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Western European

WENRA

Nuclear Regulator's Association

Benchmarking the European inspection practices for components and structures of nuclear facilities

Study by

WENRA Inspection Group

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WIG

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1. Introduction

WENRA decided to initiate work concerning benchmarking of European inspection practices for components and structures of nuclear facilities in its March 2010 meeting where the chair of WENRA presented a proposal "to benchmark European regulatory practices for verifying design and quality of the NPP structures and components both at new and existing reactors". According to the proposal the first goal was getting clear and reliable information on what are the various inspection practices that are applied in member countries to verify that the structures and components are designed, constructed/manufactured, installed and commissioned to meet their design and quality requirements. In the second phase, harmonisation needs and possibilities in the area of inspection practices should be studied. A WENRA task group (WENRA Inspection Group, WIG) was established to perform the benchmark study.

It was noted that MDEP has inspection co-operation in its vendor inspection working group but it is more focused to find out how inspectors can make use of the work done by inspectors of other regulators. The joint inspections performed in that working group are mainly quality system oriented. The intention was that the work of this new WENRA group would focus on technical issues.

Finland volunteered as the lead country for the task group. It was concluded in the WENRA meeting that a letter including a concrete proposal for the work including a tentative work plan and an invitation to send a representative to the group will be sent by Finland to all WENRA members and observers.

The original work plan of the group was the following

1. STUK makes a proposal for contents of national input reports that give a picture of the national inspection practices in the respective WENRA countries.
2. All WENRA members are asked to nominate their representative to the working group.
3. STUK starts preparing its own national report. That is aimed to be an example of how the information could be provided in the report. STUK's target was to circulate the draft of its national report before the end of May 2010.
4. The national input reports should be provided before the end of August 2010.
5. The working group meets for the first time in September 2010.

STUK prepared a list of questions and provided a model for contents of national reports to other participants in early July 2010. National reports were provided to STUK in early September

according to the request. In this phase eleven WENRA countries (Belgium, Bulgaria, Finland, France, Hungary, Lithuania, Slovak Republic, Spain, Sweden, Switzerland and UK) prepared national reports of their regulatory inspection practices.

The purpose of the national reports was to establish the basis of the work of the WIG. The first step was to get clear and reliable information on what are the various inspection practices that are applied in WENRA countries. The national reports were prepared to describe briefly the main regulatory inspection practices without going into great depth on the technical details of different types of structures and components.

After the delivery of the national reports the first working group meeting was held on 22-24 September 2010 in Helsinki to clarify the contents of national reports. The national reports were used to select issues for discussion in the meeting and to perform initial comparisons between the participating countries. However, it was noticed that the national reports were so heterogenious that they could not be used for detailed benchmarking.

Therefore, in the meeting in Helsinki, tables were developed to gather information concerning inspection practices. In the tables the activities required by the regulations to be performed by the licensees, inspection bodies and the regulatory bodies were presented related to the lifecycle of the components or structure to enable comparisons between countries. The completed tables were submitted by Belgium, Bulgaria, Czech Republic, Finland, France, Lithuania, Slovak Republic, Spain, Sweden, Switzerland and the UK.

The results of the first meeting were presented to WENRA in its Bratislava meeting in November 2010. In that presentation some typical national inspection practices based on the national reports were presented. Also first ideas concerning basic regulatory approaches and issues for good practices were presented.

The WIG had its second meeting in Bootle, UK in February 2011. In the meeting the group discussed the summary of tables completed by the participating countries and made initial conclusions concerning different national practices. Also the basic regulatory approaches and good practices were further discussed. The content of the final report of the work was agreed and a sub-group was established to write chapter 2 “Basic regulatory approaches for inspection of components and structures” and chapter 4 “Good practices for inspection of components and structures” of this final report of the group. Sweden accepted leadership of the sub-group. The sub-group had a meeting in Stockholm in early June. The other participating countries of the sub-group were Finland, France and UK.

For the final report the participating countries agreed to write short (some pages) national summaries of their inspection practices. The content of these summaries was agreed. These national summaries contributed to the chapter 3 “Benchmarking of the national practices” of this final report. The national summaries were provided by the same countries that provided the completed tables with the addition of Russia. The national summaries are attached to this report.

The final meeting of the group was in Helsinki in September 2011 where the draft report of the benchmark was reviewed by the group.

2. Basic regulatory approaches for inspection of components and structures

Basic roles and responsibilities within the nuclear field are clearly defined and accepted by all concerned. The European Nuclear Safety Directive[1] requires that Member States shall ensure that the prime responsibility for the safety of a nuclear installation rests with the license holder. This responsibility cannot be delegated. The Directive also requires that Member States shall establish and maintain a competent regulatory body in the field of nuclear safety. The regulatory body shall have the powers and resources to verify compliance with national nuclear safety requirements and the terms of the relevant license through regulatory assessments and inspections.

Regulatory bodies are responsible for finding effective and efficient[2] approaches for their regulatory work including assessment and inspection activities. Finding effective and efficient approaches is a difficult task, and will also depend on the national regulatory regime. Regulators need, for example, to establish a clear boundary between regulatory responsibilities for safety and licensee's responsibilities for safety. In selecting approaches regulators consider not only how a strategy may affect safety directly, but also possible indirect effects. Indirect effects may include such things as impacts on resources for the regulator or changes to the safety culture of the licensee. Regulators also have to reassess and adjust approaches to respond to legal, economic and technological changes.

Approaches applied have been discussed among regulatory bodies and by researchers. In an exploratory study[3] that the Swedish Nuclear Inspectorate (SKI) conducted between 2003 and 2005, the use of six different regulatory approaches for oversight of commercial nuclear power plants were studied and compared: prescriptive, case-based, goal-setting or outcome-based, risk- or hazard-informed, process-based, and self-assessment approaches. One main finding regarding the experiences of using different regulatory approaches was that regulators tend to use combinations of at least two, often three and at times four different approaches for specific examples of oversight issues.

In the area of systems, structures and components (SSC) there is a tradition in many countries to apply approaches which focus on the prescriptive element while regulators in other countries use combinations which focus on goal-setting or outcome-based approaches.

In a prescriptive approach the regulator establishes relatively detailed requirements for functions and properties of systems, components and structures in a plant. A prescriptive approach can also include relatively detailed requirements for conducting specific activities.

In a goal-setting, non-prescriptive approach the regulator establishes specific goals or outcomes for licensees to attain but does not specify how licensees attain these goals.

In the area of SSC, and in particular pressurized components, there is also a tradition in many countries to use independent inspection organizations (IO) and other conformity assessment bodies, to review, assess and supervise different activities during design, manufacture, construction and commissioning. The use of such conformity assessment bodies can be prescribed by the regulator and contracted for its task by either the regulator or by the licensee or the vendor. In other countries the regulator does not prescribe the use of independent conformity assessment

[1] COUNCIL DIRECTIVE 2009/71/EURATOM of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations

[2] In many instances these terms are interchanged quite freely, but in essence have quite different meanings. The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) has in its Guidance Book "Improving Nuclear Regulation" agreed that regulatory effectiveness means "to do the right work", whereas regulatory efficiency means "to do the work right".

[3] Regulatory Strategies in Nuclear Power Oversight, SKI Report 2005:37.

bodies but expresses expectations that the licensee contracts conformity assessment bodies for review, assessment or supervision of important aspects during design, manufacture, construction and commissioning.

Regulatory bodies can thus choose to have an emphasis in either of the two basic approaches, prescriptive and goal-setting/outcome based, for inspection of SSCs or to combine them in an appropriate manner and to differing degrees use independent conformity assessment bodies as part of the work. It should be noted that the use of independent conformity assessment bodies by its nature requires a major element of prescription in using a contract and specification to define the scope and extent of the work expected, particularly when the purpose is to assess conformity with regulations and other requirements.

3. Benchmarking of practices

3.1 Introduction

The working group was expected to describe the practices being applied in each WENRA country for arranging inspection practices of mechanical equipment, steel structures and concrete structures. The countries were to

- explain possible formal approvals of the involved third party organizations
- explain possible correlation with safety classes
- explain if two redundant inspections have to be done where responsibility is with the licensee and with the regulatory body.

As a second step of the work, the group was expected to

- discuss the satisfaction of each WENRA country with their respective approach and the possible needs/plans to modify the approach
- consider good practices that could become harmonized European practices.

The scope of the benchmarking was defined so that it covers the various review and inspection practices arranged in WENRA countries concerning

1. Mechanical components
2. Steel structures
3. Concrete structures

to provide adequate assurance that the components and structures are

- designed
- manufactured/constructed
- installed and
- commissioned

to meet their respective design and quality requirements.

Pre-service and in-service inspections and testing (non destructive testing) were left outside the scope of this study. Pre-service inspections and testing take place during commissioning and their successful performance is one of the prerequisites for starting the operation of the systems and components.

The working group defined the following additional objectives for the work

- learn from others practices to develop your own practices (according to WENRA ToR)
- discuss the added value of different basic regulatory approaches
- assure similar degree of involvement by the industry
- make use of foreign IOs easier in the long term (interchangeability, accreditation)

Because the original national reports could not be used for detailed benchmarking, the group developed, in its first meeting, tables to collect information on inspection practices in a systematic way. The tables were created for pressure equipment, steel structures and concrete structures. Regulatory and licensee inspections and auditing were filled in separate tables. The table for pressure equipment is presented as an example in the following Figure 1.

Country:

Pressure equipment life cycle																
	Design		Hold point		Manufacturing		Hold point		Installation		Hold point		Commissioning		Hold point	
Safety class	Who	How	P	O	Who	How	P	O	Who	How	P	O	Who	How	P	O

Who does?		How it does?	What is the completeness of the activity?
RB	Regulatory body	C	Comprehensive technical control
L	Licensee	T	Technical control by sampling
IO	Inspection organization	M	Management system audit
UI	Utilities inspection organization	F	Focused audit (e.g. follow up of a specified product)
CI	Contractor insp. organization	R	Reactive intervention by exception
MO	Mandated organization (Belgium)		

Hold point:

P	Predefined
O	Optional

Figure 1. Table to collect information on inspection practices, example related to pressure equipment.

Comprehensive technical control (C) refers to a practice where all relevant technical aspects are reviewed or inspected and the control covers a major proportion of structures and components.

If the control is based on sampling (T), a combination of different factors is typically used to define sample size and scope. Factors which are used as a basis may include safety significance, novelty, complexity and operating experience of the structure or component. Sample size is typically increased if issues are identified.

The completed national tables are not quite uniform. Main differences are as follows:

- Terminology of different kinds of inspection organizations (Inspection Organization, Utilities Inspection Organization, and Contractor's/Manufacturer's Inspection Organization as well as Third-Party Organization) varies and makes it difficult to ensure that inspection and auditing practices are understood in a consistent way in all countries.

- Safety classification differs from country to country. In most of the countries, for pressurized systems the primary circuit belongs to safety class (SC) 1, engineered safety features to SC 2 and other safety-related systems to SC 3. For instance, in some countries the highest (most important) safety class of concrete and steel structures is 1 while in some other countries the corresponding structures belong to safety class 2. Two countries are using four safety classes; one five. In spite of these differences, it was decided to use three safety classes in the detailed comparison (tables).

- Many countries have not reported their practices relating to the class non-nuclear safety (NNS) equipment and structures. It was decided to delete class NNS from the tables because the results could have been misleading.

A target in completing these tables was to cover both licensee and regulatory inspections and auditing. It seems that in general a system exists where the licensees first make their inspection and then the regulators (or their IOs). It also seems that the inspections by the licensees generally bound the scope of the inspections by the regulators.

However, some countries have included in their responses for licensee activities the inspections and auditing performed by contractors/manufacturers, too. Possibly this is done for the reason that the licensees rely on the contractor/manufacturer inspections and auditing in such a way that equipment/structures/organizations are not inspected/audited by the licensees themselves (and the regulators do not require this).

In all NPP projects the contractors/manufacturers perform anyway their own quality control (QC) activities and make the results available to the licensees and via the licensees to the regulators. A question rises whether it is necessary that in all cases (at least for the safety related items) the licensee conducts its own inspections.

The licensee has to satisfy itself that the component or structure meets the respective design and quality requirements and that adequate inspection is done by the licensee or on behalf of the licensee to verify this. These inspections have to be defined in the quality management (QM) system of the licensee which should be audited by the regulatory body. The responsibilities and duties of the licensee are discussed in chapter 4.1 “Licensees’ control, supervision and oversight”.

3.2 Comparison of the national tables

The summary tables were created both for licensee and regulatory inspections and auditing. An initial comparison of the completed tables was provided by STUK for the Bootle meeting of the group. In this comparison, information from the national tables was extracted and restructured. Summary tables were reformulated to have the information commensurable for benchmarking and to make comparisons easier. The summary tables for regulatory inspections and auditing are presented in appendix 3.

The summary tables combine the information from all the participating countries and are based on the following phases for pressure equipment and steel structures:

- design (design basis/detailed design)
- manufacturing
- installation and
- commissioning.

For concrete structures the following phases are used:

- design (design basis/detailed design)
- structural concreting
- commissioning.

An example of a summary table on regulatory inspections and auditing relating to design phase of pressure equipment is presented in the Figure 2. Mandatory inspections and auditing are underlined.

Safety Class	Belgium	Bulga-ria[i]	Czech Republic	Finland	France	Lithua-nia	Slovak Republic	Spain	Sweden	Switzer-land	UK
1											
(Who)	RB/MO	RB/-	RB/RB	RB/RB	RB/RB, IO	RB/RB	RB,IO/RB	RB/RB	RB/IO	RB/RB+IO	RB/IO
(How)	T/C	C/-	CM/CM	CMR/CMR	CM/CMR	C/T	CM/CM	CM,TFR/C,TFR	CM/C	C/C	TM/CMRD
2											
(Who)	RB/MO	RB/-	RB/RB	RB/RB,IO	RB/IO	RB/RB	RB,IO/RB	RB/RB	RB/IO	RB/RB+IO	RB/IO
(How)	T/C	C/-	CM/CM	CMR/CMR, CR	TM/CTMR	C/T	CM/CM	CM,TFR/C,TFR	TM/C	C/C	TM/CMRD
3											
(Who)	RB/MO or IO	RB/-	RB/RB	RB/IO	RB/IO	RB/RB	RB,IO/RB	RB/RB	RB/IO	RB/RB+IO	RB/IO
(How)	T/C	C/-	CM/CM	CR/CR	TM/CTMR	C/T	CM/CM	CM,TFR/C,TFR	TM/C	C/C	TM/CMRD

Figure 2. Summary table on regulatory inspections, example related to design phase (design basis/detailed design) of pressure equipment.

Design basis of components and structures refers to those technical requirements which have to be set on components and structures in order that they would meet the demands based on plant and system level design. Design basis includes functional requirements and loading conditions for normal and accident conditions. Also safety, seismic and quality classification are part of component or structure level design basis.

The practices across countries are fairly uniform for pressure equipment although, for regulatory practices, in this area there are variations between countries concerning especially management system audits and/or focused audits. As concerns the design and commissioning phases comprehensive technical control (C) is performed by almost all regulators. For the manufacturing and installation phases there seem to be more variations between regulators. About the same number of countries uses comprehensive technical control (C) or technical control by sampling (T) in these phases. In all the phases about half of the countries perform management system audits (M) or focused audits (F). Auditing of the QM Systems of most important manufacturers of pressure equipment by the regulatory body or in some cases by an inspection body is considered important. As concerns the design and manufacturing of the class NNS (non-nuclear safety) pressure equipment, there seem to be different inspection practices despite of the EU Directive. This observation may however be due to information being missed in the national tables.

As concerns steel and concrete structures there are larger variations in inspection and auditing practices between regulators. Also for steel and concrete structures the design is reviewed by most regulators using comprehensive technical control (C). As concerns manufacturing and structural concreting typically technical control by sampling (T) is used whereas for installation and commissioning either comprehensive technical control or technical control by sampling is used. About half of the countries perform management system audits or focused audits.

Hold points are used widely, especially for design and commissioning phases. The use of hold points is related to the national inspection approach.

Reactive intervention by exception (R) is probably made by all countries although this is not shown in the tables. This may be due to different interpretations of what to include in the tables.

3.3 Basic regulatory approach (structures and components)

A summary of regulatory oversight practices during different phases is presented in the Appendix 3, where the comparison of the completed national tables is presented phase by phase. Every participating country has regulatory oversight activities in design, manufacturing, installation and commissioning phases although the extent and focus of the inspections and supervision varies depending on the country and the phase.

As presented in chapter 2, the regulator can choose to have an emphasis in either of the two basic approaches (prescriptive or goal-setting) for inspection of SSC or to combine them in an appropriate manner. Some of the countries seem to emphasize prescriptive approach and some of the countries goal-setting approach. The regulatory approach can also vary from phase to phase. Prescriptive approach is typically emphasized in design and commissioning phases. Some regulators also use independent conformity assessment bodies to varying degrees as part of the work.

3.4 Expectations on licensees

Every participating country confirms that primary responsibility for the safety of NPPs and quality of NPP structures and components rests with the license holder. The licensee reviews and approves documents and inspections related to structure and component design, manufacturing, installation and commissioning before presenting them to the regulator for approval or to the IO for conformity assessment. Licensees are expected to take all the necessary steps and actions to fulfil applicable safety requirements and to organize quality control related to design, manufacturing, installation and commissioning of structures and components. Licensees shall verify that all the organizations related to these steps have arrangements to produce appropriate quality; in other words they have recognised quality management systems and qualified personnel.

Regarding non-conformances about half of the countries state that it is required that the licensee's management system includes procedures to process non-conformances. Most of the countries expect that licensees process non-conformances by assessing their significance, identifying the reasons for them and taking corrective and preventive actions. If the above mentioned actions are not required (or they don't show from the national summary report), it is at least required that the regulator is informed about serious non-conformances.

3.5 Regulatory inspections and correlation with safety classes

Regulatory inspections performed using comprehensive technical control (C) in different safety classes and whether they are performed by the regulator itself or are delegated to IOs are presented in the graphs in Figures 3 to 5. The graphs are composed for pressure equipment, steel structures and concrete structures on the basis of national summaries and completed tables. When looking at the graphs for steel and concrete structures it must be kept in mind that concrete and steel structures are not classified equally in the participating countries; in some countries the highest safety class is 1 while in some other countries respective structures belong to safety class 2. Also the number of safety classes differs from 1 to 3.

In the graphs, where inspections made by IOs are presented, combined inspections are shown, which are conducted:

- solely by the IO or
- by either the IO or the regulatory body (RB/IO).

The latter one (inspections made by the IO or the regulatory body) might be due to

- different safety significances of the components in the safety class in question such that the regulatory body is liable for certain components or structures which are considered more important to safety and IO is liable for others
- division between tasks in the safety class in question so that the regulatory body is responsible for some tasks and the IO for others
- the need to carry out a large number of inspections that regulatory body cannot perform by itself for some activities which can be supervised either by the regulator or the IO.

The graphs for pressure equipment are presented in Figure 3, for steel structures in Figure 4 and for concrete structures in Figure 5.

