A condition for granting the Decision-in-Principle for a significant nuclear facility is that the operation of the facility in question is in line with the overall good of society.

In the Decision-in-Principle phase STUK prepares a statement on safety and preliminary safety assessment concerning the proposed plant designs, plant sites and other relevant issues presented in the application. STUK also asks a statement from the Advisory Commission on Nuclear Safety, which is then attached to the STUK statement.

For the Construction and Operating Licence application, the Ministry of Employment and the Economy is required to seek STUK's statement on safety. In addition, construction and operating licence documents to be submitted to STUK for approval in this phase are defined in Sections 35 and 36 of the Nuclear Energy Decree. STUK asks for a statement from the Advisory Commission for Nuclear Safety. After receiving all statements for the construction and operating licence application, the Government makes the licensing decision.

The Operating Licence is granted for a period of time that depends on the facility in question and varies at the moment from 10 to 20 years. The periodic re-licensing has allowed for comprehensive, periodic safety reviews.

The licensing body (that is, the Government) has the authority to cancel a licence wholly or partly, if implementation of the general principles for the use of nuclear energy provided in the Nuclear Energy Act is essentially endangered. When cancelling a licence, the same procedure is followed, as appropriate, as when the licence was granted. Also in applying for an amendment to the construction licence or operating licence of a nuclear facility, the same provisions are followed as in the case of a new licence.

In accordance with the Nuclear Energy Decree, the different phases of construction of a nuclear facility may be begun only after STUK has, on the basis of the construction licence documents and other detailed plans and documents it requires, verified in respect of each phase that the safety-related factors and safety regulations have been given sufficient consideration.

Based on the Nuclear Energy Act, the operation of the nuclear facility or other nuclear activity shall not be started on the basis of a licence granted until STUK has ascertained that the nuclear facility meets the safety requirements set.

Review of the detailed design of structures and equipment can be begun after STUK has found that the plant and system-level design data of the system concerned are sufficient and acceptable. This assessment may take place as part of the review of the Preliminary Safety Analysis Report or separate system-specific descriptions, which are subsequently added to the Final Safety Analysis Report.

According to the Nuclear Energy Act, STUK specifies detailed safety requirements concerning the implementation of safety level in accordance with the act. These guides are YVL Guides. The licensee must follow the safety requirements of STUK established in the YVL guides, although the licensee has the right to propose an alternative procedure or solution to that provided for in the regulations. If the licensee can convincingly demonstrate that the proposed procedure or solution will implement safety level in accordance with the Nuclear Energy Act, STUK may approve this procedure or solution.

STUK Authorizations and Licensing

The Nuclear Reactor Regulation (NRR) department is the part of STUK responsible for performing the licensing (authorization) and safety review and assessment of NPPs. The divisions of NRR are Nuclear Facilities and Systems, Structures and Components and Projects and Operational Safety. For typical projects the matrix approach to the organization of work is applied.

As described above, the NPP licences are prepared by Ministry of Employment and the Economy (MEE) with STUK providing the STUK statement and safety assessment report. All changes of licence conditions must be approved by the Government through the same Ministry. STUK performs also in these cases the safety assessment to support the MEE processes.

Changes in the plant that are safety related but do not change the licensing conditions are authorized by STUK by issuing the decision, without consultation with the Ministry (MEE).

The Nuclear Energy Decree (chapter 15) gives STUK regulatory control of projects after the issuing of the construction and operating licences.

Testing and inspection of structure and components

In accordance with the Nuclear Energy Act, STUK approves the manufacturers of nuclear pressure equipment and inspection organizations or testing organizations for duties pertaining to the control of pressure equipment at nuclear facilities.

The duties of inspection and testing organizations as well as those of the qualification bodies cover not only pressure equipment but also steel and concrete structures and mechanical equipment of nuclear installations. Approvals are issued for limited period of time.

In accordance with Nuclear Energy Decree, STUK oversees the construction of the facility in detail. The purpose is to ensure that the safety and quality requirements, regulations for pressure equipment and approved plans are complied with and that the nuclear facility is constructed in other respects in accordance with the regulations. In particular, the oversight is aimed to verify that working methods ensuring high quality are employed for the construction. Before loading fuel into the reactor, an operating licence is needed.

Authorization of systems, structures and components

In general, the number of submission requiring review by STUK is enormous. STUK receives about 800 submissions per three months (average number in 2011). In connection with construction of Olkiluoto 3 NPP, altogether about 14000 documents were reviewed, out of them 9000 with request for approval. The number of reviewed and approved documents goes up to 2000 per year. About 50 % of applications are devoted to approval of mechanical components. Quite large number of submissions is also originated from operating plants; example was given from Loviisa NPP with about 700 submissions per year (including both units 1 and 2). Typically for approximately half of them the STUK issues the approvals.

When the plant is modified the formal criteria that determine the safety significance of the modification are the Safety class of the affected structures, systems and components and the extent of the modification. If the modification changes not only a single component but also design values of the system in question a pre-inspection document of the system modification is needed. If the modification is very broad (like installation of a new system, renewal of automation or emergency diesel generators) a conceptual design plan is required.

The STUK may develop additional criteria and associated procedure to include other possible attributes that may screen out less significant modifications and or components for which less detailed regulatory review and assessment can be applied. This categorization should be applied by licensee and reviewed by STUK. STUK should also oversight the process. As a result STUK may decrease the number of low safety importance modifications to review in detail and increase time devoted to more important safety issues. A better balance in this regard should be established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Para 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, 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."*
S8	**Suggestion: STUK should consider developing a graded approach for the authorization of systems, structures and components in order to focus more on issues of higher safety significance.**

Management of the documentation and traceability

STUK uses an effective document management system (SAHA) to support the coordination of the submittals, including process classification and document traceability providing easy feedback and retrieving of information for authorization, review and assessment and inspection. This enables to track how the review and how the decision has been prepared, including the requirements and conditions for the decision.

Periodic Safety Reviews

Licences for operation of NPPs in Finland are time limited by Law. When the length of the term is considered, particular attention shall be paid to ensuring safety and to the estimated duration of operations. One of the conditions of the licence is the PSR, which have to be performed at least every 10 years.

The PSR process is explained in details in the regulatory guide YVL 1.1. During the PSR the licensee is performing safety review and presenting in the report how these stipulate with regulatory requirements in various areas important to safety. The review and reassessment of all systematically collected and assessed information relevant for each safety factor are presented in the licensee report, demonstrating that the adequate processes in the plant are effective to safety during last 10 year period. As a Finish practice, if there are changes of requirements in the YVL guides, implementation decisions are issued by STUK endorsing the licensee's proposal for fulfilling the new requirements. Implementation decisions are made immediately after the renewal of the YVL guide, not waiting for the next PSR.

The review takes up to 2 years and is mostly performed by licensee's staff. During the PSR review, STUK performs inspections, checking the licensee's review process. This approach increases the level of STUK trust into the PSR process. As a result of successful PSR, STUK prepares the statement and review and assessment report, which is submitted to the MEE if the licence is expiring or sends the decision, together with the review and assessment report to the licensee confirming that the condition from the licence is fulfilled. In first case the MEE is making preparations for the licence which is issued by the Government. The open issues found by STUK and issues that came from the PSR review are inputs for the licensee's action plan.

The PSRs are treated as a very important tool for promoting the continuous safety improvement approach. The scope of the PSR is in line with the IAEA's scope of PSR safety factors and the whole process is in line with IAEA Safety Guide NS-G-2.10.

Authorization of plant operators

The training of the plant operators longs approximately two to three years. The full scope simulator is required and is available on both sites. For the new plant the simulator availability is required at least one year before the operation is starting. STUK is inspecting the process of training and qualification of plant operators. Qualification is performed completely by the licensee. STUK approves written test results and takes part in the oral exams. Finally, STUK are issuing the licence for the operators for period which corresponds to the score on exam but not longer than 4 years.

Based on the requirement on the Nuclear Energy Act STUK is approving also the Responsible manager in NPP based on the previous interview. Besides, STUK is approving responsible persons for emergency, safeguard and security and the overall management structure.

5.3. AUTHORIZATION OF FUEL CYCLE FACILITIES

Currently the only fuel cycle facilities are the spent fuel storage facilities associated with the nuclear power plants at the Olkiluoto and Loviisa sites. The spent fuel storage facilities are pool type storage that is on the same site as the power plants and are authorised in the same licence as the NPP.

At Loviisa the installation of the dense racks into the storage facility started in 2007 and continues until 2018.

At Olkiluoto NPP the wet type spent fuel storage facility was commissioned in 1987. The current capacity is adequate until 2014. The operator TVO has started the construction works for enlarging the Olkiluoto interim storage in summer 2010. The extension includes construction of three new pools and it will be

done according the updated safety requirements (Government decision 733/2008). Extension has been included in Olkiluoto NPP units 1 and 2 operating licence and has been handled as plant modification. STUK reviewed TVO's application and gave approval for construction during first half of the 2010. Extension has been planned to be ready in the end of 2013.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE FACILITIES

General

Management of low and intermediate level waste from the production to the final disposal takes place at the NPP sites. Final disposal facilities for low and intermediate level waste are in operation at Loviisa and Olkiluoto sites.

The disposal facility for LILW was taken into operation at the Olkiluoto site in 1992 and for LLW at the Loviisa site in 1998. At Loviisa site the cementation facility for solidification of ILW and the extension of the disposal facility for cemented waste are under commissioning. At Olkiluoto, wet LILW is immobilized in bitumen before transfer to the disposal facility. Sludge, radioactive concentrates and spent ion exchange resins from liquid waste treatment in Olkiluoto 3 are planned to be dried in drums.

At the Loviisa NPP site, the repository for the low and intermediate level waste is located at the depth of 110 meters in granite bedrock. It consists of two tunnels for solid low level waste and a cavern for immobilised intermediate level waste.

The repository for the low and intermediate level waste at the Olkiluoto NPP site consists of two silos at the depth of 60 to 95 meters in bedrock, one for solid low level waste and the other for bituminised intermediate level waste.

The original plan presented in the construction licence application for unit Olkiluoto 3 was to dispose all the low and intermediate level waste in the existing repository in Olkiluoto. However, the waste packages of the conditioned intermediate level waste have different dimensions compared to the waste packages from operating units in Olkiluoto. Therefore TVO will in the operating licence application propose that the conditioned intermediate level waste is first stored on-site in the existing waste storage facility, and later disposed of in the extension of the repository. The solid low level waste from Olkiluoto unit 3 can be disposed of in the existing repository.

The primary issue of radioactive waste management in Finland is the geological disposal of spent fuel. It is noted as a good practice that in Finland the political commitment to implement a geological repository and the regulatory process for implementing the geological disposal is well defined and has been in place for a long period of time (since 1983). The underground rock characterisation facility has been constructed with the disposal depth having been reached in 2010. The construction of the underground rock characterisation facility was undertaken with regulatory oversight because it is planned to be part of the repository in the future. The construction licence application for the repository is expected to be delivered to the Finnish Government in December 2012.

The decree on disposal requires that the safety case shall be updated prior to closure of the repository. YVL Guide 8.1 requires a closure plan to be submitted to the regulator but there is no corresponding requirement for spent fuel repository in guide YVL 8.5. However it is unclear how closure of the repositories will be authorised as there is currently no clear authorisation step catered for in the legislation. A similar question arises with respect to decommissioning of facilities and a recommendation addressing both these issues is included in Section 5.6 of the report.

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES

The Department of Radiation Practices Regulation (DRPR) of STUK is responsible for granting licences for all types of radiation practices. The Radiation Safety Guides issued by STUK provides description on the requirements and processes for licensing of activities and practices including:

a) Radiation therapy;

b) Diagnostic radiology;

c) Industry, research, education and commerce;

d) Shipments of radioactive waste and spent fuel;

e) Unsealed sources and radioactive wastes; and

f) Import, export, possession and use.

The safety guides describe the requirements for the practices of medical, industrial and research facilities, including licensing.

Renewal of licences is not required according to STUK safety guides, where it is laid down that the user licence will continue to be valid until further notice by STUK. Section 16 and 20 of the Radiation Act empowers STUK to amend or revoke licences. Section 16 of the act empowers STUK to include conditions to the licence necessary to ensure safety.

The procedures for applying for a licence for the different types of facilities and practices are available on the STUK web page. The internal licensing procedures have been described in the Quality Manual on Processing Licensing Application of April 2011. The manual has also described the requirements for licensing of facilities and activities, taking into consideration the risks associated with the equipment or sources used. In case of introducing or changing of requirements within one of the ST Guidance, STUK will immediately inform the concerned licensees in order to comply with the new requirements.

STUK conducts several radiation practices, as defined in the Radiation Act, (e.g. a dosimetry laboratory that provides calibration services to most of the licensees, storage of disused sealed sources when responsible party is no longer identified, environmental monitoring). The radiation activities carried by STUK operate without formal authorization. However, the IRRS team was informed that most of the radiation activities carried by STUK are inspected regularly by the Department of Radiation Practices Regulation, while, the dosimetry laboratory is inspected by the Nuclear Reactor Regulation Department. The IRRS team was informed that STUK is planning to issue a document for each activity stating that it complies with the STUK's regulatory requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 23 states that** *"Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."*
S9	**Suggestion: For its own uses of radiation, STUK should consider demonstrating, in a transparent manner, that it satisfies all the required regulatory conditions necessary for an authorization.**

STUK may issue separate licences for laboratories even if they belong to one facility, in each licence there is an assigned radiation safety officer approved by STUK.

The Radiation Act, in section 5, gives the overarching authority to the Ministry of Social Affairs and Health for all types of radiation practices, except for commercial manufacturing and trading in, and importing and exporting of radiation sources for which the authority is the Ministry of Employment and the Economy. In application of the Radiation Act, all radiation practices are directly licensed by STUK, including sources suppliers. Moreover, there are no radiation sources manufacturing in Finland. The IRRS team was informed that the Ministry of Employment and the Economy is not involved in the control of source suppliers. The IRRS team considers that when the Radiation Act is being revised, the provision related to the regulatory oversight of source suppliers be reconsidered and possibly deleted, for simplification of the legal framework.

According to Section 16 of the Radiation Act, when new sources are authorized for use, STUK requires the applicant to present a plan on measures to be taken when it becomes a disused. The annual fee specified by STUK for holding a licence depends on the number of sources in licensee's possession and, therefore, this encourages the licensees to transfer disused sources back to the provider.

In case of orphan sources the Government has the responsibility to deal with the sources safely as it has been stated in Section 51 of the Radiation Act. The IRRS team was informed that, STUK has arrangements in place to deal with gaining and regaining control over orphan sources.

In licensing the export and import of a radioactive source, STUK has a separate application form for this purpose. Section 31 of the Radiation Decree prescribes the duty of Customs in regard to import and export of radioactive sources; in addition, STUK and customs have been developing arrangements (Memorandum of Understanding) to deal with the imported or exported sources. The IRRS team was informed that, in case of importing or exporting high active source, a separate licence is required for each source transaction and the provisions of the Code of Conduct and its associated guidance on export and import are always being followed.

STUK maintains regulatory data management system, VASARA, which regularly updated by the DRPR staff. The system was recently implemented, and still under development to include other data like worker doses registry. The system handles licensing, inspection and enforcement processes and includes data on, for example:

- Facilities;
- Inventory of radiation sources;
- Inspection results;
- Corrective actions.

5.6. AUTHORIZATION OF DECOMISSIONING

As has been described, the licensing process for nuclear facilities in Finland consists of three steps: Decision in Principle; Construction Licence; and Operating Licence.

Authorisation for decommissioning of predisposal waste management facilities (and other nuclear facilities) is not explicitly covered in the legislation. At this stage there is only a requirement that a decommissioning plan is required and that such plan must be updated on a six (6) yearly basis. The regulator reviews said plans and makes a statement on their acceptability. In accordance with the IAEA safety standards, decommissioning should be viewed as a distinct stage in the life cycle of a facility, since the type of operations to be carried out, the hold points and the hazards encountered are of totally different nature than during the operational phase.

The shutdown of the research reactor (FiR1) should motivate a modification of the legislation in this sense without delay.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: SSR 5 Requirement 1 states that** *"The Government is required to establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities shall be clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed. This shall include: confirmation at a national level of the need for disposal facilities of different types; specification of the steps in development and licensing of facilities of different types; and clear allocation of responsibilities, securing of financial and other resources, and provision of independent regulatory functions relating to a planned disposal facility."*
(2)	**BASIS: GSR Part 1 Requirement 24 states that** *"The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity."*
(3)	**BASIS: GSR Part 1 Requirement 24 Para 4.29 states that** *"Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure). This includes, as appropriate, the management of radioactive waste and the management of spent fuel, and the remediation of contaminated areas. For radioactive sources and radiation generators, the regulatory process shall continue over their entire lifetime."*
(4)	**BASIS: SSR 5 Requirement 11 states that** *"Disposal facilities for radioactive waste shall be developed, operated and closed in a series of steps. Each of these steps shall be supported, as necessary, by iterative evaluations of the site, of the options for design, construction, operation and management, and of the performance and safety of the disposal system."*
R5	**Recommendation: The Government should expand the legislative framework to encompass distinct authorizations for decommissioning of facilities and closure of repositories in addition to the current authorizations for construction and operation of nuclear facilities.**

5.7. AUTHORIZATION OF TRANSPORT

For nuclear material and nuclear waste, a licence for transport is required according to the Nuclear Energy Act, unless the transport involves small quantities exempted from the transport licence, in accordance of Section 17 of the Nuclear Energy Decree. STUK has YVL guides that establish requirements for safety (YVL 6.5) and security (YVL 6.21) of transport for this material. For nuclear material such as fresh fuel, a transport plan and transport security plan are mandatory in addition to the licence. These requirements for authorization of transport of nuclear material were seen to be in compliance with the requirements of the TS-R-1.The transport of non-nuclear radioactive material is exempted from licence under the Radiation Act (Section 17 of Act 592/1991), but is regulated according to national transport regulations

on dangerous goods, based on IAEA safety standards. Therefore there is no authorization process in STUK for this practice. This issue is followed up in section 7.7 of this report.

STUK has produced a pamphlet with instructions for drivers (STUK OPASTAA / SYYSKUU 2012– *Radioaktiivisten aineiden kuljetus*, 36 pp) which is available for downloading from its web site.

5.8 SUMMARY

The team considers that, with the current exception of a process for authorization of decommissioning, STUK actually performs authorization consistent with requirements 23 and 24 of GSR Part 1 and other relevant safety standards.

The Government needs to establish a legal authorization process for decommissioning and closure.

STUK's approach in plant modification and safety class components approval are reflected in very broad and intensive authorization of all safety related items regardless to the other safety significance attributes of certain change. STUK may introduce some additional criteria to rearrange the load on graded way focusing more on safety significant items and less on less significant items.

STUK also should consider adopting formal authorization in spite that the inspecting of the dosimetry laboratory takes place regularly.

For its own uses of radiation, STUK should consider demonstrating, in a transparent manner, that it satisfies all the required regulatory conditions necessary for an authorization.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

Review and assessment is a prerequisite for any kind of authorization to be issued by STUK in connection with use of nuclear energy and radiation. Submissions requiring review and assessment are mainly associated with individual licensing steps of nuclear facilities and with modifications in nuclear facilities and radiation practices.

STUK performs thorough review and assessment by comparing the methods and results of the assessments provided in the licensee's submissions with safety requirements specified in the legally binding documents, and to more detailed level in YVL and ST guides. In addition to legally binding documents with safety requirements to be verified in review and assessment, STUK has a comprehensive system of regulatory guides. The most relevant are YVL guides (~71 guides) for use of nuclear energy and ST guides (~53 guides) for use of radiation. Review and assessment of information relevant to safety concerning radiation practices is conducted during licensing processes in accordance with the quality management guides SKV 3.2 and 3.4. Graded approach with respect to radiation risks of the practice is reflected in the scope of the required demonstrations.

Control of the review and assessment process up to the level of individual submissions is included in the SAHA electronic document management system, which covers selection of a coordinator for the review, recording and archiving submissions, task distribution among the reviewers, specification of intermediate actions, on-line monitoring of the review status, recording the STUK review/inspection reports and justification of the decisions taken. The document management system provides also for quality control of the review and assessment processes and documents. The system is a very important control tool having in mind large number of submissions.

STUK is working on further enhancement of the system to make the tool even more effective, and the team suggest in this enhancement to consider including also determination of review performance indicators, searching for previous decisions of the similar category in order to utilize experience feedback from previous submission, and providing automated link to relevant legislative or any other STUK safety requirements. There is more general suggestion on further enhancement of the management system in chapter 3 of the report.

More detailed description of the processes associated with review and assessment for different kinds of facilities and activities is given in the following sections.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

6.2.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The most complex documents requiring STUK's review and assessment are associated with the main licensing steps. For example, in the case of a construction licence, the documents include (in accordance with Section 35 of Nuclear Energy Decree) SAR, PSA Level 1 and 2, systems, structures and components classification, quality management, preliminary security and emergency plans, and plans for safeguards.

Many submissions related to NPPs belong to the category of the modifications, consisting of system modifications or component modifications, and include installation of new systems and components. In accordance with the Nuclear Energy Decree consistency with the plant design basis including detailed design documentation for structures, systems and components shall be reviewed by STUK as part of the

construction plan. This should be done in the design phase of the modification at three levels: plant level; system level; component level. The scope of the review of plant modifications depends mainly on the safety classification of the systems/components and on the scope of a modification. There are several other submissions requiring review and assessment by STUK (such as operational event reports, application for approval of selected organizations), which are less complex in comparison with licensing steps and less demanding in terms of manpower needed for the review.

In general, the number of submissions requiring review and assessment by STUK is enormous. STUK receives about 800 submissions per three months. In connection with construction of Olkiluoto 3 NPP, altogether about 14000 documents were reviewed, out of them 9000 with request for approval. About 50% of applications are devoted to approval of mechanical components. The large number of submissions is due to lack of content and quality of the original submissions which need to be complemented with additional documents. Quite large number of submissions is also originated from operating plants; example was given from Loviisa NPP with about 700 submissions per year (including both, units 1 and 2).

Internal STUK guidance for organization of the review and assessment is given in YTV guides. It was shown that this system of internal guides is very well developed. Nevertheless, STUK intends to continue developing additional internal guides in selected technical areas, such as automation, in order to further increase consistency and reduce the risk of subjectivity of the reviews. The IRRS team supports STUK's planned activities in this area.

There are annual plans for the regulatory activities prepared sufficiently well ahead of the beginning of the year. They are prepared by the project or subproject managers, in communication with the licensees. The plans identify needs of manpower for individual tasks down to the level of individual reviewers. The plans allow allocating necessary internal resources, as well as determining necessary external support. Regarding the future compliance with the plans there are some problems caused by delayed submissions from the licensees, and by very large number of certain types of submission (see section 5.2 of this report).

The need for interfacing with other authorities during the review and assessment concentrates mainly on major licensing steps, when in accordance with the Nuclear Energy Act, STUK shall ask for statement from the Ministry of the Interior regarding the issues of security and emergency preparedness. No difficulties were identified in this area.

The method and results of the regulatory review and assessment for major tasks, such as review of SAR, is documented in a detailed way, typically in a safety evaluation report. STUK demonstrated to the IRRS team the results of their review and assessment presenting the Olkiluoto 3 PSAR Inspection Report (usually called Safety Evaluation Report), published in January 2005. The report has more than 330 pages, and contains systematic assessments by STUK of all 20 chapters of the SAR. It includes also results of independent safety analysis, performed either by STUK directly, or by their main TSO - VTT.

A good example of feedback from previous regulatory actions was development of a document summarizing accumulated experience from licensing of Olkiluoto 3. The document describes all kinds of lessons learned from the licensing process, addressing such areas as project management, results from workshops, relevant international information, review reports, etc. The document also provides an input to updating YVL guides.

