



2006 ISOE INTERNATIONAL WORKSHOP

2ND ISOE REGULATORY BODY MEETING

QUESTIONNAIRES COMPILATION

Essen, 14 March 2006

In order to introduce the 2nd ISOE Senior Regulatory Body representatives meeting, a questionnaire was developed by the organisers in order to facilitate a common scheme for the presentation of the different inspection practices on occupational radiation protection in the different ISOE member countries.

The RB representatives attending the meeting agreed on the interest of sharing the questionnaires overview produced by the organisers and all individual information from every country questionnaire.

This document presents an updated compilation of all 19 questionnaires completed and sent to the organisers prior to the 2^o ISOE Regulatory Body Meeting held in Essen, Germany, 14 March 2006. The "CSN and ISOE European Technical Centre - Information Sheet No. 45" will present a general overview of all questionnaires.

The questionnaires are presented by country sorted by alphabetical order. The following table presents the summary of all participating countries, identifying the ISOE Regulatory Body and the representatives who have completed the questionnaires and/or attended the meeting for each country.

Country	Regulatory Body	Questionnaire completed by	Representative attending the meeting
Armenia	Armenian Nuclear Regulatory Authority (ANRA)	Aida Avestisyan (ANRA)	
Belgium	Federal Agency for Nuclear Control (FANC) Association Vinçotte Nuclear (AVN)	M. F. Molitor, (FANC) M. A. Vandewalle (AVN)	An Wertelaers (FANC)
Czech Republic	State Office for Nuclear Safety (SUJB)	Libor Urbancik (SUJB)	Libor Urbancik (SUJB) Hana Bilkova (SUJB)
Finland	Radiation and Nuclear Safety Authority (STUK)	Mr. Veli Riihiluoma (STUK)	Olli Vilkkamo (STUK) Mr. Veli Riihiluoma (STUK)
France	Autorité de Sûreté Nucléaire (ASN)	Sophie Corner (ASN) Stephane Calpena (ASN)	Sophie Corner (ASN) Stephane Calpena (ASN)
Germany	Federal Minister of Environment, Nature conservation and Reactor Safety (BMU, Supervisor, Federal Level) // Competent State Ministry (State level, on behalf of BMU/Federal Level)	W. Pfeffer (GRS) J. Kaulard (GRS)	J. Kaulard, (GRS) W. Pfeffer (GRS) R. Sefzig (BMU) Andreas Czepuck (BMU)
Hungary	Hungarian Atomic Energy Authority (HAEA)	Istvan VEGVARI (HAEA)	Istvan VEGVARI (HAEA)
Japan	Nuclear and Industrial Safety Agency (NISA)	Yoshihisa Hayashida (JNES)	Wataru Mizumachi, Yoshihisa Hayashida (JNES)
Korea	Government of Ministry of Science and Technology supported by the expertise from the Korea Institute of Nuclear Safety (KINS)	Dr. Seong Ho NA (KINS)	Dr. Seong Ho NA (KINS)
Lithuania	Radiation Protection Centre (RSC)	Gintautas BALČYTIS (RSC) Gintautas Klevinskas (RSC) Ramunė Stasiunaitienė (RSC)	Ramunė Stasiunaitienė (RSC)
Romania	National Commission for Nuclear Activities Control (CNCAN)	Oana Velicu (CNCAN)	Oana Velicu (CNCAN)
Slovakia	Public Health Authority of the Slovak Republic (PHA)	Dusan Viktor (PHA)	Dusan Viktor (PHA)
Slovenia	Slovenian Nuclear Safety Administration, SNSA Slovenian Radiation Protection Administration, SRPA	Dr. Helena Janzekovic (SNSA) Nina Jug Dr. (SRPA) Tomaž Šutej Dr. (SRPA)	Dr. Helena Janzekovic (SNSA) Dr.Nina Jug (SRPA)
Spain	Nuclear Safety Council (CSN)	Olvido Guzmán (CSN)	Olvido Guzmán (CSN) Manuel Rodríguez (CSN)
Sweden	Swedish Radiation Protection Authority (SSI)	Ingemar Lund (SSI)	Peter Hofvander (SSI) Ingemar Lund (SSI)
Switzerland	Swiss Federal Nuclear Safety Inspectorate	Dr. Swen-Gunnar Jahn	Dr. Swen-Gunnar Jahn
Ukraine	State Nuclear Regulatory Committee of Ukraine, (SNRCU)	Viktor Ryazantsev (SNRCU)	Viktor Ryazantsev (SNRCU)
United States	US Nuclear Regulatory Commission	James Noggle (USNRC)	

ARMENIA

Country and Representative Identification

- ☐ **Country:** REPUBLIC OF ARMENIA
- ☐ **Name of the regulatory Body:** Armenian Nuclear Regulatory Authority (ANRA)
- ☐ **Name and post of the person(s) who fill in the questionnaire:** Aida Avetisyan, Head of Radiation Safety and Emergency Planning Department

Legal Matters

- ☐ **Legal framework of the RP regulatory body**
 - **Legislation on nuclear energy and regulatory authority -**
 - 1. Law of the Republic of Armenia on Safe Utilization of Atomic Energy for Peaceful Purposes (entered into force since 1999, as amended 2001, 2004)
 - 2. Law of the Republic of Armenia on Licensing (entered into force since 8 August 2001)
 - **Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc) -**

The authorities of the ANRA are established in the Law on Safe Utilization of Atomic Energy for Peaceful Purposes and the ANRA Statute. In accordance with the President ordinance № 912-N as of 27 June 2002 the ANRA was reorganized into an inspection on nuclear and radiation safety at atomic energy utilization within the administration of the ministry for nature protection of the RA. The ANRA statute was approved under the government decree № 2183-N on 26 December 2002 (as amended, 04 March 2004)
 - **Origin of financial resources (e.g.: taxes, government budget, etc) -**

The ANRA is financed from the budget of the ministry for Nature Protection of the RA.
 - **Number of authorities with competences in radiation protection -**

The ANRA is the only Authority in charge of regulation of nuclear and radiation safety
 - **Name(s) and competences-**

The ANRA is state authority responsible for regulation of nuclear and radiation safety in the Republic of Armenia authorized by Government of Armenia
 - **Interfaces, co-operation and communication between them-**

ANRA has signed several agreements between different state authorities like Ministry of Health, Emergency Management Authorities, etc.
 - **Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...) -**
 - Develops and submits safety norms and regulations to the minister of nature protection for further submission to the RA government;
 - Performs safety assessment of activities, objects and equipment in the field of atomic energy utilization;
 - Licenses activities, as well as physical persons implementing activities and holding positions important in terms of safety in the field of atomic energy utilization;
 - Controls fulfilment of requirements of the legislation of the Republic of Armenia and issued licenses in the field of atomic energy utilization;
 - Withdraws license if a licensee does not comply with license terms;
 - Controls the preparedness of organizations and entities operating atomic energy utilization objects and involved in the national emergency response system;
 - Regulates the physical protection of atomic energy utilization objects and nuclear materials
 - Inspects atomic energy utilization objects and activities implemented there;

Legal Matters

- **Relationship between nuclear safety and radiation protection authorities –**
ANRA is responsible for nuclear and radiation safety
- **Enforcement capacity of the regulatory body on occupational RP –**
The enforcement capacity of ANRA is stipulated in General Atomic Law
 - ❑ **Legal framework on occupational radiation protection**
- **Legislation on occupational RP. Give references -**
 - ¾ Radiation Safety Norms as of August 2006
 - ¾ Radiation Safety Rules as of August 2006
 - ¾ Rules for NPP Design And Operation
 - ¾ NPP Radiation Safety Rules
 - ¾ Basic Requirements to the NPP operation – 2000 – (ministerial rules)
- **Legislation is based on (UE directives, ICRP, IAEA, others ...) –**
The mentioned regulations based on ICRP and IAEA recommendations
- **Specific legislation on occupational RP in NPPs –**
 - Rules for NPP Design And Operation
 - NPP Radiation Safety Rules
 - Basic Requirements to the NPP operation – 2000 – (local regulation)
- **Specific guidance on occupational RP in NPPs –**
 - Procedure on Radiation Safety (procedure based on general requirements of Radiation Safety)
- **Does your legal framework requires from the NPPs an official document on occupational RP? – Yes**
 - **Nature, scope and contents of such a document –**
 - The propose of document
 - Glossary (based on IAEA standard)
 - The sources of ionising radiation (including technological systems)
 - RP requirements to zones, personnel category A,B and premises
 - RP requirements to individual hygiene and to prevention of contamination dissemination
 - Individual Protective means
 - Special chapter to radioactive waste treatment and the ensuring of RP during this activities
 - Methodology of individual dose control and ALARA implementation
 - The actions during emergency situations
 - Short theoretical introduction of nuclear physics
 - **Is the document approved by the inspection authority? Are the procedures approved? –**
Yes, its approved by ANRA
 - **Are the procedures (developing and supporting the document approved? -**
Yes

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee

The description of Radiation Protection program are given in "ANPP SAR (ANPP Safety Assessment Report) Format and content" document:

- Site information including the "zero background information on radiation" in surrounding areas of ANPP
- Radiation Protection department organizational structure and trained personnel
- The type of measuring devices and the programme of maintenance and calibration, and the technological systems control programmes
- Individual dose control system, including data recording system (established reference levels)
- ALARA implementation approach and risk assessment methodologies
- Environmental control programme including public exposure control and control of airborne and liquid releases
- Safety assessment calculations and demonstration of compliance with dose and risk criteria's

Self assessment of the licensee

- **Does the licensee have a self assessment programme?. Since when? . Main characteristics –**
Yes, they have, they have started from 1997
- **The programme is an initiative of the licensee or it is required by the authority –**
It was required by WANO expert missions
- **Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially) –**
Yes

Regulatory Body organisation on occupational radiation protection control

- ❑ **Inspectorate organisation** – Inspectors team is not separated from ANRA and they are staff members of ANRA
- **Resources:**
 - **Own personnel (status) or outsourcing?** – Own personnel
 - **Total number of inspectors in your country taking care of occupational radiation protection in NPPs** – 1 (for NPP, and 3 for other IS)
 - **Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities** – Yes. In the same site of ANPP there is one Dry Spent Fuel Storage Facility and ANRA inspector involved in inspections of this facility as well.
 - **Distribution of workload per inspector, per activity: % of time on inspection, % of time on assessment, % of time on others (specify)** – 30% - inspection, 30 %-assessment and follow up actions, licensing documents consideration and 40% - development of regulations
 - **Average number of years of experience on occupational radiation protection of inspectors. Degree of rotation in the organisation** – University degree, from 6 to 30 years
- **Types of inspections:**
 - **Announced? Non announced? Both?** - announced, non announced, complex (with nuclear inspectors team),
 - **Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors)** – Yes, both (this we called complex)

Regulatory Body organisation on occupational radiation protection control

- **Existence of national teams? Regional teams? Both? Resident inspectors?** – Only ANRA team and one site (resident) inspector
 - **What is the dedication of resident inspectors to occupational radiation protection?** – The site inspector is following of the implementation of inspectors enforced requirements by utility in time frame, informing to HQ of any incompliance and has an additional right to shut down the reactor if any major violence's in limits and conditions of nuclear and radiation safety, in parallel immediately informing to HQ.
 - **Inspectors qualification and training (university studies, access to the regulatory body, retraining)** – All inspectors in ANRA have University degree, and ANRA has the program to train and retrain the inspectors
 - ❑ **Inspection organisation and programme**
 - **Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out? Only on shutdowns?** – In Armenia only one reactor in operation. ANRA has one inspector for ANPP radiation Protection issues. The inspections are carry out according Annual plan of ANRA by different topics approved by Head of ANRA and not only during outages.
 - **Number of inspectors per team per inspection** – If the inspection is not complex, it can be carry out by one inspector. In this case the support team from ANRA Technical Support Organization could be taken in order to carry out some compliance measurements or sampling.
 - **Duration of the inspection** – 1-3 days, it depend of objectives
 - **Do the inspectors also carry out assessment or they are exclusively devoted to inspection** – They do the assessments as well and make follow up actions
 - **Approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc** – 20% - preparation for inspection (inspection plan and program with letter to utility), 50% -inspection itself (its includes also discussion with managers about the inspection results), 30% - production of results (important part of inspection).
 - **Methodology of the preparation of the inspection. Documents consulted prior to the inspection** – According inspection Procedure of ANRA, which is including in ANRA's internal Quality Management Handbook, the topics and the regulatory requirements (certain chapters and point of regulations) are discussed beforehand, the places (laboratories, radiation control room, and etc.), the persons, the documentations and so on.
 - **Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public** – After inspection it depend on results the ANRA can issue 1. the Protocol about major violation, 2. Act – Enforcement (when the violations are not significant) and 3. Act when no violations were founded.
The Protocol with penalties and the Act-Enforcement are certainly submitted to the Utility. The Act about inspection could be sent to the Utility or not, it's the decision of ANRA Head. This documents are open for public.
 - **Transparency policy** – Transparency policy is stipulated by Atomic Law.
 - ❑ **Inspection procedures**
 - **Existence of inspection procedures** – The ANRA has written Inspection procedure approved by Head of ANRA, included in ANRA Quality Management Handbook and every inspector has to follow it.
- Main inspection topics:
License conditions fulfilments:
Individual dose control and medical surveillance, workplace monitoring, discharges control, Quality Management Control, environmental monitoring control ALARA Committee functions

Assessment of the effectiveness of the licensee radiation protection programme

- How is the assessment carried out
 - Only through inspection – Not only. The assessment is carry out permanently. The Annual report on Radiation Protection from utility gives lot of matter to asses the situation and an other topic for inspection as well. The modernization documents from utility are also the issue for assessment and so on.
 - Through inspection and assessment? -Yes
 - What is assessed and how? – 1.Compliance with RP risk and dose criteria's (as generally), 2.Dose calculation and reduction methods and 3.Organizational and technical measures (here the attention should be paid connection with nuclear matters too). Usually the assessment should be done by utility and agreed with ANRA. Check the calculations could be done either by ANRA staff or by staff of ANRA's TSO.
 - licensing documents – Certainly
 - inspection information – Certainly
 - shutdown final report (results) – Certainly
 - Others (specify) – Modernization and modifications documents, Technical Specifications
 - Indicators used by the authority to assess licensee performance – The radiation Protection criteria's (all)
 - National and international benchmarking – We have established only national control levels (ALARA implementation)
 - What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc. - As a practice the ANRA staff and the ANPP staff can meet and discuss any issues and usually the protocol of discussion singed from both side.

Improvement of the regulatory effectiveness

- Existence of a process to improve regulatory effectiveness. Since when? The regulatory effectiveness improvement is obligatory to all staff, which are registered in Quality Management Handbook, since 2003.
- If this process exist, briefly describe it. – The ANRA staff, especially the inspectors staff after assessment can make some suggestion to review the regulations, the local procedures, to add some topics in annual plan of inspection and etc.
- What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process? - Not yet registered
- Do you have an inspection self-assessment program? - No
- Does your RB have and external audit.? Feedback of the experience – We had IAEA IRRT and RaSIA missions. The ANRA tried to implement all recommendations and suggestions of those missions.

BELGIUM

Country and Representative Identification

- ❑ **Country:** Belgium
- ❑ **Name of the regulatory Body:** Federal Agency for Nuclear Control (FANC)
Association Vinçotte Nuclear (AVN)
- ❑ **Name and post of the person(s) who fill in the questionnaire:**
M. F. Molitor (FANC) Nuclear Inspector, Scientific Advisor
M. A. Vandewalle (AVN) Division Head of Nuclear Installations Inspections

Legal Matters

❑ **Legal framework of the RP regulatory body**

(see also information provided in the Belgian report to the International Convention on Nuclear Safety – available at http://www.avnnuclear.be/avn/CNS2005_final_not_appendix1.pdf)

▪ **Legislation on nuclear energy and regulatory authority:**

- The Law of 15 April 1994 for the protection of the population, the workers and the environment against the dangers of ionising radiations and relative to the Federal Agency for Nuclear Control.
- The Royal Decree of 20 July 2001. "General Regulations regarding protection of the population, the workers and the environment against the dangers of ionising radiation"

○ **Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc)**

- FANC: The Federal Agency for Nuclear Control is an autonomous government agency with corporate personality. The FANC is directed by a 14-headed Board; its members are appointed by the Federal Government on the basis of their particular scientific or professional qualities. The Agency is supervised by the Federal Minister of Internal Affairs via a government Commissioner who attends the meetings of the Board of Directors.

In order to perform its tasks, the Agency is assisted by a Scientific Council.

Since its creation, the FANC annually reports to the Belgian Parliament

- AVN: AVN is a non profit association. This independent organisation is authorised by the Belgian Nuclear Safety Authority (FANC) as a "Licensed Inspection Organisation" (LIO). See the web site for additional information (www.avn.be)

○ **Origin of financial resources (e.g.: taxes, government budget, etc)**

- FANC: The operation of the Agency is entirely financed by the companies, organisations or persons it renders services. In practice this is done through non-recurrent or annual fees at the expense of the holders or applicants of licences, recognitions or approvals; the tariffs are set by Royal Decree. The receipt and expenditures of the Agency have to be in equilibrium.
- AVN: Paid by the licensee on the basis of the time spent on inspections and assessments. The finances and activities of AVN are controlled by a special committee chaired by a high level public servant who is a member of the FANC.

▪ **Number of authorities with competences in radiation protection.**

○ **Name(s) and competences.**

- FANC: The Federal Agency for Nuclear Control (FANC) takes over all the functions of the Safety Authority and performs at the level of general regulation and overseeing.
- The FANC may delegate a number of tasks to the authorised inspection organisation, specially at the level of the detailed technical analysis and of the permanent supervision of the operator as required by the regulations. AVN (Association Vinçotte Nuclear) for the nuclear power plants.
- The Medical Department of the Federal Public Service Employment, Labour and Social Dialogue performs the medical supervision of the workers and collects the information about occupational exposure
- AVN is performing inspections in radiation protection in the Belgian NPP's.

▪ **Interfaces, co-operation and communication between them.**

- Periodic meetings are organised between the two organisations the FANC and AVN in order to discuss, assess and coordinate inspection activities.

- **Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)**
 - FANC
 - Assesses the NPPs with regards to radiation protection during the yearly revision and refuelling outage;
 - Supervises radiation doses from NPPs for the operator's workers and the outside contractor's workers
 - AVN:
 - Inspects and assesses the NPP's with regard to radiation protection and nuclear safety
 - Controls and supervises radiation doses from NPP's for both the workers and the general public
 - Controls Licensee activities during nuclear emergency
 - Provides support to the Authorities in case of nuclear emergency
- **Relationship between nuclear safety and radiation protection authorities.**
 - The regulatory body (i.e. FANC and AVN) is in charge of both areas
- **Enforcement capacity of the regulatory body on occupational RP**
 - FANC: the FANC has capacity to enforce remedial actions. The members of the supervision service of the Agency nominated by the King to supervise the law and its implementation decrees are of The King's Attorney. They search for infractions to the law and establish them by official entry. They can give a warning accompanied by a period (of maximum 6 months) in which the infractions must be resolved
 - AVN has no enforcement capacity
- **Legal framework on occupational radiation protection**
 - **Legislation on occupational RP. Give references.**
 - The Royal Decree of 20 July 2001."General Regulations regarding protection of the population, the workers and the environment against the dangers of ionising radiation"
 - The Royal Decree of 25 April 1997 concerning the protection of the workers against the dangers resulting from ionising radiations, this Decree transposes to Belgian law the Euratom/90/641 Directive
 - **Legislation is based on (UE directives, ICRP, IAEA, others ...)**
 - Belgium is member State of the European Union and of the European Atomic Energy Community (EURATOM),. The Belgian rules and regulations mainly within the field of radiation protection have been developed in implementation of and in accordance with the European Treaty and directives concerned. UE Directives are mainly based on ICRP recommendations.
 - **Specific legislation on occupational RP in NPPs**
 - The Royal Decree of 20 July 2001 provides the basic nuclear safety and radiological protection regulations
 - The Royal Decree of 25 April 1997
 - Belgian nuclear power plants design was done according to that legislation and, furthermore, consistent with the US regulations and in particular 10 CFR50 Appendix I and the related Regulatory guide 1.21.
 - **Specific guidance on occupational RP in NPPs.**
 - The limitation of individual or collective doses is based on the general principles of justification, of keeping the doses as low as reasonably achievable, and of compliance with the limit doses. The doses are specified in detail for professionally exposed people, for trainees and students, and for members of the public. The doses limitations comply with the European 96/29 directive.
 - **Does your legal framework require from the NPPs an official document on occupational RP?**
 - An individual passport , separate exposure sheets which have to be filled in after each series of interventions in a controlled area, completed with a computerized network system, has been foreseen by Royal Decree of April 2, 2002, but has not been implemented till now
 - **Nature, scope and contents of such a document**
An individual passport is foreseen
 - **Is the document approved by the inspection authority? Are the procedures approved?**

It is not the FANC but the Federal Public Service Employment, Labour and Social Dialogue that is competent for this matter .

No.

- **Are the procedures (developing and supporting the document approved?**

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee

Self assessment of the licensee

- **Does the licensee have a self assessment programme?** Yes, as this is included in the required features for the Quality Assurance Programme
 - **Since when?** From the start-up of the Npp's. The requirements on the QA programme are included in the SAR.
 - **Main characteristics :** As required by the QA programme
- **The programme is an initiative of the licensee or it is required by the authority**
The QA programme is required by the License and the description is included in the SAR
- **Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially)**
Results from QA audits are available to the LIO and discussed during the corresponding inspection activities.

Regulatory Body organisation on occupational radiation protection control

☐ Inspectorate organisation

- Resources:
 - **Own personnel (status) or outsourcing?**
FANC and AVN have their own staff.
 - **Total number of inspectors in your country taking care of occupational radiation protection in NPPs.**
The total staff of technical experts for AVN and FANC is about 49 people, of which inspectors dedicated to NPP's and other experts covering different specialities in this area (general RP aspects, measuring techniques, contamination control, etc).
 - **Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.**
YES, in addition to the 7 Belgian NPP's, they also inspect research centres, radioactive waste storage facility, MOX manufacturing facility, production of radionuclides as well as many other smaller facilities (hospitals, universities, Xrays appliances, etc).
 - **Distribution of workload per inspector, per activity: % of time on inspection, % of time on assessment, % of time on others (specify).**
With regard to the inspectors, it is very difficult to distinguish between inspection and assessment activities because both activities are closely linked. For dedicated inspectors, the majority (> 80%) of their working time is devoted to inspections.
 - **Average number of years of experience on occupational radiation protection of inspectors.**
As an average, inspectors have more than 10 years experience on occupational radiation protection. **Degree of rotation in the organisation.** Very few.
- **Types of inspections:**
 - **Announced? Non announced? Both?** Both types of inspections are organised.
 - **Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?**

Regulatory Body organisation on occupational radiation protection control

In addition to routine inspections performed by nuclear safety inspectors (covering radiation protection among other items), specific RP inspections are organised with nuclear safety inspectors.

- **Existence of national teams? Regional teams? Both? Resident inspectors?**
 - Both: use of dedicated inspectors (similar to resident inspectors) and radiation protection experts working in team with the dedicated inspectors.
 - **What is the dedication of resident inspectors to occupational radiation protection?**
 - About 10 % of his time in NPP's.
 - **Inspectors qualification and training (university studies, access to the regulatory body, retraining)**
 - All inspectors are required to have a university degree in scientific or technological areas. Additional education (Nuclear Technology, Nuclear Safety, Radiation Protection) and/or on-the-job training, during several years; a refresher training programme is established on annual basis.
- **Inspection organisation and programme**
- **Number of inspections per year per NPP unit on occupational RP?**
 - All inspection activities include occupational RP.
 - **When are the inspections carried out?. Only on shutdowns?**
 - Specific attention is paid to this topic during outages and other activities involving radiation exposure.
 - **Number of inspectors per team per inspection. 1 or 2**
 - **Duration of the inspection.**
 - Depending on the type of inspection performed. Inspections devoted to occupational RP can last for one or more days.
 - **Do the inspectors also carry out assessment or they are exclusively devoted to inspection.**
 - The assessment is part of the duty of the inspectors.
 - **Approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc.**
 - Depending on the type of inspection, from no preparation time for routine inspections to several days for specific inspections.
 - **Methodology of the preparation of the inspection. Documents consulted prior to the inspection.**
 - Preparation performed according to internal ISO-procedures on radiation protection available. Documents (reports, data, etc) produced by the Licensee as well as the SAR can be used.
 - **Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public.**

After the inspections an official inspection report is sent to the licensee. No report send to the public
 - **Transparency policy**

Confidentiality of inspection activities is required by law
- **Inspection procedures**
- **Existence of inspection procedures. YES – according to ISO certified QA programme**
 - **Main inspection topics**
 - Organisation and training
 - Radiation protection
 - Waste treatment
 - Discharge of radioactive fluids
 - Clearance
 - Radiation measurement
 - Radiation measurement / Instrumentation
 - Zoning of controlled areas
 - Transportation of radioactive material
 - Implementation of the ALARA-principle
 - Follow up of dose results
 - Operating experience

Assessment of the effectiveness of the licensee radiation protection programme

- **How is the assessment carried out**
 - Only through inspection NO
 - Through inspection and assessment? YES
- **What is assessed and how?**
 - licensing documents YES
 - inspection information YES
 - shutdown final report (results) YES
 - Others (specify)
- **Indicators used by the authority to assess licensee performance**
 - Collective and individual dose to personnel
 - Release of radioactive products
- **National and international benchmarking**
- **What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.**

Improvement of the regulatory effectiveness

- **Existence of a process to improve regulatory effectiveness. Since when?**
 - YES, through the QA management system (certified as by ISO 9001 in 2003)
- **If this process exist, briefly describe it.** As required by ISO-9001.
- **What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?**
- **Do you have an inspection self-assessment program?** YES, is part of the ISO 9001 system. Improvement actions can be proposed in order to optimise and harmonise the program.
- **Does your RB have an external audit?** Yes, since 2003 AVN has had external audits every 6 months. **Feedback of the experience** YES

Assessment of the effectiveness of the licensee radiation protection programme

- **How is the assessment carried out**
 - Only through inspection NO
 - Through inspection and assessment? YES
- **What is assessed and how?**
 - licensing documents YES
 - inspection information YES
 - shutdown final report (results) YES
 - Others (specify)
- **Indicators used by the authority to assess licensee performance**
 - Collective and individual dose to personnel
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Improvement of the regulatory effectiveness

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 - YES, through the QA management system (certified as by ISO 9001 in 2003)
- **If this process exist, briefly describe it.** As required by ISO-9001.
- **What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?**
- **Do you have an inspection self-assessment program?** YES, is part of the ISO 9001 system. Improvement actions can be proposed in order to optimise and harmonise the program.
- **Does your RB have and external audit?** Yes, since 2003 AVN has had external audits every 6 months. **Feedback of the experience** YES

CZECH REPUBLIC

Country and Representative Identification

- ☐ Country: Czech Republic
- ☐ Name of the regulatory Body: Státní úřad pro jadernou bezpečnost (State Office for Nuclear Safety) SUJB or Office
- ☐ Name and post of the person(s) who fill in the questionnaire: Libor Urbancik, radiation protection inspector & Head of the Regional Center SUJB

Legal Matters

❑ Legal framework of the RP regulatory body

- Legislation on nuclear energy and regulatory authority:
 - Act No. 18/1997 Coll., on Peaceful Utilization of Nuclear Energy and Ionizing Radiation (the Atomic Act) and on Amendments and Additions to Related Acts. , in amendments
 - Act No. 552/1991 Coll., on State Supervision, in amendments
 - Act. No. 500/2004 Coll., on State Administration
 - Decree of the SÚJB No. 144/1997 Coll., on Physical Protection of Nuclear Materials and Nuclear Facilities and their Classification.
 - Decree of the SÚJB No. 145/1997 Coll., on Accounting for and Control of Nuclear Materials and their Detailed Specification, amended in Decree of the SÚJB No. 316/2002 Coll.
 - Decree of the SÚJB No. 146/1997 Coll., Specifying Activities Directly Affecting Nuclear Safety and Activities Especially Important from Radiation Protection Viewpoint, Requirements on Qualification and Professional Training, on Method to be Used for Verification of Special Professional Competency and for Issue Authorizations to Selected Personnel, and the Form of Documentation to be Approved for Licensing of Expert Training of Selected Personnel, as amended by Decree of the SÚJB No. 315/2002 Coll.
 - Decree of the SÚJB No. 214/1997 Coll., on Quality Assurance in Activities Related to the Utilization of Nuclear Energy and in Radiation Activities, and Laying Down Criteria for the Assignment and Categorization of Classified Equipment into Safety Classes.
 - Decree of the SÚJB No. 215/1997 Coll., on Criteria for Sitting Nuclear Facilities and Very Significant Ionizing Radiation Sources.
 - Decree of the SÚJB No. 106/1998 Coll., on Nuclear Safety and Radiation Protection Assurance during Commissioning and Operation of Nuclear Facilities.
 - Decree of the SÚJB No. 195/1999 Coll., on Basic Design Criteria for Nuclear Installations with Respect to Nuclear Safety Radiation Protection and Emergency Preparedness.
 - Decree of the SÚJB No. 196/1999 Coll., on Decommissioning of Nuclear Installations and Working Places with Important and Very Important Sources of Ionizing Radiation.
 - Decree of the SÚJB No. 179/2002, Laying Down a List of Selected Items and Dual Use Items in Nuclear Sector.(Repeals Decree of the SÚJB No. 147/1997 Coll.
 - Decree of the SÚJB No. 307/2002 Coll., on Radiation Protection, Annexes 1-13 amended by Decree of the SÚJB No. 499/2005 Coll.
 - Decree of the SÚJB No. 317/2002 Coll., on Type Approval of Packaging Assemblies for Transport, Storage and Disposal of Nuclear Materials and Radioactive Substances, on Type Approval of Ionizing Radiation Sources and on Transport of Nuclear Materials and Specified Radioactive Substances ("on Type Approval and Transport"), Annexes. (Repeals Decrees Nos. 142/1997 Coll. and 143/1997 Coll.)
 - Decree of the SÚJB No. 318/2002 Coll., on Details of Emergency Preparedness of Nuclear Facilities and Workplaces with Ionising Radiation Sources and on Requirements on the Content of On-Site Emergency Plan and Emergency Rule.
 - Decree of the SÚJB No. 319/2002 Coll., on Performance and Management of the National Radiation Network.
 - Decree of the SÚJB No. 419/2002 Coll., on Personal Radiation Passports.
 - Decree of the SÚJB No. 185/2003 Coll., on Decommissioning of Nuclear Installation or Category III. or IV. Workplace.

Legal Matters

- Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc)

The State Office for Nuclear Safety is a governmental body as stipulated by Act. No. 2/1969 Coll. (full wording Act. No. 122/1997 Coll. - §2). The State Office for Nuclear Safety (hereinafter SÚJB or Office) is a central state administration agency independently budgeted. The SÚJB is headed by SÚJB Chairman who is appointed by the Government of the Czech Republic.

- Origin of financial resources (e.g.: taxes, government budget, etc)

Office has its own independent governmental budget.

- Number of authorities with competences in radiation protection.

Office is exclusive holder of all the competences in the field of nuclear safety, radiation protection, emergency preparedness, physical protection and technical safety of the nuclear installations in the Czech Republic.

- Name(s) and competences. **None.**
- Interfaces, co-operation and communication between them. **None.**

- Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)
- **Performing state-governed surveillance of nuclear safety, nuclear items, engineered safety features employed to ensure the physical protection of nuclear facilities, radiation protection and emergency preparedness within nuclear facilities and premises using sources of ionizing radiation;**
- **Licensing activities conducted pursuant to Act No. 18/1997 Coll., such as locating and operating nuclear facilities and premises using major sources of ionizing radiation; handling ionizing radiation sources and radioactive waste; shipping nuclear materials and radionuclide radiation sources;**
- **Approving nuclear and radiation protection related documentation as stipulated in the Atomic Act; Limits and Conditions included in Technical Specifications, methods of engineered safety features implementation, emergency rules used to govern the transportation of nuclear materials and some selected radionuclide radiation sources, on-site emergency plans for nuclear facilities and premises with sources of ionizing radiation;**
- **Determining the conditions and requirements for the public protection from radiation as well as the workers engaged in jobs involving sources of ionizing radiation (e.g. the stipulation of exposure limits, the delineation of a controlled area); defining the Emergency Planning Zone and the requirements for emergency preparedness of the License Holders as set forth in the Atomic Act;**
- **Monitoring the exposure of the public and workers handling sources of ionizing radiation;**
- **Operating the State System of Accounting for and Control of Nuclear Material and maintaining the State Registry of License Holders; imported and exported Trigger List items; sources of ionizing radiation and keeping track of the exposure of the public and of workers handling ionizing radiation sources;**
- Relationship between nuclear safety and radiation protection authorities.
The Czech State Office for Nuclear Safety (SUJB) holds the exclusive authority for nuclear safety and radiation protection. There are two sections within Office, Nuclear Safety Section and Radiation Protection Section. These sections close co-operate.
- Enforcement capacity of the regulatory body on occupational RP
The Office has capacity to enforce remedial measures including penalties.