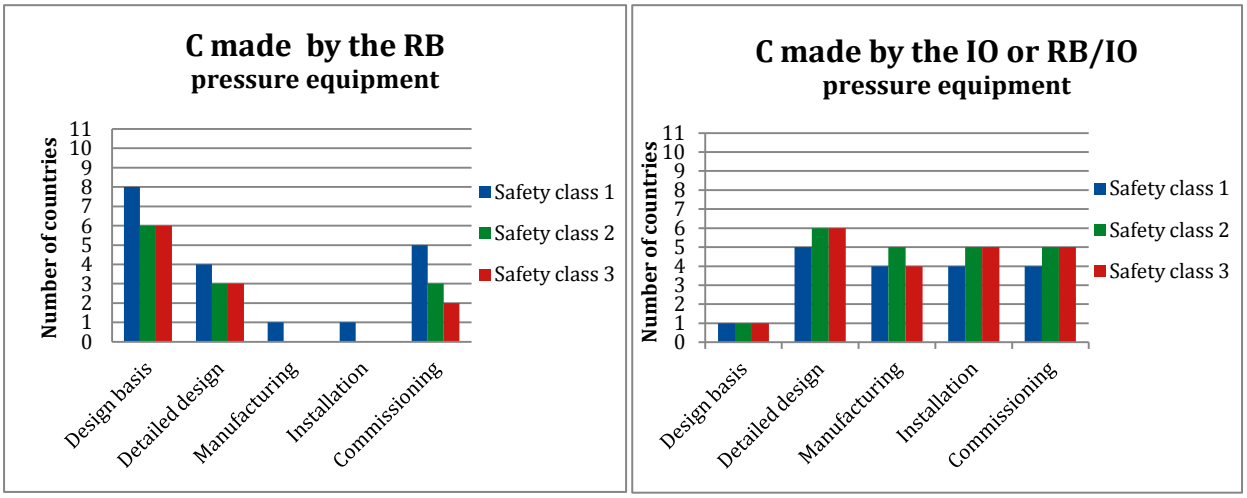

Figure 3. Regulatory inspections of pressure equipment made by regulatory body (RB) and IO in different phases of manufacturing. C = Comprehensive technical control.

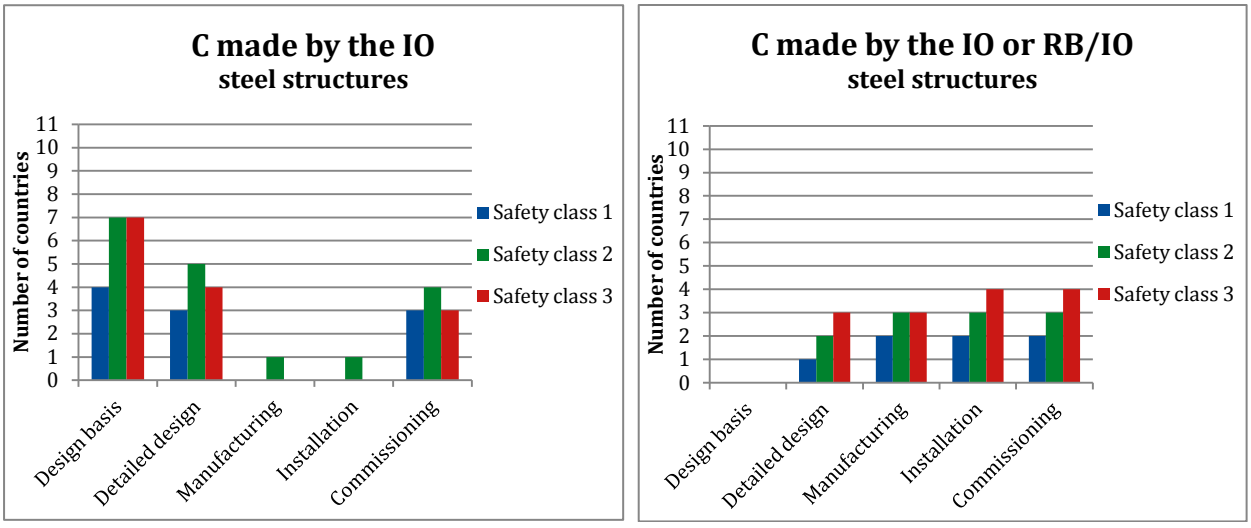

Figure 4. Regulatory inspections of steel structures made by regulatory body (RB) and IO in different phases of manufacturing. C = Comprehensive technical control. *SC1: six (6) countries, SC2: eleven (11) countries, SC3: eleven (11) countries.*

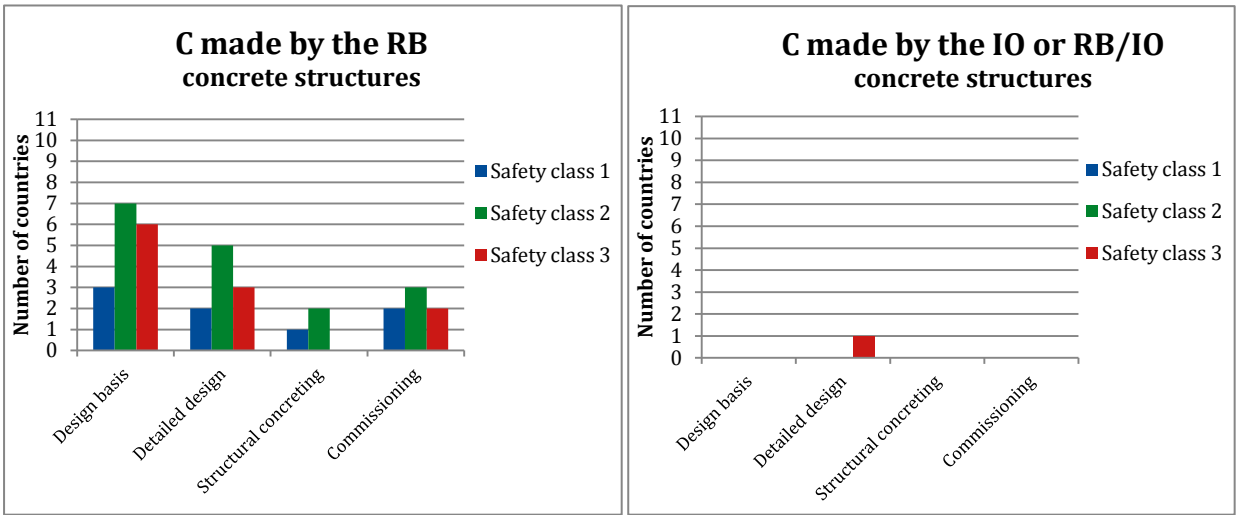

Figure 5. Regulatory inspections of concrete structures made by regulatory body (RB) and IO in different phases of manufacturing. C = Comprehensive technical control. *SC1: five (5) countries, SC2: ten (10) countries, SC3: nine (9) countries.*

Short summaries of countries' regulatory inspection practices concerning structures and components including hold point strategy are presented in the next paragraphs.

Belgium: Regulatory body in Belgium consists of FANC (Federal Agency for Nuclear Control) and Bel-V, which is the subsidiary of FANC and provides technical support. Most of the regulatory inspections of mechanical components are performed together by Bel-V and Mandated Organization (MO), which might be defined as "a regulatory IO". Only one Belgian MO is selected at the moment for this task. For pressurized steam components, the Belgian legislation requires that a MO performs the function of AIA (Authorized Inspection Agency) or the similar IO required by the ASME code. In general Bel-V assesses nuclear safety while MO has the mechanical expertise of components.

Basis for inspections of mechanical components is the ASME code. Inspections for concrete structures are not defined. FANC reviews design phase using technical control by sampling in SC1, SC2 and SC3 and supervises pressure tests of pressure equipment in SC1 and partly in SC2/SC3. Bel-V + MO perform regulatory inspections in SC1,SC2 and SC3 in all phases using comprehensive technical control. In SC2 and SC3 also IOs contracted by licensee are used for components/cases, which are out of the main scope of the MO. Hold points for design, manufacturing and commissioning (Bel-V + MO scope) of pressure equipment are predefined. For installation of pressure equipment and for all phases of steel structures hold points are optional (for concrete structures not defined).

Bulgaria: All regulatory inspections and reviews are on regulatory body's (BNRA, Bulgarian Nuclear Regulatory Agency) responsibility. Review of design basis, construction, installation and commissioning documentation of the structures and components belonging to SC1, SC2 and SC3 are on BNRA's responsibility and BNRA also inspects NPP structures and components to assess whether the requirements in BNRA safety regulations are met. For design basis and commissioning phases comprehensive technical control is used and hold points are predefined. Manufacturing and installation phases/structural concreting are supervised using technical control by sampling and

hold points are optional. Commissioning of nuclear power plant/unit can start after issuance of commissioning permit by BNRA.

Czech Republic: All regulatory inspections and reviews are on regulatory body's (SÚJB, The State Office for Nuclear Safety) responsibility. Licensees use IOs widely for all phases of pressure equipment and steel structure inspections. Review of design basis and detailed design of all structures and components in all safety classes is conducted using comprehensive technical control. Other phases are supervised using technical control by sampling. Hold points are predefined.

Finland: Review of design basis and commissioning inspections are on regulatory body's (STUK, Radiation and Nuclear Safety Authority) responsibility in SC1, SC2 and SC3. In SC1 also other inspections and reviews are solely on STUK's responsibility. IOs are used for regulatory inspections for components' supervision/inspections mainly in SC3 and in SC2 depending on equipment's safety significance. SC2 steel and concrete structures and SC3 concrete structures are on STUK's responsibility. Regulatory inspections of SC3 steel structures are on IO's responsibility. Comprehensive technical control is used and hold points are predefined.

France: IOs are used for regulatory reviews and inspections of all nuclear pressure equipment. For N1 (SC1) components, IOs are mandated by regulatory body (ASN) to perform an identified part of conformity assessment. They shall report either monthly and/or punctually for specific reasons and send a final report to ASN about inspections performed. ASN stamps N1 (SC1) pressure equipment. For N2 (SC2) and N3 (SC3) pressure equipment IOs are also used for regulatory inspections and are submitted to ASN's supervision. Comprehensive technical control is used and hold points are predefined for pressure equipment inspections. ASN is responsible for safety relevant steel and concrete structures (all phases) and supervision of them is done by sampling using optional or no hold points.

Lithuania: All regulatory inspections and reviews are on regulatory body's (VATESI) responsibility. Design phase e.g review and approval of technical specification and PSAR is supervised comprehensively, but other phases are supervised using technical control by sampling. Activities related to technical control by sampling are realized by implementing regulatory inspection plans considering safety classification, forthcoming supervision and inspection works of the licensee or results of that work as well as best practices. VATESI can contract Technical Support Organizations for regulatory review and assessment activities when considers it necessary. Hold points for design phase are predefined, otherwise they are optional.

Slovak Republic: All regulatory inspections are on regulatory body's (NRA SR-ÚJD SR) responsibility. NRA SR uses IOs during design phase for design basis assessment. Licensees use IOs widely for all phases of pressure equipment, steel structure and concrete structure inspections. Regulatory body supervises design and commissioning phases using comprehensive technical control, but otherwise supervision is conducted by sampling. Hold points for design phase and commissioning are predefined. Also during manufacturing, installation and structural concreting hold points for technical control are predefined although supervision is conducted by sampling.

Spain: All regulatory inspections and reviews are on regulatory body's (CSN) responsibility. No IOs are used for nuclear regulatory inspections and assessments except inspections according to PED that are performed by IOs under the supervision of Ministry of Industry. Comprehensive technical control is used in all safety classes for review of design (design basis and detailed design) and commissioning inspections of pressure equipment and steel structures if the structure or equipment modification entails a modification of the NPP licence. In all other cases the regulatory activities are supervised using technical control by sampling that can imply reactive and focused inspections or further regulatory activities if the results of sampling are not satisfactory. Regulatory hold points depend on a type of permit granted.

Sweden: Review of design basis is on regulatory body's (SSM) responsibility in SC1, SC2 and SC3 (and SC4/NNS). Reviews of the detailed component design documentation are delegated to IOs. SSM inspects commissioning tests of components/steel structures after major plant modifications in SC1 and SC2, IO in SC3. In minor component replacements or modifications IO supervises manufacturing, installation and commissioning of pressure equipment, components and steel structures in SC1, SC2 and SC3. SSM makes regulatory inspections on sample basis for concrete structures in SC2 and SC3 (SC1 not applicable for concrete structures). When regulatory inspections are carried out by IOs, comprehensive technical control is used. SSM uses technical control by sampling for inspections focusing on major plant modifications. Technical control by sampling is used for concrete structures. Hold points are mostly predefined; only structural concreting phase is optional.

Switzerland: Regulatory body (ENSI) reviews design basis of structures and components in all safety classes. ENSI also supervises commissioning phase with IO (see tables) in all safety classes. Regulatory inspections during manufacturing, installation and final testing (e.g. pressure tests) of SC1 and SC2 pressure equipment are conducted by IO although ENSI takes part in the inspections. IO supervises pressure tests and repairs during manufacturing of SC1 to SC3 (4) pressure equipment as well as manufacturing and installation of SC1 to SC3 (4) steel structures. All phases of concrete structures (BK I, BK II, unclassified buildings) are solely on ENSI's responsibility, but ENSI usually contracts engineering companies to conduct inspections. Hold points are predefined and mostly comprehensive technical control is used. For SC3 (and SC4) pressure equipment and steel structures manufacturing is supervised using technical control by sampling.

UK: All regulatory inspections and assessments are on the responsibility of regulatory body (ONR). Technical support contractors are used to support assessment activity and, less typically, inspection activity, but the responsibility lies with ONR. No IOs are used for direct regulatory inspection or assessment. Regulatory inspections and assessments are undertaken on a sampling basis, with high levels of sampling for safety class 1 SSCs and proportionally less or limited samples for lower safety class SSCs. A limited number of hold points require regulatory permission, many others are defined and controlled by the licensee, and the regulator can specify any of these additional hold points to be subject to regulatory control if appropriate.

3.6 Authorization of IOs

A summary of the practices concerning authorization and contracting of IOs in participating countries for pressure equipment is presented in the Figure 7.

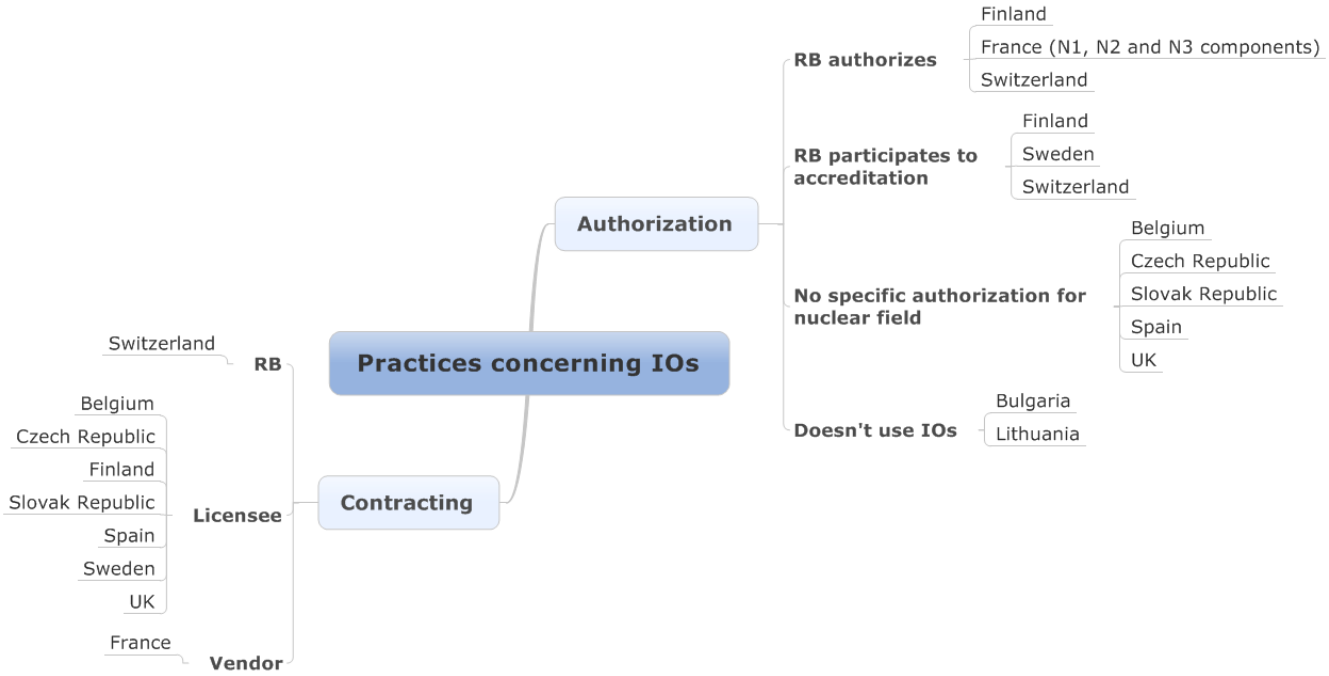

Figure 7. Practices concerning authorization and contracting of IOs in participating countries for pressure equipment.

Short summaries of countries' authorization/contracting practices are presented in the next paragraphs.

Belgium: FANC or Bel-V doesn't authorize IOs. Inspection of nuclear pressurized steam components can only be performed by a Belgian Mandated Organization (MO). MOs are accredited by Belgian Ministry of Labor. Licensee contracts MO and also other IOs, which are used for inspections that are out of the scope of MO. Licensee can also under certain conditions use its own inspection department for inspections out of the regulatory scope of the MO. Licensee shall define prerequisites to contract IO in the quality assurance program. Bel-V supervises implementation of this program.

Bulgaria: BNRA doesn't authorize or use IOs for regulatory inspections. For the purposes of licensing and safety assessment, BNRA may use IO on a specific task. Licensees don't use IOs either, but IOs might work in some cases on behalf of the contractor.

Czech Republic: SÜJB doesn't authorize or use IOs for regulatory inspections. Licensees use IOs and make the contracts with them.

Finland: STUK authorizes IOs, which shall be accredited by FINAS. STUK participates to the accreditation process as an expert. Accreditation is based on the standard EN ISO/IEC 17020, Type A. Licensee contracts IO, which shall be authorized by STUK.

France: ASN authorizes IOs for all nuclear pressure equipment. Before being authorized they shall be accredited for N1, N2 and N3 components. Authorization is based on the ASN guideline which conforms to the standard EN ISO/IEC 17020. For N1 components, manufacturers choose and contract IOs working with inspection programs approved by ASN. For N2 and N3 components IOs work independently (manufacturer contracts), but ASN may supervise their actions.

Lithuania: VATESI doesn't authorize or use IOs or third party organizations for regulatory inspections. Current practice is that licensee by its own decision uses UI for supervision of manufacturing and structural concreting phases, but there are no legal or regulatory requirements about the use of UI. If construction of a new NPP starts, VATESI considers possibility to use third party organizations for inspecting and auditing structures and components of lower safety classes.