In view of the extraordinary number of submissions, prioritization of individual review is important. Major submissions related to the licensing steps are dealt with as projects (see section 6.2.2 of this report). The projects are categorized including their prioritization depending on their safety significance and

overall importance. Less complex submissions, like those associated with approval of component modifications are dealt with in the normal organizational structure of STUK.

6.2.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

For regulatory supervision of nuclear facilities STUK has staff capacity of more than 100 people in the Department of Nuclear Reactor Regulation. There is no strict subdivision of the staff into reviewers and inspectors, rather people are specialized according to their technical expertise. With an average age of about 48 years and relatively small turnover of the staff, there is no significant problem of maintaining technical expertise in the area of review and assessment thanks to the possibility of sharing experience gained during implementation of projects related to operating of existing reactors as well as contracting new ones. Existence of a national training programme also helps to recruit highly educated potential STUK inspectors.

Existing staffing allows, in spite of the very high number of reviewed submissions, that majority of work is performed by STUK internal staff. Nevertheless, also due to existing financing model (invoicing associated regulatory cost to the applicants) STUK has adequate possibilities for hiring external support organizations in accordance with their annual plans. Financial resources used for external support amount to about four million € per year. There are strict criteria for selecting external support organizations to support STUK decisions: competence in the area of review and assessment, independence from the licensee or vendor, availability of computer codes other than the licensees' codes, and adequately validated safety codes suitable for given reactor technology. Currently there are about 20 pre-selected organizations on STUK's list, including individual consultants from all over Europe. Their involvement in review and assessment tasks depends afterwards on actual needs. Among the most important external support organizations there are VTT, Lappeenranta Technical University, GRS, and ISaR Germany.

Major review and assessment submissions, such as Olkiluoto 3, VALVE (new construction projects), LARA (automation renewal of Loviisa NPP) are managed in accordance with the internal guide YTV 4.2.2 as projects, which are under control of a dedicated unit of STUK. Typical examples of the projects are submissions associated with

- New builds
- Licence renewals and PSR
- Extensive plant modifications, because of
    - Several technical areas involved
    - High safety significance
    - Long-time implementation schedule
    - Large amount of resources needed.

A matrix structure, with involvement of any necessary division of STUK, is used for execution of the projects. Individual contributors to the work are selected from various organizational units, as necessary, based on discussion between the head of project units and other organizational units. The projects are classified as A, B, or C depending on complexity of the project and level of the project control is determined accordingly. It was demonstrated on a number of examples that the projects are carefully planned and controlled.

In accordance with the Nuclear Energy Act, Section 64, STUK in review and assessment of major licensing steps asks for an independent assessment from the Advisory Committee on Nuclear Safety

"unless the change involved in the regulation is to be considered of minor financial significance, or such that its implementation must not be delayed". No difficulties were identified in this area.

STUK has available a basic set of computer codes for independent deterministic and probabilistic safety analysis (e.g. APROS, TRAB, TRACE, MELCOR, FINPSA). There is adequate interest, in particular among young STUK staff, in utilizing computer codes for safety analysis, so that STUK is capable to maintain its capability in performing independent deterministic and probabilistic audit analysis. The codes are used mainly for maintaining adequate background knowledge in STUK, while it prefers to hire external organizations (mainly VTT) specialized in performing safety analysis for performing audit calculations.

STUK does not operate any experimental facilities, but through the national research programmes and by contracting dedicated experiments to other organizations for regulatory support they have broad possibility of obtaining necessary experimental results.

6.2.3. BASES FOR REVIEW AND ASSESSMENT

The most relevant bases for review and assessment of nuclear facilities are YVL guides (~70 guides). Many of these guides are main reference documents for the review and assessment, in particular YVL 2.2 "Transient and accident analyses for justification of technical solutions at nuclear power plants", YVL 2.4 "Primary and secondary circuit pressure control at a nuclear power plant", YVL 2.7 "Ensuring a nuclear power plant's safety functions in provision for failures", YVL 2.8 "Probabilistic safety analysis in safety management of nuclear power plants", YVL 6.2 "Design bases and general design criteria for nuclear fuel". Complete updating of the guides is on-going including those for review and assessment, with implementation period 2012-2013. In draft updated guides related to review and assessment STUK reflects recently published IAEA Safety Requirements (SSR-2/1 and GSR Part 4 in particular) and associated IAEA Safety Guides, as well as international good practices applicable in deterministic and probabilistic safety analysis.

In spite of the elaborated system of YVL guides, there is no specific guide on format and content of Safety Analysis Report (SAR) for nuclear facilities. There is only a brief requirement in guide YVL 1.1 stating that example of the content of SAR is given in the IAEA Safety Guide GS-G-4.1. In accordance with the legislation and the YVL 1.1 guide, STUK has the right to request any detailed information on each facility at its discretion. This provision allowed STUK in the process of authorization to compensate the gaps by requesting additional topical reports. There were about 95 topical reports in case of Olkiluoto 3, devoted to many subjects, such as aircraft crash, classification, validation of codes, digital I&C, spent fuel pool, diversification, severe accidents, etc. In order to minimize unnecessary effort devoted to requesting and reviewing the topical reports during the authorization process and to enhance comprehensiveness of the SAR in the future, STUK should consider feasible ways for providing more specific guidance on format and content of Safety Analysis Report. In doing so STUK should continue ensuring full consistency with the current IAEA safety standards and use lessons learned from Fukushima accident, in order to minimize future excessive needs for complementary topical reports.

The issue of consistency of similar safety assessments included in different licensing documents submitted to STUK for review and approval was discussed during the mission. This issue is relevant mainly in connection with analysis of radiological consequences of reactor accidents, which is reviewed by STUK in Environmental Impact Assessment report, SAR and in background documents for emergency plans. While methodology for such analysis to be included in SAR is adequately described in YVL 7.2, it is less explicitly defined for EIA and for emergency plans. Since potential differences in results for the same facility may cause public doubts about the quality of safety demonstration, it is advisable in on-going updating of STUK guides to harmonize methodologies for radiological analysis in the listed

documents. Although no specific discrepancy has been identified, it is also advisable to check and harmonize, if relevant, radiological acceptance criteria and other regulatory requirements introduced in YVL and ST guides, respectively.

STUK has well elaborated system of acceptance criteria and associated assessment conditions for deterministic and probabilistic safety analysis, which is considered as a good practice. The system covers all plant states from normal operation up to severe accidents, including shutdown conditions, fuel loading and outages. Comprehensiveness of the system is considered a good practice. For example, there are two classes of design basis accidents depending on frequency of their occurrence, three classes of design extension conditions (DECs) without core melt plus severe accidents. One group of DECs specifically deals with Fukushima type events. Internal and external hazards are also broadly covered in the system, including a comprehensive list of natural and man-made external hazards. Radiological acceptance criteria are defined in accordance with SSR-2/1 for all plant states, including severe accidents. Additional margins are introduced into specification of acceptance criteria. For example, for Class 1 of design basis accidents the number of fuel rods with boiling crisis shall be less than 1 % and peak cladding temperature shall be less than 650 C. For class 2 accidents, number of damaged fuel rods is limited by 10 %. Validity of fuel enthalpy limits is limited by fuel burn-up up to 40 MWd/kg, unless the licensee adequately demonstrates acceptability of higher limit. Maximum acceptable LRF is 5E-7/year instead of generally accepted 1E-6.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 4 Para 3.3 states that** *"The main factor to be taken into consideration in the application of a graded approach is that the safety assessment has to be consistent with the magnitude of the possible radiation risks arising from the facility or activity. The approach also takes into account any releases of radioactive material in normal operation, the potential consequences of anticipated operational occurrences and possible accidents, and the possibility of the occurrence of very low probability events with potentially high consequences."*
(2)	**BASIS: GSR Part 4 Para 4.50 states that** *"The consequences arising from all normal operational conditions (including start-up and shutdown, where appropriate) and the frequencies and consequences associated with all anticipated operational occurrences and accident conditions have to be addressed in the safety analysis. This includes accidents that have been taken into account in the design (referred to as design basis accidents) as well as beyond design basis accidents (including severe accidents) for facilities and activities where the radiation risks are high. The analysis has to be performed to a scope and level of detail that correspond to the magnitude of the radiation risk associated with the facility or activity, the frequency of the events included in the analysis, the complexity of the facility or activity, and the uncertainties inherent in the processes that are included in the analysis."*
GP4	**Good Practice: STUK has established a comprehensive set of technical and radiological acceptance criteria and associated safety assessment requirements for all plant states including adequate consideration of different design extension conditions and severe accidents.**

6.2.4. PERFORMANCE OF THE REVIEW AND ASSESSMENT

The process of review and assessment is quite similar for all major licensing steps, in particular those associated with development and updating of SARs (not only for main licensing steps of nuclear facilities, but also periodic safety reviews, lifetime extension, power uprating and significant plant modification). In this regard, particular attention is devoted to review of deterministic and probabilistic safety analysis. In addition to verification of the methodological correctness in accordance with the YVL 2.2 and 2.8 guides, independent regulatory audit analyses are performed. STUK also promotes use by the licensees the advanced safety analysis methods, such as application of best estimate computer codes in combination with quantification of uncertainties by incorporating use of such methods into the currently being updated YVL guides. In addition, in accordance with the Government Decree on the Safety of Nuclear Power Plants Section 3 and STUK guide YVL 2.0 Section 2.3, the licensee shall independently verify the safety assessment delivered by the designer or vendor as essential component of demonstration of the prime responsibility of the licensee for safety. An example of independent assessment by the licensee of the design of electrical systems for Olkiluoto 3 including systems for station black out and severe accidents was presented to the team during the mission. STUK's approach in promoting independent verification of safety assessment and use of advanced safety analysis methods by the licensee are considered as commendable practices.

Supervision of operating experience feedback by STUK is performed according YTV internal guides (4.5.4 for Finish, and 4.5.9 for foreign NPPs). Operational safety unit and resident inspectors monitor plant status including operating events daily. The resident inspectors attend licensees' morning meetings and have access to some of their database (e.g. permit to work system and corrective actions). Use by the licensees of lessons learned from the events, both national as international, is verified during STUK inspections.

More details about Periodic Safety Review can be found in chapter 5 of this report.

Probabilistic safety analysis (PSA) is broadly used in authorization processes as well as in the NPP operation in Finland. STUK developed its own PSA computer code FINPSA, which was afterwards transferred to VTT for maintenance and further development. The code is now used in several other organizations. STUK has introduced a number of risk-informed licensing requirements. Licensees have to provide to STUK Level 1 and 2 PSA covering also internal and external hazards. STUK makes independent PSA analyses with its own code to verify the results provided by the licensee. In addition to demonstration of compliance with the probabilistic acceptance criteria, use of PSA is required by STUK for many other purposes both during construction as well as operation phase: risk informed in-service inspections, risk informed technical specifications, risk informed in-service testing, NPP staff training, development of emergency operating procedures, development of safety classification of systems, structures and components, incident and event analysis, selection of accident scenarios for emergency exercises, and selection of severe accident scenarios for which environmental consequences are assessed for licensing of the facilities. Extensive use by STUK of PSA results in demonstration and enhancement of NPP safety is considered a commendable practice. STUK is also capable to perform an independent review of PSA studies by its own internal staff. Nevertheless, in order to provide for independent review of the comprehensiveness and quality of PSA, STUK is advised to consider inviting an IAEA IPSART mission to perform such review.

Special attention was devoted by STUK to review and assessment associated with authorization of novel design solutions, such as implementation of in-vessel molten corium retention in Loviisa NPP, or hardware provisions for aircraft crash protection, as well as all hardware provisions for mitigation of severe accidents in Olkiluoto 3 NPP design. Airplane crashes are experimentally investigated in the Finish national nuclear safety research programme (SAFIR2010). Independent analyses of plant response to

airplane crashes were performed in two independent organizations. Each of the major challenges associated with mitigation of severe accidents (coolant system depressurization, core melt stabilization, containment heat removal, hydrogen management, containment filtered venting) were independently analysed by at least two organizations by two different computer codes. Hydrogen management was in addition to integral codes analysed also by Computational Fluid Dynamics code. Coolability of molten corium outside the reactor vessel was justified experimentally by independent simulation of a section of the EPR corium spreading compartment. The scope of special independent analytical and experimental demonstration for novel design solutions is considered as a good practice.

In accordance with the Section 55 of the Nuclear Energy Act "*the STUK may, upon request by anyone planning to use nuclear energy, check the plan drawn by them and issue preliminary instructions on what should be taken into account with respect to safety, physical protection and emergency planning*." This legal provision not only allows the applicant to approach STUK before starting the formal licensing process and so that to contribute from the early stage of the process to mutual understanding of safety issues, but also gives to STUK an opportunity to learn in advance about safety provisions of potential nuclear project. Without these provisions the communication between applicant and STUK would be impossible. It was also demonstrated during the mission that in general STUK has in place an effective communication mechanism with the licensees, including organization of frequent project meetings, workshops, topical meetings and exchange of documents.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 26 Para 4.42 (c) states that** *"In performing its review and assessment of the facility or activity, the regulatory body shall … to satisfy itself that, among other factors: … (c) Operational and technical provisions, and in particular any novel provision, have been proved or qualified by experience or testing, or both, and will enable the required level of safety to be achieved."*
(2)	**BASIS: SSR-2/1 Para 4.16 states that** *"Where an unproven design or feature is introduced or where there is a departure from an established engineering practice, safety shall be demonstrated by means of appropriate supporting research programmes, performance tests with specific acceptance criteria or the examination of operating experience from other relevant applications. The new design or feature or new practice shall also be adequately tested to the extent practicable before being brought into service…"*
(3)	**BASIS: GSR Part 4 Para 4.29 states that** *"Where innovative improvements beyond current practices have been incorporated into the design, it has to be determined in the safety assessment whether compliance with the safety requirements has been demonstrated by an appropriate programme of research, analysis and testing …"*
GP5	**Good Practice: For novel design solutions adopted in new reactors, such as those associated with mitigation of severe accidents and security threats, STUK has verified the demonstration of effectiveness of such solutions by extensive independent analytical and experimental justification, including use of relevant research results.**

6.3. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

Through the legal framework, the safety of spent fuel interim storage facilities is required to be subjected to a review by the regulatory body at each important step of their life cycle (accompanying licences for

construction and operation), and when a substantial modification of the facility is to be achieved, such as extension of capacity. Further a periodic review of safety is required at ten-year intervals.

It was noted that the requirements related to airplane crash and seismicity have been updated and are applicable to new facilities. During the expansion of Olkiluoto interim storage facility, substantial upgrading against external aggression was implemented. While there are no current plans for expansion at Loviisa the situation was evaluated previously. The outcome of the evaluation was that there are no design upgrades that can be reasonably implemented.

Following the Fukushima accident a review of the safety of spent fuel storage facilities at both NPP sites was undertaken. The review resulted in proposed improvements to the external water supply to the spent fuel storage pools and installation of instrumentation on water levels at the Loviisa site. Similar improvements had been approved at Olkiluoto site during the planned expansion of the spent fuel storage pools.

For Loviisa a seismic study of the spent fuel pool was conducted following the Fukushima accident and submitted to the STUK. This is currently under review by STUK. Similarly, in response to Fukushima, an evaluation of the fire suppression system is currently in progress by the operator.

6.4. REVIEW AND ASSESSMENT FOR WASTE FACILITIES

As specified by the regulations a periodic review of waste management facilities is required every fifteen years for the disposal facilities and every ten years for other facilities.

At present the review and assessment of spent fuel disposal are based on the suite of YVL guides that apply to nuclear facilities and two specific guides on disposal of spent fuel (YVL8-4 and YVL8-5). In addition new YVL guidance is in preparation and STUK is developing a review plan that identifies the areas of importance for demonstration of safety. The aims of the STUK review will be to evaluate the repository performance in particular the functioning of the multi-barrier system. While some dose criteria have been specified the bulk of the systems and their performance will be evaluated against qualitative criteria.

Considerable effort will be allocated to the:

- Quality of the data and research work carried out to characterize the barriers (bedrock, backfill, buffer and spent fuel canister)and their behaviour; and
- Assessing the various phenomena that may occur in the different time frames (construction, operation, and post-closure) that may affect the performances of the system.

The integrated performance assessment, aiming at determining the global containment performances of the system and the achievement of dose constraints will also be reviewed. In addition, STUK will address the monitoring programme that the applicant plans to implement in the facility.

In anticipation of the licence application for the spent fuel repository at Olkiluoto, STUK has implemented a project (PORA) to identify the technical issues and expertise required for the licence review. In addition STUK may make use of external Technical Support Organizations to assist in the technical review of submissions. In this regard, STUK has enlisted the support of VTT and other international consultants. The ratio of STUK internal capacity to consultants in review and assessment in the area of waste facilities is 3:1. The STUK personnel for the project will entail about 15 man years and the support of STUK personnel from other divisions of Nuclear Reactor Regulation will assist the waste division in the review.

Additionally STUK has closely followed the developments at the Onkalo site and has engaged in numerous technical discussions with the applicant Possiva to clarify issues associated with the anticipated licence application. The review of licence is anticipated to take between 18-24 months.

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES

STUK performs review and assessment mainly during licensing of facilities and activities using different application forms. According to the practice and the risk associated, the form should contain information that has to be provided by the applicants demonstrating the safety arrangements in place. STUK reviews the completed form to ensure the safe operation of the facility as part of the licensing process.

In case of complex practices, such as radiotherapy or use of accelerators, review and assessment is connected to inspection, as STUK in most cases performs a thorough inspection before issuing the licence. In most other cases the inspection is done after issuing the licence. The requirements regarding required information submitted to STUK are described in the Safety Guides for different types of practices which form the criteria against which STUK personnel perform review and assessment.

The use of graded approach in the review and assessment is mainly based on level of information required in the licensing application form depending on the type of facility or activity in question. In practice STUK allocates more time and resources for reviewing the more complex facilities. The results and decisions of reviews and assessments for each facility are registered in the STUK's archives, as well as in the Regulatory Data Management System VASARA.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

At present no decommissioning activities are being undertaken in Finland.

A decommissioning plan is required to be submitted to the Ministry of Employment and the Economy and updated every six years. STUK reviews the plans and comments on the acceptability of the plan. It is noted also that the current research reactor is nearing the end of its planned life and will require decommissioning in the near future.

6.7. REVIEW AND ASSESSMENT OF TRANSPORT

In Finland, about twenty to thirty thousand consignments containing radioactive materials are transported annually. The majority of these is delivered to hospitals. Other users are research facilities and industry. Additionally, radiopharmaceuticals are produced in Finland for domestic use and for export. Fresh fuel is delivered to Finnish nuclear power plants (NPP) about four times per year. A container with used sources is transported under special arrangements once every 1 to 2 years to Olkiluoto. Spent nuclear fuel is planned to be sent in the future to a final repository also at Olkiluoto.

Applications for approvals of transport of nuclear material are reviewed according to STUK's internal guides, Guide YTV 5.3.1 and Guide SKV 5.2. Compliance with requirements for transport is assured by inspection and by approving operator's plans for safety, security and emergency preparedness. The transport of non-nuclear radioactive material is not subject to authorization and review by STUK, unless sent by special arrangements. There is no design, manufacturing or testing of transport packaging, special form material or low dispersible material in Finland so validation mainly involves approval of package designs by foreign manufacturers.

6.8. SUMMARY

Review and assessment processes in STUK are well established and controlled. Large number of guides related to safety assessment to be performed by the licensees, as well as well as those for control of internal review processes are available, thus providing adequate framework for review and assessment. For nuclear power plants this framework includes a comprehensive set of technical and radiological acceptance criteria and assessment conditions for all plant states, including severe accidents. STUK approach to promoting the use of the best available methods of safety analysis in the authorization process, special attention put on independent regulatory analytical and experimental assessment of the novel design solutions should be recognized as very good regulatory performance.

Systematic reassessment according the evolving STUK documents led to the safety improvements of existing facilities. Graded approach to review and assessment depending of associated risk is in place. In spite of good results achieved there are always possibilities for further improvements. Lessons learned from previously executed reviews provide an input to updating STUK guides. Examples of specific areas where further improvements are advisable include complementing the set of STUK guidelines by a guide on format and content of safety analysis report, continuing development of internal review guides for other technical areas and enhancing consistency of analysis of radiological consequences in different authorization documents.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION APPROACHES, METHODS AND PLANS

Based on the provisions of the Nuclear Energy Act (NEA) and Radiation Act, STUK is responsible for the regulatory oversight of the safety of the use of nuclear energy and any radiation practices and has the right to inspect and control operations in nuclear and radiological facilities. For this purpose it has access to any place where such an operation is being carried out, as well as to carry out measurements required for supervision, to take and to receive samples and to install equipment necessary for such supervision. STUK has responsibility also for the regulatory oversight of the construction of a nuclear facility.

The nuclear installations and facilities subjected to the regulatory inspection by STUK are those situated on the Olkiluoto site (two NPP operating units - ABB BWRs, AFR storage, LILW repository, SNF Repository site with Onkalo URCF under construction, and 1 NPP unit under construction - EPR), on the Loviisa site (two NPP operating units - VVERs, AFR storage, LILW repository) and the research reactor FiR1located in Otaniemi in Espoo. The main radiological facilities subjected to the regulatory inspection by STUK are those 14 radiotherapy centres and 26 nuclear medicine laboratories.

The departments in charge of the inspection of nuclear installations and facilities are the Nuclear Reactor Regulation (YTO) and the Nuclear Waste and Material Regulation (YMO). Radiation Practices Regulation department (STO) is in charge with the inspection of radiological facilities.

The current overall inspection programme includes announced, unannounced, proactive, and reactive inspections. The inspection methods used by STUK consist of document reviews, interviews, walk downs, observation of activities, etc.

The majority of the inspections are proactive, pre-planned and announced, as part of the Construction Inspection Programme (based on the YTV Guide 4.6.1), on the Periodic Inspection Programme of the operating installations (based on the YTV Guide 4.6.2) and on the mandatory inspections prescribed in ST and YVL Guides for verifying the implementation of their provisions. The amount of unannounced (surprise) inspections is small.

The inspections are generally notified to the licensee in accordance with the procedure that applies for each type of inspection. However, if it is suspected that inspections notified in advance may not provide all the necessary information for regulatory decision-making on any particular area, a surprise inspection is carried out.

Reactive inspections are carried out as a consequence of an operational event or of an observation of an unsatisfactory situation. This activity is done based on a case by case decision without written criteria in the internal procedures.

The preparation for inspections and the reporting is the same for all types of inspection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-G-1.3 Para 3.10 states that** *"Reactive inspections, by individuals or teams, are usually initiated by the regulatory body in response to an unexpected, unplanned situation or incident in order to assess its significance and implications and the adequacy of corrective actions. A reactive inspection may be occasioned by an isolated incident or a series of lesser*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	events occurring at the particular facility under consideration. Similarly, a reactive inspection may be made in response to a generic problem encountered at another plant or identified by the review and assessment staff of the regulatory body. Unlike planned inspections, which are scheduled, reactive inspections are only partly subject to planning by the regulatory body and may disrupt regulatory programmes and schedules. The regulatory body should assume that there will be a need for reactive inspections and should plan to meet its needs for staff and consultants accordingly. For example, in implementing the inspection programme, the regulatory body should establish a graded approach in responding to unforeseen circumstances. All available resources may be needed in responding to a serious event, whereas in the simplest of cases only one inspector may be needed. This pre-established graded approach in responding to special circumstances will assist in determining the appropriate level of resources for use in inspections."
(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."*
S10	**Suggestion: STUK should develop criteria for initiating reactive inspections.**
S11	**Suggestion: STUK should consider conducting more frequent unannounced inspections of the facilities and activities under its regulatory control.**

One of the principles of the management system of STUK is that activities of the regulatory body should focus on most safety significant matters. For example, according to STUK 1.1 and 2.1, when decisions are made, the safety significance of the matter has to be understood and requirements shall be commensurate with safety and according to STUK 3.1, regulatory oversight shall be focused on topics of most safety significance. The same principles are described in YTV 1.2. However, in the inspection YTV guides, the use of a graded approach is not clearly defined for all areas of regulatory inspection. In the case of technical inspections on SSCs, the main consideration in applying a graded approach is the safety classification. But, in the view of the team, other factors should be taken into consideration in the implementation of a graded approach in accordance with the IAEA safety standards. These include, for example, the performance record of the licensee and of the facilities, the complexity of the activities being inspected, etc.