Legal Matters

❑ Legal framework on occupational radiation protection

- Legislation on occupational RP. Give references.
 - Decree of the SÚJB No. 307/2002 Coll., on Radiation Protection, Annexes 1-13 as amended by Decree of the SÚJB No. 499/2005 Coll.
 - Decree of the SÚJB No. 419/2002 Coll., on Personal Radiation Passports.

 - Legislation is based on (UE directives, ICRP, IAEA, others ...)
 - **Original Czech Legal Framework**
 - **European Union Directives, Decisions, Regulations, Recommendations and Communications (As a member of the European Union the Czech Republic harmonized its own legislation with EU legislation)**
 - **IAEA Fundamentals, Standards, Guides and Practices**
 - **ICRP and ICRU Recommendations**
 - **Further International Experience in the Field of Radiation Protection (ISOE Reports, Proceedings and Information)**

 - Specific legislation on occupational RP in NPPs
 - Decree of the SÚJB No. 307/2002 Coll., on Radiation Protection, Annexes 1-13 amended by Decree of the SÚJB No. 499/2005 Coll.
 - Decree of the SÚJB No. 419/2002 Coll., on Personal Radiation Passports.
 - Decree of the SÚJB No. 146/1997 Coll., Specifying Activities Directly Affecting Nuclear Safety and Activities Especially Important from Radiation Protection Viewpoint, Requirements on Qualification and Professional Training, on Method to be Used for Verification of Special Professional Competency and for Issue Authorizations to Selected Personnel, and the Form of Documentation to be Approved for Licensing of Expert Training of Selected Personnel, as amended by Decree of the SÚJB No. 315/2002 Coll.

 - Specific guidance on occupational RP in NPPs.
- The Office issues internal documentation instructions and procedures. There are instruction and procedure related to the occupational radiation protection as follows:**
- **VDS040 Instruction for Radiation Protection Inspections at NPPs Performance**
 - **VDMI007 Procedure for NPP Workplaces Monitoring Surveillance**
 - **VDMI009 Procedure for NPP Occupational Exposure Monitoring Surveillance**
-
- Does your legal framework require from the NPPs an official document on occupational RP? **YES**
 - Nature, scope and contents of such a document

There are documents related to the occupational radiation protection as follows:
 - **Monitoring Programme of the NPP Workplaces (Licensing documentation approved by SÚJB)**
 - **Personal Monitoring Programme (Licensing documentation approved by SÚJB)**
 - Is the document approved by the inspection authority? Are the procedures approved? **Monitoring programmes are approved by Office but procedures not.**
 - Are the procedures (developing and supporting the document approved? **NO**



Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee:

There is the only company NPP owner in the Czech Republic. The name of the licensee is CEZ plc. That enterprise has issued several safety procedures including monitoring programmes. An example of many monitoring programmes used by CEZ plc is stated below. Following programme represents ORP core of the radiation safety matter. That is only a part of the comprehensive system of the monitoring programmes (Monitoring Programme of the NPP Workplaces, Personal Monitoring Programme, Monitoring Programme of Discharges, Monitoring Programme of the NPP Vicinity, Emergency Monitoring Programme, etc.).

Chapters of the Personal Monitoring Programme:

1. Introduction
 - 1.1. Objective
 - 1.2. Definitions
 - 1.3. List of used abbreviations
 - 1.4. Related documentation
 - 1.5. Obligation
2. Techniques of dosimetrical quantities measurement
 - 2.1. Personal dose equivalent – external exposure
 - 2.2. Bodily radioactive contamination measurement
3. Measurement areas
 - 3.1. Exposed category A and B workers
 - 3.1.1. Basic dose limits drawings monitoring
 - 3.1.2. Special dose limits drawings monitoring
 - 3.1.3. Basic dose limit drawings monitoring for the skin $H_T < 500$ mSv in a year
 - 3.1.4. Basic dose limit drawings monitoring for the lens $H_T < 150$ mSv in a year
 - 3.2. Exposed workers working under higher radiation risk conditions (R-Instruction)
 - 3.2.1. Basic dose limits drawings monitoring $H_T < 500$ mSv in a year
 - 3.2.2. Operating dose limits drawings monitoring
 - 3.2.3. Operating dose limits drawings monitoring for primary circuit equipment operators
 - 3.3. Exposed workers working under very high radiation risk conditions
 - 3.4. Exposed workers working at and controlling main circulating pumps areas
 - 3.5. Exposed workers working at boron meters
 - 3.6. Exposed workers working inside the controlled area of radwaste repository
 - 3.7. Exposed workers working inside the controlled area of the interim spent fuel storage unit
 - 3.8. Visitors and excursions
 - 3.8.1. General dose limits drawings monitoring $E < 1$ mSv
 - 3.8.2. General dose limits drawings monitoring $H_T < 15$ mSv for the lens of the eye
 - 3.8.3. General dose limits drawings monitoring $H_T < 50$ mSv for the skin
 - 3.9. Classified exposed workers
 - 3.9.1. Basic dose limits drawings monitoring from bodily radioactive contamination
 - Gamma radionuclides activity
 - ^{131}I radioactivity
 - ^3H volume radioactivity in urine
 - ^{90}Sr volume radioactivity in urine
 - Gamma radionuclides volume activity in urine
 - Specific activity separated gamma radionuclides in faeces
4. Data output
 - 4.1. Rules and means for data recording
 - 4.2. Instructions for measured results evaluating
 - 4.3. Dataways
5. Appendices
 - 5.1. List of embedded appendices

Self assessment of the licensee

- Does the licensee have a self assessment programme? Since when? Main characteristics.
Licensee has a legal obligation to operate nuclear facility in compliance with quality assurance, quality control programmes (hereinafter only "QA/QC"). The parts of these QA/QC programmes are both self-assessment and feedback evaluation. The QA/QC programmes are the part of the Czech legislation since the beginning of the nuclear facilities operation. Self-assessment is implemented as sets of safety indicators including radiological items. Every event is reviewed by investigation team and some of them with higher significance are assessed by event committee. Adopted remedial measures are focused both on the finding of the route cause of event including overexposure and on the recurrence prevention. Personnel findings and proposals have high priority in the self-assessment process. In that manner is the self-assessment based on the feedback analyses.
- The programme is an initiative of the licensee or it is required by the authority.
The programme is obligatory and resulting from the Czech legislation, i.e. this one is required by the authority and without this programme the Office can not issue the license.
- Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially)
The programme is an object of the Office inspection. Inspectors check and evaluate effectiveness of the adopted remedial measures and trends of safety performance indicators.

Regulatory Body organisation on occupational radiation protection control

☐ Inspectorate organisation

▪ Resources:

- Own personnel (status) or outsourcing?
SUJB has its own staff. SUJB is furthermore supported by the National Radiation Protection Institute which ensures radiation monitoring network operation, mobile team for radiological events operation, expert reports, analyses, etc., and by the National Institute for Nuclear, Chemical and Biological Protection.
- Total number of inspectors in your country taking care of occupational radiation protection in NPPs.
Total SUJB staff is 194 persons, of which are 107 inspectors, 57 inspectors are radiation protection inspectors, of which are 11 involved in occupational radiation protection in nuclear power plants.
- Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities? Specify number and type of facilities. **YES. Survey of all inspected nuclear facilities in the Czech Republic is stated below:**
 1. **Dukovany NPP, 4 Units: 4 x 440 MW**
 2. **Dukovany Interim Spent Fuel Storage Unit**
 3. **Dukovany Spent Fuel Storage Unit**
 4. **Dukovany Radioactive Waste Repository**
 5. **Temelín NPP, 2 Units: 2 x 1000 MW**
 6. **Temelín Fresh Fuel Storage**
 7. **Nuclear Research Institute Řez plc., Research Reactor LR-0**
 8. **Nuclear Research Institute Řez plc., Research Reactor LVR-15**
 9. **Nuclear Research Institute Řez plc., High Activity Radioactive Waste & Spent Fuel Storage**
 10. **University Research Reactor VR-1 in Prague**
- Distribution of workload per inspector, per activity: % of time on inspection, % of time on assessment, % of time on others (specify).
 - **40 % time on inspection including inspection preparation**
 - **20 % time on assessment**
 - **20 % time on administration (issuing administrative decisions)**
 - **20 % time on meetings, discussions, etc.**
- Average number of years of experience on occupational radiation protection of inspectors. **21 years** Degree of rotation in the organisation. **Practically does not exist.**

▪ Types of inspections:

- Announced? Non announced? Both?
Every inspection must be announced according to the Czech Legislation. The inspections are divided into three types:
 - **Planned routine inspections are known to licensee long before the beginning. They are announced early in year.**
 - **Planned special inspections are notified to licensee a week before their beginning.**
 - **Unplanned ad-hoc inspections are implemented in case of event and they are announced closely before their beginning.**

Regulatory Body organisation on occupational radiation protection control

- Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?)
 - **Planned routine inspections are usually multidisciplinary because they are focused on gathering of basic information about radiation protection assurance.**
 - **Planned special inspections are often specific on occupational radiation protection.**
 - **Unplanned ad-hoc inspections are exclusively specific.**
- Existence of national teams? Regional teams? Both? Resident inspectors?

Since 1997 specialized inspection teams have been established for inspection areas:

 - **Industrial sources of ionising radiation.**
 - **Medical sources of ionising radiation.**
 - **Radiotherapy.**
 - **Unsealed sources of ionising radiation.**
 - **Natural sources of ionising radiation.**
 - **Sources of ionising radiation in nuclear industry.**

These teams perform just above mentioned planned special inspections and unplanned ad-hoc inspections. Regional teams perform basically planned routine inspections and some planned special inspections. Resident inspectors acting directly at NPPs are just from nuclear safety section, the role of radiation protection resident inspectors performs inspectors from Regional Centers Ceske Budejovice for Temelin NPP and Brno for Dukovany NPP.
- What is the dedication of resident inspectors to occupational radiation protection?

Practically 70 % time is dedicated to occupational radiation protection. Some time is dedicated to additional issues like nuclear power plants vicinity monitoring and sampling.
- Inspectors qualification and training (university studies, access to the regulatory body, retraining)
- **All the SUJB radiation protection inspectors are required to have a university degree in medical, scientific or technological areas. This requirement is implemented according to the Czech legislation and exceptions do not exist. Each candidate for inspector position must pass special training focused on related Czech legislation, professional skills inclusive nuclear safety, nuclear technology, radiation protection in nuclear facilities. Then pass special examination and psychological test. Retraining is carried out as residency at foreign regulatory bodies, as participation at IAEA courses and workshops and at SUJB own seminars and workshops. One year is average time for inspector-candidate professional preparation.**

Regulatory Body organisation on occupational radiation protection control

□ **Inspection organisation and programme**

- Number of inspections per year per NPP unit on occupational RP? **10** When are the inspections carried out? **As it is stated above routine planned inspections are carried out monthly and they are related to the each NPP unit. The first inspection is performed for each unit at the shutdown beginning time, the follow-up after outage finishing. Besides, special planned and sometimes unplanned inspections are performed. Only on shutdowns? NO, they are performed also during the unit operation.**

- Number of inspectors per team per inspection. **1 – 3 inspectors in dependence on both importance and complexity of the investigated case.**

- Duration of the inspection. **Routine planned inspection takes just current month. Planned special inspection is done in week and unplanned ad-hoc inspection is carried out in dependence on importance of the event, it takes often more than one week.**

- Do the inspectors also carry out assessment or they are exclusively devoted to inspection? **Each routine monthly inspection includes radiation protection assuring assessment as well as the annual assessment which is performed by inspectors. Radiation protection inspectors are involved in licensee application assessment, as well.**

- Approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc.

Preparation:	monthly planned routine inspections < 10 % time
	special planned inspections 40 % time
	unplanned ad-hoc inspection < 10% time
Performance:	monthly planned routine inspections 50 % time
	special planned inspections 40 % time
	unplanned ad-hoc inspection 60% time
Documentation:	monthly planned routine inspections 40 % time
	special planned inspections 20 % time
	unplanned ad-hoc inspection approximately 30% time

- Methodology of the preparation of the inspection. Documents consulted prior to the inspection.
- **MONTHLY PLANNED ROUTINE INSPECTIONS**
The licensee has a statutory duty to submit to Office (SUJB) daily, weekly and monthly report on the operation. A part of this report is comprehensive information about radiation situation within units and their vicinity. Number of the submitted values is very extensive. Inspectors perform surveillance by means of a spot check and they gather all the data for the analysis, for their processing and their issue as an official report. Realized values are compared with values in approved documentation, in legal procedures, standards etc. during time of analyses and the processing.
- **SPECIAL PLANNED INSPECTIONS**
Special planned inspections are based on results of routine inspection discovering some events, mistakes or deviations in licensee operation from approved documentation. Special inspections are organized often as follow-up inspections recognizing the implementation of the remedial measures of previously investigated events. Previous inspection results are reviewed including event reports and repeated cases reports. Inspections are planned according to the analysis of the findings. Findings are compare against consulted approved documentation, operational results, discovered deviations etc.
- **UNPLANNED AD-HOC INSPECTION**
Ad-hoc inspections begin at licensee special event committee conference. The inspectors of the Office keep at disposition only raw facts from licensee early report. Further course of investigation is the same as in case of the special inspections.

Regulatory Body organisation on occupational radiation protection control

- Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internal, which are sent to the licensee and which are public.
 1. **Inspection Instruction Manual (describes course of inspection, internal document)**
 2. **Minutes (describes findings of facts, internal document)**
 3. **Protocol (official record dedicated to the licensee, it is not open for public)**
 4. **Evaluating report (describes internal opinion and assumption of the inspectors, states off-the-record remarks, internal document)**
- Transparency policy
The current transparency policy is implemented according to the Czech legislation: It is prohibited to notify to the third person whatever from inspected discovered facts. Official annual data and statement are public including important results from inspections in the SUJB Annual Report. Everybody has rights to require, to collect and to gather information. The Office has obligation to provide everyone with information in legal scope.
- ❑ **Inspection procedures**
 - Existence of inspection procedures **YES**
 - Main inspection topics
 - **Total Collective Effective Dose from Electronic Dosimetry [mSv/sum of days]**
 - **Current Collective Effective Dose from Electronic Dosimetry during Outages [mSv/day]**
 - **Number of Workers Receiving Daily Doses above 1mSv [1]**
 - **Activities of the Noble Gases in the Stacks [GBq/24 hours]**
 - **Mean Values of the Dose Rate from the Inner and Outer Teledosimetric Systems [nSv/hour]**
 - **Steam Generator Leakage Data: Activities of the Steam Generator Blowdown [kBq/kg]**
 - **Exceeding of the Intervention Level: According to the Monitoring Programmes**
 - **Reactor Coolant Activities [kBq/kg]**
 - **Number of Technical Specification Required Actions**
 - **Number of Violations to Technical Specifications**
 - **Number of Significant Incidents due to Human-Related Causes**
 - **Radioactive Iodines (Gaseous Discharges) [MBq/week], [microSv/week and individual from the critical group] [% of the limit value]: Limiting Value for Total Gaseous Discharges is 40 microSv/year - Committed Effective Dose**
 - **Radioactive Aerosols [GBq/week], [microSv/week and individual from the critical group] [% of the limit value] Limiting Value for Total Gaseous Discharges is 40 microSv/year**
 - **List of All Events Occurring at the NPP**
 - **Reactor Coolant Radiation Situation Evaluation**
 - **Fuel Cladding State Evaluation**
 - **Current Collective Effective Dose from Film Badge Dosimetry [mSv/month]**
 - **Numbers of the Staff Participating Collective Effective Dose [1]**
 - **Maximum Receiving Individual Dose for NPP Worker [mSv/Worker]**
 - **Maximum Receiving Individual Dose for Supplier Worker [mSv/Worker]**
 - **Total Number of the Persons Monitored at WBC**
 - **Number of WBC Recording Level Overexposure [>0,1mSv]**
 - **Number of Workers with Special Decontamination: Medical Intervention**
 - **Tritium Liquid Effluents [GBq/month], [microSv/month and individual from the critical group] [% of the limit value]: Limiting Value for Total Liquid Discharges is 6 microSv/year - Committed Effective Dose**
 - **Corrosion and Activated Radionuclides from Liquid Effluents**
 - **14C (Gaseous Discharges) [MBq/week], [microSv/week and individual from the critical group] [% of the limit value]: Limiting Value for Total Gaseous Discharges is 40 microSv/year - Committed Effective Dose**
 - **NPP Vicinity Monitoring Results**
 - **Alpha Radionuclides Monitoring Results**
 - **90Sr and 89Sr Monitoring Results**
 - **Implementation of the ALARA principles**
 - **Abidance by Approved Documentation (QA/QC Programmes, Tec Specs, Monitoring Programmes, Controlled Area Delineation etc.)**
 - **Events Notifying Including Contamination and Decontamination, Transport, etc.**

Assessment of the effectiveness of the licensee radiation protection programme

- How is the assessment carried out
 - Only through inspection **NO**
 - Through inspection and assessment? **YES**

- What is assessed and how?
 - licensing documents **YES**
 - inspection information **YES**
 - shutdown final report (results) **YES**
 - Others (specify) **Design Modifications, Safety Evaluation Reports, Number and Qualification of Radiation Protection Officers, Licensing Documents Modifications.**

- Indicators used by the authority to assess licensee performance
- **Total Collective Effective Dose from Electronic Dosimetry [mSv/sum of days]**
- **Current Collective Effective Dose from Electronic Dosimetry during Outages [mSv/day]**
- **Number of Workers Receiving Daily Doses above 1mSv [1]**
- **Comparing between Electronical and Film Badge Dosimetry**
- **Activities of the Noble Gases in the Stacks [GBq/24 hours]**
- **Mean Values of the Dose Rate from the Inner and Outer Teledosimetric Systems [nSv/hour]**
- **Steam Generator Leakage Data: Activities of the Steam Generator Blowdown [kBq/kg]**
- **Exceeding of the Intervention Level: According to the Monitoring Programmes**
- **Reactor Coolant Activities [kBq/kg]**
- **Number of Technical Specification Required Actions**
- **Number of Violations to Technical Specifications**
- **Number of Significant Incidents due to Human-Related Causes**
- **Radioactive Iodines (Gaseous Discharges) [MBq/week], [microSv/week and individual from the critical group] [% of the limit value]: Limiting Value for Total Gaseous Discharges is 40 microSv/year - Committed Effective Dose**
- **Radioactive Aerosols [GBq/week], [microSv/week and individual from the critical group] [% of the limit value] Limiting Value for Total Gaseous Discharges is 40 microSv/year**
- **Reactor Coolant Radiation Situation Evaluation**
- **Fuel Cladding State Evaluation**
- **Current Collective Effective Dose from Film Badge Dosimetry [mSv/month]**
- **Numbers of the Staff Participating Collective Effective Dose [1]**
- **Maximum Receiving Individual Dose for NPP Worker [mSv/Worker]**
- **Maximum Receiving Individual Dose for Supplier Worker [mSv/Worker]**
- **Total Number of the Persons Monitored at Whole Body Counter**
- **Number of WBC Recording Level Overexposure [$>0,1\text{mSv}$]**
- **Number of Workers with Special Decontamination: Medical Intervention**
- **Tritium Liquid Effluents [GBq/month], [microSv/month and individual from the critical group] [% of the limit value]: Limiting Value for Total Liquid Discharges is 6 microSv/year - Committed Effective Dose**
- **Corrosion and Activated Radionuclides from Liquid Effluents**
- **^{14}C (Gaseous Discharges) [MBq/week], [microSv/week and individual from the critical group] [% of the limit value]: Limiting Value for Total Gaseous Discharges is 40 microSv/year - Committed Effective Dose**
- **NPP Vicinity Monitoring Results**
- **Alpha Radionuclides Monitoring Results**
- **^{90}Sr and ^{89}Sr Monitoring Results**

Assessment of the effectiveness of the licensee radiation protection programme

- National and international benchmarking
ISOE database is basic source for occupational exposure benchmarking. Other sources are IAEA workshops and WANO evaluation results.
- What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.

Interfaces:

1. Periodical meeting among licensee, suppliers and Office
2. Regular annual summit between licensee and Office
3. Irregular invitation of licensee to the internal SUJB expert inspection team workshop.
4. Sharing mutual important information within common PC network.

Benefits:

1. Openness and transparency leads to radiation protection level increasing because licensee and Office have the same goal – low doses for workers and individuals in the NPP vicinity.
2. Low doses and radiological event absence create higher credibility of the nuclear industry.

Improvement of the regulatory effectiveness

- Existence of a process to improve regulatory effectiveness. Since when? **Since 2002.**
- If this process exists, briefly describe it.
This process has been started with adoption of the new harmonized legislation linked with the Czech Republic coming up to the European Union. The whole existing legislation has been improved and harmonized. New type of evaluation started together with thorough safety performance indicators implementation.
- What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?
None.
- Do you have an inspection self-assessment program? **YES**
The inspections evaluating commission is carried out regularly once a month. This commission and namely its results serve as inspection feedback.
- Does your RB have and external audit? Feedback of the experience. **YES**
IAEA IRRT mission served as an independent external audit for the Czech regulatory body. The pre-mission was carried out in 2000 and the mission in 2001. The results served as a source just for legislation and inspection procedures improvement in 2002.

FINLAND

Country and Representative Identification

- ☐ **Country:** Finland
- ☐ **Name of the regulatory Body:** Radiation and Nuclear Safety Authority, STUK
- ☐ **Name and post of the person(s) who fill in the questionnaire:** Mr. Veli Riihiluoma , senior inspector Radiation Protection

Legal Matters

❑ Legal framework of the RP regulatory body

▪ Legislation on nuclear energy and regulatory authority:

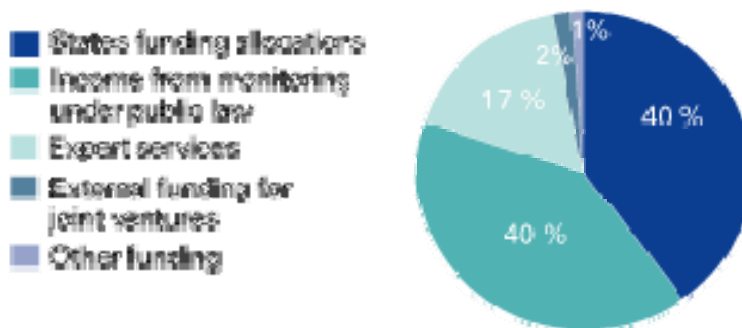
- The Nuclear Energy Act (990/1987) and Decree (161/1988) regulate the use of nuclear energy. The Act has been renewed in 1987. The Nuclear Energy Decree has been renewed in 1988. The Radiation Act and Decree were renewed in 1991.

○ Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc). *Regulatory Body*

- STUK belongs to the administration of the Ministry of Social Affairs and Health.
- As a national safety authority, STUK regulates nuclear power plants and radiation practices.
- STUK operates in a large field. It regulates the use of nuclear energy. It also carries out research work and regulates all other use of radiation (even NIR):
 - *Regulatory Body*
 - Use of nuclear reactors
 - nuclear waste and materials
 - use of radiation
 - *Research Centre*
 - radiation measuring methods
 - radioecology
 - radiation protection
 - biological effects of radiation
 - *Expert organisation*
 - preparedness for radiation accidents
 - training and public information
 - contracted expert services

○ Origin of financial resources (e.g.: taxes, government budget, etc):

- In 2004 STUK's total expenditure was €26,5 million. More than half of the expenditures was covered by the income received from safety regulation and contracted services.



Financing of activities 2004

▪ Number of authorities with competences in radiation protection.

- **Name(s) and competences.**
 - STUK is the only regulatory body for Nuclear Safety and Radiation in Finland.
- **Interfaces, co-operation and communication between them.**
 - STUK has contacts with other research institutes as well as with municipals and citizens.
 - STUK has an own information unit
 - STUK maintains contacts with the Ministry of Trade and Industry, the

Legal Matters

Ministry of the Interior, the Ministry of the Environment and the Ministry for Foreign Affairs.

- **Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)**

STUK participates in the processing of licence applications.

STUK formulates the detailed safety requirements (YVL -guides) concerning the use of nuclear energy (including RP at NPPs). In these guides it is stated e.g. what kind of reports shall be sent to STUK for review.

As an independent regulator STUK ascertains that the nuclear power plants produce energy according to the requirements (assessment, inspection...). This includes RP, emergency planning etc.

STUK's role is to carry out research and assess the quality, comprehensiveness and development of research programmes in NPP sector and waste management

STUK maintains the National Dose Registry

STUK issues Radiological Passports

STUK authorises Dosimeter Services

It advises individuals, the courts and public administration bodies on matters of nuclear safety and radiation protection. It provides technical support in the event of a nuclear emergency and approves emergency plans...

etc.

- **Relationship between nuclear safety and radiation protection authorities.** STUK is the only authority for Nuclear Safety and Radiation in Finland
- **Enforcement capacity of the regulatory body on occupational RP.** STUK has capacity to enforce remedial actions when necessary

Legal Matters

❑ Legal framework on occupational radiation protection

▪ Legislation on occupational RP. Give references..

The Radiation Act (592/1991) and Decree (1512/1991) were renewed in 1991. Also in Government Resolutions, there are details concerning RP.

▪ Legislation is based on (UE directives, ICRP, IAEA, others ...)

As a member of the European Union, Finland implemented European Union directives. Hence, in radiation protection ICRP recommendations are observed. Also the IAEA guidance is essential.

▪ Specific legislation on occupational RP in NPPs.

- RP legislation is mentioned above

▪ Specific guidance on occupational RP in NPPs.

By virtue of several acts and regulations STUK issues detailed regulations (YVL-guides) that apply to the safe use of nuclear energy and to physical protection, emergency preparedness and safeguards.

The publication of a YVL guide does not, as such, alter any previous decisions made by STUK. After having heard those concerned, STUK makes a separate decision on how a new or revised YVL guide applies to operating nuclear power plants, or to those under construction, and to licensees' operational activities. The guides apply as such to new nuclear facilities.

If deviations are made from the requirements of a YVL guide, STUK shall be presented with some other acceptable procedure or solution by which the safety level set forth in the guide is achieved

- STUK issues guidance on nuclear safety and radiation protection. Some specific guidance on occupational RP in NPPs are the following:

- YVL 7.1 Limitation of public exposure in the environment of and limitation of radioactive releases from nuclear power plants
- YVL 7.2 Assessment of radiation doses to the population in the environment of a nuclear power plant
- YVL 7.3 Calculation of the dispersion of radioactive releases from a nuclear power plant
- YVL 7.4 Nuclear power plant emergency preparedness
- YVL 7.5 Meteorological measurements of a nuclear power plant
- YVL 7.6 Monitoring of discharges of radioactive substances from nuclear power plants
- YVL 7.7 Radiation monitoring in the environment of nuclear power plants
- YVL 7.8 Environmental radiation safety reports of nuclear power plants
- YVL 7.9 Radiation protection of workers at nuclear facilities
- YVL 7.10 Monitoring of occupational exposure at nuclear facilities
- YVL 7.11 Radiation monitoring systems and equipment in nuclear power plants
- YVL 7.18 Radiation safety aspects in the design of a nuclear power plant

▪ Does your legal framework requires from the NPPs an official document on occupational RP? Radiation protection procedures (manual) is required in YVL - guides

- **Nature, scope and contents of such a document.**
Procedures on the implementation of radiation protection shall be established at the nuclear facility.
- **Is the document approved by the authority? Which authority?** Radiation protection procedures shall be delivered to STUK for information
- **Are the procedures (developing and supporting the document approved?**
No, but these may be send to STUK for information STUK can review all documents at the NPP site

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee.

Chapters of the Radiation Protection Manual

The procedures shall include according to regulatory guides (YVL 7.9) at least:

- principles of radiation protection and the organisation responsible for implementing them
- behaviour rules in the controlled and supervised areas
- radiation measurements in the controlled and supervised areas
- radiation work permit policy
- individual monitoring
- real-time and individual monitoring of doses
- medical surveillances and radiation work categories of radiation workers
- instructions for using of personal protective equipment
- decontamination of individuals.

Radiation protection procedures shall be kept up to date and evaluated regularly according to a way defined in the quality management system of the nuclear facility. In addition, activities defined in radiation protection procedures shall be evaluated as a part of quality control.

In practice the content of the Radiation Protection manual of the NPPs is much wider than the minimum requirements mentioned above.

Self-assessment of the licensee

- **Does the licensee have a self assessment programme? YES Since when? Main characteristics.** Since the beginning of the operation of the plant the licensee have had quality assurance programmes. The licensee shall systematically develop and maintain the quality assurance programme and also supervise the programme's implementation. The whole programme's relevance and efficiency shall be assessed periodically and the programme shall be amended, where necessary. The self assessment at the NPPs covers all levels including management level.
- **The programme is an initiative of the licensee or it is required by the authority?**
- It has been a joint initiative by the STUK and licensees. The existence of self assessment is programme required in the regulatory guides.
- **Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially). YES.** The regulatory body can evaluate and inspect the effectiveness of the programme. However, the findings of the self assessment are not used as a raw-material in the inspections concerning RP.

Regulatory Body organisation on occupational radiation protection control

☐ Inspectorate organisation

▪ **Resources:**

- **Own personnel (status) or outsourcing?**
STUK has its own staff. They are civil servants
- **Total number of inspectors in your country taking care of occupational radiation protection in NPPs.**
Total STUK staff is 315 people (at the end of 2005) of which around 80 have regulatory duties related with NPP. There are 2 -3 inspectors for occupational radiation protection in nuclear power plants. Also resident inspectors have a central role in issues concerning RP at the NPPs.
- **Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.**
YES: in addition to the 4 nuclear units the Otaniemi research reactor of the Technical Research Centre of Finland in Espoo is also under the regulation of STUK.
- **Distribution of workload per inspector, per activity:**

There can be quite a lot difference between successive years in the area of RP.
At the moment :
 - 10 - 20 % of time on inspection,
 - 20 - 30 % of time on assessment,
 - 20 - 40 % of time to OL3 -project
 - 20 - 30 % of time on others (specify): training, meetings, guidance, etc.
- **Average number of years of experience on occupational radiation protection of inspectors (about 15 years). Degree of rotation in the organisation** The degree of rotation in STUK is not very high. The policy in STUK is to employ new staff in order to maintain the information-flow from senior inspectors to younger. The project dealing with new NPP unit have given a positive impact to the recruitment.

▪ **Types of inspections:**

- **Announced? Non announced? Both?**
Both are in use. Inspections dealing with outages are in some degree non-announced. Periodic inspections, however, in RP have been announced. There has been only one exception after 1998. During 2001 one unannounced inspection with protocol was made in the field of the radiation protection.
- **Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?)**
Within the frames of periodic inspections multidisciplinary approach is preferable. The aim is that every year some new aspects should be included. It is recommended that different experts take part to inspections.

RP experts on the other side take part to other inspections (training, waste management, chemistry, quality control etc.)

▪ **Existence of national teams? Regional teams? Both? Resident inspectors?**

STUK inspections and control on occupational radiation protection of nuclear facilities are carried out by its inspectors at the headquarters (Helsinki). Apart from the headquarters inspectors, there are two resident inspectors per nuclear site who are available in case some special issues in RP are acute.

▪ **What is the dedication of resident inspectors to occupational radiation protection? The**

Regulatory Body organisation on occupational radiation protection control

role of resident inspectors is essential. It is difficult to put their input or role in figures.

- **Inspectors qualification and training (university studies, access to the regulatory body, retraining)**

All STUK radiation protection inspectors have an university degree in scientific or technological areas. There are training programs for new inspectors in STUK. The training includes practical well theoretical issues. All inspectors take part to the constant internal training programs in STUK. Also external courses (for example in auditing) have been used.

- **Inspection organisation and programme**

- **Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns?**

Every year there is one major periodic inspection/NPP in radiation protection. Also other kind inspections are performed. Mostly these inspections focus on some special issues (topical issues, new equipment, some modifications). In dosimetry blind tests are carried out and reported every year. During outages inspections focus on practical follow-up on the work performance and work statistics of some major repair work. Normally inspection protocol is not written during outages but a memorandum will always be done. If there is some major misconduct at the NPP, a formal protocol will be written at the NPP.

- **Number of inspectors per team per inspection.** 2 - 4 inspectors per team (periodic Inspection). During outages inspector can act alone.

- **Duration of the inspection.** A periodic inspection takes normally 2 intensive days. Other inspections last normally 1 day.

- **Do the inspectors also carry out assessment or they are exclusively devoted to inspection?**

STUK inspectors in charge of occupational radiation protection in NPPs also perform assessment of documents and radiological results. They also prepare regulatory guides.

- **Approximate % of time devoted to each phase of the inspection:**

- preparation, 50%
- on site, 25%
- production of documents, etc 25%.

- **Methodology of the preparation of the inspection. Documents consulted prior to the inspection.**

- Review of previous STUK inspection & assessment reports,
- Review of official documentation (instructions, FSAR, analysis),
- Review of operation reports (daily, monthly, outage) submitted to STUK by NPPs,
- Review of resident inspectors reports,
- Review of incident reports,
- Performance indicators,
- Discussion with other inspectors

- **Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public**

- Prior to the inspection, an agenda (inspection plan) is prepared and sent to the licensee containing the topics to be covered during inspection. Inspection plan contains 1 -2 pages.
- After performing and inspection STUK radiation protection inspectors prepare an inspection protocol at the site (written by computer). Protocol contains 4-5 pages. Changes to the content are possible. Finally responsible counterparts agree the results of the inspection by signature.
- It is also possible to prepare an official decision (later) if it is difficult to formulate (due

Regulatory Body organisation on occupational radiation protection control

to e.g. lack of time) the content of requirements at the site.

