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INTERNATIONAL ATOMIC ENERGY AGENCY

INTERNATIONAL REGULATORY REVIEW TEAM (IRRT) FOLLOW-UP MISSION

TO

Finland

HELSINKI

31 August– 9 September 2003

DIVISION OF NUCLEAR INSTALLATION SAFETY

FOREWORD

by the

Director General

The IAEA International Regulatory Review Team (IRRT) programme assists Member States to enhance the organization and performance of their nuclear safety regulatory body. Such a regulatory body must work within the framework of its national legal system which in turn should ensure both the independence and the legal powers available to the regulatory body. Additionally the national administrative and legislative system should ensure that the regulatory body has sufficient funding and resources to carry out its functions of reviewing and assessing safety submissions; licensing or authorizing nuclear safety activities, establishing regulations and criteria; inspecting nuclear facilities and enforcing national legislation. The regulatory body should be resourced and staffed by capable and experienced people to a level commensurate with the national nuclear programme. IRRT missions focus on all these aspects in assessing the regulatory body's safety effectiveness. Comparisons with successful practices in other countries are made and ideas for improving safety are exchanged at the working level.

An IRRT mission is made only at the request of a Member State. It is not an inspection to determine compliance with national legislation, rather an objective review of nuclear regulatory practices with respect to international guidelines. The evaluation can complement national efforts by providing an independent, international assessment of work processes that may identify areas for improvement. Through the IRRT programme, the IAEA facilitates the exchange of knowledge and experience between international experts and regulatory body personnel. Such advice and assistance will enhance nuclear safety in all nuclear countries. An IRRT mission is also a good training ground for observers from newly formed regulatory bodies in developing countries who follow the evaluation process. This approach, based on voluntary co-operation, contributes to the attainment of international standards of excellence in nuclear safety at the regulatory body level.

Essential features of the work of the IRRT experts and their regulatory body counterparts are the comparisons of regulatory practices with international guidelines and best practices, and a joint search for areas where practices can be enhanced. The implementation of any recommendations or suggestions, after consideration by the regulatory body, is entirely voluntary.

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 IRRT reports from different countries should not be attempted.

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SUMMARY

At the request of the Finnish Governmental Authorities, an IAEA team of experts visited the Radiation and Nuclear Safety Authority (STUK) in March 2000 to conduct an International Regulatory Review Team (IRRT) mission. The purpose of the mission was to review the effectiveness of the regulatory body of Finland and to exchange information and experience in the regulation of nuclear, radiation, radioactive waste and transport safety.

In October 2002 the Finnish Governmental Authorities requested a follow-up mission to review the measures undertaken following the recommendations and suggestions presented in the report of the March 2000 IRRT mission.

The review was conducted from August 31 to September 9, 2003 by an IAEA team of six experts. During the review the team recognized that STUK has taken a number of initiatives to improve its effectiveness and efficiency and that STUK faces several new challenges. These include those resulting from the decisions in principle to build a new nuclear power plant unit and a disposal facility for spent fuel as well as the initiatives for the modernization of existing nuclear power plants.

The team concluded that STUK has taken initiatives to address, in a systematic manner, all the recommendations and suggestions from the March 2000 IRRT mission. In the opinion of the team these initiatives have resulted in significant improvements. Nearly all the March 2000 IRRT recommendations and suggestions have been adequately addressed, particularly those for which STUK had the full responsibility for implementation. The team also concluded that STUK has acquired a high level of readiness to face its new challenges. Throughout the review, the team developed the view that STUK has a high level of commitment toward continuous improvement. Some of the good practices identified during the previous mission have also improved thus indicating the absence of complacency.

The report however still includes two recommendations. The team considers that it is important to establish a sound legal basis for regulatory control over the construction of the proposed underground research laboratory and the research to be carried out. The team also considers that the regulatory control of the transport of radioactive material should include the design, manufacture and use of non-certified packages.

The report also includes a number of new suggestions to further strengthen the regulatory body in Finland and to support the observed continuous improvement. In addition, the reviewers also identified a number of new good practices and these have been recorded for the benefit of other nuclear regulatory bodies.

STUK staff put considerable effort into the preparation of the mission. During the review the administrative and logistic support was excellent and the team was extended full co-operation during technical discussions with STUK personnel as well as the representatives of the Ministry of Trade and Industry (KTM), the Ministry of Social Affairs and Health (STM), the Ministry of Interior (SM), the Technical Research Center of Finland (VTT), the operator of the Loviisa Nuclear Power Plant (Fortum) and the Finnish Broadcasting Corporation YLE. STUK counterparts were enthusiastic and interested in obtaining further advice on the way they conduct their work and on their plans for further development.

INTRODUCTION

At the request of the Finnish Governmental Authorities, an IAEA team of experts visited the Radiation and Nuclear Safety Authority (STUK) in March 2000 to conduct an International Regulatory Review Team (IRRT) mission. The purpose of the mission was to review the effectiveness of the regulatory body of Finland and to exchange information and experience in the regulation of nuclear, radiation, radioactive waste and transport safety.

On October 17, 2002 the Finnish Governmental Authorities requested a follow-up mission to review the measures undertaken following the recommendations and suggestions presented in the report of the March 2000 IRRT mission.

The review was conducted from August 31 to September 9, 2003 by an IAEA team of six experts. Before taking part in the mission the experts reviewed the Advanced Reference Material provided by STUK. It included both descriptive material and a table summarizing the response from STUK to the set of recommendations and suggestions presented in the report of the previous mission.

The team reviewed, in a systematic manner, the response to the recommendations and suggestions from the previous mission. During the review the team recognized that STUK has taken a number of initiatives to improve its effectiveness and efficiency and that STUK faces several new challenges. These include those resulting from the decisions in principle to build a new nuclear power plant unit and a disposal facility for spent fuel as well as the initiatives for the modernization of existing nuclear power plants. During the mission, a systematic review of the measures implemented since March 2000 was completed using interviews with staff and direct observation of working practices.

The IRRT activities took place at the STUK offices in Helsinki and at the Loviisa Nuclear Power Plant. At the invitation of STUK, representatives of the Ministry of Trade and Industry (KTM), the Ministry of Social Affairs and Health (STM), the Ministry of Interior (SM), the Technical Research Center of Finland (VTT) and the Finnish Broadcasting Corporation YLE were also interviewed.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

Expert: José I. Villadóniga

1.1. PRINCIPAL LAWS OR OTHER LEGAL PROVISIONS

The Finnish Regulatory Pyramid includes Legislation (the Acts and Decrees), Regulations (Government Resolutions) and Guidelines (the STUK guides). The principal documents are listed in the following sub sections.

1.1.1. Legislation

- Nuclear Energy Act. (990/1987)
- Radiation Act (592/1991)
- Act on the Radiation and Nuclear Safety Authority of Finland (1069/1983)
- Nuclear Liability Act (484/1972)
- Nuclear Energy Decree (161/1988)
- Radiation Decree (1512/1991)
- Decree on the Radiation and Nuclear Safety Authority of Finland (618/1997)
- Decree on the Advisory Committee on Nuclear Safety (164/1988)
- Decree on the State Nuclear Waste Management Fund (162/1988)
- Decree on the Implementation of the Nuclear Liability Act (486/1972)

1.1.2. Regulations

- Government Resolution on general regulations for the safety of nuclear power plants. (395/1991)
- Government Resolution on general regulations for the physical protection of nuclear power plants. (396/1991).
- Government Resolution on general regulations for the emergency response arrangements at nuclear power plants (397/1991)
- Government Resolution on general regulations for the safety of a disposal facility for reactor waste (398/1991)
- Government Resolution on general regulations for the safety of disposal of spent fuel (478/1999)
- Government Resolution concerning the provision for Nuclear Waste Management Cost (165/1998)
- Government Resolution on the general terms and conditions of loans that are granted from the State Nuclear Waste Management Fund (166/1988)
- Ministry of Social Affairs and Health order on the upper limits for radon concentration in places of residence (944/94)

1.1.3. Regulatory Guides

- YVL Guides. Nuclear facilities
- ST Guides. Radiation Practices
- VAL Guides. Emergencies.

1.2. SCOPE OF APPLICATION

The Nuclear Energy Act applies to:

1. *"the construction and operation of nuclear facilities;*
2. *mining and enrichment operations aimed at producing uranium or thorium;*
3. *the possession, fabrication, production, transfer, handling, use, storage, transport, export and import of nuclear materials and nuclear wastes as well as the export and import of ores and ore concentrates containing uranium or thorium;*
4. *in the cases specified in the third subsection of this section, the possession, transfer, export and import of materials, devices and equipment referred to therein as well as nuclear information;*
5. *in cases to be prescribed by decree, the conclusion and execution of civil agreements, for implementation outside of Finland in regard to any of the activities referred to in points 1–4 of this subsection, with a foreign state, a foreign natural or legal person, should the agreement have pertinence to the proliferation of nuclear weapons or should the obligations under Finland's international treaties in the field of nuclear energy have bearing on the agreement".*

The Radiation Act applies to:

1. *"Ionising and non-ionising radiation.*
2. *Radiation appliances and radioactive materials*
3. *Radioactive waste.*
4. *Radiation practices.*
5. *Radiation work".*

The fundamental safety principles/requirements are included in Chapter 2 of the Nuclear Energy Act and Section 2 of the Radiation Act.

The Licensing process of nuclear facilities is covered in Chapters 4 and 5 of the Nuclear Energy Act.

The responsibility for Safety is clearly assigned to the holder of the licence in Section 9 of the Nuclear Energy Act that says:

"Licence-holder's obligations:

It shall be the licence-holder's obligation to assure the safe use of nuclear energy.

It shall be the licence-holder's obligation to assure such physical protection and emergency planning and other arrangements, necessary to ensure limitation of nuclear damage, which do not rest with the authorities.

A licence-holder whose operations generate or have generated nuclear waste (a licence-holder with a waste management obligation) shall be responsible for all nuclear waste management measures and their appropriate preparation, and is responsible for their costs (waste management obligation)".

A similar obligation is established for the users of radiation in Chapter 4, Section 14 of the Radiation Act.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S1: The legislative framework should be amended to address the activities of decommissioning of nuclear facilities.

Suggestion S2: Sufficient resources should be engaged to carry out an integrated revision of the complete regulatory framework, including legal and technical aspects, aiming to make its use more straightforward and eliminate detailed requirements that cause unnecessary burdens to the operators or STUK.

Changes since the 2000 IRRT mission

The Nuclear Energy Act has been amended (2000) to implement the new additional protocol of the IAEA Safeguards Agreement under the International Treaty on the NPT.

Several Government decrees (194/2002, 195/2002) have been issued to apply the Act on Transportation of Dangerous Materials to different forms of transportation. Also Decrees (277/2002 and 278/2002) by the Ministry of Traffic and Communication applying it in land transports.

In addition to the issuance and revision on multiple YVL and ST guides, a new group of Guides (VAL) regarding emergencies has been created.

Findings of the 2003 follow-up IRRT mission

Regarding decommissioning, giving the time still available and the activities carried out at the technical level, there has not been a modification of the legislative framework but the IRRT team considers that it should be done at least in the medium term. Other aspects (intervention, exclusion, underground laboratory licensing) that require a modification in the legal and regulatory framework are discussed in Chapters 9 an 10 of this report.

Regarding the integrated revision of the regulatory framework there has been an analysis of the need for modification of the Guides issued by STUK concluding that no major revision is

needed. The results of this review were included in the second national report to the Nuclear Safety Convention (NSC). The regulations will benefit from the integrated revision that was suggested by the 2000 IRRT mission, however given the workload to be faced by STUK in the following years (New reactor and significant modifications in operating reactors) it could be reasonable to delay such a revision until the workload peak is over.

The Government Resolutions of 1991 (351, 396, 397) were also reviewed as part of an internal self-assessment conducted in relation with the comments to the first NSC report. A comparison with the IAEA standards was performed and no significant missing elements were discovered. The revision of 395 and 397 was not considered urgent. Although revision of 396 was recommended, actions have been taken regarding physical protection that can not be incorporated in detail in the Government Resolution given their confidential nature. A decision was made by STUK concerning the new physical protection requirements to be applied in the FIN5 project and in major modifications at the operating power plants. Therefore, and given the workload expected for 2004/2005, it could be reasonable to delay their revision.

1.2.1. Recommendations and Suggestions

(1) **BASIS** - The IAEA Requirements for Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, Safety Standard Series GS-R-1, includes, among the facilities and activities to be covered by the legal framework, paragraph 1.5(12), the *decommissioning or closure of nuclear facilities and site rehabilitation"*. It also requires, in paragraph 2.2(6), that *"adequate infrastructural arrangements shall be made for decommissioning, close-out or closure, site rehabilitation, and the safe management of spent fuel and radioactive waste"*.

The present nuclear legislative framework is very comprehensive but does not cover, at the same level, the activities related to the decommissioning of nuclear facilities.

a) Suggestion: The legislative framework should be amended to establish an authorization process for decommissioning of nuclear facilities.

1.3. INDEPENDENCE OF THE REGULATORY BODY

The Nuclear Energy Act, in Section 54, indicates that "*the Ministry of Trade and Industry is responsible for the highest management and supervision of nuclear energy matters"*. In Section 55 it indicates that "*the Radiation and Nuclear Safety Authority (STUK) is responsible for the supervision of the safe use of nuclear power. In addition STUK shall be responsible for attending to the supervision of physical protection and emergency planning, and for necessary control of the use of nuclear energy to prevent the proliferation of nuclear weapons"*.

The Radiation Act, in Section 5, indicates that "*Supreme authority in supervision compliance with this Act shall be vested in the Ministry of Social Affairs and Health in matters concerning: 1) General evaluation of the health hazards caused by radiation, 2) Evaluation of the need for measures to limit exposure to radiation, and imposition of requirements on such measures, and 3) Requirements for monitoring the radiation exposure of workers and other persons exposed to radiation"*. In the same section it indicates that the supreme authority on the supervision of practices involving exposure to radiation is the Ministry of Social Affairs

and Health, except in the following branches, where the supreme authority is the Ministry of Trade and Industry*:" 1) Use of nuclear energy as referred to in the Nuclear Energy Act, 2) Work in mines as referred to in the Mining Act, 3) Commercial manufacture of and trade in radiation sources, and imports and exports of the same"*. In section 6 it indicates that *"compliance with this Act and with the provisions and regulations issued pursuant thereto shall be supervised by the Radiation and Nuclear Safety Authority - STUK"*.

In the initial IRRT report it was considered that, according to the present legal framework, there were several possibilities for Ministries with promotional or regulated activities to influence STUK. However it was recognized that the present process has not caused any problems with safety implications, but as a measure to enhance independence a suggestion was provided.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S3: The legislative framework should be modified to establish that the statements prepared by STUK shall be binding on the Ministries of Trade and Industry and Social Affairs and Health. In all decisions by the Ministries that could affect the independence of STUK (budget assigned by the Ministry of Social Affairs and Health, annual performance agreements, and nomination of STUK's Director General) the bases for these decisions should be published. The minutes of STUK's Board meetings should be published.

Changes since the 2000 IRRT mission

There have not been significant changes in this issue.

Findings of the 2003 follow-up IRRT mission

The suggested improvement of making STUK statements binding for the Ministries have been analysed and found not feasible according to KTM and STM. The budget process is documented in a way that proposal from STUK and approved budget can be traced. An annual report on the results of the performance agreement is published and therefore is available for public scrutiny. Given that the character of the Board meeting minutes is essentially administrative it was considered not appropriate to publish them, but they are available to STUK personnel in the intranet.

After further review of the issue in the follow-up mission it is considered that the opportunities for influence from STM or KTM over STUK are minimal and negative reactions that could be generated, in case of inappropriate influence, will act as a deterrent.

1.3.1. Recommendations and Suggestions

(1) **BASIS** - The IAEA Safety Standard Series GS-R-1"Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety" requires, in paragraph 2.2(2) that "*a regulatory body shall be established and maintained which shall be effectively independent from organisations or bodies charged with the promotion of nuclear technologies or responsible for facilities and activities. This is so that regulatory judgements can be made and enforcement actions taken, without pressure from interests that may conflict with safety"*. It also requires, in paragraph 4.1

that *"the regulatory body's reporting line in the governmental infrastructure should ensure effective independence from organizations or bodies charged with the promotion of nuclear or radiation related technologies, or those responsible for facilities or activities"*. Recognising that there may be several authorities involved in the licensing process paragraph 2.5 considers acceptable that *"if other authorities, which may fail to meet the requirements of independence set out in item (2) of para.2.2, are involved in granting of authorizations, it shall be ensured that the safety requirements of the regulatory body remain in force and are not modified in the regulatory process"*. The regulatory framework in Finland is *de facto* in line with these requirements, but further enhancements should be considered as regards the *de jury* aspects. The IAEA Safety Standard Series GS-G-1.1 Organization and Staffing of the Regulatory Body for Nuclear Facilities 2.2 indicates *"Furthermore, the credibility of the regulatory body to the general public depends in large part upon whether the regulatory body is considered to be independent of the organizations that it regulates as well as independent of governmental organizations and industry groups that promote nuclear technologies"*.

a) **Suggestion: STUK's independence needs to be maintained, if not enhanced, in the future and therefore there should be a permanent monitoring of actions that may affect such independence or the credibility of STUK to the general public.**

1.4. RESOURCES ASSIGNED TO THE REGULATORY BODY

The budget for STUK comes from several sources. The figures correspond to the 2002 budget.

- From the State (10,4 M€). It funds all the activities not covered by fees or by other services. (emergency preparedness, international activities, public information, research)
- From regulatory control fees (7,5 M€). It covers the activities related with nuclear power plants, and radiation users.
- From expert services (3,3 M€) provided under contract with the EU, or for Eastern countries.
- For research project (0,9 M€).
- Other funds (0,2 M€).

The budget is considered very tight and therefore the margin for dealing with unexpected needs (other than the ones chargeable by fees) is minimal. The use of expert services to compensate the limitations on the budget may demean the performance of essential tasks. In case of difficulties to meet the budget the international activities may also suffer and they are very important for the work of regulatory bodies.

In the past the fees from the nuclear power plants were collected through the State Budget and STUK got its budget from the State Budget. From the beginning of year 2000 those fees are directly collected by STUK and are included in the State Budget as income to STUK.

Regarding personnel STUK had about 296 employees by the end of 2002, and about 70 professionals are working in the field of nuclear energy. Many of the persons that were working during the licensing of the operating plants are still at STUK. Given the size of the

nuclear program it was considered in the 2000 IRRT mission that the number at that time were reasonable.

STUK has professionals in all the relevant disciplines and is also sufficiently supported by the Technical Research Center of Finland (VTT), as a technical support organisation. STUK may contract technical support services to deal with applications from the licensees and charge them the cost of the services.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S4: After experience is gained with the new system of fees directly collected by STUK from the licensees, an evaluation should be carried out of the potential positive and negative effects of such a system compared with the previous one where the fees were collected by the State, and actions taken according to the results.

Changes since the 2000 IRRT mission

The decision in principle to build a new nuclear power plant, the significant modernization modifications planned in the plants in operation, in addition to activities related with the high level waste laboratory, will produce a significant workload during several years. STUK is recruiting new personnel, among other actions, to respond to the challenge. It is considered essential that these actions to recruit and train new personnel are carried out according to the plan.

Findings of the 2003 follow-up IRRT mission

STUK has analysed the positive and negative effects of the net budgeting system concerning the regulatory control activities and found the effects of the new system have been mainly positive, but in any case is planning to follow the effects also in the future. Considering that STUK will continue to verify the impact of the net budgeting system this suggestions is considered fulfilled.

International activities will be increasing in the future in connection with the different Conventions signed by Finland, and regarding the potential developments of a safety supervision system at the European Level. However the budget for these international activities is very dependent of the State Budget that has not changed significantly.

1.4.1. Recommendations and Suggestions

(1) **BASIS** - IAEA Safety Guide on Organization and Staffing of the Regulatory Body for Nuclear Facilities 2.13 indicates that *"In addition, the funding should cover the cost of research and development, consultancy services and international co-operation, as appropriate"*. The increasing needs in international activities should receive adequate funding.

(a) Suggestion: The state budget provided to STUK for the funding of its international activities should take into account the increasing needs

resulting e.g. from the safety related Conventions signed by Finland, and the EU initiatives.

2. AUTHORITY, RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Expert: José I. Villadóniga

2.1. AUTHORITY AND POWER ASSIGNED TO THE REGULATORY BODY

Section 55 of the Nuclear Energy act establishes that:

"The Radiation and Nuclear Safety Authority (STUK) is responsible for the supervision of the safe use of nuclear power. In addition STUK shall be responsible for attending to the supervision of physical protection and emergency planning, and for the necessary control of the use of nuclear energy to prevent the proliferation of nuclear weapons."

The regulatory control activities of STUK are detailed in Chapters 15th and 16th of the Nuclear Energy Decree.

Regarding control powers Chapter 10 of the Nuclear Energy Act establishes that:

"The Radiation and Nuclear Safety Authority (STUK) shall be entitled, in order to carry out the supervision required by this Act, and by the provisions issued hereunder and by Finland's international treaties in the field of nuclear energy, to:

(a) *inspect and control operations referred to in subsection 1, points 1–4 of section 2, 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, take and receive samples and install equipment necessary for such supervision;*

(b) *oblige the licence applicant to arrange entry for the Radiation and Nuclear Safety Authority (STUK) to carry out inspections and measurements and to take samples on the premises where, according to the application, the operation referred to in subsection 1, points 1–4 of section 2 will be carried out;*

(c) *require that nuclear fuel or the buildings and equipment intended as parts of the nuclear facility be manufactured in a manner approved of by the Radiation and Nuclear Safety Authority (STUK), and oblige the licence-holder or licence applicant to arrange for STUK sufficient opportunity to control manufacture of the fuel or such buildings or equipment;*

(d) *receive necessary information and be provided with the plans and contracts and their grounds concerning the manufacture, quality control or processing of nuclear materials, nuclear waste, the nuclear facility and its buildings and equipment, as well as any material, device and equipment referred to in subsection 3 of section 2;*

(e) *oblige any person carrying out the operation referred to in subsection 1 of section 2 to submit reports in the prescribed form, as well as other necessary information and notifications, and to keep nuclear material accounting and operating records in the prescribed forms and to inspect these accountings; as well as*

(f) *issue prohibitions on measures concerning real estate when this is necessary in order to secure safety, when that real estate includes premises referred to in point 5b of section 3*

Section 67 of the Nuclear Energy Act establishes that:

"Should a defect or fault referred to in section 64 or 65 cause immediate danger, or should there otherwise be a justified cause to suspect the operation to present an immediate danger, the Radiation and Nuclear Safety Authority (STUK) may, if possible upon consulting the licence-holder, interrupt the operation or limit it until the cause which has led to the issuing of such an order has ceased to exist. STUK shall have the same right, if supervision hereunder cannot be implemented otherwise, or if the licence-holder has failed to fulfil his obligations under the Nuclear Liability Act. "

Sanctions are prescribed in the Nuclear Energy Act in Chapter 11, but they are associated with significant violations that may involve the Penal Code. Chapter 15 of the Nuclear Energy Decree identifies the regulatory control activities of STUK that may allow for enforcement.