STUK makes use of the authorized inspection organizations or testing organizations for duties pertaining to the control of the compliance of the design and manufacture of mechanical components and structures of nuclear facilities of lower safety classes. A prerequisite for the approval of an inspection and testing organization is that the inspection or testing organization is operationally and economically independent and that it carries liability insurance. In addition, the inspection organization and testing organization shall have an advanced quality system, a competent and experienced personnel as well as appropriately qualified methods, facilities and equipment for manufacturing and operation. Periodic audits are made to authorized inspection organizations by FINAS (Finnish Accreditation Body) related to accreditation to ensure that their technical and organizational capabilities are maintained.

7.1.2. INSPECTION PROCESSES AND PRACTICES

STUK uses a set of inspection programmes as a tool for the regulatory control of nuclear and radiological facilities' safety, as well as to verify the ability of the licensees to manage safety at their facilities. Currently there are several inspection programmes developed by STUK in order to cover regulatory control of nuclear facilities under construction, commissioning and operation stage. Periodic Inspection Programme for decommissioning activities is under development.

In addition to these types of inspection, STUK is performing inspections required by YVL guides that address aspects related to the planning and implementation of outages, reactor reloading, periodic inspections in accordance with Guide YVL 3.8, periodic inspections of registered pressure equipment, modifications, repairs and preventive maintenance, etc.

All premises where radioactive sources are employed are inspected by STUK regularly every 2 to 8 years, based on a graded approach depending to the type and extent of the practice. The main objective of an inspection is to validate that radioactive sources are used safely and in accordance with legislation and conditions set in the licence. Amongst other verifications, the inspector shall verify the presence and location of each device containing a sealed source. Any discrepancies to licensing information concerning placing of sources, new sources acquired and sources transferred elsewhere, are recorded for amending the licence correspondingly.

The planning and implementation of the inspection programmes are made in accordance with department specific quality manuals and specific guides such as SKV Quality Manual, YTV Quality Manual and SKV and YTV internal guides.

The SKV and YTV inspection guides comprise framework documents describing the main components of the inspection programmes and of specific guidance. The specific guidance provided for the different facilities and areas of regulatory inspections is generally not very detailed, i.e. the YTV are inspection guides rather than inspection procedures or instructions. While this approach has the benefit of providing sufficient flexibility for inspectors to take the initiative in identifying and addressing new concerns as they arise, it places more reliance on the expertise of the staff, on the "inspector judgement" for determining the significance of the findings.

The IRRS team suggests that STUK reviews the current YTV guides and the training and qualification programme for the inspectors, in order to determine the optimum balance regarding the degree of detail of the guidance provided to inspectors and considers supplementing these with more detailed procedures, instructions checklists and questionnaires, as appropriate, to ensure the consistency and uniformity of regulatory control. The systematic approach to training concept should be applied during the development and implementation of the training programme.

The process flowcharts for the various inspection processes are not currently provided in the YTV guides and the interrelation of the different inspection guides are not represented in a manner to allow an overall view of all the components of the regulatory inspection programme. It would be beneficial that STUK develop the process flowcharts for the various inspection processes in order to provide a clear image of all the components of the regulatory inspection programme, as well as of the interfaces, interactions and feedback loops between the inspection process and the other core regulatory processes (authorization, review and assessment, enforcement and development of regulations and guides).

The notification of the licensees about forthcoming inspection at the nuclear facilities is made at least 7 calendar days in advance by means of the IT TARKKA system. The inspections findings and regulatory requirements resulted from inspections are presented in inspection protocol (inspection report). The inspections are documented in a database that is used to follow-up the inspection findings. STUK's inspection findings are communicated directly to the licensee after an inspection. The person responsible

for the inspection reports on the findings and requirements of the inspection at the quarterly meetings arranged by the person responsible for the Periodic Inspection Programme. The person responsible for the inspection drafts a short summary of the inspection which is published in the quarterly report.

The results of inspections performed in radiological facilities are reported and kept as hard copies at DRPR and also stored in the Regulatory Data Management System VASARA. A copy of the inspection report is send to the licensee. The report contains the results of the inspection and the corrective actions that need to be implemented by the licensee. If during the inspection a serious violation is discovered the inspector, in accordance to the Radiation Act, can stop the practice immediately.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 29 states that** *"Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 1 Para 4.50 states that** *"The regulatory body [...] shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
(3)	**BASIS: GS-G-1.3 Para 4.10 states that** *"The particular aspects that should be considered in determining the intervals between inspections in the various areas and the level of effort to be applied in the inspection include:* - *the safety significance of the issues;* - *the inspection methods and approaches used (for example, the use of resident inspectors may influence the intervals and the intensity of inspections);* - *the qualified personnel and other resources available to the operator;* - *the performance record of the operator and the facility, for example, the number of violations, deficiencies, incidents and problems and the number of reactive inspections;* - *the results of the regulatory review and assessment;* - *the type of facility;* - *the personnel and other resources available to the regulatory body;* - *the results of previous inspections.*
(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. The guidelines should be followed to ensure a systematic and consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise."*
R6	**Recommendation: STUK should extend the use of the graded approach for planning and conducting inspections across all regulated facilities and activities. STUK should develop more detailed procedures in this regard.**

The current performance indicators used by STUK to assess the inspection process are limited to the number of the inspections and number of the inspection days. The use of these limited number of the performance indicators is insufficient for providing accurate information for the assessment of the effectiveness of the inspection process and programme. Internal audits as well as self-assessment are two methods that could be used to assess the effectiveness of the inspection programme but these are rarely used by STUK in this regard. It would therefore be beneficial that STUK implement an audit and self-assessment process for the review and monitoring of all aspects of its inspection and enforcement activities in order to ensure that they are being carried out in a suitable and effective manner.

7.1.3. INSPECTORS

The regulatory control of nuclear installations is done by STUK's personnel involved equally in licensing and review and assessment activities.

Based on Section 63 of the Nuclear Energy Act, STUK inspectors have the right to inspect and control operations in nuclear and radiological facilities and for this purpose have access to any place where such an operation is being carried out, as well as to carry out measurements required for supervision, to take and to receive samples and to install equipment necessary for such supervision.

Each new comer in STUK receives in the first year of employment an initial training in accordance with the established curricula. Subsequent training subject are established based on the individual's foreseen activities. From the discussion with STUK personnel and the presented documents, the IRRS team was not convinced that the training programme is following a systematic approach to training concept. Aspects related to the formal qualification and continuous training programme are not part of the training programme at STUK.

Approximately 65 staff members of STUK participate to the implementation of regulatory inspection programme for nuclear facilities, around 15 of them being appointed as "inspection leader" during inspections. There is no formal qualification process for the responsible leaders, these persons being appointed based on their experience and expertise.

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: GSR Part 1 Para 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills.* *The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."*
S12	**Suggestion: STUK should consider developing a formal qualification programme for inspectors of nuclear facilities as well as nuclear materials and waste.**

Highly qualified STUK resident inspectors are placed permanently at Olkiluoto and Loviisa sites.

The on-site inspector records the findings in the weekly report about NPP operating units, and this is sent to Nuclear Reactor Regulation's circulation list for information. For facilities under construction, the weekly report is appended to the minutes of the weekly monitoring meeting. The onsite inspector also participates in the regulatory control meetings organized by Operational Safety which works on putting the Projects and Operational Safety group's summary into Nuclear Reactor Regulation's quarterly and annual reports. This meeting decides on which of the findings related to the functioning of the organization will be brought up in Nuclear Reactor Regulation's overall assessment discussion. The on-site inspectors at facilities that are under construction participate in the project's weekly monitoring meetings. Findings that require urgent action are processed immediately at the facility and are brought to be processed by the Operational Safety Section, Projects and Operational Safety's Assistant Director, relevant project manager and Nuclear Reactor Regulation's management.

In case of complex practices such as radiotherapy or use of accelerators, STUK performs an inspection before issuing the licence. In most other cases the inspection is done after issuing the licence. STUK has written procedures in place for conducting inspections which have been described in the Quality Manual SKV 3.4 on Inspection at Radiation Practices Premises, last revised in March 2011.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

The Nuclear Reactor Regulation department of STUK develops annual regulatory inspection plans for the Finish Nuclear Power Plants. The annual inspection plans address operational stages. These regulatory inspection plans are addressed in the Construction Inspection Programme and in the Periodic Inspection Programme, respectively.

The Construction Inspection Programme for Olkiluoto 3 nuclear power plant is a more flexible programme that has half year planning and execution cycle. The purpose of the programme is to verify that the performance and organization of the licensee will ensure high-quality construction and implementation in accordance with the approved designs while complying with the regulations and STUK's decisions.

STUK has collected experience from the OL3 oversight since the very beginning of the construction of the facility. In addition to this, STUK has recently developed a database with the goal of collecting all oversight findings which are not reported through the protocols or decisions. The database is intended to collect in one place all the findings recorded during construction activities. It is assumed that this approach will improve the assessment of the organizational and management system issues as well as the safety culture oversight process. The system runs currently as a pilot project during construction of (OL3) and for the next new build projects (Olkiluoto 4 and Fennovoima 1).

STUK's Periodic Inspection Programme is focused on the licensee's main working processes and covers management and organizational aspects, broad overlapping processes (such as assessment and improvement of safety, safety functions, PRA, ageing management, operational safety, radiation protection and emergency preparedness), as well as detailed technical issues. During the mission, the IRRS team noticed that the inspection and assessment of the licensee's safety culture is not done in a consistent manner with respect to collection of all findings from the regulatory oversight.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Para 4.53 states that** *"In conducting inspections, the regulatory body shall consider a number of aspects, including:* *[...] — Safety culture. [...]."*
S13	**Suggestion: STUK should consider the development and implementation of a more systematic method to collect indications of and assess the licensee's safety culture.**

The annual inspection plan is developed for the Nuclear Power Units in operation with the purpose to be implemented in a period of 1 to 3 years. STUK uses the annual report of the previous years' findings in addition to the YTV guidance in forming the plan.

STUK's Periodic Inspection Programme for operating nuclear power plants has been assessed and updated frequently. The latest changes into the programme were made early 2012. The programme is described in Guide YTV 4.6.2. Each year STUK defines the programme for the next year including additional inspections as needed in order to incorporate any specific issues that may arise based on regulatory activities. The inspection programme may be supplemented with ad-hoc inspections during the year if deemed necessary.

The criterion for prioritization of the inspections and bases for establishment of their frequency is not documented in the STUK's inspection guidelines. The team therefore recommended a review of the inspection guidelines in accordance with the recommendation provided above (graded approach).

The results of inspections and other control observations of the operating nuclear power plants are considered at especially themed OPERA meetings, which are held on a quarterly basis. Observations are compiled and a plant-specific status assessment is formed in accordance with the areas presented in section 4.4.2 of YTV 4.1.2.

Quarterly and annual summaries on the different areas are drafted to assess the situation for each area and present the most significant control and inspection findings.

STUK also has strong on-site presence by the resident inspectors. This provides STUK constant flow of information and oversight capabilities. STUK has open and direct communication practices with the licensees. This gives further information on licensee's activities.

<u>Inspection at the Olkiluoto Nuclear Power Plant</u>

The IRRS team observed two inspections at the Olkiluoto NPP. One inspection was part of the construction inspection programme for the OL 3 NPP, the second one was an installation inspection according to the YVL Guides. In addition the team took interviews with three resident inspectors responsible for OL 1, 2 und 3 NPPs and with a representative of the plant management.

The first inspection observed was carried out by an inspection team (three inspectors) from STUK and covered the area of Deterministic Safety Analysis. The inspection areas were communicated to the operator in advance of the inspection.

Prior to the inspection there was a short meeting of the IRRS team and the STUK inspectors. In this meeting the STUK inspectors explained the relevant procedures, the goals and the basis for the inspection (STUK Guides YVL 2.2, 7.2 and 7.3). Based on these Guides the STUK inspectors had prepared a detailed list of topics to discuss. The team got the impression that the inspection was well prepared and that there was a clear understanding of the goals and the basis for the inspection.

The IRRS team observed the meeting partly. There was room for a frank, open and safety oriented discussion. At the exit meeting the inspection leader informed the plant staff of the results of the inspection. Based on the type of the inspection (proactive) and the safety relevance of the findings there was a decision of the inspection team that there will be no requirement in the inspection protocol. Nevertheless there were some findings communicated to the licensee. These findings will be documented in the inspection protocol and they will help the licensee to proceed in the foreseen way. The IRRS team considers the decision of the inspection team as reasonable and safety oriented.

The IRRS team observed a second inspection partly. The content of this inspection was installation inspection for safety class 2 piping. The inspection was carried out by a STUK inspector. This inspection was also well prepared and carried out in a professional manner.

The IRRS team had an interview with a plant manager concerning the activities of STUK inspectors. The plant manager stayed for more than 30 years with the power utility. From his point of view the STUK inspectors are competent. Their decisions are understandable and reasonable. Safety relevant topics can be discussed properly with them. The manager pointed out that very experienced inspectors left STUK and that therefore for the new inspectors an adequate training programme to clarify the role and the activities is needed.

The IRRS team had an interview with three resident inspectors. Their role and their duties are described in STUK Guide YTV 2.1.3 and 2.1.4. They take part for example in the morning meeting of the operator, they perform plant walk downs and they prepare a weekly report for STUK headquarters. There are clear instructions for them in place in case of an emergency. The resident inspectors stay for a long time at one plant. During the discussion with STUK managers at STUK headquarters the IRRS team got the impression that the topic of a possible regulatory capture of the resident inspectors is recognized by the management. STUK's management explained that

- The responsibilities of the resident inspectors are limited;
- All regulatory decision are taken in the headquarters or by headquarters staff at the plant; and
- STUK's management has the possibility to remove a resident inspector if there is a hint of regulatory capture.

Nevertheless, the IRRS team recommends further consideration of this topic within the safety culture suggestion given in chapter 4 of the report.

In addition, up to now there is no guidance for the resident inspectors especially for their plant walk downs and routines in accordance with the graded approach. The IRRS team suggests that such guidance be developed. With such guidance the knowledge of the resident inspectors can be preserved and it can be make sure that all relevant parts of the plant are covered.

In summary, the inspections were carried out in a professional and competent manner, and the operator was similarly responsive and professional. Based on the interactions between the inspector and the licensee's staff, the communications between the STUK inspectors and the operators appeared to be open, frank, and safety-focused.

7.3. INSPECTION OF FUEL CYCLE FACILITIES

The regulatory framework, planning and implementation process for inspecting nuclear fuel cycle facilities described in chapter 7.1 is applicable in this case as well. No specific issues were identified in this area, it was however noted that as for waste management facilities, staff involved in reviews are also involved in inspections. This is good in that reviewers are aware of the in plant conditions and inspectors are aware of the safety documentation.

7.4. INSPECTION OF WASTE FACILITIES

Regular inspections are conducted at all waste management facilities.

The team accompanied STUK inspectors on an inspection of the Onkalo underground rock characterisation facility. The inspection focused on construction activities at the facility and included review of the operator's management of sub-contractors, data acquisition related to water infiltration during shaft sinking. The team found the preparation and conduct of the inspection to be in line with what was expected in terms of the STUK management system.

It was noted that STUK has implemented a programme of inspection and review of technical issues related to regulation of the Onkalo rock characterisation facility in preparation for the review of the construction licence application that will be received in December 2012. This is considered to be good as STUK is able to identify issues of concern and the need for further clarification of assumptions that will substantiate the safety of the repository system.

Further the team visited the LILW waste repository operated by TVO at their Olkiluoto site.

In accordance with Guidance issued by STUK (YVL 8.1) it is required that wastes shall be conditioned and packed in accordance with disposal specification. It is noted that failure to comply with the waste acceptance criteria could impact the overall safety of the disposal facility during the operational phase and potentially in the long term, it is therefore important that STUK verifies that the disposal operator has sufficient demonstration that waste disposed in the repository complies with the waste acceptance criteria.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES

The inspection programme used by STUK contains elements of graded approach as those practices of higher risks are more frequently inspected compared to others. STUK has a process for developing annual inspection plan but it is not documented in their internal quality managements guides. During interviews an example was demonstrated to the team. It also appeared to the team during the discussions that some elements of the process such as the frequency of the inspection could be reviewed (see recommendation 6).

Mostly announced inspections are being conducted by STUK to check the compliance of the licensees with the safety requirements. The IRRS team was informed that un-announced inspections are rarely to be conducted. This practice seems to be common for all inspection activities, and therefore a suggestion to increase the number of announced inspections has been proposed in chapter 7.1.1 above. STUK has identified this as an action to be done in their preliminary action plan.

Inspections of all radiation practices are being carried by the DRPR. Specific check lists for inspecting different types of facilities and activities are being used by STUK's inspectors during inspections. Effective use of these checklists was noted during the site visits conducted. As part of the inspection, STUK assesses the training of the staff of the licensed organizations.

The IRRS team was informed that, licensees are required to conduct annual inventory check of the radioactive sources under their responsibilities. The inventory reports are being verified by the inspectors during the normal inspections. In case of high active sources the licensees are obliged to send the verification report annually to STUK.

Inspection at Porvoo Thermal Energy Power Station:

The IRRS team accompanied one inspector from the Department of Radiation Practices Regulation (DRPR) of STUK to inspect Porvoo Thermal Energy Power Station. The facility is equipped with Co-60 and Cs-137 sources used as industrial level and density gauges. The activities of the sources range between 40 MBq to 4000 MBq. The inspection included areas such as sources inventory check, the radiation protection officer training, safety and security systems, radiation signs and monitoring of sources and the areas around. The inspection started by a round table discussion/interview with the radiation safety officer (the Manager of the facility) and the relevant staff. All sources records were checked by the inspector. The inspectors then proceeded to the locations where sources are fixed to conduct visual inspections to the sources and the radiation signs around each one. The inspector conducted a dose-rate measurement around each source. The inspector of STUK conducted the inspection in a professional manner and had a cooperative attitude with the radiation safety officer of the facility. An inspection check list was used by the inspector during the interview and during the inspection.

Following the observation, an exit briefing was conducted with the radiation protection officer of the facility and findings of the inspection were presented and discussed.

In a separate discussion, the licensee representatives highlighted the good contact they established with STUK.

Inspection at the Radiotherapy Department of Turku University Hospital:

The IRRS team accompanied two inspectors from the Department of Radiation Practices Regulation (DRPR) of STUK to observe the inspection at the Radiotherapy Department of Turku University Hospital in Turku. The inspection verified elements related to medical and occupational exposures. A medical accelerator facility and a newly constructed high-dose rate brachytherapy facility were inspected during this visit. The inspection included general safety arrangements, doses measurements to confirm adequate shielding, verification of the adequacy, placement and functionality of safety systems. Inspectors conducted independent verification of dose planning and treatment delivery systems and source activity using a variety of tools and equipment. The inspection was systematic, comprehensive and meticulous. Communication with the licensee was open, and conducted in a professional manner with full cooperation of licensee staff.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

There are currently no decommissioning activities in progress in Finland.

7.7. INSPECTION OF TRANSPORT

The transport of nuclear material is subject to inspection, unless the quantity is so low that it is below exemption limits for the transport licence. Inspection on the road is carried out with the cooperation of the police. The IRRS team was informed that there was a limited number of transports of fresh nuclear fuel, approximately four times per year. There used to be transport of spent nuclear fuel when it was returned to the Russian Federation. The transport of spent nuclear fuels will however increase considerably in the coming years when the final repository will be in operation, and STUK has recognized that this is a challenge to be met.

When transport is a part of a licensed practice (as in industrial radiography), the transport arrangements are inspected by STUK as a part of the inspection of the practice even though the transport as such is not subject to licence.

As the Radiation Act does not require a specific licence for transport of non-nuclear radioactive material, STUK has no detailed information on carriers. However, being the competent authority for the transport of radioactive materials, STUK is responsible for monitoring compliance with transport regulations and it assessed the doses due to transport several years ago, but there is no systematic process for it. STUK has identified this issue in its action plan. There are on-going discussions at the EU level to ensure consistency of the transport directive and the radiation protection directive, with a view to establish a system of notification for the carriers, so that national registers could be established. STUK is supporting this proposal to facilitate its regulatory control of radioactive material transport.

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."*
(2)	**BASIS: TS-R-1 Para 308 states that** *"The relevant competent authority shall arrange for periodic assessments of the radiation doses to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with the basic safety standards."*
S14	**Suggestion: STUK should consider initiating an inspection programme that includes periodic assessments of the levels of workers' doses in different types of transport activities in cooperation with the relevant regulatory agencies.**

7.8. SUMMARY

Based on the documents reviewed and on the interviews conducted, the IRRS team concludes that STUK has comprehensive inspection programmes for nuclear and radiological facilities. These programmes cover the relevant areas required by the IAEA Standards and Guides. The IRRS teams took part in three inspections at the nuclear and radiological facilities. The STUK inspectors conducted these inspections in a competent and professional manner. Based on the interactions between the inspectors and the licensee's staff, the communications between the STUK inspectors and the operators appeared to be open, frank, and safety-focused.

The IRRS team acknowledges that STUK's inspection practice is in line with the IAEA requirements but there is room for improvement. The recommendations and suggestions provided by the IRRS team are aimed to optimize the existing inspection process implemented in STUK.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

The legal basis for enforcement for nuclear installations is described in the Nuclear Energy Act Sections 63 to 69. The act gives well defined powers to STUK. According to Sections 64 and 65 STUK can require changes in the construction and use of a nuclear facility or removal of defects and faults based on safety findings. The act empowers STUK to take coercive measures including conditional fines, threat that the activity is interrupted or limited and the threat that the necessary work is done at the cost of the neglecting organization.

Section 67 states that in case of an immediate danger the operation can be interrupted or limited. The act also enables STUK to ask executive assistance from other authorities to fulfil their duties.

In very severe cases, if the implementation of general principles for the use of nuclear energy as laid down in the Nuclear Energy Act is essentially endangered the authority that has granted the licence may cancel it wholly or partly (Section 26 of the NEA). STUK doesn't have the right to grant a licence and therefore STUK can't cancel a licence. In such a case STUK has to prepare the basic facts for the decision and to transfer these facts to the Licensing authority. However, in case of an imminent radiological hazard to workers, the public or the environment, STUK has the authority and will take whatever actions are necessary to restore an adequate level of safety and prevent unreasonable risk to the health, safety, security and the environment.

According to the NEA (Section 9) it is the task of the licensee to assure the safe use of nuclear energy. Therefore the enforcement actions based on a violation of the NEA are primarily addressed to the licensee and not to an individual. This is in accordance with GSR Part 1 Para 4.57. Only in the case of an intentional violation, the penal code comes into action.

8.2. ENFORCEMENT IMPLEMENTATIONS

No issues related to implementation of enforcement in the areas of nuclear fuel cycle, decommissioning, radiation practice and waste management were identified.

The enforcement policy of STUK is specified in the STUK Guides 3.1 (Regulatory Control of Radiation Practice and the use of Nuclear Energy) and in a more detailed form in the Guides 6.1 (Document Handling), 6.3 (Enforcement of Regulatory Decisions) and 3.7 (Enforcement Procedures in the Regulatory Control of the Use of Radiation). The Guides content an explanation of the general policy and provide example situations (see for example Guide YTV 6.3, chapter 4.2).