Slovak Republic: NRA SR-ÚJD SR doesn't authorize IOs and doesn't perform oversight of IOs. NRA SR-ÚJD SR might use third party organization for independent assessment of complicated safety documentation (e.g. competent technical support organizations). Licensee contracts IO and is responsible for that IO is accredited by SNAS (Slovak National Accreditation Service). Accreditation is based on the standard STN EN ISO/IEC 17020. The accreditation decision of the IO has to be available to NRA SR-ÚJD SR on request.

Spain: CSN doesn't authorize IOs. Licensee is responsible for contracting IOs (if used) and contracting shall be conducted according to licensees's Quality Assurance Manual. IOs involved with PED's requirements are accredited by ENAC (according to standard EN ISO/IEC 17020). Ministry of Industry or equivalent autonomous government organ authorizes these IOs.

Sweden: IOs shall be accredited by SWEDAC. SSM participates to the accreditation process and the accreditation decision is made in consultation with SSM. Accreditation is based on the standard EN ISO/IEC 17020, Type A. Licensee contracts IOs. In some major plant modification projects the licensee requires that the main vendor contracts IOs on behalf of the licensee.

Switzerland: ENSI authorizes IOs, which can also be an engineering company who act as an IO. For supervising/inspecting nuclear pressure equipment IO shall have accreditation in accordance with the standard EN ISO/IEC 17020, Type A. ENSI participates to the accreditation process. Contracts and case by case decisions define the details of organizing the reviews, inspections and reporting to ENSI.

UK: The licensee is responsible for contracting IOs if used. Normally, the IO activity is performed by the licensees' internal regulator providing internal inspection, assessment and oversight. For specific structures (Containment) or components (NSSS), a Third Party Inspection Organization would be contracted by the licensee, in addition to the internal regulatory function.

4. Good practices for inspection of components and structures

These good practices for reviews, assessments and inspections during design, manufacture, construction, installation and commissioning of components and structures are a result of discussions where advantages and disadvantages of different approaches have been compared.

The summaries provided for the role and functions of the licensees and the regulators are a brief set of principles as it is judged they are widely understood. The use of conformity assessment bodies is an evolving topic and these sections on good practices provide more description to show how they can be applied in a variety of regulatory regimes.

4.1 Licensees' control, supervision and oversight

As stated in the European Nuclear Safety Directive the prime responsibility for nuclear safety of a nuclear power plant rests with the license holder and this responsibility cannot be delegated. The licensee should consequently have clearly defined design, manufacturing, installation and commissioning acceptance processes which ensure that necessary reviews, inspections and examinations are performed in the different phases. The licensee should also maintain an internal oversight function which provides a comprehensive examination of activities both within the licensee's organization and external organizations. This includes examination that necessary supervision and control of vendors, contractors and suppliers is performed during different phases of a new build nuclear power plant and during modification of an existing plant. The supervision and control should include to:

- ensure that the contractor[4] has sufficient manpower and competence to carry out the assignment in a safe manner,
- ensure that the contractor has the necessary equipment for executing the assignment and that the contractor employs adequate methods and processes where applicable,
- ensure that the contractor employs management and quality systems that provide full control over safety in conjunction with the assignment and that manufactured and assembled structures, systems, components and devices meet stipulated safety requirements,
- continuously supervise the contractor's activities to ensure that all regulatory requirements[5] and licence conditions are satisfied, along with the goals and guidelines for the activity to which the assignment pertains,
- continuously examine the contractor's continuous improvement programme to evaluate and report events to the licensee and ensure that appropriate safety related measures are taken,
- when necessary, instruct the contractor to take suitable corrective measures, or take such measures himself if the contractor does not adhere to the goals and guidelines established for the assignment
- ensure that all safety and quality requirements are fulfilled in each phase, particularly before a system or component is taken into operation.

The licensee should also, in order to fulfil his responsibility, ensure that personnel from the licensee's own organization as well as from the regulatory body and independent IOs (if used) have access to those facilities where safety related components and structures are manufactured, tested and installed, and to the associated documentation.

[4] The term contractor is here used synonymously with vendor and supplier

[5] In France for pressure equipment regulatory requirements are not under the licensee surveillance: licensee only performs supervision on activities which are identified important for safety.

4.2 Regulatory approaches

Depending on the basic regulatory approach or combination of approaches that are applied the scope and focus of reviews, assessment and inspection during different phases may vary. However, some important aspects should always be subject to reviews and inspections by the regulator. These important aspects should as a minimum include:

- reviews of design basis and extended design conditions of the plant and the related design basis of the structures and components
- reviews and inspections of the licensee's organization, resources and management for internal oversight and arrangements for control and oversight of vendors, contractors and suppliers
- confirmation that independent conformity assessment bodies, including IOs , are accredited or approved for their tasks
- inspections of the licensees quality assurance audits of the supply chain
- reviews of the licensees overall process for successive testing and examination of components and structures including related hold points, which have been defined or approved by the regulatory body
- inspections of licensees arrangements for control of non-conformance, design modifications and design change requests
- reviews of functional system testing programs and other commissioning programs.

If conformity assessment bodies are used for comprehensive detailed reviews and assessments the regulator's work in other phases may be limited to inspections and reviews on a sampling basis.

4.3 Use of conformity assessment bodies

The use of different types of conformity assessment bodies, including IOs, can be prescribed by the regulator in regulations or in response to individual safety cases. The regulator can also express expectations that certain tasks should be tested, reviewed, assessed or inspected by an independent conformity assessment body. Conformity assessment bodies can be contracted either by the regulator or by the licensee or by a manufacturer. Conformity assessment bodies communicate with and report directly to the licensees, the manufacturer or the regulator depending on who has ordered the tasks. Results from their work should however always be available to the regulator.

Depending on national regulatory approach, a good practice in many situations is to apply the following stepwise and sequential approach where independent conformity assessment bodies review, inspect, test and issue certificates or approvals as a basis for further work. Similar sequential approaches may be developed and managed by the licensee. The specific type of document needed to get clearance to move from one phase to another may vary depending on the safety case. This example is adapted to mechanical components and steel structures, but can with some modification also be applied to concrete structures.

<u>Design</u>

A conformity assessment body performs comprehensive reviews of the detailed design documentation based on the regulators review and assessment of the design basis. This detailed design documentation typically includes standards and criteria adopted, structural and other analysis, structural and isometric drawings, material specifications, welding and fabrication/manufacturing processes and their qualification, control/examination plans and procedures for destructive and non-destructive testing. If the conformity assessment body's review, which may include their own verification analysis, show that relevant requirements are met, the body may issue a *design examination certificate or equivalent*.

Manufacturing

The design examination certificate or equivalent should in principle be a prerequisite to start of manufacturing. During manufacturing independent bodies perform supervision and testing in different phases according to the control and examination plans including testing at works, for example visual examination and hydrostatic test. Qualification of welding procedures and welding personnel are supervised and evaluated by a certification body. After testing is completed the results are evaluated with outliers assessed by the licensee and the conformity assessment bodies. Deviations and non-conformances are also reviewed and the results evaluated. If these reviews and evaluations show that relevant requirements are met, the conformity assessment body may issue a *manufacturing examination certificate or equivalent*.

Installation

The manufacturing examination certificate or equivalent should in principle be a prerequisite to the start of installation. During installation independent bodies perform supervisions, examinations and testing according to the control and examination plans. After the installation of a component or structure in the plant an inspection body should verify that

- the component has been installed in accordance with controlled drawings and flowcharts and that performance meets safety requirements,
- deviations and non-conformances identified during installation are reported and evaluated by the licensee and the inspection body as appropriate,
- surface finishes and coatings of installation are finished to the required final state,
- tests have been done to show that the safety valves and other safety equipment operate properly and that the component was not exposed to harmful vibrations or other loads, for which no account is taken when designing the control. The inspection body should witness the tests.

If these verifications and tests show that relevant requirements are met, the body may issue an *installation examination certificate or equivalent.*

Commissioning

The design, manufacture and installation certificates or their equivalents are the basis for the inspection bodies' final assessment of conformity with the regulations or other requirements in the specific safety case. These types of conformity assessments include confirmation that all necessary measures have been taken and that the component or structure has been manufactured and installed according to the design documentation and meets all applicable requirements. Included in the assessments is also confirmation that deviations of various kinds have been handled and remedied correctly and that the necessary maintenance and in-service testing can be undertaken.

If these controls show that relevant requirements are met the body may issue a *certificate of conformity or equivalent*. A certificate of conformity should be a condition for taking a system, component or a structure into overall system functional testing to confirm the limits and conditions of operation identified by the design. The system functional testing should be controlled by the licensee and reviewed by the regulatory body.

Satisfactory system level tests are a prerequisite for taking the system into operation which is beyond the scope of this report.

4.4 Accreditation, authorisation and surveillance of independent inspection, testing and certification organizations

4.4.1 Accreditation

The use of independent inspection, testing and certification organizations in support of the regulators and licensees work with verifying compliance with national nuclear safety requirements and license conditions assumes that there is confidence in their inspection activities. This confidence can be supported by an accreditation of such organizations delivered by a national accreditation body.

If bodies that carry out inspection, testing and certification activities are accredited, this should be done for their tasks in question in the nuclear field based on applicable regulations and standards. This means that the bodies should be accredited in accordance with recognized accreditation standards and for those specific inspection, testing and certification tasks that result from applicable national nuclear safety regulations.

The international standards define general requirements for conformity assessment bodies in the accreditation process and they should be followed in the accreditation. These standards are listed in the appendix 5 of this report.

Accreditation decisions should be based on inspections (audits) and comprehensive reviews of the organizations' management systems (including working procedures and professional training programs), technical competence, personnel resources and work practice for verification that the requirements in relevant accreditation standards and relevant national nuclear safety regulations are met. A national accreditation body carries out its inspections and reviews in accordance with standards and specifications agreed with the national nuclear regulatory body, both before an accreditation decision and during subsequent surveillance. A good co-operation and information flow between the national nuclear regulatory body and the national accreditation body are consequently essential. However, it is the national accreditation body that makes the independent accreditation decision.

An accreditation certificate should clearly specify the scope of accreditation, and thus the field in which the body may act in its role as an accredited body. This means for example that an accreditation certificate should include information on those regulations and other rules against which conformity assessment can be made. An accreditation certificate should also:

- include conditions related to reporting and co-operating with the national accreditation body and the national nuclear regulatory body
- define the mandates with regard to results of reviews and inspections.

Depending on the regulatory regime an accreditation certificate may include additional information if an authorization by the national regulatory body is also needed in order to act as conformity assessment body (see section 4.4.2).

4.4.2 Authorisation

Some regulatory regimes also require authorisation for these organizations in addition to accreditation. This is generally applied when the regulator has limited engagement in the accreditation process, but can also be a part of the applied regulatory approach. When existing, the authorisation process may include additional reviews and inspections by the national regulatory body of such organization, its management system with working procedures, adequacy of their resources and technical competence. The process results in an authorisation delivered by the

regulatory body in order to allow these organizations to perform defined tasks during specified time periods.

4.4.3 Impartiality, independence and competence

Independent conformity assessment bodies, including inspection organizations, that perform different kinds of reviews, assessments, testing and inspections during design, manufacturing and installation of component and structures in support of the regulators work should meet the requirements of impartiality and independence of a type A body according to the standard EN ISO / IEC 17020. Type B bodies can however have an important role for example in the licensee's inspections. The degree of impartiality and independence should be defined by the national regulatory body depending on the situation and safety case.

Organizations that audit and certify management systems for different kinds of manufacturing processes including welding should meet the requirements of impartiality and independence in accordance with EN ISO / IEC 17 021. Organizations that certify welding personnel should meet the requirements of impartiality and independence in accordance with EN ISO / IEC 17 024. Organizations that certify components, processes and services according to EN 45011 should meet the same requirements of impartiality and independence as a type A body.

Bodies performing destructive testing and non-destructive testing (laboratories) of safety significant components should normally also meet the same requirements of impartiality and independence as type A bodies according to the standard EN ISO / IEC 17025. For other types of components and structures less stringent requirements of impartiality and independence can be accepted.

Inspection, certification and testing bodies should have systems that specify the knowledge and skills needed for their personnel to carry out the inspection, certification and testing tasks in question. Competency should be determined by examination at the individual level and result in a personal certificate that specifies the tasks to be performed. The validity of certificates should be limited for a certain time period.

Examples of personnel knowledge and skills needed for a conformity assessment body active in the area of nuclear mechanical components is given in Appendix 2.

4.4.4. Non- conformances and reporting

An accredited conformity assessment body should be able to handle and decide on acceptance of non-conformances within those limits that are given in their working procedures, and which have been approved in the accreditation process. When non-conformances outside the limits are observed a certificate of conformity with national regulations cannot be issued, and the components should consequently not be taken into operation. In such situations a licensee or a manufacturer has to take measures to correct the non-conformance or justify and apply to the national regulator for an exception from the relevant requirement. In some regulatory regimes the inspection organization should also report non-conformance to the regulatory body.

It is also important that the terms of accreditation or authorization include conditions requiring accredited organizations to report general problems and serious deviations direct to the national regulatory body.

4.4.5. Collaboration

Collaboration between the relevant stakeholders is important in regulatory systems in which accredited bodies carry out important inspection activities.

The national accreditation body and the national regulatory body should collaborate, both in relation to accreditation and subsequent follow-up and surveillance activities. The national accreditation body should immediately inform the national nuclear regulatory body if a surveillance reveals such deficiencies in an accredited body's activities that accreditation may be withdrawn.

Accredited organizations should be involved in such experience feedback meetings that the national accreditation body and nuclear regulatory body organize. This should also be stated in their terms of accreditation.

4.4.6 Mutual recognition of accreditations

Generally, accreditation is performed according to harmonized standards for specific tasks according to product or facility requirements. In the nuclear safety field requirements concerning systems, structures and components may vary between different countries. Mutual recognition of accreditations is therefore not possible as a general rule. However, for specific areas where there are similar national safety requirements, mutual recognition of accreditations can be made by agreements between accreditation bodies after consultation and agreement of the regulatory bodies.

5. Summary

WENRA decided to initiate work concerning benchmarking of European inspection practices for components and structures of nuclear facilities at its March 2010 meeting**.** A working group was established for this purpose. The working group was expected to describe the practices being applied in WENRA countries for arranging inspection activities of mechanical equipment, steel structures and concrete structures. The countries were to:

- explain possible formal approvals of the involved third party organizations
- explain possible correlation with safety classes
- explain if two redundant inspections have to be done where responsibility is with the licensee and with the regulatory body.

As a second step of the work, the group was expected to:

- discuss the experience gained in WENRA countries with their respective approach
- discuss possible future development plans and needs to modify the approach
- consider good practices that could become harmonized European practices.

The detailed objectives of the group were defined as follows:

- to learn from others practices to develop your own practices
- to discuss the added value of different basic regulatory approaches
- to assure similar degree of involvement by the industry
- to make use of foreign IOs easier in the long term (interchangeability, accreditation)

In the early phase of the work national reports were provided by the participating countries. These were used to make initial comparisons between the countries and to focus the work of the group on the most essential issues. An overall scheme of the inspection practices was developed by the group for the structures and components which were studied. The group developed in its first meeting tables to collect information on inspection practices in a systematic way. The tables were created for pressure equipment, steel structures and concrete structures. Regulatory and licensee inspections and auditing were completed in separate tables. In the final phases of the work countries provided short national summaries of their inspection practices. All this information provided by the participating countries was crucial in developing this unique benchmarking report.

Every participating country confirms that the primary responsibility for the safety of NPPs and quality of NPP structures and components rests with the license holder. The licensee reviews and approves documents and inspections related to component and structure design, manufacturing, installation and commissioning before presenting them to the regulator for approval. Licensees are expected to take all the necessary steps and actions to fulfil applicable safety requirements and to organize the necessary quality control. Licensees shall verify that all the organizations related to these steps have arrangements to produce appropriate quality.

A general conclusion is drawn that all countries see it necessary that the most important SSCs have inspections undertaken by the regulatory body. As the nuclear safety significance and the safety classification of a SSC reduces, the role of the regulatory body tends to reduce and that of conformity assessment bodies, and in particular inspection bodies tends to increase. Similarly the independence of the conformity assessment bodies is at its highest level for the most important SSCs and tends to reduce as the nuclear safety significance and the safety classification of the SSC tends to reduce.

The practices across countries are fairly uniform for pressure equipment although, as concerns regulatory practices, also on this area there is variation between countries concerning especially management system audits and/or focused audits. As concerns the design and commissioning phases comprehensive technical control is performed by almost all regulators. In some cases the regulatory body reviews only the design basis of components and structures and independent IOs are used to review the detailed design. For the manufacturing and installation phases there seem to be more variations between countries. Auditing of the QM systems of the manufacturers of the most important pressure equipment by the regulatory body or an IO is generally considered important.

There are larger variations in inspection and auditing practices between regulators as concerns steel and concrete structures. Also for them a comprehensive technical review of the design or the design basis is done by most regulators. As concerns manufacturing and structural concreting typically technical control by sampling is used whereas for installation and commissioning either comprehensive technical control or technical control by sampling is used.

Hold points between the different lifecycle phases of structures and components are used widely in most countries. Especially for design and commissioning phases all participating countries use regulatory hold points.

There is a tradition in many countries to use independent conformity assessment bodies to review, assess and supervise different activities during design, manufacture, construction and commissioning of components and structures, especially the pressurized components. The use of such conformity assessment bodies can be prescribed by the regulator and contracted for its task by either the regulator or by the licensee or the vendor. In some countries the regulator does not prescribe the use of independent conformity assessment bodies but expresses expectations that the licensee contracts conformity assessment bodies for review, assessment or supervision of important aspects during design, manufacture, construction and commission. Regulatory bodies can thus choose to have an emphasis in either of the two basic approaches, prescriptive and goal-setting/outcome based, for inspection of components and structures or to combine them in an appropriate manner and to differing degrees use independent conformity assessment bodies as part of the work. The regulatory approach may have influence on the use of independent IOs as well on their regulatory oversight.

One of the basic tasks of the group was to “consider good practices that could become harmonized European practices”. For this purpose a subgroup was established which also studied the harmonized European practices applied on the conventional side. Based on the work of this subgroup good practices for inspection of components and structures are presented in chapter 4 of this report. These good practices cover the following issues:

-licensees control, supervision and oversight

-regulatory approaches

-use of conformity assessment bodies in different phases

-accreditation, authorization and surveillance of independent inspection, testing and certification organizations

Especially concerning the use of independent inspection, testing and certification organizations good practices are presented for the following issues:

-accreditation

-authorization

-impartiality, independence and competence

-non-conformances and reporting

-collaboration

-mutual recognition of accreditations.

The good practices are generic in nature. They were developed especially for safety-related pressurized equipment but can be applied to all types of components and structures.

These good practices should be adopted by all WENRA countries when they are developing their inspection practices either by introducing them in the national regulations or by applying them into individual safety cases.