- an official inspection report can also be prepared, if the content of protocol need some additional information. Unofficial memoranda containing subjective conclusions can also be made by inspectors.

- **Transparency policy.** All inspection documents are official. If a member of public wants to have a copy of inspection documents he or she can have it. On STUK website the description of the main results of inspection process can be seen in annual reports.

☐ **Inspection procedures**

- **Existence of inspection procedures:** YES

- **Main inspection topics:**

Inspections focus on different topics every year. Some possible topics are:

- Review of the ALARA- programme, organisation and engagements. Practical implementation.
- Dosimetry (blind tests)
- Documentation (instructions, dose rates, maintenance protocols etc.)
- Internal audits in occupational radiation protection
- Human and technical resources of the radiation protection service
- Training
- Instrumentation/automation, protective equipment etc.
- Dose estimations and events during the outage. Incident analysis/reports/INES
- Work planning, management of work permits
- General conditioning or radiological areas and general personnel behaviour (visit to controlled areas)
- Entry/exit to contaminated zones, practical arrangements
- General control of radioactive material
- Water chemistry, leaking fuel, waste management
- Materials specification
- System modifications
- Accident analyses

Assessment of the effectiveness of the licensee radiation protection programme

- **How is the assessment carried out?**
 - Only through inspection? NO
 - Through inspection and assessment? YES.
- **What is assessed and how?**
 - licensing documents. YES
 - inspection information. YES
 - Outage final report (results). YES
 - Others (specify): design modifications, source term reduction programme, etc.
- **Indicators used by the authority to assess licensee performance.**
 - Practical implementation of the ALARA Programme in the plant
 - All the information obtained prior (STUK has a PI follow-up) and during inspections
 - Numerical indicators such as: evolution of collective doses, estimations versus final results, maximum and average dose, dose per activity (evolution and estimation versus reality), evolution of dose rates at significant points, number of contaminated workers, etc.
- **National and international benchmarking:** YES. ISOE database is used for international benchmarking.
- **What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.**
 In Finland, there are meetings (training-days) with the under-contractors. There are also many informative meetings prior plant-modifications. Also some ad-hoc meetings with more specific technical or administrative subjects are possible. The leadership of STUK and licensees met also regularly. The feedback is taken in account.

Improvement of the regulatory effectiveness

- **Existence of a process to improve regulatory effectiveness.** YES. **Since when?** it is an on-going process

- **If this process exist, briefly describe it.**
 - It is an on-going process.
 - Indicators are used to evaluate the effectiveness
 - The periodic inspection (PI) program was up-dated in 1998. Target was to focus on essential processes in nuclear and radiation safety. PI -program was evaluated in 2002. In 2006 the program will be evaluated once again.
 - The IRRT - mission (2000, 2003) concentrated into the effectiveness of regulatory work.

- **What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?** The baselines of this process have been jointly established between STUK and the licensees. Other stakeholders, such as the public can participate at a communication level as receptors of the results of the system. International contacts have given many ideas to improve process. Ministries are stakeholders to which the results are reported. One of the main annual targets in regulatory work has under the recent years been the effectiveness of the periodic inspection programme.

- **Do you have an inspection self-assessment program?** YES .

- The results of program are always evaluated at the end of year. This gives feedback for planning the PI -program of the next year. Special themes will be selected as a result of the experience collected by the inspectors.

- STUK has also a wider self-assessment program and a team who conduct self-assessment inspections in a larger scale. Every year different areas are assessed by specially trained experts from STUK. Also external experts are used in self-assessments.

Does your RB have and external audit.? YES.

- An IAEA team of experts visited STUK in March 2000 to conduct an International Regulatory Review Team (IRRT) mission. The major purpose of the mission was to evaluate STUK's effectiveness as an authority in ensuring nuclear and radiation safety. The review (follow up) to review the measures undertaken following the recommendations and suggestions presented in the IRRT-report was conducted in September 2003.

Feedback of the experience. As a consequence of the results of these audits (and internal audits) there have been improvements in the inspection practices.

FRANCE

Country and Representative Identification

- ☐ **Country:** France
- ☐ **Name of the regulatory Body:** Autorité de Sûreté Nucléaire (Nuclear Safety Authority). ASN
- ☐ **Name and post of the person(s) who fill in the questionnaire:** **Sophie FORNER & Stéphane CALPENA** radiation protection and safety inspectors.

Legal Matters

❑ Legal framework of the RP regulatory body

▪ Legislation on nuclear energy and regulatory authority:

- Nuclear Installation Licensing Decree (1963).
- Nuclear Safety Authority Foundation (1973)
- Radiation protection and Nuclear Safety reorganisation in France (DGSNR creation 2002 Decree).
- Public Health Act (2004) appointing radiation protection inspectors and setting out their status.

○ **Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc).**

For the time being, the French Nuclear Safety Authority belongs to the Ministry of Industry and has also to report to 3 Ministers dealing each with Industry, Environment and Health. A law is being prepared to cut the French Nuclear Safety Authority off the Ministry of Industry.

○ **Origin of financial resources (e.g.: taxes, government budget, etc):**

- Its financial resources come from the government budget, however Nuclear Installations need to pay specific taxes every year to the Government (Total: 345,000,000 Euros in 2004).
- Allocated Budget for 2004: 34,000,000 Euros + 53,800,000 Euros for IRSN for technical expertise.

- **Number of authorities with competences in radiation protection.**

○ **Name(s) and competences.**

- Following on from the 2002 reorganisation, the French nuclear Safety Authority, in collaboration with the Labour Department, regulates and inspects all Licensees (medical, industrial, research sites, etc.)

○ **Interfaces, co-operation and communication between them.**

- There are regional agreements in the regions for inspection issues. Furthermore, both headquarters, in Paris, need to agree about the regulation content.
- **Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)**
- It drafts, with the Labour department, radiation protection regulations. Nuclear Safety itself is drafted only by the French Nuclear Safety Authority.
- It inspects nuclear and radioactive facilities, may ask for remedial actions and may also undertake enforcement actions.
- It provides technical support to the regional authorities for emergency response and also approves nuclear safety emergency schedules.
- French inspectors cannot gain access to nominative workers' doses.
- It provides licences to private companies dealing with compulsory radiation protection technical yearly inspections ("qualified experts ?") and also any companies dealing with radiological measurement.
- It provides authorisations for radioactive source or X-ray emitter owners
- It does not approve Dosimeter Services
- It does not inspect or regulate military radiological sites
- Military facilities or equipment cannot be inspected or regulated yet by ASN
- It deals with patient medical radiation protection
- It deals with environmental issues, gaseous and liquid discharges...
- It deals with transport inspection and provide transport Licences
- IRSN (the technical support organisation) centralises all occupational doses and monitors all data throughout a specific national database ; it also centralises all data dealing with source owners.
- IRSN manages the National Environmental Radiological Monitoring Network

▪ **Relationship between nuclear safety and radiation protection authorities.**

- The French Nuclear Safety Authority deals with both since 2002.

▪ **Enforcement capacity of the regulatory body on occupational RP. The ASN can enforce remedial actions when necessary**

Legal Matters

- ❑ **Legal framework on occupational radiation protection**
 - **Legislation on occupational RP. Give references..**
 - Public radiation protection and Licensing issues (2002 Decree)
 - Occupational radiation protection (2003 Decree)
 - Radiological Emergency response (2003 Decree)
 - Patient medical radiation protection (2003 Decree)
 - All these Decrees are backed up by detailed ministerial Orders and when necessary ASN's "decisions" (regulatory direction).
 - **Legislation is based on (UE directives, ICRP, IAEA, others ...)**
France has to write down the radiation protection regulation deriving from the European directives. Such Directives are mainly based on ICRP recommendations. Furthermore, IAEA guidance is also taken into account when drafting the regulation.
 - **Specific legislation on occupational RP in NPPs.**
ASN monitors Licensees' own arrangements dealing with radiation protection. In any case, such Licensees need to comply with the regulation pieces mentioned above. PWRs' outages are closely monitored by the ASN regional offices. Such a monitoring and related inspections include occupational radiation protection.
 - **Specific guidance on occupational RP in NPPs. No.**
 - **Does your legal framework requires from the NPPs an official document on occupational RP? It requires several documents including :**
 - **Nature, scope and contents of such a document. ...**
 - Licensee's Arrangements dealing with general actions to be undertaken prior any plant work : projected dose estimate, risk assessment, ALARA issues, QA, training, staff qualification issues, internal contamination and radiation exposure surveillance, etc.
 - There are also umbrella documents dealing with RP organisation, rules, QA, recording, incident reporting, etc..
 - **Is the document approved by the authority? Which authority?**
Any PWR outage planning is approved, this planning may include RP issues. But the rule of thumb, for the French regulator, is to avoid approving too many documents to keep Licensees solely responsible of their installations so far.
 - **Are the procedures (developing and supporting the document) approved? No,** see previous comment.

Radiation Protection Programme of the licensee

In case an official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee.

Chapters of the Radiation Protection Manual

- Not relevant.

Self-assessment of the licensee

- **Does the licensee have a self assessment programme? YES Since when? Main characteristics.**
For nuclear Safety and RP: external assessment, independent internal assessment and self-assessment are usually performed. Improvement actions are then put in place. (e.g.: Audits from Licensee's headquarters, from other nuclear sites, throughout an OSART mission, when inspected by ASN... Internally by the site's health & safety inspectors and so on.)
- **The programme is an initiative of the licensee or it is required by the authority? Licensees were pushed, for years, by the Regulator, to enhance Licensees' RP, to recruit Health physicists and RP staff and to organise self assessment actions. There are, now on, ALARA committees on nuclear sites monitoring and piloting improvement actions and PWR sites are, now on, properly staffed for radiation protection.**
- **Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially). YES.**
Licensees are usually very open and often provide ASN inspectors with any documents dealing with safety and radiation protection.

Regulatory Body organisation on occupational radiation protection control

□ Inspectorate organisation

- **Ressources:**
 - **Own personnel (status) or outsourcing?**
ASN has its own staff. Most of them are civil servants, a few of them are contracted for a certain period of time and 30 % are seconded from IRSN.
 - **Total number of inspectors in your country taking care of occupational radiation protection in NPPs.**
Total ASN staff about 380 persons in which 150 nuclear installation inspectors and 50 for other facilities (concerned by ionising radiation). All nuclear installation inspectors have to deal with nuclear safety and occupational radiation protection. Moreover, there are also about 5 inspectors or "project officers", in the headquarters, dealing only with occupational radiation protection for nuclear installations.
 - **Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.**
It is possible but it's not the rule of thumb.
 - **Distribution of workload per inspector, per activity:**
 - 25 % of time on inspection,
 - 35 % dealing with PWR outages, Tech. Specs waivers, incidents, authorisations and so on.
 - 40 % of time on others (specify): training, meetings, analyses, meeting, mail, information, etc
 - **Average number of years of experience on occupational radiation protection of inspectors (5 years). Degree of rotation in the organisation : the turn over is high in the French organisation, about 5 years.**
- **Types of inspections:**
 - **Announced? Non announced? Both?**
75 % announced, 25 % unannounced.
 - **Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?**
There are specific occupational radiation protection inspections and also mixed nuclear safety & radiation protection inspections, sometimes with experts from IRSN, sometimes with specialised inspectors.
- **Existence of national teams? Regional teams? Both? Resident inspectors?**
The bulk of radiation protection regulatory monitoring is performed by the regional teams of the

Regulatory Body organisation on occupational radiation protection control

ASN especially during PWRs' outages and maintenance activities on chemical plants.

- **What is the dedication of resident inspectors to occupational radiation protection?** *ASN hasn't got any resident inspectors.*
- **Inspectors qualification and training (university studies, access to the regulatory body, retraining)**
Inspectors are all, at least, chartered engineers (Master of Sciences) and they undergo a specific 9 month-training organised by ASN.

□ Inspection organisation and programme

- **Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns?**
 - 3 PWR outage inspections where radiation protection is also scrutinised.
 - A couple of inspections per PWR site are also performed a year.
- **Number of inspectors per team per inspection.** 2 or 3 inspectors plus an IRSN expert.
- **Duration of the inspection.** 1 day preparation before going on site, 1 day on site, 2 days for analysis, follow-up letter and report.
- **Do the inspectors also carry out assessment or they are exclusively devoted to inspection?**
Devoted only...
- **Approximate % of time devoted to each phase of the inspection:**
 - preparation, 25%
 - on site, 25%
 - production of documents, etc 50%.
- **Methodology of the preparation of the inspection. Documents consulted prior to the inspection.**
 - Review of previous ASN Inspection & Assessment reports
 - Review of the licensees' documents (headquarters' and sites')
 - Review of incident reports
- **Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internal, which are sent to the licensee and which are public**
 - Prior to the inspection, an agenda is prepared by inspectors. The main topics and specific points to be investigated are sent to the licensee before the inspection.
 - After the inspection, a follow-up letter is sent to the Licensee and issued to the public via the ASN web site. An internal report may also be produced by the inspector if necessary.
- **Transparency policy.** ASN publishes a detailed annual report of nuclear safety. It also publishes a two-monthly report including all nuclear safety events which occurred during such a period of time, this report includes also several pages dealing with one nuclear safety or radiation protection topic such as : ageing, contractors, patient dosimetry, etc.

□ Inspection procedures

- **Existence of inspection procedures:** There are pieces of topical guidance, different agendas to be used, documents to be filled in, etc.
- **Main inspection topics:**
 - 1/ NPP housekeeping especially during outages and maintenance operation...**
 - Contamination control on plant works,
 - Means : proper dress and dressing organisation in cloakrooms, sticky mats, proper CCA limits, proper signs, to avoid spreading contamination...
 - Adequate work organisation,
 - To enforce Foreign Material Exclusion (FME),
 - To separate as far as possible Entrance & Exit,

Regulatory Body organisation on occupational radiation protection control

- Constant proper depression (airborne contamination issues),
- No wood policy (or kept wrapped),
- To improve behaviour, housekeeping and FME culture,
- 2 full height gas flow proportional detectors (clothes/body : 4Bq/cm² beta) + a third detector before going off-site (@ 10000 Bq gamma) + 4Bq/cm² handheld pancake G + CPO @ 580 Bq)
- Qualification, training, preparation, QA, etc.
- And "common sense" : pathways, desk location, etc.

2/ PWR radiation protection during especially during outages or maintenance operations :

- Qualification, training, preparation, QA, documents, organisation, etc.
- Radiation protection practices on the plant works including : common sense, appropriate desk location for QA, etc. ALARA desks to be settled down (low dose area with a green desk to check and fill in QA documents), how to get rid of hot spots, how to reduce the source term...
- Proper means (appropriate radiological protections + proper RCA limits and signs)
- Appropriate work organisation, appropriate "time, shield, distance", appropriate behaviour and attitude as regards RP
- Radiation protection management to be inspected : Licensees performance indicators, and their uses,
- Discussions on comparisons with other PWRs,
- How the Licensee intend to improve RP
- Clear protagonists' missions and global organisation
- To take stock of Licensees' internal RP audits and inspections (different from the assessment and analyses branch)
- Staff commensurate to work and missions,
- Proper use of competence, site's difficulties...
- Licensee's cross audits analysis (between sites),
- Adequate means, pieces of equipment, logistics,
- Interfaces management between contractors, different Licensee's teams and both,
- Training, competence, adequacy man/work, test ?
- How to take into account RP & safety before contracting...
- RP debrief prior any work...
- How the Licensee take into account its own and others' feedback experience...
- Human factors consideration...
- Attitude or behaviour correction organisation,
- Involvement of all top managers,
- Etc.

3/ ALARA approach (how Licensees optimise RP),

- 1/ To get systematic Projected Dose Estimate for all maintenance operations or interventions,
- 2/ involving all Licensee's top managers in this approach,
- 3/ to investigate Licensees' projected investments to reduce doses,
- 4/ investigates performance indicators used by Licensees to improve on ALARA issues,
- 5/ to ask for the creation for each Licensee of an ALARA COMMITTEE,
- 6/ to push to use others' feedback experience,
- 7/ to investigate the Licensee procedures / organisation to perform adequate Projected Dose Estimate (division into elementary tasks, measurement issues for each task, how to choose relevant hypotheses dealing with timing and dose rates for PDEs, interfaces Licensees/contractors when performing PDE, how records are used to perform PDEs, dose rates measurement prior intervention and investigation into Licensees' remedial action organisation when significant discrepancy, adequate PDE QA depending on the dose stakes, shift hand-over organisation (PDE review ? Concerns to be dealt with, etc., pieces of equipment and tools choice policy, projected organisation / ground reality discrepancies)
- 8/ More ground Licensee surveillance (a third party would be welcome)
- 9/ to divide jobs performing maintenance like surgery operation...
- 10/ to improve balance awareness between Cost, Reliability, Nuclear Safety and Radiation protection

-

Assessment of the effectiveness of the licensee radiation protection programme

- **How is the assessment carried out?**
 - Only through inspection? NO
 - Through inspection and assessment? YES.
- **What is assessed and how?**
 - Licensing documents. YES
 - Inspection information. YES
 - Outage final report (results). YES
 - Others (specify): design modifications, source term reduction programme, etc.
- **Indicators used by the authority to assess licensee performance.**
 - All the information obtained during inspections
 - Numerical indicators such as: evolution of collective doses, estimations versus final results, maximum and average dose, dose per activity (evolution and estimation versus reality), evolution of dose rates at significant points, number of contaminated workers, etc.
- **National and international benchmarking:** Only via international joint inspections with other regulators and exchange of inspectors between regulators. Licensees perform a few benchmarking operations.
- **What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.**
International symposium, national congresses organised by the "Société française de radioprotection".

Improvement of the regulatory effectiveness

- **Existence of a process to improve regulatory effectiveness.** Rather poor. Since when?
- **If this process exist, briefly describe it.**
- **What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?** There were not any other involved stakeholders but ASN, IRSN and Licensees.

Do you have an inspection self-assessment program?

Does your RB have and external audit ?

Feedback of the experience ?

ASN has organised an internal audit routine performed on regular bases by some regional inspectors and the ASN headquarters. Such audits cover general aspects : QA, organisation, training, performance indicators, management process, etc. They did not cover technical issues. We also undergo external audit from the Ministry of Industry, every 3 years. The latter goes more in depth than the former with individual interviews and contacts with Licensees and other stakeholders. Last but not least, the ASN General director has asked the IAEA to perform an IRRT in 2007.

There are of course some feedback experience actions deriving from the audits mentioned above.

GERMANY

Country and Representative Identification

- ☐ **Country:** Germany
- ☐ **Name of the regulatory Body:**
Federal Minister of Environment, Nature conservation and Reactor Safety (BMU, Supervisor, Federal Level)
Competent State Ministry (State level, on behalf of BMU/Federal Level)
- ☐ **Name and post of the person(s) who fill in the questionnaire:**
W. Pfeffer, J. Kaulard, GRS, consultant to Federal Level

Legal Matters

- ❑ **Legal framework of the RP regulatory body**
 - **Legislation on nuclear energy and regulatory authority:**
Atomic Energy Act December 1959, last amended 2005
Radiological Protection Ordinance (2001, 2002)
 - **Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc)**
Ministry of Federal/State Government due to Federal structure of Germany
(Consulting Commissions RSK, SSK, Consultant organisations TÜV)
 - **Origin of financial resources (e.g.: taxes, government budget, etc)**
Government Budget,
supporting/consulting technical expert organisations paid by utility according to effort
 - **Number of authorities with competences in radiation protection.**
One on Federal Level, one in each State for Radiation Protection/Supervisory Authority, in the States competencies may be separated to more than one competent organisation to cover the fields of Radiation Protection and Reactor Safety
 - **Name(s) and competences.**
Federal Minister of Environment (BMU) on federal level
(Supervision of activities of competent State Ministries)
Competent State Minister on State level (different names in different States)
(Licensing and supervision of nuclear facilities in reactor safety and radiation protection)
 - **Interfaces, co-operation and communication between them.**
Reporting between State and Federal Level
Regular Meetings of dedicated competent working groups with representatives of the competent Ministries
 - **Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)**
On Federal Level: Supervision of activities of the State Authorities, Regulatory Guidelines under Legislative Framework
On State level: Licensing and Supervision of nuclear facilities, inspection, assessment.
For support of authorities independent expert organisations (TÜV, GRS for special issues) are implemented to do evaluations, judgements and inspection.
 - **Relationship between nuclear safety and radiation protection authorities.**
On Federal level both are sub-departments of the Federal Ministry
On State level, depending on the governmental structure, both departments may be in the same or in different ministries
 - **Enforcement capacity of the regulatory body on occupational RP**
Independent expert organisations in reactor safety and radiation protection,
Competent advisory groups to cover more generic problems
- ❑ **Legal framework on occupational radiation protection**
 - **Legislation on occupational RP. Give references.**
Radiological Protection Ordinance (StrlSchV)
Dedicated guide lines, especially "IWRS II" (Guideline on the radiation protection of personnel performing activities in repair, maintenance, disposal and dismantling of nuclear facilities, Part 2: Radiation protection measures during operation and decommissioning, re-published 10th of December 2004) to cover new StrlSchV and new guidance on dosimetric issues
 -

Legal Matters

- **Legislation is based on (UE directives, ICRP, IAEA, others ...)**
Directly to cover EU-Directives (as obligatory), other guidance considered.
-
- **Specific legislation on occupational RP in NPPs**
No special legislation than those documents already addressed
- **Specific guidance on occupational RP in NPPs.**
See above: IWRS, dosimetric guidance, special KTA-guidelines (KTA: kerntechnischer Ausschuss, (German) Nuclear Safety Standards Commission)
- **Does your legal framework requires from the NPPs an official document on occupational RP?**
NPPs have to work out special RP-Documents, which is broken down in quite detailed procedures to be covered, which are evaluated and checked by independent experts and agreed by the authorities.
 - **Nature, scope and contents of such a document**
see above
 - **Is the document approved by the inspection authority? Are the procedures approved?**
yes, see above
 - **Are the procedures (developing and supporting the document approved?**
yes, see above

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee

The Licensee has to work out a "Radiation Protection Regulation" according to the demand of the Radiation Protection Ordinance (StrlSchV: Legal Prescription) and of the detailed prescriptions of the KTA-Standard "Requirements for the Operating Manual". Especially organisational structure and responsibilities, radiological surveillance of areas, public and personnel (dosimetry), storage and handling of radioactive material and relevant documentation have to be covered.

Self assessment of the licensee

- **Does the licensee have a self assessment programme? Since when? Main characteristics. Definition of self-assessment is open:**
According to IWRS (self-)assessment has to be performed since the early time of this regulatory document for dose relevant tasks. These reports have to be submitted to the authorities and are checked there too.
- **The programme is an initiative of the licensee or it is required by the authority**
see above, initiatives of the licensee are additional possibility
- **Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially)**
yes, see above

Regulatory Body organisation on occupational radiation protection control

☐ **Inspectorate organisation**

▪ **Resources:**

- **Own personnel (status) or outsourcing?**
own personnel for state authorities,
personnel of subordinate authorities,
Personnel of independent expert organisations.
- **Total number of inspectors in your country taking care of occupational radiation protection in NPPs.**
Only a few persons per State, but more are available covering RP-issues together with other topics
- **Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.**
For Authorities: Depending on organisation of State authorities
For personnel of expert organisation yes.
- **Distribution of workload per inspector, per activity: % of time on inspection, % of time on assessment, % of time on others (specify).**
Cannot be defined due to complexity of organisation and number of plants.
- **Average number of years of experience on occupational radiation protection of inspectors. Degree of rotation in the organisation.**
Cannot be defined due to complexity of organisation and number of plants, but due to age-structure long experience for most of the persons is probable, but changing due to retirement.

▪ **Types of inspections:**

- **Announced? Non announced? Both?**
Both
- **Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?**
Differing tasks, but normally inspectors (of authorities OR expert organisations) are specific for their tasks, but may participate in inspections covering nuclear safety.

▪ **Existence of national teams? Regional teams? Both? Resident inspectors?**

Regarding authorities, the teams are not national-wide, but linked to a state, expert organisations may cover more than one state, in a certain sense over-regional.
There are no residential inspectors, but normally representatives of the authorities (or experts acting on behalf of them) are present in the plant very often to inspect/discuss specific tasks

▪ **What is the dedication of resident inspectors to occupational radiation protection?**

No resident inspectors

▪ **Inspectors qualification and training (university studies, access to the regulatory body, retraining)**

Members of Ministry, with university education
Independent experts technical education of university and long term practical experience

▪

Regulatory Body organisation on occupational radiation protection control

- ☐ **Inspection organisation and programme**
 - **Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns?**
 Example for one State:
 2 review inspections per site at least on different items
 (additional) different inspections per year during operation and outage
 - **Number of inspectors per team per inspection**
 Review inspection: 2 experts from consulting (independent expert) organisation;
 Others: (1 inspector), 1 expert
 (Remark: in Germany acting of independent experts on behalf of the authorities with the possibility of a member of the authorities participating the inspection is "normal practice")
 - **Duration of the inspection**
 Review inspection: 2 days
 Others: 1 day
 - **Do the inspectors also carry out assessment or they are exclusively devoted to inspection**
 Both
 - **approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc**
 ?
 - **Methodology of the preparation of the inspection. Documents consulted prior to the inspection.**
 List with scope of review inspection
 - **Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public.**
 expertise document by expert organisation
 document normally are available to the licensee, but are not public
 - **Transparency policy**
- ☐ **Inspection procedures**
 - **Existence of inspection procedures**
 Yes for review inspections
 - **Main inspection topics**
 Review inspection: total scope of RP programme over 2 years

☐

Assessment of the effectiveness of the licensee radiation protection programme

- **How is the assessment carried out**
 - **Only through inspection**
 - **Through inspection and assessment?**
Both
 -
 -
- **What is assessed and how?**
 - **licensing documents**
no, that is an issue of the licensing procedure
 - **inspection information**
yes
 - **shutdown final report (results)**
yes
 - **Others (specify)**
Reports on scientific items as backfitting, Reports on waste and emission/releases
- **Indicators used by the authority to assess licensee performance**
Collective dose, individual dose, emission results, differences of calculated / measured doses
- **National and international benchmarking**
ISOE, WANO
- **What interfaces** (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.

Improvement of the regulatory effectiveness

- **Existence of a process to improve regulatory effectiveness. Since when?**
- **If this process exists, briefly describe it.**
- **What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?**
- **Do you have an inspection self-assessment program?**
- **Does your RB have and external audit? Feedback of the experience**

HUNGARY

Country and Representative Identification

- ☐ **Country:** Hungary
- ☐ **Name of the regulatory Body:** Hungarian Atomic Energy Authority (HAEA).
- ☐ **Name and post of the person(s) who fill in the questionnaire:** Mr. Istvan Vegvari, inspector, expert in RP

Legal Matters

- ☐ **Legal framework of the RP regulatory body**
 - **Legislation on nuclear energy and regulatory authority:**
 - Act CXVI of 1996 on Atomic Energy;
 - Governmental Decree 89/2005. (V. 5.) on the nuclear safety requirements of nuclear facilities and the related regulatory activities (with Nuclear Safety Regulations);
 - Governmental Decree 114/2003. (VII. 29.) on the duties, scope of authority and the jurisdiction of imposing penalties of the Hungarian Atomic Energy Authority, and on the activity of the Atomic Energy Co-ordination Council.
 - **Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc).**
 - The Hungarian Atomic Energy Authority (HAEA) is a central public administration, dealing with the peaceful use of nuclear energy under the supervision of the Government.
 - HAEA is independent both organisationally and financially interested in promoting the application of atomic energy and reports annually to the Hungarian Parliament.
 - **Origin of financial resources (e.g.: taxes, government budget, etc):**

The Act on Atomic Energy provides two financial sources:
a specific sum is provided annually from the state budget

 - to cover the costs of technical support activities assisting the work of the Authority,
 - to cover the development costs related to the emergency preparedness and response activities and
 - to cover the costs of the Authority as a consequence of its international obligations;

Licensees of nuclear installations are obliged to pay an inspection fee to the Authority in the manner and to the extent defined in the Act on Atomic Energy.
 - **Number of authorities with competences in radiation protection.**
 - **Name(s) and competences.**

The Act on Atomic Energy allocates regulatory, official and professional administrative tasks to several ministries.

 - The technical side of plant radiation protection is the task of the Hungarian Atomic Energy Authority (HAEA),
 - the regulation of radiation protection (radiation protection directly affecting humans) belongs to the Ministry of Health,
 - while the issue of releases and thus the protection of the environment belong to the Ministry of Environmental Protection.

Concerning the radiation protection in Paks NPP, the three competent authorities are:

 - State Public Health and Medical Officer's Service,
 - Nuclear Safety Directorate of the HAEA,
 - Lower Danube Valley Environmental Inspectorate
 - **Interfaces, co-operation and communication between them.**

With regard to the complexity of scope of the above authorities and their interconnection, the HAEA signed an agreement with the National Public Health and Medical Officer Service (NPHAMOS) in March, 2003. Its objective is to harmonize the inspections, the investigations of technical radiation protection and

Legal Matters

radiation protection, and to ensure full scope supervision of these fields within the nuclear installations. This bilateral agreement will be extended to a trilateral one to harmonize the activities of the above authorities.

- **Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)**

- Role of HAEA

Govt. Decree 89/2005 (V. 5.) placed the technical issues of radiation protection related to nuclear installations and their systems and equipment in the Authority's scope of competence. These issues are addressed in the Nuclear Safety Regulations (NSRs) that are appendices of the Decree.

- Vol #1 of the NSRs defines the contents of the radiation protection related sections of the Preliminary SAR necessary for the request of the installation and operating licenses and that of the same section of the FSAR. The same volume prescribes the regular analysis of the radiation protection indicators of the operation and the utilization of the experience within the framework of the PSR.
- Vol #3 sets out the main radiation protection principles related to the design of NPPs, the stipulations concerning the handling of fresh and irradiated fuel and radioactive waste, and the requirements towards dosimetry control systems, shielding, and systems influencing radioactive emission.
- Vol #4 summarizes the requirements concerning the execution and documentation of radiation protection activities. The same volume deals with the requirements relating to the handling of nuclear fuel and radioactive wastes.

Regular and unplanned inspections of HAEA focus on the following fields of technical radiation protection:

- source evaluation;
- operation of systems providing operational adequacy;
- technical radiation protection during maintenance;
- management and collection of radioactive wastes;
- abnormal radiation situations

- Role of NPHAMOS

The Tolna County Institute of NPHAMOS regularly inspects the workplace radiation protection conditions of the Paks NPP, and, in accordance with the above agreement, fortnightly consults the resident inspectors of the HAEA. Exchange of the actual inspection records and experience takes place during these consultations.

- **Relationship between nuclear safety and radiation protection authorities.**

- The Hungarian Atomic Energy Authority (HAEA) holds the exclusive authority for nuclear safety in Hungary.
- As concerning radiation protection, the Act on Atomic Energy allocates regulatory, official and professional administrative tasks to the above mentioned authorities.
-

- **Enforcement capacity of the regulatory body on occupational RP.**

Both HAEA and NPHAMOS have capacity to enforce remedial actions when necessary.

Legal Matters

❑ Legal framework on occupational radiation protection

▪ Legislation on occupational RP. Give references..

- Decree of the Minister of Health 16/2000 (VI. 8.) on the execution of certain provisions of Act CXVI of 1996 on Atomic Energy associated with radiation protection
- Decree of the Minister of Health 30/2001 (X.3.) on the operational radiation protection of the outside workers.
- Govt. Decree 89/2005 (V. 5.) focuses on the technical part of radiation protection in nuclear facilities.

▪ Legislation is based on (EU directives, ICRP, IAEA, others ...)

As a member of the European Union, Hungary has to carry out the transposition of European directives. The above mentioned ministerial decrees are mainly based on ICRP 60, IAEA SS-115, Council Directives 96/29/EURATOM and 90/641/EURATOM.

▪ Specific legislation on occupational RP in NPPs.

According to the Decree of the Minister of Health 16/2000 (VI. 8.),

- The licensee is obliged to establish a Radiation Protection Service and to provide all personnel and material means necessary to operate it. The Radiation Protection Service prepares the Workplace Radiation Protection Regulations (Workplace RPR).
- The tasks of the Radiation Protection Service are defined in details in the Workplace RPR, taking into consideration the requirements of this Decree.

According to the Govt. Decree 89/2005 (V. 5.),

- The NPP shall prepare regular reports and special incident reports and shall submit such reports to the HAEA. These reports contains all relevant information about the radiation protection performance of the licensee.
- The types of reports (quarterly, annually or after outages), their content and formal requirements, the range of incidents subject to reporting obligation, as well as the methodology of and deadlines for reports are prescribed by the Nuclear Safety Regulations Vol #1.

▪ Specific guidance on occupational RP in NPPs.