Within these Guides a graded approach is described. Based on the safety significance of the assessed deviation there are coercive measures. It is clearly stated in the Guide that the objective of the measure is to achieve a verified correction to the licensee's operation. Some of the measures can be executed by an individual inspector (Inspectors oral notice and Inspectors request for action by a protocol), the more severe measures (written notice, order to take measures, imposing a conditional fine by STUK decision, threat of interruption or restriction of operations) have to be issued at STUK headquarters and signed by STUK's management. In case of severe measures (order to take measures, imposing a fine, interruption or restricting an activity) the decision is notified to the Ministry of Employment and the Economy for information and dependent on the situation to the Ministry of the Interior (security reasons). In all cases of severe measures a press release is prepared. The involvement of the applicant including the consultation obligation related to the preparation of the decision is described in STUK Guide 6.1.

The most often used enforcement tool in STUKs regulatory practice are the oral notice and STUK's decision. The more severe enforcement tools are very rarely used. Therefore there is not so much experience in STUKs staff concerning these enforcement measures. To close this gap the IRRS team suggests a training programme for inspectors on this topic. STUK has identified this matter within their self-assessment and has implemented it in their action plan.

In the case when STUK uses an inspection organization, STUK is responsible for the enforcement of findings of this organization. If there are deviations from the requirements within the work of this inspection organization these deviations have to be reported to STUK. If there are enforcement measures related to this activity needed it is the responsibility of STUK to do this. The IRRS team considers based on the presented documents and the interviews that there is a clear understanding within STUK about the role of STUK in this process.

STUK presented the IRRS team three examples of the use of enforcement tools for NPPs within their regulatory practice. The first example illustrates a STUK's decision (Olkiluoto unit 1 main steam isolation valves repair on power, 2009) where STUK required updating a work plan with respect to the ALARA-principles. The second example (Loviisa unit 1, operability of pressurizer spray system during start up, 2012) shows that STUK made a decision that the plant shall be brought down to the hot shutdown state with respect to the fact that there was not enough proof that the spray system is fulfilling the OL&C requirements. The third example was a decision of STUK Director General (Olkiluoto unit 2, faults detected in overpressure protection system valves, 2011). He required that the Olkiluoto 1 plant (in operation at that time) has to be repaired within three weeks. The consequence was an additional repair outage.

In radiation practices the Radiation Act provides STUK with the authority to carry out enforcement actions in relation to non-compliance with the act or safety guides in relation to radiation safety.

The power of STUK to control radiation practices and to enforce regulatory requirements is prescribed in Chapters 14 and 15 of the Radiation Act (592/1991).

An order to discontinue or restrict a practice can be issued by an individual inspector onsite if a practice causes an obvious detriment to health or the danger thereof. In this case the Section Head and the Director of the Radiation Practices Regulation Department have to be informed without delay. The order is confirmed formally later by a written decision by the Director of the Radiation Practices Regulation Department.

Section 54 of the Radiation Act provides STUK with the authority to issue orders pertaining to ensuring the safety of radiation operations. This act also provides STUK with the authority to amend or revoke a licence issued if it is found that the conditions under which it was issued are no longer complied with or serious violations of the radiation protection rules have occurred. STUK's enforcement policy is described in the quality management guides SKV 3.7.

Enforcement actions are implemented by STUK with regard to radiation practice as a result of inspections carried out during the authorization process, or as a result of announced inspections of authorised facilities and activities. The following enforcement actions are used:

- Verbal notification of non-compliances requiring corrective actions at the conclusion of the inspection;
- Written notification of non-compliances requiring corrective actions in the report of the inspection. The time period allowed for the implementation of the corrective action is related to the magnitude of the risk associated with the non-compliance. Follow-up inspections are carried out to ensure that the corrective actions have been made by the licensee;

- For severe non-compliances, written notification is sent prior to sending the full report of the inspection;
- If the licensee has not corrected the non-compliances, as observed through follow-up inspections, then the enforcement of regulatory requirements can be pursued through the judicial system.

8.3. SUMMARY

Based on the interviews and the review of the presented documents the IRRS team states that the Nuclear Energy Act and Radiation Act gives STUK adequate enforcement tools to fulfil their duties. The examples show that the graded approach for NPPs described in the STUK Guides is in action. The IRRS team states that the reaction of STUK to non-conformities in the presented cases was clearly related to the safety significance of the non-conformity. STUK has a well described process to do enforcement actions.

In radiation practices enforcement actions as well as the graded approach are being implemented in accordance to international requirements.

Nevertheless it is STUKs policy not to threat the licensee with fines or penalties. STUK wants to motivate the licensee on high level quality of work and safety culture and to encourage on straight discussions with the regulator. The IRRS team considers this policy as reasonable and safety oriented.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

Development of regulations and guides

In Finland, legally binding regulatory principles and requirements are stipulated through relevant acts of Parliament and (mainly) through specific Government or Ministerial decrees. Appropriate authorization in the Law allows Government or individual Ministries to issue decrees in defined areas. STUK makes proposals for the development of legislation related to its competence according to the Decree on STUK. The Ministries (Social Affairs and Health, the Interior, Employment and the Economy) are those who have the legal basis to initiate changes to the legislation. Therefore, STUK needs to cooperate with relevant ministries in the legislative process to maintain an appropriate framework of regulatory principles and requirements relevant to its areas of competence. As STUK's authority in this legislative process is not precisely defined in existing legislation, the IRRS team recommends measures (see Section 1.3 of the report) that would align the situation in Finland in this area with IAEA requirements and best practices.

Inside STUK, the decision to prepare a proposal for a new Government decree or renewal of an existing one is at the discretion of the Director General. A project involving relevant STUK departments and experts is launched in each case. The timetable and possible constraints for preparation are discussed with the relevant Ministry at a very early stage. STUK prepares a justification memorandum that includes a general justification regarding the impact of the requirements with respect to financial aspects, society, environment and regulatory activities together with the draft text of legislation. The proposal for any new text or amendments to an existing decree is subject to several levels of scrutiny. The first level of scrutiny is organized inside STUK and includes consideration of feedback collected from the licensees and other relevant stakeholders. The next level of scrutiny is where the proposal is submitted together with the justification memorandum to the Advisory Commission for Nuclear Safety and Advisory Commission on Nuclear Security when relevant. It is only after discussion in the advisory committees is completed that the Director General decides the final draft and submits it together with the justification memorandum to relevant Ministry. This Ministry then carries out the official hearing and organizes/coordinates the process for final adoption of a new decree or amendment of existing one.

Based on provisions in Radiation Act and Nuclear Energy Act, STUK issues detailed regulatory guides (YVL, ST, VAL) to provide details relating to the main principles and requirements stipulated in acts and decrees. The legislation together with YVL and ST guides constitute an integral system of regulations for the use of nuclear energy and the use of radiation. Some of the requirements in the YVL and ST regulatory guides are overlapping.

The regulatory guides are not legally binding. The licensees have the right to propose an alternative procedure or solution to that provided in the regulations. If the licensee can convincingly demonstrate that the proposed procedure or solution will implement safety standards in accordance with or greater than the regulatory guides, STUK may approve the procedure or solution by which this safety level is achieved. In addition, STUK can approve exemptions to the YVL and ST guides if this is properly justified.

Review and updating of regulatory guides

STUK has a system for periodic review and upgrade of regulatory guides. The status of the regulatory guides is considered in the annual work planning and budgeting process. The preparation process of the regulatory guides includes internal hearings, external hearings of the stakeholders, and review by STUK's relevant advisory commissions and committees. The public participation is made possible through the website of STUK where the drafts for external hearings and all the regulations are also available. There

are criteria for the review and updating of the regulations: each guide has to be evaluated five years after publication and all guides need to be updated after ten years. There are more than 120 regulatory guides in use for all areas of STUK competence. Relatively stringent criteria for updating regulatory guides create quite a high demand for resources. This applies especially for radiation safety area, where major modifications both in legislation and regulatory guides are expected arising from the upcoming revision of the Euratom Basic Safety Standards directive.

In 2006 STUK launched a comprehensive programme for renewal of YVL regulatory guides. The goal of this renewal is to have more user-friendly and consistent guidance to the stakeholders. In addition the guides will incorporate relevant international guidance (mainly IAEA and WENRA), and take account of STUK's regulatory experience. Last but not least, the renewal programme will implement the graded approach into the safety guidance to a greater extent than already exists. At the beginning of the YVL regulatory guide renewal project a new form of stakeholder involvement was established. For each of the YVL regulatory guides a reference group composed of experts from stakeholder organizations was established. In addition a reference group for the overall project for renewal of the regulations was established. These groups help to take into account stakeholders' feedback more efficiently and in a timely manner. The remaining timetable for the renewal programme is quite demanding and is planned to be completed for the major part by the end of February 2013. Deadline for that part of the guidance related to structures and components of a nuclear facility is end of August 2013. The new set of regulatory guides will have high degree of consistency with the IAEA requirements and up-to-date best practices. The IRRS team therefore encourages STUK to complete the comprehensive renewal programme and proposes to STUK to use the experience gained with safety regulatory guides (YVL) in renewing guides in radiation safety area (ST). In this area STUK may encounter financial and human resources constraints, especially after the revised Euratom Basic Safety Standards directive has been approved.

Compliance of legislation with international standards and best practices

Legislation in Finland and STUK regulatory guides are regularly checked for compliance with international standards and recommendations (mainly EU, IAEA and WENRA). It is primarily the responsibility of STUK to undertake the appropriate screening and propose appropriate modifications (legislation) or implement (regulatory guides) latest developments at international level.

The new edition of YVL regulatory guides is benchmarked against IAEA requirements and WENRA reference levels. ST regulatory guides are subject to similar scrutiny. Relevant legislation and ST guides will be benchmarked against new BSS when adopted. In the radiation safety area the support to the legislative process (both at national level and EU level) together with necessary development/upgrading of regulatory guidance represent a major challenge for STUK with respect to availability of appropriate human and financial resources. The IRRS team has reflected this situation in its chapter 1 recommendations/suggestions.

Finland is a member of the EU and thus Euratom regulations, directives and decisions are followed in Finland. EU directives are implemented through Finnish legislation. EU Commission and Council regulations are directly applicable. STUK participates actively in the preparation of safety standards and recommendations of international organizations such as IAEA, ICRP, WHO, UNSCEAR, ILO, WENRA, OECD/NEA and of standardization organizations like IEC and ISO. International standards and recommendations are also used as references when preparing the Finnish safety requirements on nuclear and radiation safety (see above).

Finland is also a party of all relevant international conventions and agreements. These conventions and agreements are implemented through the Finnish legislation.

Fukushima lessons learned

In the area of regulations and guides STUK reacted to Fukushima accident promptly. There is already a package of proposals arising from a review of Fukushima that is available to allow modification of legally binding legislation.

All YVL guides affected by lessons learned from Fukushima are planned to be modified by the end of February 2013, or by the end of August in case of those related to structures and components of nuclear facilities.

At this moment STUK is probably one of the most advanced nuclear safety regulators in the preparation and implementation of relevant changes to its regulations and guides with respect to lessons learned from Fukushima accident. Changes to both legislation and regulatory guides are clearly identified and are in advanced stage of adoption.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"The regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.*
S15	**Suggestion: STUK should complete its comprehensive programme for the renewal of its nuclear safety regulatory guides (YVL) in accordance with its approved implementation plan. In addition, STUK should use the experience gained in upgrading nuclear safety regulatory guides in preparing for renewal of radiation safety regulatory guides (ST).**

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

The system of safety requirements for nuclear facilities (and NPPs in particular) as contained in legally binding documents (acts and decrees) and other STUK documents (YVL guides in particular) forms a basis for the review and assessment regulatory control, and subsequently for issuing the authorizations. Several specific documents for these two areas are listed in chapters 5 and 6 of this report. In the areas of authorization and review and assessment the mission found that the system is reasonably comprehensive and consistent, although with different level of details in different technical areas. Comprehensiveness of the system is also important for Periodic Safety Review in Finland, which is based on systematic assessment of compliance with evolving guidance documents. In the areas of authorization and review and assessment for nuclear facilities the system reflects the IAEA safety standards and STUK has demonstrated very good performance in its systematic and speedy incorporation of recently published Standards into the system.

Nevertheless, the IRRS team identified certain areas where STUK can further improve comprehensiveness and consistency of the system, in particular by ensuring better consistency of assessment of radiological consequences in different authorization documents (namely EIA, SAR and emergency plans).

9.3. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

Specific guidance on spent fuel storage facilities is given in YVL guide 6.8. This guidance defines the primary requirements so as to meet the safety objectives for handling of nuclear fuel and storage thereof including safe management of spent nuclear fuel. These objectives concern:

- Prevention of criticality and damage to the fuel;
- Ensuring adequate cooling; and
- Ensuring that handling operations may not lead to load drops that may jeopardize the safety-related systems, components and structures of the facility.

The STUK guidance in this area is generally consistent with IAEA safety standards.

9.4. REGULATIONS AND GUIDES FOR RADIOACTIVE WASTE FACILITIES

While several guides related to waste disposal have been prepared it was noted that there is currently no detailed guidance/requirements related to closure and institutional control of the repositories in operation or planned for the future.

With the above exception and noting the general guidance applicable to all nuclear facilities the STUK guidance's are largely consistent with IAEA safety standards.

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES

There are 53 ST Guides in force, available on STUK's website. In addition to ST Guides, STUK has issued decisions on selected topics on the application of the safety guides.

The Radiation Safety Guides are based on the current Euratom Basic Safety Standards as well as the relevant IAEA safety standards and reports. The Radiation Safety Guides provide basic conditions and requirements that are applicable to all types of facilities and activities. The guides include both general licensing and safety requirements. There are also criteria for the following activities and facilities: diagnostic radiology, nuclear medicine, radiotherapy, management and disposal of radioactive waste, research and education and industrial radiography.

Finnish requirements on the control of high-activity sealed radioactive sources and orphan sources are based on the European Council Directive 2003/122/Euratom of 22 December 2003 on the "control of high-activity sealed radioactive sources and orphan sources". The purpose of these requirements is to prevent exposure of workers and the public to ionizing radiation arising from inadequate control of high-activity sealed radioactive sources and orphan sources and to define specific requirements for the controls that should be implemented, in order to ensure that each such source is kept under control. STUK is the competent authority for the recovery of orphan sources and for the dealing with radiological emergencies due to orphan sources as well as for the drawing up of appropriate response plans and measures.

The Radiation Decree provides, for example, for the powers of STUK, limits of radiation doses, application for licence, accidents and the duties of the Advisory Board for Radiation Safety.

9.6. REGULATIONS AND GUIDES FOR DECOMISSIONING

It was noted that a new draft guide has been prepared related to decommissioning of nuclear facilities. The draft guide is generally consistent with the IAEA requirements and guidance on decommissioning of nuclear faculties and activities.

It was further noted that in the suite of YVL guides there are requirements that decommissioning be considered during the design of nuclear facilities to ensure the prevention of unnecessary waste generation during decommissioning and to facilitate easier decommissioning operations and that decommissioning plans that periodically reviewed and updated through the life cycle of the facility.

Consistent with IAEA recommendations the national policy is that decommissioning of nuclear facilities should be not be deferred without justification.

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

The Ministry of Transport and Communications is responsible for the development of legislation and requirements for the transport of all dangerous goods. The requirements of TS-R-1 are incorporated into national regulations which are based on the ADR, RID, IMDG Code and ICAO-TI. In the Act on the Transport of Dangerous Goods (719/1994), STUK is defined as the competent authority for the transport of radioactive materials. STUK oversees the radioactive material transports in cooperation with police, Customs, Border Guard and the Defence Forces.

Regulatory requirements for the transport of nuclear material and nuclear waste are given in Guides YVL 6.4 (packages), 6.5 (transport safety) and 6.21 (transport security). STUK's regulatory requirements are currently being revised. STUK grants the licences for nuclear material and nuclear waste transports, for these a licence is needed with some exceptions (Section 17 of 161/1988) for small quantities.

The national regulations governing transport by road in Finland are based on the ADR regulations. The version in use agrees for the most part with TS-R-1, with the exemption of not using external markings on vehicles in some specific cases (excepted packages and medical unsealed sources). Even though the deviation from TS-R-1 is a minor one and of limit relevance for safety, the IRRS team is of the view that TS-R-1 should be implemented in the relevant Finnish legislation without any exemptions.

9.8. SUMMARY

All areas of STUK's competence are covered by regulations and guides with the exception of some specific cases that are identified in subchapters 9.2 to 9.7. Regulations and guides reflect IAEA and other relevant international recommendations. Regular updates are keeping regulations and guides up to date.

STUK needs to cooperate with relevant ministries in the legislative process to maintain an appropriate framework of binding regulatory principles and requirements relevant to its areas of competence. As STUK's authority in this legislative process is not clearly and unambiguously defined in existing law, the IRRS team recommends measures (see Section 1.3) that would align the situation in Finland in this area with IAEA requirements and best practices.

A comprehensive renewal programme for safety regulatory YVL guides is in advanced stage of implementation and will be finalized by end of February 2013, resp. by the end of August 2013 in case of those related to structures and components of nuclear facilities. When completed, STUK will have available a very well structured modern set of regulatory guidance coherent with most recent international standards and best practices.

STUK's Regulatory guides are updated in accordance with stringent review periods. This may be quite challenging for STUK with respect to the availability of resources, especially in the radiation safety area.

In the area of regulations and guides STUK reacted to Fukushima accident promptly. There is already a package of proposals for modification of legally binding legislation, and the regulatory guides are in advanced stage of implementation.

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. GENERIC REQUIREMENTS

In accordance with the Emergency Powers Act (1080/1991) all authorities in Finland have obligations for emergency planning for all types of emergencies that can happen in or influence the country. In order to ensure consistent plans and arrangements for incidents and emergencies the Government issues every fourth year, a Resolution on the Security (Safety) Strategy for the Finnish society. The latest update of the Strategy was issued in 2010. The Strategy defines the coordination and decision making mechanisms for emergency preparedness and response, as well as the roles and responsibilities of the coordinating bodies on governmental level.

Another basic emergency document is the Rescue Act (379/2011). The act includes the basic requirements for emergency planning and response. The Ministry of the Interior (MoI) is responsible for issuing decrees based on the act. The designated rescue authorities and other responsible bodies who have a duty to respond in an emergency situation are listed in the Rescue Act. According to Section 46 of the act STUK is the principal authority responsible for all aspects of emergency preparedness in the event of a nuclear or radiological emergency. STUK is responsible for maintaining preparedness for abnormal situations, monitoring the radiation situation in Finland and issuing general guides concerning radiation and nuclear safety in accordance with the Nuclear Energy Act (YeL. 990/1987) and the Radiation Act.

The Guide on Radiological and Nuclear Emergencies and Incidents: Roles and Responsibilities of all involved authorities issued by the Ministry of the Interior (2012) gives a more detailed description of emergency response in Finland during early and intermediate phases of a nuclear or radiological emergency. The Guide defines the coordination and decision making mechanisms for emergency preparedness and response, and the roles and responsibilities of the coordinating bodies, on governmental, regional and municipal level. Further, the Food Act (23/2006) and Health Protection Act (763/1994 define the roles and responsibilities of various authorities concerning the protection of people's health, food and environment.

The Government Decree on the Emergency Preparedness of Nuclear Power Plants (735/2008) provides the general regulations concerning the on-site emergency preparedness and response. STUK's VAL guides prescribe protective measures for early and intermediate phases of a nuclear or radiological emergency, and set out the requirements for monitoring of external radiation in an emergency.

STUK has registered its response capabilities to the Response Assistance Network (RANET) and is in the process of strengthening its membership by registering more national capabilities into RANET. However, concern arises regarding the implementation of international assistance in case of a severe nuclear accident on regional basis because, presumably, the national resources registered into RANET will be needed within the country and would not be available for providing assistance. Additionally, the issue of financing such an assistance (unplanned and on a short notice) was also discussed. Additional planning and preparation of the corresponding procedures is needed for requesting assistance from other countries concerning e.g. monitoring resources and also to make use of assistance efficiently in national response, especially during large scale and long-lasting emergencies, by integrating the received assistance capabilities into the national response scheme.

The IRRS team considers that the requirements of the IAEA standards set forth for the basic responsibilities of the GS-R-2 are basically met. Nevertheless, the implementation of international assistance (never having deployed or requested by Finland) needs further considerations and planning.

Assessment of threats

The licensees of the nuclear power plants have to provide to STUK a level 2 Probabilistic Risk Analysis (PRA) covering internal and external hazards. STUK makes parallel PRA analyses with its own code to verify the results provided by the licensee. PRA is used to select accident scenarios for emergency exercises and to select severe accident scenarios for which environmental consequences are assessed for licensing of the facilities. However, the design basis of emergency arrangements is based on deterministic analyses.

STUK has analysed in details the possible consequences of various types of nuclear or radiological emergencies such as a severe nuclear power plant accident or an explosion of radioactive dispersion device (RDD). As an appendix of STUK's emergency plan there is a summary of possible threats and their consequences related to radiation safety of Finnish population, environment and the society. The threats included in the summary and related analyses are reviewed and revised when necessary and at least every second year in connection with updating STUK's emergency plan.

The IRRS team suggests that results of threat analyses should be modified into more user-friendly form and made easily available for STUK's emergency response organization as background material, in order to ensure consistent preliminary safety assessments in case of an urgent incident, especially during outside office hours when STUK's response organization is not yet fully operational.

Finland has threat categorization system which is very detailed and covers all possible nuclear or radiological emergencies including security rated events and malicious acts. Threats are divided in a following way:

- Reactors, where ever located, in fixed facilities and e.g. in nuclear powered boats;
- Nuclear weapons in other countries;
- Nuclear materials including re-entry of satellite with plutonium; and
- Use of radiation and radiation sources including melt down of radiation sources

In STUK's emergency plan threats have been divided into approximately 70 different scenarios (anomalies, incidents and emergencies including malicious acts) in order to make sure that STUK's initial response is timely and correct; detailed procedures have been issued accordingly for expert on duty activating STUK's response.

It is clear that Finland has appropriate use of threat categories to implement a graded approach to establish and maintain emergency response arrangements in accordance with the safety requirement GS-R-2.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-2 Para 3.1 states that "***Despite all the precautions that are taken in the design and operation of nuclear facilities and the conduct of nuclear activities, there remains a possibility that a failure [, an intentional act] or an accident may give rise to a [nuclear or radiological] emergency. … Adequate preparations shall be established and maintained at local and national levels and, where agreed between States, at the international level to respond to [nuclear or radiological] emergencies."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S16	**Suggestion: STUK should, in cooperation with relevant Government authorities, consider improving national arrangements for timely provision of assistance requested by other countries (including through RANET) and for effectively integrating assistance received by Finland into the national response system.**

10.2. FUNCTIONAL REQUIREMENTS

Establishing emergency management and operations

The emergency management system and organization of the operations are well developed in Finland and many efforts are invested in the development of proper coordination between the different response organizations - on-site responders and off-site responding organizations.

Off-site emergency plans are prepared by the respective regional rescue authorities in close cooperation with licensees. Plans are coordinated adequately with other regions and authorities. Requirements for cooperation are presented in the Decree of the Ministry of the Interior (406/2011). On-site emergency plans for nuclear facilities are reviewed and approved by STUK and STUK actively takes part in the preparation of off-site plans.

STUK has established its own protected web pages (FINRI) containing safety assessments, recommendations for protective measures, radiation situation, background material, etc. Access has been given to a wide range of authorities in Finland and in in neighbouring countries, as well as international organizations.