Definitions

For this benchmarking it was defined that

- ✓ Concrete structures meant in this report include buildings and other concrete, reinforced concrete and post-tensioned concrete structures.
- ✓ Steel structures include, for instance, the liner of the containment, liners and structures of spent fuel and reactor internal pools, hoisting equipment, pipe whip restraints, and fire doors.
- ✓ Mechanical components include, pressure vessels, piping, pump units, valve units, reactor internals, diesel generators, etc.
- ✓ Conformity assessment is a demonstration that **specified requirements** relating to a **product, process, system, person or body** are fulfilled.
- ✓ Conformity assessment body is a body that performs conformity assessment services. In this report following conformity assessment bodies are mentioned:
    - Testing organization means organizations which conduct non-destructive or destructive testing.
    - Inspection body or inspection organization means organizations that conduct activities (other than testing organizations) intended to verify safe design and achievement of specified quality of structures and components and to audit quality management systems.
    - Certification body or certification organization is a body operating a product certification system. The word "product" includes also processes and services.
    - In this report IO is used for inspection body or certification body. IO can be accredited also for both activities.
    - Notified body is a conformity assessment body fulfilling requirements in Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.
- ✓ Constructor inspection organization means a type B (second-party) organization of the constructor. Constructor might also contract a third-party organization for specific conformity assessment tasks.
- ✓ Utilities inspection organization means type B (second-party) organization that conducts inspections and assessments to certain group of equipment and structures (e.g. one licensee)
- ✓ Mandated organization is an organization mandated with the inspection of pressure retaining equipment (including NPP pressure equipment) and steel structures defined in ASME XI in Belgium. It has to be accredited by the Belgian Ministry of Labor.
- ✓ Third-party organizations are understood as organizations that make conformity assessment activities which are independent of the person or organization that provide the object and also independent of the end user of the object. They have proven professional competence and properly verified qualification system to conduct independent inspections. (Conformity assessment body may fulfill these requirements or it may fulfill second-party assessment body's requirements.)
- ✓ Accreditation is a third-party attestation related to conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Examples of knowledge and skills needed for a conformity assessment body active in the field of nuclear mechanical components and structures

A conformity assessment body working with mechanical components in nuclear power plants should have competence in

- Structural integrity including aspects of design, manufacturing and installation
- Safety systems and process engineering
- Safety and quality classification systems used in nuclear power plants
- National nuclear safety regulations for components

Within the organization there should therefore be sufficient personnel who have demonstrable knowledge and competence in the following areas. For each main area (design/materials, manufacturing and inspection/testing), there should also be at least one person who has expertise competence in the area.

Design and materials

- Mechanical properties of materials
- Weldability and heat treatment of materials
- Environmental impact on material and degradation mechanisms
- General design rules for machine elements, plates, shells, pressure vessels, piping, valves, pumps, supports
- Methods for deriving load input data from design basis
- Design rules according to European harmonized standards for pressurized components
- Design rules according to recognised international standards such as ASME, RCCM and KTA for nuclear mechanical components
- Drawing Rules
- Strength analysis according to European harmonized standards for pressurized components
- Strength analysis according to recognised international standards such as ASME, RCCM and KTA for nuclear mechanical components
- FEM analysis

Manufacturing technology

- Methods for forming, moulding, bending, forging, surface preparations - possibilities and limitations
- Welding methods - possibilities and limitations for different material and material combinations
- Welding qualification procedures for welding procedures and personnel[6]

[6] Certificate to assess welding personnel and welding procedures should be issued on the basis of education, training and proficiency testing, and experience that apply to the International Welding Engineer (IWE) or *equivalent qualification requirements.*

Inspection and testing

- Manufacturing and installation inspection and control planning according to European harmonized standards for pressurized components
- Manufacturing and installation inspection and control planning according to recognised international standards such as ASME, RCCM and KTA for nuclear mechanical components
- Visual and dimensional inspection techniques
- Pressure and leak testing techniques
- Non-destructive testing methods - possibilities and limitations
- Functional system testing methods and commissioning

Conformity assessments

- Review and assessment of non-conformance
- Issuing of certificates

Summary tables
Regulatory inspections and auditing

Definitions to abbreviations used in the tables:

Who does?

RB	Regulatory body
IO	Inspection organization
CI	Contractor inspection organization
MO	Belgian mandated organization (IO)

How it does? What is the completeness of the activity?

C	Comprehensive technical control
T	Technical control by sampling
M	Management system audit
F	Focused audit (e.g. follow up of a specified product)
R	Reactive intervention by exception
D	Control of inspection documentation

Mandatory inspections and auditing are underlined.

Comprehensive technical control (C) refers to a practice where all relevant technical aspects are reviewed or inspected and the control covers a major proportion of structures and components.

If the control is based on **sampling (T)**, a combination of different factors is typically used for sampling. Factors which are used as a basis may include safety significance, novelty, complexity and operating experience of the structure or component. Sample size is typically increased if problems occur.

Design basis of components and structures refers to those technical requirements which have to be set on components and structures in order that they would meet the demands based on plant and system level design. Design basis includes functional requirements and loading conditions for normal and accident conditions. Also safety, seismic and quality classification are part of component or structure level design basis.

Pressure equipment

Design phase (design basis/detailed design)

Safety Class	Belgium	Bulgaria[7]	Czech Republic	Finland	France	Lithuania	Slovak Republic	Spain[8]	Sweden	Switzerland	UK
1 (Who)	RB/MO	RB/-	RB/RB	RB/RB	RB/RB, IO	RB/RB	RB,IO/RB	RB/RB	RB/IO	RB/RB+IO	RB/IO
(How)	T/CMF	C/-	CM/CM	CMR/CMR	CM/CMR	C/T	CM/CM	CM,TFR/C,TFR	CM/C	C/C	TM/CMRD
2 (Who)	RB/MO, IO	RB/-	RB/RB	RB/RB,IO	RB/IO	RB/RB	RB,IO/RB	RB/RB	RB/IO	RB/RB+IO	RB/IO
(How)	T/CMF	C/-	CM/CM	CMR/CMR, CR	TM/CTMR	C/T	CM/CM	CM,TFR/C,TFR	TM/C	C/C	TM/CMRD
3 (Who)	RB/MO, IO	RB/-	RB/RB	RB/IO	RB/IO	RB/RB	RB,IO/RB	RB/RB	RB/IO	RB/RB+IO	RB/IO
(How)	T/CMF	C/-	CM/CM	CR/CR	TM/CTMR	C/T	CM/CM	CM,TFR/C,TFR	TM/C	C/C	TM/CMRD

Manufacturing

Safety Class	Belgium	Bulgaria	Czech Republic	Finland	France	Lithuania	Slovak[9] Republic	Spain	Sweden	Switzerland	UK
1 (Who)	MO	RB	RB	RB	RB, IO	RB	RB,IO	RB	IO	RB,IO	RB,IO
(How)	CMF	T	TMFR	CMR	CMR	T	TMFRD	TM	C	C	TMFR
2 (Who)	MO,IO	RB	RB	RB, IO	IO	RB	RB,IO	RB	IO	RB,IO	RB,IO
(How)	CMF	T	TMFR	CMR, CR	CTMR	T	TMFRD	TM	C	C	TMFR
3 (Who)	MO,IO	RB	RB	IO	IO	RB	RB,IO	RB	IO	IO	RB,IO
(How)	CMF	T	TMFR	CR	CTMR	T	TMFRD	TM	C	TD	TMR

Installation

Safety Class	Belgium	Bulgaria	Czech Republic	Finland	France	Lithuania	Slovak[9] Republic	Spain	Sweden	Switzerland	UK
1 (Who)	MO	RB	RB	RB	RB, IO	RB	RB,CI	RB	IO	RB,IO	RB,IO
(How)	CMF	T	TMR	CMR	CMR	T	TMFRD	TM	C	C	TMR
2 (Who)	MO,IO	RB	RB	RB, IO	IO	RB	RB,CI	RB	IO	RB,IO	RB,IO
(How)	CMF	T	TMR	CMR, CR	CTMR	T	TMFRD	TM	C	C	TMR
3 (Who)	MO,IO	RB	RB	IO	IO	RB	RB,CI	RB	IO	IO	RB,IO
(How)	CMF	T	TMR	CR	CTMR	T	TMFRD	TM	C	CD	TMR

[7] Detailed design is supervised by the licensee.
[8] For design basis CM in all safety classes when associated to a modification licence; otherwise TFR. For detailed design: C in all safety classes when associated to a modification licence; otherwise TFR.
[9] Quality management and quality requirements documentation (D) for manufacturing and installation phase are approved by RB.

Commissioning

Safety Class	Belgium	Bulgaria	Czech Republic	Finland	France		Lithuania	Slovak Republic	Spain	Sweden[10]	Switzer-land	UK
1 (Who)	MO and RB[11]	RB	RB	RB	RB, IO		RB	RB,IO,CI	RB	RB/IO	RB,IO	RB,IO
(How)	CMF	CTMFR	CM	CMR	CTMR		T	CMD	CM	TM/C	CD	TMFR
2 (Who)	MO,IO and RB[11]	RB	RB	RB	IO	RB	RB	RB,IO,CI	RB	RB/IO	RB,IO	RB,IO
(How)	CMF	CTMFR	TM	CMR	CTM	TMR	T	CMD	CM	TM/C	CD	TMFR
3 (Who)	MO,IO	RB	RB	RB	IO	RB	RB	RB,IO,CI	RB	RB/IO	RB,IO	RB,IO
(How)	CMF	CTMFR	TM	CMR	CTM	TMR	T	CMRD	CM	TM/C	CD	TMFR

[10] IO = focus on functional tests in safety classes 1, 2 and 3.
[11] RB= pressure tests and pre-operational tests in safety classes 1, 2 and 3.

Steel structures

Design phase (design basis/detailed design)

Safety Class	Belgium	Bulgaria[12]	Czech Republic	Finland	France	Lithuania	Slovak Republic	Spain[13]	Sweden	Switzerland	UK
1 (Who) (How)	RB/MO,IO T/C	RB/- C/-	-	-	-	RB/RB C/T	-	RB/RB CM,TFR/C,TFR	-	RB/RB CD/C	RB/CI TMFR/CMRD
2 (Who) (How)	RB/MO,IO T/C	RB/- C/-	RB/RB CM/CM	RB/RB CMR/CMR	RB/RB TMFR/TMFR	RB/RB C/T	RB/RB CM/CM	RB/RB CM,TFR/C,TFR	RB/IO TM/C	RB/RB CD/C	RB/CI TMFR/CMRD
3 (Who) (How)	RB/MO,IO T/C	RB/- C/-	RB/RB CM/CM	RB/RB[14],IO CMR/CMR, C R	RB/RB TMFR/TMFR	RB/RB C/T	RB/RB CM/CM	RB/RB CM,TFR/C,TFR	RB/IO TM/C	RB/RB CD/C	RB/CI T/CRD

Manufacturing

Safety Class	Belgium	Bulgaria	Czech Republic	Finland	France	Lithuania	Slovak[15] Republic	Spain	Sweden	Switzerland	UK
1 (Who) (How)	MO,IO C	RB T	-	-	-	RB T	-	RB TM	-	IO CD	RB,CI TMFR
2 (Who) (How)	MO,IO C	RB T	RB TM	RB CMR	RB TMFR	RB T	RB,CI TMD	RB TM	IO C	IO CD	RB,IO TMFR
3 (Who) (How)	MO,IO C	RB T	RB TM	RB, IO CMR	RB TMFR	RB T	RB,CI TMD	RB TM	IO C	IO TD	RB,IO T

Installation

Safety Class	Belgium	Bulgaria	Czech Republic	Finland	France	Lithuania	Slovak[15] Republic	Spain	Sweden	Switzerland	UK
1 (Who) (How)	MO,IO C	RB T	-	-	-	RB T	-	RB TM	-	IO CD	RB,CI TMFR
2 (Who) (How)	MO,IO C	RB T	RB TM	RB CMR	RB TMFR	RB T	RB,CI TMD	RB TM	IO C	IO CD	RB,CI TMFR
3 (Who) (How)	MO,IO C	RB T	RB TM	RB, IO CMR	RB TMFR	RB T	RB,CI TMD	RB TM	IO C	IO CD	RB,CI T

[12] Detailed design is supervised by the licensee.
[13] For design basis CM in all safety classes when associated to a modification licence; otherwise TFR. For detailed design: C in all safety classes when associated to a modification licence; otherwise TFR.
[14] STUK reviews the plans related to physical protection of NPP's.
[15] Quality management and quality requirements documentation (D) for manufacturing and installation phase are approved by RB.

Commissioning

Safety Class	Belgium	Bulgaria	Czech Republic	Finland	France	Lithuania	Slovak Republic	Spain[16]	Sweden	Switzer-land	UK
1 (Who) (How)	MO,IO C	RB CTMFR	-	-	-	RB T	-	RB CM,TFR	-	RB,IO CD	Not applicable
2 (Who) (How)	MO,IO C	RB CTMFR	RB T	RB CMR	RB TMFR	RB T	RB CTMFRD	RB CM,TFR	RB/IO TM/C	RB,IO CD	Not applicable
3 (Who) (How)	MO,IO C	RB CTMFR	RB T	RB CMR	RB TMFR	RB T	RB,IO CTMFRD	RB CM,TFR	RB/IO TM/C	RB,IO CD	Not applicable

[16] For design basis CM in all safety classes when associated to a modification licence; otherwise TFR. For detailed design: C in all safety classes when associated to a modification licence; otherwise TFR.

Concrete structures

Design phase (design basis/detailed design)

Safety Class	Belgium	Bulgaria[17]	Czech Republic	Finland	France	Lithuania	Slovak Republic	Spain[18]	Sweden	Switzerland	UK
1 (Who) (How)	RB/RB Not defined	RB/- C/-	-	-	-	-	-	RB/RB CM,TFR/C,TFR	-	RB/RB CT/C	RB/CI TMFR/ CMRD
2 (Who) (How)	-	RB/- C/-	RB/RB CM/CM	RB/RB CMR/CMR	RB/RB TMFR/TMFR	RB/RB C/T	RB/RB CM/CM	RB/RB CM,TFR/C,TFR	RB/RB[19] TM/TM	RB/RB CT/C	RB/CI TMFR/ CMRD
3 (Who) (How)	-	RB/- C/-	RB/RB CM/CM	RB/RB[20], IO CMR/CMR, CR	RB/RB TMFR/TMFR	RB/RB C/T	RB/RB CM/CM	RB/R CM,TFR/C,TFR	RB/RB[19] TM/TM	-	RB/CI T/CRD

Structural concreting

Safety Class	Belgium	Bulgaria	Czech Republic	Finland	France	Lithuania	Slovak[21] Republic	Spain	Sweden	Switzerland	UK
1 (Who) (How)	RB Not defined	RB T	-	-	-	-	-	RB TM	-	RB CT	RB,CI TMFR
2 (Who) (How)	-	RB T	RB TM	RB CMR	RB TMFR	RB T	RB,CI TFD	RB TM	RB[19] TM	RB CT	RB,CI TMFR
3 (Who) (How)	-	RB T	RB TM	RB TMR	RB TMFR	RB T	RB,CI TFD	RB TM	RB[19] TM	-	RB,CI T

Commissioning

Safety Class	Belgium	Bulgaria	Czech Republic	Finland	France	Lithuania	Slovak Republic	Spain	Sweden	Switzerland	UK
1 (Who) (How)	RB Not defined	RB CTMFR	-	-	-	-	-	RB T	-	RB CT	RB,CI TRF
2 (Who) (How)	-	RB CTMFR	RB T	RB CMR	RB TMFR	RB T	RB TFD	RB T	RB TM	R CT	RB,CI TRF
3 (Who) (How)	-	RB CTMFR	RB T	RB CMR	RB TMFR	RB T	RB D	RB T	RB TM	-	Not audited

[17] Detailed design is supervised by the licensee.
[18] For design basis CM in all safety classes when associated to a modification licence; otherwise TFR. For detailed design: C in all safety classes when associated to a modification licence; otherwise TFR.
[19] Using IOs for reviews of detailed design and other inspection tasks during construction and facility modifications are being prepared. An investigation is underway on how SSMs regulations should be changed.
[20] STUK reviews the plans for reactor island, fuel and safety buildings, circulation water structures and physical protection of NPP's (airplane crach).
[21] Quality management and quality requirements documentation (D) for structural concreting phase are approved by RB.

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BELGIUM

NATIONAL SUMMARY

Foreword

The Belgian inspection practices as discussed here focus on present practices related to plant modifications (most of them are repairs and replacements).

Those modifications are dealt with, conform with the Belgian regulations, according the prescriptions of ASME-code, section XI, as amended by Belgian regulatory documents.

The regulatory oversight of the few, recently build concrete structures has been limited to a general overview of those activities by Bel V. This should not be considered as standard practice. Therefore, no detailed answers for concrete structures are provided hereafter.

A Basic regulatory approach in the country (structures and components)

Organizations competent at regulatory level: Belgian Regulatory Body and Mandated Organization

The FANC (Federal Agency for Nuclear Control) is the competent authority in the field of nuclear applications. Its subsidiary Bel V provides the technical expertise for carrying out inspections in licensed facilities. Together, FANC and Bel V form the Regulatory Body (RB).

Additionally, all NPP pressure retaining component are subject to inspections by a Belgian Mandated Organization (MO) in charge of inspection of steam components according to the Belgian legislation. The MO investigates the mechanical safety by verifying that the requirements of ASME III and XI are met. The MO has its primary expertise in mechanical safety whereas Bel V also assures the global nuclear safety, taking into account radiation protection and probabilistic safety assessments (PSA).

Applicable regulations in Belgium

Generally speaking, Belgium has chosen the American rules for the design and construction of its nuclear power plants, i.e. the requirements of the Code of Federal Regulations (10CFR50), as well as of the ASME code, of the ANS/IEEE standards and of the documents issued by the US-NRC such as the Regulatory Guides, the Standard Review Plans, the NUREGs…Safety classes are defined according to the US rules (R.G. 1.26, R.G. 1.29 & R.G. 1.143)

Historically, the basic Belgian pressure equipment regulation has been the General Rules for protection at Work (RGPT/ARAB), which are still the legal basis. It has evolved with time, e.g. to endorse the Pressure Equipment Directive 97/23/CE. These regulations do not address explicitly the production of steam by a nuclear reactor.

Regarding the pressure vessels which are part of the nuclear installations, a derogation has been established to allow the replacement of the Belgian rules (RGPT/ARAB) by the American ones.
Transpositions in Belgium of the regulatory aspects of the ASME code (sections III & XI) specify the scope of the inspector assignments as defined by the code which are entrusted to the Mandated Organization and to Bel V. The Authorized Inspection Agency assignment may also entrusted to certain independent entities subject to conditions defined in the transposition (ASME, section XI).

The Mandated Organization and those independent entities act thus as third-party Inspection Organizations (IO) having expertise in mechanical components.

Additionally, for major plant modifications implying a possible modification of the license, e.g. the steam generator replacement and associated thermal power up-rates, the licensee has to prepare a Preliminary Safety Analysis Report (PSAR), which must be approved by Bel V before plant modifications may be implemented.

Hold-points and witness points

Hold-points and witness points are as defined by the ASME-code.

B Expectations on licensees

The licensees have the primary responsibility for the safety of NPPs and the quality of their structures and components.