Director General of HAEA issues guidance on nuclear safety. Some specific guidance on radiation protection in NPP are the following:

- Guideline # 1.20: Inspection of Technical RP in NPPs;
- Guideline # 3.7: Technical RP Aspects of Design for System Components in NPPs
- Guideline # 4.4: Technical RP Inspection in NPPs

▪ Does your legal framework requires from the NPPs an official document on occupational RP? YES. Workplace Radiation Protection Regulations (Workplace RPR).

○ Nature, scope and contents of such a document.

The Workplace Radiation Protection Regulations is a licensing document reflecting the practical implementation of the licensee's responsibility for RP through the adoption of safety policies, radiological and medical surveillance, training, procedures and other measures implemented to apply the ALARA principle.

○ Is the document approved by the authority? Which authority?

YES. The Workplace RPR is to be approved by the Chief Medical Officer of the NPHAMOS, based on the expert's opinion of the National Research Institute for Radiobiology and Radiohygiene (NRIRR). The acquisition of the expert's opinion is the responsibility of the NPP

○ Are the procedures (developing and supporting the document approved? NO.

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee.

Chapters of the Workplace Radiation Protection Regulations

- Generalities
- Responsibilities and commitments
- Organigram.
- Connection to the Authorities
- Norms for Radiation Protection
- Access and working conditions in radiological zones
- Sources of the radiation exposure
- Access to/from the controlled area
- Rules of conduct and personal hygiene in the controlled area
- Radiological surveillance
- Administrative measures for radiation protection
- Technical measures for radiation protection
- Procurement, management, storage, recording and control of radioactive and nuclear materials (fuels excepted)
- Transport of equipments, objects and materials containing radioactive or nuclear material (fuels excepted)
- Giving medical aid for potentially contaminated injuries
- Complementary radiological measures for the operation of Maintenance and Practising Centre
- Annexes

Self-assessment of the licensee

- **Does the licensee have a self assessment programme? YES Since when? Main characteristics.** Since the beginning of the operation of Paks NPP the licensee have had quality assurance programmes. Since year 1997, according to the new Nuclear Safety Regulations a comprehensive method of self assessment is being implemented.
- **The programme is an initiative of the licensee or it is required by the authority?** It has been a common initiative of the licensee and the nuclear safety authority (HAEA).
- **Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially). YES.** The HAEA has to evaluate the programme of the licensee. E.g. submitting corrective actions after an event/incident to the regulatory body is mandatory.

Regulatory Body organisation on occupational radiation protection control

☐ Inspectorate organisation

- **Resources:**
 - **Own personnel (status) or outsourcing?**
HAEA has its own staff. The nuclear safety inspectors are government officials.
 - **Total number of inspectors in your country taking care of occupational radiation protection in NPPs.**
 - Total staff of HAEA Nuclear Safety Directorate: 50 people, of which around half are nuclear (and radiation) safety inspectors. There are 5 resident inspectors in the Paks NPP.
 - The Tolna County Institute of NPHAMOS4 has 2 inspectors for radiohygienic inspections of the nuclear power plants.
 - **Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.**
YES: In addition to the 4 nuclear units of Paks NPP, they also control the Interim Spent Fuel Storage Facility at Paks and the two research reactors located in Budapest.

Regulatory Body organisation on occupational radiation protection control

-
- **Distribution of workload per inspector, per activity:**
 - 35 % of time on licensing
 - 35 % of time on inspection and assessment
 - 30 % of time on others (specify): training, meetings, emergency preparedness, etc
- **Average number of years of experience on occupational radiation protection of inspectors** (10 years, experience on nuclear safety). **Degree of rotation in the organisation** The degree of rotation in HAEA is not high.
- **Types of inspections:**
 - **Announced? Non announced? Both?**
 - Although the system of HAEA allows for non announced inspections, almost 100% of the inspections are announced.
 - The local representatives of NPHAMOS inspect the NPP regularly (weekly). Non-announced inspections are also allowed.
 - Other categorization of inspections of HAEA:
 - i) 'target-inspections' and
 - ii) 'comprehensive inspections'.
 - The radiation protection is one of the permanent topics of the 'comprehensive inspections'.
 - **Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?)**
 - Inspections of HAEA focus nuclear, radiation and waste safety.
 - Inspections of NPHAMOS are specific on radiation protection (radiohygiene).
- **Existence of national teams? Regional teams? Both? Resident inspectors?**
 - HAEA's inspection on nuclear and radiation safety is carried out by its inspectors at the headquarters (Budapest). The five resident inspectors of HAEA in Paks devote significant rate of their time to supervise radiation protection and radwaste safety issues.
 - The radiohygienic inspections of NPHAMOS are carried out by its local responsible organisation (Tolna County Institute).
- **What is the dedication of resident inspectors to occupational radiation protection?**
The technical radiation protection is one the most focused areas of their inspection activities (15-20 % of their time)
- **Inspectors qualification and training (university studies, access to the regulatory body, retraining)**
 - All HAEA inspectors are required to have a university or academic degree in scientific or technical areas.
 - Additionally, in order to belong to the Authority, it is necessary to participate a comprehensive conversation (interview). A significant part of the candidates have been rejected.
 - According to the Decree of the Minister of Health 16/2000 (VI. 8.), a comprehensive radiation protection training shall be provided to those
 - performing the regulatory control of workplaces of occupational exposure
 - providing expertise services in the field of radiation hygiene and radiation protection.
The periodicity these comprehensive courses is 5 years.
- **Inspection organisation and programme**
 - **Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns?**
 - Generally 1 per year during the refuelling outages. (The Paks NPP has 4 units). These 3-4 weeks outages are supervised (from radiation protection point of view) by the resident inspectors of HAEA.
 - The 'comprehensive inspection' involving radiation protection is carried out also annually.
 - There are also special inspections in case of: supporting the licensing process in case of design modifications.

Regulatory Body organisation on occupational radiation protection control

- **Number of inspectors per team per inspection.** 2 or 3 inspectors per team. (focused on radiation protection)
- **Duration of the inspection.** On average, a routine inspections takes 1 day, the 'comprehensive inspections' takes 4 days.
- **Do the inspectors also carry out assessment or they are exclusively devoted to inspection?**
HAEA inspectors perform assessment of documents and radiological results (exposures of the personnel, airborne and liquid discharges, etc.).
- **Approximate % of time devoted to each phase of the inspection:**
 - Preparation 30 %
 - on site, 30 %
 - production of documents, etc 40%.
- **Methodology of the preparation of the inspection. Documents consulted prior to the inspection.**
 - Review of previous Comprehensive Inspection reports
 - Review of licensing official documentation (HAEA's resolutions)
 - Review of Quarterly Reports (or Annual Reports) submitted to HAEA by Paks NPP.
 - Review of minutes (written by resident inspectors)
 - Review of event/incident reports.
- **Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public**
The legal framework for HAEA inspections is established in the Nuclear Safety Regulations (Annexes to the Governmental Decree 89/2005. (V. 5.) on the nuclear safety requirements of nuclear facilities and the related regulatory activities).
 - Prior to the inspection, an inspection plan is prepared and an official letter sent to the licensee containing the topics to be covered during inspection.
 - The names of the inspectors are also indicated. The 'Comprehensive inspections' are co-ordinated by a designated inspector.
 - After performing an inspection, HAEA inspectors are obliged to write an official report about the topics. The whole report is compiled by the designated leader of the inspection process. There is no time limitation for it, but practically should be issued not later than 1 month after inspection completion.
 - The main conclusions of these inspections are summarized in the Annual Report of the HAEA-NSD and HAEA's Annual Report to the Hungarian Parliament. These are public and can be downloaded from the website of the regulatory body.
- **Transparency policy.**
 - The transparency is one of the key elements of the HAEA's safety policy.
 - Policies, annual reports and other relevant documents (reports of international expert missions) can be downloaded from the website of HAEA.

□ **Inspection procedures**

- **Existence of inspection procedures:** YES.

▪ **Main inspection topics:**

Inspection topics of HAEA:

- Review of the ALARA programme, special focuses on outages.
- Human resources of the radiation protection service.
- Instrumentation. (Validity of the certifications)
- Dose estimations (external and internal exposures).
- Source term reduction initiatives.
- Shielding activities.
- Management of radiological work permits
- Entry/exit to the controlled areas
- Training activities

Inspection topics of NPHAMOS:

- Supervise modifications and extraordinary events
- Check compliance with radiation safety (radiohygiene working conditions , occupational aptitude for employees, training of employees, external, internal dose);

Regulatory Body organisation on occupational radiation protection control

- Perform in situ radiation surveys
- Take samples for laboratory measurements
- Make a protocol or take a decision in the case of any abnormal situation

Assessment of the effectiveness of the licensee radiation protection programme

- **How is the assessment carried out?**
 - Only through inspection? NO
 - Through inspection and assessment? YES.
- **What is assessed and how?**
 - licensing documents. YES
 - inspection information. YES
 - Outage final report (results). YES
 - Others (specify):
 - Quarterly Reports,
 - Annual Reports
 - Periodic Safety Reviews
 - Design modifications
- **Indicators used by the authority to assess licensee performance.**
 - Information obtained during 'Comprehensive inspections'.
 - Information obtained from Quarterly Reports and Annual Reports
 - Distribution of individual doses
 - Trends in collective doses
 - Dose rates at main components
 - Number of contaminated workers
 - Internal exposure
- **National and international benchmarking:** YES. ISOE database is used for international benchmarking.
- **What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.**
 - a) The licensees are involved in legislation process, especially in the amendment of the Nuclear Safety Regulations.
 - b) The main event for the Hungarian experts in radiation protection is a 3-day seminar, organized by the Hungarian Radiation Protection Association (Associate Society to IRPA). This meeting is good opportunity to share the experiences.

Improvement of the regulatory effectiveness

- **Existence of a process to improve regulatory effectiveness.** YES. Since when? Since 2006, IT IS IN ELABORATION.
- **If this process exist, briefly describe it.**
- **What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process? Do you have an inspection self-assessment program?**
- **Does your RB have and external audit.? Feedback of the experience.**

JAPAN

Country and Representative Identification

- ☐ **Country:** Japan
- ☐ **Name of the regulatory Body:** Nuclear and Industrial Safety Agency (NISA)
- ☐ **Name and post of the person(s) who fill in the questionnaire:**
Yoshihisa HAYASHIDA
Senior Officer & Senior Researcher
Safety Information Research Division
Japan Nuclear Energy Safety Organization (JNES)
(JNES is an Independent Administrative Agency, which is an expert organization who conducts
specialized and fundamental activities to ensure nuclear safety, in collaboration with NISA.)

Legal Matters

- ❑ **Legal framework of the RP regulatory body**
 - **Legislation on nuclear energy and regulatory authority:**
 - Atomic Energy Basic Law (1955)
 - Law on Regulation for Nuclear Source Material, Nuclear Fuel Material and Reactors (1957)
 - Electricity Business Law (1964)
 - **Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc).**
It is an organization in the Ministry of Economy, Trade and Industry (METI).
 - **Origin of financial resources (e.g.: taxes, government budget, etc):**
 - The source of financing is the government budget.
 - NISA budget for 2004: About 300,000,000 euros
(In which, about 240,000,000 euros for nuclear energy)
 - **Number of authorities with competences in radiation protection.**
 - **Name(s) and competences.**
 - Nuclear and Industrial Safety Agency (NISA): Authority for nuclear safety and radiation protection on nuclear power plant.
 - Ministry of Health, Labour and Welfare (MHLW): Authority for safety of workers. (health care, environment management of workplace etc.)
 - Ministry of Education, Culture, Sports and Technology (MEXT): Authority for nuclear safety and radiation exposure on research reactor, and control of radioisotopes.
 - Nuclear Safety Commission of Japan (NSC): Oversight of administrative agency from neutral and expert position.
 - **Interfaces, co-operation and communication between them.**
 - NISA reports status of radiation protection of nuclear facility to the Nuclear Safety Commission of Japan, and contacts MEXT and MHLW if necessary.
 - **Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)**
 - It proposes to the Government rules and regulations in nuclear safety and radiation protection
 - It inspects nuclear facilities and enforces remedial actions when necessary
 - It authorizes licensee's "Operational Safety Program" which establish the basic matters for safety of the nuclear power plant.
 - It performs "Nuclear Safety Inspection" to confirm observance of the "Operational Safety Program"
 - It performs contingency plan in the event of a nuclear emergency.
 - It oversees the utility's occupational exposure management.
 - **Relationship between nuclear safety and radiation protection authorities.**
 - Nuclear and Industrial Safety Agency (NISA) controls both of nuclear safety and radiation protection.
 - **Enforcement capacity of the regulatory body on occupational RP.**
 - The NISA has capacity to enforce remedial actions when necessary in the range of its jurisdiction.

Legal Matters

- ❑ **Legal framework on occupational radiation protection**
 - **Legislation on occupational RP. Give references..**
 - Law on Regulation for Nuclear Source Material, Nuclear Fuel Material and Reactors (1957)
 - Industrial Safety and Health Law (1958)
 - Law Concerning Prevention from Radiation Hazards due to Radio-Isotopes, Etc. (1958)
 - Special Law on Nuclear Disaster Countermeasures (1999)
 - **Legislation is based on (UE directives, ICRP, IAEA, others ...)**
The law on radiation protection is based ICRP.
 - **Specific legislation on occupational RP in NPPs.**
 - Regulation Concerning Establishment, Operation and others of Practical Power Generation Nuclear Reactor. (1978)
 - Regulation Concerning Prevention from Radiation Hazards due to Ionizing Radiation. (1972)
 - Regulation of Laws Concerning the Prevention from Radiation Hazards due to Radioisotopes and Others. (1960)
 - **Specific guidance on occupational RP in NPPs.**
 -
 - **Does your legal framework requires from the NPPs an official document on occupational RP? YES. Operational Safety Program.**
 - **Nature, scope and contents of such a document.**
The Operational Safety Program establish the basic matters for safety of the nuclear power plant which include matters on radiation protection such as radiation education and control of dose and radioactive material.
 - **Is the document approved by the authority? Which authority?**
YES. By the NISA.
 - **Are the procedures (developing and supporting the document approved?**
NO

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee.

Items on radiation protection in the Operational Safety Program

- Basic policy
- Establishment and cancellation of control area
- Classification of the control area
- Special measure in the control area
- Management of going in and out to controlled area
- Observance items of person going in and out to controlled area
- Safety maintenance area
- Peripheral observation area
- Estimation of exposure
- Decontamination of floor, wall and others
- Measurement of dose rate
- Management of radiation measuring instruments
- Carrying out from controlled area and transportation
- Transportation outside power plant
- Radiation protection of contractor
- Safety education of the staff
- Execution policy for safety education of the staff
- Safety education of contractor employee
- Execution policy for safety education of contractor employee
- Record

Self-assessment of the licensee

- **Does the licensee have a self assessment programme? YES Since when? Main characteristics.**
In 2003, the licensee started to establish the quality assurance system in the "Operational Safety Program". This includes the following items: Organization, responsibility and authority, Clarification of resource, Observation, Clarification of measuring item and internal assessment.
- **The programme is an initiative of the licensee or it is required by the authority?**
It was required by the authority.
- **Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially).**
YES.

Regulatory Body organisation on occupational radiation protection control

- ❑ **Inspectorate organisation**
(Inspectors of Japan perform inspection for radiation protection as a part of the Nuclear Safety Inspection.)
 - **Resources:**
 - **Own personnel (status) or outsourcing?**
NISA has its own staff.
 - **Total number of inspectors in your country taking care of occupational radiation protection in NPPs.**
NISA doesn't have inspector of working full-time in the radiation protection. About 100 inspectors for Safety Management of Nuclear Installations, who are stationed at nuclear installations throughout the country, perform inspection for radiation protection as a part of the nuclear safety activity.
 - **Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.**

Regulatory Body organisation on occupational radiation protection control

- If there are other nuclear facilities in the region, they inspect these facilities. For example, 2 fuel manufacturing facilities, one reprocessing facility.
- **Distribution of workload per inspector, per activity:**
-
 - **Average number of years of experience on occupational radiation protection of inspectors. Degree of rotation in the organisation**
-
- **Types of inspections:**
 - **Announced? Non announced? Both?**
Both.
 - **Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?**
They inspect items of radiation protection as a part of Nuclear Safety Inspection.
 - **Existence of national teams? Regional teams? Both? Resident inspectors?**
Inspectors for Safety Management of Nuclear Installations of NISA are stationed at nuclear installations.
 - **What is the dedication of resident inspectors to occupational radiation protection?**
-
 - **Inspectors qualification and training (university studies, access to the regulatory body, retraining)**
For example, it is required as a recruitment condition to have graduated from university in science or technology course, and to have the experience of three years or more in the safety related business.
There are various training course such as quality assurance, inspection skill and radiation control.
- **Inspection organisation and programme**
- **Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns?**
Inspection for radiation protection is performed as a part of the "Nuclear Safety Inspection". The "Nuclear Safety Inspection" is done 4 times a year (not necessarily on shutdowns). Because the items in the "Operation Safety Program" are selectively checked, as for the inspection for radiation protection, some of radiation protection related items are checked around once a year.
 - **Number of inspectors per team per inspection.**
A few person (depends on the scale of the power station).
 - **Duration of the inspection.**
Though the period of "Nuclear Safety Inspection" is 3 weeks, the period for check of radiation protection is very limited.
 - **Do the inspectors also carry out assessment or they are exclusively devoted to inspection?**
The inspectors also carry out assessment.
 - **Approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc.**
-
 - **Methodology of the preparation of the inspection. Documents consulted prior to the inspection.**
-
 - **Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public**
Nuclear Safety Inspection report (submitted to the Nuclear Safety Commission of Japan, public)
Detailed material (internals)

Regulatory Body organisation on occupational radiation protection control

- **Transparency policy.**
Nuclear Safety Inspection report is made public.
- **Inspection procedures**
 - **Existence of inspection procedures:** YES
 - **Main inspection topics:**
 - Management of going in and out to controlled area
 - Dose control
 - Contamination control of floor, wall and others
 - Dose rate measurement in controlled area
 - Management of radiation measuring instruments
 - Management of materials at entry/exit to controlled area
 - Radiation protection of contractor
 - Radiation education

Assessment of the effectiveness of the licensee radiation protection programme

- **How is the assessment carried out?**
 - Only through inspection? NO
 - Through inspection and assessment? YES.
- **What is assessed and how?**
 - licensing documents. YES
 - inspection information. YES
 - Outage final report (results). -
 - Others (specify): design modifications, change of Operational Safety Program, etc.
- **Indicators used by the authority to assess licensee performance.** -
- **National and international benchmarking:** -
- **What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.**
-

Improvement of the regulatory effectiveness

- **Existence of a process to improve regulatory effectiveness.** NO. Since when?
 - **If this process exist, briefly describe it.**
 - **What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?**
 - **Do you have an inspection self-assessment program?** NO.
 - **Does your RB have and external audit.?** Nuclear Safety Commission of Japan observes administrative body from neutral and expert position.
- Feedback of the experience.**

KOREA

Country and Representative Identification

- ☐ **Country:** Korea, Republic of
- ☐ **Name of the regulatory Body:** Government of Ministry of Science and Technology supported by the expertise from the Korea Institute of Nuclear Safety (KINS)
- ☐ **Name and post of the person(s) who fill in the questionnaire:** **Dr. Seong Ho NA, Project Manager, Radiation Safety Research Group**

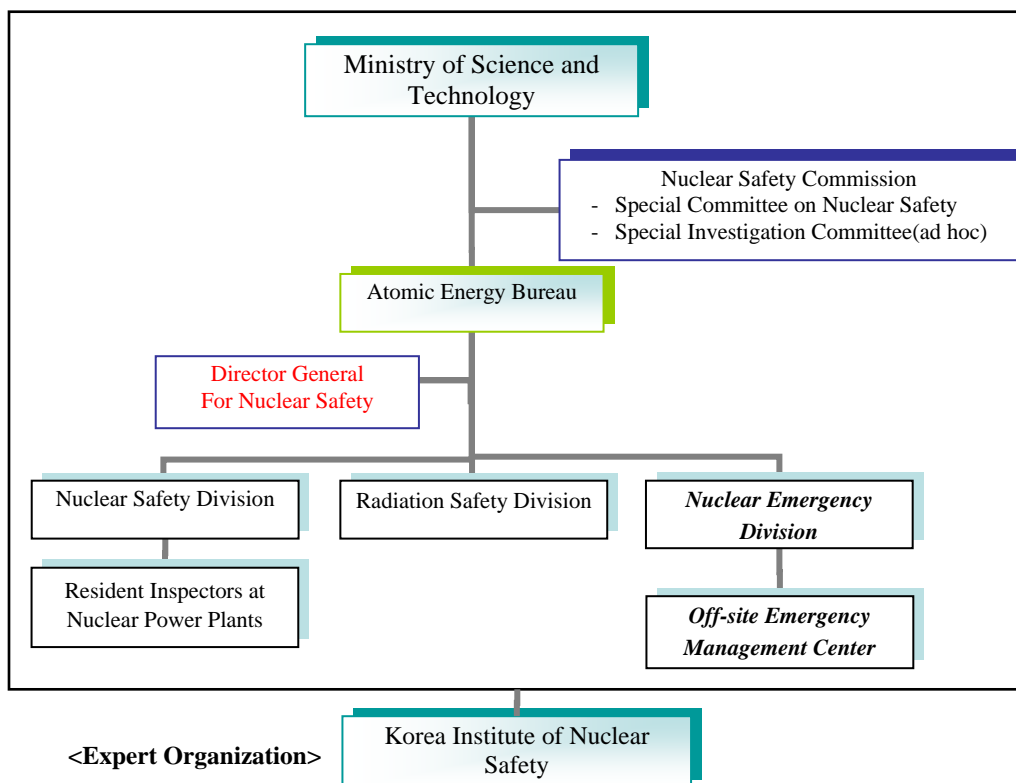
Legal Matters

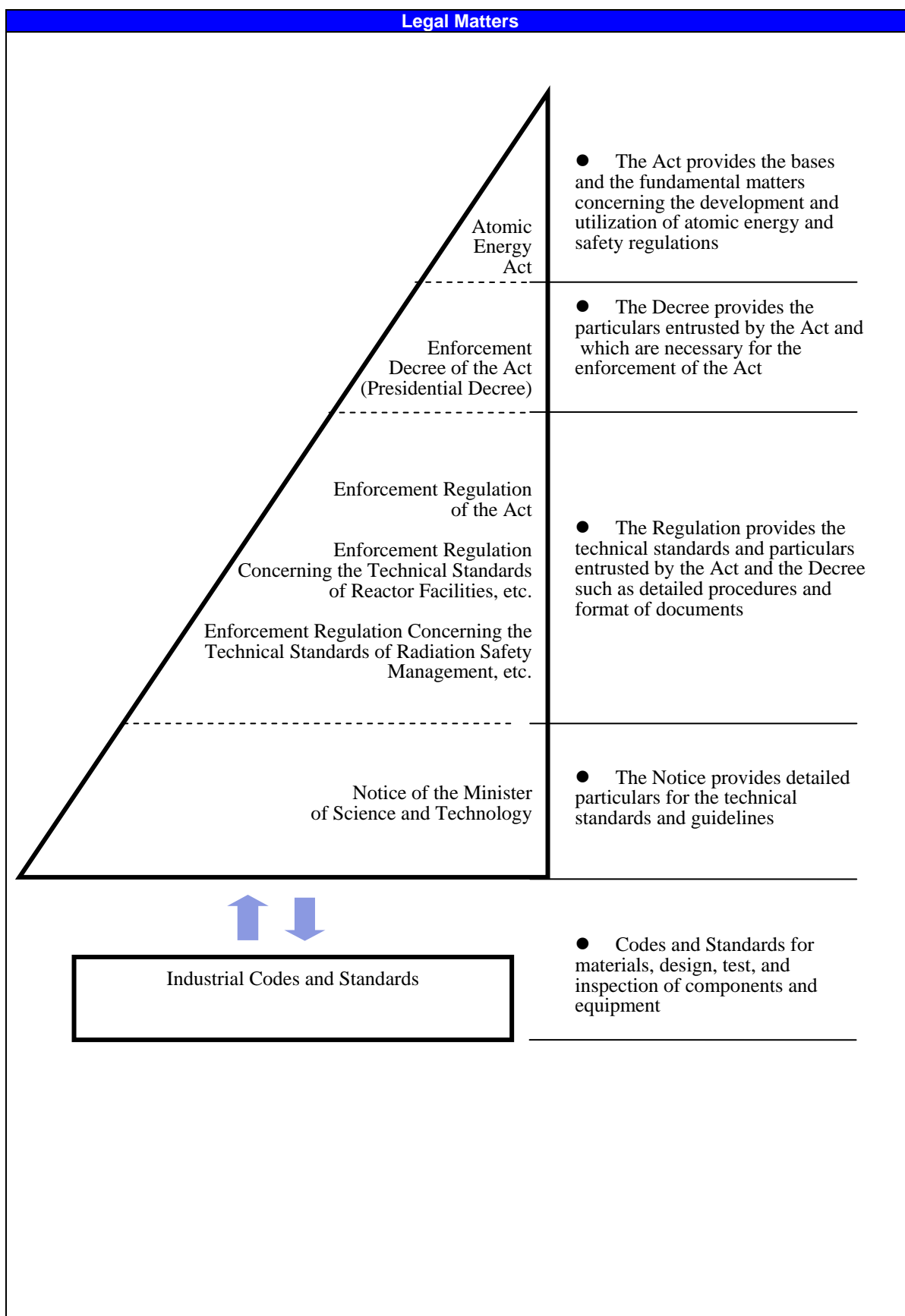
- ❑ **Legal framework of the RP regulatory body**
 - **Legislation on nuclear energy and regulatory authority:**
 - Atomic Energy Act (AEA) enacted by (1958)
 - Wholly amended by 1982 and amended by 1986, 1993, 1995, 1996, 1997, 1999, 2001, 2003
 - **Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc).**
 - The MOST is a governmental organization and Central administration, with its own legal status and assets. Since its creation, MOST annually reports to the Korea Parliament.
 - The KINS was founded through a special legislation by the National Assembly in 1990 with a specific mission to develop and implement nuclear safety regulation. The KINS is entrusted as a technical expert organization by the MOST, the regulatory authority, to perform various regulatory activities such as safety reviews and inspections, development of regulatory standards, and to monitor the environmental radiations across the Korean peninsula, etc
 - **Origin of financial resources (e.g.: taxes, government budget, etc):**
 - The partial source of financing is the fee for services rendered by the Atomic Act 111(3) (48% of the total budget). Fees for services rendered by the Atomic Act describes the amount and services which include: inspection and assessment of all facilities using ionising radiation, reports, license exams, etc ...
 - Budget for 2005: 41,400,000 Euros (10,000,000 from National Budget, 20,000,000 from Fees, 11,400,000 from Research Fund)
 - **Number of authorities with competences in radiation protection.**
 - **Name(s) and competences.**
 - The KINS holds the technical responsibility for Nuclear Safety and Radiation in Korea and the MOST has the official Authority in general. The Ministry of Commerce, Industry and Energy (MOCIE) supervises the nuclear power program and the Ministry of Environment (MOE) holds responsible for regulating issues on the general environment excluding the radiological environment. In addition, there are two organizations supporting regulatory activities of MOST, namely, the Korea Atomic Energy Research Institute (KAERI) and the Korea Radioisotopes Association (KRIA) which transact the trusted affairs relevant to legal retraining for the radiation worker. The KRIA is in charge of maintaining and keeping the related documents to occupational radiation exposures of the radiation worker.
 - **Interfaces, co-operation and communication between them.**
 - All facilities including nuclear installations, KINS has direct responsibility for licensing review and annual inspection. The KINS has secretarial responsibility in general for co-operation and communication between organizations.
 - **Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)**
 - It proposes to the Government rules and regulations in nuclear safety and radiation protection
 - It issues mandatory and binding reports to the Government prior to any authorisation for nuclear and radioactive facilities
 - It inspects nuclear and radioactive facilities and enforces remedial actions when necessary
 - It provides technical support in the event of a nuclear emergency and approves emergency plans
 - It controls and supervises radiation doses which may be received both by exposed workers and the general public
 - It examines and grants licenses for radiation protection officers and other qualified experts
 - It advises the courts and public administration bodies on matters of nuclear safety and radiation protection

Legal Matters

- It carries out and promotes research programs on nuclear safety and radiation protection
- It authorises Dosimeter Services and Radiation Protection Units
- It manages the National Environmental Radiological Monitoring Network
- **Relationship between nuclear safety and radiation protection authorities.**
 - The KINS holds the technical responsibility for Nuclear Safety and Radiation in Korea and the MOST has the official Authority in general.
- **Enforcement capacity of the regulatory body on occupational RP.** The KINS prepares report for the MOST to enforce remedial actions when necessary.

<Regulatory Body>





Legal Matters

❑ Legal framework on occupational radiation protection

▪ Legislation on occupational RP. Give references..

- AEA Chapter 4 for Construction and operation of nuclear power reactors and related facilities, Chapter 6 for Nuclear fuel cycle enterprise and use, etc. of nuclear materials, Chapter 7 for Radioisotopes and radiation generating devices, Chapter 9 for Personnel dosimetry service, and Chapter 11 for Regulation and supervision on the subject of establishment of exclusion area and preventive measures against radiation hazards

▪ Legislation is based on (UE directives, ICRP, IAEA, others ...)

AEA is mainly based on ICRP recommendations. IAEA guidance is also observed

▪ Specific legislation on occupational RP in NPPs.

After confirming the KINS report the MOST issues regulations in the form of "Notices of the Minister of Science and Technology". They are binding. Some examples related to occupational RP in NPP:

- No.2002-23 Standards on Radiation Protection, etc.
- No.2004-11 Standard for Establishment, etc. of the Radiological Emergency Plan for the Nuclear Related Enterprises
- No.2001-10, Guideline for Preparation of radiation safety report
-

▪ Specific guidance on occupational RP in NPPs. FSAR, Law and specific KINS guidance on for the review of licensing and the periodic inspections

▪ Does your legal framework requires from the NPPs an official document on occupational RP? No other than Radiation Protection Guidance in FSAR.

- **Nature, scope and contents of such a document.** The FSAR is a licensing document in Korea reflecting all aspects of safety. Chapter 11 & 12 includes the practical implementation of the licensee responsibility for radiation protection through the adoption of management structures policies, plans, risk assessment, radiological surveillance, training, procedures and other measures developed and implemented to achieve continuing compliance with the legislation in force and to apply the ALARA principle.
- **Is the document approved by the authority? Which authority?** YES. By the MOST based on the report from the KINS.
- **Are the procedures (developing and supporting the document) approved?** NO. They are only reviewed during the inspection.

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee.

Chapters of the Radiation Protection Manual

- Generalities
- Radiological risks in the plant
- Radiological classifications of workers
- Radiological surveillance
- Workplace classification
- Access, permanence and working conditions in radiological zones
- Protection against radiation and contamination.
- Workers monitoring and surveillance
- Public monitoring and surveillance
- Monitoring and control of radioactive material
- Organisation and responsibilities in radiation protection
- Qualification and training in radiation protection
- ALARA programme
- Revisions, inspections and audits in radiation protection
- Procedures and Definitions: ALIs, DACs, Contamination Limits, CVCS limits, etc)

Self-assessment of the licensee

- **Does the licensee have a self assessment programme? YES Since when? Main characteristics.**
Since the beginning of the operation of the plant the licensee have had quality assurance programmes. Since the year of 2002, a new process of self assessment is being implemented. This new program is not a systematic, however, it is harmonised for all the sites, and its corrective actions prioritised and presented during the annual ALARA workshop. It covers: external assessment, independent internal assessment, self-assessment, personnel findings, good practices applied in outage activities.
- **The programme is an initiative of the licensee or it is required by the authority?** It has been a joint initiative by the IAEA and Korean NPPs. An IAEA project introduced the content and method of self assessment in the year of 2001 and its implementation has been encouraged thereafter.
- **Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially).**
Partially. Specifically, during the QA Audit. The regulatory body has to evaluate and inspect the effectiveness of the programme, through its results and the implementation of corrective actions.

Regulatory Body organisation on occupational radiation protection control

Inspectorate organisation

- **Resources:**
 - **Own personnel (status) or outsourcing?**
KINS has its own staff. They are civil servants
 - **Total number of inspectors in your country taking care of occupational radiation protection in NPPs.**
Total KINS staff: 350 people, of which 280 are inspectors. 8 inspectors (including 4 inspectors devoting all aspects of inspection of dosimetry services) for occupational radiation protection in nuclear power plants
 - **Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.**
YES: in addition to the 20 nuclear units, they also control one fuel manufacturing facility, one national research institute (KAERI), and one research nuclear facility.