Identifying, notifying and activating

STUK is the body in Finland receiving information of all actual, potential or perceived situations with possible radiation hazards. Information may concern (a) safety and security related anomalies/incidents/emergencies in domestic nuclear facilities or in use of radiation, (b) detection of abnormal levels of radiation, (c) observations in border control, (d) transport of radioactive or nuclear material, (e) re-entry of nuclear satellite, (f) orphan sources or melting of radioactive sources, (g) any other event including false rumours related to radiation.

STUK has a 24/7 duty system which receives all signals from domestic or foreign partners. The expert on duty has available all the time detailed instructions for actions needed in each situation: anomaly, incident or severe nuclear or radiological situation of various types. Activation of STUK's partial or full response shall take place in 15 minutes if needed. The expert on duty needs to be able to report at STUK's premises within one hour. STUK has an alerting system for receiving any message sent by fax, CoDeCS (ECURIE), email or SMS. The same system is used for activating STUK's emergency response with freely formulated messages. A redundant and diverse alert system is available as back-up.

STUK's emergency plan describes target times for activation of STUK's emergency response:

- Emergency organization fully operational within two hours;
- Experts to be sent to the event site, to act as liaison officers in various response groups or to carry out radiation monitoring within three hours; and
- Readiness for gamma-spectrometric analysis within three hours; full availability of laboratory capacities within 12 hours.

STUK uses an emergency classification system whose criteria for declaring these emergencies are stricter than those proposed in GS-R-2. More specifically, in Finland a three-step classification system is used whereas GS-R-2 requires using four emergency classes.

Taking mitigatory actions

In abnormal radiation situations such as accidents and malicious acts related to radiation, the role of STUK is the expert body advising the rescue authorities and other counterparts in case of emergency. STUK sends, if necessary, radiation experts and measurement team on-the-scene.

The first responders are the teams of regional Departments for Rescue Services. Teams are equipped with electronic dose rate meters and staff of these response teams is trained in proper care and use of these instruments.

Taking urgent protective action

The VAL Guides issued by STUK are comprehensive and address all aspects of emergency response. VAL Guides contain reference levels of exposure during the first year and factors, other than radiation, affecting choice of protective measures and protective measures to be considered during nuclear or radiological emergencies and transition to recovery. In the preparation of the VAL Guides, STUK requested comments from stakeholders. In addition, the Guides have been tested during various kinds of emergency exercises (NPP accident, malicious acts). VAL Guides were in active use during the Fukushima accident. The VAL Guides incorporate the latest advice from ICRP as well as international guidance on emergency response.

Providing information and issuing instructions

STUK is responsible to inform the public about a nuclear or radiation emergency and its consequences to the population, environment and society. Emergency announcements are simultaneously transmitted via all radio stations and TV channels nationwide. An emergency announcement interrupts all programmes irrespective of channel. STUK's emergency plan VA 1 and procedures VA 3.12 details how STUK informs public and the media. STUK publishes information on internet and in teletext pages, arranges media conferences, gives interviews to media, issues information via social media and provides advice via phone. STUK publishes information in Finnish, Swedish and in English, if needed.

Protecting emergency workers

VAL Guides include principles for reducing exposure of various parts of the society. They include principles and dose limits for protection of workers in the early and intermediate phases of a nuclear or radiological emergency. Indicative operational intervention levels for different protection measures of emergency workers are presented as well intervention levels for workers involved in urgent protection measures, mitigating the consequences of the accident and other necessary work. Principles and dose limits are in accordance with the Radiation Act and Decree in which the EU Basic Safety Standard is adopted.

In the early phase of a nuclear or radiological emergency the principles and dose limits are given for workers involved in urgent protective and mitigation measures, as well as other workers, who may be exposed to radiation at levels higher than other population. For events involving licensed facilities, workers conducting urgent measures are most likely licensee staff, but may also include rescue personnel, police and medical personnel.

In the intermediate phase of a nuclear or radiological emergency the protection of workers in the contaminated area during an intermediate phase of an emergency is included in VAL Guides. Principles

and dose limits are given for the workers who are mitigating consequences and for those who conduct other necessary work during the intermediate phase.

VAL Guides include also operational intervention levels to reduce radiation dose to workers and actions to reduce radiation dose to members of the public exercising their own profession in contaminated areas.

According to STUK's emergency plan and emergency procedures the doses received by emergency workers are registered at STUK. The licensee or other responsible party or an approved dosimetric service sends dose results of workers involved in urgent protective and mitigation measures, as well as other necessary workers, who may be exposed to radiation at levels higher than other population and other workers that practice their own profession in the contaminated area.

Assessing the initial phase

STUK has trained monitoring teams for dose rate monitoring, mobile spectrometers (VASIKKA) and a laboratory vehicle (SONNI). SONNI has state of the art monitoring equipment for gamma (HPGe), alpha and an air sampler. VASIKKA and SONNI report location and dose rate results in 30 second interval to the emergency response organization of STUK. STUK is prepared to constantly evaluate the situation and to provide this information and advice to the local officials. Operational intervention levels for protective measures are described in the VAL Guides.

Different authorities are prepared to make dose rate or spectrometric measurement during a nuclear or radiological emergency. For instance the Finnish Defence Forces can equip a jet or helicopter for aerial survey with gamma spectrometric devices.

In Finland, there is a network of environment and foodstuffs laboratories which have the capability to measure gamma radioactivity levels in the food and environmental samples. STUK coordinates operation and provides technical support if needed. In addition, STUK has provided regional hospitals with equipment for monitoring iodine in thyroid.

STUK is prepared to provide guidance and advice and to collect measurement results made by different authorities to make overview picture of the radiation levels in contaminated area. This information is needed to focus monitoring to the areas of interest.

Keeping the public informed

It is STUK's responsibility to inform the public on the radiation situation and its consequences to the radiation safety of population, environment and the society. STUK also has a mandate to issue emergency announcements which are published immediately in all TV and radio channels. During emergencies STUK will establish an additional 24/7 duty system dedicated for contacts with media in order to be able to promptly respond to questions of media and news issued. STUK's emergency plan and procedures define how STUK communicates with public and media. STUK also monitors the news media and social media discussions and is prepared to respond, when needed. STUK publishes information and serves media in Finnish, Swedish and English, if needed. STUK coordinates with other responsible authorities and organizations in public communication.

Coordination arrangements for informing the public and media during emergencies should be further developed together with other organizations, and STUK's relevant procedures should be updated accordingly.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-2 Para 4.19 states that** *"The operator of a facility or practice in threat category I, II, III or IV shall make arrangements for the prompt identification of an actual or potential nuclear or radiological emergency and determination of the appropriate level of response. This shall include a system for classifying all potential nuclear and radiological emergencies that warrant an emergency intervention to protect workers and the public, in accordance with international standards, which covers emergencies … at facilities … and other emergencies ..."*
R7	**Recommendation: STUK should include the additional class of "facility emergency" in its emergency classification scheme in order to ensure that appropriate on-site emergency response actions are taken for the protection of the workers and that important information is communicated consistently to relevant parties.**
(1)	**BASIS: GS-R-2 Para 4.35 states that** *"Arrangements shall be made to provide expertise and services in radiation protection promptly to local officials and first responders responding to actual or potential emergencies involving practices in threat category IV. This shall include arrangements for on-call advice and arrangements to dispatch to the scene an emergency team that includes radiation specialists capable of assessing threats involving radioactive or fissile material, assessing radiological conditions, mitigating the radiological consequences and managing the exposure of responders."*
GP6	**Good practice: All teams of the regional Departments for Rescue Services of the Ministry of Interior are equipped with electronic dose rate meters and responders are trained in their use. This allows first responders to detect the radiation hazards and take appropriate actions in a timely manner.**
(1)	**BASIS: GSR Part 1 Para 2.18 states that** *"…The Government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as: … (4) Emergency preparedness and response ..."*
(2)	**BASIS: GS-R-2 Para 4.83 states that** *"Arrangements shall be made for: providing useful, timely, truthful, consistent and appropriate information to the public in the event of a nuclear or radiological emergency; responding to incorrect information and rumours; and responding to requests for information from the public and from the news and information media."*
S17	**Suggestion: The Government should consider improving arrangements for the coordination of information to the public and media during emergencies to ensure that the messages issued by different authorities are consistent.**

10.3. REQUIREMENTS FOR INFRASTRUCTURE

Organization, plans and procedures

STUK is prepared to act in all kinds of nuclear or radiological emergencies and incidents as well as in threat of them. Emergency response at STUK consists of three levels: basic response, intensified response and full response which are activated or deactivated adjustably and smoothly.

STUK's emergency plan describes the main emergency response tasks and how these tasks are divided to different expert groups within the emergency organization. The number of defined tasks in STUK's emergency organization is about 80. Each task has its own detailed procedure and instructions. All STUK staff members (about 360 persons) have an obligation to act as a member of STUK's emergency organization. All staff has been appointed to take care of a primary and a secondary task and has been regularly trained and exercised for emergencies. For each task there is a primary person and 2 to 4 substitutes. In large scale situations, STUK has prepared to work 24/7 in shifts.

Based on requirements given by the Rescue Act and relevant decrees of the Ministry of the Interior the rescue authorities and the nuclear facilities have emergency plans and these plans and arrangements are kept up-to-date in cooperation with other counterparts such as STUK.

The IRRS team visited the Department for Rescue Services of the Ministry of the Interior. The impression of the visit is that there is very good cooperation and coordination between STUK and the rescue authorities.

Logistical support and facilities

Analytical tools and computer programmes:

STUK receives data via secured direct data connection on the plant parameters, weather parameters and external dose rate. Dedicated telephone lines are used in communication with STUK and NPP.

STUK and the Finnish Meteorological Institute (FMI) have jointly developed a web application (KETALE) for calculating and presenting dose and dispersion calculations and forecasts and recommendations for protective actions. The Finnish Meteorological Institute has provided a meteorological workstation which is connected to its network. This work station has full access to all meteorological data. The RODOS is used as a decision support system.

The USVA system is a user interface for the automatic dose rate monitoring network results. The automatic network consists of about 250 stations monitoring external dose rate. The network has 22 stations with spectrometers situated around NPP's and in Helsinki.

A main function of Research and Environmental Surveillance includes emergency preparedness. The Department has a large quantity of measurement equipment used for radiochemical and biological treatment, analyses of environmental samples and direct measurements of radioactivity in the environment and in people. The department has mobile environmental measurement laboratories and mobile whole body counter laboratory. Whereas the equipment is well maintained, there is a need to keep the equipment updated For example, the available scintillators are good for monitoring some isotopes, but are not able to measure all isotopes that arise in case of emergency, the whole body counter is one from the 60-ies. The maintenance and further development of the measuring equipment is a basic requirement from the point of view of appropriate response in case of an emergency leading to the contamination of people and the environment (see recommendation 4 in chapter 1).

Emergency Response Centre of STUK

STUK has an Emergency Response Centre (ERC) in its premises which is fully equipped with necessary tools, redundant communication means, hardware and software and background material (e.g. for prognostic calculation, simulations, radiation monitoring data handling and presentation, plant safety parameter display system, event logbook, emergency information exchange platform etc.). The ERC is available all the time. Other parts of STUK's premises are utilized during emergencies such as for establishment of a media centre to STUK's library. STUK and its ERC is supplied with a back-up power supply, uninterruptible power supply (UPS), separate air-conditioning, cooling, dedicated phone lines, satellite communication, authority networks, video conferencing system, dedicated data transfer lines

from NPPs, internal TV-network, multifax, LT/UTC shown in all rooms, procedures, background material, text models, forms for notifications, STUK's alarming and communication system, meteorological work station, special alarming and communication system for EU Member States, computer models for dose and dispersion calculations, real-time external radiation monitoring system.

Emergency Response Centres of regional rescue authorities and nuclear facilities

Rescue authorities have emergency response centres equipped with necessary tools, redundant communication means, hardware and software and background material. The location of the emergency response centre of rescue authority responsible for acting during emergencies in Loviisa NPP is in Porvoo which is approximately 40 km west of the plant. The location of the emergency response centre of rescue authority responsible for acting during emergencies in Olkiluoto NPP is in Rauma which is approximately 15 km southeast of the plant. Olkiluoto and Loviisa nuclear power plants have their emergency response centres located at the plant sites. These centres are equipped with necessary tools, redundant communication means, software and background material which are kept up-to-date.

Training, Drills and Exercises

The Emergency Preparedness Unit of STUK arranges and coordinates emergency training. Regular and systematic emergency training is arranged for the STUK staff. There is an annual training programme and a long-term training programme. According to the emergency plan the cycle of training is two years for those persons taking care of critical tasks in STUK's emergency organization. The cycle for other tasks is 1 to 3 years and always when procedures have changed. There are additional groups of experts such as those on duty who participate annually in training.

The training consists of (a) general training regarding safety and security related matters and protective measures during emergencies, (b) general training on Finland's and international emergency arrangements, (c) training concerning operation of the emergency organization and its expert groups for individual tasks. In addition STUK regularly provides training to other organizations such as meteorologists, those responsible for emergency planning in hospitals and staff in local laboratories.

During the last ten years STUK has arranged and/or participated in 3-10 exercises each year. These exercises include annually arranged national NPP exercises, other national exercises, STUK's internal exercises, international exercises (e.g. INEX and ConvEx) and exercises with neighbouring countries. Some of the exercises have been arranged on an unannounced date. Exercise scenarios vary from various types of nuclear or radiological emergencies and incidents, different phases of event and different seasons of year. Registration of participation in training and exercises is maintained in emergency training database. The conduct of the exercises is evaluated. STUK gathers feedback from training and exercises for improving and developing its own emergency arrangements and response.

The decision makers participate in the national exercises. In the large scale exercises also the political level is involved.

The IRRS team observed an exercise with emergency scenario in Olkiluoto NPP. During the exercise the emergency response team (about 65 staff members) was fully activated. The observation of the IRRS team is that the emergency staff of the ERC performed the assigned task on a highly professional level, all of the players were familiar with the procedures and available tools. Everybody showed strong motivation and dedication to the tasks.

Quality Assurance Programme

The licensee is obliged to organize emergency response arrangements, including supplies, equipment, communications systems etc. Emergency response functions are part of the management system of the licensee.

STUK controls these arrangements. Changes to these arrangements are reviewed by STUK As part of STUK's operational inspections programme management system and emergency response functions are annually inspected.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(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 … These support items shall be located or provided in a manner that allows their effective use under postulated emergency conditions."*
GP7	**Good Practice: STUK has excellent tools, facilities and organizational arrangements to perform the necessary evaluation of the emergency in a timely manner and to provide appropriate recommendations for protective measures. The organization and conduct of the emergency exercises and the coordination with other stakeholders is exemplary.**
(1)	**BASIS: GS-R-2 Para 5.35 states that** *"The officials off the site responsible for making decisions on protective actions for the population within the precautionary action zone and/or the urgent protective action planning zone … shall be trained in the strategy for protective action and shall regularly participate in exercises …*"
GP8	**Good practice: Decision makers at high political level participate in national emergency exercises which strengthens their engagement and proper preparedness for the decision making challenges required during a real emergency.**

10.4. SUMMARY

STUK has developed and maintains a comprehensive and efficient emergency preparedness and response system. The experience of the response to the Fukushima Dai-ichi nuclear emergency, as well as the exercise observed by the IRRS team, showed a high level of competence and strong motivation from the side of the STUK staff. The legal documents reflect a well-designed, coordinated national emergency management system. This system is in good compliance with the IAEA safety standards.

In spite of the generally impressive capabilities of STUK in the area of emergency preparedness and response some improvements are necessary to be done. The Recommendation and Suggestions given in the Chapter are intended to call the counterpart's attention to these issues.

The Good Practices of the Chapter are intended to acknowledge the proficiency and commitment of the STUK staff.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

STUK exercises regulatory control over the full range of activities that involve medical exposures, from dental x-rays to screening mammography to the delivery of radiation therapy treatments using accelerators. A graded approach is incorporated into the regulatory programme in the following way: for a low-risk activity such as dental x-rays, users of the equipment must self-register with the authority and participate in a programme of postal verification to confirm that their equipment meets the regulatory expectations and quality control standards. For a high-risk activity such as radiation therapy, the licensing requirements are more prescriptive and authorization to treat patients is granted only after an inspection by STUK that confirms that the operator is qualified to undertake the activity. Inspection type and frequency is commensurate with the relative risk of the authorized activity. Note that the term diagnostic radiology refers to the practices of nuclear medicine as well as x-ray diagnostics.

A total of 15 staff undertake all regulatory activities related to medical uses of ionizing radiation for both occupational and medical exposures involving just over 600 licences (excluding dental units). In Finland, under the Radiation Act, all medical practices using radiation must have a clinical audit once every 5 years to further ensure that radiation exposures are optimized and properly justified. Reporting requirements related to medical events are laid out in regulatory guidance and they address criteria for timely reporting of overdoses as well as under-doses. STUK is an active participant in the EU initiative on reporting of medical events. STUK's regulatory guides set out the requirements for training and qualifications of medical personnel. The training programme for inspectors, whose responsibility includes the monitoring of medical exposures, includes a clinical rotation component, which gives them an opportunity to work in a medical clinic to gain an in-depth understanding of new medical technologies.

The Radiation Act stipulates that all medical practices undertake a periodic clinical audit of their radiation practices. STUK is responsible for compliance monitoring of clinical audits. STUK has issued a number of comprehensive regulatory guides that set out its regulatory expectations concisely in plain language. These guides are supplemented by topical advisory documents on emerging issues related to medical exposures such as the control of dental x-ray practices, control of exposures in Cone Beam CT, quality control guidelines for medical equipment etc.

Diagnostic reference levels are used in medical imaging to ensure optimum image quality while minimizing patient exposure to ionizing radiation. DRLs provide imaging parameters to be used under specific standard imaging situations, allowing the operator to monitor equipment performance on an on-going basis. In Finland, under Section 16 of the Decree of the Ministry of Social Affairs and Health on the Medical Use of Radiation, STUK has been delegated the authority for issuing DRLs. GSR Part 3 Requirement 34, "Responsibilities of the Government specific to medical exposure" requires that the Government, in setting the DRLs, ensure that relevant professional bodies and medical practitioners are adequately consulted. This is further reiterated in RS-G-1.5 Para 2.59.

STUK's process for revising DRLs involves a three-step process. First, STUK collects detailed information related to a given practice from practitioners and analyses the collected information. Next, STUK, in consultation with practitioners, determines whether and what changes are necessary to the DRLs in question. Finally, once a determination is made to revise DRLs, STUK conducts extensive outreach to widely disseminate this information to practitioners. Practitioners are involved in all phases of the activity. In the early phases, outreach activities are aimed at ensuring that all practitioners have a common understanding of the information that must be submitted to STUK for analysis. In the

intermediate phase, results of the analysis are presented and the proposed changes finalized after discussion with practitioners. In the final phase, STUK conducts outreach activities to ensure consistent interpretation and implementation of the changes by practitioners. Inspectors conduct communication and outreach individually with practitioners during site inspections and collectively at annual meetings of professional associations. A similar process is followed for setting DRLs for new imaging practices. These activities are supplemented by the monitoring data collected by STUK inspectors during routine inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Para 2.34 states that** *"Competence for safety: The Government shall make provision for building competence of all parties having responsibilities in relation to the safety of facilities."*
GP9	**Good Practice: STUK inspectors responsible for compliance monitoring of medical exposures have the opportunity for hands-on training in a clinic conducting the licensed activity. This allows the inspectors to obtain a thorough understanding of all aspects of the regulated practice.**

All inspectors involved in the regulation of activities that involve the medical use of ionizing radiation, regardless of the extent of their regulatory experience, have the opportunity for training at a working clinic. For a new inspector, the time allowed for this type of experiential learning can be as long as is deemed necessary. In the medical sector, where new technologies are introduced frequently, this training is really important and the IRRS team considers it a good practice.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 21 states that** *"The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison."*
(2)	**BASIS: GSR Part 1 Requirement 21 Para 4.23 states that** *"As its primary purpose, the regulatory body shall carry out oversight of facilities and activities. The regulatory body, while maintaining its independence, shall liaise with authorized parties to achieve their common objectives in ensuring safety."*
(3)	**BASIS: GSR Part 3 Requirement 35 states that** *"The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they meet the requirements for education, training and competence in the relevant specialty."*
(4)	**BASIS: GSR Part 3 Requirement 35 Para 3.149 states that** *"The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel...to take on the responsibilities specified in these Standards only if they:* *(a) are specialized in the appropriate area; […]"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
GP10	**Good Practice: STUK has developed outstanding expertise in the area of quality assurance of all aspects of radiation dose delivery in radiation therapy and diagnostic radiology.**

Members of the IRRS team accompanied STUK inspectors to the Turku University Hospital in Turku, to observe a routine inspection of a radiation therapy accelerator and the commissioning of a new high-dose rate brachytherapy system at the same hospital. Inspectors performed a series of comprehensive independent tests of a number of parameters associated with dose delivery to patients, from dose planning to delivery using an extensive array of tools and equipment. They also observed licensee staff performing their quality assurance activities to ensure that staff was knowledgeable in the proper set up and use of the calibration equipment. Data recording was detailed and meticulous.

Rather than assuming a passive role in exercising its mandate in the area of medical exposures, STUK's inspectors perform rigorous independent verification of all aspects of therapeutic radiation treatment, from treatment planning to dose delivery. Licensees appreciate the competence of STUK's inspectors and welcome the objective independent review that the inspectors conduct of their activities. The IRRS team was impressed with the depth and breadth of the inspectors' expertise in the area of medical exposure. STUK, jointly with professional medical associations, has issued a number of guides related to radiation safety in special diagnostic procedures, with special emphasis on reduction of radiation exposure to children. In an era when the rise in radiation doses from diagnostic procedures is becoming a growing concern, it is important to highlight STUK's leadership role in this regard.

It is the opinion of the IRRS team that STUK should consider investing in additional IT support to this part of the organization so that the expertise of STUK's staff is used more efficiently. A number of administrative tasks related to licensing and compliance are repetitive and could be easily automated, allowing inspectors to make better use of their time.

In the area of medical exposures, it is the opinion of the IRRS team that STUK meets the relevant recommendations set out in GSR part 1, GSR part 3 and the guidance issued by the IAEA in RS-G-1.5. The due diligence exercised by STUK inspectors in this regard is exemplary. A number of STUK initiatives have been adopted in other EU countries. STUK's competence and expertise in the area of medical uses of ionizing radiation is recognized and respected by licensees in Finland and other countries in the European Union.

11.2. OCCUPATIONAL RADIATION PROTECTION

In Finland, of the order of 16,000 workers are occupationally exposed to radiation annually. Of these, about 8,000 are workers involved in the use of radiation appliances and radioactive sources in medicine, industry and research; about 4,000 work at nuclear power plants; 3,600 are airline pilots and cabin crew and a few dozen are workers exposed to radon in excavation work and regular workplaces. The number of Category A workers in 2011 was 3835.

STUK publishes two separate annual reports dealing with Regulatory Oversight of Nuclear Safety in Finland and Radiation Practices. Both reports include information on occupational exposures and abnormal incidents occurring during the year. For 2011, the highest individual dose to a worker at a Finnish nuclear power plant was 9.9 mSv and to a worker in a radiation practice was 12.2 mSv. There were no cases in which the annual dose limit of 50 mSv was exceeded. Six incidents resulting in

unintended exposure of workers involved in radiation practices were reported to STUK during 2011. The individual doses were small in each case.

Legal/Regulatory Framework

The legislative/regulatory framework governing all occupational exposure is set out in the Radiation Act and the Radiation Decree. While there is separate legislation governing the use of nuclear energy in general, some provisions of the Radiation Act (Section 2, General principles and Chapter 9, radiation work) and the Radiation Decree also relate to the radiation protection of nuclear workers.

In the revised system of YVL guides currently under development, Guide C.2 will deal with radiation protection and dose control of the personnel of a nuclear facility. Currently, the relevant guides are YVL 7.9 dealing with radiation protection of workers at nuclear facilities and YVL 7.10 dealing with monitoring of occupational exposure at nuclear facilities. Guides relating to design of facilities and emergency preparedness arrangements also address aspects of occupational exposure.