The licensee shall ensure that every organization the activities of which are connected to design, manufacture, installation, testing and inspection of structures and components, have appropriate quality and management systems and qualified personnel for the work they perform. The licensee must review and approve all the documentation, perform inspections and approve tests before presenting those to Bel V or the Mandated Organization. The licensee is responsible that regulatory requirements and guides are followed. The licensee delivers a Certificate of Authorization to Contractors based on a QA audit performed by the MO.

Identified non-conformances are assessed and corrective and preventive actions are be taken. This is governed by the licensee's management system, which includes procedures to process non-conformances identified in processes and products.

C Regulatory review of design documentation (RB/IO, safety class)

Neither licensing of a design organization nor auditing of the management thereof are foreseen for the Owner or for the Owner's Agent, i.e. the organizations to which the tasks are entrusted by the Owner to be carried out under the responsibility of the Owner. The manufacturing follow-up agreements passed with the MO cover the Code's requirements regarding the Owner and the Owner's Agent.
Design documentation is established, and reviewed and approved by the IO as foreseen by the ASME-code.

Design inputs are evaluated by Bel V as part of its role related to the global nuclear safety.
The design reports are distributed to the RB and IO for inspection for approval or information according to the detailed requirements of the transpositions.

<u>Control of non-conformances</u>

With a view to the practical application of the ASME-code in a non-US context, the requirements of the code may be replaced by requirements that offer at least equivalent guarantees.

The party applying for shall submit a request for derogation in parallel both to the Owner or the Owner's Agent and to the MO. Should that party be not conform to the advice given by the MO, the latter will enter a reservation on the "Data Report". For any aspects that may have an impact on the nuclear safety, Bel V has also to approve the request.

The same approach applies in case of non-conformities (i.e. deviation or deficiency with respect to the adopted code or set of rules).

D Regulatory inspections of structures and components (RB/IO, safety class, during manufacturing/after manufacturing/installation/commissioning)

All activities at design stage, off-site manufacturing, on-site construction, manufacturing and installations, and commissioning are dealt with according to the ASME-code, sections III and XI, as transposed to the Belgian context. The corresponding regulatory inspections as required by the code are all performed by the AIA, i.e. an IO as described in §§ A & E.

Off-site manufacturing

An approval is required for material, component and structure manufacturers. Auditing of the manufacturers is done by the IO.

Fabrication and inspection methods (welding, hard facing, heat treatment etc.) as well as fabrication and inspection personnel are validated by the IO.

Manufacturing records are reviewed by the IO.

Regulatory inspection of products and witnessing of functional and pressure tests by the manufacturers are done by the IO.

On-site construction, manufacturing and installations & commissioning activities are managed by the Licensee, Owners Agent and by the MO or other IO (construction/inspection inspectors). The nuclear regulator will intervene in case nuclear safety may be affected. Additionally, Bel V monitors all pre-service tests .

The control of non-conformances follows the same rules as at design stage.

E Authorization of IOs

AIB-Vincotte is one of the Belgian Mandated Organization for inspection of pressurized steam components. It is currently selected by the licensee for inspection related to these components in the Belgian NPPs, including assuming the role of AIA as required by the ASME codes. It is accredited by the Belgian Ministry of Labor.

The Owner may also entrust the AIA assignment to an independent entity only in the case of repair or replacement of some class 2 or 3 equipment which are out of the main scope of the MO. The most significant case is the AIA assignment entrusted to the Owner's or the Engineer's inspection department. This possibility is currently not used. The intervention modalities of this inspection department are specified in the Owner's Quality assurance Program. The verification of the proper implementation of this program rests with Bel V.

F Use of management system audits/focused audits

The Owner delivers authorizations after audits or equivalent verifications by the MO or by the IO.
The nuclear regulatory body does not deliver any authorisation.

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BULGARIA

NATIONAL SUMMARY

A. Basic regulatory approach in the country (structures and components)

State control on the safe use of nuclear energy and ionizing radiation and safe management of radioactive waste and spent fuel is carried out by the Chairman of the Nuclear Regulatory Agency, named further "Agency", who is independent specialized body of Government.

The Bulgarian nuclear regulatory body, Bulgarian Nuclear Regulatory Agency (BNRA) issues a number of permits, mentioned as a hold points below and has the responsibility to supervise licensees' activities by reviewing siting, design, construction, installation and commissioning documentation as well as by inspecting NPP structures and components to assess whether the requirements in BNRA safety regulations are met. Before BNRA reviews any documentation, the licensee must have approved it. The licensee also performs and approves inspections before BNRA inspection. The licensee has the primary responsibility for the safety of NPPs and the quality of their structures and components.

Hold-points

Conceptual design of nuclear power plant and proposed plant site are subject of regulatory review and approval (hold point).

Regulatory review of the design basis of nuclear facilities (nuclear power plant/unit, research reactor, etc.) is conducted as part of the licensing process (design permit and order of approval of technical design) (hold points). Order of approval of technical design is a prerequisite for next step of licensing, namely application for construction permit (hold point). Modifications of systems, structures and components (SSC), important to safety are performed after issuance of permit by BNRA (hold point).

Nuclear power plant construction works start after issuance of construction permit by BNRA (hold point). Construction permit is issued by BNRA only if the submitted documentation by the licensee is in compliance with the requirements of ASUNE and applicable regulations. Extra hold points regarding carrying out construction works and schedule can be put through the conditions of the permit.

Commissioning of nuclear power plant/unit start after issuance of commissioning permit by BNRA (hold point). If nuclear power plant is commissioned at several stages a commissioning permit is required for each stage. Such stages are initial on-site nuclear fuel storage, initial loading of the reactor core and testing at a subcritical condition, initial reactor criticality and low-power testing, initial power start-up of the unit at stage-by-stage power increase, trial-testing operation – for a new type nuclear reactor. Until the beginning of each commissioning stage, a commission of NRA inspectors appointed by the NRA Chairman shall inspect the site for confirming correspondence with stated data and circumstances and preparedness for carrying out the respective stage.

B. Expectations on licensees

The primary responsibility for the safety of NPP rests on the licensee. In order to ensure safety of NPP licensee shall take all appropriate measures to ensure that systems, structures and components are designed, manufactured, installed and commissioned with quality commensurate with their safety significance. Documentation of SSC is reviewed and approved by the licensee before its submission to BNRA.

The holder of permit for design and construction of nuclear facility is obliged to ensure that mechanical components are manufactured in accordance with the approved technical design. To ensure compliance with that requirement the license holder controls the manufacturing of the mechanical components at the place of manufacturing. The control includes verification of the quality system of the manufacturer as well as follow-up inspections. Necessary condition for start of manufacturing of a piece of equipment is the presence of coordinated design and technological documentation. For each piece of equipment is foreseen step by step acceptance of operations in hold points of Quality plans and in main stages called "Key events"(hold points). The inspection includes review of the quality management documents related to the manufacturing of the specific equipment, review and assessment for compliance of the submitted documents about the performed operations until the relevant hold point with the requirements set in the quality assurance documents and the design and technological documentation including reports (quality records), inspection of the real condition of the equipment/equipment's parts in manufacturing plant, check of the markings and interview of the personnel.

Control of non-conformances

Non-conformances in processes and products shall be assessed and documented according to procedures for control of non-conformances that are part of the quality management system of the Licensee. Depending of the significance of detected non-conformances appropriate corrective and preventive actions shall be taken.

C. Regulatory review of design documentation (RB/IO, safety class)

As it is mentioned above regulatory review of the design basis of nuclear facilities (nuclear power plant/unit, research reactor, etc.) is conducted as part of the licensing process (design permit and order of approval of technical design). Subject of review are technical design/project of NPP and Interim safety analysis report (ISAR), including topical reports for innovative design features, such as new passive safety systems or new structures and components. Topics of review for all safety classes SSC are following: component/structure design basis, operating experience and/or type test data, material specifications or construction materials, strength/structural analysis, structural or isometric drawings, coatings, quality assurance programs of licensee and main contractor/vendor of NPP and other subcontracting organizations that are involved in the design, manufacture and construction of NPP.

D. Regulatory inspections of structures and components (RB/IO, safety class, during manufacturing/after manufacturing/installation/commissioning)

Concerning the steel structures and mechanical components, as main practice, arranging a proper supervision with specific hold points during manufacturing is the responsibility of the License Holder. For selected most safety-significant structures and components NRA may conduct certain inspections during manufacturing. Requirements on these inspections and on the related hold points are given in connection with the approval of the technical design documents and construction permit.

E. Authorization of IOs

BNRA does not authorize inspection organizations. However, for the purposes of licensing and safety assessment, NRA may delegate an independent expertise on a given problem to inspecting organizations.

F. Use of management system audits/focused audits

BNRA conducts management system audits and focused audits of the licensee's activities, mainly on supervision of the licensee's procedures, competence and resources for conducting their own assessment of manufacturers and suppliers.

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CZECH REPUBLIC

NATIONAL SUMMARY

A. Basic regulatory approach in the country

The State Office for Nuclear Safety (SÚJB), [RB] is a governmental body as stipulated by Act. No.2/1969, Coll. and as regulatory body is responsible for governmental administration and supervision in the fields of uses of nuclear energy and radiation protection. The authority and responsibilities of the RB, as stipulated by Act. No.18/1997, Coll on Peaceful Utilisation of Nuclear Energy and Ionising Radiation (Atomic Act), include the following issues in particular:

- State supervision of nuclear safety of nuclear facilities, nuclear items, physical protection of nuclear facilities, radiation protection, and emergency preparedness of nuclear facilities and workplaces handling ionizing radiation sources,
- Licensing of activities as specified by Act. No.18/1997, e.g. for the sitting, construction, particular stages of commissioning, operation and decommissioning of nuclear facilities
- Reviewing and approving documentation related to nuclear safety and radiation protection as laid down by the Atomic Act, limits and conditions for the operation of nuclear facilities.

The RB controls every stages of the NPP life cycle according to a/m Atomic Act and associated regulations. The RB inspections activities concern classified equipment defined by Regulation No.132/2008, Coll, on quality assurance (in activities related to the utilization of nuclear energy) and Regulation No.309/2005, Coll., on assuring technical safety defining classified equipment specially designed (in compliance with the European Parliament and Council Directive No.97/1997 [PED]).

Classified equipment specially designed – equipment their potential failure can cause release of radionuclides into environment and threaten of human health.

Independent inspection organizations control design, manufacturing and selected installation of classified equipment specially designed and performs assessment of accordance the respective nuclear pressure components, systems and structures with technical requirements and procedures specified executive legislation.

Hold point strategy

The strategy is anchored in principles of licensing process defined a/m Atomic Act and associated regulations.

B. Expectations on licensees (including control of non-conformances)

The licensee holder is responsible for the nuclear safety. Effective management of organization with clearly defined strategic objectives respecting desired level of nuclear safety, established processes assuring principal organizational activities including their supporting activities and feedback effectiveness evaluation are considered as basic organization's capability.

Accomplishment adequate quality management system of the licensee holder is also substantial assumption for granting a licence and respective documents about quality management system is subject of RB approval before issuing RB a license according to a/m Atomic Act.

Recognised non-conformances are solved according to defined processes within quality management system of the licensee holder and categorised. In case of the category "one" with impact on nuclear safety - including classified equipment (categories "one, resp. two"), evaluation and fixation of non-conformances is submitted to the RB for approval resp. acceptance.
Existence of accredited inspection team of the licensee holder regularly performing inspections during installation, commissioning and operation stages, audits of licensee contractors (including designers and manufacturers) and internal organizational audits are also important aspects regarding to expectations on licensee holder.

The licensee holder demonstrates active co-operation with independent inspection organizations.

C. Regulatory review of design documentation (RB/IO, safety class)

Design documentation of new NPPs are elaborated in compliance with respective regulations and submit by licensee within licensing process, because design documentation of significant parts of the NPP from nuclear safety point of view is part of preliminary safety report and therefore is reviewed by RB. Inspection activities of the licensee holder are focused on quality management system of design organization performed by accredited inspection team.

In case of design documentation of NPP modification, licensee is obliged to categorize respective modification and those modification categorised as "category one" are submitted to the RB for approval. Others are only announced to the RB.

D. Regulatory inspections of structures and components (RB/IO, safety class, during manufacturing/ after manufacturing/ installation/commissioning/ clarification of Tables)

Regulatory inspections during manufacturing are performed randomly or as reactive inspections after indication of non-conformances related to classified equipment and classified equipment specially designed.

Regulatory inspections during installation, commissioning and operation stages related to classified equipment and classified equipment specially designed are specified as routine inspections performed by resident inspectors or special inspections performed systems inspectors from the RB headquarter. Those inspections activities are managed in compliance with internal RB guidelines and procedures and incorporated into semi-annual inspection plan.

In case of unplanned emergency reactor scram, indications potentially serious deficiencies regarding to quality management system, the QA processes, or non-conformances of components and structures indicating potentially common course failure, the RB applies reactive inspections.

Co-operation of the RB including information exchange with independent inspection organizations brings synergy effect regarding to performance of independent inspection activities.

E. Authorisation of IO

Independent inspection organizations are authorised by the Czech Office for Standards Metrology and Testing. The Office was established by the Czech National Council Act No. 20/1993, Coll, on the Organization of the State Administration in the field of Standards, Metrology and Testing as the state administration body responsible for such activities.

The RB (SÚJB) actively acts the role of advisory body for those Office and the RB inspection activities are regularly focused on overall status or a specific performance, etc. of the independent inspection organizations, including existence of respective contracts with licensee holder. Frequent

communication, e.g. on daily basis according to respective inspection requests is in competence of the licensee holder.
The RB does not receive any copies of documentation and conformance assessments issued by the independent inspection organizations, only on the base of individual requirements are these documents submitted to the RB.

F. Use of management system audits/focused audits

The RB inspections focused on the processes of the quality management system (QMS) of the licensee holder are regularly included into RB semi-annual inspection plans. Majority of those audits are focused audits or audits based on sampling. The RB also regularly performs audits/ inspections of the QMS contractors of the licensee holder and authorised independent inspection organizations.

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FINLAND

NATIONAL SUMMARY

A. Basic regulatory approach in the country (structures and components)

The Finnish nuclear regulatory body, Radiation and Nuclear Safety Authority (STUK), has the responsibility to supervise licensees' actions by reviewing design and manufacturing documentation as well as by inspecting NPP structures and components in various inspections defined in YVL Guides. Before STUK reviews any documentation, it must have been approved by the licensee. The licensee also performs and approves inspections before STUK's inspection. The licensees have the primary responsibility for the safety of NPPs and the quality of their structures and components.

Inspection Organizations (IO) carrying out regulatory type reviews and inspections of structures and components on behalf of STUK have to be authorized by STUK. IOs shall have accreditation specifically for activities related to NPPs and their structures and components. IOs can be utilized to review manufacturing and installation documentation, to conduct control of manufacturing and to inspect structures and components in safety class 3 and partly in safety class 2 (division of tasks between STUK and IO is presented in the Guide YVL E.1). Review of design basis is always at STUK's responsibility (SC1, SC2 and SC3).

Hold-points

Regulatory review of system level design basis is conducted as part of the licensing process (construction license and operating license) and when modifications of an existing system are made. System level design basis approval is a prerequisite to construction plan review (hold point).

Construction plans for manufacturing are reviewed. Approval of essential parts of a construction plan (e.g. design basis of component/structure, drawings, strenght/structural analysis, welding, heat treatment) is a prerequisite to start manufacturing of components (hold point). For concrete structures also concreting plan shall be approved and readiness inspection shall be passed before manufacturing starts (hold point).

In the construction inspection manufacturing documentation is reviewed, completed component/steel structure is inspected visually, its dimensions are checked and possible tests are supervised (e.g. pressure, leak tightness, functional, loading) (hold point). If inspection becomes more difficult as manufacturing proceeds, an adequate number of parts of construction inspection shall be carried out during manufacturing. Hold points during manufacturing are placed case by case. For concrete structures material test results of concreting are reviewed (witness point).

Installation construction plans of components are reviewed. Approval of the plan is a prerequisite to start installation (hold point). In the installation construction inspection installed component/structure is inspected visually, possible tests are supervised and installation documentation is reviewed (hold point).

Commissioning inspection is STUK's hold point in safety classes 1, 2 and 3. In the first phase of the commissioning inspection it is verified that all the previous steps have been performed and documented as expected, the remarks and non-conformances from previous steps have been cleared, location of component is in accordance with the approved plans and possible accessories are inspected. For concrete structures concrete work report is reviewed. After this commissioning can proceed to the

second phase and temporary permit for starting preoperational performance tests of components/systems can be issued. The second phase can be approved after the performance tests have been conducted and documented. After approved performance tests components/systems are ready for operation.

B. Expectations on licensees

The licensee has the primary responsibility for the safety of NPP structures and components. The licensee shall see to it that every organization the activities of which are connected to design, manufacture, installation, testing and inspection of structures and components, have appropriate quality and management systems and qualified personnel for the work they perform. The licensees must review and approve all the documentation, perform inspections and approve tests before presenting those to STUK for approval. The licensee is responsible that regulatory requirements and guides are followed.

Control of non-conformances

Licensee's management system shall include procedures to process non-conformances observed in processes and products. Significance of detected non-conformances shall be assessed, reasons for those determined and corrective and preventive actions decided. If necessary, modifications of the plant or components shall be made or procedures or management system shall be improved.

C. Regulatory review of design documentation (RB/IO, safety class)

Review of design documentation covers similar topics in safety classes 1, 2 and 3. The contents of reviews do not differ between STUK and IO. Topics of comprehensive review are following:

- manufacturer approval (pressure vessels) or description of manufacturer[22]
- NDT-organization approval[23]
- accreditation certificate of DT-organization[2]
- component/structure design basis
- operating experience and/or type test data
- material specifications or construction materials
- strength/structural analysis
- welding procedure specifications and their qualification[2]
- manufacturing procedures (qualification for demanding jobs)
- structural or isometric drawings
- coatings
- quality control plans
- NDT procedures including also functional, pressure and leak tightness tests.

Safety class 1:	-STUK makes the comprehensive review of components' design documentation. -SC1 is not applicable for steel and concrete structures.
Safety class 2:	-Review of components' design documentation is divided between STUK and IO depending on components safety significance. -Design documentation of steel and concrete structures is reviewed by STUK.
Safety class 3:	-IO makes the comprehensive review of components' and steel structures' design documentation. -Design documentation of concrete structures is reviewed by STUK.

[22] For concrete structures description of manufacturer contains description of the organization chain between the licensee, the plant supplier, the structural designer and the contractor.

[23] Not applicable for concrete structures

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D. Regulatory inspections of structures and components (RB/IO, safety class, during manufacturing/after manufacturing/installation/commissioning)

Safety class 1: -STUK supervises manufacturing and makes construction inspections, installation construction inspections and commissioning inspections for components.
-SC1 is not applicable for steel and concrete structures.

Safety class 2: -Components are divided between STUK and IO depending on components safety significance. STUK or IO supervises manufacturing and makes construction inspections and installation construction inspections, but STUK makes always commissioning inspections.
-STUK makes regulatory inspections for steel and concrete structures.