Regulatory Body organisation on occupational radiation protection control

- **Distribution of workload per inspector, per activity:**
 - 35 % of time on inspection,
 - 55 % of time on assessment,
 - 10 % of time on others (specify): training, meetings, guidance, etc
 - **Average number of years of experience on occupational radiation protection of inspectors (10 years). Degree of rotation in the organisation** (the degree of rotation in the field of radiation safety in KINS is about 5 – 10 years. Once the personnel became a inspector it remains in the KINS almost all his professional life in similar field. The average time spent in the same department is not longer than 10 years in general.
- **Types of inspections:**
 - **Announced? Non announced? Both?**
Both but non announced inspections are rarely carried out.
 - **Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?**
There have been multidisciplinary inspections for the cases of unusual events including radiation protection; however, in the case of radioactive related, independent staff is allocated.
- **Existence of national teams? Regional teams? Both? Resident inspectors?**
Inspection and control on occupational radiation protection of nuclear facilities is carried out by KINS inspectors at the headquarters (Daejeon). Apart from the headquarters inspectors, there are local resident inspectors per nuclear site (only for NPPs) who devote 100% of their time to nuclear safety issues. The site office is operated by the MOST and the total number of inspector is six: three from KINS and three from the MOST.
- **What is the dedication of resident inspectors to occupational radiation protection?** About 10% of their time.
- **Inspectors qualification and training (university studies, access to the regulatory body, retraining)**
All KINS radiation protection inspectors are required to have a university degree in scientific or technological areas.
2 years experience and additional 4-week training is required to become an inspector.
Refreshment training of one-week per 3 years is required. In addition, 20 hours per year of professional training or education is encouraged by the KINS.
- **Inspection organisation and programme**
 - **Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns?**
Officially 1 per the refuelling outage which is about 18 month (not longer than 20) in general. Proper inspection time is proposed by the licensee and it is confirmed by the MOST in co-operation with the KINS. As a seasonal matter, inspection activities are not carried out during the summer time except special cases.
From the year of 2005, KINS started to perform secondary system inspections.
In case of: supporting the licensing process in case of design modifications involving radiation protection issues or supporting assessment procedures following radiation protection incidents, the site office is carrying out inspection and the KINS is reviewing them during the periodic inspection.
 - **Number of inspectors per team per inspection.** 40 per team for one NPP reactor (including 2 for RP, 5 for secondary system): about 50 % of those actually dispatches to the site and others for supporting the inspection.
 - **Duration of the inspection.** On average, a periodic inspection takes 4 – 6 weeks (about 4 weeks for CANDU type and about 5 weeks for PWR).
 - **Do the inspectors also carry out assessment or they are exclusively devoted to inspection?**

Regulatory Body organisation on occupational radiation protection control

They perform inspectional objects: document review and confirmation of assessment results.

- **Approximate % of time devoted to each phase of the inspection:**
 - preparation, 20%
 - on site, 50%
 - production of documents, etc 30%.
- **Methodology of the preparation of the inspection. Documents consulted prior to the inspection.**
 - Review of previous Inspection & Assessment reports
 - Review of licensing official documentation
 - Review of plans and procedures submitted to KINS by NPPs.
 - Review of historical status of the NPPs
 - Review of any specific issues
- **Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internal, which are sent to the licensee and which are public**
 The legal framework for Korean radiation protection inspections is established in the Regulations for Nuclear and Radioactive Facilities (1979, amended several times thereafter). In the year of 1990, the KINS was founded by the law.
 - In order to activate the inspection, the licensee should send an official request letter including outage plan to the MOST and follow-up procedures are leaded by the KINS.
 - Historical status and any amended subjects are reviewed and discussed by the KINS and NPPs prior to the periodic inspection.
 - All inspection activities are supported by the site office which is operated by the MOST.
 - All aspects of inspections including findings and violations which should be included in the official inspection report to the MOST not later than 30 workdays after inspection completion (in the case of findings and violations they are issued within two weeks).

Before publishing the official inspection report, regulatory inspectors issue individual finding notices or recommendation notices. These notices are classified into two levels: one for the violation of the law which is issued by the Ministry of MOST and the other for findings which are confirmed and issued by the site office. After the official inspection report is issued by the Ministry of Science and Technology all follow-up actions are ensured by the KINS.

- In general, the Licensee shall take corrective actions to prevent reoccurrence and report them to the regulatory body within due date clarified in the notices. The due date of corrective actions is decided by the both parties after in-depth discussion.
- **Transparency policy.** The current policy transparency is described in the above paragraphs. At present a process of improvement of this transparency policy is being developed and some of inspection reports are opened in KINS website, <http://nsic.kins.re.kr>).

□ Inspection procedures

- **Existence of inspection procedures:** Yes. KINS applies in-house checklist and guidance on inspection items.
- **Main inspection topics:**
 - Review of the ALARA programme, organisation and engagements. Practical implementation.
 - Internal audits in occupational radiation protection
 - Practical implementation of the ALARA principle in the outage programme and main activities.
 - Human and technical resources of the radiation protection service
 - Radiation monitoring system
 - Instrumentation.
 - Dose estimations and especial events during the outage
 - Source term reduction initiatives: follow-up.
 - Management of radiological work permits

Regulatory Body organisation on occupational radiation protection control

- General conditioning or radiological areas and general personnel behaviour (visit to controlled areas)
- Entry/exit to contaminated zones
- Radiological control of materials and personnel at the exit of radiological areas
- General control of radioactive material

Assessment of the effectiveness of the licensee radiation protection programme

- **How is the assessment carried out?**
 - Only through inspection? NO
 - Through inspection and assessment? YES.
- **What is assessed and how?**
 - licensing documents. YES
 - inspection information. YES
 - Outage final report (results). YES
 - Others (specify): design modifications, source term reduction programme, etc.
- **Indicators used by the authority to assess licensee performance.**
 - All the information obtained during inspections
 - Numerical indicators such as: evolution of collective doses
- **National and international benchmarking:** No
- **What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.**

In Korea, public information and open discussion is getting a main mechanism of communication. Taking these requests into account, KINS organizes annual meetings, for example, Safety Regulation Conference (SRC), as well as other symposiums and workshops participated by the licensee and regulatory group. By the use of the ISOE activities further in-depth information and topics of common interest are discussed. Sometimes specific technical subjects are discussed and any improvements are followed as fee-back actions.

Improvement of the regulatory effectiveness

- **Existence of a process to improve regulatory effectiveness.** YES. **Since when?** Since 1998
- **If this process exist, briefly describe it.**
 - It has had different phases: a) safety culture, b) Risk Informed Regulation, c) team-work system instead of task basis to carry out periodic inspection, d) quality management system (QMS)
 - A) Organize safety forum to enhance communication with the public (3 in 2005), open communication with the residence around NPPs especially with the issues of inspection results.
 - B) Risk informed regulation is practically applied in the year of 2006 after two-year period of pilot test. The target items are selected such as Risk Informed Periodic Inspection (RIPI), RI Technical Specification (RI-TS), RI-ISI, Adaptation of Updated Maintenance Rule
 - C) Team-work system is a new challenge in the year of 2006 to upgrade the efficiency of inspection not only on the subject of workload but also the quality of inspector. 40 inspectors are assigned per one reactor and one of three groups is despatching for site inspection according to the outage plan. It is expected to reduce 20 % of the man-days of inspection and enhance the generalized professionalism of individual. It is also expected to enhance the quality of performance of inspection by eliminating any miscellaneous interruptions during the inspection period.
 -
 - D) QMS for KINS has been implemented to improve the quality of regulatory activities. The quality management manual was developed in January 2006 and its application has been highlighted as a main performance indicator. Further improved procedures and instructions are expected by the first half year of 2006.
- **What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?** The baselines of this process have been jointly established by the KINS, the MOST and the licensees. Other stakeholders, such as the public will participate at a communication level as receptors of the results of the new system.
- **Do you have an inspection self-assessment program?** Yes. The results of periodic inspection including findings and violations are reviewed and assessed by the independent review committee on nuclear safety before the inspection report is finalized. The reviewing organization is a standing committee which is composed by 13 KINS staff (general director of nuclear regulation division, directors of departments in charge of various technical areas, and a technical advisor on nuclear safety to the president of KINS who is the chairman of the committee).
- **Does your RB have and external audit.?** YES, almost every year. the external audit covers general operational aspects and sometimes it covers a quality point of performance and a subject of policy in ganisational and management process. Generally, it does not include technical issues.
- **Feedback of the experience.** As a consequence of the results of these audits there have been a series of improvements in the organisational and managerial system of the KINS.

LITHUANIA

Country and Representative Identification

- ☐ Country: *Lithuania*
- ☐ Name of the regulatory Body: *Radiation Protection Centre (RSC)*
- ☐ Name and post of the person(s) who fill in the questionnaire: *Gintautas BALČYTIS, Chief Specialist, Division of Supervision and Control of Nuclear Facilities, Gintautas KLEVINSKAS, Head of the Division of Supervision and Control of Nuclear Facilities, Ramunė M. STASIŪNAITIENĖ, Deputy Director, .*

Legal Matters

❑ Legal framework of the RP regulatory body

- Legislation on nuclear energy and regulatory authority:
 - Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc)

Radiation Protection Centre (RSC) is national institution under the Ministry of Health. Radiation Protection Centre is the authorized institution, exercising state supervision and control of compliance with requirements of the Radiation Protection Law, other legal documents and licenses, enforcement. The central office of RPC is located in Vilnius, and divisions are in Kaunas, Siauliai, Klaipeda and Panevezys.

- Origin of financial resources (e.g.: taxes, government budget, etc)
Government budget.

- Number of authorities with competences in radiation protection.

Two regulatory authorities.

- Name(s) and competences.
 1. *Radiation Protection Centre (concerning nuclear facilities: responsible for state supervision and control of occupational and public radiation protection);*
 2. *Ministry of Environment (concerning nuclear facilities: responsible for control of radioactive discharges, establishment of clearance levels).*

State Nuclear Power Safety Inspectorate (VATESI) is responsible for state supervision and control of nuclear safety in nuclear facilities.

Activities Subject to Licensing:

<i>1) design, construction or reconstruction, operation and decommissioning of nuclear facilities*, transport of nuclear material;</i>	<i>Issuance – VATESI Co-ordination with: Ministry of Environment, RSC, Local authority in its territory</i>
<i>2) practices with radioactive sources, transport of radioactive material and radioactive waste;</i>	<i>Issuance – RSC (as well as single permits for transport of radioactive material and radioactive waste) Co-ordination with: VATESI (only for nuclear materials)</i>
<i>3) collection, sorting, pre-treatment, treatment and conditioning, storage, recovering and decontamination of radioactive waste;.</i>	<i>Issuance for small waste producers** – RSC</i>

** **Nuclear facility** - a nuclear power plant, a nuclear reactor, a storage facility for nuclear materials and radioactive waste, and their processing facility.*

*** **Small waste producer** - a waste producer with the exception of the operator of a nuclear plant.*

Interfaces, co-operation and communication between them.

RPC is involved in issuing licences by VATESI for nuclear facilities, take place in some joint projects (e.g. PHARE project 2003/005-825.01.01.0002 "Support to RPC licensing activities related to the decommissioning of the Ignalina Power Plant"), communication between authorities is performed by letters, discussions at the conferences, seminars, meetings etc.

- Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)
Inspections, assessment, setting and providing of requirements, enforcement if necessary.
- Relationship between nuclear safety and radiation protection authorities.
Coordination of activities, discussions, agreements, in some cases cooperation of work (e.g. writing reports on nuclear safety and radiation protection in nuclear facilities), etc.
- Enforcement capacity of the regulatory body on occupational RP
Warning note, Act of offences (According to Code on Administrative Offences, 1984), to suspend a license for practise with sources, to turn to other public administration or local authorities and legal institutions.

❑

❑ **Legal framework on occupational radiation protection**

- Legislation on occupational RP. Give references.
- *Law on Radiation Protection, No. VIII-1019 (adopted on 1 April 1999);*
- *Law on Nuclear Energy, No. I-1613 (adopted on 1 January 1997);*
- *Law on the Management of Radioactive Waste, No. VIII-1190 (adopted on 9 June 1999);*
- *Lithuanian Hygiene Standard HN 73:2001 "Basic Standard of Radiation Protection";*
- *Government Resolution No. 651 On the Establishment of the State Register of Radiation Sources and Exposure to Workers and Approval of its Statute (adopted on 25 May 1999);*
- *Order No. 335 On the Procedure of Presenting the Information to the State Register of the Sources of Ionizing Radiation and Exposure of Workers – on the sources of Ionizing Radiation and the date of the Workers that Acts with the sources of Ionizing Radiation (adopted on 20 July 1999).*
- *Order of director of RPC No. 44 On the Procedure of Monitoring of Radiation Exposure and Workplaces (adopted on 31 December 1999);*
- *and other (more than 20). Further list available at www.rsc.lt*

- Legislation is based on (UE directives, ICRP, IAEA, others ...)

The basic standards and safety requirements for occupational and public exposure in practices with sources of ionizing radiation and also in management of radioactive waste in Lithuania are established in Lithuanian Hygiene Standard HN 73:2001 „Basic Standards of Radiation Protection”, which is in line with the requirements of Safety Series No. 115, International Basic Safety Standards for Protection against Ionizing Radiation and the Council Directive 96/29/EURATOM of 13 May 1996 Basic safety standards for the protection of the health of workers and the general publics against the dangers arising from ionizing radiation.

- Specific legislation on occupational RP in NPPs
- *Lithuanian Hygiene Standard HN 87:2002 "Radiation Protection in Nuclear Facilities" (2002)*
- Specific guidance on occupational RP in NPPs.
- Does your legal framework requires from the NPPs an official document on occupational RP?

Yes, Radiation Protection Programme.

- Nature, scope and contents of such a document

The following items shall be included in the programme:

- 1) classification of working areas and access control,*
- 2) local rules, measures of supervision of safety at work and order of organisation of work,*
- 3) investigation levels of workes and dose constraints, procedures of monitoring of workplaces and individual monitoring of workers,*
- 4) individual protective equipment, rules of their application,*
- 5) main premises, control systems for assurance of radiation protection,*
- 6) requirements for management of radioactive waste;*
- 7) radiation protection measures applied during the accident;*
- 8) application of optimisation principle (ALARA) and measures for exposure reduction,*
- 9) order of workers health surveillance,*
- 10) mandatory training of workers and their instructions.*

- Is the document approved by the inspection authority? Are the procedures approved?

Radiation Protection Programme must be approved by the regulatory authority.

- Are the procedures (developing and supporting the document approved?
- Yes.*

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee
See the answer above.

Self assessment of the licensee

- Does the licensee have a self assessment programme?. Since when? Main characteristics.
The licensee (Ignalina NPP) has Quality Assurance Programme, which was updated at 2004, taking into account the changing situation with Unit 1 due to the decommissioning process. Procedures of internal audit and inspections are described in the Programme. Ignalina NPP Safety and Quality Assurance Policy makes necessary provisions for encouragement of all INPP employees to actively participate in safety and quality improvement process and in continual assessment of INPP performance for the purpose of quality improvement.
The INPP has established a three level QA documentation system.
The Quality Assurance Manual is the 1st level document applicable to development, implementation and improvement of the Quality Assurance System. It specifies the Safety and Quality Assurance Policy and objectives and establishes the basis for effective management of all activities performed at INPP.
The 2nd level of QA system documents is the so-called management procedures. The INPP developed, implemented and regularly update 24 management procedures.
The 3rd level documents are detailed work procedures. They are developed in accordance with the requirements of management procedures and specify how work shall be done.
- The programme is an initiative of the licensee or it is required by the authority
Quality Assurance Programme is required document for getting license for operating of NPP unit.
- Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially)
Yes.

Regulatory Body organisation on occupational radiation protection control

☐ Inspectorate organisation

- Resources:
 - Own personnel (status) or outsourcing?
Own personnel.
 - Total number of inspectors in your country taking care of occupational radiation protection in NPPs.
Two inspectors and one civil servant is under preparation for his nomination as an inspector.
 - Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.
Inspectors also inspect one radioactive waste disposal facility (at Maisiagala site) and also organizations, which workers work at NPP as outside workers.
 - Distribution of workload per inspector, per activity: % of time on inspection, % of time on assessment, % of time on others (specify).
15 –20 % of time on inspection; 12-15% - on assessment; 5-6 % - on preparation for inspections; 25-30% - expertise of legal documents, projects, reports, etc.; 5-10% preparation for legal documents, procedures; 15-20% - on study of new publications, on meetings, seminars, trainings; 10-15% preparation of plans, reports, presentations; the rest time - other works (e.g. organizational work; translations; consultations, answers to official letters, etc.).
 - Average number of years of experience on occupational radiation protection of inspectors. Degree of rotation in the organisation.
6 year. During the last 4 years 1 inspector left and 1 (under preparation for his nomination as an inspector) was taken into service.

- Types of inspections:
 - Announced? Non announced? Both?
Announced, as a rule.
 - Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?)
Specific on occupational RP.
 - Existence of national teams? Regional teams? Both? Resident inspectors?
No.
 - What is the dedication of resident inspectors to occupational radiation protection?
-
 - Inspectors qualification and training (university studies, access to the regulatory body, retraining)
University studies, audition; work experience, further training (courses, seminars, study of publications, etc.). Inspector is a public servant and the Law on Public Service (1999) is applicable for his placement and further retraining.
- **Inspection organisation and programme**
- Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns?
2.5-3 per year, not only on shutdowns (2 units).
 - Number of inspectors per team per inspection
Usually 1-2 inspectors, but sometimes 3 (if the issue is complex).
 - Duration of the inspection
2-3 days.
 - Do the inspectors also carry out assessment or they are exclusively devoted to inspection
Yes, they do.
 - Approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc
Preparation – 30%; inspection on site 27%; assessment (including report writing) – 36%; other work – 7%.
 - Methodology of the preparation of the inspection. Documents consulted prior to the inspection.
Making of the plan of inspection; review of the related legal acts, local instructions and procedures, documents of license.
 - Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public.
Remarks, copies of related documents (internals), inspection report (to be sent to the licensee).
 - Transparency policy
Discussions at the end of inspection with responsible officials in the inspected facility.
- **Inspection procedures**
- Existence of inspection procedures
Yes. The Guide on Performing of State Supervision and Control on Radiation Protection (2004).
 - Main inspection topics
 - *implementation of radiation protection requirements on use and storage of sources;*
 - *planing and implementation of radiation protection requirements and use of radiation protection measures during outages;*
 - *occupational dose planing and assessment;*
 - *inspection on performing work place and individual monitoring;*
 - *radiation protection requirements in radioactive wastemanagement;*
 - *transportation of radioactive material.*
 - *emergency preparedness;*
 - *training of the personnel on radiation protection.*

Assessment of the effectiveness of the licensee radiation protection programme

- How is the assessment carried out
 - Only through inspection
No
 - Through inspection and assessment?
Yes
 - What is assessed and how?
 - licensing documents
Yes
 - inspection information
Yes
 - shutdown final report (results)
Yes
 - Others (specify)
Current information about occupational doses, all other documents related to the subject.
-
- Indicators used by the authority to assess licensee performance
Number of workers, qualification, occupational doses (individual and collective), number of sources in use and storage, conditions of use and storage of sources, implementation of radiation protection requirements during the work.
 - National and international benchmarking
Projects with IAEA (LIT/4/002), PHARE project, ISOE system, etc.
 - What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.
Workshops and regulatory meetings, discussions via e-mail, phone.

Improvement of the regulatory effectiveness

- Existence of a process to improve regulatory effectiveness. Since when?
Since 2000.
- If this process exist, briefly describe it.
Procedure of assessment of regulatory effectiveness is described in the The Guide on Performing of State Supervision and Control on Radiation Protection (Approved by Director of RPC at 2004). The results of inspections are discussed with immediate superior of the inspector. Experience acquired during inspections is analysed and used during the forthcoming inspections.
- What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?
Representatives of the operator take part in discussions at the end of inspection. Their arguments and point of view are taken into account, however, the regulatory authority makes a final decision.
- Do you have an inspection self-assessment program?
Yes.
- Does your RB have and external audit.? Feedback of the experience
Yes, from the founder (Ministry of Health), from the National Audit Office, also IAEA peer-review missions.

ROMANIA

Country and Representative Identification

- ☐ **Country:** ROMANIA
- ☐ **Name of the regulatory Body:** National Commission for Nuclear Activities Control (CNCAN)
- ☐ **Name and post of the person(s) who fill in the questionnaire:** Oana Velicu, expert, Radioprotection and Radwaste Division of CNCAN

Legal Matters

❑ Legal framework of the RP regulatory body

- Legislation on nuclear energy and regulatory authority:
 - Nature and dependency of the regulatory body: CNCAN is the national competent authority in the nuclear field, which exercises the regulation, licensing and control as stipulated in Law on the safe deployment of nuclear activities no.111/1996, republished, with consequent completion and modification; CNCAN is a national public institution, acting as a legal entity, being headed by a president who is also a state secretary, and co-ordinated by the Prime Minister
 - Origin of financial resources: The CNCAN financing is fully provided by extra-budgetary revenues, obtained from tariffs for the authorisation and control of nuclear activities and contributions from international institutions.
- Number of authorities with competences in radiation protection.
 - Name(s) and competencies: CNCAN holds the exclusive authority for radiation protection in Romania
 - Interfaces, co-operation and communication between them: N/A
- Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)
 - CNCAN proposes to the Government draft laws in the nuclear field, it issues its own regulations for the detailed specification of the general requirements for protection against ionising radiation, including the licensing and control procedures, it advises draft laws with implications in the nuclear field
 - CNCAN controls the implementation of the provision of international agreements in force on the control of radiation protection
 - CNCAN issues licences for nuclear activities, according with the licensing procedure typical for each kind of activity or source
 - CNCAN designates the qualified radiation protection organisations, the qualified dosimetric organisations, the qualified certifying personnel organisations and the qualified experts in radioprotection
 - CNCAN examines and issues exercising permits for nuclear activities, according to the provision of the specific CNCAN regulations
 - CNCAN issues acceptance certificates for outside undertakings and radiological passports for the individual radiological surveillance of outside workers
 - CNCAN manages the national register of radiation doses received by the occupational exposed workers (including the outside workers)
 - CNCAN exercises the preventive, prompt and current, as well as the subsequent control of the compliance with the provisions of Law no.111/1996 and the specific CNCAN regulations, by its specially empowered representatives, at the applicants or authorisation holders
 - After a control, the CNCAN inspectors can order the suspension of the activity, the taking out of operation the nuclear or radiological installation, radioactive or nuclear material or other nuclear interest material, device, equipment or information, which are unauthorised or whose operation or holding may be dangerous
 - After conclusion of the control, the CNCAN inspectors have the power to propose the suspension or withdrawal the authorisation or practice permit, to propose the information of the legal prosecution bodies, to order the authorisation holder to apply disciplinary sanctions to the guilty personnel, to apply the contravention sanctions provided under the provision of Law no.111/1996
- Relationship between nuclear safety and radiation protection authorities: CNCAN holds the exclusive authority for nuclear safety and radiation protection in Romania
- Enforcement capacity of the regulatory body on occupational RP: CNCAN has capacity to enforce remedial actions, when necessary

❑ **Legal framework on occupational radiation protection**

- Legislation on occupational RP. Give references.
 - Fundamental Norms on Radiological Safety (NSR-01), approved by CNCAN President Order No.14/2000, published in Romanian Official Gazette No.404b/29.08.2000
 - Norms on individual dosimetry (NSR-06), approved by CNCAN President Order No.180/2002, published in Romanian Official Gazette No.769b/22.10.2002
 - Norms regarding the issuing of exercising permits for nuclear activities and designation of qualified radioprotection experts (NSR-07), approved by CNCAN President Order No.202/2002, published in Romanian Official Gazette No.936/20.12.2002
 - Norms on Radiological Safety – acceptance procedures for outside undertaking (NSR-09), approved by CNCAN President Order No.228/2002, published in Romanian Official Gazette No.50b/29.01.2003
 - Norms on Radiological Safety regarding the operational radioprotection of outside workers (NSR-02), approved by CNCAN President Order No.353/2001, published in Romanian Official Gazette No.764b/30.11.2001
- Legislation is based on: European Council Directive 96/29/Euratom, IAEA Basic Safety Standard No.115 implicitly, other applicable IAEA guides
- Specific legislation on occupational RP in NPPs: No, the CNCAN specific regulations regarding RP requirements are addressing both the nuclear and radiological installations
- Specific guidance on occupational RP in NPPs: No, the norms issued by CNCAN stipulate the legal requirements and, in the same time, provide a technical guide, if case
- Does your legal framework requires from the NPPs an official document on occupational RP? Not explicitly, it is a regulatory disposition: the NPP holder has to prepare a set of reference documents addressing the occupational RP aspect, which has to be approved by CNCAN during the authorisation process.
 - Nature, scope and contents of such a document
 - RP2, Radiation safety program, general description;
 - RP3, Radiation safety policies and principles;
 - RP5, Radiation safety training and qualification programme;
 - RP6, Personal dosimetry program;
 - RP 9, Radiation protection regulations for Cernavoda NPP;
 - RP 11, ALARA program for Cernavoda NPP.
 - Is the document approved by the inspection authority? Are the procedures approved? Yes, the documents have to be approved by CNCAN.
 - Are the procedures (developing and supporting the document) approved? No

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee

▪ **RP2, Radiation Safety Program for Cernavoda NPP, General description**

- Purpose: the general description of the radiation safety program for NPP
- Content: program design, organization and management, personnel selection, training and qualification, occupational radiation control, public radiation control, emergency operations, radiation safety program monitoring and assessment, appendix

▪ **RP3, Radiation safety policies and principles**

- Purpose: to describe the policies and principles underlying the Cernavoda NPP radiation safety program
- Content: objectives, responsibilities, policies: general, personnel qualifications, radiation exposure limits and targets, plant and facility operations, contamination of air, surfaces and liquids, hazard identification and assessment, exposure control, dose assessment, radioactive waste management, incidents and emergencies

▪ **RP5, Radiation safety training and qualification program**

- Purpose: to describe the radiation protection training program, the qualification system for workers at Cernavoda NPP and the procedure to issue permits for working in nuclear field for Cernavoda NPP
- Content: responsibilities, Cernavoda NPP qualification coding, CNCAN permit issuing, rights and restriction for each qualification, requalification requirements, training and examination requirements for each qualification, high hazard training, administration, appendices

▪ **RP6, Personnel dosimetry program for Cernavoda NPP**

- Purpose: to describe the dosimetry system that applies to NPP in order measure, assign and record all the significant radiation doses received by an individual working at NPP.
- Content: general principles (hazards and exposure structure, conceptual basis, frequency, sensitivity and accuracy, principles of monitoring, outline of program structure, documentation and record keeping), internal dosimetry program (introduction, details of internal dosimetry program), external dosimetry program (technical basis, whole body dosimetry, skin dose assessment, extremity dosimetry), appendices

▪ **RP9, Radiation protection regulation for Cernavoda NPP**

- Purpose: to establish the standards applicable to the Cernavoda NPP radiation safety program.
- Content: general, personnel management, limits (general, principle of minimum exposure, dose limits, emergency exposures, medical exposure during employment, contamination control limits), radiation measurement and assessment (general, radiation protection instrumentation, radiation surveys, personal dosimetry), radiation hazard management (radiological, access control areas, hazard monitoring system, posting of hazard warnings, personal protective equipment, decontamination, storage and use of licensed sources), radioactive waste management, transportation of radioactive material, incident and emergencies, information management, appendices

▪ **RP11, ALARA Program for Cernavoda NPP**

- Purpose: to describe the elements of Cernavoda radiation safety program which ensures that all radiation exposures are kept as low as reasonably achievable, social and economic factors being taken into account.
- Content: responsibilities, ALARA program (introduction, ALARA in CANDU –PHW reactors, ALARA elements of the Cernavoda radiation safety program, description of ALARA elements, other processes and methods to improve radiation safety performance, quantitative optimization and decision making during operation, application of procedure, records, appendix

Self assessment of the licensee

- Does the licensee have a self-assessment programme? Since when? Main characteristics.
Yes, the Cernavoda NPP has a self-assessment program, which is fully implemented since 2005. Regarding the radioprotection, this self-assessment program covers the following topics: management & leadership, personnel training, external exposure management, internal exposure management, radioactive sources control, dosimetry and radioprotection facilities, equipment & systems. For each of these topics, there are established performance indicators, which must be continuously surveyed and reported quarterly to the NPP managers.
- The programme is an initiative of the licensee or it is required by the authority?
This program is required by CNCAN, as an authorisation condition, the self-assessment requirement being also stipulated in the following CNCAN Quality Management Norms:
 - Norms regarding the general requirements on Quality Management Systems applied to fabrication, operation and decommissioning of nuclear installations, approved by CNCAN President Order No.66/2003, published in Romanian Official Gazette No.681b/26.11.2003
 - Norms regarding the requirements on Quality Management Systems applied to the operation of nuclear installations, approved by CNCAN President Order No.74/2003, published in Romanian Official Gazette No.681b/26.11.2003
- Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially)
CNCAN evaluates the annually report of the self-assessment program results, sent by the NPP holder.

Regulatory Body organisation on occupational radiation protection control

□ Inspectorate organisation

- Resources:
 - Own personnel (status) or outsourcing?
CNCAN has its own personnel: 131 employees (contractual personnel)
 - Total number of inspectors in your country taking care of occupational radiation protection in NPPs.
Not all the CNCAN personnel is empowered to perform controls; from the total number of approx.46 CNCAN "inspectors", only 12 have the attribution to control the RP in NPP, as follows:
 - 4 persons from the Nuclear Reactors Division (DRN), with the main responsibility of the general control of NPP
 - 4 persons from the Radioprotection and Radwaste Division (DRDR), with the responsibility of the RP control of NPP
 - 4 persons from the Quality Control Division (DCC), with the responsibility of controlling the QM requirements regarding the RP in NPP
 - Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.
Yes, excepting the DRN personnel (1 director and 3 residents in Cernavoda NPP). DCC personnel controls all the nuclear installations in Romania. DRDR personnel controls also 2 nuclear research reactors, 2 radwaste treatment facilities, 1 national repository for radwaste, 1 post irradiation examination laboratory.
 - Distribution of workload per inspector, per activity: % of time on inspection, % of time on assessment, % of time on others (specify).
 - the CNCAN dedicated inspectors (3 residents in Cernavoda NPP) are fully involved in NPP inspection, 10% of time being dedicated to RP inspection;
 - the personnel working in the CNCAN headquarters are not divided into controllers, regulators or assessors; for each division of CNCAN, some of the high educated and experienced personnel is empowered by the CNCAN President to perform controls, in the competence area of the division they are working for. Thus, the workload per activity for the CNCAN headquarters personnel with control right is approx.: 20% regulation, 40% assessment, 20% authorisation, 10% control, 10% other (training, meetings).
 - Average number of years of experience on occupational radiation protection of inspectors. Degree of rotation in the organisation.
The average number of experience years for the CNCAN personnel performing RP inspections are 7 years, this personnel being still employed in CNCAN since 1998.
- Types of inspections:
 - Announced? Non announced? Both? Both
 - Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors)? Both
- Existence of national teams? Regional teams? Both? Resident inspectors? As we answered before, the inspections are performed by the headquarters inspectors and site residents, together and separately.
- What is the dedication of resident inspectors to occupational radiation protection? 10% of time
- Inspectors qualification and training (university studies, access to the regulatory body, retraining)
The CNCAN personnel with control right has to have an university degree in scientific or technical areas (physics, chemistry, nuclear engineering) and to have some experience in the nuclear field (according to the number of years of experience and the availability of a position of higher degree, the employee can advance only by passing an examination including topics related to the competencies area of the job). The personnel is retrained, based on the annually Training program of CNCAN staff, which is elaborated by each division according to its specific needs.

❑ **Inspection organisation and programme**

- Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out? Only on shutdowns?
Generally, 3 per year, from which 1 in outage.
- Number of inspectors per team per inspection: minimum 2 inspectors; for multidisciplinary inspections, the team consist in 1-2 inspectors for each field of inspection
- Duration of the inspection: 1-3 days
- Do the inspectors also carry out assessment or they are exclusively devoted to inspection: yes, they also perform assessments
- Approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc: 20% preparation, 50% on site, 30% documents elaboration
- Methodology of the preparation of the inspection. Documents consulted prior to the inspection. According to the inspection subject, the documents consulted prior the inspection are: review of the previous inspection reports, review of the appropriate licensing documentation, review of the appropriate NPP periodic reports and incident reports, review of the appropriate NPP procedures in force
- Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public. Immediately after the inspection, the CNCAN inspection team issues an inspection report, containing the observations made on site, the CNCAN dispositions regarding the corrective actions to be taken by the controlled facility (institution or person), the identification data of the controlled facility and of the CNCAN, the names, functions and signatures of the CNCAN team members and the controlled facility representatives; this report is elaborated together with the representatives of the controlled facility, it is registered in the evidence of the controlled facility, and copied; CNCAN will keep a copy, the controlled facility will keep the original.
- Transparency policy CNCAN elaborates annually a report, which includes the radioprotection issues in the major nuclear installations; this report is published and also posted on the CNAN web site.