As part of its planned revision of the ST guides to incorporate implementation of the new BSS, STUK intends to incorporate all mandatory requirements relating to occupational exposure directly into the radiation protection legislation and to develop its system of ST guides for different practices as a set of guidance documents, rather than as binding documents. This will result in a clearer expression of the requirements and will allow for greater flexibility in the development of guides. In updating the ST guides, the IRRS team noted that STUK will need to ensure consistency of requirements relating to occupational exposure between the YVL and ST guides. Some inconsistencies have been identified in the current sets of guides in relation to, for example, requirements concerning the safety culture for nuclear power plant workers and workers in radiation practices (see below).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 22 Para 4.26 states that** *" The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body.*
S18	**Suggestion: STUK should ensure further that its nuclear safety and radiation safety guides are consistent with respect to common requirements related to occupational exposure.**

Effective and equivalent dose limits for exposed workers, apprentices and students are set out in the Radiation Decree. In respect of pregnant workers, dose limits to the foetus are also set out. The Radiation Decree (Section 7) provides for STUK, as necessary, to set dose constraints when these are warranted to implement the ALARA principle. In line with this provision, STUK sets dose constraints to be applied to nuclear activities and certain radiation practices and these are set out in the corresponding YVL and ST guides.

The BSS (GSR Part 3 Para 1.22) distinguishes between the use of dose constraints in controlling occupational and public exposure. For occupational exposure, the BSS identifies the employer as the appropriate entity to set the constraints, whereas for public exposure it identifies the Government or regulatory body. The current practice in Finland is for STUK to set the dose constraints for radiation practices. With regards to nuclear power plants, STUK sets a dose constraint for the collective radiation dose of personnel at a plant of 2.5 manSV per GW net electric power over an average of two consecutive

years. In addition, in YVL 7.9, the licensees are requested to set dose constraints to maintain individual radiation exposures low. In the context of updating its ST guides, STUK could consider providing for the setting of occupational dose constraints by the employer for radiation practices.

The Radiation Decree (Section 8) specifies a special limit of 0.5 Sv that may be applied to emergency workers and the conditions for its application. In GSR Part 3, Requirement 45, the limit on exposure of emergency workers is set at a lower value, but the conditions for the application of this limit are more explicit that those given in the Radiation Decree. In the context of the implementation of the revised EU BSS, STUK could consider the appropriateness of the limits specified in the Radiation Decree and whether further requirements in relation to emergency occupational exposure should be included in national regulations.

Safety culture is not mentioned explicitly in the Government Decree (733/2008) on the Safety of Nuclear Power Plants (Chapter 7, Section 28), but it is referred to in the Nuclear Safety Decree and in the both the YVL and ST guides. In the Nuclear Safety Decree, it is stated that a good safety culture will be maintained. In relation to the use of radiation generally, Guide ST 1.1, chapter 6 defines safety culture, and states that staff "will be safety conscious and motivated, with expertise and appropriate training". Given the fundamental importance of safety culture in maintaining occupational exposures ALARA, STUK should consider introducing greater clarity with respect to its requirements concerning safety culture (see suggestion 13).

The requirement to appoint qualified experts, and the qualifications and duties of qualified experts are also set out in the safety guides. In "exceptionally demanding uses of radiation" STUK will set out the individual qualifications necessary in the specific case.

General responsibilities of registrants, licensees and employers

The regulations explicitly assign responsibility for the protection of workers to the licensee or employer and detailed requirements are set out in the YVL and ST guides. The responsibility also applies to operations or circumstances in which exposure to natural radiation causes or may cause a health hazard (ST Guide 12.1). STUK has a comprehensive and systematic approach to identifying and monitoring workplaces where occupational exposure to radon is of such a level as to be of concern. In circumstances where the radon concentration is above 400 Bq/m^3, STUK may issue orders to reduce the radon concentration. Where the measures taken are not effective, STUK can control the workplace in line with the requirements applying to occupational exposure in planned exposure situations. In 2011, some 21 workers were occupationally exposed to radon in their workplaces with an average dose of 5 mSv (max 13.4 mSv). While information concerning the number of workplaces where radon exposure of workers was monitored is included in the annual report on radiation practices, the number of workers involved and the actual exposure information is not. Given that the doses received by this group are among the highest received by any group of workers occupationally exposed in Finland, the IRRS team suggests that these data should be included in the annual report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 36 Para 4.69 states that** *"Public information activities shall reflect the radiation risks associated with facilities and activities, in accordance with a graded approach.*"
S19	**Suggestion: STUK should include information on the doses received by workers occupationally exposed to radon in its annual report on radiation practices.**

The definition of the employer's responsibilities is clearly set out in the regulations and guides, including the requirement to ensure that occupational exposures are kept below specified limits and that they are optimised. In nuclear power plants, a specific ALARA action programme must be developed setting out both short-term and long-term plans as to how the ALARA principle will be met and sent to the STUK for information. For radiation practices, responsibility for ALARA is also assigned to the employer. As indicated above, further consideration could be given to the practical use of dose constraints by licensees in the optimisation process.

The Occupational Health Care Act (743/1978) governs occupational health care requirements in general and this act is specifically referred to in the Radiation Act as regards the medical surveillance of Category A workers. STUK has set out specific requirements concerning the duties of employers as regards medical surveillance, the qualifications of the practitioner, the nature of the surveillance required and the records needed. (ST Guide 7.5)

General responsibilities of worker

The responsibilities of workers in radiation practices and nuclear power plants are generally clearly set out in the regulations (Radiation Act, Section 36) and in the underpinning YVL and ST guides. In particular workers are required to follow the rules and procedures specified by the employer, to use the protective equipment and monitoring devices supplied, to cooperate with the employer with respect to health and safety and to attend to their own radiation safety and to that of others.

Requirements for radiation protection programmes

The Radiation Act, Chapter 9 establishes the requirement for employers and licensees to designate controlled and supervised area. Further detail is provided in the Radiation Decree and in the YVL and ST guides. The requirement to provide personal protective equipment for workers and appropriate health surveillance for Category A workers is governed under the provisions of Occupational Safety and Health Act and further elaborated in radiation regulations and safety guides. The general duty of care of an employer towards workers and, in particular, the requirement to provided suitable alternative employment in circumstances where the worker may no longer continue in employment receiving occupational exposure is also set out in the regulations/safety guides. Employers are required to arrange for the assessment of individual exposure for workers and to establish and maintain a programme of monitoring for the workplace on the advice of a qualified expert. The Radiation Act (Section 36) sets out the requirement for employers to provide training and instructions for workers appropriate to their work and to provide the results of exposure monitoring to STUK for inclusion in the Dose Register (Section 34).

Monitoring programmes and technical services

STUK is assigned responsibility as the competent authority for the approval of dosimetry services and for the approval of training services for radiation protection officers. STUK itself is required to maintain the Dose Register so there is no separate approval process in place for other dose record keeping services. There is one commercial dosimetry service operating in Finland, providing external dose measurement. Loviisa NPP operates its own dosimetry service. In Olkiluoto the service is operated by the commercial dosimetry service. These services are approved by STUK in accordance with criteria set out in Regulatory Guides ST 1.9 and YVL 7.10.

STUK itself provides the only internal dosimetry service available in Finland. Neither the commercial dosimetry service nor the nuclear power plants have this capability, and so they rely on STUK's service to enable them to meet their obligations in this regard. STUK's service is accredited by the Finnish accreditation service Finas and there are some internal processes to demonstrate compliance with the approval criteria for dosimetry services. In smaller countries, it is not uncommon that situations arise where the approval body for certain technical services is itself a service provider. In STUK's case, in the

interests of transparency, the IRRS team suggests that STUK should consider how it could demonstrate that its internal dosimetry service meets the approval criteria for dosimetry services applied to the other dosimetry service providers.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 13 Para 2.41 states that** "*Technical services do not necessarily have to be provided by the Government. However, if no suitable commercial or non-governmental provider of the necessary technical services is available, the Government may have to make provision for the availability of such services. The regulatory body shall authorize technical services that may have significance for safety, as appropriate.*"
S20	**Suggestion: For its own technical services, STUK should consider demonstrating, in a transparent manner, that it satisfies all the required regulatory conditions necessary for an approval.**

Site visit to Loviisa NPP on 17 October 2012

During the mission, one member of the IRRS team visited the Loviisa NPP, accompanied by two STUK inspectors. The visit commenced with a presentation about Loviisa given by the radiation protection manager, focusing particularly on the arrangements for the protection of workers and the plants ALARA programme. It also included a visit to the controlled area of unit 1 and discussion of some aspects of the arrangements of emergency preparedness and environmental monitoring. The visit ended with an overview discussion with the plant manager and the radiation protection manager.

11.3. PUBLIC AND ENVIRONMENTAL EXPOSURE CONTROL

The Radiation Decree states that notwithstanding the dose limits given in the decree (Sections 3 to 5), e.g. the 1 mSv/a limit for the general public, STUK may, in individual cases, set constraints lower than the maximum values, if such constraints are needed to take account of radiation exposure originating from different sources and to keep the exposure as low as reasonably achievable.

The control of discharges at nuclear facilities is managed through a system of authorised discharge limits. The limits for discharges are set in Government Decree 733/2008, Section 8, and Government Decree 736/2008, Sections 3 and 4, as dose limits. The actual discharge limits as activity limits are set for each nuclear facility based on these basic requirements. ALARA and BAT (best available techniques) principles are required to be taken into account in the abatement of discharges.

According to the YVL Guide 7.6 "Monitoring of discharges of radioactive substances from a nuclear power plant" there shall be instruments for measurements of radioactive discharges to the appropriate extent. The environment monitoring programme in the vicinity of the nuclear facility shall be implemented according to the Guide YVL 7.7 "Radiation monitoring in the environment of a nuclear power plant". In the section 2 of the Guide YVL 7.1 it is required that discharges during NPP normal operation must be kept as low as practically possible, and Best Available Technology (BAT) must be used to reduce discharges.

According to the Guide YVL 7.7 the purpose of the environmental monitoring programme is to ensure that the exposure of the public is as low as reasonably achievable. In the planning of the programme the timing and the routes of the discharges and estimated radiation doses based on them are taken into account.

Environmental radiation monitoring in the vicinity of NPPs is undertaken by the licensees to supplement the measurements of radioactive releases from the nuclear power plant and the models used for estimating the transport of releases. Based on this principle STUK may require licensees to perform additional monitoring and surveillances if needed.

The IRRS team noted that at present STUK operates the national environmental laboratory, which undertakes a major part of the environmental monitoring, as a service to the licensees. Further it was identified that while STUK undertakes national environmental surveys and reports on these STUK does not currently undertake independent verification of the effluent control and environmental surveillance in the vicinity of nuclear facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Requirement 30 Para 3.127 states that** *"registrants and licensees, for sources under their responsibility, shall establish, implement and maintain: …* *f) Provision for appropriate monitoring equipment, surveillance programmes and methods for assessing public exposure;* g) *Adequate records of surveillance and monitoring"*
(2)	**BASIS: GSR Part 3 Requirement 32 states that** *"The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available"* **and Para 3.135 states that** *"The regulatory body shall be responsible, as appropriate, for:* *a) Review and approval of monitoring programmes of registrants and licensees, which shall be sufficient for: (i) Verifying compliance with the requirements of these Standards in respect of public exposure in planned exposure situations; (ii) Assessing doses from public exposure;* *b) Review of periodic reports on public exposure (including results of monitoring programmes and dose assessments) submitted by registrants and licensees;* *c) Making provision for an independent monitoring programme"* **and Para 3.137 states that** *"Registrants and licensees shall, as appropriate: …* *c) Report or make available the results of the monitoring programme to the regulatory body at approved intervals, including, as applicable, the levels and composition of discharges, dose rates at the site boundary and in premises open to members of the public, results of environmental monitoring and retrospective assessments of doses to the representative person; …* *h) Publish or make available on request, as appropriate, results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure."*
(3)	**BASIS: SSR 2/1 Requirement 82 states that** *"Equipment shall be provided at the nuclear power plant to ensure that there is adequate radiation monitoring in operational states and design basis accident conditions and, as far as is practicable, in design extension conditions"* **and Para 6.84 states that** *"Arrangements shall be made to assess exposures and other radiological impacts, if any, in the vicinity of the plant by environmental monitoring of dose rates or activity concentrations, with particular reference to:*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	2) exposure pathways to people, including the food-chain; *3) radiological impacts, if any, on the local environment;*"
(4)	**BASIS: SSR 2/2 Requirement 21 Para 5.19 states that** *"The operating organization shall establish and implement procedures consistent with international standards, national regulations and licence conditions for the monitoring and control of discharges of radioactive effluents. These procedures shall be made available to the regulatory body if required. The volume and activity of radioactive discharges to the environment shall be reported periodically to the regulatory body"* **and Para 5.20 states that** "*The operating organization shall ensure that a programme is established and implemented for monitoring the environment in the vicinity of the plant site, to assess radiological consequences of any radioactive releases to the environment. Results from this monitoring shall be made available to the public, and in particular to the public living in the vicinity of the plant site."*
R8	**Recommendation: STUK should withdraw from the current practice of conducting the environmental monitoring programmes in the vicinity of the nuclear facilities based on commercial contracts with the licensees. Furthermore, STUK should implement an independent monitoring programme for the environment, to verify the results of the off-site environmental monitoring programmes required from the licensees.**

Experience gained from operation of Finnish nuclear facilities shows that the dose constraints have not been exceeded. Further the results of environmental surveillance programmes show that the amount of radioactive materials in the environment of the NPP sites, originating from the Finnish nuclear facilities, has been very low. Calculated radiation exposures to the critical groups in the environment of the NPPs are currently less than one per cent of the dose constraint. In view of the above and noting that the system of authorised discharges is established in line with a dose constraint of 0.1 mSv, which is significantly higher than the releases realised in practice, it is suggested that STUK should consider requiring the operators to implement a system of constraints that are consistent with the actual releases from normal operation of the facilities so as to ensure that release are maintained ALARA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Para 3.123 states that** *"The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges. These operational limits and conditions:* *a) Shall be used by registrants and licensees as the criteria for demonstration of compliance after the commencement of operation of a source;* *b) Shall correspond to doses below the dose limits with account taken of the results of optimization of protection and safety;* *c) Shall reflect good practice in the operation of similar facilities or activities;* *d) Shall allow for operational flexibility;* *e) Shall take into account the results of the assessment of the potential radiological environmental impacts undertaken in accordance with national requirements."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S21	**Suggestion: Noting that actual releases from nuclear facilities are far below the authorised limits, STUK should consider requiring the operators to implement a system of constraints commensurate with the actual releases from normal operation.**

NORM Issues

The IRRS team held policy discussions related to regulation of NORM activities in particular uranium mining, with the Finnish counterpart and during mission. The policy discussion started with an introduction by STUK providing an overview of the current situation in Finland, and plans for the future.

It was noted that while there were no current uranium mining activities (there had been some uranium mining and processing in the past), a number of companies had recently expressed interest in undertaking prospecting and possible uranium mining activities.

In light of this STUK informed that NORM is covered in the current regulatory framework (Radiation Act, Radiation Decree, Guides ST 12.1 and 12.2) however, STUK has started work to complement its regulatory framework to better address this issue, and is seeking for international advice and experience sharing.

The policy discussion highlighted that management of waste produced by mining activities with significant concentration of natural radionuclides has some unique challenges most notably the very large volumes that generally require on-site management and the need to evaluate the very long term evolutions of disposal sites due to long lived activity of waste.

These challenges require that the identification of definition of appropriate dose constraints that may be deemed acceptable should encompass careful consideration of the particularities of NORM. Further the radiological risks related to NORM are not the only ones to be addressed, and sometimes the conventional and chemical hazards can dominate. Therefore the importance of addressing all issues in a comprehensive manner was stressed when developing new regulations.

Early regulatory (STUK) involvement was advocated to avoid creation of environmental problems that would lead to need for remediation or creation of legacy issues. It was also noted that the involvement of interested parties, including the general public is very important. Special care should be given to the local conditions of living in the vicinity of the sites and all models used for estimating the impact should be adjusted. The public needs to be educated to understand the difference and the specificities of such sites, not to be influenced, but to be informed. The environmental monitoring programme, before, during and after operation of a mine or any site where NORM will be disposed of is crucial to this respect.

11.4. SUMMARY

The IRRS team considers that STUK meets the IAEA requirements with respect to regulatory control of medical exposures. STUK's competence and expertise in the medical uses of ionizing radiation are acknowledged by licensees in Finland and by international peers and the team identified good practices with respect to the competence of inspectors.

The team also found that that occupational exposure at nuclear facilities and radiation practices is controlled effectively in Finland. The team made suggestions aimed at improving the consistency of STUK's requirements with respect to occupational exposure and transparency concerning the approval of technical services provided by STUK itself.

The arrangements for the control of public and environmental exposures are well established and effective. Environmental surveillance programmes show that the amount of radioactive materials in the environment as a result of releases from the NPP sites has been very low and radiation exposures to the critical groups are also very low. The IRRS team recommends that operators maintain the primary responsibility for off-site environmental monitoring programmes, but that STUK establishes a separate monitoring programme to independently verify the licensees' programmes. The team also suggests that STUK considers further its requirements with regard to optimisation of releases from NPPs.

The Policy discussions on uranium mining and milling, norm and associated waste highlighted that:

- When considering the future regulations on NORM material care should be taken to ensure that an appropriate and consistent approach is taken for the regulation of all NORM material including both instances where the material is exploited for its radioactive properties as well as when the material is not exploited for its radioactive properties;
- It must be recognised that when dealing with NORM material a pragmatic approach with respect to the specifying of dose limits may be needed and STUK is encouraged to consider the international experience in this regard.

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

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

12.1. IMMEDIATE ACTIONS TAKEN BY THE REGULATORY BODY

12.1.1. EMERGENCY RESPONSE BY STUK

The emergency response organization of STUK was alerted and activated immediately following the TEPCO Fukushima Dai-Ichi accident on March 11, 2011. STUK's accident assessment group remained active on a 24/7 basis for about three weeks. STUK's media service group was available for several months. The first summary report on the event was published by STUK within 9 hours of the first notification.

About 70 members of STUK were involved in emergency response activities. Licensee representatives and Government institutions participated in the work of the emergency response organization. The activity of the emergency organization was manifold and extensive, and it included regular provision of information to the media. About 40 press releases were issued on a variety of subjects of interest to the Finland's citizens, private enterprises and the Government, ranging from the compilation of daily safety reports to recommendations and instructions to Finnish citizens in Japan. Finnish citizens in Japan received iodine tablets, although finally there was no need for the administration of iodine.

In addition to continuously monitoring the Japanese and international news media, STUK used effective and innovative means of obtaining information. Thus it kept regular contact with the Finnish embassy in Tokyo; a Japanese interpreter was employed in the emergency centre of STUK to translate information only available in Japanese; STUK provided and air sampler the Finnish airlines Finnair that provided air samples daily from Tokyo's Narita airport to be analysed by STUK. The Finnish Meteorological Institute provided dispersion and meteorological data to STUK at regular intervals.

Early on in the crisis, STUK realized the importance of reliable and competent communication with media. To this end, it assigned six spokespersons to be at the disposal of the media. The intense media interest was evident in the fact that 31 STUK experts were interviewed; eleven STUK experts were interviewed more than 10 times. Dedicated telephone lines were established for inquiries from the general public and the media. These telephone lines received more than 1100 calls in March 2011; STUK's social media sites were also activated for disseminating information. The updating frequency of the TV teletext page displaying radiation monitoring data was increased from once a week to 3-4 times a day.

STUK normally operates two websites, one open for the general public and another with restricted access by domestic and foreign authorities for crisis communication. As a backup to the normal site STUK has a so called dark site that is not in use when normal site is running. In a case when the normal site does not work STUK can replace it with this dark site. The traffic on the public website increased to such an extent following the accident, with over 15,000 visitors eager to get information that it crashed. STUK subsequently released its dark site to the public to disseminate information.

The protected web pages (Finri)) were in use during the TEPCO Fukushima Dai-ichi accident and STUK provided information on Finri in Finnish and English languages e.g. on results of dispersion calculations; monitoring data and summary of actions concerning travelling recommendations to Japan; Finnish citizens in Japan; and import of foodstuffs and other goods form Japan.

STUK has performed a self-assessment of its emergency response organization after the early stage of the accident was over, and concluded that the functioning of the organization was successful and that the organization had learned important lessons and gained valuable experience from it. These lessons learned, have since contributed to the development of the emergency arrangements of STUK.

12.1.2. SAFETY EVALUATIONS

On March 17, 2011 the Ministry of Employment and Economy requested that STUK initiate a national review of nuclear safety in Finland in the light of the early consequences of the TEPCO Fukushima Dai-ichi accident. On March 22, 2011, STUK instructed all licensees of nuclear power plants to perform a safety assessment and submit the results to STUK by April 15, 2011. The assessment did not assume any new analysis, rather based on the existing safety analyses it was meant to concentrate on the possible consequences of events similar to those occurred in Japan as well as on the available safety margins at the nuclear power plant sites. Summarizing the results submitted by the licensees STUK reported to the Ministry that there is no need for immediate actions due to the threats revealed by the accident. However, STUK recognized the need to continue investigations to take into account other external, low probability natural events as well as those events that could affect multiple reactor units.

Following the licensees' report STUK requested both Fortum (in August, 2011) and TVO (in October, 2011) to carry out further actions and investigations in the subject with a deadline of December 15, 2011. The actions included plans for ensuring heat removal and ultimate heat sink in various cases of extreme external conditions, including loss of offsite power and further detailed investigations were requested into the possible related issues. These actions again concluded that no short term actions were needed to enhance the safety of the Finnish nuclear power plants; nevertheless a number of measures to enhance safety were foreseen in order to extend the design basis to extreme events similar to those in Fukushima. STUK assessed the results of the second set of evaluations and took a decision on actions required by licensees in July, 2012.

Parallel to the Finnish national efforts, the European Commission has also initiated a programme of targeted safety reassessment (also called in short "stress test") of the European nuclear power plants. At the end of March 2011 the stress test vas initiated on EU level and after a series of technical discussions by WENRA end ENSREG, national nuclear safety authorities in the EU countries were requested by the Energy Commissionaire to perform the exercise. A progress report was due to be submitted by September 15 and a national report by December 30, 2011. In the period of January to April 2012 the national reports were subject to international peer reviews under the auspices of ENSREG. The peer reviews concluded with peer review country reports. The main results of the safety assessments and reviews mentioned above are summarized in the next section.

12.2. TECHNICAL AND OTHER ISSUES CONSIDERED IN THE LIGHT OF THE ACCIDENT

12.2.1. TECHNICAL ISSUES

Technical issues related to the accident were investigated both in national safety assessment initiatives as well as in conjunction with the so called "stress test" of the Finnish nuclear power plants in the framework of a request by the European Council to the European Nuclear Safety Regulators' Group (ENSREG) and the European Commission to undertake a comprehensive and transparent risk and safety assessment of European nuclear power plants. The stress tests were meant to investigate the effects of earthquakes, flooding and extreme meteorological conditions on the safety of the nuclear power plants. Furthermore, possibilities and consequences of loss of vital safety functions (electrical power supply,

cooling and ultimate heat sink) as well as the capability for management of severe accidents were also investigated.

ENSREG specified the contents of the stress test investigations to be performed by the licensees of all operating nuclear power plants as well as of the one under construction. Results of the investigation were reported by licensees to STUK. Following this, STUK prepared and submitted a National Report to ENSREG on December 31, 2011. A peer review of the national reports has been performed under the auspices of ENSREG. Conclusions of the National Report on the technical issues considered as well as some of the peer review conclusions are summarized below.