However the lack, at the time of the IRRT mission, of an established enforcement basis for small violations was considered that could give the operator the vision that those violations are not important and the development of an Enforcement Policy was recommended.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R1: STUK should develop an Enforcement Policy for all areas under their regulatory control that clearly lays out the practices and procedures to be followed by STUK personnel for the implementation of enforcement actions that are used consistently to ensure compliance by licensees with regulatory requirements.

Changes since the 2000 IRRT mission

STUK has revised Guide STUK 3.1 "Principles of Regulatory Activities" (21.12.2001), and issued Guide YTV 4.14 "Enforcement measures for Regulatory Requirements" (04.02.2002) and Guide SKV 3.7 "Enforcement Measures in Regulatory Control of Radiation Practices" (21.08.2003).

Findings of the 2003 follow-up IRRT mission

Given the status of development of the new enforcement policy the recommendation is considered fulfilled, however the practical application of the policy is discussed in Area 6 "Inspection and Enforcement". The recommendation R1 is also addressed in the section 6.6, 10.6.2 and 11.2.5 of this report.

2.2. THE ROLE OF THE REGULATORY BODY AND THE OPERATOR

The legislation assigns the prime responsibility for safety to the operator, and according to the Nuclear Energy Act , Chapter 8, section 55 "The supervisory authority (STUK)" is responsible for "the supervision of the safe use of nuclear power" and that STUK in particular shall:

"2) supervise the observance of licence conditions as well as set detailed requirements concerning the operations referred to in the licence;

3) issue detailed regulations and put forward the proposal for the general regulations referred to in the subsection 2 of section 81…….

5) set qualification requirements for persons involved in the use of nuclear energy and control that their requirements are met."

In the Nuclear Energy Decree Chapter 15 "Regulatory Control" Section 109 it is further required that "After a construction licence has been granted STUK controls the implementation of the facility project in detail" and according to Section 112 in the same document "If the licence-holder intends to carry out modifications in the nuclear system or structures, in nuclear fuel or in the way the facility is operated, and these modifications would involve changes in the plans or documents approved by STUK the licence-holder shall obtain an approval from STUK for these modifications before they are carried out."

STUK has also been given responsibility for regulatory control of pressure equipment (Section 117 of the Nuclear Energy Decree). In the area of safety culture, STUK has a dual role, to supervise and to inform. Before the 2000 IRRT mission STUK had taken initiatives by lecturing on the topic and also inspecting the area. There are no formal requests on the operator to have in-house capabilities in the topic of behavioural sciences.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S5: The regulatory framework should be modified to allow STUK to advance, in the already initiated process oriented approach, in a way that allows the operator to always assume responsibility for safety.

Suggestion S6: STUK should take a strong position on the need for the operator to have in-house capabilities on topics such as behavioural sciences, and step back and assume only the role as the regulator, to avoid diminishing the role of the operator.

Changes since the 2000 IRRT mission

No significant changes occurred. However recent events at the nuclear power plants suggest that the importance of in-house capabilities, at the utilities, in behavioural sciences, and their use in understanding event causes, has increased.

Findings of the 2003 follow-up IRRT mission

Since the previous IRRT mission STUK has advanced in the direction of being more selective in its control activities of nuclear power plants, reinforcing the responsibility of the licensees: inspection of equipment is focused in the most important for safety, independent safety assessments by the licensee are required in YVL 2.0, some inspections previously done by STUK now have to be done by the utility and reported to STUK. Although this is a continuous improvement activity, considering the trend followed by STUK the suggestion is considered

fulfilled.

STUK is also paying attention to the organizational performance of the licensees by several means including inspection of processes (Level B of the periodic inspection program) and inspection of safety management (Level A).

The need for expertise in the utilities about behavioural sciences has been discussed between STUK and the utilities in the framework of the periodic inspection programme, especially in the A-inspection "safety management". Expertise in organisational performance has been created in the publicly funded research programs. Recent incidents indicate that the issue deserves attention and STUK has decided to include requirements concerning such an expertise in Guide YVL 1.7 presently under revision. Although this is not enough because the internalisation of the need by the licensees is also required, this step from STUK is essential to provide a clear message to the licensees about the importance of the issue. Taking in to account STUK's decision this suggestion is considered fulfilled.

2.3. RESPONSIBILITIES ASSIGNED TO THE REGULATORY BODY

STUK has been assigned three different roles. These different roles are:

- Regulating and assessing/inspecting,
- Research
- Expert duties including services

Research activities carried at STUK are separated from the regulatory role. Several departments have activities covering the different roles.

During the previous IRRT mission it was found that in some cases the services that were performed by one part of STUK were evaluated by a different department of STUK. This raised questions concerning the possibility that the role of the operator may be diminished. There were also some other tasks performed by STUK that may have an impact on the regulatory role: the fact that STUK was responsible for taking care of the waste from activities other than nuclear power plants, transporting it to the storage site and there carrying out the inspections on the same material.

STUK also has a dual role regarding information and training of personnel at hospitals and other organisations were radiation is being used and at the same time making inspections at these facilities.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R2: An analysis should be carried out of the potential conflict in the different roles and activities that STUK is covering. Based on that analysis a decision should be taken about organisational changes or the establishment of appropriate controls to reduce the conflict to a minimum.

Changes since the 2000 IRRT mission

STUK performed the recommended analysis and transferred to a private company the dosimetry services that was providing directly in the past. Regarding other functions measures have been taken to avoid or reduce to minimum conflicts of interest as discussed in chapters 10.5.2 and 11.2.2.

Findings of the 2003 follow-up IRRT mission

The analysis performed and the actions taken satisfy the recommendation. Specifics suggestions to go further in the direction of minimizing conflict of interest are presented in chapter 10. Therefore this recommendation is considered fulfilled.

2.4. TECHNOLOGICAL INFRASTRUCTURE FOR THE REGULATORY BODY

The research supported by STUK aims to produce new knowledge and information related to the use, occurrence and effects of radiation and to improve the supervision of nuclear safety. Research activities are aligned with STUK's primary goals, the prevention and limitation of the harmful effects of radiation.

The areas of the STUK research program are:

- Nuclear safety
- Nuclear waste management
- Use of radiation
- Natural radiation
- Environmental surveillance and emergencies
- Exposure of the population to radiation
- Radiobiology
- Epidemiology
- Non-ionising radiation

The Government Resolution on the safety of nuclear power plants (395/1991) requires that plant safety be continuously developed, taking into account operating experience feedback, the results of safety research as well as scientific and technical developments. Licensees are responsible for the safety of the use of nuclear energy and this requires sufficient investment in safety research. STUK is responsible for the regulatory control of the safe use of nuclear energy and to accomplish this function an essential element is safety research carried out independently from the licensee.

At the time of the IRRT mission there was a national program on nuclear power plant safety named FINNUS covering years 1999 – 2002, with a total budget of FIM 100 mill. that is coordinated by the Technical Research Centre of Finland (VTT). The funding for the program was from STUK, the Ministry of Trade and Industry and VTT. After FINNUS a new research

program called SAFIR has been established.

Given the small number of organisations in the country it is difficult to find organisations that are not providing services for the operators. STUK had identified the issue and has carried out audits to ensure proper independence of VTT and other organisations providing services to STUK.

The allocated funding for research activities at the time of the year 2000 IRRT mission, together with the important infrastructure provided by VTT ensured a significant support for the regulatory activities of STUK.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S8: STUK should apply similar actions to the ones being used with VTT to avoid conflict of interests, to other organisations procuring services for STUK. This should be included in STUK internal procedures.

Changes since the 2000 IRRT mission

Additional audits have been conducted in other departments of VTT and at the Geological Survey of Finland (GTK). The need for independence has been stated as a basis in the guide YTV 8.1 "Planning, ordering, monitoring and reporting of safety review research".

STUK has carried out and published an international independent review of the research activities conducted at STUK in the area of radiation safety: "*Evaluation of the research activities of STUK, Finnish Radiation and Nuclear Safety Authority. Report of the Evaluation Pane. January 2001"*. A similar national review has been conducted for the FINNUS program.

Along the years the funding for the national research program provided by KTM (Ministry of Trade and Industry) has been decreasing. To ensure a stable budget KTM is preparing a modification to the Nuclear Energy Act that will require utilities to provide funds for the national research program. It is not clearly stated up to now which will be the role of STUK in this new setting.

Findings of the 2003 follow-up IRRT mission

YTV guide establishes requirements to ensure independence of organisations providing services to STUK and audits have been carried out and will be carried out periodically. This suggestion is considered fulfilled.

The independent review of research carried by STUK is a good approach to ensure that research carried out is focused in the important issues and the quality of the research is of a high level.

2.4.1. Recommendations and Suggestions

(1) **BASIS** - IAEA Safety Guide on Organization and Staffing of the Regulatory Body for Nuclear Facilities 3.34 indicates that *"Regardless of how the research is carried out, the regulatory body should ensure that it is focused on regulatory needs,… "*

(a) Suggestion: In the future system to finance research in nuclear safety matters STUK should share a leading role in the overall management of research programs and projects.

2.4.2. Good Practices

(1) **BASIS** - IAEA Safety Guide on Organization and Staffing of the Regulatory Body for Nuclear Facilities 3.33 indicates that *"The regulatory body should encourage facility operators to carry out the research and development necessary to produce an adequate body of knowledge about safety. However, there may be situations in which the operator's research and development is insufficient or in which the regulatory body requires independent research and development to confirm specific important findings". The independent review of STUK's research activities goes beyond this recommendation.*

(a) Good Practice: STUK has carried out an independent review of its research activities.

3. ORGANIZATION OF THE REGULATORY BODY

Expert: José I. Villadóniga

3.1. THE ORGANIZATION OF THE REGULATORY BODY

The overall mission of STUK as Radiation and Nuclear Safety Authority is to protect people, society, environment, and future generations from harmful effects of radiation. According to STUK strategy 2003-2006 it undertakes activities in the following areas: Regulation of radiation safety, regulation of nuclear safety, emergency preparedness, research, surveillance of environmental radioactivity, metrology, public communication, services.

The head of STUK, Director General, is assisted by two Directors.

The STUK Management system particularly addresses personnel issues, resources and working culture. As stipulated in the QA manual STUK 2.1 (Rules of Administration) - "Safety culture followed in the activities of STUK requires always that safety significance of the matter or situation to be dealt with at the time is recognised, responsibility related to decisions and resolutions is recognised, bases of decisions and resolutions are found out and presented, personnel at all levels of the organisation is committed to high quality".

STUK has the following departmental structure: Nuclear Waste and Material Regulation (YMO), Nuclear Reactor Regulation (YTO), Radiation Practices Regulation (STO), Research and Environmental Surveillance (TKO). For certain activities STUK structure includes specialist units. Non-ionising Radiation (NIR), Public Information, Emergency Preparedness, Expert Services, Administration and internal services are specialist units reporting directly to the Director General. The areas of responsibility for each department are clearly defined in the QA manual and other relevant documents.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S7: STUK should develop an integrated strategy to respond to the challenges of deregulation of the electricity market.

Changes since the 2000 IRRT mission

In Nuclear Reactor Regulation a Safety Management Office and a Plant Projects office have been created, the last to coordinate review activities related to the 5th reactor (FIN-5) to be built in Finland and also to coordinate major modifications at the operating nuclear power plants. Also six new recruits have been incorporated to help in the FIN-5 work.

The organisation of Radiation Practices Regulation has also been changed. From the Research and Environmental Surveillance a unit for Medical Radiation was transferred to Radiation Practices Regulation, and the laboratory for Non-ionising Radiation was established as a separate unit.

At the time of the IRRT mission STUK provided also dosimetric services to the organisations using radiation. However these services were sold to a private company that is subject to STUK's regulatory control.

Findings of the 2003 follow-up IRRT mission

Regarding the topic of market deregulation STUK set up a task group on year 2000 to assess its potential effects. The task group report was completed in 2001. According to the report pressures for economic cut downs are not expected to grow considerably from their present levels. Overseeing general financial matters, which may have a delayed impact on the safety of the plant, is not assigned to STUK in the legislation. The report recommends the increase of the efficiency of STUK's oversight procedures should be considered in areas related with organizational changes, number and competence of personnel, maintenance of components critical to safety, reporting of events by the utilities and operating experience analysis activities.

All this actions are essentially of a reactive nature, and some proactive actions are considered beneficial.

3.1.1. Recommendations and Suggestions

(1) **BASIS** - IAEA Safety Standard on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, 5.10 *"The regulatory body shall follow the development of a facility…from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout"*. *Moreover* IAEA Safety Guide on Review and Assessment of Nuclear Facilities by the Regulatory Body, Appendix A.7(c) indicates that *"At all stages of the facility's lifetime, the operator should demonstrate that:…(c) It has resources available to meet its obligations and liabilities in connection with an authorization*."

(a) Suggestion: STUK should reinforce the supervision of the process by which licensees of Nuclear Power Plants select safety related improvements and modifications in order to ensure that they are not unduly limited by financial reasons.

3.2. STAFFING AND TRAINING

In the previous IRRT mission it appeared that STUK had adequate resources regarding staffing needed to perform its regulatory functions effectively. Currently STUK has about 296 employees; about 70 professionals are working in the field of nuclear energy. Many of the persons that were working during the commissioning of the plants are still at STUK. A systematic approach to training was introduced in STUK. Training Policy is defined in an internal guideline on training administration. The training system is covered in guides of the STUK Quality Assurance System - Training of Personnel at YTO Guide YTV 8.2, Introductory and Basic Training Programme for a New Employee Guide YTV 8.3, Principles of Personnel Administration STUK 5.1 and other relevant documents.

The necessary competence has been defined in a program containing basic skills, professional skills and managerial skills. The training program also takes into account the Finnish culture and the needs that STUK has to integrate the work in a more efficient way. This has resulted

in more mentoring and more on the job training and work in groups. STUK is aware and concerned about the closeness to the plant (mainly the 4 resident inspectors).

In the previous IRRT mission it was considered that participation in research projects promotes general analysis preparedness and develops professional skills. Strategic planning of STUK is aimed to continue the funding of research projects. Part of the research funding must be reserved for independent comparison analyses and development of regulatory operations. STUK intends to improve co-ordination and follow-up of safety research projects as well as utilisation and communications of research results.

Recommendations and Suggestions from the 2000 IRRT report

No need for recommendations or suggestions was identified in this area.

Changes since the 2000 IRRT mission

In 2002 a competence inventory was carried out in STUK. The aim was to get a common view on competencies and competence level in STUK. Based on the inventory, development programs and future training policy will be planned. The focus is on unit-based competencies.

A knowledge management project was started in 2002 covering the whole STUK. The aim of the project is to systematically evaluate different areas of knowledge management and to take in use the appropriate tools.

The Ministry of Trade and Industry (KTM) appointed in March 2000 a working group to study ways of maintaining and developing knowledge of nuclear energy. The working group concluded that public research programmes are a fertile means of improving knowledge and therefore should be continued. The working group also urges power companies to continue projects for technology development and plant modernisation, since the projects help maintain knowledge. According to the group the most important topical changes in the operating environment are deregulation of the energy market and the retirement of many older nuclear energy experts. They could be offset by constantly developing the standard of knowledge and by following the availability of expert services. The study provides recommendations to respond to the challenges.

Findings of the 2003 follow-up IRRT mission

3.2.1. Good practices

(1) **BASIS** - IAEA Safety Standard on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, 4.6 *"The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities"*

(a) Good Practice: STUK has advanced in the elaboration of a competencies inventory and has initiated a project in knowledge management. These activities reveal the commitment of STUK to continuous improvement and to anticipate response to future problems of corporate memory losses.

(2) **BASIS** - IAEA Safety Guide on Organization and Staffing of the Regulatory Body for Nuclear Facilities 4.9 indicates that *"It should be considered whether it is appropriate to develop a future supply of suitable potential recruits, for example, by encouraging and supporting relevant courses at academic institutions"*.

(a) Good Practice: KTM has commissioned a study of the nuclear energy competences needed in Finland and has identified actions to ensure the availability of those competences.

3.3. QUALITY AND EFFICIENCY OF THE REGULATORY BODY WORK

The mission of STUK in the quality policy may seem too far reaching, for a regulatory body, but can be understood when taking into account the different roles and tasks that are included in STUK. A strategic planning process is used to develop long-term goals. Annual plans are developed in accordance to the strategic plan and the process is iterative and involves the whole organisation. There are various tools and ways to feed information into the annual plan as well as to follow up on the results.

For the regulatory part of STUK, guidance on the role of the regulator, including ethical rules are included in the QA system.

Assessment of the organisational culture of STUK with support from the Technical Research Center of Finland (VTT) has been done and the results are being used to improve the work processes. STUK has a modern quality system that has been assessed based on the Finish Quality Award. Self-assessment is being carried out at many levels and in accordance to procedures. Yearly "result- and development-discussions" are held in accordance with the procedures in the quality system.

The quality system has many loops for feedback and improvement on different levels of the organisation.

STUK has been discussing internally the appropriate balance between the development and use of detailed guides/procedures and the freedom for specialists to exercise their professional judgement. STUK has taken the position to develop guidelines to a level needed for a competent staff to be able to accomplish their duties.

Indicators have been developed to be able to evaluate the performance of nuclear safety regulatory functions. These indicators are divided into two types: those that reflect the safety levels at the plants; and those that look more at the performance of STUK. The limitations of the present approach are acknowledged and opportunities for improvements of the indicators are being sought.

For the regulatory function of STUK the quality system needs a clear balance between results orientation and assessment of the quality of the work.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S9: STUK should review its quality system to ensure that the present results orientation is balanced with attention to quality and improvement processes.

Changes since the 2000 IRRT mission

In addition to the development of the Quality System more attention has been paid to its implementation and a Quality Group is in charge of coordinating such implementation. Several self-assessments have been performed. STUK participated in the Finish Quality Award competition in 2001. The Quality Policy of STUK was reviewed in 2003. STUK is at the moment moving towards a process-based quality management system.

STUK uses the approach of the Balanced Score Card to identify success factors and develop strategies and indicators beyond those commonly used that are related directly with the results of the organizations. As an example the areas of development and work capacity, processes and structures are included.

In one Department there are activities oriented to the development of the organizational culture. Groups are established to deal with values and issues of relevance for the department work and suggestions for improvements are collected and integrated in the planning of the next year. The work is coordinated with wide projects such as process orientation and knowledge management.

Findings of the 2003 follow-up IRRT mission

Performance Indicators (quantitative) are just a tool used by STUK but proper attention to quality (qualitative) is obtained by several means, among them: The annual management quality review, internal quality audits to verify that the decision process established has been applied properly, reviews of quality during the assessment process, etc. These means are indicated in the Quality Policy of STUK. The "*Results Agreement between the Ministry of Social Affairs and Health and Radiation and Nuclear Safety Authority*" for the year 2003 includes qualitative and quantitative goals.

Although giving adequate attention to quality is a matter that requires continuous improvement, considering the present situation and the commitment for improvement the suggestion is considered fulfilled.

The work on organizational culture issues contributes to the motivation of the personnel and rises opportunities for further improvement.

3.3.1. Good practices

(1) **BASIS** - IAEA Safety Guide on Organization and Staffing of the Regulatory Body for Nuclear Facilities 3.10 indicates that *"In developing the regulatory management system, the regulatory body should identify its main functions and should take into account support functions and control functions derived from the main functions"*.

(a) Good Practice: By using an approach to strategic and annual planning such as the Balanced Score Card STUK considers factors beyond those commonly used directly related to the organization results.

(2) **BASIS** - IAEA Safety Guide on Organization and Staffing of the Regulatory Body for Nuclear Facilities 3.9 indicates that *"For a regulatory body to fulfil its statutory*

obligations, it should develop a regulatory management system with the necessary arrangements for achieving and maintaining a high quality of performance in regulating the safety of nuclear facilities under its authority".

(a) Good Practice: STUK's Activities to develop organizational culture facilitate proper attention to organizational culture issues that affect effectiveness of the work performed.

3.4. ADVISORY BODIES TO THE REGULATORY BODIES.

STUK is supported by an Advisory Committee on Nuclear Safety, which is appointed by the Council of State. The role and tasks of the committee is described in "Decree on the Advisory Committee on Nuclear Safety". The Advisory Committee shall have no more than five members, a chairman and vice chairman.

The Advisory Committee shall follow the development in the field of the safe use of nuclear energy and give statements, make suggestions, review and assess rules and guides on safety, and help maintain and promote co-operation between authorities and associations dealing with issues related to the safe use of nuclear power.

The Advisory Committee is assisted by subcommittees carrying out preparatory work as needed. The subcommittees are formed by the members of the Advisory Committee and other specialists. The subcommittees are suggested by STUK and approved by the Ministry of Trade and Industry.

Since the Advisory Committee has an overview of the safety issues, and since they meet approximately ten times a year, the committee is of sufficient support to STUK. However the review team considered that the committee could be more proactive and could be involved earlier in the process of developing regulations and guides.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S10: STUK should involve the Advisory Committee on Nuclear Safety in providing advice regarding the overall approach to regulation, including the strategy for the development of regulations and guides.

Changes since the 2000 IRRT mission

STUK's new overall strategy was finalised in the spring of 2003. It includes the basic approach to rulemaking. Based on the strategy an action plan for rule making is being prepared.

Findings of the 2003 follow-up IRRT mission

STUK has decided that the overall strategy for rule making and the results of the review of the YVL guides will be presented to the Advisory Committee on Nuclear Safety. Based in that decision this suggestion is considered fulfilled.