❑ **Inspection procedures**

- Existence of inspection procedures: yes
- Main inspection topics:
 - inspection of the organisation responsible for the implementation of RP program (structure of the organisation, procedures applied for the RP program implementation, effectiveness of the management related to RP, including the optimisation principle application - by reviewing the levels of exposure of the workers, the levels of contamination in working places, the levels of releases, the levels of exposure of the public, the results of the self-assessment program -)
 - control of the occupational radiation doses records (by reviewing the records of individual doses, including internal and external doses, by observing the activities related to internal and external dosimetry, by inspection of the controlled and surveyed areas, by assessing the records of the RP training and retraining)

Assessment of the effectiveness of the licensee radiation protection programme

- How is the assessment carried out
 - Only through inspection **No**
 - Through inspection and assessment? **Yes**
- What is assessed and how?
 - licensing documents **Yes**
 - inspection information **Yes**
 - shutdown final report (results) **Yes**
 - Others (specify): **NPP quarterly and annually technical reports, NPP incident reports**
- Indicators used by the authority to assess licensee performance: **the RP related performance indicators, which are periodically reported by the NPP, are the radioactive emission to environment (equivalent dose to critical group) and the station dose (man*Sv); DRDR personnel assesses the following chapters of the NPP technical reports: reportable events, in-station radiation, general radioactive conditions & trends, gamma irradiation field, dose statistics (radiation incidents, dose distribution by work group, neutron dose, extremity dose, body counts), radioactive emissions, environmental monitoring, employee safety (unplanned events occupational health & safety related, accidents, performance indicators: industrial safety accident rate indicators, lost-days unavailability percentage due to industrial safety accidents).**
- National and international benchmarking: **ISOE database; results of the international intercomparison exercises for dosimetry laboratories of NPPs**
- What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? **Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.: regular and at request meetings between CNCAN staff and NPP staff, regarding RP aspects; also, between CNCAN and NPP staff there is a permanent and free communication, at our initiative and their initiative, too.**

Improvement of the regulatory effectiveness

- Existence of a process to improve regulatory effectiveness. Since when? Yes, since 2003
- If this process exist, briefly describe it. CNCAN has a Quality Management System, designed in accordance with ISO 9000:2000 provisions; there are internal audits and external audits.
- What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process? Regarding the regulation process, the stakeholders are involved in the process, by sending to CNCAN their comments on the regulation drafts, and by participating to the advisory meetings organised by CNCAN for each elaborated norm. Regarding the control process, the stakeholders have the right to dispute the regulatory dispositions, according to the national legislation.
- Do you have an inspection self-assessment program? No, not a program, there is a self-assessment procedure, in a trial version.
- Does your RB have and external audit? Feedback of the experience. Yes, in the last years CNCAN has had several Peer Review independent assessment missions, such as IRRT and RASSIA. Also, Phare experts evaluated the Quality Management System of CNCAN. All the reports resulting from these external missions are used by CNCAN in the process of its effectiveness improvement.

SLOVENIA

Country and Representative Identification

- ☐ **Country:** Slovenia
- ☐ **Name of the regulatory Body:** Slovenian Nuclear Safety Administration, SNSA
- ☐ **Name and post of the person(s) who fill in the questionnaire:** Dr. Helena Janzekovic, inspector counsellor of the Slovenian Nuclear Safety Administration, dr. Nina Jug, undersecretary of the Slovenian Radiation Protection Administration and dr. Tomaž Šutej, inspector counsellor of the Slovenian Radiation Protection Administration

Legal Matters

- ☐ **Legal framework of the RP regulatory body**
 - **Legislation on nuclear energy and regulatory authority:**
 - Ionising Radiation Protection and Nuclear Safety Act (2002 with supplements)
 - Act on Transport of Dangerous Goods (1999 with supplements)
 - Inspection Act (2002)
 - The predecessor of the regulatory body, the Slovenian Nuclear Safety Administration (SNSA), was established in 1987 and the Slovenian Radiation Protection Administration (SRPA) was established in 2003.
 - **Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc)**
 - The SNSA is established within the Ministry of the Environment and Spatial Planning and the SRPA within the Ministry of Health. According to the law the SNSA is responsible with cooperation with other ministries for the preparation of the annual report concerning radiation protection and nuclear safety which should be reported to the Parliament.
 - **Origin of financial resources (e.g.: taxes, government budget, etc)**
 - The SNSA and SRPA are financed by the state budget. The SNSA budget for year 2004 was 4 665 000 000 USD and the SRPA budget for that year was about 410 000 USD.
- **Number of authorities with competences in radiation protection.**
 - **Name(s) and competences.**
 - The Slovenian Nuclear Safety Administration (SNSA) is a regulatory body in the area of radiation and nuclear safety and the Slovenian Radiation Protection Administration (SRPA) is competent for surveillance of radiation sources used in medicine or veterinary, radiation protection, medical surveillance and education and training of exposed workers, records on personal doses of exposed workers, protection of general population, general monitoring of food and drinking water. Two inspection units exist, each one, within the mentioned authorities.
 - **Interfaces, co-operation and communication between them.**
 - The responsibilities and competences of SNSA and SRPA are defined in the Governmental Decree on Administrative Authorities within Ministries. No regional administrations exist. Both authorities co-operate and communicate through ministries on the Government level, but in practice they co-operate and communicate directly.
- **Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)**

- Both regulatory authorities propose rules and regulations.
 - The authorisation of nuclear facilities as well as all other activities within nuclear facilities is performed by the SNSA.
 - The SRPA is competent for approval of the document "*Evaluation of the Protection of Exposed Workers against Radiation*". Approved evaluation is a licensing condition.
 - The inspection of nuclear facilities as well as activities within nuclear facilities is performed by the inspectors of the SNSA and partly by the SRPA.
 - The SNSA activates in case of an emergency event special teams with a task to support an emergency plan in the country.
 - The SRPA authorises qualified experts, the dosimetry services and manage a central dose register in the country.
 - The SNSA manages a national environmental monitoring network.
 - Both regulatory authorities together with the ministry responsible for agriculture manage the monitoring program concerning radioactivity in the environment.
- **Relationship between nuclear safety and radiation protection authorities.**
 - The SNSA and SRPA shares the responsibilities as defined in the above-mentioned governmental degree and the Ionising Radiation Protection and Nuclear Safety Act.
 - **Enforcement capacity of the regulatory body on occupational RP**
 - The SNSA and SRPA have a capacity to enforce a remedial action according to the Ionising Radiation Protection and Nuclear Safety Act, as well as according to the Minor Offences Act (2003 with supplements). The Ionising Radiation Protection and Nuclear Safety Act defines penalties for specific violations of the rules. Inspectorates act as units within both regulatory authorities.
- ❑ **Legal framework on occupational radiation protection**
- **Legislation on occupational RP. Give references.**
 - Decree on Practices Involving Radiation
 - Decree on Dose Limits, Radioactive Contamination and Intervention Levels
 - Regulation on the Obligations of the Person Carrying out a Radiation Practice and Person Assessing an Ionising Radiation Source
 - Regulation on the Requirements and Methodology of Dose Assessment for the Radiation Protection of the Population and Exposed Workers
 - Regulation on Health Surveillance of Exposed Workers
 - Regulation on Approving of Experts Performing Professional Tasks in the Field of Ionising Radiation
 - Regulation on the Method of Keeping Records of Personal Doses due to Exposure to Ionizing Radiation
 - On Siting, Construction, Commissioning, Start-up and Exploitation of Nuclear Facilities (with appendix on QA)
 - On Preparation and Content of Safety Analysis Reports and other Documentation Relevant for the Assessment of Safety of Nuclear Facilities
 - **Legislation is based on (UE directives, ICRP, IAEA, others ...)**
 - Legislation is mainly based on the EU directives and EU documents. IAEA safety standards and ICRP recommendations were also considered.
 - **Specific legislation on occupational RP in NPPs**
 - No specific legislation is fully dedicated to the RP in NPPs, but some articles are specific for the RP in nuclear facilities.
 - **Specific guidance on occupational RP in NPPs.**

- No specific guidance is published.

▪ **Does your legal framework requires from the NPPs an official document on occupational RP?**

○ **Nature, scope and contents of such a document**

- According to legislation the general occupational RP programme is handled in the TS, the "*Safety Report*" as well as in the document "*Evaluation of the Protection of Exposed Workers against Radiation*". The document "*Radiation Protection Manual*" is part of internal procedures of the NPP which was also a subject of the Periodic Safety Review programme authorised by the SNSA.
- According to legislation the employers must draw up a document "*Evaluation of the Protection of Exposed Workers against Radiation*", which gives a preliminary evaluation of the nature and the extent of radiation risks for exposed workers, and produces an optimisation plan for protection against ionising radiation in all working conditions in practices involving radiation. The evaluation is according to the law a part of the application for licensing. Such document is also required for activities of an outside worker in the licensing procedure of such activities.

○ **Is the document approved by the inspection authority? Are the procedures approved?**

- According to legislation the document "*Evaluation of the Protection of the Exposed Workers against Radiation*" has to be approved by the SRPA. The approved evaluation is a licensing condition.
- Other internal documents of the NPP are not approved by the inspection authority.

○ **Are the procedures (developing and supporting the document approved?**

- The procedures of the developing and supporting the document are given in regulations as well as the content of the document. Evaluation should be checked by an independent radiation protection expert.
- Other internal documents are not approved by the inspection authority.

Radiation Protection Programme of the Licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee

- Basic Chapters of the main document named "*Radiation Protection Manual*"
 1. Purpose and scope
 2. References
 3. Responsibilities
 4. Definitions and abbreviations
 5. Instruction
 - External Radiation Exposure Control
 - Internal Radiation Exposure Control
 - Control of Radioactive Contamination
 - Control of Solid Radioactive Waste
 - Control of Works Involving Radiation
 - Self Assessment
 6. Appendices
- In addition, a list of internal procedures related to radiation programme includes:
 - "Internal Organisation of the Radiation Protection Unit"*
 - "ALARA Manual"*
 - "ALARA Planning"*
 - "Rules for Carrying off Equipment, Tools and Material from the Controlled Area"*
 - "Personal Dosimetry"*
 - "Rules for Entering Equipment, Tools and Material to the Controlled Area"*
 - "Radiation Working Permit"*
 - "Calibration Requirements of Radiation Protection Equipments used for the Control of Ionising Radiation"*
 - "ALARA Post Analysis"*
 - "Rules of ALARA Groups"*
 - "Intercomparison Program"*
 - "Self-ssessment Program of the Radiation Protection Unit"*
 - "Organisation and Equipment of the Personal Dosimetry Laboratory"*
 - "Alarm Values of the Ionising Radiation Monitors".*
- In addition the content of the document "*Evaluation of the Protection of Exposed Workers against Radiation*" is general for all practices and it is prescribed in the Rules on the Requirements and Methodology of Dose Assessment for the Radiation Protection of the Population and Exposed Workers. Its content is in an appendix.

Self Assessment of the Licensee

- **Does the licensee have a self assessment programme? Since when? Main characteristics.**
 - The QA programme exists from the beginning of the NPP operation. The QA programme of the NPP is based on the 10CFR 50 - Appendix B, ANSI N 18.7-1976, ASME B&PV Code Section III NCA-4200, ANSI/ASME NQA-1, IAEA 50 C QA and on the regulations On Siting, Construction, Commissioning, Start-up and Exploitation of Nuclear Facilities (with appendix on QA)
 - In addition, a Periodic Safety Review was initiated in the year 2001 and concluded in 2005 with a foreseen predefined period of 10 years.
 - A self assessment program started in the NPP in 2003 as a supplement to the QA programme.
 - The licensee has to review the document "*Evaluation of the Protection of Exposed Workers against Radiation*" and submit the report to SRPA in prescribed terms.
- **The programme is an initiative of the licensee or it is required by the authority**
 - The QA programme is a requirement prescribed by the law.
 - The Periodic Safety Review was initiated by the SNSA with a full agreement of the NPP, while a self assessment programme was initiated by the NPP.
 - Review of the "*Evaluation of the Protection of Exposed Workers against Radiation*" evaluation is required by the law.
- **Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially)**
 - The SNSA has a full access to the self-assessment programme.

Regulatory Body Organisation on Occupational Radiation Protection Control

- **Inspectorate organisation**
 - **Resources:**
 - **Own personnel (status) or outsourcing?**
 - Both regulatory organisations have only their own inspectors.
 - **Total number of inspectors in your country taking care of occupational radiation protection in NPPs.**
 - At the SNSA which has around 50 staff members 6 inspectors are employed. Two of them take care of occupational radiation protection in the NPP. At the SRPA which has 5 staff members two inspectors are dedicated to radiation protection.
 - **Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities? Specify number and type of facilities.**
 - Yes, inspections are also performed at two other nuclear facilities, the Central Interim Storage of Radioactive Waste and at the Research Reactor TRIGA of the Jozef Stefan Institute. In addition, the inspectors are involved in inspection of all other practices related to ionising radiation, the inspectors of the SNSA also perform inspection of research institutes, waste storages and industry, while an inspector from the SRPA controls medical and veterinary use of ionising radiation.
 - **Distribution of workload per inspector, per activity: % of time on inspection, % of time on assessment, % of time on others (specify).**
 - 60% time on inspection
 - 20% time on assessment
 - 20% time on training, education, preparation of reports not related to specific

inspection, international cooperation, preparation of legislation, ...

- **Average number of years of experience on occupational radiation protection of inspectors. Degree of rotation in the organisation.**
- The SNSA inspectors on average have 15 years of experience in radiation protection and 10 years in occupational exposure. On average the rotation in the organisation is performed every 5 years. SRPA inspectors have on average 7 years of experience.
- **Types of inspections:**
 - **Announced? Non announced? Both?**
 - Usually all inspections are announced although an announcement is not required by legislation.
 - **Specific on occupational RP? Multidisciplinary? With other RP inspectors or with nuclear safety inspectors?**
 - Usually two inspectors perform the inspection in a nuclear facility, one of them is very often dedicated mainly to nuclear safety.
- **Existence of national teams? Regional teams? Both? Resident inspectors?**
 - No national team is established as well as no regional team. There are no resident inspectors except at the refuelling period.
- **What is the dedication of resident inspectors to occupational radiation protection?**
 - The resident inspector has a possibility to inspect occupational exposure on the daily basis during the refuelling period. The dedicated time is approximately 10%.
- **Inspectors qualification and training (university studies, access to the regulatory body, retraining)**
 - Both SNSA inspectors who take care for the occupational exposure in the NPP have a diploma degree in physics. One has a Ph. D. in physics and the other inspector is going to finish M. Sc. study concerning nuclear technologies. Both SRPA inspectors have a diploma degree in physics. One has a Ph. D. in physics and the other one a Ph.D. in nuclear technologies. In addition, all inspectors went and are still going through extensive training program provided by different organisation (NRC, IAEA...).
 - According to legislation an inspector has to fulfil the following conditions: university or high professional degree, 5 years of working experience, general exam for a civil servant and a professional exam for inspector. Directors of inspection are obliged to prepare detailed programs for additional training.
- **Inspection organisation and programme**
 - **Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out? Only on shutdowns?**
 - On average the occupational RP programme is inspected twice per year by SNSA, usually once just before the outage. During the refuelling a resident inspector regularly inspects the doses as well as other RP programme themes, if needed.
 - In average SRPA performs 3 inspections per year devoted to occupational RP. Frequencies and fields of inspections depend on outage periods and perceived problems.
 - **Number of inspectors per team per inspection**

- As a rule two inspectors are usually present at the inspection.
- **Duration of the inspection**
 - The inspection takes one day as a rule.
- **Do the inspectors also carry out assessment or they are exclusively devoted to inspection**
 - The inspectors regularly perform also the assessments and other tasks.
- **Approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc**
 - 30% preparation
 - 40% on site including the preparation of the report
 - 30% post inspection assessment
- **Methodology of the preparation of the inspection. Documents consulted prior to the inspection.**
 - The documents consulted are TS, USAR, PSR, "OSART Mission Report", internal procedures of the NPP, "Periodic Safety Review Report", reports of the NPP, report of the past inspections as well as IAEA documentation, EC guidelines, NRC guidelines, document etc.. The SRPA inspectors usually refer to the data from the document "Evaluation of the Protection of Exposed Workers against Radiation". The inspectors can ask the licensee for any document she/he deems necessary.
- **Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public.**
 - A short announcement of the inspection theme is usually sent in advance, a few days before an inspection. The agenda of the inspection is orally presented in the beginning of the inspection. The minutes taken by an inspector during the inspection are not presented to the facility.
 - The final act of the inspection is a preparation of a detailed report written by an inspector. The report is signed by the representative of the facility as well as by the inspector in charge. As a rule this report is prepared and signed on the day of the inspection. If this is not the case legislation requires that this report should be sent to the licensee within 8 days. The enforcement acts are usually provided within a week.
 - No specific reports related to inspection are presented to the public.
 - However, a general annual report of the authorities is published and accessible to the general public.
- **Transparency policy**
 - The "Annual Report on Radiation and Nuclear Safety in the Republic of Slovenia" includes information related to the inspection practice.
 - On request the access to specific data related to inspection is assured by legislation namely by the Ionising Radiation Protection and Nuclear Safety Act as well as by the Act on the Access to Information of Public.
- ❑ **Inspection procedures**
 - **Existence of inspection procedures**
 - The SNSA initiated the preparation of internal inspection procedures more than a decade ago. Today 17 procedures are prepared. The SRPA has no specific procedures.
 - **Main inspection topics**

- The SNSA which was in the past responsible only for nuclear safety, today has among 17 written procedures two related only to radiation protection namely Control of the Occupational Doses and Control of Effluents.
- Inspections performed by the SRPA refer to a whole scope of the document *"Evaluation of the Protection of Exposed Workers against Radiation"*.

Assessment of the Effectiveness of the Licensee Radiation Protection Programme

- **How is the assessment carried out**
 - **Only through inspection**
 - No
 - **Through inspection and assessment?**
 - Yes
- **What is assessed and how?**
 - **licensing documents**
 - Yes
 - **inspection information**
 - Yes
 - **shutdown final report (results)**
 - Yes
 - **Others (specify)**
 - The internal procedures and programmes, design modification etc. are also assessed.
 - The SRPA is competent to approve the document *"Evaluation of the Protection of Exposed Workers against Radiation"*.
 - The SNSA is responsible for the licensing procedure of an NPP.
- **Indicators used by the authority to assess licensee performance**
 - Information gained on inspection is compared to international practice (ISOE, IAEA reports related to conventions, EC documents, NRC reports etc.). Main indicators related to occupational exposure are collective dose, average dose, maximum doses for specific activities, implementation of ALARA program, implementations of RP measures specified in the evaluation of the protection of exposed workers against radiation, etc.
- **National and international benchmarking**
 - No specific national or international benchmarking except dose limits are used in legislation.
- **What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.**
 - No specific structured interfaces exist, usually an annual meeting at the NPP of all inspectors from the SNSA was conducted. In addition, main modifications are usually presented by the NPP staff to the SNSA staff during authorisation procedure.

Improvement of the regulatory effectiveness

- **Existence of a process to improve regulatory effectiveness. Since when?**
 - The QA system at the SNSA has been extensively developed since the year 2001. At that time some of the written internal procedures of the SNSA already existed (emergency procedures, inspection procedures etc.). No formal QA system has been developed at SRPA yet.

- **If this process exists, briefly describe it.**
 - The main processes were recognised in the year 2001 and the “QA Manual”, “Strategic Plan” and “Annual Plan” were prepared. Written procedures are graded into three levels. Today around 100 internal procedures exist. The process is conducted by a dedicated QA manager at the SNSA.

- **What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?**
 - The whole administration in the state is in the process of developing an effective system stakeholder driven system by introducing transparent internet presentations of administration activities as well as the possibility to use internet or e-mail as an effective tool for the communication between administration and all stakeholders.
 - The main users of the ionising radiation actively participated during the preparation of new legislation and regulations.

- **Do you have an inspection self-assessment program?**
 - Yes, but it is not fully operational.

- **Does your RB have and external audit? Feedback of the experience**
 - No external audits were conducted recently at the SNSA or the SRPA. The last comprehensive one was IRRT (IAEA) mission in the year 1999. The ORPAS mission (IAEA), which focused only on the occupational exposure was conducted in the year 2001. Both missions reflected in the numerous improvements. No external audits performed by the national bodies have been conducted so far.

The content, extent and form of the evaluation of the protection of exposed workers against radiation
(Appendix 1 of Rules on the requirements and methodology of dose assessment for the radiation protection of the population and exposed workers (OJ RS, No. 115/2003) -unofficial translation)

1. General data on radiation practice and the person carrying out the practice

- 1.a Legal person and his representative (name, title, address)
- 1.b Radiation protection officer (name, education, experience)
- 1.c Radiation protection unit (title, address, number of workers)
- 1.č Description of the radiation practice (essential characteristic, dangers, work places)

2. Data on radiation sources and premises where they are used

- 2.a Description of radiation sources and appliances (type, mark, capacity) and the conditions for their use
- 2.b Data on maximum dose rates and the possibility of contamination
- 2.c Description of premises where the sources are used and kept and description of neighbouring areas
- 2.č Classification of the areas to controlled and supervised areas
- 2.d Radioactive waste handling and releases
- 2.e Expected period of use and the way of keeping the source after use period

3 Radiation protection of workers and population

- 3.a Shielding of sources and premises (materials, thickness, arrangements of shields)
- 3.b Safety systems (warning systems, interlocks)
- 3.c Administrative systems (assigning the responsibilities, organisation of the work process, written work procedures)
- 3.č Radiation surveillance program (description of measurements; methods, measuring points, duration of measurements, frequency, calibration of the equipment)
- 3.d Conditions for use of personal dosimeters and other radiation meters
- 3.e Personal protective equipment
- 3.f Surveillance of external and internal exposure at the workplaces and in the environment according to the program.

4. Exposure due to radiation practice

- 4.a Description of the radiation riskful work processes (duration, dose rates, intakes)
- 4.b Categorisation of workers in groups A and B according to risk involved
- 4.c Assessment of effective and equivalent doses due to normal work (data on dosimetry control)
- 4.d Assessment of effective dose for the most exposed members of the public

5 Potential exposure

- 5.a Identification of emergency events and assessment of possibility for such events
- 5.b Assessment of temporal and spatial distribution of eventual contamination
- 5.c Assessment of effective and equivalent doses for workers at emergency events
- 5.č Assessment of effective doses for members of the public at emergency events
- 5.d Assessment of the radiation total risk due to radiation practice

6 Plan for radiation protection optimisation

- 6.a Elaboration of reports on implementation of radiation protection measures and on radiation doses of exposed workers
- 6.b Follow up of the radiation risk indicators (doses, emergency events, other measures)
- 6.c Defining and checking dose constraints including reporting criteria
- 6.č Plan for reduction of radiation risk (human, administrative and technical factors)
- 6.d Qualifications and number of workers for safe performance of work procedures
- 6.e Plan of measures to prevent emergency events
- 6.f Plan of measures to reduce emergency event impacts

7 Professional opinion of the approved radiation protection expert and recommended measures for reduction of radiation risk

8 Other explanations for determination of radiation protection situation (premises plans, photos of radiation sources, technical documentation, other enclosures)

SLOVAKIA

Country and Representative Identification

- ☐ **Country:** Slovakia
- ☐ **Name of the regulatory Body**
Public Health Authority of the Slovak Republic (PHA) (Úrad verejného zdravotníctva SR)
- ☐ **Name and post of the person(s) who fill in the questionnaire:**
Dusan Viktory, head of department for RP in NPPs, PHA

Legal Matters

❑ **Legal framework of the RP regulatory body**

- Legislation on regulatory authority:
 - **Act on protection of the human Health, 1994, several times amended**
 - Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc): **Regulatory body: Public Health Authority of the Slovak Republic (Úrad verejného zdravotníctva SR), it is a national authority governed (administered) by the Health Ministry,**
 - Origin of financial resources (e.g.: taxes, government budget, etc) **government budget – Health Ministry (not direct item of PHA in the budget)**
- Number of authorities with competences in radiation protection. **1+4**
 - Name(s) and competences. **Public Health Authority of the Slovak Republic: licensing on national level of all practices, inspections and supervision of NPPs and other national important practices; Regional Public Health Authorities (4) responsible for inspections, supervision (except of NPPs and other national important practices) and radiation monitoring**
 - Interfaces, co-operation and communication between them: **Public Health Authority of the Slovak Republic is a super-ordinate authority of the Regional Public Health Authorities.**
- Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)
 - **development of proposal for RP regulations**
 - **assessment and issuing of licences for practices**
 - **assessment and issuing of licences for activities important from RP point of view (personal monitoring, services in RP, education in RP)**
 - **inspections**
 - **radiation monitoring**
 - **public exposure assessment (including natural radiation) and regulation**
 - **technical support in emergencies**
 - **certification of RP officers and experts**
 - **information and technical support for the public**
 - **maintaining of national registers and databases**
 - **international co-operation**
- Relationship between nuclear safety and radiation protection authorities.
In Slovakia there is a separate authority for nuclear safety – Nuclear Regulatory Authority of the SR (Úrad jadrového dozoru SR). It is an independent office of state administration with its own budget item in governmental budget. There exist the official agreement on co-operation of Nuclear Regulatory Authority of the SR and the Ministry of Health.
- Enforcement capacity of the regulatory body on occupational RP **On a base of the legislation the PHA has enforcement capacities on radiation protection.**

❑ **Legal framework on occupational radiation protection**

- Legislation on occupational RP. Give references.
 - **Act on protection of the human Health, 1994, several times amended**
 - **Regulation on radiation protection, 2001**
- Legislation is based on (UE directives, ICRP, IAEA, others ...)

The legislation is based on ICRP 60, and EC directive 96/29/Euratom
- Specific legislation on occupational RP in NPPs
none
- Specific guidance on occupational RP in NPPs.
none

- Does your legal framework requires from the NPPs an official document on occupational RP?
Yes, Radiation Protection Program
 - Nature, scope and contents of such a document **It is a kind of a cover document for RP documentation (procedures, instructions, methods), details are below**
 - Is the document approved by the inspection authority? Are the procedures approved? **The document is approved**
 - Are the procedures (developing and supporting the document approved? **No, but any change in these documents must be reported to the authority.**

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee

- **basic legislative requirements**
- **system and structure of RP unit**
- **responsibilities and duties**
- **goals of RP**
- **Alara application**
- **methods and techniques**
- **documentation structure and list of documents**
- **classification of areas and workplaces**
- **regime on site and in controlled area**
- **work organization and task preparation**
- **basic rules and requirements for radiation monitoring on workplace, of personal and of environment**
- **reference levels**
- **education and training in RP**
- **assessment of RP**
- **identification and evaluation of declinations, anomalies and incidents**
- **information system of workers and public**
- **reporting to authorities**

Self assessment of the licensee

- Does the licensee have a self assessment programme?. Since when? . Main characteristicst. **Yes, since 1999, Characteristics: RP effectiveness indicators and their evaluation, list of deviations and their analyzes, assessment of particular practices (activities), Alara application –Alara commission activities, summary assessment, proposal of measures and tasks**
- The programme is an initiative of the licensee or it is required by the authority **Licensee**
- Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially) **Yes**

Regulatory Body organisation on occupational radiation protection control

- ❑ **Inspectorate organisation**
 - Resources:
 - Own personnel (status) or outsourcing? **Staff of PHA**
 - Total number of inspectors in your country taking care of occupational radiation protection in NPPs. **3 inspectors**
 - Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities. **One unit in decommissioning, temporary storage of spent nuclear fuel, installations for treatment and conditioning of radwaste, radwaste repository (near surface)**
 - Distribution of workload per inspector, per activity: % of time on inspection, % of time on assessment, % of time on others (specify).
 - Average number of years of experience on occupational radiation protection of inspectors. Degree of rotation in the organisation. **10**
 - Types of inspections:
 - Announced? Non announced? Both? **Both**
 - Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors? **Mainly RP specific, rarely with NS inspectors**
 - Existence of national teams? Regional teams? Both? Resident inspectors? **No national teams, no resident inspectors**
 - What is the dedication of resident inspectors to occupational radiation protection?
 - Inspectors qualification and training (university studies, access to the regulatory body, retraining) **University graduated, special post-gradual education in the public health**
- ❑ **Inspection organisation and programme**
 - Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns? **8 -15 one day inspections, focused (specific) inspections, not only during shutdowns**
 - Number of inspectors per team per inspection **1- 3**
 - Duration of the inspection **Usually 1 day**
 - Do the inspectors also carry out assessment or they are exclusively devoted to inspection **They carry out the assessment as well**
 - Approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc
 - Methodology of the preparation of the inspection. Documents consulted prior to the inspection. **Usually but not always**
 - Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public. **Usually, there is only one document produced – a report, which contains the goal, the agenda, list of participants, minutes of inspection, statement of participants and findings. The official call up of PHA or the decision of PHA follows in the case of important findings or if the operator does not agree with findings and required measures.**
 - Transparency policy
- ❑ **Inspection procedures**
 - Existence of inspection procedures. **There exist only self prepared Inspection procedures (guides), they are not official or authorized.**
 - Main inspection topics
 - Regular inspections focused on**
 - outages
 - important changes or new technologies or new work procedures
 - special activities or special workplaces
 - individual dose monitoring system
 - monitoring of discharges, evaluation of environmental impact
 - activities of the RP department
 - monitoring system on site and off site and results
 - emergency preparedness
 - radiation protection during operation of the reactors
 - Alara application
 - system of training and education in RP
 - radioactive waste management and clearance of radioactive material
 - etc

Enforced inspections in case of

- anomalies, incidents or accidents
- complaint
- request of the other authorities or state administration institutions
- follow up inspections
- transportation of radioactive material
- temporary workplaces (industrial radiography)
- emergency exercises

Assessment of the effectiveness of the licensee radiation protection programme

- How is the assessment carried out
 - Only through inspection
 - Through inspection and assessment? **Yes**
- What is assessed and how?
 - licensing documents - **accomplishing of conditions and requirements in licence**
 - inspection information – **correspondence with reported information and with reported procedures, international experience or practice, legislation and international recommendations**
 - shutdown final report (results)
 - Others (specify)
- Indicators used by the authority to assess licensee performance **Individual dose distribution, collective doses, task collective doses, number of exposed workers, activities of Alara committee, activities of NPP management in RP, levels of radiation on workplace and in the environment, activity of discharges, kind and number of anomalies and deviations and measures taken, kind of findings during the inspections**
- National and international benchmarking **Mainly ISOE database and information are used for benchmarking, however RB has only very limited access to useful data in ISOE, unfortunately.**
- What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc. **Meetings with management of NPP are not on a regular basis, meetings with staff of Nuclear Regulatory Authority are periodically.**

Improvement of the regulatory effectiveness

- Existence of a process to improve regulatory effectiveness. Since when? **The systematically process of improvement of regulatory effectiveness does not exist at present.**
- If this process exist, briefly describe it.
- What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?
- Do you have an inspection self-assessment program? **The approved self assessment program does not exist at present, however the results and effectiveness of inspections are discussed.**
- Does your RB have and external audit.? Feedback of the experience **Only international missions (IRRT) have been focused on our RB. There has not been any other external audit on our RB.**

SPAIN

Country and Representative Identification

- ☐ **Country:** Spain
- ☐ **Name of the regulatory Body:** Consejo de Seguridad Nuclear (Nuclear Safety Council). CSN
- ☐ **Name and post of the person(s) who fill in the questionnaire:** Olvido Guzmán, radiation protection inspector & expert

Legal Matters

- ❑ **Legal framework of the RP regulatory body**
 - **Legislation on nuclear energy and regulatory authority:**
 - Nuclear Energy Act (1964)
 - Nuclear Safety Council Foundation Act (1980). Nuclear Safety Council Statute (1982 and amendments)
 - National Electric Industry Regulation Act (1997)
 - **Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc).**
It is a public entity independent of the State's Central administration, with its own legal status and assets.
Since its creation, CSN annually reports to the Spanish Parliament.
 - **Origin of financial resources (e.g.: taxes, government budget, etc):**
 - The main source of financing is the fee for services rendered by the CSN (93% of the total budget). Fees for services rendered by the CSN Act (1993) describes the amount and services which include: inspection and assessment of all facilities using ionising radiation, reports, license exams, etc ...
 - Budget for 2004: 48,267,000 euros
 - **Number of authorities with competences in radiation protection.**
 - **Name(s) and competences.**
 - The Spanish Nuclear Safety Council (CSN) holds the exclusive authority for Nuclear Safety and Radiation in Spain.
 - **Interfaces, co-operation and communication between them.**
 - For facilities other than nuclear installations, CSN may have delegation agreements with regional administrations
 - **Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)**
 - It proposes to the Government rules and regulations in nuclear safety and radiation protection
 - It issues mandatory and binding reports to the Government prior to any authorisation for nuclear and radioactive facilities
 - It inspects nuclear and radioactive facilities and enforces remedial actions when necessary
 - It provides technical support in the event of a nuclear emergency and approves emergency plans
 - It controls and supervises radiation doses which may be received both by exposed workers and the general public
 - It examines and grants licenses for radiation protection officers and other qualified experts
 - It advises the courts and public administration bodies on matters of nuclear safety and radiation protection
 - It carries out and promotes research programs on nuclear safety and radiation protection
 - It authorises Dosimeter Services and Radiation Protection Units
 - It manages the National Registry of Outside Undertakings and the Radiological Passport
 - It manages the National Environmental Radiological Monitoring Network
 - **Relationship between nuclear safety and radiation protection authorities.**
 - The Spanish Nuclear Safety Council (CSN) holds the exclusive authority for Nuclear Safety and Radiation in Spain.
 - **Enforcement capacity of the regulatory body on occupational RP.** The CSN has capacity to enforce remedial actions when necessary

Legal Matters

- ❑ **Legal framework on occupational radiation protection**
 - **Legislation on occupational RP. Give references..**
 - Royal Decree 1836/1999 for Nuclear and Radioactive Facilities
 - Royal Decree 783/2001 on the Sanitary Protection against Ionising Radiation
 - Royal Decree 413/1997 for the Operational Protection of Outside Workers
 - **Legislation is based on (UE directives, ICRP, IAEA, others ...)**
 As a member of the European Union, Spain has to carry out the transposition of European directives. In the case of radiation protection, UE Directives are mainly based on ICRP recommendations. IAEA guidance is also observed
 - **Specific legislation on occupational RP in NPPs.**
 CSN issues regulations in the form of "[CSN Safety Instructions](#)". They are binding. Some examples related to occupational RP in NPP:
 - IS-01, Format and content of the individual radiological passport.
 - IS-02 Shutdown documentation for light water reactors (including RP content)
 - IS-03, Qualifications required for experts in radiation protection
 - IS-06, Training programmes (general and specific) for workers in nuclear facilities
 - **Specific guidance on occupational RP in NPPs.**
 CSN issues guidance on nuclear safety and radiation protection. Some specific guidance on occupational RP in NPPs are the following:
 - GSG-01.12 Practical implementation of the optimization principle in NPPs
 - GSG-07.06, Content of Radiation Protection Manuals for nuclear facilities
 - GSG-07.03, Basis for the establishment of Radiation Protection Services
 - GSG-07.02, Qualifications required to obtain the degree of Head of the Radiation Protection Department
 - GSG-07.01 Technical and administrative requirements for authorised individual dosimetry services
 - **Does your legal framework requires from the NPPs an official document on occupational RP? YES.** Radiation Protection Manual.
 - **Nature, scope and contents of such a document.** The Radiation Protection Manual is a [licensing document](#) in Spain reflecting the practical implementation of the licensee responsibility for radiation protection through the adoption of management structures policies, plans, risk assessment, radiological surveillance, training, procedures and other measures developed and implemented to achieve continuing compliance with the legislation in force and to apply the Alara principle
 - **Is the document approved by the authority? Which authority? YES.** By the CSN.
 - **Are the procedures (developing and supporting the document approved? NO**

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee.