Safety class 3: -IO supervises manufacturing and makes construction inspections and installation construction inspections for components and steel structures, but STUK makes always commissioning inspections.
-STUK makes regulatory inspections for concrete structures.

E. Authorization of IOs

a. Accreditation

IO applies accreditation from FINAS (the Finnish Accreditation Service) and the accreditation is based on the standard EN ISO/IEC 17020 (type A). When operation area of IO includes review of design documentation, IO shall be accredited also against EN 45011. If IO is situated abroad, FINAS will be the contact between a corresponding foreign organization. The operation area of IO, e.g. pressure equipment, hoisting devices, valves, pumps etc., the related standards and YVL Guides shall be defined in the application.

FINAS administers the accreditation process and STUK's specialist acts as an expert. When accreditation is approved by FINAS, IO can apply authorization from STUK.

STUK approves the IOs for the inspections based on the application submitted to STUK by the IO. The operation area of the IO is defined in the STUK's approval decision and the area is based on the IO's own profile. References in the approval decision are YVL Guides, applicable standards and STUK decisions. The authorized IOs are listed on the STUK web-pages where licensees can choose the suitable IO for their use.

b. Contracting, organizing daily inspection requests

The licensee makes a contract with the IO and invites the IO to the defined inspections.

c. Reporting to RB, oversight of IOs by RB

IOs have to report their actions monthly to STUK e.g. decisions in/decisions out, inspections and significant non-conformances. IOs are obliged to send also annual report and participate to annual experience feedback meetings.

STUK supervises IOs' activities by making observations at the NPPs or at the vendors' premises. STUK analyses IOs' reports as well as NPP plants' operation experience and ISI-reports. STUK also participates to annual evaluations related to the accreditation.

d. Conformance assessment

Conformance assessment is a stepwise process, the steps of which are hold points. These hold points are listed under title "A. Basic regulatory approach in the country (structures and components)" in this summary. For the IOs the hold points related to design base approval and commissioning are not applicable, because STUK is responsible for those phases.

At every hold point conformance is assessed and a certificate of conformance is given by a qualified person. The certificate is a basis to continue work and proves that the requirements related to the hold point are fulfilled.

F. Use of management system audits/focused audits

STUK participates to audits arranged by the licensee as an observer, but has the right to make observations and remarks and issue non-conformances. STUK gets an invitation to the audits mentioned below and attends them widely.

a. Which organizations are audited by the RB?
   - safety class 1 and 2 components' design organizations
   - safety class 1 and 2 pressure equipment manufacturers and installation companies approved by STUK
   - safety class 2 steel structure design organizations, manufacturers and installation companies
   - safety class 2 and 3 concrete structure design organizations, manufacturers and installation companies
   - commissioning organizations

b. Is this auditing based on sampling?

No.

c. When do you use management system audits and when focused audits?

Mainly management system audits are used although auditing of manufacturing process is usually focused to the deliverable product. Focused audit might be used if there are doubts that some part of the design/manufacturing/ installation/commissioning process is not functioning properly.

STUK also performs own audits, especially in the construction license phase to assess the readiness of the licensee, plant vendor and main contractors to start construction.

Appendix 4

National summary reports

WENRA, Inspection Working Group

FRANCE

NATIONAL SUMMARY, Pressure Equipment

A. Basic regulatory approach in the country

ASN is the regulatory body in charge of oversight activities (Nuclear pressure equipment department and Nuclear Power Plant Department) meeting the Law of 13 June 2006.

ASN mainly involves third party organisations through a mandate. Difference is made between level N1, N2 and N3 equipments defined by the order of 12 December 2005 based on Pressure Equipment Directive (PED).

- N1 equipments: primary and secondary circuits and equipments which are essentials to maintain the nuclear power plant in safe conditions;
- N2 equipments: non classified N1 equipments and those which the failure can lead to radioactive waste higher than 370GBq.
- N3 equipments: non classified N1 and N2 equipments which the failure can lead to radioactive waste higher than 370MBq.

Third party organisation may be mandated by ASN for the N1 equipments.
Third party organisations are in charge of regulatory activities for N2 and N3 equipments.

Hold points are applied according to the inspection plan established by ASN or by the third party organisation. Inspection plan is mainly based on the risk analysis. There is no regulatory text regarding hold points, this is only “good practice”.

Appendix 4

National summary reports

The table below presents the modules issued from Pressure Equipment Directive (PED) applicable for conformity assessment of nuclear pressure equipments.

Pressure equipment categories from I to IV are defined in the PED.

<table>
<tr><th>Level</th><th>N1</th><th>N2</th><th>N3</th></tr>
<tr><td>Pressure vessel or pressure accessories or safety accessories Category I or II</td><td>H+G</td><td>B+F ; B+D ; G ; H1 ; B+C1 ; B1+F ; B+E ; B1+D ; H</td><td rowspan="3">See table 1 below, applicable conformity assessment procedures required by order 21/12/1999.</td></tr>
<tr><td>Pressure vessel or pressure accessories or safety accessories Category III or IV</td><td>H+G</td><td>B+F ; B+D ; G ; H1</td></tr>
<tr><td rowspan="2">Pipes</td><td>H+G</td><td rowspan="2">B+F ; B+D ; G ; H1 ; B+C1 ; B1+F ; B+E ; B1+D ; H</td></tr>
<tr><td>Pipes of primary circuit with nominal size (DN) ≤ 50 and others from categories I or II and for DN ≤ 100 :
B+F ; B+D ; G ; H1</td></tr>
<tr><td>Pressure accessories with CE marking</td><td>Non applicable</td><td colspan="2">If conformity assessment has been performed with module A, the equipment can not be used as nuclear pressurised equipment. For other cases, complementary assessment shall be performed by third organisation or inspection organisation.</td></tr>
<tr><td>Assemblies</td><td colspan="3">- Evaluation of each nuclear pressure equipment if necessary.
- Evaluation of elements integrated to assembly according to the highest level and category included in assembled equipments.
- Evaluation of assemblies between nuclear pressure equipments according to the highest level and category included in assembled equipments.
- Evaluation of the assembly protection according to the highest level and category included in assembled equipments.
- Final assessment and proof test, assemblies of equipment being constituted.</td></tr>
</table>

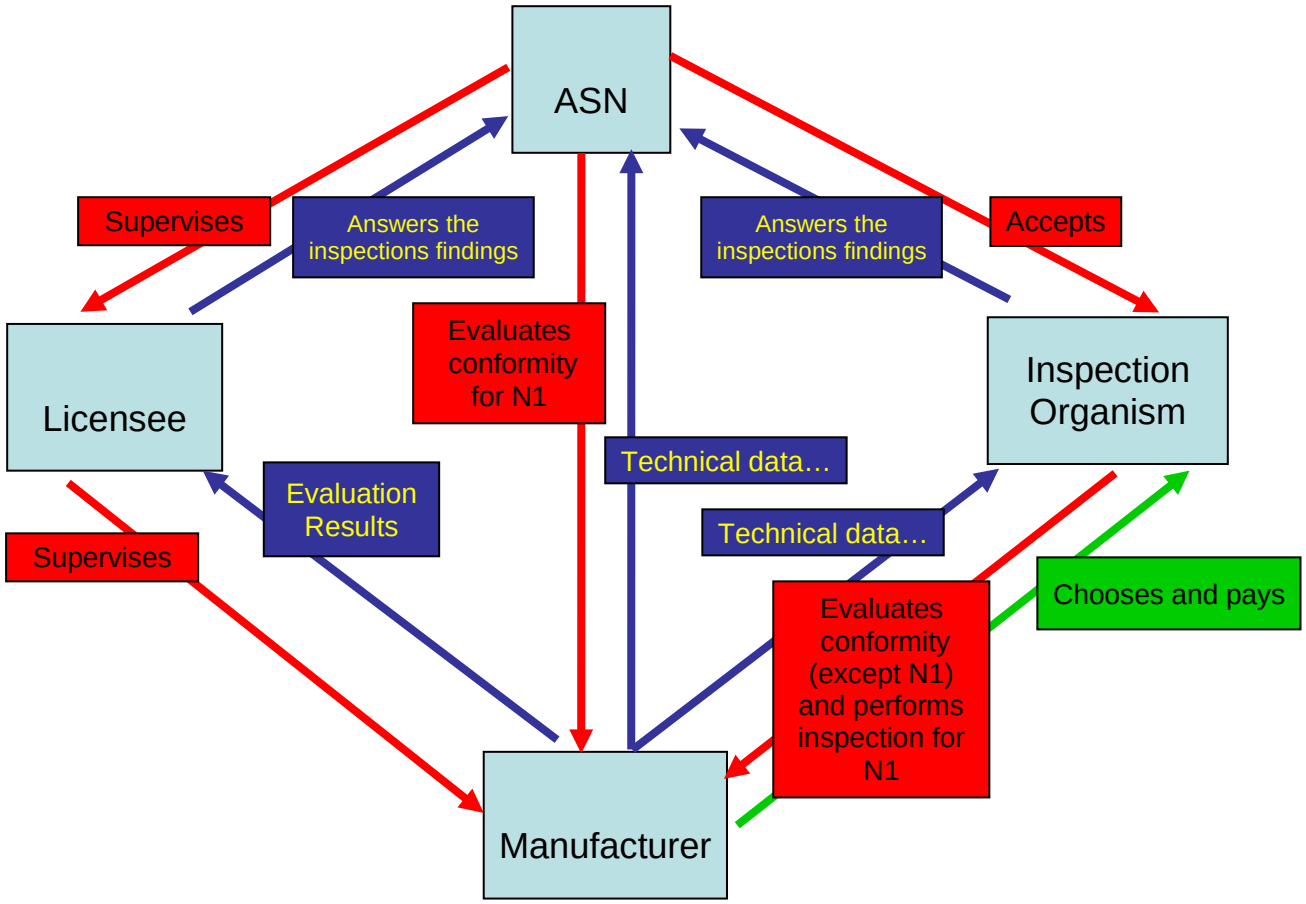
Table 1 :

Risk categories	Without quality assurance		With quality assurance	
	In series	Unit	In series	Unit
Cat. I	A		A	
Cat. II	A1		D1 (Production) ou E1 (Product)	
Cat. III	B+C1	B1+F	B+E or B1+D or H	H or B1+D
Cat. IV	B + F	G	B +D or H1	H1

Appendix 4

National summary reports

Description of the current conformity evaluation for nuclear pressure equipments (revision is on-going):



B. Expectations on licensees

- The licensee shall fulfill the requirements of the order of 10 August 1984 concerning quality assurance system.
- Identify important elements for nuclear safety (structures, equipments, assemblies and working conditions)
- Implement a quality management
- Demonstrate quality achievement for the identified components
- Identify activities concerned by the quality. These dispositions are applicable to all organizations working in the NPP.
- Define licensees' responsibilities, surveillance of sub-contractors and controls of furniture
- Write a manual for quality assurance and demonstrate its used
- Demonstrate adequacy between the human and technical means and the organization install to fulfill requirements
- Identify and qualify the personnel concerned
- Supervise quality concerned activities
- Analyse feedbacks from past experiences

- Inspector shall not be the operator
- Quality assurance system should be defined by independent and competent people. They regularly check its effectiveness and perform corrective actions in case of abnormal situations.
- Manual for quality assurance shall :
    - Define process of control, acceptance criteria and treatment of non conformities
    - Specify that inspections shall be described in reports
    - Describe actions program
    - Demonstrate actions performed
    - Assessment shall be drawn up
- Documents shall be saved and archived
- Describe anomalies and incidents, and their status
- Identify significant findings and notify the French nuclear Safety Authority
- Analyses shall be conducted and shall lead to a feedback. ASN shall be informed.

C. Regulatory review of design documentation (RB/IO, safety class)

Assessment shall be finished before pronouncing the conformity of the equipment assessed.

Documentation to be handed over and reviewed (ASN guide n°8):

- The licensee shall provide the manufacturer with a description of all the situations which may apply to the equipment, in accordance with the safety report of the installation for which it is intended, supplemented by the associated files as well as the loads to be taken into account for each situation.
- The manufacturer shall perform the risk analysis laid down in indent 3 of preliminary comments of annex 1 of Decree of 13 December 1999, taking account of the data provided by the user and the radioactive nature of the fluid that will be contained.
- The list of harmonized norms meeting requirements of ESPN decree of 12 December 2005
- Design and manufacturing drawings.
- Base material certificates
- Specifications dedicated to base and filler materials.
- Strength calculation reports
- Marking procedures
- Test reports for experimental design.
- Welding procedure qualification reports, welders qualification, heat treatment and NDE procedures and certificates of the personnel performing NDE.

National summary reports

D. Regulatory inspections of structures and components (RB/IO, safety class, during manufacturing/after manufacturing/installation/commissioning)

Licensee

Pressure equipment life cycle																
	Design		Hold point		Manufacturing		Hold point		Installation		Hold point		Commissioning		Hold point	
Safety class	Who	How	P	O	Who	How	P	O	Who	How	P	O	Who	How	P	O
N1	L	TMFR		X	L	TMFR		X	L	TMFR		X	L	TMFR		X
N2	L	M		X	L	M		X	L	M		X	L	M		X
N3	L	M		X	L	M		X	L	M		X	L	M		X

Regulator

Pressure equipment life cycle																
	Design		Hold point		Manufacturing		Hold point		Installation		Hold point		Commissioning		Hold point	
Safety class	Who	How	P	O	Who	How	P	O	Who	How	P	O	Who	How	P	O
N1	RB/ RB,IO	CM/ CMR		X	RB, IO	CMR		X	RB, IO	CMR		X	RB, IO	CTMR		X
N2	RB/ IO	TM/ CTMR		X	IO	CTMR		X	IO	CTMR		X	IO RB	CTM TMR		X
N3	RB/ IO	TM/ CTMR		X	IO	CTMR		X	IO	CTMR		X	IO RB	CTM TMR		X

E. Authorisation of IOs (if used)

a. accreditation

Third party organisations shall be qualified as notified organisation (decree of 13 December 1999) and shall be authorized by ASN (ESPN order of 12 December 2005).

They shall be in compliance with an ASN guideline based on ISO 17020 (guide ASN n°5).

b. contracting, organizing daily inspection requests

In practise, for N1 equipment, manufacturers propose a third party organisation per equipment and usually ASN accepts this proposal (but can also refuse).

Manufacturers are also contractors.

ESPN order of 12 December 2005 emphasized manufacturers' duties for pressure equipment.

c. reporting to RB, oversight of IOs by RB

For N1 equipment, latest mandates specify a monthly and a final report for the inspections performed by third party organisations.

Organisations may be subjected to inspection by ASN in the frame of the mandate.

For N2 and N3 equipments, third party organisations are working independently but their actions can also be supervised by ASN to make sure their agreement is still valid.

d. conformance assessment

For N1 equipment third party organisations are performing inspections following their own guide. Inspections reports are provided to ASN.

With regards to results of inspections conducted for each equipment (module G - PED) and to quality management assessment of the manufacturer (module H - PED), ASN would stamp the component.

For N2 and N3 equipments, third party organisations are working independently (except for the description of the situations which may be applied to the equipment, which is reviewed by ASN).

F. Use of management system audits/focused audits

a. which organisations are audited by the RB?

ASN performs agreement of third party organisations and inspection organisations (belonging to a licensee).

The manufacturer's management system is audited by a third party organisation, which is accepted by ASN (module H - PED). ASN can assist to those audits by supervising the third party organisation.

b. is this auditing based on sampling?

All points included in ISO 17020 "General Criteria for the operation of various types of bodies performing inspection » and additional requirements described in ASN guide n°5 should be audited within 3 years.

c. when do you use management system audits and when focused audits?

Audits are performed following ISO 17020.

National summary reports

WENRA, Inspection Working Group

LITHUANIA

STATE NUCLEAR POWER SAFETY INSPECTORATE SUMMARY

The State Nuclear Power Safety Inspectorate (VATESI) have regulatory oversight experience of operating Nuclear Power Plant including design modification, experience of design, construction and operation of Radioactive Waste Management Facilities, including Spent Fuel Storage Facility, but have no regulatory oversight experience in design, construction and commissioning process of Nuclear Power Plants.

A. Basic regulatory approach in the country

VATESI is the main nuclear safety regulatory institution, which sets safety requirements, controls whether they are complied with, issues licences and permits, performs safety assessments and other regulatory functions.

VATESI performs review and inspection activities which cover all important aspects of site evaluation, designing, manufacturing, construction and commissioning, operation and decommissioning of NPP. An important part of these aspects is using of proven technologies at all stages of NPP life cycle. The oversight of VATESI inspectors focuses in the safety culture, the Regulatory Body (RB) also verifies that the licensee implements its safety and quality management.

The basic objective of the review and assessment is to determine whether the operator's submissions demonstrate that the facility complies throughout its lifetime with the nuclear safety requirements approved by the regulatory body.

Sampling of activities is undertaken to demonstrate conformity with the regulatory requirements.

Hold-points

As VATESI has only regulatory oversight experience of operating NPP the hold points were used only during the plant modifications in accordance with regulatory document "Requirements for modifications in nuclear facilities". Additional to that Ignalina NPP have to agree with VATESI all technical proposals, which are related to safety (nuclear fuel unloading program, safety related components in service inspection manual, programs and methodology and others).

For the new Nuclear Facilities currently it is foreseen some key hold points: approval of technical specification of Nuclear Facility; issue of Construction license; approval of commissioning program. Taking into account expected scope of activities related with new NPP VATESI is going to determine hold points during regulatory oversight of design, manufacturing, installation and commissioning of safety related systems and components of new NPP.

B. Expectations on licensees

Licensee has the prime responsibility for nuclear safety, ensuring the quality, control and supervision of the construction activities and organizations that are involved in the design of structures and components, material production, component manufacturing, installation, construction, testing, and inspection.

In respect to the agreed by VATESI technical design and Construction License requirements Licensee should verify and ensure that all manufactured concrete and steel constructions or mechanical components meet their design requirements, also verify how the manufacturer is complying with its quality management system, handling of base and welding material, calibration of working and testing equipment, management of subcontracting, qualification of personnel etc. In addition to this Licensee should prepare and present to VATESI the schedule of performing works where, according to the license requirements should be determined in details activities, related to safety important systems and components design, off-site manufacturing, construction, installation and commissioning.

According to the presented schedule VATESI determines the most important topics and prepares regulatory inspection programs/plans and oversights, controls how Licensee follows the determined requirements during manufacturing related to structures and components. The Safety Class of structures and components is taken into account on preparing the inspection programs and determining the scope of inspection.

Licensee should report VATESI about the manufacture and supplement of all safety related mechanical components, steel and concrete structures: the list of all contracted manufacturers and providers, information and results of all performed inspections and management system audits, all data about fixed discrepancies and non-conformances according to safety requirements and standards, the reasons of non-conformity, taken corrective measures and administrative actions.

Control of non-conformances

In respect with the regulatory requirements "Requirements of Management System" Licensee must identify the reasons and significance of all discrepancies and non-conformances, provide for and check the conformance, adjustment, other corrective measures and administrative actions to remove the potential and(or) identified reasons of discrepancies in order to prevent any further non-conformances. Once the negative trends of processes or other non-conformances according to the requirements, which adversely affects or could affect nuclear safety, are identified it is necessary to analyze the factors which led to such cases also to establish and carry out corresponding improvement actions.