4. AUTHORISATION

Expert: Derek Lacey

4.1. AUTHORISATION FOR NUCLEAR FACILITIES

The Nuclear Energy Act establishes that the licensing of nuclear facilities has three stages. The first stage is the decision in principle (DiP), which is given by the Council of State and is subject to approval by the Parliament. It is a declaration that the construction of the nuclear facility is for the overall good of society. The second and third stages are the Construction and Operating Licences. These stages confirm that the nuclear facility meets safety requirements that are stated in law or required by STUK.

Recommendations and Suggestions from the 2000 IRRT report

No recommendations or suggestions were identified in this area.

Changes since the 2000 IRRT mission

In the period since the 2000 IRRT mission a Decision in Principle was made on the construction of a fifth nuclear power plant unit in Finland. The project for this power plant is called FIN5. There have also been proposals of major re-construction programmes at the four existing nuclear power plant units for which authorisations will be required. This has led to a reorganisation within STUK and the development of a more process oriented approach to regulatory decision-making.

At the time of the follow up mission STUK was undertaking preparatory work to ensure that it is ready to carry out the work required to issue a construction licence for FIN5. STUK was preparing to respond to an application, which was expected to be submitted early in 2004, and it was anticipated that a construction licence could be issued, subject to satisfactory resolution of all important safety issues, by the end of 2004. A decision on the type of LWR to be built had not been made at the time of the follow-up mission and the review team noted that not all of the designs, which are currently being considered, have been licensed in the country of origin.

Findings of the 2003 follow-up IRRT mission

STUK's approach to the authorisation of FIN5 was considered. The discussions focussed on preparatory work and the regulatory process.

During preparation for the FIN5 project STUK has completed the following:

- The reorganisation of the Nuclear Reactor Regulation division, the establishment of a project team within the new organisation and the commencement of new recruitment;
- a preliminary review of the Government Resolution which confirmed that there is no urgent need for changes prior to the issuing of the construction licence;
- a clear statement of the documents to be presented by the licence applicant, is given in the Nuclear Energy Decree (e.g. PSAR, Safety classification, QA programme, level 2 PSA, emergency plan;

- the identification and communication of important issues to the applicant at the DiP stage;
- the developement and up-dating of YVL guides (these are now more goal setting than earlier versions and have been reviewed against recent IAEA standards and other international standards where available); and
- the development of its analysis capability.

It was also noted that the utility has reviewed the European Utility Requirements (which the various designs must meet) against the requirements of the YVL guides.

The process STUK has established for the licensing of FIN5 is called the requirements management system. This is a means by which all the tasks that STUK must complete to demonstrate that the requirements in the YVL guides are satisfied are identified and only closed out when the required tasks have been satisfactorily concluded. This approach also includes a means of decision-making within STUK for sentencing open issues that involves consensus building among inspectors and consideration by management. STUK's recent re-organisation means that inspectors with specialist knowledge, undertake both review and assessment and inspection activities and are closely involved in decision-making. Further information on the requirements management system is provided in section 5.1 of this report.

It was noted that although the YVL guides are the main basis for the authorisation process there is the possibility for STUK to introduce additional requirements if it is found that the guides are not comprehensive. This power is given in Section 27 of the Government Resolution on the general regulations for the safety of nuclear power plants 1991/395 which allows STUK to require safety enhancements based on operating experience, research and development and advances in science and technology.

It was also confirmed that YVL guides cover STUK responsibilities during construction and commissioning i.e. regulatory hold points are established for key stages, and that arrangements are in place for regulatory approval of significant design changes.

It was concluded that STUK's preparation for authorisation of FIN5 has been thorough and that a systematic and rigorous approach has been developed for the construction and operational licence phases.

4.1.1. Recommendations and Suggestions

(1) **BASIS** – The IAEA Safety Requirements "Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety" (GS-R-1) state in paragraph 5.3: "Prior to the granting of an authorisation, the applicant shall be required to submit a detailed demonstration of safety……. the control applied shall be commensurate with the potential magnitude and nature of the hazard presented." In addition the IAEA Safety Guide "Regulatory of Nuclear Facilities by the Regulatory Body" (GS-G-1.2) state in paragraph 3.4: "For regulatory effectiveness, the review and assessment efforts should usually be focussed more on those aspects of site evaluation design or operation which involve untested (innovative) features."

a) Suggestion: STUK should ensure that it fulfils its intention to undertake in-depth review and assessment of any design features that have not been confirmed by prior operational experience.

4.1.2 Good Practices

(1) **BASIS** – The IAEA Safety Requirements "Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety" (GS-R-1) state in paragraph 5.3: "Prior to the granting of an authorisation, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed in accordance with clearly defined procedures."

a) Good Practice: STUK preparations for the FIN5 construction licence have been thorough and the requirements management system that has been introduced provides a robust basis for identification of regulatory issues that need to be addressed prior to the granting of the construction licence.

(2) **BASIS** – The IAEA Safety Requirements "Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety" (GS-R-1) state in paragraph 3.2: "the regulatory body….shall establish, promote or adopt regulations and guides…shall review and assess submissions on safety….shall provide for issuing, amending, suspending or revoking authorizations….shall carry out regulatory inspections"

a) Good Practice: STUK has developed an approach to authorisation in which the rule making, review and assessment, and inspection functions are effectively integrated.

4.2. NUCLEAR POWER PLANT MODIFICATIONS

The mission conducted in 2000 concentrated on the major modifications to nuclear power plant resulting from activities such as power up-grades or major reconstruction. During this follow-up mission discussions were held on more specific plant modifications and on STUK's authorisation activities.

Findings of the 2003 follow-up IRRT mission

It was found that STUK's regulatory guides clearly set out the types of plant modifications that require regulatory approval. As a result STUK has a substantial programme of work each year to process licensees' applications and carry out associated review and assessment and inspection work. There was no evidence to suggest that STUK's activities undermine the licensees' responsibility for maintaining adequate safety during plant modifications (see IAEA Safety Guide NS-G-2.3). It was also noted that STUK inspects the adequacy of the licensees' arrangements for modifications and at the time of the follow-up mission two such inspections were planned. STUK also has the option to require that a licensee change its arrangements if improvements are necessary.

4.2.1. Recommendations and Suggestions

No recommendations or suggestions were identified in this area.

5. REVIEW AND ASSESSMENT

Expert: Thierry Foult

5.1. PERFORMANCE OF MAJOR REVIEW AND ASSESSMENT TASKS

5.1.1. Coordination of multidisciplinary major tasks.

During the 2000 IRRT mission it was shown the high technical competence of the STUK experts. However some concerns arose concerning the co-ordination of major review and assessment tasks. The process under which these tasks were undertaken is rather subject oriented. For these major tasks (which are in other organisations often treated as "projects") STUK nominates a "co-ordinator". Although STUK has a well-developed system of internal guides (QA and YTV series) there is no such guide on the management of major review and assessment tasks, which typically require a multidisciplinary approach. The IRRT reviewers considered there is a need for better identification of responsibilities of all intervening persons, i.e. technical experts in specific fields and persons assuring co-ordination. It was noted that STUK planed to add a guide to its quality system, which will provide detailed guidance for the licensing process. This will draw on the experience gained during the recently completed re-licensing projects and is in the work plan for 2000. The experts believed this should address organisation of the review process.

In the Nuclear Reactor Regulation Department, there are now, coordinating units which are at an intermediate level between the Director and the technical units. Inside the coordinating units are the coordinator for review and assessment of important plant projects (important plant modifications or FIN5 project). The sub coordinators are from the technical units; their responsibility is to take care of the review process in their field of competence, while the project manager in the coordinating unit is responsible of the global coordination of the project.

For the FIN5 licensing project, there are periodic coordinating meeting driven by the project manager; there is also a steering committee to which attends the STUK's Director General. The project coordinator attends the periodic meetings of the steering committee. For all the important project plants, the same organisation will be implemented.

Recommendation and Suggestions from the 2000 IRRT report

Recommendation R3: It is recommended that STUK should evaluate the current approach for the internal management of review and assessment tasks requiring a multidisciplinary approach. Herein, attention should be paid to improving synergy between organisational units.

Changes since the 2000 IRRT mission

Before the 2000 IRRT mission the organisation of the Nuclear Reactor Regulation was functional. Now it has liaison positions in the new plant projects office. This organisation runs since about 1.5 year and gives full satisfaction to STUK.

After the 2000 IRRT mission there has been a Decision in Principle to build a new nuclear power plant. This creates a significant new work load on the review and assessment activities of STUK.

Findings of the 2003 follow-up IRRT mission

The recommendation has been considered and a new organization is now in force to efficiently manage transverse projects, which involves different entities of the regulatory body. The important added value of the coordinator function in the review and assessment process is now fully recognized by the STUK management that takes benefit from this new organization.

5.1.1.1. Good Practices

A Good practice has already been identified on this area in the § 4.1 2 of this report, concerning STUK's preparations for the review and assessment of the FIN 5 project. It can be extended to the important NPP modifications projects.

5.1.2. Internal Guidance for Review and Assessment.

Concerning the review and assessment of technical documents submitted by the licensee, the 2000 IRRT mission considered that there was room for improvement in the field of internal guidance (procedures) for performing the review and assessment. In former times, the Standard Review Plan (SRP, developed by the USNRC) was sometimes used as a technical guidance, but the use of the SRP was phased out gradually.

Since ensuring consistency is an objective of this guidance, the degree of detail of the guidance to be developed can take into account the size of the staff to which it is addressed and the number of different designs in the nuclear program.

In response to those concerns the situation today is the following:

1) A Requirement Management System (RMS) has been developed. The RMS provides the list of requirements from the YVL guides, including acceptance criteria from each system and subsystem. In addition, it gives for the reviewer the actual status of each issue (closed or still open). The acceptance for the system is given only when all the associated issues are closed.

At each step of the review new information are saved in the RMS, which is thus enriched, and which makes the traceability of the decision easier.

This RMS is a unique procedure used for the assessment of the FIN5 project and of the important modifications of existing plants (like the new future I&C digital system for Loviisa and Olkiluoto).

The RMS is a tool to control the progress of STUK Safety Assessment and finally STUK statement on Safety. It will also give an answer to the problem of traceability.

There is a separate database, which refers to appropriate national and international data, such as experimental results, experience feedback, regulatory guides and other old documents, which are the background of the requirements. This database is in use for the reviewers.

This internal guidance will be available in the future (via STUK web site) to the operators and to some extent to the public as recommended in IAEA guide GS-G-1.2 § 3.2.

At the time of this IRRT follow-up mission it is still partly under development and, therefore, it has not yet been officially communicated to the operators but the RMS has been discussed

with them in an early phase and they know precisely what is planned inside STUK for the review and assessment process.

For internal use, some guidance to the reviewer on this RMS will be given in the Quality Manual Guide YTV 4.15 (Licensing and Re-licensing Process) which will be issued at the end of 2004: this guide, part of the Quality Manual, describes the whole process of review and assessment; it gives reference to the RMS and, above all, it includes the commitment of the STUK management.

As it is difficult to control the whole review and assessment process due to the important number of guides to be considered, this RMS is an help for the reviewer and in particular for the licensing work of the FIN5 project.

2) In addition to the RMS, a specific organisation is implemented for the FIN5 project. According to STUK quality manual, a document (project plan) has been issued which explain how the license work is organised between the different organisations (STUK, VTT, utilities, contractors and subcontractors) and how the tasks are distributed for the review and assessment process.
This document clarifies also how STUK will verify the Quality Management program of the suppliers for the more important safety class 1 and 2 components (pressure vessel components and some safety systems). From the Nuclear Energy Act, it is a legal obligation for STUK to perform these verifications. The quality control of safety class 3 and 4 components have been delegated to other accredited companies.

Due to its legal responsibility, STUK will, therefore, carry out inspection to several suppliers for the FIN5 project. From the discussion with STUK it cannot be interpreted as a transfer of responsibility from the utilities to the safety authority as the operators do actually exercise their responsibilities to ensure the safety of their plants.

A steering committee has been created for the licensing work of the FIN5 project. The project plan document gives for each expert reviewer an evaluation of the workload. It refers also to an international network of safety authorities and TSOs with which collaborations are under way for the FIN5 project.

The same project plan document will be implemented for the important plant modifications of the existing plants, for example, for the renewal of the I&C systems for Loviisa and Olkiluoto.

Recommendation and Suggestions from the 2000 IRRT report

Recommendation R4: It is recommended that STUK should develop internal guidance for review and assessment which should include how to make appropriate use of relevant technical reference material.

Changes since the 2000 IRRT mission

The Requirements Management System is a complete new development. Also the FIN 5 has lead STUK to introduce a new organization, to issue a project plan and to create a Steering Committee. This organization is now extended to important plant modifications projects.

Findings of the 2003 follow-up IRRT mission

STUK's internal guidance for the review and assessment process was considered; the discussion focussed on the new Requirement Management System still partly under development and on the commitment of the STUK management to this process. It focussed also on the new specific organisation implemented for the FIN5 project, with the elaboration of the project plan document which clarifies how the license work is organised inside STUK and with the external organisations (utilities, VTT, contractors,…).

All the features described here above (Requirement Management System, project plan document), are part of STUK preparation for the FIN5 licensing project; they have been considered in § 4.1 of this report "Authorisation for nuclear facilities".

5.1.2.1. Good Practices

A Good Practice has been identified in § 4.1 2 on STUK's internal guidance for the review and assessment process.

5.1.2.2. Recommendations and Suggestions

No further recommendation and suggestion were identified in this area.

5.2. USE OF PSA AND MOVE TOWARDS A RISK INFORMED REGULATORY APPROACH

It was already noted in the 2000 IRRT report that PSA plays an important role in the regulatory process and in the safety management of Finnish NPPs.

Typical PSA application to be submitted to STUK concerns:
- change to Technical specifications
- Exemption from Technical Specifications
- Plant modification and Backfittings
- Programs for risk informed in-service inspection and testing

For example: "the testing program of safety significant systems and components which is set forth in the context of technical specifications must be argued by the aid of risk assessment and the results of the analysis have to be submitted to STUK for information. The testing program must be regularly evaluated on risk basis during the operation of the plant.

Recommendations and Suggestions from the 2000 IRRT report

No recommendations and suggestions were identified in this area.

Changes since the 2000 IRRT mission

The updated regulatory guide YVL 2.8 (PSA Analysis in Safety Management of NPPs), set forth a requirement that the licensee has to submit a design phase PSA level 1 and 2 in context of application for a construction permit and finalize level 1 and 2 PSA in context of

application for an operating license. The guide also explains how PSA is to be used during operation.

Probabilistic design objective for the whole reactor power plant are given in the guide §3.1. In the § 2.2 and 2.3 of the guide it is explained how the risk informed approach is used during the design and construction phases. In § 3.2 it is explained how the licensee has to use the result of PSA in support of decisions on operational safety issues (Risk Informed approach.)

Findings of the 2003 follow-up IRRT mission

In the regulatory process, PSAs level 1 and 2 play an important role at the design, construction and operating phase; both the deterministic and the probabilistic approach are considered and combined in support of decision making. No decision is taken relying exclusively in PSAs results.

STUK is assessing annually the risk significance of the component failures at the nuclear power plants; STUK is assessing also the risk significance of preventive maintenance and of the conditions in non-compliance with the technical specifications.

5.2.1. Good Practices

a) **Good Practice: STUK is assessing annually the risk significance of the component failures at the nuclear power plants; STUK is assessing also the risk significance of preventive maintenance and of the conditions in non-compliance with the technical specifications**.

5.3. DOCUMENTATION PRODUCED BY THE REGULATORY BODY

The results and conclusions of the review and assessment process were documented in Memoranda of Justification and Memoranda for Inspection. The former focus mainly on the bases for the conclusions, while the latter are more oriented towards detailed technical justifications. It was found that these memoranda could be improved in terms of better describing the basis for the decisions.

Recommendations and Suggestion from the 2000 IRRT report

Suggestion S11: In view of future tracability of its decisions, it is suggested that STUK should evaluate the typical content of its Memoranda of Justification and the Memoranda of Inspection to the list of topics referred in the draft Safety Guide on Review and Assessment, and identify improvements where needed.

Changes since the 2000 IRRT mission

In the Requirement Management System described in the § 5.1 above, the structure and the content of the memo are created to support the preparation of the STUK's safety evaluation report. In plant modification, it provides information on the scope, the content and the

objectives of the modification; it provides also information how the modification fulfils the acceptance criteria and when it has been carried out.

The regulatory guide YTV 4.3, dealing with handling of documents, has been updated and will be revised again when the database will be completed. This guide gives the procedure to create a new memorandum.

Findings of the 2003 follow-up IRRT mission

As part of the new Requirement Management System, a database is already in operation to manage the issue of traceability of the decisions.

The suggestion has been met and its in implementation is in progress.

5.3.1. Recommendations and Suggestions

No further recommendation and suggestion were identified in this area.

6. INSPECTION AND ENFORCEMENT

Expert: Derek Lacey

6.1. INSPECTION PROGRAMME FOR NUCLEAR FACILITIES

The current overall inspection program consists primarily of periodic, topical, reactive and resident inspections. The topical inspections are those that the utilities are obliged to request (for example, restart after a refueling outage). The periodic inspections include functional area inspections that can be planned and scheduled in advance (for example, operation of the plant, periodic tests, radiation protection, etc.). A periodic inspection program was reintroduced in 1998 and the IRRT mission in 2000 concluded that this was necessary and acknowledged STUK's aspiration to further develop this approach to improve regulatory effectiveness.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R5: STUK should produce a YTV Guide (for example, 4.0) to describe the overall inspection program including inspection objectives. Program development should ensure all appropriate operational inspection areas (including human performance in all areas) are included as described in 50-SG-G4 Section 3. Program development should also consider issues such as inspection durations. This will ensure understanding and integration of the parts of the current inspection program.

Suggestion S12: If a new unit is to be constructed, STUK should begin development of a pre-operational phase inspection program.

Recommendation R6: STUK should develop inspection policy and guidance regarding unannounced inspections.

Changes since the 2000 IRRT mission

The main elements of STUK’s inspection programme are the same as in 2000. At that time the IRRT mission recognised the value and importance of the Periodic Inspection Programme and STUK have continued to develop this approach.

Findings of the 2003 follow-up IRRT mission

In response to this recommendation Guide YTV 4.0 on “Overall regulatory control of nuclear safety” has been produced. This document provides more information than was envisaged in the IRRT recommendation because it describes, in a very clear manner, STUK’s powers and responsibility for regulatory oversight. The overall inspection programme is described in two guides: Guide YTV 4.2 on “Regulatory oversight of nuclear facilities, Inspections presupposed by the YVL guides” and Guide YTV 4.1 on “Regulatory oversight of nuclear power plant safety: Periodic Inspection Programme”.

A review of the contents of these documents and discussions with STUK staff led to the conclusion that recommendation R5 has been adequately addressed for nuclear power plants.

After the decision in principle was made for a fifth nuclear power plant unit, a planning project on the regulatory control of the new unit was started. The Department of Nuclear Reactor Regulation was reorganised and a project unit with responsibility of co-ordinating the regulation of the new unit has been established. A project plan has also been finalised. At a more detailed level the requirements chains (referred to in chapter 4) have been developed and these will clearly identify the STUK inspection activities that are required to authorise the new unit.

It is concluded that suggestion S12 has been adequately addressed for nuclear power plants.

The principles for unannounced inspections are included in Guide YTV 4.0 and principles for unannounced inspections are described in YTV 4.2, which was issued 15.6.2003. STUK has conducted this type of inspection, reviewed its usefulness and concluded that it does not need to be a part of its regular ongoing programme of inspections. It does however retain it as an option if it is judged to be useful in specific circumstances.

It is concluded that recommendation R6 has been adequately addressed for nuclear power plants.

6.1.1. Recommendations and Suggestions

No further recommendations or suggestions were identified in this area.

6.2. INSPECTION STAFF

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S13: STUK should consider further development of guidance and implement their Principles of Regulatory Activities. Issues to consider include stock ownership, social relationships, length of tour for the resident inspectors, etc

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Changes since the 2000 IRRT mission

There have not been any major changes in STUK's approach to staffing of inspection activities since the 2000 mission. The practice of using the same inspectors to carry out both inspection and review and assessment tasks in their technical areas continues, as does the practice of team working. STUK has commenced a recruitment programme since the 2000 mission and the practice of team working during inspections allows new staff members to become familiar with STUK's inspection methods in an efficient manner.

Findings of the 2003 follow-up IRRT mission

The issues associated with this suggestion have been discussed by the STUK Management Group. They concluded that the possibility of loss of objectivity is very small and that there are features of STUK's activities that protect against it. For example, the local inspectors have

continuous contacts with STUK, and inspections made with and by other inspectors guarantee that the local inspector does not work in isolation, but continuously collaborates with other STUK inspectors. STUK management concluded that there was no evidence or argument to change the present procedures presented in guide HA 1.5.

It is concluded that suggestion S13 has been adequately addressed for nuclear power plants.

6.2.1. Recommendations and Suggestions

No further recommendations or suggestions were identified in this area.

6.3. INSPECTION PLANNING

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R7: STUK should assess inspection program planning and resource allocation to ensure development of an integrated plan that provides for a consistent and effective verification of the level of operational safety performance at the NPPs. This plan should cover more than one year to ensure that over time all important areas are covered since all things can not be covered annually.

Changes since the 2000 IRRT mission

During the mission in 2000 the IRRT found that the Periodic Inspection Programme, which had been introduced in 1998 had resulted in improved inspection effectiveness. Since the IRRT mission in 2000 STUK has continued to develop this programme and has produced quality management guide YTV 4.1 in which the programme is described.

The programme is divided into three parts (A, B and C). The programme allows STUK to inspect:

- the licensees' safety management (including safety culture, quality management and competence management);
- the licensees' arrangements for defined main functions (safety assessment and enhancement, operations, plant maintenance and protection); and
- the licensees' performance in specific technical areas (e.g. mechanical engineering, radiation protection, fire protection and QA).

The implementation of this programme was discussed and a number of positive features were identified:

- there is an emphasis on thorough preparation of inspections;
- licensees procedures are used as a basis for inspections as well as regulatory guides and inspection findings include deviations, which have a basis in regulatory requirements, and recommendations, which are based on inspectors judgement;
- the implementation of specific inspections requires team working between inspectors and the peer review of findings;
- the results of inspections during one year informs the planning process for subsequent year; and
- inspection teams are seeking to identify any generic issues.

STUK found that it is sometimes difficult to complete the Periodic Inspection Programme and it therefore introduced greater discipline and achieved improved performance. The IRRT follow up review concluded that some further efficiency gains could be achieved in conducting all types of regulatory inspections.