Earthquakes do not represent a particular concern for the Finnish nuclear power plants for the low level seismicity in Southern Finland. No seismic requirements were in force at the time of the construction of the first nuclear units in Finland. Since that time seismic studies have been completed and seismic requirements have been established for the existing units. The stress test did not reveal any important issue or concern; it stated that "further studies will be conducted to confirm adequate robustness of certain vital structures such as the spent fuel pool structures and fire water systems". Specifically, for Loviisa NPP, the spent fuel pool analysis from the point of view of earthquake resistance has concluded that there is very low probability of spent fuel leakage due to the expected peak accelerations from this plant. For the units Olkiluoto 1 and 2 this analysis remains to be performed. In case of the unit under construction the design adequately covers the possible seismic challenges.

The ENSREG peer review considered the design basis acceptable and acknowledged the on-going measures to further increase the earthquake robustness of the power plants. STUK was advised to consider further assessment of the seismic endurance of critical systems and components.

Flooding due to tsunamis or tidal effects is extremely unlikely in the Baltic Sea. On the other hand there exists the possibility that specific meteorological and seasonal circumstances or long term geological changes may result in an increase in the seawater level. The stress test report concluded that it is extremely unlikely that the sea level will rise to the extent required to adversely affect safety. However, Loviisa NPP is expected to further investigate possible preventive actions against flooding (water tightness, protection against water inflow). The ENSREG peer review acknowledged the statements in the national report.

Extreme weather conditions were taken into account in the original design of the Finnish NPPs according to the general Finnish building code and the design practices of conventional industrial facilities, but the approach is nowadays considered insufficient for nuclear installations. Later the effects of more severe weather conditions and other external events have been analysed and several significant safety improvements have been carried out. Previous results as well as investigations related to the stress test pointed to the possibility of certain adverse effects of extreme weather conditions and led to considerations related to the establishment of alternative ultimate heat sink, improvements in emergency feed-water pumping system, cooling, ventilation and water-tightness issues. A Finnish research programme on this subject is on-going and its results will be used to inform further improvement measures as needed. The ENSREG peer review acknowledges the conclusions of the licensees and the regulatory body in this subject.

In the investigation of the possibilities of losing electrical supply and/or ultimate heat sink, the stress test report presented the multiple redundancy of the electrical power supply system of the Finnish NPPs. It concluded that in the worst case, with multiple failures, core damage is expected within 1 hour of the reactor scram in the Olkiluoto 1 and Olkiluoto 2 units, indicating that these units may need further independent heat sink via a feed-water system that did not rely on AC power supply and seawater. The other units (operating and under construction) seem to be adequately protected from this point of view. Nonetheless establishment of small scale cooling towers not relying on seawater is being investigated for

Loviisa NPP and the use of mobile devices for providing power and/or water are also being considered for all operating units.

STUK has reviewed the assessments submitted by the licensees and also performed independent analyses related to the time available before core damage.

For severe accident management it is worth quoting the Finnish stress test report: "A comprehensive severe accident management (SAM) strategy has been developed and implemented both at Olkiluoto 1 and 2 and Loviisa 1 and 2 plant units. Development of the strategies started after the accident in Chernobyl in 1986, and the latest measures were in place in 2003. These strategies are based on ensuring the containment integrity which is required in the existing national regulations. STUK has reviewed these strategies and has made inspections in all stages of implementation. Severe accidents have been considered in the original design of Olkiluoto 3. STUK has reviewed the overall SAM strategy and the approach has been accepted. No changes to this approach are needed based on the stress tests". Nonetheless, further investigations are needed e.g. on hydrogen management outside the containment, on the behavior of the spent fuel pool in severe accidents and for the case of accident affecting more than one units.

In connection with the emergency preparedness of the units restoration and ensuring of the access routes as well as establishment of alternative access control modes are being considered by the utility.

The ENSREG peer review states that the requirements set by STUK regarding severe accident management are more stringent than those in the IAEA safety standards. In specific topics further investigations and tests are suggested.

12.2.2. IMPACT ON THE PUBLIC

STUK played a central role in informing the public about details and progress of the accident. As mentioned above two websites of STUK served for disseminating information, while dedicated telephone lines as well as several experts were at continuous disposal of the interested public. In order to obtain a picture about the impact of STUK activities related to the accident, STUK obtained the services of professional companies to perform media analysis and conduct public poll.

The media analysis concentrated in the appearance of STUK in the internet versions of the Finnish news-media published right after the accident in March 2011. The analysis revealed that in 80% of the articles published STUK was either mentioned or quoted. In 34% of these articles STUK was the main player or the source of information. It is worth noting that in 97% of these publications STUK was considered a neutral (i.e. unbiased) source of information.

The poll on media impact of STUK was conducted in May 2011. The polls surveyed 1001 citizens between the ages of 17 and 79 years, representative to the entire population of Finland. 79% of the respondents were satisfied with the information they received about the accident, 11% considered it too much and only 11% considered it to be not enough. The poll has proven again that he main source of information for a large majority of the population was television. A large number felt overwhelmed by the information available on the internet and in web editions of news media. These results emphasized the importance of the frequent appearance of STUK in the electronic and written media and indeed further result of the survey proved the effectiveness of this approach. Notably, on an average 89% of the respondents remembered news about the TEPCO Fukushima Dai-ichi accident where STUK or experts from STUK were involved, while 77% of the respondents considered that that the information provided by STUK concerning the accident was appropriate. The respondents were requested to rate the reliability of the information provided by STUK on a scale from 1 (very unreliable) to 4 (very reliable). 85% of the respondents considered the information rather reliable or reliable.

CONCLUSION [1]

The IRRS team considers that the actions taken by STUK immediately after the TEPCO Fukushima Dai-ichi accident were timely and effective in requesting the licensees to summarize the prompt and longer term actions related to the safety of the power plants operating and under construction in Finland that follow from the immediate lessons learned from the accident. It was exemplary how STUK took the responsibility of providing adequate, professional and effective information to the partner governmental organizations, to the media and to the general public on the events in Fukushima and on their consequences.

12.3. PLANS FOR UPCOMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE ACCIDENT

The developments and investigations found necessary by national investigations and the European stress test shall be included into enhancement plans of the utilities. As mentioned before, STUK assessed the plans of the licensees and incorporated into a regulatory decision the most important actions to be performed. Some of them have already been mentioned in Section 12.2.1, the most important ones are: for Loviisa alternative ultimate heat sink; improvement of auxiliary feed-water pumps; possible application of mobile devices; ensuring long-term diesel operation; etc.; for Olkiluoto independent water supply to the pressure vessel; independent cooling of the emergency feed-water pumps; use of mobile diesels and aggregates for various purposes; etc.

STUK has also concluded that certain changes are needed in the legal and regulatory framework of nuclear safety in Finland. Thus the Government should require emergency preparedness to cope with multi-unit emergencies, and for this purpose to establish an off-site emergency centre and set requirements for a higher level autonomy of the plant. The suite of YVL guides should be expanded to address requirements necessary for power plants coping with the consequences of extreme external conditions. The emergency preparedness and response organization of STUK also needs further development in the light of the European stress test.

CONCLUSION [2]

The IRRS team concludes that STUK initiated a thorough and timely reassessment of the nuclear safety of the Finnish nuclear power plants in order to reveal possible necessary safety enhancement measures in light of the TEPCO Fukushima Dai-ichi accident. The assessments have not identified any safety issue that would necessitate short term actions. Nevertheless a number of safety enhancements have been initiated while others are still under investigation.

12.4. CONCLUSIONS BY 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 Finland 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 Finland.***

Module 1: Responsibilities and Functions of the Government

The roles, responsibilities and response of the Government and the regulatory body to the TEPCO Fukushima Dai-ichi accident are described and discussed in Section 12.1.

The TEPCO Fukushima Dai-ichi accident highlighted the importance of having a strong, competent and independent nuclear regulatory body. The IRRS team identified that STUK operates in practice as an independent regulatory body, however, the team recommended in Section 1 that the legal regulatory framework should be strengthened by embedding, in law, STUK as a regulatory body separated from entities that have responsibilities or interests that could unduly influence its decision-making.

A general lesson from Fukushima was the importance of nuclear safety competence. On the initiative of the Ministry of Employment and Economy (MEE) the long term competence needs of the nuclear energy sector was estimated and summarized in a report. Based on these investigations the necessity of securing the sufficient number of highly qualified experts for both Government and industry has been recognized. The first steps towards the satisfaction of this need have been made e.g. through various training courses in which a great number of experts took part from practically all players of the Finnish nuclear infrastructure.

CONCLUSION [3]
The TEPCO Fukushima Dai-ichi accident highlighted the need for regulatory bodies to be clearly independent of Government and industry. This reinforces the recommendations in Section 1 of this report to strengthen the legal basis for STUK's independence. **The Government's initiative in securing the long term competence needs of nuclear safety of the country is outstanding among countries with operating NPPs and is in line with the general lessons learned from the TEPCO Fukushima Dai-ichi accident.**

Module 2: Global Nuclear Safety Regime

Finland 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. STUK is very active internationally, participating in the OECD, IAEA, WENRA, the Network of Regulators of Countries with Small Nuclear Programmes (NERS), and other institutions. STUK's international activities have been identified as a good practice under Module 2 in the main report. These activities allow STUK to stay abreast of and influence current international thinking with regard to safety improvements that should be considered in relation to the TEPCO Fukushima Dai-ichi accident, and also allows STUK to share its findings and initiatives with regard to improving safety with the global community.

Furthermore, as reported in Module 9, STUK is undertaking a comprehensive review of its regulatory guides and it has already adopted findings from the accident into the guides.

CONCLUSION [4]
The team recognises that STUK is actively involved in international activities following the TEPCO Fukushima Dai-ichi accident, including the EU Stress Test, and has already taken initial actions to enhance the safety of Finnish NPPs.

Module 3: Responsibilities and Functions of the Regulatory Body

The team found that during the TEPCO Fukushima Dai-ichi accident, STUK demonstrated that they had adequate independent nuclear and radiological safety regulatory control in Finland and they had adequate decision-making authority. STUK has the right to intervene and/or take timely actions to ensure safety during normal operation as well as during an emergency/accident. They have the correct structure and responsibilities in place that they can set requirements and conduct oversight to minimize the possibility of an accident occurring and in the event of an accident, mitigate their consequences. These actions are pre-planned and described in procedures up to and following a severe accident, including adequate communication tools to all stakeholders. STUK takes seriously its responsibility to inform the public on the radiation situation and its consequences to the population, environment and society.

STUK promptly requested nuclear facilities to conduct their own safety assessments and participate in the EU stress tests and they asked the Advisory Commission on Nuclear Safety for their opinions on the results of the EU stress tests conducted.

CONCLUSION [5]

With regard to the TEPCO Fukushima Dai-ichi accident, the IRRS team found that STUK's actions were consistent with its responsibilities and functions.

Module 4: Management System

As a consequence of the TEPCO Fukushima Dai-ichi accident STUK has conducted a self-assessment on emergency response. As an outcome of the self-assessment for the IRRS mission, they recognized the need for more clearly defining graded approach as well as the regulatory safety culture in STUK's management system. In addition the recommendation was made that results of threat analyses should be modified to make it more user-friendly and this information should be made easily available to STUK's emergency response organization as background material. STUK has a comprehensive HR-management system, including provisions of resources and competence management.

CONCLUSION [6]

The IRRS team found that as an immediate response to the TEPCO Fukushima Dai-ichi accident STUK performed a self-assessment of the emergency response procedures and made modifications accordingly. No other immediate modifications to the management system were identified by STUK, but continuous improvements will be made as suggested in chapter 4 of the report.

Module 5: Authorization

Several of the design provisions recognized as priorities in post-accident action plans elsewhere were in fact, implemented in Finland many years before the accident in Fukushima happened. Some examples are as follows: hardware and procedural provisions for more effective severe accident management, external hazards re-evaluations and strengthening, effective emergency preparedness, etc.

Approximately one week after the accident STUK required by decision from utilities to perform the first evaluation of their preparedness for impacts of extreme natural phenomena and reliability assessment for electricity supply and submit the results for evaluation within a very short time period of three weeks. Based on utilities response, STUK send in next months the new decision, requiring more comprehensive evaluation including the participation in the stress tests. Based on these evaluations, it was concluded that

there is no need for additional immediate actions. Later on, action and investigation plans were established, as a normal safety improvement activity. The reader is directed to Section 12.1 for full details of the regulatory actions taken by STUK.

The basis for STUK decisions is found in Nuclear Energy Act, section 7a – Guiding Principles and Government Decree on Safety, section 24 – Operation Experience Feedback and Safety Research.

STUK also prepared an action plan for regulatory actions, including revision of certain safety guides as detailed in to the section on Module 9 below.

The Fukushima action plan is considered an exceptional process, but all the implications will be comprehensively covered by the next PSRs.

Based on the self-evaluation of STUK's response to the Fukushima accident, there is no need to change the existing process of authorization, except for the revision of certain guides.

CONCLUSION [7]
As a follow-up to the TEPCO Fukushima Dai-ichi accident no need was identified for modification of the authorization process.

Module 6: Review and Assessment

Due to the continuous update of the STUK guidance documents, many issues associated with review and assessment of the Fukushima type accidents were addressed before the accident. Finland belongs to countries applying the principle of continuous safety improvements in compliance with evolving legislation. This fact allowed not only performing adequate review and assessment shortly after the accident using existing at that time system of STUK documents, but also to confirm that many provisions identified as post-Fukushima priorities (e.g. enhanced resistance against earthquakes and flooding, and hardware provisions for mitigation of severe accidents) were already implemented in Finland before Fukushima.

The results of post-Fukushima assessments were summarized by the licensees and by STUK in the European stress tests reports. It was concluded that existing STUK documents and subsequent review and assessment, in particular those related to accident management, are more stringent than usually established in many other countries.

In spite of these positive results, further improvements to increase the NPP robustness in situations beyond the design basis were identified, including additional strengthening against extreme natural hazards, against long-term losses of power supply and the ultimate heat sink, and enhancement of severe accident provisions to cope with multiunit accidents, accidents in spent fuel pools and storages. A number of additional studies were also requested by STUK from the licensees.

CONCLUSION [8]
STUK's approach to regulatory review and assessment contributed to an enhanced robustness of nuclear power plants against extreme external hazards and capabilities for coping with severe accidents before the TEPCO Fukushima Dai-ichi accident. STUK continues to implement its approach in review and assessment in order to further strengthen the safety of NPPs taking into account safety requirements based on the lessons learned from the TEPCO Fukushima Dai-ichi accident.

Module 7: Inspection

STUK's resident inspectors performed routine inspections of the electrical systems and UHS design features following the events at Fukushima. There were no significant findings that required immediate actions from the licensees as a result of these inspections.

The IRRS team reviewed various aspects of the STUK inspection framework to understand whether there were any programme vulnerabilities which might be exposed by an accident similar to Fukushima. The IRRS team reviewed and discussed programmatic aspects such as: inspection planning, the baseline inspection programme, reactive inspections, performance indicators, and trending of performance data. In addition, the IRRS team reviewed several issues relating to the qualification, and authorities of STUK inspectors, training, objectivity, access, and enforcement authority.

As soon as the details of licensees' plans to address the Fukushima upgrades are finalised, the regulatory oversight plans are updated to include specific compliance checks, including inspections of the implementation at the stations.

CONCLUSION [9]

The IRRS team concluded that the additional inspections performed by STUK in response to the TEPCO Fukushima Dai-ichi accident were prompt and focused on the areas contributing to the accident. The inspection process in place enabled STUK to conduct the necessary additional inspections. There is no additional need to change the inspection programme, beyond the findings in chapter 7 of the report, as a consequence of the TEPCO Fukushima Dai-ichi accident.

Module 8: Enforcement

STUK uses a graded enforcement approach whereby the selection and execution of the enforcement action depends on the risk significance of the situation being addressed. This approach was in place prior to the Fukushima accident

For situations deemed to be serious and considered to pose an imminent radiological hazard to workers, the public or the environment, STUK has the authority and will take whatever actions are necessary to restore an adequate level of safety and prevent unreasonable risk to the health, safety, security and the environment.

There were no enforcement activities of STUK in the aftermath of the Fukushima accident. STUK requested the licensees to perform additional safety assessments. The design provisions at the Finnish NPPs were reassessed in connection with the national and European stress tests post-Fukushima. STUK requested the licensees to review the areas defined in the stress tests and STUK has made decisions concerning the results and the proposed improvement measures. The schedule for the corrective actions has been agreed between STUK and the licensees through these decisions and STUK will follow-up on the implementation in the given time frame.

CONCLUSION [10]

The IRRS team concluded that the lessons learned from the TEPCO Fukushima Dai-ichi accident had no implications for enforcement activities. With respect to this and taking into account the assessment of the IRRS team in chapter 8, there is no need to change STUK's enforcement process in place with respect to lessons learned from the TEPCO Fukushima Dai-ichi accident.

Module 9: Regulations and Guides

STUK has reacted to the accident in Fukushima quite promptly by identifying a package of proposals to modify legally binding legislation. Identified issues requiring particular attention in the light of Fukushima are addressed through regulations and guides systematically (except tsunamis which are not considered possible at Finnish coasts). The most important implications of the TEPCO Fukushima Dai-ichi accident are planned to be included in the Government Decree on nuclear safety (733/208) and Government Decree on emergency preparedness at nuclear power plants (735/2008). No changes were identified as necessary concerning the licensing process. This implies that there is no need for changes in acts and decrees in this respect.

A project to amend regulatory guides was started at the beginning of 2012. A guideline was formulated to assist the process of amendments/modifications of the YVL regulatory guides as a result of lessons learned from the TEPCO Fukushima Dai-ichi accident ("Effects of Fukushima accident on the YVL Guides", 5.1.2012). At the time of the IRRS mission almost all the guides were in draft phase in under the comprehensive renewal programme. Most of the identified modifications were simply inserted into the ongoing process. There were a few exceptions where the relevant guides were already in an advanced stage of revision. Appropriate special measures had to be taken in these cases.

STUK plans to modify all YVL guides by the end of February 2013. Proposals for changes in the decree level were already sent to the relevant ministries and the legislative process shall be started in the near future.

CONCLUSION [11]
The IRRS team concludes that STUK is well advanced in preparation and implementation of changes to its regulations and guides to account for the lessons learned up to date from the TEPCO Fukushima Dai-ichi accident.

Module 10: Emergency Preparedness and Response

STUK's response to the TEPCO Fukushima Dai-ichi nuclear emergency was prompt and appropriate. Details of the actions taken are described in Section 12.1 of this report and will not be repeated here. STUK's role was essential in the following areas:

- Assessment of the situation, based on the information collected through all channels available for the regulatory body;
- Advising the Government, as well as the other agencies in Finland, as well as the Finnish embassy in Japan regarding the prevailing situation and the recommended countermeasures;
- Preparing and facilitating the iodine prophylaxis for the citizens staying in Japan;
- Providing timely, truthful and unbiased information to the public in Finland.

Based on the post-emergency reviews and feedback analyses STUK's performance in all the above areas were considered appropriate, well measured and highly professional. Nevertheless, the lessons learned from the emergency led to the revisions of some of the legal documents and the introduction of certain improvements in the emergency preparedness systems (especially regarding the possible international assistance).

CONCLUSION [12]
The IRRS team concludes that STUK's emergency response to the TEPCO Fukushima Dai-ichi accident was prompt and appropriate. STUK addressed adequately the concerns of the general public. Post-event analysis of STUK's response revealed findings, detailed in chapter 10, which STUK is currently addressing.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
1. **JAMET** Philippe	Autorité de Sûreté Nucléaire (ASN)	philippe.jamet@asn.fr
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APPENDIX II – MISSION PROGRAMME

14 October, Sunday							
16:00 – 18:00	Opening Team Meeting (Meeting room Ambassador II at Scandic Continental) H. Koponen, A. Tanninen, E. Oksanen from STUK						
15 October, Monday							
09:00 – 12:00	Entrance Meeting (Auditorium) • Opening of the meeting, Director General Tero Varjoranta • Opening remarks by Ministry of Employment and the Economy, Deputy Director General Herkko Plit • Opening remarks by Ministry of Social Affairs and Health, Director Jari Keinänen • Opening remarks, Team Leader Philip Jamet, introduction of the team • IAEA opening remarks, Team Coordinator Adriana Nicic • Overview of STUK activities, Tero Varjoranta, introduction of counterparts						
	Group A Röntgen 4386	*Group B* Raporttihuone 3114	*Group C* Alfa 5329	*Group D* Gamma 5373	*Group E* Story 4427	*Group F-1 (Med)* Iso 3101 *Group F-2 (Occ)* Beta 5356	*Group G-R* Talli 4519 *Group G-W* YMO 3443
13:00 – 17:00	Interviews Module 1	Interviews Module 3	Interviews Module 5	Interviews Module 7	Interviews Module 10	Interviews Module 11 Medical Exposure (F-1) Occupational Exposure (F-2)	Interviews Module 11 Transport of Radioactive Material (G-R) Waste, Decommissioning, Fuel Cycle (G-W)
17:00 – 18:00	Daily Team Meeting (Meeting room 3127)						

16 October, Tuesday							
	Group A Röntgen 4386	*Group B* Raporttihuone 3114	*Group C* Alfa 5329	*Group D* Gamma 5373	*Group E* Story 4427	*Group F-1 (Med)* Iso 3101 *Group F-2 (Occ)* Beta 5356	*Group G-R* Talli 4519 *Group G-W* YMO 3443
09:00 – 11:00	Ministry of Employment and the Economy	Interviews Module 3	Interviews Module 5	Interviews Module 7	Ministry of the Interior	Interviews Module 11	Interviews Module 11
11:00 – 12:00	Interviews Module 1				Interviews Module 10	Medical Exposure (F-1) Occupational Exposure (F-2)	Transport of Radioactive Material (G-R) Waste, Decommissioning, Fuel Cycle (G-W)
13:00 – 17:00	Interviews Module 1	Interviews Module 3	Interviews Module 5	Departure to Rauma Accommodation at the Hotel Cumulus	Interviews Module 10	Interviews Module 11 Medical Exposure (F-1) Occupational Exposure (F-2)	Interviews Modules 5-9 Rad. Sources (G-R) Departure to Rauma (G-W) Accommodation at the Hotel Vanha Rauma
17:00 – 18:00	Daily Team Meeting (Meeting room 3127)						
18:30 – 20:30	Social Event						

17 October, Wednesday							
	Group A Röntgen 4386	*Group B* Raporttihuone 3114	*Group C* Alfa 5329	*Group D* Gamma 5373	*Group E* Story 4427	*Group F-1 (Med)* Iso 3101 *Group F-2 (Occ)* Beta 5356	*Group G-R* Talli 4519 *Group G-W* YMO 3443
09:00 – 10:00	Meeting of Team Leader and STUK Management						
09:00 – 12:00	Interviews Module 9	Interviews Module 4	Interviews Module 5	Site visit Olkiluoto NPP	Interviews Module 10	Interviews Module 11 Medical Exposure (F-1) Site visit Loviisa NPP (F-2)	Site visit Porvoo Energy, Thermal power station (G-R) Site visit Posiva Onkalo (G-W)
13:00 – 16:00	Interviews Module 9	Advisory Commission for Nuclear Safety, Interviews Module 4	Interviews Module 6		Interviews Module 10	Interviews Module 11 Medical Exposure (F-1) Site visit Loviisa NPP & Occupational Exposure (F-2)	Interviews Modules 5-9 Rad. Sources (G-R) Site Visit Posiva Onkalo (G-W)
16:00 – 17:00	Writing preliminary findings, submit to TC						
17:00 – 18:00	Daily Team Meeting, discussion of findings (Meeting room 3127)						
20:00 – 24:00	Compilation of first finding into report Report writing (Meeting room Senator II at Scandic Continental)						