C. Regulatory review of design documentation (RB/IO, safety class)

VATESI review and approves technical design documentation of mechanical components, steel and concrete structures, also PSAR, which are the bases for Construction License.

In accordance with legislation VATESI issues license only to operating organizations, no other organizations are licensed in the framework of nuclear safety regulation.

Independent design verification is required together with Site Evaluation Report during sitting of NPP and Preliminary Safety Analysis Report before the construction.

Regulatory oversight activities foreseen by VATESI during the design, manufacture, construction and commissioning of steel/concrete structures and mechanical components in general we can describe dividing activities into 3 general stages (this concept of regulatory oversight activities is foreseen in drafted Law on Nuclear Safety):

1 Stage. Safety assessment and review before construction:

VATESI performs review and assessment of design documentation and preliminary safety analysis report (PSAR) of steel/concrete structures and mechanical components against established national safety requirements and good practice (for instance IAEA safety standards) before construction license is issued.

2 Stage. Inspections/safety assessment and review during construction and before the permit for first transportation of fuel into the site:

VATESI performs inspection activities during manufacture, construction and cold performance tests of steel/ concrete structures and mechanical components which are important to safety. The Safety Class of structures and components is taken into account on determining the scope of inspection. Before receiving a permit for first transportation of fuel into the site license holder shall prepare and agree with VATESI updated safety analysis report.

3 Stage. Inspections/safety assessment and review after permit for first transportation of fuel into the site and before commercial operation:

VATESI performs inspection activities of steel/ concrete structures and mechanical components which cover important aspects of plant safety. The Safety Class of structures and components is taken into account on determining the scope of inspection. Before receiving a permit for commercial operation and starting commercial operation license holder shall prepare and agree with VATESI final safety analysis report.

D. Regulatory inspections of structures and components (RB/IO, safety class, during manufacturing/after manufacturing/installation/commissioning)

VATESI has implemented safety classification model in General requirements for design of NPP and Nuclear Safety Requirements for modifications of Nuclear Facilities according to the IAEA safety standards. All structures, systems and components are classified into 4 Safety Classes on the basis of their perform function and significance with regard to safety. Mechanical components, steel and concrete structures are designed, constructed and maintained such that their quality and reliability is commensurate with this classification.

Licensee is responsible for full scope supervision and maintenance of mechanical components, steel and concrete structures of all Safety Classes. VATESI regulatory oversight based on sampling covers NPP structures and components, which are related to safety (safety classes 1-3). Safety Class 4 (non-nuclear safety) is under supervision of other competent institutions according to Lithuania legislation and in respect with EU directive 97/23/EC.

According to the current legislation there is not foreseen obligatory provision of use of any third-party organizations by VATESI nor by Licensee for support in inspection activities. As a result VATESI performs regulatory oversight activities by sampling taking into account the labour force and scope of structures and components or pressure equipment.

The Safety Class of structures and components, the best practise and international recommendations are taken into account on preparing the inspection programs/plans and determining the scope of inspections. Steel and concrete structures are classified according to design assigned safety functions.

E. Authorization of IOs

During regulatory oversight of Ignalina NPP the support of Third-Party Organizations were not used. Design modifications of safety related systems and components, including lower safety classes, during operation of Unit 1 and 2 were implemented under supervision of VATESI. Taken into account expected scope of regulatory oversight activities during design, manufacturing, installation and commissioning of safety related systems and components of new NPP VATESI will consider possibility to use Third-Party Organizations after review of other WENRA countries inspection practice report and recommendations.

F. Use of management system audits/focused audits

It is foreseen that all management system audits shall be carried by the Licensee according to VATESI requirements „Requirements for Management System“, which were approved in 2010. Additionally licensee is responsible for organizing independent reviews and audits of management system. Regulatory Body does not carry any audits, but have the right participate in any audits arranged by Licensee as an observer. Any discrepancies and non-conformances fixed during observation are presenting directly to the Licensee.

According to the „Requirements for Management System“ it is required that the documents of management system should determine and foreseen the analysis and justification of nuclear facility design conformity to the nuclear safety requirements, including independent verification of design results performing alternative calculations based on other computational techniques.

Licensee is responsible for ensuring performance of independent verifications (management system audits, license application draft documents review and other independent verification). Licensee must conduct all audits in the process to determine if the management systems and processes meet the requirements for management system and other requirements, if management systems and processes are effectively implemented and improved, processes and management system improvement opportunities.

The independent verification should be carried out under the responsibility of the operating organization by a team of experts who are independent of the designers and those performing the safety assessment. Personnel are considered independent if they have not participated in any part of the design and safety assessment. The aim of the design verification is the comparison of the design results and the original design input. This independent verification is in addition to the quality assurance (QA) reviews carried out within the design organization.

Currently Ignalina NPP (Licensee) is performing audits of their contractors and reporting about these audits results to VATESI. Additional to that VATESI specialists performs inspections in components manufacturing facilities with the aim to verify how Licensee carries out their audits and inspections.

Appendix 4

National summary reports

WENRA, Inspection Working Group

RUSSIA

NATIONAL SUMMARY

A. Main approaches to regulation in Russia (equipment and components)

Regulatory authority in the field of nuclear and radiation safety of Russia (Rostechnadzor) reviews and assesses main documents justifying safety of NPPs developed by designers of NPPs. When necessary, specialized organizations are engaged by Rostechnadzor to participate in the review and assessment. Rostechnadzor reviews justifying documents and issues licenses to the Operators for siting, construction, commissioning, operation and decommissioning of NPPs. The review of system design documents forms part of the licensing procedure.

Also, Rostechnadzor or its regional representative authorities issue licenses to designers and manufacturers of equipment for the right to develop design documents for NPP components and for manufacture of equipment.

In order to verify that the license conditions are being fulfilled by organizations and that organizations' activities meet the requirements of safety regulations, Rostechnadzor performs inspections (supervision) at all stages of construction and operation of NPPs and requires to submit the necessary information.

In any case the responsibility for NPP safety rests with the organization holding a respective Rostechnadzor license (i.e. the licensee).

To perform safety assessment and analysis Rostechnadzor engages its subordinate organization, Scientific and Engineering Centre for Nuclear and Radiation Safety (SEC NRS). To control the design and manufacture of equipment, Mandated organizations are appointed. To assess process issues (use of materials, welding, nondestructive and destructive tests), specialized organizations approved by Rostechnadzor are engaged.

The review and approval of design and process documents (drawings, calculations, welding and heat treatment procedures) are performed before the start of manufacture of equipment and its components by engaging Mandated organizations. Supervision of manufacture of 1, 2 and 3 safety classes components is entrusted with Mandated organizations and inspection organizations on contract basis with the licensee. Documents are reviewed and supervision is performed to verify compliance with Rostechnadzor documents.

Supervision during construction of building structures is performed in accordance with Russian federal law "On self-regulating organizations" by appointed organizations who perform certification of the performers of the works. The process of construction is continuously followed-on by the licensee.

During design and manufacture of new or one-of-a-kind equipment, sample tests are performed under supervision of a committee consisting of the licensee, the customer, a Mandated organization, the manufacturer and the designer.

Supervision over manufacture of 1, 2, and 3 safety classes equipment is performed by the Mandatory organization together with the licensee, engaging, when necessary, inspection and specialized

organizations, in which case the functions are being divided between the mentioned organizations according to respective Rostechnadzor and licensee documents.

B. Licensing development of documents and manufacture

Licensing is preceded by examination of the prospective licensed organization by specialists of Rostechnadzor and/or Mandated organization.

During examination Quality Management System of the organization is audited and capabilities of the organization to design and manufacture equipment fulfilling the specified safety and quality requirements is assessed.

Non-conformance control

Decisions on non-conformances regarding 1,2, and 3 classes components which have an impact on safety are eliminated. In case it is impossible to eliminate them, the decisions to admit non-conformances are being agreed upon with the designer, the customer, material engineering organization, and are approved by Rostechnadzor.

Decisions on non-conformances which have no impact on safety are taken by the licensee with participation of the designer.

C. Review of Design Documents

Rostechnadzor reviews and approves system documents developed by the designer (Safety Analysis Reports (PSAR, FSAR), Probabilistic safety analysis, and other system documents).

Mandated organization reviews design documents on components to verify that they comply with the safety regulations. Documents on 1 safety class components are reviewed engaging, when necessary, independent specialists and organization.

New components are certified by organizations accredited according to the established procedure and tested in laboratories accredited by the licensee.

D. Inspection of equipment and components during design, manufacture, installation, and commissioning

For components of 1, 2, and 3 safety classes, acceptance is performed at the manufacturer by the specialists of the Mandated organization and the licensee to verify the compliance of the components to Rostechnadzor regulatory requirements and the requirements of the designer. Acceptance procedure is determined by Rostechnadzor and licensee documents.

Supervision over components during their installation and commissioning is performed by the licensee. Rostechnadzor approval is required for the start and completion of individual procedures.

E. Accreditation of inspecting organizations

Inspecting organizations (IO) contracted to perform certain works shall be approved by the licensee and, in some cases, by Rostechnadzor. IOs perform their activities under contracts awarded by licensees.

Regarding foreign companies who develop and manufacture components for Russian NPPs, there is a special control procedure approved by Rostechnadzor.

IOs report on the progress of work to licensees, and in any case Rostehnadzor maintains full access to IOs reports. Assessment of non-conformances found by IOs is performed according to the procedure mentioned above.

F. Audits of organizations' Quality Management Systems

QMS audits are performed by Rostechnadzor during licensing stage, and by licensees during stage of awarding contracts for design and manufacture of equipment and components, and during the process of manufacture with use of Mandated organizations.

Appendix 4

National summary reports

WENRA, Inspection Working Group

SLOVAK REPUBLIC

NATIONAL SUMMARY

A. Basic regulatory approach in the country

Nuclear Regulatory Authority of the Slovak Republic (**NRA SR – ÚJD SR**) is a central administrative state office of the Slovak Republic responsible for the nuclear regulatory activities. The Licensees are fully responsible for nuclear safety.

hold-point strategy

In Slovak Republic Regulatory body (**RB**) controls every stages of the Nuclear Facilities – design, construction, commissioning and decommissioning. For all stages are applied hold - points as a necessary condition to go into next stage.

Technical and administrative preparedness from design through Construction to decommission permission, lies on the licensee according to §3, §5 and §10 of the Atomic Law. Every violations in technical specifications, non-conformances, design modifications, new procedures (welding, maintenance, repairs, quality inspections, operation) have to be approved by the RB before realization.

Hold points during manufacturing are not applied from the point of RB view, it is in the licensee responsibility. Concrete structure material is tested continuously by accredited test organization, and results are stored by licensee and have to be available to the RB on request.

B. Expectations on licensees

-includes control of non-conformances

According to Atomic Law emphasize responsibility for nuclear safety is putt on the licensee. On the basis of this the licensee is responsible for organizing quality controls. QA and QC are performed by accredited inspection team from utility or accredited 3rd party organizations. This ISI body issue protocols Conformity with quality documents. All of the protocols must be acceptable before unit commissioning. Accredited inspection of the 3rd party bodies communicates with and report directly to the NPP licensee. Results from their work have to be available to the RB on request. Third-party inspection bodies shall report general problems and serious deviations also to the expert meeting for ISI evaluation organized before the NPP starts up with the regulatory participation. Utilities apply the national and international IO with notification for the NPP area.

As independent third-party organisations the licensee during refuelling and overhauling cooperates with the manufacturer for supervisions during maintenance and repair of most important components (manufacturer of RPV, MCT, SG, etc.).

C. Regulatory review of design documentation (RB/IO, safety class)

The RB activity has focus on review documentation according to legislative documents (Law and Regulations), manuals and guides. According to licensee internal rules every documents prepared to submission to the RB shall be approved by the licensee. The quality documentation is listed in

Regulation No. 56/2006 Col. specify requirements on important documentation which have to be submitted to the RB before realization for receiving decision. During assessment of complicated safety documentation submitted according to §10 of the Atomic Law the RB utilizes 3rd party for independent assessment. For the RB technical support organization (TSO) if could be an expert organization, research institutes, universities, etc. Every design modifications have to be submitted to the RB with the Ministry of environment statement based on European requirements.

The RB according to §4 article 2, letter a), number 2 of the Atomic Law reviews and approves every important documents such as the design basis, categorization of classified equipments into safety classes, Technical specifications, quality assurance documentations, quality requirements on classified equipments, implementations of modifications of nuclear facilities and list of classified equipments. NRA issues agreement or decision for sitting of nuclear facilities or implementation of modifications.

List of documentations which are necessary to present to RB for individual stage of nuclear facilities are in appendix No.1 of the Atomic Law. The documentation which is necessary for following stages of nuclear facilities:

- sitting of the nuclear facility (permition)
- construction (decision)
- commissioning and operation (decision)
- decommissioning (decision)

RB reviews and approves following documentations:

- design documentations and design modifications (with design basis)
- quality plan for each individual classified equipments
- classification of the equipment into safety classes
- pre-service inspection and ISI programs
- technological documentation of the manufacture, assembly, repairs and modifications of classified equipment,

Quality requirements of the classified equipments is reviewed and approved in two stages:

1. Design stage
2. Manufacturing and assembly stage

Review of the components' design documentation for every safety classes is fully in RB competence.

In decision No. 68/2007 are prescribed list of regular announcements for the RB information in which the licensee has a duty to submit to the RB following documentation (status of the nuclear devices during operation – components failures, quarterly and yearly safety assessment of the operation, refuelling and outage plan, ISI evaluation report, and other details) to create picture about safety operation.

D. Regulatory inspections of structures and components (RB/IO, safety class, during manufacturing/after manufacturing/installation/commissioning)

According to legislation the RB does not have competence to supervise on–site manufacturing process. The RB performs on-site inspection during construction and operation of nuclear facilities by sight inspectors and by inspection teams in accordance with the yearly inspection plan. The main purpose of the inspection during the construction is to oversee assembly of classified components mainly primary site, their testing and reviewing documentation. On-site inspections check, by multi professional team focused on procedures for verification, actual equipment status and their conformance verification according to valid documentation. The outputs of these inspections are written reports or, in case when non-conformances are found, the outputs are protocols with the important observations and corrective

measures which have to be implemented by the licensee. The RB in complicated cases if it is necessary to employ expert assessment utilized by 3rd party organization for review details (during repairs using welding procedures, NDT tests etc.).

The RB oversees to the IOs activities during overhaul and assesses conformance with valid documents. The Authorised organization certificates conformity with regulations, it is a condition for taking a component or system for operation.

E. Authorisation of IOs

a. Accreditation

SNAS – Slovak National Accreditation Service

SNAS is Governmental Organization and Central State Administration Organization for technical metrology, for standardization and Conformance assessment applying Slovak and European Standards and European Directives, manage and organize accreditation system in SR.

SNAS accredits each organizations base on request for specific activity with time limitation. The RB doesn´t control accreditation of IOs. The licensee is responsible for assuring accredited IO in tender. RB verifies if IO was certified.

The RB defines minimal requirements for qualification of the systems for NDT in nuclear field in Regulatory guide BNS II.5.4/2009 - Qualification of systems for non-destructive examination in nuclear power engineering.

Substantial documents for each of the licensee are Quality Management and Quality Control system (QM), (QC). The RB has been approving QM and QC system. Application of these systems is verified by the RB once in three years and by certified auditing organisation, for example Det Norske Veritas, TÜV SÜD, etc., accredited in accordance with international standard ISO 9001 based on utility request.

b. Contracting, organising daily inspection requests

Organising daily inspection is fully in licensee responsibility and competence. Scope and organization of inspection is based on valid QC procedures for selected components.

c. Reporting to RB, oversight of IOs by RB

During inspection the RB has controlls personnel certificates, ISI group structure and scope of training. The accredited IO submitts its accreditation to licensee during selection process only. The IO accreditation has to be available to RB on request. RB doesn´t perform an oversight of IOs.

d. Conformance assessment

The accreditation is realized fully in conformance with European and national standards and directives.

All requirements which licensee has to observe are specified in the legally binding Slovak Atomic Act and Slovak RB Regulations.

Requirements for a quality management system are specified by the International Standard ISO 9001:2008 documentation.

F. Use of management system audits/focused audits

a. Which organisations are audited by the RB?

The RB performs audits of licensee only based on international standard ISO 19 011 and IAEA recommendations. Except for RB, licensee is audited by 3rd party - independent organizations with SNAS accreditation base on request.

b. Is this auditing based on sampling?

The RB has audited licensees based on sampling according to regulatory internal procedures.

c. When do you use management system audits and when focused audits?

Licensees organize internal and external audits. Internal audits are managed by self audit team to recognized internal faults, and external audits which identify mainly structural faults. External audits are realized by 3rd party accredited organization. The RB can require audit to the licensee when we need to identify responsibility for an incorrect activity. Management system audit shows complexity of the licensee organization structure. Management system audit is applied mainly during a utility assessment personnel reduction, personnel optimization etc. to offer detailed information.

Appendix 4

National summary reports

WENRA, Inspection Working Group

SPAIN (CSN)

NATIONAL SUMMARY

Discussion of regulatory approach for design modifications on Nuclear Power Plants in operation

A. Basic regulatory approach

For each design modification the **licensee** must perform and analysis to verify if the criteria, rules and conditions on which its permit is based are still met. If from the analysis conducted the licensee concludes that criteria, rules and conditions are still meeting, the licensee may carry out the modification or tests periodically informing the Ministry of Industry and CSN (is the case "B" in the next paragraph). In the event that the modification entails a modification of criteria, rules and conditions on which operating permit is based, the licensee must request for a modification authorization (is the case "A" in the next paragraph .

Consequently **CSN (Spanish Nuclear Regulatory Body)** adopts a proportionate approach to regulation based on the two main circumstances explained in the foregoing paragraph. That is:

(A) If it is granted a permit (authorization) for the design modification.

In this case the actuations of the Regulatory Body are close to a comprehensive one (consult tables to see some exceptions as in manufacturing).

(B) If it is not necessary to grant a permit for the design modification.

In this case sampling of regulatory nuclear activities is undertaken.

Regardless of the aforementioned authorization when in opinion of CSN or Ministry of Industry the modification is far-reaching or entails significant construction or assembly works national regulators shall require the licensee to apply for a modification execution and assembly authorization (is also the case "A" in the foregoing paragraph)

The hold points required by regulators in the different phases of the equipment life cycle depend on the permit or authorization granted. The European Directive on pressure equipment must be complied. This is the only regulator hold point for the equipment.