Findings of the 2003 follow-up IRRT mission

On its own initiative, and in response to recommendation R7, STUK has continued to improve inspection programme planning and this is producing observable improvements. Suggestions are provided in the following sub-section which provide STUK with advice on how further improvements can be made in this area.

6.3.1. Recommendations and Suggestions

(1) **BASIS** – The IAEA Safety Requirements "Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety" (GS-R-1) state in paragraph 5.14: "The regulatory body shall establish a planned and systematic inspection programme." In addition the IAEA Safety Guide "Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body" (GS-G-1.3) state in paragraph 4.9: "The regulatory body should have an overall plan for the programme of inspections that it is to undertake at a facility. In determining the intervals between inspections and the level of effort to be applied, the regulatory body should take into account the relative significance for the safety of the facility of each authorisation stage and inspection area."

a) Suggestion: STUK should plan its inspection activities so that, over a pre-determined period of time, the licensees' compliance with regulatory requirements is sampled. The periodicity of such inspections should be chosen to ensure that there is no unnecessary repetition of inspections.

b) Suggestion: STUK should (1) monitor the resource distribution between the Periodic Inspection Programme, YVL inspections and major projects, and (2) improve the efficiency of YVL inspections in order to ensure that sufficient resources are available to improve the performance of its Periodic Inspection Programme.

(2) **BASIS** – The IAEA Safety Requirements "Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety" (GS-R-1) state in paragraph 5.13: "The main purposes of regulatory inspection and enforcement are to ensure that…….the operator is managing safety in a proper manner." In addition the IAEA Safety Guide "Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body" (GS-G-1.3) state in paragraph 4.4: "The inspection programme should be developed so that the regulatory body can determine whether the operator has a functional self-assessment system of high quality and is conducting activities in accordance with its own established procedures for ensuring that regulatory objectives and requirements are met."

a) Suggestion: STUK should continue to develop efficient inspection practices that confirm that the licensees have processes, systems or arrangements that achieve the required level of safety.

6.3.2. Good Practices

(1) **BASIS** – The IAEA Safety Requirements "Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety" (GS-R-1) state in paragraph 5.14: "The regulatory body shall establish a planned and systematic inspection programme." In addition the IAEA Safety Guide "Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body" (GS-G-1.3) state in paragraph 4.9: "The regulatory body should have an overall plan for the programme of inspections that it is to undertake at a facility. In determining the intervals between inspections and the level of effort to be applied, the regulatory body should take into account the relative significance for the safety of the facility of each authorisation stage and inspection area."

a) Good Practice: STUK has developed a structured inspection programme (the Periodic Inspection Programme) that enables it to obtain information on the licensees' management of safety. This information is used to develop ideas and to plan for the next annual cycle of inspections. It is also used, with other information on the licensees' safety performance, to produce an annual report which is open to the public.

6.4. IMPLEMENTATION OF THE OVERALL INSPECTION PROGRAMME FOR NPPs

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R8: STUK should develop written inspection guidance to support their YTV guides for their inspections (including periodic, topical, reactive and resident inspections) including the topics referenced in IAEA Safety Guide No. 50-SG-G4 (Rev 1) "Inspection and Enforcement by the Regulatory Body for Nuclear Power Plants" Paragraphs 505 – 523. This will enhance effectiveness, consistency and transparency of inspection. In STUK's development of inspection guidance, particular care should be given to ensure appropriate focus on observation and evaluation of operator and worker performance.

Recommendation R9: STUK should develop a process to periodically evaluate all inspection findings and relevant information to determine if revised regulatory actions are needed.

Suggestion S14: Current STUK staff are highly experienced and should document their extensive knowledge to assist others. Additionally, STUK should use the IAEA Safety Guide No.50-SG-G4 (Rev 1) "Inspection and Enforcement by the Regulatory Body for Nuclear Power Plants" in developing guidance.

Changes since the 2000 IRRT mission

The changes that affect the overall inspection programme for NPPs since the 2000 IRRT mission have been described in sections 6.1 and 6.3.

Findings of the 2003 follow-up IRRT mission

The responses to recommendations R8 and R9 are covered by the STUK actions that are described in sections 6.1 and 6.3 and it is concluded that these recommendations have been adequately addressed for nuclear power plants.

It is concluded that recommendation R9 has been adequately addressed for nuclear power plants.

Suggestion S14 was concerned with the management of competence within STUK and, in particular, the retention of corporate knowledge. Since the 2000 mission STUK has undertaken a number of activities that address this issue, including:

- the up-dating of regulatory guides in preparation for the FIN5 project;
- the involvement of recent recruits in the process of up-dating regulatory guides;
- the involvement of recent recruits in small teams for the completion of regulatory activities;
- a project dealing with knowledge management of the regulatory control of nuclear safety control was started in 1999 (the aim of this initiative was to define core- and support processes of the regulatory control and respective changes of information); and
- a competence analysis for the whole STUK (completed for the first time in 2002-2003).

It is concluded that suggestion S14 has been adequately addressed for nuclear power plants.

6.4.1. Recommendations and Suggestions

No further recommendations or suggestions were identified in this area.

6.5. INSPECTION DOCUMENTATION

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S15: STUK should consider utilizing the guidance on inspection documentation in Section 7 of 50-SG-G4 as they review their process for reporting inspection results.

Changes since the 2000 IRRT mission

In the period since the 2000 IRRT mission STUK has produced an enforcement policy and new YVL guides 4.1 and 4.2 that have an impact on the way in which STUK records the result of inspections.

Findings of the 2003 follow-up IRRT mission

IAEA 50-SG-G4 was assessed and partly taken into account in updating YTV-guides (YTV 4.1, YTV 4.2, YTV 4.0, YTV 6.1 and YTV 6.2). STUK has also encouraged more prompt completion of inspection reports and has improved communication of inspection findings to the licensee. As mentioned in section 6.3 the results of inspections also contribute to STUK's annual report on the licensee's safety performance.

It is concluded that suggestion S15 has been adequately addressed for nuclear power plants and that improvements in inspection documentation have been achieved.

6.5.1. Recommendations and Suggestions

No further recommendations or suggestions were identified in this area.

6.6. REGULATORY ACTION AND ENFORCEMENT

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R1: STUK should develop an Enforcement Policy for all areas under their regulatory control that clearly lays out the practices and procedures to be followed by STUK personnel for the implementation of enforcement actions that are used consistently to ensure compliance by licensees with regulatory requirements.

Changes since the 2000 IRRT mission

Section 2.1.1 of the 2000 IRRT mission contained recommendation R1 which was concerned with the development on an Enforcement Policy. STUK has responded to this recommendation and the resulting changes are described below.

Findings of the 2003 follow-up IRRT mission

A response to this recommendation was developed by a working group that reviewed STUK's enforcement principles. The results of this working group were included in the following quality management guides:

- Guide STUK 3.1: Principles of Regulatory Activities (complemented and renewed, 21.12.2001);
- Guide YTV 4.14: Enforcement Measures for Regulatory Requirements (4.2.2002).

The new enforcement approach was introduced to inspectors at training events and reinforced through staff meetings. Examples of the use of the enforcement policy were presented during the follow-up mission and discussions with inspectors provided further evidence that the policy has been adopted at the working level. It was also noted that the use of the new approach has led to enforcement actions that are clearer to the licensee.

It is concluded that recommendation R1 has been adequately addressed for nuclear power plants.

6.6.1. Recommendations and Suggestions

No further recommendations or suggestions were identified in this area.

6.7. INTERACTION WITH OTHER REGULATORY ACTIVITIES AT THE NUCLEAR POWER PLANTS

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S16: STUK should develop arrangements with other regulatory bodies involved in nuclear power plant sites to ensure consistent practices are used to avoid any potential adverse effects on nuclear safety.

Changes since the 2000 IRRT mission

There have been no changes that affect this topic since the IRRT mission in March 2000.

Findings of the 2003 follow-up IRRT mission

STUK has considered this suggestion and has concluded that no action is necessary because it has responsibility for the main regulatory activities at nuclear facilities (i.e. nuclear safety, radiation protection, environmental protection and pressure vessel equipment) and because there is a legal basis for any other regulators to be subject to STUK.

It is concluded that suggestion S16 has been adequately addressed for nuclear power plants.

6.7.1. Recommendations and Suggestions

No further recommendations or suggestions were identified in this area.

6.8. INSPECTION OF PRESSURISED EQUIPMENT

Recommendations and Suggestions from the 2000 IRRT report

No recommendations or suggestions were identified in this area.

Changes since the 2000 IRRT mission

In 2002 STUK introduced a new version of YVL 3.0 that sets out responsibility for the final approval of pressurised equipment. This guide provided for the first time the option to transfer responsibility to the licensee s' accredited inspection organisation for the final approval of equipment outside safety classes 1 and 2.

Findings of the 2003 follow-up IRRT mission

STUK's new arrangements for final approval of pressurised equipment were reviewed to establish whether the licensee has the appropriate degree of responsibility for safety. It was found that all documentation is provided to STUK by the licensee and that STUK's role is not to carry out any testing or non-destructive examination but to give the final confirmation that

all the appropriate testing or inspection have been completed to the required standard. The purpose of the STUK inspections during commissioning is to evaluate and confirm the completeness of the previous design, manufacturing and inspection documentation.

It is concluded that STUK's inspection activities are intended to confirm that the licensee has fulfilled its responsibility for safety of pressurised components and do not in any way diminish the licensee's responsibilities. STUK's transfer of the authority for the final approval of some pressurised equipment to the licensees' accredited inspection organisation has improved its efficiency in this area and permits a concentration on the components with the greatest safety significance.

6.8.1. Recommendations and Suggestions

No recommendations or suggestions were identified in this area.

7. DEVELOPMENT OF REGULATIONS AND GUIDES

Expert: Thierry Foult

7.1. POLICY FOR DEVELOPMENT OF REGULATORY GUIDES

STUK has the statutory duty to prepare general regulations and issue detailed guides concerning nuclear safety and radiation protection. From the initial stages of the nuclear programme up till now there have been different approaches at different times. A great deal of General Regulations and especially more detailed technical guidance has been developed.

However, during the 2000 IRRT mission, it was found that a formal policy, discussed with the licensee and accepted by concerned authorities and licensees, did not exist.

As of today, for the elaboration of the Regulatory Guides, the whole process is described in detail in the Quality Manual (guide YTV 3.1), from the Document Preparation Profile (DPP) until the final document. When the second draft is issued, the different parties concerned by the guide (licensees, VTT, manufacturers) are consulted. At the end of the process, an Advisory Committee makes comments and gives its agreement before the guide is issued by STUK. The whole revision process of a YVL regulatory guide takes between 2 and 3 years. The main Committee is composed of 7 members nominated by the government for 3 years (members of VTT, ministries, universities), of 2 invited experts and of the Director General of STUK. In addition there are between 6 and 8 senior experts coming from one of the three technical sections (Reactor safety, Waste safety matters, Emergency preparedness and radiation protection and safeguards systems). The chairman is one of the 7 members of the main Committee.

Today there are 73 YVL guides.

In order to decide on the revision of a guide, a first review is planned when it reaches 5 years and in any case, after 10 years, the guide will be revised. Nevertheless, at any moment, the Department is allowed to decide that a revision is needed.

The priorities for the elaboration or revision of the guides are defined by the appropriate Department. Due to the FIN5 project, a first priority is now given to those guides addressing the design requirements. Thereafter, the priority will be given to the guides related to the operational requirements.

For the FIN5 project, the planned time schedule is as follows: about two third of the guides (about 25) related to the design phase will be revised for the end of 2003 (about 15) except 10 of them for which the revision process will last until spring 2004. For the operation phase, all the appropriate guides (about 10) should be revised before the end of 2005. Due to the high STUK workload during the FIN5 project, the new revision of the guides, according to the new action plan for rulemaking, will start at the earliest, after 2006.

It is obvious that mainly the inspectors who are not involved in the safety review of the FIN5 project, will participate to the revision of the guides for the operation phase; the others due to lack of time will however be consulted. The important human resources required during the

next three years for the revision process of the guides will be balanced by the recruitment of about 10 new STUK members.

Two databases support the rule making process, one on nuclear information (about 200 legal documents like act, decrees and YVL guides), the other for the preparation of the regulatory guides (for each guide, the status of the revision work is presented and there is a link to the previous draft already issued. Goal time schedule for the work is given and updated if necessary);

Recommendation and Suggestions from the 2000 IRRT report

Recommendation R10: STUK should perform a comprehensive evaluation of the approach to development of regulatory guides resulting in a broadly accepted statement on the fundamental characteristics of the system for this rule-making on different levels and areas.

Changes since the 2000 IRRT mission

A complete process for development of guides has been established. In addition, since the first IRRT mission there is a trend to develop a new strategy towards decreasing the total number of guides and for the remaining future guides to be less prescriptive and more goal and risk-informed oriented.

The FIN-5 project has prompted the review and updating of the guides to make sure that they are updated for a plant in the design stage and a plan has been established for the review of the most relevant guides. However STUK has identified gaps not covered by the present guides that should also be addressed

Findings of the 2003 follow-up IRRT mission

The whole revision process of the YVL guide, notably actually in use also to support the FIN5 project license application, is described in the STUK Quality Manual. It clarifies the internal organisation which has been established, the role of the external organisations, when and how comments are considered in the iterative process, which can take until 3 years.

The discussions highlighted that the inspectors in charge of the existing plants will have an important role and major workload to update the existing guides; it is expected by STUK that it should not weaken the global amount of inspection as far as it will be balanced by the recruitment of new members in the NRR Department.

In order to maintain Good Practices that are mentioned in § 4.1 of this report (Authorisation for nuclear facilities), concerning STUK preparations for the review and assessment of the FIN 5 project, STUK management should ensure that the reviewers in charge of the FIN5 project will really be consulted for the revision of the guides they will have to refer during the operation phase.

To benefit from the experience in the application of existing guides it is considered important that in early stages of the revision of one existing guide comments are sought from the

licensees about their experience with the existing guide, since this can help to identify issues to be addressed in the revision.

STUK already identified some missing safety issues among the existing YVL regulatory guides in course of revision. For example the issues concerning decommissioning, containment and external threats will have to be considered thus resulting in the elaboration of new guides or incorporation in the revision of existing ones.

7.1.1. Recommendations and Suggestions

(1) **BASIS** – The IAEA Safety Guide GS-G-1.4 on "Documentation for use in regulating nuclear facilities", states in § 3.18: "Other sources of information that should be considered in the development of regulations include: … experience in the nuclear industry;…"

a) Suggestion: At an early phase in the revision of each regulatory guide, STUK should invite comments from the licensees on the experience from the use of the existing guide.

(2) **BASIS** - The IAEA Requirements GS-R-1. on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety states in § 3.2 (1) : "In fulfilling its statutory obligations, the regulatory body: shall establish, promote or adopt regulations and guides upon which its regulatory actions are based;…".

a) Suggestion: STUK should prepare the additional regulatory guides in order to address those identified areas that are not adequately covered by the existing guides.

7.2. CAPACITY FOR RULEMAKING

During the 2000 IRRT mission it was found that in previous years the resources assigned in the Annual Plans for rulemaking activities were not made available in practice, thus resulting in at least a backlog of guides to be revised.

Concerning Periodic Safety Review, in the Finnish practice it is the same as re-licensing; it takes place about every 10 years. The description of the legal process and the obligation of the licences are described in the draft guide YVL 1.1 chapter 3.2 which has been sent to the licensee for comments: feedback is waited within few weeks and final guide will be issued at the end of 2003. In addition, for internal guidance, the future quality guide YTV 4.15 (the issue is planned at the end of 2004) will describe the safety review as part of the licensing process.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S17: Given the difficulty to realise the programme for developing new safety guides and revision, according to the schedule, of existing safety guides as laid down in the annual plans, STUK should agree and implement allocation of resources to reserve adequate capacity for these tasks.

Recommendation R11: STUK should develop guidelines for PSR indicating in addition to what is prescribed in the law/decree for operating licence, what is needed for performing a PSR..

Changes since the 2000 IRRT mission

Now there is a commitment of the management through a new STUK strategy for 2003-2006. In a high level, STUK document, "Actions plan for rulemaking" (final drafting for September 2003), the requirements for the rulemaking process are described in detail.
The status of the rulemaking process must be presented periodically at the Department meeting every 1 to 2 months. As a consequence of the management commitment, there is also a change of appreciation among the inspectors on the importance of the review and assessment on rule making tasks.

New recruitments are planned in 2004 for inspection tasks, which should save time for the reviewers in charge of the rule making process.
Furthermore, the working time of inspectors will be planned in relation with the supervisor, and will specify the annual time allocated to the different tasks (review, inspection, training,..).

Findings of the 2003 follow-up IRRT mission

The IRRT suggestion and recommendation have been fully considered and their implementation is in progress.

7.2.1. Recommendations and Suggestions

No further recommendation and suggestion have been identified.

8. EMERGENCY PREPAREDNESS

Expert: Alan Muller

Emergency preparedness in Finland is addressed in the Nuclear Energy Act (990/87) and the Nuclear Energy Decree (161/88). The Council of State Decision (397/91) specifies the general regulations for nuclear power plant emergency preparedness. The Act on Rescue Services (561/1999) and Decree (875/1999) specify STUK's responsibilities during nuclear accidents and radiological emergencies. The Decree by the Ministry of the Interior (774/2001) specifies emergency planning and public information arrangements during a nuclear or radiological emergency. The Emergency Power Act (1080/1991) gives an obligation for authorities to plan for all types of emergencies.

Finland has ratified international conventions and made several bilateral agreements with neighbouring countries. STUK, as a national contact point and a competent authority, has a responsibility to fulfil the requirements of these arrangements.

STUK is responsible for regulation of emergency arrangements at Finland's nuclear power plants and other locations within the country where nuclear materials are used and transported. They are also responsible for monitoring international nuclear events and taking action as appropriate. In addition, STUK is also responsible for providing advice on protective measures to local, provincial and national organisations, for protection of the public. These depend on the severity of the national or international event.

8.1. RESPONSE AND TRAINING OF STUK

All relevant STUK staff members have responsibilities for responding in the event of a nuclear accident or radiological emergency being declared which requires mobilisation of its resources. The Emergency Preparedness Group within STUK reports directly to the Director General. The responsibilities of the Emergency Preparedness Group cover emergency planning and training, co-ordination issues and a duty system. Guidance on the STUK arrangements for responding to an event is provided in the Quality Manual, Guide STUK 3.4 and the STUK Emergency Preparedness Manual (VA 1 to VA 5). This consists of six parts namely; the emergency plan, internal regulations, procedures, protection of IT systems, laboratory measurements and security.

STUK has prepared an emergency plan to respond to nuclear or radiological emergencies. The plan is supported by procedures detailing the arrangements STUK emergency staff should follow. STUK routinely tests its emergency preparedness arrangements for national and international events and all staff are routinely trained and their performance evaluated. STUK has actively sought feedback on exercise performance from participants and specialists in the operation of emergency management processes.

The whole of STUK’s staff are regularly trained and exercised according to the emergency plan and internal regulations.

Changes since the 2000 IRRT mission

Within STUK, there are annually several exercises having different types of scenarios and different phases of the accident situation (early/late phase). These exercises are either internal,

domestic, multi/bilateral or international exercises. Annually, one of these exercises is held within STUK at an unannounced time and date.

Findings of the 2003 follow-up IRRT mission

The organization of exercises outside office hours constitutes a good practice.

8.1.1. Good Practices

(1) **BASIS** - These changes, and in particular the organization of unannounced exercises that include exercises outside office hours are considered to constitute a good practice.

a) Good practice: STUK annually organises several exercises (both early and late phase) of which one is held on an announced day and time and takes place outside of normal office hours.

8.2. REGULATION OF LICENSEE'S EMERGENCY PREPAREDNESS

STUK regulates the licensee's emergency arrangements, which including approval of their emergency plan. Nuclear Power Plant Emergency Preparedness is covered in the STUK Guide YVL 7.4 that provides requirements the licensee should follow. An inspection plan is drawn up which covers all elements of the emergency arrangements to be inspected including training, procedures, equipment and facilities. It also includes interactions with other emergency response organisations involved in worker and public safety. Emergency plans for the sites are in place, which has been approved by STUK and routine training is carried out by the operator. There are annual exercises organized at each site that STUK regularly observes. National exercises involving off-site organizations are carried out every three years at each site.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R12 : STUK should ask the licensee to demonstrate their emergency arrangements to ensure that over a period of time they systematically cover all elements of the plan and accident scenarios including the protection of all people on site and e.g. access and egress onto site for emergency services and shift staff.

Changes since the 2000 IRRT mission

STUK has performed at the nuclear power plants annual inspections, which cover licensee emergency procedures and training activities, including training for those persons not working regularly at the plant sites. Subcontractors are especially trained for the outage activities and special emphasis is placed on emergency procedures during shutdown. On-site tours are organised for rescue services, and the interaction between on-site and off-site fire services is also tested during emergency exercises.

The training of handling and transport of a contaminated patient has been performed and was included in the emergency exercises at the plants; both licensees have also arranged common emergency exercises and training courses with local fire safety authorities. Annual fire alarm exercises have been arranged regularly at both sites.

Findings of the 2003 follow-up IRRT mission

The Guide YVL 7.4 contains guidance for licensees on how to analyse different scenarios for emergency planning. A planning group consisting of STUK, other organizations and the licensee has held regular meetings where the objectives of the exercise and those aspects that were tested in previous exercises are discussed. The objectives and the outcome of the annual exercise are verified during inspections. Although previous exercise reports and areas that have been identified for testing are taken into account during planning, no summary exists to demonstrate that the licensee systematically shows to STUK that all important elements of the emergency response plans are tested and what training has been completed over a specific period.

8.2.1. Recommendations and Suggestions

(1) **BASIS -** The IAEA Safety Requirements GS-R-2 on "Preparedness and Response for a nuclear or radiological emergency" states in paragraph 5.33 that "exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for facilities in threat category I, II or III and the national level programmes for threat category IV or V are tested at suitable intervals. These programmes shall include the participation in some exercises of as many as possible of the organizations concerned. The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body. The programme shall be subject to review and updating in the light of experience gained (see paras 3.8, 3.16, 5.37 and 5.39 for further requirements in relation to exercises)".

a) Suggestion: STUK should require that the licensee ensures that a systematic approach is adopted, over a defined period of time, whereby all elements of the emergency plans are evaluated and tested at different frequencies and at the same time flexibility is maintained in planning.