18 October, Thursday							
	Group A Röntgen 4386	*Group B* Raporttihuone 3114	*Group C* Alfa 5329	*Group D* Gamma 5373	*Group E* Story 4427	*Group F-1 (Med)* Iso 3101 *Group F-2 (Occ)* Beta 5356	*Group G-R* Talli 4519 *Group G-W* YMO 3443
09:00 – 11:00	Fukushima Session, Room 4427						
09:00 – 10:00	Interviews Module 2	STUK's Advisory Commission	Interviews Module 6	Interviews Module 8	Interviews Module 10 Emergency Exercise (*10:00-12:00* Room 4340)	Interviews Module 11 Medical Exposure (F-1) Occupational Radiation Protection (F-2)	Interviews Modules 5-9 Rad. Sources (G-R) Waste, Decommissioning, Fuel Cycle (G-W)
10:00 – 12:00		Interviews Module 4					
11:00 – 13:00	Ministry of Social Affairs and Health						
13:00 – 17:00	Interviews Module 2	Interviews Module 4	Interviews Module 6	Interviews Module 8	Emergency Exercise	Team members write the report	Team members write the report (G-R) Interviews Modules 5-9 Waste, Decommissioning, Fuel Cycle (G-W)
17:00 – 18:00	Daily Team Meeting, discussion of findings (Meeting room 3127)						
20:00 – 24:00	Report writing (Meeting room Senator II at Scandic Continental)						

<table>
<tr><th colspan="8">19 October, Friday</th></tr>
<tr><td></td><td>Group A
Röntgen 4386</td><td>Group B
Raporttihuone 3114</td><td>Group C
Alfa 5329</td><td>Group D
Gamma 5373</td><td>Group E
Story 4427</td><td>Group F-1 (Med)
Iso 3101
Group F-2 (Occ)
Beta 5356</td><td>Group G-R
Talli 4519
Group G-W
YMO 3443</td></tr>
<tr><td>09:00 – 10:00</td><td colspan="5">Meeting of Team Leader and STUK Management</td><td rowspan="3">Site Visit
Turku University Hospital (F-1, G-R)

F-2 as Groups A-E</td><td>Meeting of Team Leader and STUK Management</td></tr>
<tr><td>09:00 – 12:00</td><td colspan="5">Team members write the report TL and DTL review introductory parts
Submittal of the draft texts</td><td>Team members write the report</td></tr>
<tr><td>13:00 – 15:00</td><td colspan="5">Policy Issues
1. Uranium mining and milling, NORM and associated waste (meeting room 3443)
2. Interface between safety and security (meeting room 3101)
Team members write the report
Submittal of the draft texts
TL and DTL review introductory parts</td><td>Policy issues / Team members write the report, Submittal of the draft texts</td></tr>
<tr><td>15:00 – 17:00</td><td colspan="5">Secretariat edits report
Cross reading by Team Members
Release of preliminary draft report</td><td colspan="2">Secretariat edits report
Cross reading by Team Members
Release of preliminary draft report</td></tr>
<tr><td>17:00 – 18:00</td><td colspan="7">Daily Team Meeting (Meeting room 3127)</td></tr>
<tr><td>20:00 – 24:00</td><td colspan="7">Team members read the Draft (Meeting room Senator II at Scandic Continental)</td></tr>
</table>

20 October, Saturday	
09:00 – 12:00	Team Meeting to discuss Draft Cross reading TL, DTL, TC, DTC read the entire Draft
13:00 – 18:00	Finalization of the Draft Report
20:00 –24:00	Secretariat edits the report
21 October, Sunday	
15:00 -17:00	Social Programme / Helsinki sight-seeing bus tour Reading, cross-reading the report
22 October, Monday	
09:00 – 10:00	Meeting of Team Leader and STUK Management
09:00 – 12:00	Individual discussion with the Host counterparts on the findings Cross reading TL, DTL, TC, DTC read the entire Draft
13:00 – 15:00	Policy Issue 3: Possible conflict of interest Meeting room 4386
15:00 – 17:00	Individual discussion with the Host counterparts on the findings
17:00 – 18:00	Daily Team meeting
20:00 -	Secretariat includes changes
23 October, Tuesday	
09:00 – 12:00	Cross reading TL, DTL, TC, DTC read the entire Draft Finalization by the Team Members Meeting room 3127
13:00 – 18:00	Discussion of the report by the Team TC, DTC prepare Executive Summary and exit meeting presentation Meeting room 3127
20:00 -24:00	Secretariat finalizes text

24 October, Wednesday	
09:00 – 10:00	Team meeting to read through the Draft report Submission of the Draft to the Host
13:00 – 17:00	Host counterparts read Draft report TL finalizes Executive Summary and exit meeting presentation TC drafts the Press Release
25 October, Thursday	
09:00 – 10:00	Meeting of Team Leader and STUK Management Working time for Team Members
10:00 – 12:00	Discussion with the Host Counterparts
13:00 – 17:00	Host submits their written comments Team Meeting to finalize the report
17:00 – 18:00	Briefing the DIR Finalization of the Press Release
18:00 – 20:00	Social Event
26 October, Friday	
09:00 – 10:00	Submission of the Final Draft to the Host
10:00 – 12:00	Exit Meeting (Auditorio) • Opening of the meeting, Director General Tero Varjoranta • Summary of the findings of the mission, Team Leader Philip Jamet • Remarks by IAEA • Remarks by the Ministries and STUK Press Conference
	Departure of the Team Members

APPENDIX III – SITE VISITS

Facilities visited:	
1.	Olkiluoto NPP
2.	Porvoo Energy, Thermal power station
3.	Posiva Onkalo Waste Repository
4.	Loviisa NPP
5.	Turku University Hospital

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	STUK Lead Counterpart	STUK Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	M. Bassett A. Sapozhnikov P. Krs	T. Vajoranta	H. Koponen L. Reiman
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	M. Bassett A. Sapozhnikov P. Krs	T. Vajoranta	H. Koponen P. Tiipana
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	E. Oehlen R. Cid P. Holahan	P.Tiippana	K. Koskinen E. Oksanen A. Tanninen E. Kettunen P. Salo T. Ikäheimonen
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	E. Oehlen R. Cid P. Holahan	K. Koskinen	A. Kannisto P. Tiippana A. Tanninen E. Oksanen E. Kainulainen

	IRRS EXPERTS	STUK Lead Counterpart	STUK Support Staff
5.	**AUTHORIZATION**		
	J. Misak D. Vojnovic S.E. Palsson I. Shadad F. Besnus T. Pather	T. Virolainen	M. Markkanen J. Heinonen J. Nevalainen K. Valtonen
6.	**REVIEW AND ASSESSMENT**		
	J. Misak D. Vojnovic S.E. Palsson I. Shadad F. Besnus T. Pather	K. Valtonen	M. Markkanen J. Heinonen T. Virolainen
7.	**INSPECTION**		
	C. Ciurea-Ercau T. Wildermann S.E. Palsson I. Shadad F. Besnus T. Pather	K. Alm-Lytz	M. Vilpas M. Markkanen J. Heinonen
8.	**ENFORCEMENT**		
	C. Ciurea-Ercau T. Wildermann S.E. Palsson I. Shadad F. Besnus T. Pather	K. Alm-Lytz	M. Vilpas M. Markkanen J. Heinonen

	IRRS EXPERTS	STUK Lead Counterpart	STUK Support Staff
9.	**REGULATIONS AND GUIDES**		
	M. Bassett A. Sapozhnikov P. Krs S.E. Palsson I. Shadad F. Besnus T. Pather	L. Reiman	M-L.Järvinen R. Havukainen A.Tanninen M. Markkanen J. Heinonen
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**		
	M. Nizamska P. Zombori	H. Aaltonen	
11.	**CONTROL OF MEDICAL EXPOSURES, OCCUPATIONAL RADIATION PROTECTION, PUBLIC AND ENVIRONMENTAL EXPOSURE CONTROL**		
	F. Besnus K. Murthy A. McGarry T. Pather	R. Bly H. Korpela R. Paltemaa A. Lahkola	M. Lehtinen J. Sovijäri O. Vilkamo T. Siiskonen I. Jokelainen P. Sipilä H. Järvinen A. Isolankila J. Heinonen
12.	**REGULATORY IMPLICATIONS OF THE TEPCO DAI-ICHI ACCIDENT**		
	I. Lux	P. Tiippana	H. Aaltonen R. Isaksson T. Routamo J. Sandberg L. Reiman

APPENDIX V – RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	**R1**	The Government should embed, in law, STUK as an independent regulatory body separated from other entities having responsibilities or interests that could unduly influence its decision making.
	R2	The Government should seek to modify the Nuclear Energy Act so that the law clearly and unambiguously stipulates STUK's legal authorities in the authorisation process for safety. In particular, the changes should ensure that STUK has the legal authority to both: • specify any licence conditions necessary for safety; and • specify all regulations necessary for safety.
	S1	The relevant Ministries and STUK should develop Memoranda of Understanding for implementing their roles, responsibilities and cooperation with a view to ensuring that STUK is accountable while clearly maintaining its regulatory independence.
	GP1	In Finland the political commitment to implement a geological repository and the regulatory process for implementing the geological disposal is well defined and has been in place for a long period of time (since 1983).
	R3	Recognising that Finland has successfully implemented many strategic decisions related to radioactive waste management, in particular the disposal options for low and intermediate level waste and spent fuel, the Government should incorporate these and strategies for other radioactive waste into a comprehensive policy and strategy.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	GP2	The Government report on Nuclear Energy Competence in Finland is commendable and the IRRS team encourages the Government to continue to progress the actions arising from this work.
	R4	The Government should ensure that STUK has sufficient resources to fulfil the responsibilities placed on it by the Government to provide technical services.
2. GLOBAL NUCLEAR SAFETY REGIME	**GP3**	STUK has an excellent record of active contribution to the global improvement of radiation and nuclear safety through its participation in relevant international activities. STUK has devoted high quality expertise to this activity and intends to continue in the future.
	S2	STUK should consider improving its processes for sharing information on matters that have generic implications with all relevant stakeholders (including the public) in a timely manner.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**S3**	STUK and the Government should consider reviewing all the advisory commissions to evaluate consistency of roles, functions and reporting lines. STUK should also propose a formal mechanism to address potential conflicts of interest for advisory commissions.
	S4	In order to ensure that previous regulatory positions are captured and support consistency in decision-making over time STUK should consider developing further processes and tools to manage requirements.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**S5**	STUK should consider explicitly addressing safety culture in its management system in order to ensure a common understanding of key safety culture characteristics to support individuals and groups to: • Reinforce a learning and questioning attitude at all levels of the organization; • Continuously develop, assess and improve the safety culture; and • Prevent regulatory capture.
	S6	STUK should consider further improving its management system with respect to the following aspects: • Reviewing the requirements for managing the organization to ensure that the relevant requirements are addressed in a coherent manner; • Reviewing and revising the existing quality manuals and guidance documents for consistency and elimination of potential duplications; • Improving overall descriptions of the processes including sub-processes and their interdependency; and • Ensuring the easy identification of relevant procedures and documents.
	S7	STUK should consider developing further a systematic long-term programme for self-assessments, internal and external audits, including follow-on actions and evaluations of the effectiveness of the processes. The programme should be monitored, recorded and reflect STUK's strategic plan.
5. AUTHORIZATION	**S8**	STUK should consider developing a graded approach for the authorization of systems, structures and components in order to focus more on issues of higher safety significance.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S9	For its own uses of radiation, STUK should consider demonstrating, in a transparent manner, that it satisfies all the required regulatory conditions necessary for an authorization.
	R5	The Government should expand the legislative framework to encompass distinct authorizations for decommissioning of facilities and closure of repositories in addition to the current authorizations for construction and operation of nuclear facilities.
6. REVIEW AND ASSESSMENT	**GP4**	STUK has established a comprehensive set of technical and radiological acceptance criteria and associated safety assessment requirements for all plant states including adequate consideration of different design extension conditions and severe accidents.
	GP5	For novel design solutions adopted in new reactors, such as those associated with mitigation of severe accidents and security threats, STUK has verified the demonstration of effectiveness of such solutions by extensive independent analytical and experimental justification, including use of relevant research results.
7. INSPECTION	**S10**	STUK should develop criteria for initiating reactive inspections.
	S11	STUK should consider conducting more frequent unannounced inspections of the facilities and activities under its regulatory control.
	R6	STUK should extend the use of the graded approach for planning and conducting inspections across all regulated facilities and activities. STUK should develop more detailed procedures in this regard.
	S12	STUK should consider developing a formal qualification programme for inspectors of nuclear facilities as well as nuclear materials and waste.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S13	STUK should consider the development and implementation of a more systematic method to collect indications of and assess the licensee's safety culture.
	S14	STUK should consider initiating an inspection programme that includes periodic assessments of the levels of workers' doses in different types of transport activities in cooperation with the relevant regulatory agencies.
9. REGULATIONS AND GUIDES	**S15**	STUK should complete its comprehensive programme for the renewal of its nuclear safety regulatory guides (YVL) in accordance with its approved implementation plan. In addition, STUK should use the experience gained in upgrading nuclear safety regulatory guides in preparing for renewal of radiation safety regulatory guides (ST).
10. EMERGENCY PREPAREDNESS AND RESPONSE	**S16**	STUK should, in cooperation with relevant Government authorities, consider improving national arrangements for timely provision of assistance requested by other countries (including through RANET) and for effectively integrating assistance received by Finland into the national response system.
	R7	STUK should include the additional class of "facility emergency" in its emergency classification scheme in order to ensure that appropriate on-site emergency response actions are taken for the protection of the workers and that important information is communicated consistently to relevant parties.
	GP6	All teams of the regional Departments for Rescue Services of the Ministry of Interior are equipped with electronic dose rate meters and responders are trained in their use. This allows first responders to detect the radiation hazards and take appropriate actions in a timely manner.
	S17	The Government should consider improving arrangements for the coordination of information to the public and media during emergencies to ensure that the messages issued by different authorities are consistent.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	GP7	STUK has excellent tools, facilities and organizational arrangements to perform the necessary evaluation of the emergency in a timely manner and to provide appropriate recommendations for protective measures. The organization and conduct of the emergency exercises and the coordination with other stakeholders is exemplary.
	GP8	Decision makers at high political level participate in national emergency exercises which strengthens their engagement and proper preparedness for the decision making challenges required during a real emergency.
11.ADDITIONAL AREAS	**GP9**	STUK inspectors responsible for compliance monitoring of medical exposures have the opportunity for hands-on training in a clinic conducting the licensed activity. This allows the inspectors to obtain a thorough understanding of all aspects of the regulated practice.
	GP10	STUK has developed outstanding expertise in the area of quality assurance of all aspects of radiation dose delivery in radiation therapy and diagnostic radiology.
	S18	STUK should ensure further that its nuclear safety and radiation safety guides are consistent with respect to common requirements related to occupational exposure.
	S19	STUK should include information on the doses received by workers occupationally exposed to radon in its annual report on radiation practices.
	S20	For its own technical services, STUK should consider demonstrating, in a transparent manner, that it satisfies all the required regulatory conditions necessary for an approval.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R8	STUK should withdraw from the current practice of conducting the environmental monitoring programmes in the vicinity of the nuclear facilities based on commercial contracts with the licensees. Furthermore, STUK should implement an independent monitoring programme for the environment, to verify the results of the off-site environmental monitoring programmes required from the licensees.

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

AREA	NO.	CONCLUSION
IMPACT ON THE PUBLIC	**C 1**	The IRRS team considers that the actions taken by STUK immediately after the TEPCO Fukushima Dai-ichi accident were timely and effective in requesting the licensees to summarize the prompt and longer term actions related to the safety of the power plants operating and under construction in Finland that follow from the immediate lessons learned from the accident. It was exemplary how STUK took the responsibility of providing adequate, professional and effective information to the partner governmental organizations, to the media and to the general public on the events in Fukushima and on their consequences.
PLANS FOR UP-COMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE ACCIDENT	**C 2**	The IRRS team concludes that STUK initiated a thorough and timely reassessment of the nuclear safety of the Finnish nuclear power plants in order to reveal possible necessary safety enhancement measures in light of the TEPCO Fukushima Dai-ichi accident. The assessments have not identified any safety issue that would necessitate short term actions. Nevertheless a number of safety enhancements have been initiated while others are still under investigation.

AREA	NO.	CONCLUSION
RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	**C 3**	The TEPCO Fukushima Dai-ichi accident highlighted the need for regulatory bodies to be clearly independent of Government and industry. This reinforces the recommendations in Section 1 of this report to strengthen the legal basis for STUK's independence. The Government's initiative in securing the long term competence needs of nuclear safety of the country is outstanding among countries with operating NPPs and is in line with the general lessons learned from the TEPCO Fukushima Dai-ichi accident.
GLOBAL NUCLEAR SAFETY REGIME	**C 4**	The team recognises that STUK is actively involved in international activities following the TEPCO Fukushima Dai-ichi accident, including the EU Stress Test, and has already taken initial actions to enhance the safety of Finnish NPPs.
RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**C 5**	With regard to the TEPCO Fukushima Dai-ichi accident, the IRRS team found that STUK's actions were consistent with its responsibilities and functions.
MANAGEMENT SYSTEM	**C 6**	The IRRS team found that as an immediate response to the TEPCO Fukushima Dai-ichi accident STUK performed a self-assessment of the emergency response procedures and made modifications accordingly. No other immediate modifications to the management system were identified by STUK, but continuous improvements will be made as suggested in chapter 4 of the report.

AREA	NO.	CONCLUSION
AUTHORIZATION	**C 7**	As a follow-up to the TEPCO Fukushima Dai-ichi accident no need was identified for modification of the authorization process.
REVIEW AND ASSESSMENT	**C 8**	STUK's approach to regulatory review and assessment contributed to an enhanced robustness of nuclear power plants against extreme external hazards and capabilities for coping with severe accidents before the TEPCO Fukushima Dai-ichi accident. STUK continues to implement its approach in review and assessment in order to further strengthen the safety of NPPs taking into account safety requirements based on the lessons learned from the TEPCO Fukushima Dai-ichi accident.
INSPECTION	**C 9**	The IRRS team concluded that the additional inspections performed by STUK in response to the TEPCO Fukushima Dai-ichi accident were prompt and focused on the areas contributing to the accident. The inspection process in place enabled STUK to conduct the necessary additional inspections. There is no additional need to change the inspection programme, beyond the findings in chapter 7 of the report, as a consequence of the TEPCO Fukushima Dai-ichi accident.
ENFORCEMENT	**C 10**	The IRRS team concluded that the lessons learned from the TEPCO Fukushima Dai-ichi accident had no implications for enforcement activities. With respect to this and taking into account the assessment of the IRRS team in chapter 8, there is no need to change STUK's enforcement process in place with respect to lessons learned from the TEPCO Fukushima Dai-ichi accident.
REGULATIONS AND GUIDES	**C 11**	The IRRS team concludes that STUK is well advanced in preparation and implementation of changes to its regulations and guides to account for the lessons learned up to date from the TEPCO Fukushima Dai-ichi accident.

AREA	NO.	CONCLUSION
EMERGENCY PREPAREDNESS AND RESPONSE	**C 12**	The IRRS team concludes that STUK's emergency response to the TEPCO Fukushima Dai-ichi accident was prompt and appropriate. STUK addressed adequately the concerns of the general public. Post-event analysis of STUK's response revealed findings, detailed in chapter 10, which STUK is currently addressing.

APPENDIX VII – STUK 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: Authorisation* - *Module 6: Review and Assessment* - *Module 7: Inspection* - *Module 8: Enforcement* - *Module 9: Regulations and Guides* - *Module 10: Emergency Preparedness and Response* - *Module 11: Control of Medical Exposures, Occupational Radiation Protection, Public and Environmental Exposure Control* - *Module 12: Regulatory Implications of the Tepco Fukushima Dai-Ichi Accident*
[2]	**Relevant Documentation**
STUK Internal Documents	
	1. *ST Guides* 2. *YVL Guides* 3. *STUK Guides* 4. *SKV Guides* 5. *YTV Guides*
EU Directive	
	1. *EU Directive 2009_71 Nuclear safety*
Legislation	
	1. *Decree of the Ministry of Social Affairs and Health on the medical use of radiation* 2. *Decree on the Advisory Commission for Nuclear Safety* 3. *Government Decree on Emergency Response Arrangements at Nuclear Power Plants* 4. *Government Decree on the Safety of Disposal of Nuclear Waste* 5. *Government Decree on the Safety of Nuclear Power Plants* 6. *Government Decree on the Security in the Use of Nuclear Energy* 7. *Nuclear Energy Act* 8. *Nuclear Energy Decree* 9. *Radiation Act* 10. *Radiation Decree* 11. *Rescue Act* 12. *STUK Act* 13. *STUK Decree*
Policy Issue 1:	
	Uranium mining and milling, NORM and associated waste
Policy Issue 2:	
	Interface between safety and security
Policy Issue 3:	
	Possible conflict of interest

APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1, IAEA, Vienna (2010).
2. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3, IAEA, Vienna (2006).
3. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Preparedness and Response for Nuclear and Radiological Emergencies, Safety Requirement Series No. GS-R-2, IAEA, Vienna (2002).
4. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No. GSR Part 3 (Interim Edition), IAEA, Vienna (2011).
5. **INTERNATIONAL ATOMIC ENERGY AGENCY** - International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA Safety Series No. 115, Vienna (1996).
6. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4, IAEA, Vienna (2009)
7. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Radioactive Waste, General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009).
8. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Facilities Using Radioactive Material Safety, , Safety Requirement Series No. WS-R-5, IAEA, Vienna (2006).
9. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Power Plants: Design, Specific Safety Requirements No. SSR-2/1, IAEA, Vienna (2012).
10. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements Series No. SSR-2/2, IAEA, Vienna (2011).
11. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Site Evaluation for Nuclear Installations, Safety Requirement Series No. NS-R-3, IAEA, Vienna (2003).
12. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Fuel Cycle Facilities, Safety Requirement Series No. NS-R-5, IAEA, Vienna (2008)
13. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Disposal of Radioactive Waste, Specific Safety Requirements No. SSR-5, IAEA, Vienna (2011)
14. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002).
15. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002).
16. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002).
17. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Documentation Used in Regulating Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002).

18. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)

19. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna 2011)

20. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Commissioning for Nuclear Power Plants, Safety Guide Series No. NS-G-2.9, IAEA, Vienna (2003)

21. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Periodic Safety Review of Nuclear Power Plants, Safety Guide Series No. NS-G-2.10, IAEA, Vienna (2003)

22. **INTERNATIONAL ATOMIC ENERGY AGENCY** - A System for the Feedback of Experience from Events in Nuclear Installations, Safety Guide Series No. NS-G-2.11, IAEA, Vienna (2006)

23. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Occupational Radiation Protection, Safety Guide Series No. RS-G-1.1, IAEA, Vienna (1999)

24. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Assessment of Occupational Exposure Due to Intakes of Radionuclides, Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)

25. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Assessment of Occupational Exposure Due to External Sources of Radiation, Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)

26. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005)

27. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)

28. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)

29. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)

30. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)

31. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)

32. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Nuclear Power Plants and Research Reactors, Safety Guide Series No.WS-G-2.1, IAEA, Vienna (1999)

33. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide Series No.WS-G-2.3, IAEA, Vienna (2000)

34. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Nuclear Fuel Cycle Facilities, Safety Guide Series No.WS-G-2.4, IAEA, Vienna (2001)

35. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Low and Intermediate Level Radioactive Waste, Safety Guide Series No.WS-G-2.5, IAEA, Vienna (2003)

36. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of High Level Radioactive Waste, Safety Guide Series No.WS-G-2.6, IAEA, Vienna (2003)

37. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009)

38. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006)

APPENDIX IX – ORGANIZATIONAL CHART