Chapters of the Radiation Protection Manual

- Generalities
- Radiological risks in the plant
- Radiological classifications of workers
- Radiological surveillance
- Workplace classification
- Access, permanence and working conditions in radiological zones
- Protection against radiation and contamination.
- Workers monitoring and surveillance
- Public monitoring and surveillance
- Monitoring and control of radioactive material
- Organisation and responsibilities in radiation protection
- Qualification and training in radiation protection
- Optimization programme
- Revisions, inspections and audits in radiation protection
- Anexes (e.g.: procedures, definitions, ALIs nad DACs, etc)

Self-assessment of the licensee

- **Does the licensee have a self assessment programme? YES Since when? Main characteristics.**
Since the beginning of the operation of the plant the licensee have had quality assurance programmes. Since year 2000, a new process of self assessment is being implemented. This new program is systematic, harmonised for all the sites, and its corrective actions prioritised. It covers: external assessment, independent internal assessment, self-assessment, personnel findings, improvement actions proposal in routine activities.
- **The programme is an initiative of the licensee or it is required by the authority? It has been a joint initiative by the CSN and Spanish licensees . A joint group (NPPs licensees-CSN) has established the content and scope of the new programme In the new supervision system at the CSN (SISC), the self-assessment programme of the licensee is a key aspect**
- **Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially). YES.**
The regulatory body has to evaluate and inspect the effectiveness of the programme, through its results and the implementation of corrective actions.

Regulatory Body organisation on occupational radiation protection control

☐ Inspectorate organisation

- **Resources:**
 - **Own personnel (status) or outsourcing?**
CSN has its own staff. They are civil servants
 - **Total number of inspectors in your country taking care of occupational radiation protection in NPPs.**
Total CSN staff: 440 people, of which around 130 are inspectors. 4 inspectors for occupational radiation protection in nuclear power plants
 - **Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.**
YES: in addition to the 9 nuclear units, they also control one fuel manufacturing facility, one radioactive waste facility, one research nuclear facility and a uranium mine under dismantling

Regulatory Body organisation on occupational radiation protection control

- **Distribution of workload per inspector, per activity:**
 - 35 % of time on inspection,
 - 45 % of time on assessment,
 - 20 % of time on others (specify): training, meetings, guidance, etc
- **Average number of years of experience on occupational radiation protection of inspectors (8 years). Degree of rotation in the organisation** (the degree of rotation in CSN is not very high. Once the personnel became a civil servant it remains in the CSN almost all his professional life in different department. The average time spent in one department is varies between not less than 5 years (general) and 20 years.
- **Types of inspections:**
 - **Announced? Non announced? Both?**
Although the system allows for non announced inspections, 100% of the inspections are announced.
 - **Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?**
Normally, they are specific on occupational radiation protection. In the field of nuclear safety, for three years, there has been multidisciplinary inspections, but not in radiation protection.
- **Existence of national teams? Regional teams? Both? Resident inspectors?**
CSN inspection and control on occupational radiation protection of nuclear facilities is carried out by its inspectors at the headquarters (Madrid). Apart from the headquarters inspectors, there are two resident inspectors per nuclear site (only for NPPs) who devote around 10% of their time to RP issues.
- **What is the dedication of resident inspectors to occupational radiation protection?** 10% of their time.
- **Inspectors qualification and training (university studies, access to the regulatory body, retraining)**
All CSN radiation protection inspectors are required to have a university degree in scientific or technological areas.
Additionally, in order to belong to the CSN Technical Body, it is necessary to pass a competitive examination including topics on Nuclear Technology, Nuclear Safety, Radiation Protection and Legislation matters (preparation takes around 1 year in addition to specific education). Periodical training of CSN radiation protection inspectors is performed according with a general training programme approved by the CSN Technical Management (As of the end of 2004 the Council's training efforts included 1114 trainees during 44733 hours, with an average of 2.53 attendances per person 2004)
- **Inspection organisation and programme**
 - **Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns?**
Generally 1 per year during the refuelling outages. Sometimes 2, in such a case the inspection carried out during shutdown is devoted to operational aspects specific to the activities during shutdown. The other one is devoted to documentary issues and engagement. revision.
There are also special inspections in case of: supporting the licensing process in case of design modifications involving radiation protection issues or supporting assessment procedures following radiation protection incidents.
 - **Number of inspectors per team per inspection.** 2 or 3 inspectors per team.
 - **Duration of the inspection.** On average, a routine inspections takes 4 days
 - **Do the inspectors also carry out assessment or they are exclusively devoted to inspection?**
CSN inspectors in charge of occupational radiation protection in NPPs also perform assessment of documents and radiological results.

Regulatory Body organisation on occupational radiation protection control

- **Approximate % of time devoted to each phase of the inspection:**
 - **preparation**, 35%
 - **on site**, 25%
 - **production of documents**, etc 40%.

 - **Methodology of the preparation of the inspection. Documents consulted prior to the inspection.**
 - Review of previous CSN Inspection & Assessment reports
 - Review of licensing official documentation
 - Review of monthly operation reports submitted to CSN by NPPs.
 - Review of resident inspectors reports
 - Review of incident reports

 - **Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internal, which are sent to the licensee and which are public**
 The legal framework for CSN radiation protection inspections is established in the Regulations for Nuclear and Radioactive Facilities (1972, amended 1999)
 - Prior to the inspection, an agenda is prepared and sent to the licensee containing the topics to be covered during inspection
 - After performing and inspection CSN radiation protection inspectors are required to prepare an official inspection report which should be issued not later than 12 workdays after inspection completion. The content of this report has to be objective not allowing for subjective judgements.

In accordance with national regulations, official inspection reports are sent back to the Licensee to allow him for making any allegation about the contents. CSN inspectors are officially required to take (or not) into consideration the allegations. The whole set: inspection report, allegations and inspector approval (or rejections) of allegations are considered as "public documentation" and it is sent to the Local State Agency of Ministry of Industry.

 - In general, not internal reports are produced after inspections, except for special events. One the refuelling outage is finished the licensee is required to send the CSN a report containing the results of the outage. This report is assessed but the inspectors who produce and assessment internal report.

 - **Transparency policy.** The current policy transparency is described in the above paragraphs. At present a process of improvement of this transparency policy is being developed. Among its cornerstones, the official inspection reports would be published in the CSN website.
- ❑ **Inspection procedures**
- **Existence of inspection procedures:** YES

 - **Main inspection topics:**
 - Review of the Alara programme, organisation and engagements. Practical implementation.
 - Internal audits in occupational radiation protection
 - Practical implementation of the Alara principle in the outage programme and main activities.
 - Human and technical resources of the radiation protection service
 - Training
 - Instrumentation.
 - Dose estimations and especial events during the outage
 - Source term reduction initiatives: follow-up.
 - Management of radiological work permits
 - General conditioning or radiological areas and general personnel behaviour (visit to controlled areas)
 - Entry/exit to contaminated zones
 - Radiological control of materials and personnel at the exit of radiological areas
 - General control of radioactive material

Assessment of the effectiveness of the licensee radiation protection programme

- **How is the assessment carried out?**
 - Only through inspection? NO
 - Through inspection and assessment? YES.
- **What is assessed and how?**
 - licensing documents. YES
 - inspection information. YES
 - Outage final report (results). YES
 - Others (specify): design modifications, source term reduction programme, etc.
- **Indicators used by the authority to assess licensee performance.**
 - Practical implementation of the ALARA Programme in the plant
 - All the information obtained during inspections
 - Numerical indicators such as: evolution of collective doses, estimations versus final results, maximum and average dose, dose per activity (evolution and estimation versus reality), evolution of dose rates at significant points, number of contaminated workers, etc.
- **National and international benchmarking:** YES. ISOE database is used for international benchmarking.
- **What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.**

In Spain, there is a joint group between the CSN and the association of nuclear operators in Spain (UNESA). In this group, topics of common interest are discussed. Sometimes ad-hoc groups inside this joint group are created in order to deal with more specific technical subjects.

Improvement of the regulatory effectiveness

- **Existence of a process to improve regulatory effectiveness.** YES. **Since when?** Since 2000
- **If this process exist, briefly describe it.**
 - The process started in 2000. It has had different phases: a) identification and analysis of areas of improvement; b) analysis of the international context; c) proposal of improvement actions; d) implementations of an action plan.
 - The analysis carried out covered 4 activities (+ communication): a) legislation; b) assessment; c) inspection and control and d) corrective actions.
 - One main conclusion has been: "The regulatory process have to focus on essential areas for the nuclear safety and radiation protection with a risk-informed basis. Corrective actions must be in harmony with the significance of the findings on the basis of a good licensee safety management system and a continuous assessment of the licensee performance by the CSN.
 - The plan action included nine task, among them: policies documents, legislation hierarchy, ROP adaptation, corrective action programme, sanction regime modification, analysis and adaptation of risk-informed legislation, assessment process improvement, etc...
 - As a consequence of this process a new inspection and control system is being implemented in Spain: SISC, Integrated System for NPP's supervision
- **What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?** The baselines of this process have been jointly established between the CSN and the licensees. Other stakeholders, such as the public will participate at a communication level as receptors of the results of the new system.
- **Do you have an inspection self-assessment program?** YES . The CSN has an inspection office. This office carries out a follow-up and supervision of the CSN inspection programme and proposes corrective actions in order to optimise and harmonise the programme. It also propose criteria and practices in relation to the inspection and control mission of the CSN
- **Does your RB have and external audit.?** YES. For several years the CSN has had external audits covering general aspects from a quality point of view, process reengineering and process improvement. They covered organisational and management process. They did not covered technical issues. **Feedback of the experience.** As a consequence of the results of these audits there have been a series of improvements in the organisational and managerial system of the CSN.

SWEDEN

Country and Representative Identification

- ☐ **Country:** Sweden
- ☐ **Name of the regulatory Body:** Swedish Radiation Protection Authority (Statens strålskyddsinstitut) SSI
- ☐ **Name and post of the person(s) who fill in the questionnaire:** Ingemar Lund, Ph. D., Radiation Protection Officer

❑ Legal framework of the RP regulatory body

Sweden

- Legislation on nuclear energy and regulatory authority:
 - The Radiation Protection Act (**SFS 1988:220**)
 - The Act (**SFS 1984:3**) on Nuclear Activities
 - Nature and dependency of the regulatory body
 - The SSI is a central government authority responsible for the radiation protection issues in Sweden. The SSI is empowered to issue regulations in its Code of Statutes, SSI FS.
 - Origin of financial resources (e.g.: taxes, government budget, etc)
 - The SSI activities inside the nuclear sector are financed via annual fees from the licensees/operators of nuclear facilities.
- Number of authorities with competences in radiation protection.
 - Name(s) and competences.
 - The SSI is the appointed competent Swedish radiation protection authority but naturally, the Swedish Nuclear Inspectorate, the SKI, is indeed very important for radiation protection in it's role as a "nuclear safety authority".
 - Interfaces, co-operation and communication between them.
 - The SKI and the SSI has close co-operation. Their General Directors have seats in the other authorities board, several annual meetings between the managements occur. Issued regulations are co-ordinated and both inspection and licensing activities are co-ordinated to the extent needed in order to achieve good safety and radiation protection conditions at the NPPs.
- Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)
 - The SSI directs, through regulations issued in its Code of Statutes, SSI FS, the radiation protection at the Swedish nuclear installations. It is empowered to do so by the Government in the Radiation Protection Ordinance (**SFS 1988:293**) and the SSI also issues certain permits in accordance with the Ordinance (**SFS 1984:14**) of Nuclear Activities. Another important Ordinance for the SSI is: Ordinance with instructions for the Swedish Radiation Protection Authority (**SFS 1988:295**)
- Relationship between nuclear safety and radiation protection authorities.
 - Due to the connection and overlapping issues of nuclear safety and radiation protection, the Swedish authorities, the SKI (nuclear safety) and the SSI (radiation protection) tries to harmonise, co-operate and organise their activities, following assigned duties and formal competences, in a close and fruitful way. E.g. some common working groups are established, common assessment procedures are established, the representation in national and international bodies is co-ordinated, and the management of the authorities have several annual meetings. Occasionally common inspections are carried out. The two authorities prepare a joint annual report to the Government on the Safety and RP status at the NPP's.
- Enforcement capacity of the regulatory body on occupational RP
 - License conditions and decisions by the SSI can be decided under penalty of a fine.
 - The SSI can issue prohibitions against manufacture, sale, acquisition or use of materials containing radioactive substances.
 - Licences under both the Radiation Protection Act as well as the Nuclear Act can be revoked if regulations or conditions imposed pursuant to the Acts have been violated in a significant respect or there otherwise are strong reasons for revocation.
 - Violations, if considered not to be trivial or minor, by the license holders are reported to the Swedish court system for judgement and possible consequences if sentenced (maximum 2 years' imprisonment)

❑ Legal framework on occupational radiation protection

- Legislation on occupational RP. Give references.
 - The Radiation Protection Act (**SFS 1988:220**)
 - The Ordinance (**SFS 1988:293**) on Radiation Protection
 - **SSI FS 1996:3** Regulations on Outside Workers at Work with Ionising Radiation
 - **SSI FS 1998:3** The Swedish Radiation Protection Institute's Regulations on Categorisation of Workplaces and Workers at Work with Ionising Radiation
 - **SSI FS 1998:4** Regulations on Dose Limits at Work with Ionising Radiation
 - **SSI FS 1998:5** The Swedish Radiation Protection Institute's Regulations on Monitoring and Reporting of Individual Radiation Doses
 - **SSI FS 1998:6** Regulations on Medical Examinations for Work involving Ionising Radiation

- Legislation is based on (UE directives, ICRP, IAEA, others ...)
As a member of the European Union, Sweden has to obey the EU-legislation and carry out the transposition of European Directives. The philosophy and advices of the ICRP and the IAEA are used when no conflicts between these and the binding EU-legislation exists.
- Specific legislation on occupational RP in NPPs
The following regulations are directed towards nuclear facilities (and especially NPPs):
 - **SSI FS 2000:10** Regulations on Radiation Protection of Workers Exposed to Ionising Radiation at Nuclear Plants
 - **SSI FS 2000:11** Regulations on Radiation Protection Manager at Nuclear Plants
 - **SSI FS 2002:4** Regulations on Planning for and during Decommissioning of Nuclear Facilities
- Specific guidance on occupational RP in NPPs.
 - **SSI FS 2000:6** General Advice on the Competence of Radiation Protection Experts
 - Begränsningskrav angående aktivitet i kylsystemens mellankylkretsar, 1990-01-16, **8200/46/90**
 - Instructions on how to report radiation doses and results from area supervision, 1994-12-13, **8200/3315/94**
 - Revised instructions on reporting experiences from annual outages and other major activities (estimated dose > 100 mmanSv) on controlled areas, 2000-11-06, **560/3094/00**
 - Requested information to be reported to the SSI in connection with planned power uprates at nuclear reactors, 2003-10-23, **560/3150/03**
 - SSI-policy: Avoiding the risk for double registration of radiation doses from work at nuclear facilities, 2000-11-22, **580/3195/00**
- Does your legal framework requires from the NPPs an official document on occupational RP?
 - Yes, Written radiation protection instructions
 - Nature, scope and contents of such a document
The local (plant) RP instructions should at least encompass:
 - Categorisation of workers
 - Controlled and supervised areas
 - Radiation protection education
 - Monitoring of individual doses
 - Contamination control
 - Calibrations and control of instruments and equipment
 - Management and transport of radioactive material on the site
 - Visitors to controlled areas
 - Documentation, Archiving, and
 - Reporting
 - Is the document approved by the inspection authority? Are the procedures approved?
The adequacy and content of the instructions are periodically checked during inspections but no formal approval is given.
 - Are the procedures (developing and supporting the document approved?
No approval is given.

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee

An official RP-programme is not requested but the SSI (these do anyhow exist!) requests an official "ALARA-programme":

SSI FS 2000:10 4- 5 §§:

Optimisation

§ 4 The work shall be performed in such a way that human exposures are limited as far as reasonably achievable, social and economical factors taken into account. For this purpose the licence holder shall ensure that goals and needed actions for control are established and documented and that needed resources are available.

§ 5 The goals and actions of control shall be adjusted with respect to the prerequisite of the plant and be drawn up to take care of the daily as well as the long-term radiation protection. All individuals that are exposed to ionising radiation or are decision-makers in matters that affect the individual doses shall have the knowledge of concern regarding the goals and the means of control.

The practice, including the goals and actions of control, shall regularly be followed up and evaluated with respect to what is stated in section 4. Such evaluations shall be performed at least once a year. Documentation on the evaluation shall be sent to the Swedish Radiation Protection Authority.

The SSI has given advice on the nature and types of goals and actions which are referred to in these paragraphs: *Follow-up on the "ALARA-programmes" at the Swedish nuclear power plants 1995, SSI-report, Unit of nuclear facilities and transport, 1995-12-11*. An overview of the radiation protection at the Swedish nuclear power plants during 1994 – 2002 was performed and published by the SSI in the report: *Radiation protection at Swedish NPP's during the period 1994-2002 and reflexions on the future development* (in Swedish). The main results from this evaluation were presented at the ISOE-meeting in Lyon, 2004.

Self assessment of the licensee

- Does the licensee have a self-assessment programme? Since when? . Main characteristics.
The inspection and assessment programme of the SSI is based on the knowledge of that the licensees have existing and functioning QA- and self-assessment programmes. In many ways the SSI controls the self-assessment of the licensees. From time-to-time the SSI tests and controls the actual performance of the radiation protection activities but these checks are sparse and random in nature (due to inspection resources).
- The programme is an initiative of the licensee or it is required by the authority
The present system is formally required for certain activities (i.e. QA-systems are required in certain SSI regulations i.e. in connection with dosimetry, dismantling activities, management of sources etc. The SSI however plan to update the regulations: **SSI FS 2000:10 Regulations on Radiation Protection of Workers Exposed to Ionising Radiation at Nuclear Plants** in such a way that self-assessment and organisation of radiation protection work is more directly addressed. The SSI has, however, so far not identified or registered any major deficiencies in this area. The nuclear industry is used to work according to existing and updated ISO-standards and regular self-assessment activities are performed (sometimes involving experts from other Swedish NPPs) and the utilities are active within the WANO-system.
- Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially)
The Radiation Protection Act (**SFS 1988:220**) and the corresponding RP Ordinance (**SFS 1988:293**) Empowers the SSI to request any written documentation, which the SSI finds relevant to its inspection and enforcement activities within the radiation protection area. This right should however not be misused and the SSI rarely requests to share information/results from internal self-assessment or WANO-missions at Swedish NPPs. The licensees however, usually brief the SSI about findings and any "Areas of Improvements".

Regulatory Body organisation on occupational radiation protection control

□ Inspectorate organisation

- Resources:
 - Own personnel (status) or outsourcing?
The SSI has its own staff of inspectors (civil servants)
 - Total number of inspectors in your country taking care of occupational radiation protection in NPPs.
In total, six inspectors perform the inspections of the RP activities at the NPPs.
 - Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.
Yes. Two other facilities, the nuclear installations at the industry center at Studsvik (waste management, radiation sources and until 2005 also research reactors) and the nuclear fuel production of Westinghouse Sweden Electric AB at Västervik.
 - Distribution of workload per inspector, per activity: % of time on inspection, % of time on assessment, % of time on others (specify).
On average, 20 % of the time is spent on inspections, 40 % of the time on assessments and 30-40 % of the time on other SSI-activities (emergency, preparedness, education, presentations to the public, reports etc.)
 - Average number of years of experience on occupational radiation protection of inspectors. Degree of rotation in the organisation.
Average experience: 12 years, Rotation between the facilities at least every 5th year.
- Types of inspections:
 - Announced? Non-announced? Both?
Even if the SSI has the right to perform non-announced inspections these are not used as long as the SSI does not expect any criminal activities.
 - Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?)
In the area of occupational exposure the RP inspections are separate from the nuclear safety inspections. However, before outages or major refurbishment activities at the NPPs
- Existence of national teams? Regional teams? Both? Resident inspectors?
All the inspections on RP at the nuclear facilities are performed by the central SSI-inspectors. No regional teams or site inspectors are used.
- What is the dedication of resident inspectors to occupational radiation protection?

- Inspectors qualification and training (university studies, access to the regulatory body, retraining)
The SSI tries to recruit persons with university studies in radiation protection, physics, chemistry or civil engineering. Depending on background further internal training in radiation protection and, of course, as civil servants is necessary (legislation, the SSI procedures, etc.). No fixed training programmes exist, these are rather tailored to the individual need and background of the employee.
Before any inspector is assigned as responsible for contacts and inspections at a nuclear power plant, quite some experience is necessary. The SSI has lately employed two former inspectors of the SKI (with extensive earlier knowledge of the safety issues, nuclear power plants and the role and duties of a civil servant) and for these two persons, it has been possible to become full inspectors at the NPP sites earlier (in a couple of years with extra RP-training) than otherwise would be required.

□ Inspection organisation and programme

- Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns?
The average is about 10 inspections per site. At the Barsebäck site (now with two closed NPPs since 2005) only 4 – 5 inspections are performed per year. Each of the other sites has 3 – 4 reactor units. 1-2 inspections per reactor and outage are performed. About 40 – 50 % of the inspections are performed when the units are operating. These are usually addressing the self-assessment issues of the licensee and specific requirements of the SSI regarding education, dosimetry (external/internal), ALARA-programme, instruments, organisation etc.
- Number of inspectors per team per inspection
1-2 inspectors per inspection. During some special theme/topical inspections (performed in the same way and with the same content at each site) the number is increased to 3-4 inspectors.
- Duration of the inspection 1-2 days

- Do the inspectors also carry out assessment or they are exclusively devoted to inspection?

The inspectors also perform the assessment of the inspection results. However, the assessment could be performed by a team of several inspectors and the final judgement is made by the head of the inspection unit (in contra signing protocols and, if needed, making decisions on the need of any corrective actions needed)

- Approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc

Preparation: 33 % for each of the three parts (inspection, preparation, evaluation & documentation). However, for theme inspections

- Methodology of the preparation of the inspection. Documents consulted prior to the inspection.

Documents consulted are:

- Regulations and binding license conditions
- Earlier inspection protocols from inspections of the topic of interest
- Documented experience from the other NPPs relating to the inspected area/topic.
- Technical documentation, layouts etc.

Often, a document with the questions and issues that will be raised by the SSI is sent to the licensee so that access to relevant personnel and documentation can be guaranteed at the inspection.

- Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public.

The SSI only produces one type of official inspection protocols that can be requested by anyone (public documents). These protocols are archived at the SSI and can be requested by journalist or any other person. They are always sent to the licensee and sometimes to the SKI (nuclear inspectorate) for information.

- Transparency policy

According to the Swedish law, all civil servant work should be performed transparently. The only documents which are not accessible to the general public refers to personal dose registers and nuclear safety issues (i.e. access information, details on storage of radioactive substances and fissile material, drawings etc) and documents which are classified as being of commercial interest (i.e. inventions, costly investigations and information that could affect the free competition on the market)

□ **Inspection procedures**

- Existence of inspection procedures

The SSI has a policy and guidelines for its inspections. Furthermore on the department and unit level, written instructions exist on how inspections should be prepared, carried out and followed-up (including documentation).

- Main inspection topics

- The radiation protection safety issues (no situations or activities should be allowed that can result in deterministic effects due to high doses)
- The ALARA-work (to keep number of persons exposed, the individual doses and the potential doses, when these are not certain to be achieved, as low as reasonably achievable). The SSI controls that such work is ongoing and that it is in accordance with the SSI requirements.
The SSI should also support and promote improvements in the RP situation – these activities should not be coupled, in any way, to the enforcement process. The final decisions on what is ALARA or not must and should be made by the licensee..
- The calibration and use of modern and relevant equipment (dosimetry, alarms, instruments, etc)
- The documentation and archiving of lessons learned and relevant data in order to secure feed-back experience etc.. (doses, radiation levels, work procedures, instructions, policies, lessons learned during unusual events, documentation needed for future refurbishment or decommissioning activities etc...)
- Organisation, education programmes and Man-Technology-Organisation issues
- Planning and performing of outage work /refurbishment activities
- Co-operation with contractors and education/information to external workers (dose pass-ports, medical examinations, division of responsibilities for RP-issues, etc..)
- The quality assurance work and any tendering or out-sourcing activities that could affect the RP situation

Assessment of the effectiveness of the licensee radiation protection programme

- How is the assessment carried out
 - Only through inspection **NO** - also by studying other reported data and feed-back experience requested by the SSI regulations or/and delivered by the licensees in other ways (telephone, e-mail, at other meetings etc...)
 - Through inspection and assessment?
- What is assessed and how?
 - Licensing documents **YES** – Before issuing and also if issued by other body (the Government or the SKI or any other authority if conditions could affect the RP situation in any negative way)
 - Inspection information **YES** – Compared to requirements in the SSI regulations and/or in any relevant license condition. The general RP-situation (doses, radiation levels) is also assessed on a long-term basis in order to identify trends.
 - Shutdown final report (results) **YES** – during inspections changes in radiation levels or other relevant parameters (water chemistry, oxidation etc...),. From the final reports all the relevant dose statistics, lessons learned, organisational issues, experience from the co-operation with contractors etc.. The information is read and assessed in order to identify problems or issues that needs to be resolved.
Often the SSI avoids regulating issues if the identified problems can be resolved by the utilities themselves or in co-operation with contractors. The SSI brings up the issues in the contacts with the licensees and checks on any future actions taken to improve the situation. Only if this is not possible/achieved, the SSI formally requires actions in written decisions or by other means.
 - Others (specify)
- Indicators used by the authority to assess licensee performance

Number of deviations & incidents, trends in dose and dose rate data, follow-up on ALARA-programmes, judgement of safety culture & RP awareness (high, average, low) at different levels of the licensee organisation
- National and international benchmarking

The inspection and authority work of the SSI has been evaluated in international studies (latest: Swedish Nuclear Activities SOU 1996:73) and in Swedish Government investigations (i.e. Safety and Radiation Protection at nuclear power plants, SOU 2003:100). Sweden is also comparing its work and activities through the channels established by the Conventions (*Sweden's third national report under the Convention on Nuclear Safety*, Ministry of the Environment, DS 2004:44 and *Sweden's second national report under the Joint Convention on the safety of spent nuclear fuel management and on the safety of radioactive waste management*, Ministry of Sustainable Development, DS 2005:44)
- What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.

Annual meetings are held between the higher management of the SSI (General Director and the Head of departments) and the higher management of the NPPs (Managing Director). Annual meetings are held between the SSI inspectors and the radiation protection experts (managers) of the NPPs. Annual meetings (where the SSI participates with observers) are held between the dosimetry personnel at the NPPs.

Weekly contacts between the appointed SSI inspectors (to the NPP) and the radiation protection experts (usually appointed at the NPPs as contact persons in matters of radiation protection) are held by telephone and e-mail.

Annually, different ad-hoc groups, with participants from the industry and the authorities, meet to discuss and resolve new situations or existing procedures. These meetings could take place at the facilities, at the authorities offices or at outside meeting places (airports, conference facilities etc.)

These official and unofficial contacts are instrumental for sharing information, presenting the views of the industry and the authorities. The SSI needs to have an actual and factual ground on which it can base its regulations and guidelines. The SSI also need to have a good knowledge of the personnel and the organisation of the NPP, without limiting or compromising its exercise of public authority, in order to construct and uphold a modern and cost-effective supervision.

Improvement of the regulatory effectiveness

- Existence of a process to improve regulatory effectiveness. Since when?
Such processes have always existed since the SSI was founded as an authority at 1965. They however are given new shapes and new contents as the society changes and different issues come into the foreground. Presently (since a year back) the SSI has started a process to review its inspection and regulatory activities at the power plants.
- If this process exists, briefly describe it.
For the moment, the role and tasks of the SSI (in the area of occupational exposure at the nuclear facilities) are re-evaluated and studied. After that, new indicators for the effectiveness of the SSI regulatory work, as well as changes in the information and inspection policies will be carried out.
- What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?
So far, only informal outside inputs to the process (in discussions) have been collected. In a later stage, any changes and/or new policies will be submitted to the NPPs for comments.
- Do you have an inspection self-assessment program?
Yes - But it will be further improved and extended
- Does your RB have and external audit? Feedback of the experience
As mentioned above, international reviews have been performed. Some benchmarking is received through international comparisons in other fora (European Union, International Conventions, IAEA&NEA groups etc). Good bi-lateral co-operation (in the area of occupational exposure supervision) exists with colleagues at the STUK in Finland

SWITZERLAND

Country and Representative Identification

- ☐ **Country:** **Switzerland**
- ☐ **Name of the regulatory Body:** **Swiss Federal Nuclear Safety Inspectorate**
- ☐ **Name and post of the person(s) who fill in the questionnaire:**
Dr. Swen-Gunnar Jahn, RPE, Division for Radiation Protection and Emergency Preparedness,
Section "Occupational Radiological Protection"

Legal Matters

❑ Legal framework of the RP regulatory body

- Legislation on nuclear energy and regulatory authority:
 - Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc) **national office, from 2008 on more independent than nowadays**
 - Origin of financial resources (e.g.: taxes, government budget, etc) **around 98 % charges for services rendered, 2% government budget**
- Number of authorities with competences in radiation protection.
 - Name(s) and competences.
 - 1. Swiss Federal Nuclear Safety Inspectorate (Regulatory body of all nuclear facilities: NPP, Interim Storage, Nuclear Research Reactors and Hotlaboratories Facilities)**
 - 2. Swiss Federal Health Office (Regulatory body in the medical and research field)**
 - 3. Swiss accident assurance agency (Regulatory body of industrial field)**
 - Interfaces, co-operation and communication between them.
Commission and Coordination Meetings (several times per year)
- Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...) **Proposition of regulations as e.g. ordinances, compilation of guidelines, assessment (licences, approvals), control of reports about normal operation and events, inspection incl. enforcement actions, education and licensing of RPO and RPE, reporting to the public and advisory service for members of parliament, approval emergency plans and supervision of emergency exercises, support communication in an emergency situation, authorization of Dosimetry Services and QA on transportation of radioactive goods**
- Relationship between nuclear safety and radiation protection authorities.
In the Swiss Federal Nuclear Safety Inspectorate both are in two divisions together in one building. Assessments, report control, inspection and the all over review (integral supervision) is done together.
- Enforcement capacity of the regulatory body on occupational RP
The Swiss Federal Nuclear Safety Inspectorate can disbar a licence or close a facility or parts of it, if the RP is not complying with the legislation

❑ Legal framework on occupational radiation protection

- Legislation on occupational RP. Give references.
<http://www.admin.ch/ch/d/sr/81.html#814.5>
- Legislation is based on (UE directives, ICRP, IAEA, others ...) **ICRP 60**
- Specific legislation on occupational RP in NPPs
No specific legislation on occupational RP except in the education field
- Specific guidance on occupational RP in NPPs.
guidance about zone and areas: http://www.hsk.ch/deutsch/files/pdf/R-007_D.PDF
guidance about protection objectives: http://www.hsk.ch/deutsch/files/pdf/R-011_D.PDF
guidance about reporting personal doses: http://www.hsk.ch/deutsch/files/pdf/R-012_D.PDF
guidance about reporting on results of monitoring (periodically), reporting events and on modifications http://www.hsk.ch/deutsch/files/pdf/R-015_D.PDF
guidance about RP-education: http://www.hsk.ch/deutsch/files/pdf/R-037_D.PDF
- Does your legal framework require from the NPPs an official document on occupational RP?
 - Nature, scope and contents of such a document: **The RP directive has to show how is the responsibility deputed, how looks like the RP organisation, what are the rights and duties of the RP persons, how does the RP works together with other divisions in the NPP,**
 - Is the document approved by the inspection authority? Are the procedures approved? **With the new legislation about nuclear energy (since Feb 2005) the Swiss Federal Nuclear Safety Inspectorate has to approve the RP directives**
 - Are the procedures developing and supporting the document approved? **YES**

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Radiation Protection Programme of the licensee

In case an official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee

A Quality Assurances Program (= Quality Management System, QMS) is requested by the Swiss Federal Nuclear Safety Inspectorate and has to cope with: RP planning (especially for outages) including optimization process, source reduction, shielding and other measures, monitoring, transportation, education, ...