8.3. OFF-SITE EMERGENCY PREPAREDNESS

The Ministry of the Interior is responsible for public safety in the event of a nuclear emergency where actions are needed to protect the public. This responsibility is implemented through the State Provincial Offices and the Municipalities. The legislation establishes: the rules and responsibilities of those organisations involved in off site emergency planning; emergency plans; the scope of emergency exercises tested; emergency exercise frequency; handling the media; management of emergency exposures; and recovery arrangements during emergency situations and after termination.

There is an overall framework within Finland for managing nuclear accidents and radiological emergencies; there is guidance and information available describing the roles and responsibilities of organisations involved in emergency response; off-site emergency plans have been prepared around each of the nuclear power plant sites; emergency preparedness is included in training programmes; exercises are routinely carried out by those responding to a nuclear emergency; and there is a general process described for monitoring and reviewing exercise performance.

The planning group consisting of STUK and the intervening organisations jointly agrees which objectives are to be tested during the 3-yearly nuclear power plant exercises.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R13: Those organisations involved in providing support to the off-site emergency plans around nuclear power plants should ensure they systematically review their emergency preparedness to ensure all parts of their plans are tested over a period of time.

Changes since the 2000 IRRT mission

Coordination for the exercises is the responsibility of the Provincial Authority and STUK provides advice and training to the off-site organisations. Full-scale exercises (3 yearly) were arranged for the Loviisa NPP on 7/9/2000 and for the Olkiluoto NPP on 5/9/2001 where coordination between different organisations was tested.

The Security and Defence Committee issues instructions for planning and for coordination of the contents of emergency plans. A revised national strategy the "National Emergency Plan" will come into force during 2003. This strategy defines the responsibilities of various counterpart organisations as well as rules for coordination and cooperation during emergencies. It also addresses exercise schedules and a summary of possible threats to Finnish society. The strategy will be updated every fourth year.

The provincial and municipal authorities are responsible for duties within their own sphere of responsibility during emergencies. The Decree of the Ministry of the Interior (774/2001) concerning emergency planning and public information during nuclear or radiological emergencies came into force on 15/9/2001.

Findings of the 2003 follow-up IRRT mission

Special attention is being paid to coordination of decision making at national, provincial and local levels and groups have been established for coordination purposes. This coordination is tested at all levels. A matrix exists whereby the organisations ensure that all the elements of the plan including training and type of scenario are tested over a period of three years covering 2003 to 2005. In view of these developments it is considered that this recommendation has been addressed satisfactorily.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S18: Arrangements for how the transition from emergency management to normal government functions would be managed and how long term recovery actions of the various ministries, organisations and agencies would be co-ordinated should be tested during local and national emergency exercises at the two nuclear power plants.

Changes since the 2000 IRRT mission

A revised national strategy issued by the he Security and Defence Committee defines the responsibilities of various organisations as well as rules of coordination and cooperation during emergencies.

In addition to early phase nuclear power plant exercises, which are organised regularly twice a year, exercises have been organised in which later phase aspects of fallout situations are assessed.

In September 2000, a severe crisis exercise called VALHA was held, which involved all authorities at the national (including the Council of State and the Parliament), provincial and municipal levels and the Finnish Broadcasting Company. VALHA consisted of several phases and scenarios (NPP, nuclear weapon) and lasted for four days.

STUK's involvement ranges from exercising its own response in recovery phases to participating in organising late phase exercises at the national, provincial and municipal levels. STUK's own staff members have been trained to respond in a late phase situation when the accident situation itself is already under control. STUK organised two internal late phase exercises for its own staff in 2000 and in 2003. The objective was to exercise the provision of laboratory services, analysis and decision-making on radiological consequences for the population and the environment, decontamination methods as well as advice for industry and commerce.

Findings of the 2003 follow-up IRRT mission

In terms of the new national strategy, special attention is being paid to coordination at national, regional and local levels of decision making and there are groups established for coordination purposes.

The involvement of STUK and the intervening organisations in late phase activities has been exercised frequently at all levels of government, including the activities performed by the coordination group during recovery operations and in the return from emergency to normal conditions.
In view of the above arrangements, the suggestion from the previous mission is considered to have been fulfilled.

8.4. MEASUREMENTS

Changes since the 2000 IRRT mission

STUK is planning implementation of the upgrading of the severe crisis laboratories for radiation measurements in Finland. The crisis organisation consists of four regional laboratories (two STUK laboratories, one owned by the Defence Forces, one in the town Kuopio in cooperation with the Finnish Meteorological Institute) and about fifty municipal laboratories. During 2003 STUK will provide new measurement equipment to municipal and regional laboratories. Laboratory staff will be trained by STUK.

Findings of the 2003 follow-up IRRT mission

The upgrade and training programme that STUK is planning will ensure that the network of laboratories are equipped with the latest technologies, and will ensure harmonisation of all laboratories in terms of calibrations, measurements and training.

8.4.1. Good Practices

(1) **BASIS -** The IAEA Safety Requirements GS-R-2 on "Preparedness and Response for nuclear or radiological emergency states in paragraph in 5.28. that "laboratories shall be designated to make the necessary arrangements to be able to perform appropriate and reliable analyses of environmental and biological samples and measurements of internal contamination for the purposes of an emergency response. It shall be ensured that these facilities would be operational under postulated emergency conditions."

a) Good Practice: STUK has initiated activities to upgrade equipment and to train staff in the use of the new measurement systems in over fifty laboratories countrywide.

8.5. HANDLING THE MEDIA

If needed, overall co-ordination with the media is assisted by the Information Unit of the Council of State. Each organisation responding to an emergency situation also has responsibilities for liaison with the media on their own activities. STUK issues information concerning the accident, the radiation situation and the impact of the situation on public health and safety. In addition, STUK can make announcements via television and radio during the early stages of an event to inform the public of its occurrence. The arrangements are routinely tested.

With improved communication systems both nationally and internationally the quality, clarity and timing of information to the media is important to avoid information being misunderstood which could cause unnecessary panic for the public in Finland and other countries. It is important for all organisations involved in handling the media to ensure consistent information is provided.

The Finnish Broadcasting Corporation (YLE) participates in exercises, and also provides evaluators to assess the role of STUK during exercises. YLE has made use of Radio Data systems to ensure that following an emergency message from STUK that announcements are made on all public and private radio stations (300 stations). Agreements exist between YLE and Rescue Authorities, Police and other organizations on emergency broadcasts.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S19: Those involved in handling the media during a nuclear emergency should review their interactions with other responders routinely to confirm consistent and quality information is provided for the public in Finland and other countries, taking account of continually improved communications

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Changes since the 2000 IRRT mission

National, regional and municipal authorities provide information on their own activities and give instructions regarding their own sphere of responsibility. In very serious situations, the information unit of the Council of State assists in coordination of public information. The Decree of the Ministry of Interior (774/2001) which specifies to all organisations how to communicate to the public has been put into force.

In addition, a recommendation by the Council of State regarding public information for the state administration was implemented in 2002.

Every third year a full-scale exercise, with participation of all relevant counterparts at the national, regional and local levels is held at both nuclear power plants. Representatives of the media and the private sector are also invited to participate. The co-operation between all intervening organisations in providing public information was tested during emergency exercises for Olkiluoto nuclear power plant in 2001 and for Loviisa in 2002.

It is STUK's responsibility to inform the public on radiation situations and their consequences to the population, the environment and on society in general. STUK is the Finnish National Warning Point as well as the Competent Authority for receiving and sending information on all exceptional events where radioactive substances are involved. STUK has participated in the developing and revision of guides concerning public information during nuclear and radiological emergencies.

Findings of the 2003 follow-up IRRT mission

The suggestion has been considered and strategies for public communication have been issued. In very serious situations, the information unit of the Council of State will assist in the coordination of public information. However, for all exercises between organisations, the interface between the different intervening public communication units has been tested.

In view of the above arrangements it is considered that the suggestion from the previous mission has been addressed adequately.

9. WASTE MANAGEMENT AND DECOMMISSIONING

Expert: Phil Metcalf

9.1. WASTE MANAGEMENT INFRASTRUCTURE ARRANGEMENTS

9.1.1. General

Most of the waste generated in Finland arises from the operation of the Olkiluoto and Loviisa nuclear power plants. These wastes are defined as “Nuclear Wastes” and the Nuclear Energy Act regulates their management. It clearly specifies that an operator generating, or having generated, nuclear waste shall be responsible for all waste management and their appropriate preparation and is responsible for their costs. This is called the “waste management obligation”.

In addition, “radioactive waste” is generated by other radiation practices and stored in a module of the Olkiluoto disposal facility. The Radiation Act regulates the management of this radioactive waste. It clearly specifies that the responsible party is required to take all the “measures needed to render radioactive waste arising from its operation harmless”, which are defined as means and measures needed to treat, isolate or dispose of the radioactive waste, or to restrict its use so that it does not endanger human health or the environment.

In this section, the term “nuclear waste” is used to refer to waste submitted to the Nuclear Energy Act and the term “radioactive waste” for the waste subject to the Radiation Act. If both are considered, the term “waste” is used. The exception to this rule is when quotes are given from IAEA Standards.

The spent fuel management strategies of the nuclear power plants have been different. Loviisa originally returned spent fuel to Russia, while Olkiluoto has stored spent fuel on site. In 1994, the Nuclear Energy Act was amended in such a way that both the export and import of nuclear waste were de facto prohibited. The transfer of spent fuel from the Loviisa plant to Russia stopped at the end of 1996.

The Nuclear Energy Act empowers the Ministry of Trade and Industry to “order various licence-holders with a waste management obligation to undertake nuclear waste management measures jointly, if by doing so safety can be increased or costs can be substantially reduced or if any other weighty reason so requires”. On the basis of that possibility given by the law, a new company, Posiva, jointly owned by the two power plant companies, was founded. The company was assigned the responsibility to develop a deep geological repository for the disposal of spent fuel from the nuclear power plants. The company carried out a detailed characterisation at four sites and a submission was made to the government requesting a decision in principle (DiP) to develop a geological disposal facility. The project includes an encapsulation plant for the conditioning of spent fuel into canisters prior to disposal. Governmental Decision 478/1999 on the safety of disposal of spent nuclear fuel contains requirements to plan for long term safety, including a general requirement that “the implementation of disposal should not be unnecessarily delayed” and a requirement that

retrievability of the spent fuel canisters shall be maintained to provide for such development of technology that makes it a preferred option.

As regards other operational nuclear waste arising from both the Loviisa and Olkiluoto nuclear power plants, it is first stored and then transferred to on-site disposal facility for low and intermediate level waste. These are located in the bedrock at depths of 60 to 110 metres. The disposal facilities have separate modules for low-level and intermediate-level waste. In addition, it is planned to build additional modules at both sites for the disposal of decommissioning waste.

Changes since the 2000 IRRT mission

There have not been any major changes in the activities that generate radioactive waste in Finland since the previous IRRT mission in 2000. The main producers remain the two nuclear power stations; Loviisa and Olkiluoto. The rate of waste production from users of radioactive material in research, industry and medicine also remain similar. The law to dispose of all waste generated in Finland within the national borders still stands.

Nevertheless, since the previous IRRT two major decisions have been made which will impact on waste management activities within the forthcoming few years, namely the decision to construct an additional nuclear power station and the decision to go ahead with the development of the geological disposal facility for spent nuclear fuel. Plans remain in place to build additional modules at the two exiting LILW disposal facilities at the two power station sites for the waste that will arise from decommissioning activities. An investigation has also been carried out into radioactive waste containing natural radionuclides.

In line with the decision to move forward with the development of a geological disposal facility for spent fuel, the guides on operational and long term safety for spent fuel disposal (YVL 8.4 Long term safety of disposal of spent nuclear fuel, 23 May 2001 and YVL 8.5 Operational safety of a disposal facility for spent nuclear fuel, 23 Dec. 2002) have been updated. These address the needs for development of the conditioning and disposal facilities facilitating the legal obligation to move forward with disposal without delay and clarifying requirements in respect of retrievability.

9.1.1.1. Good Practices

(1) **BASIS** - According to the GS-R-1, “In fulfilling its statutory obligations the regulatory body: shall establish ……guides upon which its regulatory actions are based”.

a) Good Practice: STUK has issued a safety guide has been issued on the long term safety of spent fuel disposal which clearly sets out requirements and provides guidance on meeting the requirements, including how the issue of retrievability must be addressed.

9.1.2. Planning and funding for nuclear waste management

The Nuclear Energy Act stipulates that “the Ministry of Trade and Industry or the Radiation and Nuclear Safety Authority (STUK) having granting a licence for operations generating nuclear waste, shall decide, having consulted, if necessary, the Ministry of the Environment in the matter, the principles on the basis of which the waste management obligation is to be

implemented. For this purpose the Ministry of Trade and Industry or STUK may obligate the licence-holder with a waste management obligation to present a plan for carrying out nuclear waste management".

This is further elaborated in the Nuclear Energy Decree which requires that "a licence-holder with a waste management obligation shall each calendar year submit the following plans and reports on his nuclear waste management measures to the authority:

(1) a plan on how the licence-holder with a waste management obligation has planned to carry out the nuclear waste management measures and their preparation; the plan shall include at least the following parts:

   (a) an overall plan for carrying out the licence-holder's entire nuclear waste management obligation, with the relevant timetables and specifications, including the necessary preparations and research and the administrative arrangements and other duties required by the waste management obligation;

   (b) a detailed plan on measures that the licence-holder intends to undertake during the next calendar year; and

   (c) an outline plan on the measures that the licence-holder plans to undertake in the course of the next five years.

(2) a description of the agreements and other arrangements that the licence-holder has made to arrange nuclear waste management; and

(3) any other information considered necessary by the authorities.

If some significant changes take place in nuclear waste management, the licence-holder must notify the said authority thereof without delay."

When the waste management obligation includes the decommissioning of a nuclear facility, the nuclear waste management plan submitted by the licence-holder shall contain the following information:

(1) the methods and timetable of the decommissioning or cessation of operations;

(2) storage of the nuclear waste resulting from the decommissioning or cessation of operation before disposal, and a description of the disposal; and

(3) any other information considered necessary by the authority.

The Nuclear Energy Act also establish a funding mechanism, the State Nuclear Waste Management Fund, whereby the operators having a waste management obligation are obliged to contribute to the Fund according to the costs of the future management of generated nuclear waste and in connection with the licence for these operations. This scheme is then up-dated periodically. Provisions for the security of the Funds are also addressed in great detail. At present, provision has been made for the full currently estimated liability for the future management of all existing nuclear waste.

Changes since the 2000 IRRT mission

It has been approved by the Ministry that the nuclear power companies can rationalize their work on annual plans demanded on the basis of the Nuclear Energy Act by making references to a long-term comprehensive and detailed plan, which they would submit every three years beginning from December 2003. Three year plans will enable a much clearer picture to be developed of how radioactive waste arisings will be managed in the long term and how realistic and feasible are proposed decommissioning plans.

9.1.2.1. Good Practices

(1) **BASIS** - According to the GS-R-1, "Adequate infrastructure arrangements shall be made for … the safe management of spent fuel and radioactive waste".

a) Good Practice: The requirement to have a detailed waste management plan prepared periodically that enables assessment of the feasibility of waste management proposals from normal operations and decommissioning and evaluation of the adequacy of associated financial arrangements.

9.1.3. Management of waste from radiation practices**.**

The Radiation Act regulates the radioactive waste generated by radiation practices. STUK's Research and Environmental Surveillance Department receives and manages the residual wastes from such practices. The waste generator is obliged to pay for these services. An inventory of sources, a registry of practices, and the requirement on users to pay an annual fee, allow STUK to maintain overall control over the use of radioactive materials and in particular the waste arising and the end of practices.

The radioactive waste is transferred to one of the modules of the Olkiluoto disposal site for storage pending a final decision as regards their disposal. This is based on an agreement established in 1998 for a twenty-year period between the Ministry of Social Affairs and Health and the operator of the Olkiluoto Power Plant.

Thus, planning and funding mechanism exist for the management of the radioactive waste and actions are taken toward their final disposal in the low and intermediate disposal module and possibly in the future modules dedicated to decommissioning waste.

It is recognized by STUK that the management of this waste and the regulatory control of such management need to be carried out as separate activities and that if an independent organization could undertake the waste management tasks in a competent and cost effective manner it would be a preferable situation. There is an effective separation of these functions in as much that the waste management activities are carried out by the Research and Environmental Surveillance Department of STUK and regulatory oversight is the responsibility of the Office of Waste Management.

The storage arrangements for this waste are safe and in line with best international practice. Nevertheless if an arrangement could be agreed to enable direct disposal of waste that is acceptable for disposal in the existing disposal facilities, it would obviate the need for subsequent handling and possible additional treatment of the waste before its final disposal and would avoid any burden on future generations to have to deal with this waste.

9.1.3.1. Recommendations and Suggestions

(1) **BASIS** - According to SS 111-F, "Radioactive waste shall be managed in such a way as to secure an acceptable level of protection for human health" and "Radioactive waste shall be managed in such a way that it will not impose undue burdens on future generations". According to SS 120, "For exposure from any source, …., the dose, the number of people exposed and the likelihood of incurring exposure shall all be kept as low as reasonably achievable".

a) Suggestion: Consideration should be given to setting up arrangements to dispose of radioactive waste from small scale use of radioactive material, that meets the relevant waste acceptance criteria, directly into existing waste disposal facilities.

9.1.4. Arrangements for intervention

The Nuclear Energy Act states that, should any substance, object or information be detected and should no owner or possessor be identified, it shall belong to the State. The Nuclear Energy Decree allocates the responsibility for the retention of these substances, objects or information to STUK.

Moreover, the Radiation Act requires that if a responsible party does not meet the requirements, the State shall take the necessary measures to render the radioactive waste harmless and to decontaminate the environment and that it shall also take these measures if the origin of the waste is unknown, or if no primary responsible party can be found. Finally, it stipulates that detailed regulations on the measures to be taken by the State accordingly shall be issued by Decree.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S20: The legislation should provide the framework for the implementation of the necessary measures to manage the waste or decontaminate the environment in situations where the origin, owner or possessor of the waste is not known and no primary responsible party can be found.

Findings of the 2003 follow-up IRRT mission

Following consideration of the suggestion by STUK it was concluded that there was no need to amend the legislation as the responsibility in such circumstances is clearly assigned to STUK. It was also indicated that there are not many situations have been identified were such measures would be necessary and that it may be preferable to retain flexibility to deal with any situations that may arise on a case by case basis.

Similar suggestions were made in respect of intervention following accidents and in respect of radiation protection (8.3 and 10.1.1) and similar response were indicated. Whilst the legislation may be adequate in assigning sufficient powers and authority to STUK, this is an area were additional planning appears to necessary to identify scenarios were STUK may have

to undertake intervention type activities and to identify issues that could arise. On the basis of these considerations, decisions could be made on the need for additional internal guidance procedures to be developed.

9.1.4.1. Recommendations and Suggestions

(1) **BASIS -** According to the GS-R-1, the Government shall appoint organisations to be responsible for making the necessary arrangements for intervention to ensure that remedial action is taken to protect the public, workers and the environment. The intervening organisation shall have the necessary resources and authority to fulfil its function. Moreover it states that a legislative and statutory framework shall be established to regulate the safety of facilities and activities, which includes site rehabilitation and activities in waste management. A general recommendation on the legal framework for intervention is included in section 10.1.

a) Suggestion: An investigation should be undertaken by STUK to identify circumstances in which it may have to undertake intervention actions. It should be confirmed that the legislation adequately enables STUK to undertake the measures that may be necessary. STUK should develop internal procedures that may be necessary to implement these actions.

9.2. CLASSIFICATION OF WASTE

The Finnish waste classification system is established by the Nuclear Energy and the Radiation Acts. Waste arising from the use of nuclear energy is called nuclear waste and includes:

- waste in the form of spent fuel or in other form generated in connection with, or as a result of, the use of nuclear energy; and

- materials, objects and structures which, having become radioactive in connection with, or as a result of, the use of nuclear energy and having been removed from use, require special measures because of the danger arising from their radioactivity.

All this nuclear waste has to be appropriately managed in accordance with the requirements of the Nuclear Energy Act. There is nevertheless a clearance system established since 1992 with precise regulatory procedures and a set of criteria for the removal from regulatory control of waste, which, due to their low activity are not regarded as nuclear waste. It is described in the guidance material YVL 8.2. The procedures applied for the clearance of this waste, including the methods used for the determination of its radioactive content, shall be described in detail and submitted for approval to STUK. STUK controls by inspections the removal of the waste and a summary of all cleared waste shall be presented every year to STUK.

In the Radiation Act, the term radioactive waste is used and it covers radioactive materials, and equipment, good or materials contaminated by radioactive materials, that has no use and must be rendered harmless owing to its radioactivity. Specific guidance material, ST 6.2, describes requirements for the clearance of this radioactive waste from practices. However, in

its preparation the approach used for the derivation of clearance levels differed from the approach taken in the YVL 8.2 document.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R19: The Radiation Act should be amended to devote special sections to exemption and clearance. This is the approach adopted in the IAEA BSS.

Findings of the 2003 follow-up IRRT mission

At the time of the 2000 IRT mission Guide ST 6.2 "Radioactive Waste and Discharges", July 1999, was in place and since the mission Guide YVL 8.2 "Premises fro Removal of regulatory Control from Nuclear Waste" March 2002, has been developed and published. As such, from a waste management perspective there is clear guidance available in respect of clearing materials from regulatory control from both radiation practices and nuclear installations. ST 6.2 also deals with disposal to landfill sites. Whilst it is so that a different approach has been used in the derivation of levels by the two documents, the basic criteria are the same. In addition, the methodology adopted is appropriate for the circumstances to which the two documents apply. In its response to the recommendation STUK indicate that they do not see this as an urgent issue and one that can be addressed the next time there is a substantial revision to the legislation. This is a reasonable suggestion and will allow time for the international position on exemption, clearance and exclusion, on which there is not unanimity at this stage, to clarify. In view of the above it is considered that this recommendation has been adequately addressed.

9.3. LEGISLATIVE FRAMEWORK FOR THE AUTHORIZATION PROCESS OF WASTE MANAGEMENT FACILITIES AND ACTIVITIES

The Nuclear Energy Act applies to the construction and operation of nuclear facilities. This includes facilities performing extensive disposal of waste and facilities used for handling or storage of waste.

The basic legislative and regulatory framework for the authorization process of nuclear power plants addressed in the Sections 1 and 4 also applies to the pre-disposal and disposal facilities. It is not addressed in this section.

There are, however specific activities carried out for the waste management or the decommissioning of nuclear facilities that require an authorization process.

9.3.1. Decommissioning

For the decommissioning of nuclear facilities, the legal framework does not explicitly establish a specific authorization process. The decommissioning activities could, however, be considered as a major modification of the nuclear facility that would have an effect on the safety and would involve changes in the plans and documents approved by STUK. This framework is particularly designed to cover the construction and operational phases of nuclear facilities but not for the authorization of the performance of the decommissioning activities. Decommissioning plans are submitted by the operators and are reviewed by STUK. The result of this review could serve as a basis toward the preparation of a national policy on the general

options for the decommissioning of nuclear facilities, taking appropriately into account the proposal of the operators as regards the maintenance of knowledge and technical capability and the funding arrangements.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S21: A national policy should be established on the decommissioning options, taking into account the issues related to the limited number of nuclear power plants and operators, and the legal framework should be amended (Nuclear Energy Act and Nuclear Energy Decree) with a view to establishing an appropriate legal framework for the authorization process for the decommissioning of nuclear facilities.

Findings of the 2003 follow-up IRRT mission

The matter had been considered by both STUK and the Ministry of Trade and Industry who had concluded that decommissioning could be seen as a logical extension of plant operation and that it could be dealt with from a regulatory perspective by the modification control process.

The matter was discussed with representative of both STUK and the Ministry of Trade and Industry. It was emphasized that significant changes can take place when a facility goes into a decommissioning phase, such as certain systems and services no longer being available, reduced income and significant reduction in the availability of experienced personnel. The wastes that have to be managed can have significantly different characteristics from those arising from normal operations and the quantities can be much greater. Major decisions have to be taken well in advance and careful attention has to be paid to the resources that need to be available and the information that has to be preserved from the operating period. These various factors emphasize the need to give careful consideration to transferring to the decommissioning phase and for viewing this transition as a key step in the lifetime of a facilty such as commencing construction or plant operation. This suggestion is considered to warrant further consideration.

9.3.2. Authorization process for an underground research laboratory

In May 1999, Posiva Ltd submitted to the Government an application for a Decision in Principle on a disposal facility for spent nuclear fuel proposed to be located in the vicinity of the Olkiluoto site. The authorization process used is the same as for a nuclear facility of considerable general significance that requires a Decision in Principle and further licences for the construction and operational phases. For the disposal facility the whole process is expected to last about 20 years because construction is planned for the 2010s and the start of operation is planned for 2020.

The first part of the process involves considerable research and development works as well as continuation of site characterization. This will involve the construction of an underground research facility at the site before actual construction of the repository itself. This research facility is not a nuclear facility and is not subject as such to the Nuclear Energy Act. However, it is foreseeable that part of the underground research facility may be used for the possible future disposal facility and that on-site characterization activities might have an impact on the isolation capability of the natural barrier. Finally, these research and development works are of considerable importance for the assessment of the safety of the disposal facility prior to the construction licence.

Although the Council of State Decision in Principle of November 1983 provides a framework for the objectives to be observed in carrying out research, surveys and planning in the field of nuclear waste management and on their review by the Ministry of Trade and Industry, there is no clear legal framework for the direct review by STUK of these activities.

Changes since the 2000 IRRT mission

The major change that has taken place since the 2000 IRRT mission was the decision made in May 2001 by the Finnish Parliament to ratify the Decision-in-Principle taken by the government. In January 2001 Posiva published a programme for research, development and technical design work in the pre-construction period. The focus of this work is site investigation, technical design and development work and research into the long-term safety of the facility. STUK has commented on the proposals and informed Posiva of aspects it wishes to have investigated and how it intends to review the pre-construction investigations to be undertaken at the underground laboratory. STUK is entitled to make on site inspections during this period. STUK has established four working groups including outside experts who will review

- Investigation and modeling of geological structure
- Geohydrological investigations
- Geochemical investigations
- Bedrock movement investigation

A fifth group will be established later dealing with underground construction and rock mechanics. The comments from the review groups will be sent to Posiva and will also be sent to the Ministry.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R14: STUK should take steps to propose a legal basis providing for an approval process for the construction and operation of the proposed underground laboratory and for the direct review by STUK of the research activities that will be performed during and after the construction of the underground research laboratory.

Findings of the 2003 follow-up IRRT mission

STUK did raise this issue with the Ministry of Trade and Industry as recommended by the previous IRRT mission. The matter was again raised during the follow-up IRRT mission with representatives of both STUK and the Ministry. There is clearly a good working relationship between all the parties and Posiva are responding to the comments from STUK. However, compared to the FIN5 project, activities in the underground laboratory will be closely connected to the development and licensing of a future disposal facility and part of the underground laboratory may form an integral part of the future disposal facility. When construction work commences certain irreversible steps will be taken in relation to the actual construction activities and certain construction deadlines will have to be met and cost constraints respected. Any limitations STUK may consider necessary during this site characterization and research period may lead to dispute and it would be preferable for STUK to have a stronger legal mandate to deal with any such situation that may arise. There is also a

need to adopt a formal management system to ensure adequate quality assurance is applied to following the research activities and ensuring control over the documented outcomes of the programmes in the longer term (see section 9.5.3.2). It is therefore considered that this recommendation warrants further consideration.

9.3.2.1. Recommendations and Suggestions

(1) **BASIS -** According to the GS-R-1,"Government shall ensure that appropriate research and development programmes for radioactive waste disposal and implementation, in particular for long term safety". This calls for a formal approval process and a thorough review of these research and development activities by the regulator.

a) Recommendation: Steps should be taken to establish a legal basis to provide for regulatory control over the construction and operation of the proposed underground research laboratory. It should include a process for STUK to review and approve the construction and development of the laboratory and the research activities that will be undertaken in the laboratory. Guidance should be developed by STUK for the quality management system that needs to be applied to the research and development programme to ensure that the basis and outcomes of the programme are adequately recorded, together with any decisions based on these outcomes.

9.4. ORGANISATION AND STAFFING OF THE REGULATORY BODY AS REGARDS WASTE MANAGEMENT AND DECOMMISSIONING

Within STUK, the primary responsibility for the regulatory control of waste management activities is allocated to the Nuclear Material and Waste Department. The Department's general obligation and duties are described in the STUK's Organizational Order (Order STUK 2.2).

The sphere of responsibilities covers:

- the regulatory control of waste management (low, intermediate and spent nuclear fuel);
- the regulatory control of nuclear materials (safeguards, SSAC, export/import controls);
- the regulatory control of transportation of radioactive materials and waste;
- the regulatory combating of illicit trafficking of radioactive materials; and
- the regulatory function of National Data Center for the Comprehensive Nuclear Test Ban Treaty.

The regulation of waste, including waste from decommissioning, is allocated to a nuclear waste management office within the Department. This office consists of 8 well qualified staff members with expertise in the areas of:

- safety assessment;

- modeling of thermo-hydro-mechanical effects;
- geochemistry, release and migration of radionuclides;
- geological and hydrogeological modeling;
- site investigation, geological structures and repository design;
- radiation protection;
- waste canister performance; and
- biology and biosphere modeling.

Although there exists expertise in the predisposal area, the staffing of the nuclear waste management office and its activity are rather oriented toward the regulatory control of disposal activities. Other predisposal activities such as control of waste generation, collection, pre-treatment, treatment, storage, conditioning of waste are worth considering, where they can have an impact on the safety of the disposal facilities.

Other Departments within STUK play a role in the overall regulatory control of waste management: The Nuclear Reactor Regulation Department for the safety of predisposal nuclear waste management activities and the decommissioning of nuclear facilities, the Radiation Practices Regulation Department for the management of radioactive waste from non-nuclear practices and the Research and Environmental Surveillance Department for the collection of radioactive waste arising from non-nuclear practices.

This calls for a formal co-ordination process to be established to ensure appropriate consideration of all safety aspects of the waste management and particularly the interdependence between the various steps in waste management. Such a process is now implemented on a case by case basis and could be improved by ensuring a continuous follow-up of issues related to aspects in the predisposal area that are of importance for the safety of the repositories.

Changes since the 2000 IRRT mission

The major change since the 2000 IRRT mission is the decision to move ahead with geological disposal of spent fuel and to construct the encapsulation plant and deep geological disposal facility at the Olkiluoto site. These are major long-term projects and will need the necessary human resources to regulate and will have to call upon the broader technical resources of STUK to review the associated safety assessments. An internal co-ordination committee has been established that meets periodically during the year to address issues of co-operation. In addition an assessment of human resource needs has been undertaken addressing both staff attrition due to retirements and project demands.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R15: A standing, formal co-ordination process should be established, involving all the concerned Departments, for the regulation of the overall safety of the waste management activities, including consistency between the approaches chosen and to ensure a regulatory oversight of those predisposal management and

decommissioning activities that might have an impact on the safety of the disposal repositories.

Findings of the 2003 follow-up IRRT mission

The recommended co-ordination mechanism has been established and is functional and as such the recommendation has been satisfactorily addressed. As the spent fuel disposal project develops, licensing of the spent fuel storage and encapsulations facilities will become a significant project which under the present organizational arrangement would be the responsibility of both the Nuclear Waste and Material Regulation Department and the Nuclear Reactor Regulation Department. It would be worthwhile considering making this project (spent fuel storage and encapsulation) the responsibility of one department with the necessary support being provided from the other department.

9.4.1. Recommendations and Suggestions

(1) **BASIS** - According to the IAEA Safety Fundamentals on the Principles of Radioactive Waste Management, 111-F, ”Interdependencies among all steps in radioactive waste generation and management shall be appropriately taken into account”. This is primarily a principle that applies for the waste generators and the operators of waste management facilities, but the control of its actual implementation requires also its appropriate consideration within the regulatory body. The logistics of spent fuel receipt, storage and conditioning prior to disposal and the associated operational and long-term safety aspects will require an integrated consideration.

a) Suggestion: STUK should consider arrangements for exercising regulatory control over the future spent fuel reception, storage and conditioning facilities associated with the disposal of spent fuel. These arrangements should adopt an integrated approach that will ensure the various interdependencies associated with these activities and taken into consideration.

9.5. ACTIVITIES OF THE REGULATORY BODY AS REGARDS WASTE MANAGEMENT AND DECOMMISSIONING

9.5.1. Developing regulation and guides

Detailed provisions related to the safety of nuclear and radioactive waste management are provided by the Nuclear Act, the Radiation Act, the corresponding implementation Decrees, the Council of State decision for the safety of a disposal facility for reactor waste (398/1991), the Government Decision on the safety of disposal of spent nuclear fuel (478/1999) and the Council of State Decision on the objectives to be observed in carrying out research, surveys and planning in the field of nuclear management. It is worth noting that the bases for this legal framework were provided by STUK, which shows its large involvement in the development of the legal framework.

Changes since the 2000 IRRT mission

Several guidance documents have been published to complement this detailed legal framework and since the previous mission a number have been updated and new guides issues particularly relating to the spent fuel disposal project. These include the following:

- YVL 8.1: disposal of reactor waste (2003);
- YVL 8.2: clearance from regulatory control of nuclear wastes (2002);
- YVL 8.3: treatment and storage of radioactive waste at a nuclear power plant (1996);
- YVL 8.4 Long term safety of disposal of spent nuclear fuel, (2001);
- YVL 8.5 Operational safety of a disposal facility for spent nuclear fuel (2002) and
- ST 6.2: radioactive wastes and discharges (1999).

As mentioned in 9.1.2, the operators of nuclear power plants have to submit plans and reports on their nuclear waste management measures. Very general guidance is given in the YVL 1.5 document on reporting nuclear power operation. It is useful, owing to the acquired experience by STUK, to establish more precise guidance on the subject.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S22: On the basis of the experience acquired through the review of the plans and reports on nuclear waste management measures submitted by the operators of the nuclear power plants, STUK should consider the preparation of guidance material on the establishment of such plans and reports for nuclear waste management.

Findings of the 2003 follow-up IRRT mission

Guidance on exemption and clearance has been updated and specific guides have been issued in the area of spent fuel storage and disposal. Guidance in respect of reporting has been updated and in general the suggested actions have been satisfactorily addressed. The need for harmonization between guides is recognized particularly in the area of spent fuel storage, conditioning and disposal.

9.5.2. Waste packaging and acceptance criteria

The operators of nuclear power plants are also operators of the on-site waste management activities, including the disposal facilities. In order to ensure that an appropriate system is in place to verify compliance of the waste package with the waste acceptance requirements established by those responsible for the disposal facilities, it would be useful to require the establishment of an independent waste package quality control system involving independent checking of the radioactive content and characteristics of the waste packages actually produced. STUK would then control the establishment and implementation of this system

with a view to satisfying itself that the waste packages produced and disposed of in the repositories comply with the waste acceptance requirements.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S23: STUK should implement the conclusion of the STUK-YTO-TR-162 Report by requiring the establishment by both operators of nuclear power plants of a system for independent waste package quality control system and control the establishment as well as the implementation and the results achieved by such a system to satisfy itself of compliance of the waste packages produced with the waste acceptance requirements.

Findings of the 2003 follow-up IRRT mission

The Finnish Technical Research Centre (VTT) has been commissioned to propose an independent package testing regime for all waste streams in Finland. The proposals drawn up by VTT appear to be technically sound and STUK's decision will be made upon finalization of the proposals and their technical review. The suggestion has been adequately addressed.

9.5.3. Records of documentation

With regards to the disposal of spent fuel, numerous research and development activities will be carried out, involving several research institutes that will report to Posiva. It is important to adequately record the corresponding documentation on strategies for the research programmes, decision, protocols and results to ensure their availability, to ensure their maintenance for an appropriate time-scale and to ensure that a sufficient expertise capability is established and maintained for their future use by the operator. It seems appropriate that such objectives and requirements are developed in guidance material at the time it is expected that an underground research laboratory will be constructed.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R16: In relation with the implementation of the Recommendation 9.3.2.1 a), STUK should prepare guidance material with a view to ensuring adequate records of the documentation on strategies for the research programmes, decision, protocols and results, to ensuring their availability, to ensuring their maintenance for an appropriate time-scale and to ensuring that a sufficient expertise capability is maintained for their future use by the operator.

Findings of the 2003 follow-up IRRT mission

There has been ongoing dialogue between STUK and Posiva regarding the research and development programme for the underground laboratory and Posiva has responded positively to STUK's comments. As indicated in the findings from Recommendation 14 there are still issues to address relating to the legal status of the regulatory process during the pre-construction phase and these decisions will impact on this recommendation also. The need remains to carefully document and control the research conducted in the pre-construction phase and the outcomes from the research as this will contribute to the design basis for the facility and will provide important input to regulatory submissions. It is necessary to give further consideration to this recommendation and formal guidance needs to be drawn up to

address the manner in which a quality management system will be applied to the research programme.

9.5.4. Review and assessment of the Posiva's application for spent fuel disposal

In May 1999 Posiva Ltd submitted an application to the Government for a Decision in Principle on a disposal facility for spent nuclear fuel from the Finnish nuclear power plants (see 9.3.2). STUK was involved in the early phases of the project and has continued with the review of the application for the DiP with a view to preparing its statement and preliminary safety appraisal for the Ministry of Trade and Industry. STUK carries out its own research and development activities in support of its safety review of spent fuel disposal, which it plans on an annual basis. STUK is further strongly involved in the steering of the JYT 2001 research programme on the long-term safety of spent fuel disposal as funded by the Ministry of Trade and Industry.

Throughout review and assessment of the above-mentioned application, and in order to complement its own review and assessment capability, STUK engaged an ”External Review Group” consisting of ten prominent scientists. The team gave their findings, included in nine thematic reports and a consensus report by the whole team, to STUK in October 1999. In addition, STUK has requested statements and expert judgment from several Finnish research institutes, which have participated in the publicly funded waste management research programme.

STUK’s preliminary safety appraisal was based on the safety criteria that were issued as Government Decision of March 1999 (478/1999) and submitted it to the Ministry of Trade and Industry in January 2000. It documents the results of the review and assessment process and includes statements on the Decision in Principle as well as recommendations for the future phases of the project.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S24: STUK should establish an overall research strategy and a long-term, for example, 5-10 year programme for its research activities related to the safety of spent fuel disposal.

Findings of the 2003 follow-up IRRT mission

STUK is closely involved with the various research initiatives associated with the spent fuel disposal project. These are at three levels; the research activities conducted by Posiva, the national research programme and STUK’s own research programme. STUK has been influential in these various programmes and has provided appropriate guidance and influence. The overall research programme is balanced and focused. As such this suggestion has been adequately addressed.

9.5.5. Inspection of waste management activities

In terms of the STUK inspection programme of nuclear power plants, nuclear waste management aspects is covered in one type C, topical major inspection per year of 2 to 3 days duration. An inspection plan that includes the topics that will be covered during the inspection is prepared by STUK and sent to the NPP well in advance. The inspection is typically undertaken by a STUK team with expertise that is relevant to the inspection topics. During the inspection, issues arising from the previous discussion as well as future developments in

nuclear waste management are discussed. At the end of the inspection, findings are summarized during a meeting with the operator. An inspection report is sent to the operator within one week of the inspection. Such reports include dates for corrective action related to any unsatisfactory findings identified during the inspection.

Between the above-mentioned type of inspections, the resident inspector will follow-up specific nuclear waste management issues. In respect of nuclear waste management, no specific inspections are undertaken during outages.

Radioactive waste management issues associated with radiation practices are inspected during routine inspections described in section 10.6 of this report.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S25: In the development of an inspection program as mentioned in section 6.1, STUK should consider provisions for shorter, in-depth inspections on nuclear waste management to complement the topical inspections, particularly after outages.

Findings of the 2003 follow-up IRRT mission

This action was addressed by an internal memorandum requesting additional inspection on clearance and verification of waste package verification. In discussions with on site inspection personnel the impression was gained that the type C inspections are followed up with more detailed inspection of areas requiring attention. The suggestion is considered to have been addressed, but it is an area where attention should be maintained.

9.5.6. Communication with governmental bodies and the public

The annual report established by STUK for the year 1998 on Nuclear Safety is relatively detailed as regards the regulatory control activities for nuclear power plants, including information on technical issues, but is rather general as regards the regulatory control of nuclear waste management activities and facilities.

The annual report established by STUK for the year 1998 on Radiation Practices does not address the regulatory control of radioactive waste arising from other practices than Nuclear Power plants.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R17: STUK should report on the regulatory control of the management of waste from radiation practices in its annual report on Radiation Practices;

Suggestion S26: STUK should provide more information in its reporting on the regulatory control of nuclear waste management in its annual report on Nuclear Safety.

Findings of the 2003 follow-up IRRT mission

A discrete section has been included in the annual reports since 2001. Both the recommendation and the suggestion have been adequately addressed.

9.5.7. Radioactive Waste Containing Naturally Occurring Radionuclides

Since the 2000 IRRT mission an interdepartmental group was established to look at legislative aspects of dealing with waste containing naturally occurring radioactive material and with the quantities of such material that may need to be controlled. The results of the work of the group indicate that there are materials that warrant control and also that consideration will have to be given modification of both the Nuclear Energy Act and the Radiation Act to address regulatory control of these materials and also that guidance will have to be developed in this area. It has also been concluded that there are some gaps in knowledge and some further investigations will have to be made. It has also been recognized that storage and disposal options will have to be developed for these materials.

9.5.7.1. Good Practices

(1) **BASIS** - According to the GS-R-1, "the regulatory body …. Shall ensure that its regulatory principles and criteria are adequate and valid …. And …. Shall advise the government on matters related to the safety of facilities and activities ..."

a) Good Practice: The need to exercise regulatory control over activities giving rise to the generation of radioactive waste containing naturally occurring radionuclides has been investigated and proposals are being formulated by STUK for the necessary changes to legislation. Waste management options are being investigated and safety guidance will be developed.

10. RADIATION PROTECTION

Expert: Alan Muller

10.1. LEGISLATIVE FRAMEWORK

The legislative framework for the regulation of radiation sources and practices in Finland is contained in the Nuclear Energy Act and the Radiation Act. Section 82 of the Nuclear Energy Act and section 70 of the Radiation Act enable the issuing of legally-binding decrees that provide more detailed provisions on the implementation of the respective Acts. The Nuclear Energy Decree issued in terms of the Nuclear Energy Act came into effect on 1 March 1988 and the Radiation Decree issued in terms of the Radiation Act on 1 January 1992.

The Nuclear Energy Act and Nuclear Energy Decree cover 'nuclear facilities', which, by definition, include nuclear reactors and facilities within the nuclear fuel cycle, while the Radiation Act and Radiation Decree cover so-called 'radiation practices' in industry, medicine, agriculture and research as well as exposures from natural sources. The Radiation Act, however, states that the section containing the radiation protection system for practices and the section on radiation work in that Act also applies to nuclear facilities as defined in the Nuclear Energy Act.

The Radiation Act, which came into effect on 1 January 1992 has been amended on a number of occasions to incorporate, inter alia, many of the radiation protection concepts contained in the European Basic Safety Standards. By introducing these through amendments rather than a complete re-write of the legislation, the legislative basis for concepts such as exclusion, exemption, clearance and intervention is not always explicit.

By virtue of section 45 of the Radiation Act, industrial undertakings involving natural sources are required to investigate the radiation exposure resulting from their activities and may be regarded as radiation practices if exposures exceed specified action levels. The same applies to an employer if it is discovered or suspected that the radiation exposures in its working facilities may cause a health hazard. The approach is similar to the European Basic Safety Standards where so-called 'work activities' are excluded from the requirements unless the Member States have undertaken investigations and determined otherwise.

The radiation dose limitation system for practices is contained in the Radiation Act and dose limits applicable to specific situations, including accidents, are elaborated in the Radiation Decree. Both the system and the limits are consistent with the IAEA BSS.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R18: The Radiation Act should more explicitly exclude exposure not amenable to control such as K-40 in the body and cosmic rays at the surface of the earth, from its scope.

Changes since the 2000 IRRT mission

The concept of exclusion is included in the Radiation Act and Radiation Degree but there is no explicit reference to, for example, Potassium-40 or cosmic radiation. A working group led

by STUK's legal representative concluded that the amendment to the legislation is not considered urgent in view of no problems having been experienced in this area.

Findings of the 2003 follow-up IRRT mission

ST 1.5 has been in place since 1999, and refers explicitly to the two types of exposures that are not amenable to control as mentioned above. No reference is made to exposures that are not amenable to control in the YVL guidance documents.