Self assessment of the licensee
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- Does the licensee have a self assessment programme? **Some licensees, not all up to now**
Since when? **The program was developed since 2000 and finished in 2003. 2 NPP are using the program since 2003**
Main characteristics? **It s a part of QM-System (ISO 9004). It has to cope with the IAEA Safety Series No. 50-C especial with Safety Guide Q5.**
- The programme is an initiative of the licensee or it is required by the authority? **The program was developed by the umbrella group of all Swiss NPP (GSKL). Since 2003 the Swiss Federal Nuclear Safety Inspectorate requires an self assessment program in NPP**
- Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially) **Yes, within inspection the program and its implementation has to be accessible**

Regulatory Body organisation on occupational radiation protection control

- ❑ **Inspectorate organisation**
 - Resources:
 - Own personnel (status) or outsourcing? **Own personnel.**
 - Total number of inspectors in your country taking care of occupational radiation protection in NPPs. **6 (5 Units)**
 - Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities. **Yes, 2 interim storages, 3 research reactors, 2 reactors for education, 1 special hot laboratory with fuel research, 1 incinerator, 1 waste management facility, 1 field laboratory for geological storage research**
 - Distribution of workload per inspector, per activity: **around 20 % of time on inspection, 35 % of time on assessment (approvals, licenses), % of time on others (the RP Inspectors group works expertise on water chemistry, radiation biology, epidemiology, coordination of supervision of nuclear research facilities, education, control of periodical and event reports, ...).**
 - Average number of years of experience on occupational radiation protection of inspectors. **More then 10 years.** Degree of rotation in the organisation. **In the RP-group every year the allocation of an inspector to one NPP rotates**
 - Types of inspections:
 - Announced? Non announced? Both? **Mostly announced, one per year not announced**
 - Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors? **70% specific on occupational RP 30 % together with nuclear safety inspectors or transport inspectors or safe guards**
 - Existence of national teams? Regional teams? Both? Resident inspectors? **There is only the one and only national team (for five units).**
 - What is the dedication of resident inspectors to occupational radiation protection? **In Switzerland we have no resident inspectors.**
 - Inspectors qualification and training (university studies, access to the regulatory body, retraining) **Our inspectors should have a university degree (physics, chemistry, engineering) or technical high school and a long experience in RP. Additionally they have to go to each NPP for a 14 days hands-on training. We have no further optional professional development.**
- ❑ **Inspection procedures**
 - Existence of inspection procedures: **yes there are some checklists**
 - Main inspection topics: **compliance with legislation, regulation of the body and of the NPP. How is the principle of optimization implemented in the daily work**

□ **Inspection organisation and programme**

- Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out? Only on shutdowns? **One or two during normal operation and at least one inspection per week during outage (this means 3 till 10 depending on the outage duration)**
- Number of inspectors per team per inspection **mostly two inspectors at one inspection**
- Duration of the inspection: **3-4 hours, including an introduction talk and a final discussion of the findings**
- Do the inspectors also carry out assessment or they are exclusively devoted to inspection. **The inspectors do all what has to be done in a regulatory body (assessments, reviews, developing legislation and guidelines, reporting (annual reports), teaching, consultancy, international contacts ...)**
- Approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc **few hours preparation, half a day on site, and writing reports around 1 day (depending on the complexity of the thematic focus)**
- Methodology of the preparation of the inspection. Documents consulted prior to the inspection. **Example: the RP planning report of an outage, which has to be sent several weeks before begin of the outage**
- Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public. **One report per inspection. Each report is sent to the licensee. Information, which are by law not for the public (personal data, safety aspects against sabotage, company secret) have to be put into an appendix, which will not be given to other people then the licensee and the RB. In Switzerland a new law came up this year (1. July 2006) resulting in a better transparency of each public services (including regulatory bodies) to the public. From this moment all inspection reports (without the appendix) may be public.**
- Transparency policy.
Each person from the public may ask to have a look in the inspection reports. He or she has to assign a reason to get a copy of the report. In the past an overview of the results of all inspections is given in the annual reports. In future a comprehensive report about the inspection results will be given on the internet page of the Swiss Federal Nuclear Safety Inspectorate.

□ **Inspection procedures**

- Existence of inspection procedures: **yes there are some checklists in the management handbook of the inspectorate as well for special inspection topics**
- Main inspection topics:
Compliance with the legislation, with the regulations of the body and of the NPP. Implementation of optimization principle in the daily work

Assessment of the effectiveness of the licensee radiation protection programme

- How is the assessment carried out
 - Only through inspection **not only**
 - Through inspection and assessment? **Both**
- What is assessed and how?
 - licensing documents: **Yes**
 - inspection information: **Yes**
 - shutdown final report (results): **Yes**
 - Others (specify) **Planning reports (before the outages begin). All together will be compared (e.g. supervision results with scheduled values) and checked in terms of traceability**
- Indicators used by the authority to assess licensee performance
dose rates at different parts of the primary loop, collective dose (under consideration of special circumstances of each outage), maximum individual dose, internal dose, amount of RP personnel, ...
- National and international benchmarking: **national benchmarking is difficult, because of the differences between the units (different manufacturer, different generations), international benchmarking on special jobs only in few cases,**
- What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc. **Expert talks, meetings and seminars**

Improvement of the regulatory effectiveness

- Existence of a process to improve regulatory effectiveness. Since when? **since 2002 with an certificated QMS**
- If this process exists, briefly describe it. **All what a QMS has to include: e.g. periodical statistics (trends) on inspections, control of harmonization of the structure of inspection reports, talks with the licensee about customer satisfaction, ...**
- What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process? **The main role have the employee of the regulatory body with a wide experience on an international scale**
- Do you have an inspection self-assessment program? **From this year every inspection report has to be controlled by a so called "inspection coordinator". New inspectors (mostly experts without inspection practise) have to be escorted by experienced inspectors during the first five inspections.**
- Does your RB have an external audit? Feedback of the experience. **Yes, we had an IRRT audit (2001) and a follow up audit (2004). There was no suggestion or recommendation on the RP section. One suggestion was to develop a special training course for inspectors. Because of few personnel resources this has not be implemented yet. Some suggestions are hardly to be realized, because of a special Swiss culture.**

UKRAINE

Country and Representative Identification

- ☐ **Country:** Ukraine
- ☐ **Name of the regulatory Body:** State Nuclear Regulatory Committee of Ukraine, SNRCU;
- ☐ **Name and post of the person(s) who fill in the questionnaire:** Viktor Ryazantsev, Head of the radiation sources safety section & state inspector;

Legal Matters

- ☐ **Legal framework of the RP regulatory body**
 - **Legislation on nuclear energy and regulatory authority:**
 - [Law of Ukraine "On the Use of Nuclear Energy and Radiation Safety"](#)
 - [Law of Ukraine "On Radioactive Waste Management"](#)
 - [Law of Ukraine "On Uranium Ore Mining and Milling"](#)
 - [Law of Ukraine "On Permissive Activity in the Area of Nuclear Energy Utilisation"](#)
 - [Law of Ukraine "On Human Protection from Impact of Ionising Radiation"](#)
 - [Law of Ukraine "On physical protection of nuclear facilities, nuclear material, radioactive waste, other radiation sources"](#)
 - [Law of Ukraine "On basic grounds of further on operation and decommissioning of the Chernobyl NPP and conversion of the destroyed unit#4 of the ChNPP into environmentally safe system"](#)
 - [Law of Ukraine "On Ratification of Agreement between Ukraine and The International Atomic Energy Agency on the safeguards implementation in relation to the Non-Proliferation Treaty"](#)
 - [Law of Ukraine "On Ratification of the Nuclear Safety Convention"](#)
 - **Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc).**
The SNRCU is the central executive power authority with a special status, which activity is guided and co-ordinated by the Cabinet of Ministers of Ukraine. Since 2000 the SNRCU is an independent state body, established according to the Decree of the President of Ukraine No. 1303/2000 dated 5 December 2000. SNRCU plays the key role in the implementation of the State policy in the field of regulation of nuclear energy use and reports directly to the Government of Ukraine.
 - **Origin of financial resources (e.g.: taxes, government budget, etc):**
 - The source of financing is the State budget, and the international technical assistance;
 - Budget for 2006: 11.070.500 UAH;
 - **Number of authorities with competences in radiation protection.**
 - **Name(s) and competences.**
The SNRCU:
 - establishes regulatory criteria and sets licensing requirements to operating licenses for nuclear facilities and radiation sources (rulemaking);
 - grants operating licenses for nuclear facilities and radiation sources (licensing);
 - supervision over compliance with regulatory requirements and licensing conditions (supervision).**Ministry of Health** - involved with State regulation of radiation safety in developing and implementing Sanitary Standards and Radiation Safety Rules in the area of nuclear energy utilisation;
Ministry of Environmental Protection – involved with State regulation of environmental radiation protection;

Legal Matters

- Certain regulatory functions are performed by the National Commission on Radiation Protection of Population
- Ministry of Internal Affairs;
 - Security Service of Ukraine;
 - Ministry for Emergencies and Protection of Population against the Consequences of Chernobyl Accident.
- **Interfaces, co-operation and communication between them.**
 - Implemented in accordance with the Ukrainian legislation and the Protocol of co-operation and differentiation of authorities
- **Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)**
 - It provides the Government with the proposed rules and regulations in nuclear safety and radiation protection;
 - It inspects nuclear installations and facilities using radiation technologies and enforces corrective measures when necessary;
 - It conducts safety level evaluation and safety assessments of nuclear installations and radwaste management facilities, uranium facilities;
 - It carries out and promotes research programs on nuclear safety and radiation protection;
 - It draws up conclusions on compliance with nuclear and radiation safety requirements during export, import and transit of radioactive materials;
 - It develops annual reports on the status of nuclear and radiation safety in Ukraine, reports and overviews on these issues and submits these papers to the President of Ukraine, the Parliament of Ukraine, other State authorities, local authorities and public organisations as well;
 - **Relationship between nuclear safety and radiation protection authorities.**
 - The SNRCU coordinates central and local executive power authorities discharging functions of the State regulation of nuclear and radiation safety in accordance with the legislation;
 - **Enforcement capacity of the regulatory body on occupational RP.** The SNRCU has a capacity to enforce corrective measures when necessary.

Legal Matters

❑ Legal framework on occupational radiation protection

▪ Legislation on occupational RP. Give references..

- [Law of Ukraine "On Human Protection from Impact of Ionising Radiation";](#)
- Radiation Safety Standards of Ukraine (NRBU-97), 1998;
- Radiation Safety Standards of Ukraine. Supplement: Radiation Protection against Potential Exposure from Radiation Sources (NRBU-97/D-2000), 2000;
- Basic Sanitary Rules for Radiation Safety of Ukraine, 2005

▪ Legislation is based on (UE directives, ICRP, IAEA, others ...)

The current Ukrainian legislation is mainly based on ICRP and IAEA recommendations.

▪ Specific legislation on occupational RP in NPPs.

Some examples related to occupational RP in NPP:

- Sanitary rules for NPP designing and operation (SP AS-88);
- Rules of radiation safety during NPP operation (PRB AS-89);
- General Provisions on Ensuring Safety in the course Decommissioning of Nuclear Power Plants and Research Reactors (NP 306.2.02/1.004-98);
- Provisions on Personnel Certification and Personnel Training at Ukrainian NPPs (NP 306.2.02/2.010-98);
- Licensing Requirements to Personnel Training at Ukrainian NPPs (NP 306.5.02/3.011-98);
- Requirements to QA Programme at all Stages of a Nuclear Installation Life-Time;
- General Provisions of Ensuring Safety of Nuclear Power Plants (NP 306.1.02/1.034-2000);
- Requirements to Structure and Content of Safety Analysis Reports on Decommissioning Stages of Nuclear Power Plants and Research Reactors;

▪ Specific guidance on occupational RP in NPPs.

Some specific guidance on occupational RP in NPPs are the following:

- Permissible radionuclide concentrations in the air of NPP controlled area rooms. Agreed with MOH of Ukraine
- Permissible gaseous radioactive releases of NPP. Agreed with MOH of Ukraine
- Permissible water discharges of radioactive substances by NPP. Agreed with MOH of Ukraine
- Regulation of NPP radiation monitoring
- Radiation monitoring system. Maintenance and repair instructions
- Provisions on exposure dose monitoring system
- Exposure dose optimization program (ALARA program)
- Planned indicators of NPP personnel exposure
- Provisions on calibration and verification of health physics measuring equipment
- NPP radiation safety instructions

▪ Does your legal framework requires from the NPPs an official document on occupational RP? Yes. Quarterly and Annual Reports on RP Status at the NPP.

Nature, scope and contents of such a document. A document required to be submitted by the licensing conditions.

Contents:

1. General
2. Personnel Exposure
3. Airborne releases to the atmosphere

Legal Matters

4. Liquid discharges to the cooling pond
5. Analysis of deviations from reference levels
6. Radionuclide content in the environment
7. Meteorological parameters
8. Radiation monitoring during transport of nuclear and radioactive materials
9. Conclusions

- **Is the document approved by the authority? Which authority?** Yes. By the Ministry of Health and SNRCU.

Are the procedures developing and supporting the document approved? Yes. By the SNRCU letter “Requirements to the content and format of the RP Report”

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee. **Radiation Protection Programme (RPP)** is a document required in licensing conditions, but only for commissioned and decommissioned NPP (Rovno NPP, Khmelnytsky NPP, Chernobyl NPP). Its content complies with the IAEA Safety Guide RS-G-1.1 “Occupational Radiation Protection”.

Self-assessment of the licensee

- Does the licensee have a self assessment programme? **No** Since when? Main characteristics.
- The programme is an initiative of the licensee or it is required by the authority?
- Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially).

Regulatory Body organisation on occupational radiation protection control

☐ Inspectorate organisation

▪ **Resources:**

- **Own personnel (status) or outsourcing?**
SNRC has its own staff. They are civil servants.
- **Total number of inspectors in your country taking care of occupational radiation protection in NPPs.**
SNRCU inspector staff is 65 persons, directly conducting inspections at NPPs.
- **Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.**

Yes. In addition to the operating NPPs (15 units), they also inspect two research reactors (in Kiev and Sevastopol), dry spent fuel store in Zaporizhzhie NPP, spent fuel and radioactive waste management complex in Chernobyl exclusion zone and radwaste management facilities at UkrSE Radon specialised plants.

- **Distribution of workload per inspector, per activity:**
 - For the Headquarters inspectors: 50%, 20%, 20% (training, meetings, guidance, etc);
 - For resident inspectors: 10%, 20%, 10% (training, meetings, guidance, etc).

- **Average number of years of experience on occupational radiation protection of inspectors. Degree of rotation in the organisation** Minimum experience in radiation protection: 7-10 years. During the last 5 years the number of inspectors has been unchanged.

▪ **Types of inspections:**

- **Announced? Non announced? Both?**
Although the system allows for non announced inspections, 100% of the inspections are announced.
- **Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?**
Normally, the occupational RP is conducted during announced inspections.

▪ **Existence of national teams? Regional teams? Both? Resident inspectors?**

Routine inspections are conducted by resident inspectors. Multidisciplinary inspections – by inspection teams with participation of the Headquarters inspectors.

▪ **What is the dedication of resident inspectors to occupational radiation protection?** 10% of working time.

▪ **Inspectors qualification and training (university studies, access to the regulatory body, retraining)**

All inspector staff have higher scientific or engineering education, experience working at NPP or other nuclear energy using facilities. In compliance with “Provisions on carrying out certification of SNRCU staff who deal with the function of the State nuclear and radiation safety regulation” (NP 306.1.115-2006), contender has certificates when getting a job and after 3 years is periodically certified. Periodical training of SNRCU staff (including inspectors) is performed according to a general training programme.

Regulatory Body organisation on occupational radiation protection control

- ❑ **Inspection organisation and programme**
 - **Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns?**
Headquarters inspector carry out 7 inspections per year – 5 NPP and 2 research reactors (included RP), resident inspectors – during routine inspections. Not only during the planned outage (between fuel campaigns). There are also special inspections in case of supporting the licensing process.
 - **Number of inspectors per team per inspection.**
5-7 inspectors per one multidisciplinary inspection.
 - **Duration of the inspection.** one week.
 - **Do the inspectors also carry out assessment or they are exclusively devoted to inspection?**
SNRCU inspectors also perform assessment (review) of documents and radiological results.
 - **Approximate % of time devoted to each phase of the inspection:**
 - preparation – 30%
 - on site – 50%
 - assessment and production of documents – 20%
 - **Methodology of the preparation of the inspection. Documents consulted prior to the inspection.**
According to the “Procedure for the State supervision over compliance with nuclear and radiation safety requirements under nuclear energy use” (NP 306.2.01./1.081-2003):
 - review of inspection plan (objective, staff, due date, inspection procedure, list of documentation used, etc.)
 - review of previous inspection results;
 - review of the official licensing documentation;
 - review of resident inspector reports
 - **Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public**
According to the “Procedure for the State supervision over compliance with nuclear and radiation safety requirements under nuclear energy use” (NP 306.2.01./1.081-2003)
 - Prior to the inspection, an agenda (inspection plan) is prepared;
 - After the inspection, prescriptions or inspection certificate and official inspection report are prepared. The content of such report has to be objective and allowing for no subjective interpretations.

In accordance with national regulations, the official inspection reports perform a basis for taking regulatory decisions on licensing.
 - **Transparency policy.**
The inspection official results are published on the SNRCU website.
- ❑ **Inspection procedures**
 - **Existence of inspection procedures:** Yes
 - **Main inspection topics:**
 - Review of the RP programme.
 - Human and technical resources of the radiation protection service.
 - Training.
 - I&C equipment.
 - Dose estimations and specific nature events during the outage.

Regulatory Body organisation on occupational radiation protection control

- Radiological work permits management.
- Personnel conduct (visits to the controlled areas).
- Entry/exit to contaminated zones.
- Radiological monitoring of materials and personnel health physics monitoring at the exit from controlled areas.
- General control of radioactive materials.
- Practical implementation of the ALARA principle in the outage programme and main activities.

Assessment of the effectiveness of the licensee radiation protection programme

- **How is the assessment carried out?**
 - Only through inspection? **No**
 - Through inspection and assessment? **Yes.**
- **What is assessed and how?**
 - licensing documents. **Yes**
 - inspection information. **Yes**
 - Outage final report (results). **Yes**
 - Others (specify): **for example, design modifications.**
- **Indicators used by the authority to assess licensee performance.**
 - All information obtained during inspections
 - Numerical indicators such as: collective doses, maximum and average dose, dose distribution, dose per activity, etc.
- **National and international benchmarking:** **Yes, ISOE database, UNSCEAR reports are used for international benchmarking.**
- **What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as:** **Web group subscription, specific industry meetings of value, regulatory meetings, etc.**

Improvement of the regulatory effectiveness
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| <ul style="list-style-type: none"> ▪ Existence of a process to improve regulatory effectiveness. Yes. Since when? Since 2001 ▪ If this process exist, briefly describe it.
 In order to improve inspection activity of the Regulator, the following is planned for the nearest period: <ul style="list-style-type: none"> • Further improvement of inspection procedures for nuclear facilities at different stages of activity (construction, commissioning, operation, decommissioning); • Upgrading quality of resident inspector activity, introducing of staff rotation system for resident inspectors; • Arranging and exercising supervision over accountancy, control and physical protection of nuclear material at the facilities; • Using analytical simulator in the process of testing and training of personnel. ▪ What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process? The main contributors are to it are the SNRCU Board Meetings and SNRCU Public Board. Representatives of different organizations could take part in the meetings of these Boards to be involved in consideration of certain issues. ▪ Do you have an inspection self-assessment program? Formally No, but efficiency of each SNRCU inspector is assessed annually. ▪ Does your RB have an external audit? No. But for several years SNRC has had special external audits for development of SNRCU QA system. |
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UNITED STATES

Country and Representative Identification

- ☐ **Country:** USA
- ☐ **Name of the regulatory Body** US Nuclear Regulatory Commission
- ☐ **Name and post of the person(s) who fill in the questionnaire:** James Noggle, Sr Health Physicist, Region I

Legal Matters

- ☐ **Legal framework of the RP regulatory body**
 - Legislation on nuclear energy and regulatory authority: code of federal regulations and plant-specific technical specifications associated with operating license
 - Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc) A national organization with 4 independent regional offices that report directly to the Executive Director for Operations, who reports to 5 Commissioners.
 - Origin of financial resources (e.g.: taxes, government budget, etc) 90% of operating budget is recovered from license fees. Remaining is derived from the general government budget
 - Number of authorities with competences in radiation protection. Specific to NPP radiation protection, there are approximately 5 in headquarters and 5 in each of the 4 regional offices
 - Name(s) and competences. 1) Nuclear Reactor Regulation, Division of Inspection and Regional Support, Health Physics Branch 2) Regional Office, Division of Reactor Safety, Plant Support Branch
 - General background is B.S. degree in Health Physics, some graduate level and Health Physics Certification from the American Board of Health Physics
 - Interfaces, co-operation and communication between them. Regional offices operate independently. Some consistency is attempted through the headquarters organization in discussion of potential violations, although the Regions reserve this authority. Also, any new policy issues are relayed up through the headquarters office.
 - Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...) inspection with a highly structured reactor over sight process to determine assessment of findings.
 - Relationship between nuclear safety and radiation protection authorities. They exist side by side in both the headquarters and regional offices.
 - Enforcement capacity of the regulatory body on occupational RP Regional Offices conduct all enforcement actions. Graded inspection findings relay the dose significance of regulatory violations. Usually no financial penalties are imposed.
- ☐ **Legal framework on occupational radiation protection**
 - Legislation on occupational RP. Give references. Title 10 Code of Federal Regulations Part 20
 - Legislation is based on (UE directives, ICRP, IAEA, others ...) ICRP 26/30
 - Specific legislation on occupational RP in NPPs 10 CFR 20 and Technical Specifications attached to operating license
 - Specific guidance on occupational RP in NPPs. Regulatory Guide 8.38
 - Does your legal framework requires from the NPPs an official document on occupational RP? No.
 - Nature, scope and contents of such a document 10CFR20 requires annual review of RP program, but no specific requirements for a program document.
 - Is the document approved by the inspection authority? Are the procedures approved? No.
 - Are the procedures (developing and supporting the document approved? No.

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee not applicable.

Self assessment of the licensee

- Does the licensee have a self assessment programme?. Since when? . Main characteristicst. Yes. An annual RP audit is required by 10CFR20, therefore, many forms of licensee self-assessment exist. This requirement was imposed in 1991. Most licensees provide self-assessments in various RP subject areas scheduled over a 3 year period, which is then repeated.
- The programme is an initiative of the licensee or it is required by the authority Required by USNRC.
- Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially) Self-assessments are inspected routinely by NRC inspectors (every year).

Regulatory Body organisation on occupational radiation protection control

□ **Inspectorate organisation**

- Resources:
 - Own personnel (status) or outsourcing? All are permanent federal employees.
 - Total number of inspectors in your country taking care of occupational radiation protection in NPPs. Approximately 20.
 - Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities. No. We specialize in NPPs.
 - Distribution of workload per inspector, per activity: % of time on inspection, % of time on assessment, % of time on others (specify). Approximately 3 -4 NPP sites are assigned to each inspector, which requires 35-50% travel for inspection at these sites. No other duties normally.
 - Average number of years of experience on occupational radiation protection of inspectors. Degree of rotation in the organisation. Region I average is high, 20-35 yrs. Other Regions have a higher turnover in staff, 5-30 yrs is typical. Very little rotation. NPP assignments are switched every 5 years, approximately.
- Types of inspections:
 - Announced? Non announced? Both? Only announced inspections.
 - Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors? Most inspections are solo RP inspections. Occasional RP team inspections are utilized. 2 Regions combine several RP inspection procedures and take 2-3 RP inspectors to work together. There is this latitude between Regions.
- Existence of national teams? Regional teams? Both? Resident inspectors? Every NPP site has at least 2 resident inspectors. All other inspectors operate out of 4 Regional offices. Teams are assembled out of the Regional offices based on abnormal event response.
- What is the dedication of resident inspectors to occupational radiation protection? None.
- Inspectors qualification and training (university studies, access to the regulatory body, retraining) Health physics degree, generally. A 1-2 year qualification program is required before independent inspections are permitted.

□ **Inspection organisation and programme**

- Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns? Approximately 3 to include every shutdown. In addition, we perform effluent, environmental, transportation, and instrument inspections on a biennial basis.
- Number of inspectors per team per inspection Usually only one.
- Duration of the inspection 1 week.
- Do the inspectors also carry out assessment or they are exclusively devoted to inspection Generally, only inspection. The reactor oversight process is designed to assign assessment significance using the Significance Determination Process on identified RP issues.
- Approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc 75% onsite inspection, 5% preparation, 20% documentation.
- Methodology of the preparation of the inspection. Documents consulted prior to the inspection. Technical Specification requirements, annual dose performance, outage schedule of activities, post-job ALARA reviews and dose estimates.
- Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internals, which are sent to the licensee and which are public. Inspection reports that are sent to the licensee (with a large external public distribution list). All inspection reports are public information.
- Transparency policy NRC mission statement is that our assessment processes are transparent and most meetings are open to public observation.

□ **Inspection procedures**

- Existence of inspection procedures Yes. We have occupational RP and ALARA inspection procedures. Also, effluent, environmental, instrumentation, and transportation inspection procedures for a total of 6 RP inspection procedures.
- Main inspection topics Mentioned above.

Assessment of the effectiveness of the licensee radiation protection programme

- How is the assessment carried out
 - Only through inspection Yes.
 - Through inspection and assessment? Inspection incorporates assessment only on identified issues. No overall assessment is performed.
- What is assessed and how? No overall assessment is performed.
 - licensing documents
 - inspection information only inspection information is used.
 - shutdown final report (results)
 - Others (specify)
- Indicators used by the authority to assess licensee performance Both graded inspection findings (Green, White, Yellow, Red), and graded Performance Indicators. They are equally weighted.
- National and international benchmarking No international benchmarking. I hope this group will provide this function.
- What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc. Industry NPP RPs have a web server, which provides a very good forum for asking for advice and soliciting opinions. The NRC has a web page that lists licensee performance assessment for each NPP. Also, we have set up special web pages for significant NPP issues (e.g. Indian Point ground water tritium contamination). Two important industry/regulatory authority conferences are held each year: ISOE ALARA conference and a RETS/REMP workshop (effluents and environmental programs). In addition, several regions conduct annual Radiation Protection Manager/ Regulatory Authority meetings to openly discuss perceptions and generic issues can be discussed.

Improvement of the regulatory effectiveness

- Existence of a process to improve regulatory effectiveness. Since when? Not a real program.
- If this process exist, briefly describe it. Not applicable.
- What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process? Since 1999, there is a significant lobbyist, Nuclear Energy Institute, to wield considerable authority to challenge the regulatory authority. In addition, members of Congress have learned how to redirect the USNRC to local NPP issues on behalf of their constituents.
- Do you have an inspection self-assessment program? Yes. At least on the books. But mainly geared to inspection report quality.
- Does your RB have and external audit.? Feedback of the experience Our inspections have an audit? We occasionally have issues where State RP inspectors have an interest and provide accompaniment to our inspections. However, no true audits are the result of these activities.

PRELIMINARY QUESTIONNAIRE TO THE REGULATORY BODY MEETING ESSEN 2006

OBJECTIVES OF THE MEETING

The main objectives of the meeting are:

- To meet with inspectors from other organisations
- To exchange information regarding regulatory inspection and control practices on occupational radiation protection in NPPs
- To help to improve national regulatory effectiveness on occupational radiation protection by putting into perspective national reality versus international context

AGENDA

- Introduction of the different representatives
- Brief presentation on national inspection practices
- Discussion
- Conclusions

OBJECTIFS OF THE QUESTIONNAIRE

In order to introduce the senior Regulatory Body representatives meeting it is expected to draw an overview of the inspection in the different ISOE member countries with their similarities and differences. Therefore we would like you to answer, briefly, to the following very short questionnaire.

Please do not go into the details, just describe a few "objective data".

Even in case you will not be able to attend the meeting the information you can provide is precious . If you agree, questionnaires filled in by national authorities will be sent to the regulatory contacts participating in ISOE.

Country and Representative Identification

- ☐ **Country:**
- ☐ **Name of the regulatory Body**
- ☐ **Name and post of the person(s) who fill in the questionnaire:**

Legal Matters

- ☐ **Legal framework of the RP regulatory body**
 - Legislation on nuclear energy and regulatory authority:
 - Nature and dependency of the regulatory body (e.g.: national or regional agency, independent organisation, General Direction, Office, etc)
 - Origin of financial resources (e.g.: taxes, government budget, etc)
 - Number of authorities with competences in radiation protection.
 - Name(s) and competences.
 - Interfaces, co-operation and communication between them.
 - Role of the regulatory body on occupational RP (e.g.: inspection, assessment, both, others ...)
 - Relationship between nuclear safety and radiation protection authorities.
 - Enforcement capacity of the regulatory body on occupational RP
- ☐ **Legal framework on occupational radiation protection**
 - Legislation on occupational RP. Give references.
 - Legislation is based on (UE directives, ICRP, IAEA, others ...)
 - Specific legislation on occupational RP in NPPs
 - Specific guidance on occupational RP in NPPs.
 - Does your legal framework requires from the NPPs an official document on occupational RP?
 - Nature, scope and contents of such a document
 - Is the document approved by the inspection authority? Are the procedures approved?
 - Are the procedures (developing and supporting the document approved?

Radiation Protection Programme of the licensee

In case and official RP programme is requested by the authority, give brief description of the chapters of radiation protection programme of the licensee

Self assessment of the licensee

- Does the licensee have a self assessment programme?. Since when? . Main characteristicst.
- The programme is an initiative of the licensee or it is required by the authority
- Accessibility of the authority to the self-assessment programme (e.g.: yes, no, partially)

Regulatory Body organisation on occupational radiation protection control

☐ Inspectorate organisation

- Resources:
 - Own personnel (status) or outsourcing?
 - Total number of inspectors in your country taking care of occupational radiation protection in NPPs.
 - Do inspectors on NPP occupational radiation protection inspect also other nuclear facilities. Specify number and type of facilities.
 - Distribution of workload per inspector, per activity: % of time on inspection, % of time on assessment, % of time on others (specify).
 - Average number of years of experience on occupational radiation protection of inspectors. Degree of rotation in the organisation.
- Types of inspections:
 - Announced? Non announced? Both?
 - Specific on occupational RP? Multidisciplinary? (with other RP inspectors or with nuclear safety inspectors?)
- Existence of national teams? Regional teams? Both? Resident inspectors?
- What is the dedication of resident inspectors to occupational radiation protection?
- Inspectors qualification and training (university studies, access to the regulatory body, retraining)

☐ Inspection organisation and programme

- Number of inspections per year per NPP unit on occupational RP? When are the inspections carried out?. Only on shutdowns?
- Number of inspectors per team per inspection
- Duration of the inspection
- Do the inspectors also carry out assessment or they are exclusively devoted to inspection
- Approximate % of time devoted to each phase of the inspection: preparation, on site, production of documents, etc
- Methodology of the preparation of the inspection. Documents consulted prior to the inspection.
- Documents produced associated with the inspection, e.g.: agenda, minutes (character), reports. Specify which are internal, which are sent to the licensee and which are public.
- Transparency policy

☐ Inspection procedures

- Existence of inspection procedures
- Main inspection topics

Assessment of the effectiveness of the licensee radiation protection programme

- How is the assessment carried out
 - Only through inspection
 - Through inspection and assessment?
- What is assessed and how?
 - licensing documents
 - inspection information
 - shutdown final report (results)
 - Others (specify)
- Indicators used by the authority to assess licensee performance
- National and international benchmarking
- What interfaces (besides inspection and license amendment correspondence) do you have with your licensees and what benefit do they provide? Such as: Web group subscription, specific industry meetings of value, regulatory meetings, etc.

Improvement of the regulatory effectiveness

- Existence of a process to improve regulatory effectiveness. Since when?
- If this process exist, briefly describe it.
- What has been the role of the different stakeholders in the improvement of the regulatory effectiveness process?
- Do you have an inspection self-assessment program?
- Does your RB have and external audit.? Feedback of the experience