10.1.1. Recommendations and Suggestions

(1) **BASIS -** Paragraph 204 2.4 (2) of the IAEA Safety Requirements for Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, GS-R-1 states that the legislation shall 'specify facilities, activities and materials that are included in the scope of legislation and what is excluded from the requirements of any particular part of the legislation', 'establish authorization and other processes (e.g. notification, exemption), taking into account the potential magnitude and nature of the hazard ...' and 'specify the process for removal of a facility or activity from regulatory control'.

a) Suggestion: STUK should consider proposing that explicit reference be made to those exposures that are not amenable to control in the next amendment to the legislation.

Recommendations and Suggestions from 2000 IRRT report

Recommendation R19: The Radiation Act should be amended to devote special sections to exemption and clearance. This is the approach adopted in the IAEA BSS.

Changes since the 2000 IRRT mission

STUK has developed a new guidance document YVL 8.2 (March 2002) that specifies conditional and unconditional clearance criteria. STUK has indicated that they will consider proposing amendments in the legislation regarding exclusion, exemption and clearance.

Findings of the 2003 follow-up IRRT mission

Sections 11 and 17 of the Radiation Act contain the principles of exemption and the Radiation Decree Section 24 addresses clearance. Guide ST 1.5 specifies exemption levels. The documents ST 6.2 (1999) and YVL 8.2 (March 2002) specify conditional and unconditional clearance criteria. It is considered that this recommendation has been addressed adequately.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R20: Legislation should be amended to ensure that the system of intervention is consolidated and clarified.

Changes since the 2000 IRRT mission

Section 25 in the Radiation Decree "Secondary duty of care" states that STUK shall perform the duties of the Sate as stipulated in Sections 50 and 51 in the Radiation Act which apply to radioactive waste. If the responsible party fails to discharge the duty of care referred to in section 50, then the State shall take the measures necessary to render any radioactive waste harmless and to decontaminate the environment. The State shall also take measures of the kind referred to in paragraph 1 hereof when the origin of the waste is unknown, or when no responsible party subject to a primary duty of care can be found. Detailed regulations on the manner in which the State shall attend to the measures referred to in paragraph 1 hereof shall be issued by decree.

More work need to be carried out to ensure that intervention activities are addressed adequately (See Chapter 9.1.4)

10.2. DEVELOPMENT OF REGULATIONS AND GUIDES

Section 70 of the Radiation Act, Section 55 of the Nuclear Energy Act and Section 1(8) of the Decree on STUK (No. 618/1997) enable STUK to issue guides concerning radiation and nuclear safety. An extensive set of guidance has been issued by STUK. The Nuclear Reactor Regulation Department and the Nuclear Waste and Materials Department have issued YVL guides in support of the Nuclear Energy Act, while the Radiation Practices Regulations Department has issued ST guides in support of the Radiation Act.

STUK Guide STO 7.2 describes the process for preparing ST guides by the Radiation Practices Regulation Department and provides for involvement of other STUK departments, the European Commission and other external interested and affected parties

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R21: All guides pertaining to radiation protection should be reviewed and revised taking due account of the latest IAEA Safety Standards Series publications. During this review process, STUK should also aim to consolidate its guidance to have the optimum number of guides and to reduce the potential duplication between guides issued by different departments.

Changes since the 2000 IRRT mission

All departments are requested to provide comments during the process of reviewing guides, which is carried out by working groups. The heads of sections decide annually which guides need updating. A document custodian for radiation practices is responsible to ensure that guidance documents are reviewed and updated. The recommendations and guidance from IAEA standards will be included by means of incorporating of EU standards. The Advisory Body in RP can also be requested to comment on documents.

According to STO 7.2 both RP departments take part in the reviews process.

The report on Recommendation 2 from the previous IRRT mission will address potential duplication of radiation protection guidance documentation and is due to be completed by the end of 2003.

Findings of the 2003 follow-up IRRT mission

The requirement to take into account international developments during reviews of guidance documents is explicitly stated in paragraph 4.7 of STO 7.2 (March 2000), but not in the quality document concerning YVL guides.

No cases have been reported or encountered where potential duplication has or would result in conflicting requirements being placed on licensees. The report on conflicting requirements and duplication of STUK departments will assess whether the number of radiation protection documents are considered adequate. The ongoing investigation is considered to be adequate to address Recommendation 2 from the previous report.

10.3. AUTHORIZATION

10.3.1. General Aspects

Chapter 5 of the Radiation Act describes the licensing system for so-called radiation practices. In addition to authorization by issuing of safety licences, the licensing system also authorizes STUK to exempt or issue an order that allows notifiable licence-free use. Such an order may only require notification or require the user to submit specified documentation and information for review and approval prior to use. The latter will be similar to authorization by registration as described in the IAEA BSS.

STUK has established a complete source inventory and updates this inventory when granting or amending licences. Apart from various legally-binding measures to ensure that STUK is aware of all sources being imported into Finland (e.g. the completion of an annual questionnaire by importers), the principal importers of sealed sources also informs STUK on a voluntary basis of all such imports. A mechanism has been implemented whereby STUK's Administration Department provides feedback to the Radiation Practices Regulation Department regarding the payment of the annual authorization fee by radiation practices. The mechanism complements the established regulatory control mechanisms over sources and where sources are not inspected on an annual basis it could assist in early identification of abandoned sources.

By virtue of section 16 of the Radiation Act, STUK has the authority to set conditions that are necessary to ensure safety. Since most requirements are included in the Radiation Act or the Radiation Decree, the safety licences issued to radiation practices generally refer to relevant STUK guides and contain few additional conditions.

Certain radiation sources are essentially subject to the process of 'notification' by STUK order (as explained in the IAEA BSS, in that no authorization is required from STUK prior to their use). Other sources, such as dental X-rays,(again by STUK order) are essentially subject to a process that appears to be the equivalent to registration (as explained in the IAEA BSS). Lastly, some sources are exempt from licensing.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S27: STUK should document the criteria for deciding on the authorization or other process applicable to a particular source or practice.

Changes since the 2000 IRRT mission

No actions have been taken by STUK. STUK guide SKV 3.2 (1998) deals with the processing of license applications and preparing conclusions. Although the guide is sufficient for dealing with normal authorizations, it is not sufficient in exceptional more complex cases e.g. linear accelerators. In such cases assessments can involve a number of disciplines and staff members.

Findings of the 2003 follow-up IRRT mission

General principles and criteria for authorizations are presented in 16 § and 17 § of the Radiation Act. The Radiation Decree describes the safety licence criteria in Section 14 which includes, amongst other things, the protective and safety systems to be used, the arrangements for monitoring radiation exposure, the manner of handling radioactive waste and rendering it harmless, a description of the user's organisation, and significant information required to ensure the safety of the operations. It is considered that no further action is necessary.

10.3.2. Processing applications and issuing of licences

The STUK quality manual contains detailed guidance (Guide STO 3.2) on processing licence applications and on preparing conclusions. The different authorization and other processes are described in section 10.3.1 of this report, but STO 3.2 requires that the that the provisions set out in the Radiation Act Chapter 2, i.e. justification, optimization and dose limitation, are met.

For a large number of routine licences, forms provided by STUK and completed by the applicant contain all the necessary information. For more complicated projects, STUK will, based on preliminary information, define the documentation necessary for the licensing process. As an example of such a non-routine process, the licensing of the boron-neutron capture medical treatment facility was reviewed. As provided for in STO 3.2., STUK obtained in this case a statement from the Advisory Committee on Radiation Safety on justification of the practice. The basis for the licensing decision did not, however, include the list of documents on which the decision was based nor was it a formalized document.

Normally, once STUK has issued a licence, the corresponding activity may commence, provided STUK has not explicitly stated in the licence that the start-up inspection should be performed first.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S28: STUK should revise STO 3.2 to ensure that the basis for licensing decisions would be a formal document containing a list of all documents on which the decision was based. STUK should also implement a system, preferably electronically searchable and retrievable, to ensure that at any date staff not originally involved in a specific licensing procedure has easy access not

only to the outcome but also the documentation that was generated during the entire licensing process.

Findings of the 2003 follow-up IRRT mission

No actions have been taken to address the suggestion. STUK guide SKV 3.2 (1998) deals with the processing of license applications and preparing conclusions. Although the guide is sufficient for dealing with normal authorizations, in exceptional cases were complex authorisations have to be assessed it is not adequate. Although these type of authorizations are not so frequent, new staff need to have a sound basis to work from, and records of how to deal with possible new technologies need to be available.

10.3.2.1 Recommendations and Suggestions

(1) **BASIS -** It is stated in the IAEA Safety Requirements for Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety GS-R-1; Paragraph 5.5 that: ”the regulatory body shall formally record the basis for these (authorization) decisions. Since most requirements are included in the Radiation Act or the Radiation Decree, the safety licences issued to radiation practices generally refer to relevant STUK guides and contain little additional conditions.

(a) Suggestion - SKV 3.2 should be updated to address the approval of non-routine authorisations and the process for recording the basis for the regulatory decision.

10.4. REVIEW AND ASSESSMENT

The general ALARA requirement, as given in the Radiation Act Chapter 1, is detailed in the guide YVL 7.9. Prescriptions about worker dose limits are shown in section 3 of the Radiation Decree. The statistical data presented in STUK´s annual report for internal and external accumulated doses show that limits are not exceeded. The total collective dose for nuclear power plant workers was *4.1 Person-Sv.* By virtue of the above-mentioned YVL Guide 7.9, detailed ALARA planning has to be submitted to the regulatory body before the start of a job if the planned collective dose is above 0.1 Person-Sv.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R22: The guideline value of 0.1 Person-Sv as a dose threshold for reporting requirements concerning detailed ALARA planning, particularly for outage tasks associated with nuclear power plants, should be significantly reduced.

Changes since the 2000 IRRT mission

The collective occupational dose for both Loviisa and Olkiluoto plants was 1.13 person Sv and 1.18 person Sv respectively for 2001. For Loviisa 2 in 2001 the outage dose was 0.29 person Sv and for Olkiluoto 1 the outage dose totalled 0.27 person Sv .

The STUK guide YVL 7.9 was updated with the new requirement for an outage task dose upper value of 0.05 personSv.

Findings of the 2003 follow-up IRRT mission

The STUK guideline for outages per unit is 2.10 person Sv averaged over two successive years. For 2003 no cases were reported where the task dose exceeded 0.05 person Sv. Should this value be exceeded, STUK would require the licensee to investigate the issue and submit a report, which is reviewed by STUK. In the following outage, STUK would ensure by means of inspections that such an occurrence is not repeated.
This recommendation is considered to have been adequately addressed by STUK.

10.5. ORGANISATIONAL RADIATION PROTECTION MATTERS

10.5.1 Radiation protection activities within STUK

Radiation protection aspects are handled within STUK by all of the four departments:

- ”Nuclear reactor regulation” with an office of ”Radiation protection" covering the two NPP sites and the research reactor.

- ”Radiation practices regulation” responsible for medical and industrial use of radiation but also for maintaining the national metrological standards on radiation measurements, as well as a section charged to keep the centralized national personal dose register, for all workers exposed to ionising radiation.

- ”Research and environmental surveillance” maintaining a national network of dose rate measuring stations and performing environmental measurements in the vicinity of the nuclear power plants.

- ”Nuclear waste and materials regulation department” in a general way.

Evidently significant interfacing between the departments is required. STUK STO Guide 3.2 on the processing of licence applications makes provision for appointing a person in charge of a new licensing process, while STUK STO Guide 7.2 makes provision for a multi-departmental working group to prepare a radiation protection guide. No dedicated project structure exists for such work, but line managers are responsible for coordination.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S29: STUK should establish a standing, formal, co-ordination process involving all relevant departments to ensure a consistent approach on general radiation protection matters such as the radiation protection system and clearance.

Changes since the 2000 IRRT mission

STUK has developed a new guide; STUK 2.6, which specifies the establishment of the working groups within STUK. The Director General is responsible to ensure that efficient cooperation exist between working groups within STUK. The duties of the permanent working groups are set in this guide. The composition of each group is presented in the annexes of this guide as changes have to be agreed in the meeting of STUK’s management

group or they have been otherwise decided (YTY, HYRY, labour protection branch). The duty of a working group can be such that it requires more detailed procedures than provided in the guide. In that case the Director General gives the necessary additional instructions. The group considers the issues of principle in radiation protection; follows international developments and norms of radiation protection and organises training related to radiation protection.

Findings of the 2003 follow-up IRRT mission

The new guide on the establishment of the working groups STUK 2.6 includes the formation of a Radiation Protection group, which consists of six members from different departments. The group coordinates the common issues of radiation protection between different departments. It considers the arrangements when necessary, on regulatory control of radiation safety so that unified procedures are followed in STUK.

10.5.2. Roles and Activities performed by STUK

Changes since the 2000 IRRT mission

STUK has considered this recommendation and a report prepared on potential conflict in the different roles and activities undertaken by STUK will be finalised by December 2003. This report will include recommendations on measurements on radon as well as the environmental radiation measurements that STUK performs. STUK has already approved a private company called DOSECO to perform the dosimetry service for workers in practices excluding those workers at the Nuclear Power Plants.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R2 *An analysis should be carried out of the potential conflict in the different roles and activities that STUK is covering. Based on that analysis a decision should be taken about organisational changes or the establishment of appropriate controls to reduce the conflict to a minimum.*

Findings of the 2003 follow-up IRRT mission

The dosimetry service was privatised on 1 January 2002. STUK's role now is to supervise the radiation exposure of employees, to maintain the national dose register of radiation workers, and to approve dosimetry services. STUK's internal guides SKV 6.4 "Approval of Dosimetric Service" and SKV 6.6 "Regulatory Control of Dosimetric Service" (both drafts) need to be finalised to reflect the process for approval of the service.

10.5.3. Advisory Committee On Radiation Safety

An Advisory Committee on Radiation Safety has been established in terms of section 7 of the Radiation Act, which shall, by virtue of section 30 of the Radiation Decree:

- Address questions of principle concerning radiation safety;
- Follow general developments in radiation safety;

- Make proposals and suggestions on matters concerning radiation safety;
- Issue opinions concerning radiation safety; and
- Carry out any other tasks assigned to it by the Ministry of Social Affairs and Health.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S30: Consideration should be given to the establishment of an expert body, independent from STUK, to provide STUK with advice on radiation safety matters.

Changes since the 2000 IRRT mission

The term of office of the previous Advisory Board on Radiation Safety, which also had members from STUK, ended on 31/12/2000. Negotiations were conducted with the Ministry of Social Affairs and Health before the nomination of the present Advisory Board on Radiation Safety. The new body has a three-year term of office until 31/12/2003 and STUK has been notified by letter of the appointment of board members. . Reports of activities by the Advisory Board are filed in the Ministry, and STUK receives copies of the reports.

Findings of the 2003 follow-up IRRT mission

The Radiation Decree (Section 30) specifies details of the duties to be performed by the Advisory Board. STUK is not represented on the Advisory Board. In terms of the process, STUK sends a request with timeframes to the Advisory Board. The Board can initiate projects on its own, and can also contribute to the review of radiation protection guides if required. This suggestion has been addressed adequately.

10.6. INSPECTION AND ENFORCEMENT

10.6.1. Inspection

A clear distinction has to be made between inspections at the limited number of nuclear facilities and the large number of radiation practices.

As part of the STUK Guide YTV 4.1 on periodic inspections at nuclear power plants, radiation protection inspections cover all aspects of radiation protection (discussion about previous inspection results, accumulated doses, planning, training, optimisation etc.) in one major inspection per year of 2 to 3 days duration. An inspection plan is prepared by STUK and sent to the NPP well in advance. Additional, more technical inspections are performed looking at specific jobs especially during outages. These inspections might be done on shorter notice but actual unannounced inspections are not made as far as radiation protection is concerned.

Radiation practices are inspected in defined intervals as specified in STUK STO Guide 3.4. These intervals can be up to five years depending on the use of radiation. STUK´s inspectors, each one having fields of specialization in e.g. x-ray diagnostics, veterinary use, radioisotope

applications etc. An inspection plan for routine inspection exists, but the actual inspection procedure seems to rely heavily on the experience of the inspector.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R23: In the inspection of Radiation Practices, appropriate account should be taken of the recommendations R5 to R9

Changes since the 2000 IRRT mission

A registry for the inspection findings was implemented in 2000. The inspection findings in the register can be reviewed and retrieved at any time. It is reviewed on an annual basis when developing action plans for the following year.

Findings of the 2003 follow-up IRRT mission

STUK has committed to update the guide STO 3.4 (SKV 3.4) with a target date of 31/12/2003. Human performance aspects, the duration of inspections, operator and worker performance, inspection policy and unannounced inspections will be addressed in the revised STO 3.4. It would appear that this is an area for further consideration.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S31: Since international experience indicates that the inspection frequency for practices such as radiotherapy and industrial radiography may be low, STUK should review the inspection frequency of radiation practices.

Changes since the 2000 IRRT mission

By 2002 all facilities had implemented QA programmes in accordance with STUK requirements. Forty radiotherapy devices were inspected, including two inspections on new equipment. Five cases were reported of shortcomings relating to radiotherapy equipments, radiation safety and QC methods. For the twenty-two treatment planning systems all showed less than 5% deviation between calculated and measured doses. Of the order of one hundred and forty inspections were carried out in 2002 for radiation practices in industry, research and education.

No serious accidents involving radiation occurred in 2002, or any incidents that could have led to radiation accidents. STUK investigated ten incidents involving the use of radiation that were considered to be abnormal. Three of these were related to industrial and research activities, five to medical use of radiation, one to transport of radioactive material and one to the use of non-ionising radiation.

Findings of the 2003 follow-up IRRT mission

The inspection frequencies for radiation practices were not changed. The frequencies are based on the IAEA Safety Series 102. No trends of increasing non-compliance or occurrences have been observed since 2000. It is considered that no further action is necessary to address the suggestion from the previous report.

10.6.2. Enforcement

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R1: STUK should develop an Enforcement Policy for all areas under their regulatory control that clearly lays out the practices and procedures to be followed by STUK personnel for the implementation of enforcement actions that are used consistently to ensure compliance by licensees with regulatory requirements.

Changes since the 2000 IRRT mission

STUK 3.1 "Principles of Regulatory Activities" valid from 2002 has been used to develop enforcement documents. This guide lays down the principles and procedures for STUK's regulatory activities. It concerns the regulatory control of radiation practice and the use of nuclear energy. Enforcement actions are described in YVT 4.14 and SKV 3.7 for Nuclear Activities and Radiation Practices respectively. Both guides specify the different type of enforcement actions to be taken including oral notices, requests for actions in the form of a protocol, written notices, order for actions and coercive measures. It is considered that the recommendation has been addressed adequately.

Findings of the 2003 follow-up IRRT mission

The new guides that were developed after the 2000 IRRT mission will address any non-conformance aspects. The guides specify the different type of enforcement actions to be taken including oral notices, requests for actions in the form of a protocol, written notices, order for actions and coercive measures. It is considered that the recommendation has been addressed adequately.

10.7. INTERFACING WITH OTHER RELEVANT AUTHORITIES

Although STUK is the regulatory authority for all sources of radiation in Finland including nuclear facilities, medical, industrial and nuclear applications as well as natural sources, general national legislation on occupational safety and environmental protection does not explicitly exclude radiation. The Finnish interpretation of statutes, however, is clear that specific legislation such as the Radiation Act would have precedence over legislation that is of a more general nature.

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S32: Although STUK is effectively the only regulatory body in the area of radiation protection and although no specific problems regarding the cooperation with other authorities have been experienced, STUK should establish arrangements with the Ministry of Environmental Affairs and the Department of Occupational Safety in the Ministry of Social Affairs and Health.

Changes since the 2000 IRRT mission

STUK has had annual meetings with other authorities including the National Agency for Medicines, Stakes, Tukes, regional offices for industrial safety and the industrial safety department of the Ministry of Social Affairs and Health.

Findings of the 2003 follow-up IRRT mission

STUK cooperates with the National Agency for Medicines, Stakes, Tukes, regional offices for industrial safety and the industrial safety department of the Ministry for Social Affairs and Health. A formal record is made of the meeting proceedings.

11. TRANSPORT OF RADIOACTIVE MATERIAL

Expert: Phil Metcalf

11.1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

A sound and complete legislative structure exists which defines clearly the responsibilities of STUK in regulating the safe transport of radioactive material in Finland.

11.1.1. Applicable Regulations

The applicable regulations for transport of radioactive material in Finland and for international transport into, through or from Finland are currently based on the 1996 Edition (Revised) of the IAEA "*Regulations for the Safe Transport of Radioactive Material*" (Safety Standards Series No. TS-R-1 (ST-1, Revised). The basis for Finland's transport regulations is established at three levels:

- legislative acts and decrees,
- regulatory decrees by ministries and other governmental bodies, and
- guides issued by STUK.

The *Radiation Act* (592/1991), passed in Helsinki on 27 March 1991, establishes that:

> "A licensee who commissions the transport of radioactive materials or imports such materials is required to ensure that:
>
> 1) The transport package meets the safety requirements laid down for it.
> 2) The mode of transport used is appropriate for safety purposes.
> 3) The carrier has all the information and instructions needed for safe transport.
> 4) Proper advance notification has been made of the transport in cases where it is stipulated under this or some other Act that advance notification is required."

The *Act on Transport of Dangerous Goods* (719/1994), adopted in Helsinki, 2 August 1994, establishes the top-level framework for regulatory authority, with the purpose "to prevent and avert any damage or hazard which the transport of dangerous goods may cause to people, the environment or property". Through the Ministry of Transport and Communications, the authorities are specified, including:

- authorities and duties;
- obligations and requirements on consignors, carriers, and drivers (in road transport);
- prohibitions;

- supervision;
- coercive means and consequences; and
- transfers, appeals and enforcements.

That Act is supported by individual decrees relating to each mode of transport. These decrees provide modal regulatory authority based upon the regulatory documents issued by the respective international modal bodies, including:

- by road – the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR, established for domestic road transport by decree 194/2002, and for international road transport by decree 185/1982),
- by rail – the General Agreement Concerning the International Transports on Rail (COTIF – OCTR/RID, established for domestic rail transport by decree 195/2002, and for international rail transport by decree 59/1985),
- by water – the International Maritime Dangerous Goods Code (IMO – established for both domestic [including transport by inland waterways] and international water transport by decree 666/1998); and
- by air – the ICAO-Technical Instructions (ICAO – established for both domestic and international air transport by decree 210/1997).

Regulations for road and rail transport are translated into Finnish, but those for water and air transport are not.

The decrees and decisions in force at present are:

- The Decree of the Ministry of Transport and Communications on the Transport of Dangerous Goods by Road (277/2002) issued 21/03/2002.
- The Decree of the Ministry of Transport and Communications on the Transport of Dangerous Goods by Rail (278/2002) issued 27/03/2002.
- The Decision of the Finnish Maritime Administration on the Transport of Dangerous Goods in Packaged Form by Sea issued 07/30/1998, and
- The Aviation Regulations OPS M1-18, Amendment 2, issued by the Flight Safety Authority (Civil Aviation Administration).

The Finnish road and rail regulatory documents cited above specifically reference and refer to the IAEA's *Regulations for the Safe Transport of Radioactive Material, Safety Standards Series No. TS-R-1 Edition (Revised)*. Certain parts of the Agency's regulatory documents are not reproduced in the Finnish documents or the ADR/RID documents, so users of the Finnish regulations may have to refer to Safety Standards Series No. TS-R-1. Thus the safe transport of radioactive material in Finland is regulated using the Agency's Transport Regulations, the regulatory documents issued by each of the four international modal agencies, and national regulatory documents as discussed below in Section 11.1.3.

11.1.2. Competent Authority

The Act on Transport of Dangerous Goods (719/1994 – Section 6) specifies that "compliance with this Act and provisions and regulations issued there under shall be supervised by….the Finnish Center for Radiation and Nuclear Safety ….in their own field of activities as further provided by Decree". Thus, STUK is the Finnish national competent authority for the safe transport of radioactive material by all modes of transport, for both domestic and international shipments. Further, all of the decisions/regulations issued by the ministries (see section above) establish STUK as the competent authority in Finland for radioactive material packaging and transport.

11.1.3. Guides

The transport safety responsibility within STUK is assigned to the Nuclear Materials section of the Nuclear Waste and Materials Regulation department, reporting directly to the Director General's office of the Authority. STUK has issued three supportive guides. The "Authorization" text for YVL guides indicates that they "are rules an individual licensee or any other organization concerned shall comply with….",

The guides in the transport area are:

- YVL 6.4 – Transport packages for Nuclear Material and Waste (under revision – target date end 2003),
- YVL 6.5 – Transport of Nuclear Material and Nuclear Waste (under revision - target date end 2003), and
- YVL 6.21 – Physical Protection of Transport of Nuclear Fuel (confidential).

The present revisions to the guides will bring them in line with TS-R-1 (ST-1, Revised)

11.2. STUK'S RESPONSIBILITIES RELATING TO THE TRANSPORT OF RADIOACTIVE MATERIAL

11.2.1. Responsibilities and Staffing

STUK, as the designated Finnish competent authority for radioactive material transport, has all of the regulatory authorities and responsibilities commonly assumed by competent authorities, including those related to:

- issuing competent authority approvals on
  - ♦ package designs,
  - ♦ special form radioactive material,
  - ♦ low dispersible radioactive material
  - ♦ special arrangements,

- shipments,
- radiation protection programmes, and
- calculation of unlisted A_1 and A_2 values (see, e.g., paragraph 402 of Safety Standards Series No. TS-R-1, 1996 Edition (Revised));

In addition, STUK performs research and also obtains some extra-budgetary funding in expert areas.

Finland does not design or fabricate any Type B or fissile material packages requiring competent authority certification. Where such packages are required to support the operation of its nuclear power reactors, research reactor, or for other uses of radioactive material, Finland has relied upon packages designed, certified and manufactured in other countries. STUK re-validates the competent authority certificates for use of those packages within its country. STUK has issued Guide YVL 6.4 deals with the details of what is needed to accomplish such revalidations in section 3.2.

In addition YVL 6.4 covers approval for new package designs. Further, for these new designs, STUK has required that it (a) should be informed on the dates of any testing of package designs, and (b) supervises the tests as necessary. These specifications in the guide are commendable, and demonstrate that STUK is looking to the future, being prepared should such a design be forthcoming from a Finnish organization.

STUK issues approximately 5 to 6 package design revalidations each year, and about the same number of shipment approvals each year. The revalidations may require assessing the adequacy of a design for containment, shielding, criticality safety, and structural and thermal performance. The STUK transport staff will arrange for expertise elsewhere in STUK to evaluate these issues on a design or a shipment approval should it, in his/her judgment, be needed.

In contrast to the limited number of shipments in Finland involving certified package designs, Finland has many shipments (approximately 20,000 per year) of radioactive material, which are made in packages that do not require competent authority approval certificates (i.e., shipments in excepted, industrial or Type A packages). There are no STUK guides dealing with these shipments.

STUK acts as an advisor for radioactive material transport emergencies. The carrier is responsible for notifying STUK and the consignor of an emergency and the consignor is, in turn, responsible for notifying STUK. Initially, this communication is by telephone (STUK staff members are available on 24-hour call basis for this). Later, for each emergency, written documentation is provided by the consignor to STUK and then placed into archival files.

In the area of training and education, STUK does not arrange for training, but provides supportive lectures at training courses arranged by other agencies or bodies. Primarily, STUK provides lectures and training material at courses given to trainers of drivers of road vehicles.

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R24: STUK should evaluate the responsibilities it has as competent authority for transport safety, define an appropriate staffing level for those responsibilities and allocate staff accordingly.

Changes since the 2000 IRRT mission

The volume of radioactive material transportation remains at a similar level. Around five to six movements fresh nuclear fuel take place each year and between 20 000 25 000 shipments of other radioactive materials take place. These are mainly movements of radiopharmaceuticals but also include around 200 to 300 shipments of radiation sources for various industrial, research and medical applications. Small amounts of radioactive waste are transported from the premises of users of radioactive material to either the premises of STUK in Helsinki, and to the Olkiluoto site.

The former ministerial decisions on transport by road and rail have been changed to ministerial decrees and they have been updated to include reference to the latest standards of the Agency Safety Standards Series TS-R-1, 1996 Edition (Revised). The STUK guides on transport safety are under revision with a target date for completion of both guides being the end of 2003. The revision will bring the guidance in line with TS-R-1.

A further member of staff has been assigned responsibilities in transport safety, a research project to gather data on the types of radioactive materials being transported and their routing has been initiated and a project to asses radiation doses associated with transport of radioactive materials is underway.

Findings of the 2003 follow-up IRRT mission

At the time of the 2000 IRRT mission there was one member of staff dedicated to Competent Authority work related to transport safety. This was deemed to be a limited effort to be able to undertake all the related duties. Since that time an additional staff member has been allocated and will have around 30% of his time assigned to transport duties in the future. One of the recommendations from the 2000 IRRT mission was that more attention should be paid to assurance activities in respect of package designs and shipment which do not require competent authority approval, but nevertheless require competent authority oversight. Limited progress has been made in this regard which could be ascribed to the limited staff resources available in this area. It would appear that this remains an area for ongoing consideration.

11.2.2. Potential Conflict-of-Interest

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R2: An analysis should be carried out of the potential conflict in the different roles and activities that STUK is covering. Based on that analysis a decision should be taken about organisational changes or the establishment of appropriate controls to reduce the conflict to a minimum.

Changes since the 2000 IRRT mission

STUK obtains some extra-budgetary funds. Unless care is taken, this could result in a potential conflict-of-interest should STUK accept funds for their expertise from a licensee of an organization for which STUK is responsible as the regulator. That is, the regulated could be providing part of the salary of those doing the regulating. To date, it appears that, in the transport area, this has not been a problem. However, unless care is taken, additional work for holders of licences, consignors, or carriers could introduce a conflict-of-interest.

Findings of the 2003 follow-up IRRT mission

The only extra budgetary funding received b STUK related to transport safety activities derive from work carried out as part of an EC funded project. Whilst there may be some consideration of competing staff time demands, it does not seem that carrying out this work would give rise to any conflict of interest. A certain amount of advice is given to consignors of radioactive materials in respect of compliance with regulatory requirements. This is not unusual, particularly for consignors using only small amounts of radioactive materials and who do not have specialists in this area. Again it does not appear that providing such advise would constitute an undue conflict of interest. As such in the transport safety area it is considered that this recommendation has been adequately addressed.

11.2.3. Radiation Protection Programme

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S33: STUK should consider expanding the evaluation of doses incurred during the transport to include all radioactive material categories, not just radio pharmaceuticals, and define doses incurred by workers and members of the public. This assessment should be done periodically in order to be in compliance with the guidelines in paragraph 203 of Safety Series No. 6 (1985 Edition (as amended 1990), and will ensure "that the system of dose limitation for transport workers and members of the public, as set forth in the Agency's Basic Safety Standards, is being complied with".

Changes since the 2000 IRRT mission

STUK's primary focus in evaluating doses to workers and members of the public has been on nuclear power plant operations. However, STUK has evaluated doses due to the transport of radiopharmaceuticals in non-certified packages (i.e., in excepted and Type A packages). They estimated that the expected exposure of individual transport workers would be less than 1 mSv/y.

Findings of the 2003 follow-up IRRT mission

With a view to evaluating radiation doses arising from transportation of radioactive materials other than those associated with the nuclear installations a programme of measurements has been initiated. It was recognized that the majority of radioactive shipments pass through Jyväskylä airport and the measurement programme has thus been focused on the traffic of radioactive materials through this location. The workers at the airport associated with the handling of these shipments have been identified and issues with radiation dosimetry. To date

the programme has confirmed that radiation doses remain low with no worker having received a measurable radiation dose above the monthly threshold of 0.1 mSv. It is considered that this suggestion has been adequately addressed, but nevertheless this remains an ongoing obligation of the national competent authority.

11.2.3.1. Recommendations and Suggestions

(1) **BASIS –** Paragraph 304 of Safety Standards_Series TS-R-1, 1996 Edition (Revised) requires "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".

a) Suggestion: On the basis of the experience gained with the radiation dose evaluation exercise STUK should establish a formalized programme for the periodic assessment of radiation doses to persons from the transport of radioactive material.

11.2.4. Regulation of Non-Certified Packages

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R25: STUK should expand its regulatory inspection and enforcement efforts to include the design, manufacture and use of non-certified packages, with a focus on design documentation, as-fabricated conditions, preparation of packages for shipment by consignors, stowage by carriers and – for any reusable packages – application of specified maintenance procedures.

Changes since the 2000 IRRT mission

The emphasis of the transport safety regulatory efforts at STUK is focused largely on the transport of nuclear fuel cycle material in certified packages. For example, YVL 6.4 focuses only on nuclear material and waste. There are no guides for package requirements for non-certified packages (i.e., for excepted, industrial and Type A – non-fissile). STUK does not carry out inspections on the documentation for non-certified packages used by consignors in Finland, nor is monitoring undertaken to ensure that packaging used has been manufactured to the applicable design specifications. The only compliance actions taken relative to these packages have focused on the identification and correction of improper shipping documents and labels, most of which have been identified by the police. Since there are about 20,000 shipments of radioactive material each year in Finland accomplished using non-certified packages, this appears to be a significant issue.

Findings of the 2003 follow-up IRRT mission

After consideration of this recommendation, no significant expansion of inspection activities in this area was been deemed to be necessary, but it was indicated that spot checks would be made. The radiation practices in which radioactive materials are used are subject to inspection, but the inspections do not address these aspects of transport safety and no specific inspections in this area have been undertaken. Paragraph 311 of Safety Standards_Series TS-

R-1, 1996 Edition (Revised) states "the competent authority is responsible for assuring compliance with these Regulations. Means to discharge this responsibility include the establishment and execution of a programme for monitoring the design, manufacture, testing, inspection and maintenance of packaging, special form radioactive material and low dispersible radioactive material, and the preparation, documentation, handling and stowage of packages by consignors and carriers, to provide evidence that the provisions of these Regulations are being met in practice." As such it appears that further consideration should be given to this recommendation.

11.2.4.1. Recommendations and Suggestions

(1) **BASIS –** Paragraph 311 of Safety Standards_Series TS-R-1, 1996 Edition (Revised) states that "the competent authority is responsible for assuring compliance with these Regulations. Means to discharge this responsibility include the establishment and execution of a programme for monitoring the design, manufacture, testing, inspection and maintenance of packaging, special form radioactive material and low dispersible radioactive material, and the preparation, documentation, handling and stowage of packages by consignors and carriers, to provide evidence that the provisions of these Regulations are being met in practice." These requirements apply to all types of radioactive material shipments, not just those in Type B and fissile material packages.

a) Recommendation: STUK should expand its regulatory inspection and enforcement efforts to include the design, manufacture and use of non-certified packages, with a focus on design documentation, as-fabricated conditions, preparation of packages for shipment by consignors, stowage by carriers, and – for any reusable packages – application of specified maintenance procedures.

11.2.5. Actions on Findings of Non-Compliance by Consignors or Carriers

Recommendations and Suggestions from the 2000 IRRT report

Recommendation R1: STUK should develop an Enforcement Policy for all areas under their regulatory control that clearly lays out the practices and procedures to be followed by STUK personnel for the implementation of enforcement actions that are used consistently to ensure compliance by licensees with regulatory requirements.

Changes since the 2000 IRRT mission

STUK has been primarily relying upon police and border personnel to identify non-compliance situations relative to shipping documents, markings, labeling, etc.. It has not had a well-defined effort for inspection and enforcement of transport activities, including adequacy of material characterization and packaging, except possibly in activities related to the operation of nuclear power plants.

Safety Standards_Series TS-R-1, 1996 Edition (Revised) does not specifically specify actions to be taken in the event of non-compliance, but the International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources (Safety Series No. 115, 1996 Edition) provide guidance on what steps can and should be taken.

In fulfilling its inspection and enforcement responsibilities, authorities and activities, STUK may need to strengthen, based upon Act 719/1994, its policy and necessary procedures for imposing sanctions for non-compliance situations in the transport of radioactive material. It is further suggested that any sanction programme be structured using a graded approach so the more flagrant and unsafe non-compliances are to receive the greater punishment. The graded approach specified in IAEA Safety Series No. 50-SG-G4 (Rev 4) should be adopted.

Findings of the 2003 follow-up IRRT mission

The issue of enforcement has been reviewed and guidance has been written and updated namely Guide STUK 3.1: Principles of Regulatory Activities (complemented and renewed, 21.12.2001), Guide YTV 4.14: Enforcement Measures for Regulatory Requirements (4.2.2002), Draft Guide SKV 3.7: Regulatory Rights of STUK and Enforcement (11/2001). In the transport area it is considered that off-site enforcements issues are still best dealt with by civil authorities, either at their own initiative or called upon by STUK. This seems a reasonable approach. In terms of general enforcement, it is considered that if recommendation R25 is pursued, the guides mentioned above could address any aspects of non-conformance. In view of these developments it is considered that this recommendation has been adequately addressed.

11.2.6. Transition to New Regulations

Recommendations and Suggestions from the 2000 IRRT report

Suggestion S34: STUK should consider what is going to be required in terms of added resources over the next two years to properly inform holders of licences, consignors and carriers concerning changes to the transport regulations. It may need to provide adequate and enhanced training to accomplish this. In addition, its guides will need to be revised to reflect the new regulations, and this will also require additional effort by STUK.

Suggestion 35: In revising its guides, STUK should pay attention to making sure they communicate clearly and completely. This should include use of the same terminology used in international regulatory documents.

Findings of the 2003 follow-up IRRT mission

The actual updating of national regulations has taken place through the modal decrees and decisions for road, rail, water and air. In addition the schedule for updating STUK guides for applying the regulations is the end of 2003. In terms of passing information to affected parties, information is made available of the STUK website and the main consignors or radioactive materials are informed directly by STUK. The Ministry of Transport and Communications maintains a liaison committee with national carrier associations, which also provides a conduit of providing information on updated regulations. Particular attention is also being given to the use of terminology with a view to maintaining compatibility with international standards. In view of the above, it is considered that these two suggestions have been adequately addressed.

ANNEX I – SYNOPSIS OF RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Recommendations

RF.1 Steps should be taken to establish a legal basis to provide for regulatory control over the construction and operation of the proposed underground research laboratory. It should include a process for STUK to review and approve the construction and development of the laboratory and the research activities that will be undertaken in the laboratory. Guidance should be developed by STUK for the quality management system that needs to be applied to the research and development programme to ensure that the basis and outcomes of the programme are adequately recorded, together with any decisions based on these outcomes.

RF.2 STUK should expand its regulatory inspection and enforcement efforts to include the design, manufacture and use of non-certified packages, with a focus on design documentation, as-fabricated conditions, preparation of packages for shipment by consignors, stowage by carriers, and – for any reusable packages – application of specified maintenance procedures.

Suggestions

SF.1 The legislative framework should be amended to establish an authorization process for decommissioning of nuclear facilities.

SF.2 STUK's independence needs to be maintained, if not enhanced, in the future and therefore there should be a permanent monitoring of actions that may affect such independence or the credibility of STUK to the general public.

SF.3 The state budget provided to STUK for the funding of its international activities should take into account the increasing needs resulting e.g. from the safety related Conventions signed by Finland, and the EU initiatives.

SF.4 In the future system to finance research in nuclear safety matters STUK should share a leading role in the overall management of research programs and projects.

SF.5 STUK should reinforce the supervision of the process by which licensees of Nuclear Power Plants select safety related improvements and modifications in order to ensure that they are not unduly limited by financial reasons.

SF.6 STUK should ensure that it fulfils its intention to undertake in-depth review and assessment of any design features that have not been confirmed by prior operational experience.

SF.7 STUK should plan its inspection activities so that, over a pre-determined period of time, the licensees' compliance with regulatory requirements is sampled. The periodicity of such inspections should be chosen to ensure that there is no unnecessary repetition of inspections.

SF.8 STUK should (1) monitor the resource distribution between the Periodic Inspection Programme, YVL inspections and major projects, and (2) improve the efficiency of YVL inspections in order to ensure that sufficient resources are available to improve the performance of its Periodic Inspection Programme.

SF.9 STUK should continue to develop efficient inspection practices that confirm that the licensees have processes, systems or arrangements that achieve the required level of safety.

SF.10 At an early phase in the revision of each regulatory guide, STUK should invite comments from the licensees on the experience from the use of the existing guide.

SF.11 STUK should prepare the additional regulatory guides in order to address those identified areas that are not adequately covered by the existing guides.

SF.12 STUK should require that the licensee ensures that a systematic approach is adopted, over a defined period of time, whereby all elements of the emergency plans are evaluated and tested at different frequencies and at the same time flexibility is maintained in planning.

SF.13 Consideration should be given to setting up arrangements to dispose of radioactive waste from small scale use of radioactive material, that meets the relevant waste acceptance criteria, directly into existing waste disposal facilities.

SF.14 An investigation should be undertaken by STUK to identify circumstances in which it may have to undertake intervention actions. It should be confirmed that the legislation adequately enables STUK to undertake the measures that may be necessary. STUK should develop internal procedures that may be necessary to implement these actions.

SF.15 STUK should consider arrangements for exercising regulatory control over the future spent fuel reception, storage and conditioning facilities associated with the disposal of spent fuel. These arrangements should adopt an integrated approach that will ensure the various interdependencies associated with these activities and taken into consideration.

SF.16 STUK should consider proposing that explicit reference be made to those exposures that are not amenable to control in the next amendment to the legislation.

SF.17 SKV 3.2 should be updated to address the approval of non-routine authorisations and the process for recording the basis for the regulatory decision.

SF.18 On the basis of the experience gained with the radiation dose evaluation exercise STUK should establish a formalized programme for the periodic assessment of radiation doses to persons from the transport of radioactive material.

Good Practices

GF.1 STUK has carried out an independent review of its research activities.

GF.2 STUK has advanced in the elaboration of a competencies inventory and has initiated a project in knowledge management. These activities reveal the commitment of STUK to

continuous improvement and to anticipate response to future problems of corporate memory losses.

GF.3 KTM has commissioned a study of the nuclear energy competences needed in Finland and has identified actions to ensure the availability of those competences.

GF.4 By using an approach to strategic and annual planning such as the Balanced Score Card STUK considers factors beyond those commonly used directly related to the organization results.

GF.5 STUK's Activities to develop organizational culture facilitate proper attention to organizational culture issues that affect effectiveness of the work performed.

GF.6 STUK preparations for the FIN5 construction licence have been thorough and the requirements management system that has been introduced provides a robust basis for identification of regulatory issues that need to be addressed prior to the granting of the construction licence.

GF.7 STUK has developed an approach to authorisation in which the rule making, review and assessment, and inspection functions are effectively integrated.

GF.8 STUK is assessing annually the risk significance of the component failures at the nuclear power plants; STUK is assessing also the risk significance of preventive maintenance and of the conditions in non-compliance with the technical specifications.

GF.9 STUK has developed a structured inspection programme (the Periodic Inspection Programme) that enables it to obtain information on the licensees' management of safety. This information is used to develop ideas and to plan for the next annual cycle of inspections. It is also used, with other information on the licensees' safety performance, to produce an annual report which is open to the public.

GF.10 STUK annually organises several exercises (both early and late phase) of which one is held on an announced day and time and takes place outside of normal office hours.

GF.11 STUK has initiated activities to upgrade equipment and to train staff in the use of the new measurement systems in over fifty laboratories countrywide.

GF.12 STUK has issued a safety guide has been issued on the long term safety of spent fuel disposal which clearly sets out requirements and provides guidance on meeting the requirements, including how the issue of retrievability must be addressed.

GF.13 The requirement to have a detailed waste management plan prepared periodically that enables assessment of the feasibility of waste management proposals from normal operations and decommissioning and evaluation of the adequacy of associated financial arrangements.

GF.14 The need to exercise regulatory control over activities giving rise to the generation of radioactive waste containing naturally occurring radionuclides has been investigated and proposals are being formulated by STUK for the necessary changes to legislation.

Waste management options are being investigated and safety guidance will be developed.

ANNEX II - TEAM COMPOSITION

Mr. Dominique Delattre Team leader	IAEA, Regulatory Activity Unit Division of Nuclear Installation Safety Department of Nuclear Safety and Security
Mr. Thierry Foult	Institute for Radiation Protection and Nuclear Safety France
Mr. Derek Lacey	Health & Safety Executive Nuclear Installations Inspectorate United Kingdom
Mr. Phil Metcalf	IAEA, Waste Safety Policy Unit Division of Radiation, Transport and Waste Safety Department of Nuclear Safety and Security
Mr. Alan Muller	National Nuclear Regulator South Africa
Mr. Jose Villadoniga	Nuclear Safety Council Spain