The other hold points that CSN applies are related to the design modification as a whole process (not to each equipment). That is: the hold point is the permit to be granted itself (obviously this permit implies a review of the documentation of design basis, structural analysis, material specifications, non conformance and corrective actions, etc, but the asses done by CSN staff does not imply the approval of each document in an individual format). In these sense there are two possible hold points in a design modification:

1. Hold point or permit which shall have to be effect prior to the modification coming into service.
2. Regardless of the hold point already mentioned a previous hold point or permit for assembly in the cases when in opinion of Ministry of Industry or CSN the modification is far

reaching or entails significant construction or assembly work. In this case the licensee cannot start activities of assembly or construction prior to the granting of the corresponding authorization

If during sampling inspections the inspectors detect Non Conformances than the licensee has not detected by himself or in the case that the correction actions are not appropriated, CSN performs reactive inspections and can require further activities to the licensee (as strategic plans that CSN asses and audit)

B. Expectations on licensees

Control, analysis, and verification of every step in the different processes in design, manufacturing, installation and commissioning of the equipment and structures in accordance with permits and all nuclear standards applicable.

Non conformances must be analyze and resolved.

C. Regulatory review of design documentation

- *Regulatory body (CSN)*
  - Control and approval of design if it is associated to a modification license. The analysis of design of pressure equipment, steel structures and concrete structures associated to the modification is included in the assessment for approve.
  - If is not require a license the design control is by sampling.
  - No other external verification

D. Inspection and control responsibilities of structures and components

D1 Inspection and control responsibilities in manufacturing and installation

- *Regulatory body (CSN)*
  - Technical control and control of the management system of manufacturers and assemblers (installation in facility) of safety equipment is done by sampling. If has been granted an authorization for assembly the licensee cannot start any activity of assembly prior to the granting of the authorization (hold point).
  - No other external verification under the direct supervision of CSN. CSN does not audit or give an authorization to the IO´s
- *Licensee*
  - His activities are regulated by permits and nuclear Spanish standards in safety equipment. The licensee controls and approves manufacturing and installation. They can contract IO's for these jobs.
  - The IO´s contracted by the licensee to inspect manufacturing and assembling have to be audited and approved (by him) respect to nuclear standards. The IO´s report to licensee. The manufacturers report to licensee.

D2 Inspection and control responsibilities in Commissioning

- *Regulatory body (CSN)*
  - Attend to final proofs of the design modification associated to an authorization and review final documentation and corrective actions of non conformances.

- Attend to specific proofs of pressure equipment and special activities in the manufacturer facility.

There is an external and mandatory administration control of the accomplishment with conventional regulations of pressure equipments (European Directive of Pressure equipment). This is competency of the Ministry of Industry who grand specific authorizations. This job is transferred to autonomic governments and practices can vary, but not in the important things. The Ministry of Industry contracts IO´s accredited, with a quality system certificated. They are audited by governmental personnel.

- *Licensee*
  - His activities are regulated by permits and nuclear Spanish standards in safety equipment. They control and approve the jobs.
  - He (and manufacturer) most report to CSN the defects found in equipment if they are already ensemble in plant.

E. Authorization of IOs

- Not applicable for CSN
- IOs contracted by the Ministry of industry to control the accomplishment with conventional regulations of equipments (European Directive of Pressure equipment) are accredited, and they have a certificated quality system. They are audited by governmental personnel. They report to Ministry of Industry.

F. Use of systems audit/focused audits

- *Regulatory Body (CSN)*
  - *CSN performs specific* audits to the management systems of licensee and principal enterprises of engineering if the modification is associated to a license. If some problem is detected can be programmed a focused audit or a reactive audit. As part of the authorization these audits are hold points.
  - If the modification is not associated to a design modification CSN performs periodical audits to the licensee. If some problem is detected can be programmed a focused audit or a reactive audit, and as consequence of them may be required further activities to the licensee (as strategic plans than CSN asses and audit).

National summary reports

WENRA, Inspection Working Group

SWEDEN

NATIONAL SUMMARY

A. Basic regulatory approach in the country (structures and components)

The Swedish nuclear regulatory body, Swedish Radiation Safety Authority (SSM), has the responsibility to supervise licensees' actions by reviewing design, manufacturing, construction, installation documentation as well as by inspecting NPP structures and components to assess whether the requirements in SSM's safety regulations, SSMFS, are met. Before SSM reviews any documentation, it must have been approved by the licensee. The licensee also performs and approves inspections before SSM's inspection. The licensees have the primary responsibility for the safety of NPPs and the quality of their structures and components.

Inspection Organizations (IO) that carrying out regulatory type reviews and inspections of structures and components have to be accredited for their tasks by Swedish Board for Accreditation and Conformity Assessment (SWEDAC) under SWEDAC's general accreditation rules and regulations issued by the Swedish Radiation Safety Authority (SSM). For some mechanical components notified bodies have assessment and inspection tasks during manufacture according to European directives (such as Pressure Equipment Directive, PED). Reviews and inspections by independent IOs are prescribed by SSM for all mechanical components and structures in all safety classes, but with varying extent. Review of design is performed by SSM.

It should be noted that the current Swedish regulations for inspections of mechanical components and concrete structures are based on the present situation with the operation and modification of the ten existing NPP. This means for example that no major changes are made to the reactor containment and other concrete structures. If new nuclear power plants will be built in Sweden, parts of the present control scheme, with different types of accredited organizations, need to be modified.

<u>Hold-points</u>

The design basis including all boundary conditions for design, coming from plant/systems level design, shall be notified to SSM before an IO review component level design documents. The IO will consider in its review comments and observations from SSM on the design basis. If the IOs review, which may include their own control analysis, confirm that relevant requirements are met, the body issues a design examination certificate. (Hold point).

The design examination certificate is in principle a prerequisite to start manufacturing. In practice however, manufacturing starts from time to time at the commercial risk of the vendor or the licensee before they have a design examination certificate. During manufacturing accredited laboratories, or the manufacturing organisation under supervising by an IO, perform testing in different phases. Qualification of welding procedures and welding personnel are supervised and evaluated by an IO. All results are reported to and reviewed by IO. If these reviews confirm that relevant requirements are met, the IO issues a manufacturing examination certificate. (Hold point).

The manufacturing examination certificate is in principle a prerequisite to start installation. During installations accredited laboratories perform testing according to the control and examination plans. After the installation of a mechanical component in the plant shall

- an IO verify that the component has been installed in accordance with examined drawings and flowcharts, and that performance meets safety requirements,
- an commissioning/operation tests have been done to demonstrate that safety valves and other safety equipment operates properly and that the device not is exposed to harmful vibrations or other loads, for which no account has been taken in the design. An IO shall witness the operation tests.

If these verifications and tests confirm that relevant requirements are met, the IO issues an installation examination certificate. (Hold point).

Before new mechanical components and modified plant systems can be taken into operation an IO conducts a final assessment based on previously issued design, manufacture and installation certificates. If all examinations, supervisions and controls confirm that the requirements are met, the IO issues a certificate of conformity with relevant SSM regulation. This certificate of conformity with SSM regulation is a legal condition for taking a component or a system in operation. (Hold point).

This means that any outstanding issues or discrepancies must be resolved at that time. In situations when a certificate of conformity not can be issued for any reason the licensee must apply for exemption, based on necessary safety justifications. Such applications are then assessed and decided by SSM. (Hold point).

For major plant modifications, such as thermal power up-rates, SSM reviews commissioning test programs, inspect and follow the test operation, which normally lasts for an full operational period with subsequent maintenance outage.

B. Expectations on licensees

The licensee has the primary responsibility for the safety of NPP structures and components. The licensee consequently has to take all necessary steps and actions to fulfill applicable safety requirements. This includes audits and controls of the licensee's manufacturers, suppliers and contractors. Particular for contractors used at NPP site the licensee should

- ensure that contractors has sufficient manpower and competence to carry out the assignment in a safe manner,
- ensure that contractors has the necessary equipment for executing the assignment and that the contractors employs adequate methods and processes where applicable,
- ensure that contractors employs management and quality systems that provide full control over safety in conjunction with the assignment and that manufactured and assembled structures, systems, components and devices meet stipulated safety requirements,
- continuously supervise the contractor's activities to ensure that all regulatory requirements and license conditions are satisfied, along with the goals and guidelines for the activity to which the assignment pertains,
- continuously follow up the contractor's evaluation and reporting to the licensee of events and ensure that appropriate safety-related measures are taken,

- when necessary, instruct the contractors to take suitable measures, or take such measures himself if the contractor does not adhere to the goals and guidelines established for the assignment.

The licensees must review and approve all the documentation, perform inspections and approve tests. The licensee is responsible that regulatory requirements and guides are followed.

Control of non-conformances

Identified non-conformances shall be assessed and corrective and preventive actions shall be taken. This shall be governed by the licensee's management system, which shall include procedures to process non-conformances identified in processes and products. The management system shall include criteria for determine significance of non-conformances so that, if necessary, modifications of the plant or components are made or procedures are improved.

C. Regulatory review of design documentation (RB/IO, safety class)

For major plant modifications, such as thermal power up-rates the license has to prepare a Preliminary Safety Analysis Report (PSAR), which must be approved by SSM before plant modifications may be implemented. This PSAR should be based on the plant's existing Safety Analysis Report (SAR) and provided with

- details of the plant designed and lay out after planned modifications
- details of the planned mode of operation including operating limits
- transient and accident analysis and structural analysis that has been made of planned new or modified parts or functions of the plant and of such parts of the plant that has not changed but are affected by changes
- references to the verifying analysis

Any other plant modifications shall be based on up-to-date design specifications. Before the design specifications can be applied, the design basis on which they are based shall be notified to and reviewed by SSM. The design basis should also contain information on loads and load combinations during normal operating conditions, expected events, minor incidents and design basis accidents.

IOs review component design specifications after SSM has reviewed the design basis. This applies to all safety classes (SC1-SC3) and some non-safety classified components.

Design specifications should, to the appropriate extent, contain information concerning the function of the component, boundaries to other components and loads at these boundaries, requirements on pressure relief, internal and external environments, accessibility and testability as well as, where applicable, any neutron radiation that the components might be exposed to. Furthermore, the following should be included: information concerning safety and quality classification, materials requirements, lists of standards and other documents determining design, lists of valves and seals which during operation shall be locked in an open or closed position as well as referrals to documents that describe criteria for operational readiness. The design specifications for plant modifications should also contain analyses of how the modifications affect loads on and operating limits for existing components in the specific system and components in connecting systems. Detailed component level design documents shall also include

- structural and other analysis
- structural and isometric drawings
- material specifications
- welding and fabrication/manufacturing processes and their qualification
- inspection plans and procedures for destructive and non-destructive testing.

This inspection and review scheme including IOs does not yet apply to concrete structures.

D. Regulatory inspections of structures and components (RB/IO, safety class, during manufacturing/after manufacturing/installation/commissioning)

Safety class 1: IOs supervises manufacturing and installation inspections, including welding qualifications, and commissioning inspections for components. SSM inspect commissioning tests after major plant modifications

SC1 is not applicable for steel and concrete structures.

Safety class 2: IOs supervises manufacturing and installation inspections including welding qualifications, and commissioning inspections for components. SSM inspect commissioning tests after major plant modifications

SSM makes regulatory inspections on sample basis for concrete structures.

Safety class 3: IOs supervises manufacturing and installation inspections including welding qualifications, and commissioning inspections for components.

SSM makes regulatory inspections on sample basis for concrete structures.

E. Authorization of IOs

a. Accreditation

IOs as well as testing organizations (laboratories) for destructive and non-destructive testing have to be accredited for their tasks by SWEDAC. Accreditation decisions are based on inspections (audits) and reviews of the organizations management systems (including working procedures, education and professional training programs), technical competence, personnel resources and work practice for verification that SWEDAC's general accreditation rules and relevant regulations issued by SSM are met. SWEDAC do their inspections and audits before accreditation decisions in consultation with SSM.

SWEDAC's general accreditation rules are based on harmonized European and international standards such as EN ISO/IEC 17020 and EN ISO/IEC 17025. SSM states technical and personnel competence, which shall be reflected in the accredited organizations management systems and in their internal competence system to perform different tasks. References in the approval decision are applicable EN ISO/IEC standards and SSM regulations. The accredited IOs and testing organizations (laboratories) are listed on the SWEDACs web-pages where licensees can choose the suitable IO and testing organization for their use.

In the manufacture of mechanical components in another country may other certification and inspection bodies and laboratories carry out certain certification, inspection and testing tasks if they have been accredited under provisions equivalent to those for Swedish accredited organizations. These tasks are related to welding qualifications and testing of materials, welding and components.

b. Contracting, organizing daily inspection requests

The licensee or its vendor makes a contract with the IO and order the IO for the tasks.

c. Reporting to RB, oversight of IOs by RB

IOs communicate with and reports directly to the licensee and in some situations with the vendor/supplier Results from their work shall however be available to SWEDAC and SSM on request. Under the terms of accreditation, IOs shall report general problems and serious deviations also to the SSM. They must also be involved in experience feedback meetings SWEDAC or SSM organize.

SWEDAC and SSM staff perform annual oversight of IOs that have been accredited for inspection and review tasks in NPP under SSM's rules. This includes controls on sample basis of reviews performed by the IO in question as well as witnessing of how they perform inspections.

d. Conformance assessment

Conformity assessments are conducted by IOs stepwise during the process from design over manufacturing and installation to commissioning as have been described above. During these stepwise assessments, with clear hold points, IOs can handle and decide on acceptance non-conformances within those limits that are given in their working procedures, and which have been approved in the accreditation process. When non-conformances outside the limits is observed a certificate of conformity with SSM regulation cannot be issued, and the components can consequently not be taken into operation. In such situation a licensee have to take measures or justify and apply at SSM for an exception from the relevant requirement.

F. Use of management system audits/focused audits

In addition to the described inspection and review scheme SSM conducts management system audits and focused audits of the licensee’s activities on a sample basis.

SSM has no mandate under the current Swedish legislation to audit license’s manufacturers and suppliers. SSM's focus is presently instead on supervision of the licensee’s procedures, competence and resources for their own manufacturers and suppliers assessments and that they carry out audits with good quality.

However, discussions are now underway in Sweden to change the legislation so that the SSM as part of the oversight of licensees' supplier assessments also will be able to monitor the work of manufacturers and suppliers to verify that licensees have made correct audits.

Appendix 4

National summary reports

WENRA, Inspection Working Group

SWITZERLAND

NATIONAL SUMMARY

A. Basic regulatory approach in the country (-includes hold-point strategy)

In Switzerland oversight responsibilities and scope are regulated in national laws, ordinances and regulatory guides of the Swiss Federal Nuclear Safety Inspectorate (ENSI). Where nuclear safety and security are concerned, the ENSI is appointed as supervisory authority in accordance with the Federal Act of 22 June 2007 on the Swiss Federal Nuclear Safety Inspectorate. Nuclear safety includes also fire protection and radiation protection in nuclear installations.

Inspection organizations are contracted by ENSI to review the detailed design and manufacturing documentation and to conduct the inspections during manufacturing and concreting on-site and in the workshops. The inspection organization for nuclear pressure equipment has an accreditation as an inspection body Type A in accordance with ISO/IEC 17020.

Hold-point strategy

Modifications and new installations of components and structures important to safety (classified equipment) need permits that are granted in 4 steps (hold points) by ENSI. The areas of Reactor Engineering, Civil Engineering, Systems Engineering, Mechanical Engineering, Electrical and I&C Engineering, Radiation Protection, Security, Organization and Personal are covered depending on the type of project. In principal the 4 steps are: (1) approval of the concept, (2) approval of the design, (3) approval of the implementation, (4) approval of the final documentation.

B. Expectations on licensees (-includes control of non-conformances)

The licence holder is responsible for the nuclear safety. Established or proven high-quality processes, materials, technologies and organisational structures and processes must be used in connection with design, construction, commissioning and operation of nuclear installations. This applies especially to the areas of planning, manufacture, testing, operation, surveillance, maintenance, quality assurance, evaluation of operational experience feedback, ergonomic design as well as basic and advanced training and professional development.

The licensee must have a quality management system that fulfils the requirements mentioned above. Depending on the nature of non-conformances deviations concerning classified equipment have to be registered, evaluated, reported or submitted for approval to ENSI or to the IO, which was contracted to supervise the work. Deviations with respect to the concept or the design left in place have to be approved by ENSI.

C. Regulatory review of design documentation (RB/IO, safety class)

The permits based on the review of design documentation for mechanical components of all safety classes (SK 1 to 4) and for all buildings are issued by ENSI. The review of design documentation is conducted by ENSI, which contracts IOs or engineering service companies for support as necessary. For

non-nuclear safety mechanical equipment it is expected that industrial rules and standards are applied by the licensee.

The four review steps in mechanical engineering are: (M1) Design basis, (M2) Design specification, (M3) documentation of manufacturer for construction, manufacture and pre-service testing, (M4) start-up and final documentation. Review of M3 and M4 documentation is delegated to the IO in the case of classified pressure equipment as defined in ENSI-guideline G11. For minor modifications a simplified review process in one step may be used.

The four review steps in civil engineering are: (B1) Layout concepts, (B2) Building layout specifications, (B3) Building arrangement and installation, (B4) Building documentation. The review work is supported by engineering companies (IOs) that are contracted by ENSI.

D. Regulatory inspections of structures and components (RB/IO, safety class, during manufacturing/after manufacturing/installation/commissioning/clarification of Tables)

Regulatory inspections during manufacturing, installation and final testing of nuclear pressure equipment of safety class SK1 and 2 are conducted by the IO as defined in ENSI-guideline G11 or by ENSI. For safety class SK3 and case by case SK4 the documentation of the utility's inspection is reviewed by the IO. Pressure tests and repairs during manufacturing for all classified pressure equipment (SK 1 to 4) are inspected by the IO.

Regulatory inspections on classified steel structures and on all buildings are conducted by ENSI or by engineering companies (IOs) that are contracted by ENSI.

E. Authorisation of IOs (if used) (-accreditation, -contracting, organising daily inspection requests, -reporting to RB, oversight of IOs by RB, -conformance assessment)

The authorization of IOs or engineering companies that act as IOs is given by a contract with ENSI. The ENSI-guideline G11 and the contract for the supervision of nuclear pressure equipment requires an accreditation in accordance with ISO/IEC 17020 Type A. ENSI takes part in the accreditation process. The contracts and case by case decisions regulate the details of organizing the reviews and inspections and of the reporting to ENSI. For practical reasons the daily inspection work is organized in direct contact between the licence holder and the IO. ENSI receives copies of all documentation and conformance assessments issued by the IO.

F. Use of management system audits/focused audits (-which organisations are audited by the RB? -is this auditing based on sampling? -when do you use management system audits and when focused audits?

ENSI takes part in the audits concerning the accreditation of the contracted IO for nuclear pressure equipment. ENSI inspects the processes of the quality management system of the licence holders based on sampling.

National summary reports

WENRA, Inspection Working Group

UK

NATIONAL SUMMARY

A. Basic Regulatory Approach in the Country

The UK nuclear safety regulatory authority is the Health and Safety Executive (HSE). Within HSE the Office for Nuclear Regulation (ONR) deals with nuclear facilities. ONR includes the nuclear safety regulator formerly known as the Nuclear Installations Inspectorate. ONR includes nuclear safety, security and transport regulation, it also works closely with the UK Environment Agencies.

Within the UK regulatory system, the operators of nuclear plant are licensed by HSE/ONR. No other organisations are licensed or approved in the framework of nuclear safety regulation.

The basic regulatory approach in the UK is outcome focussed, goal setting regulation. The licensee is responsible for safety.

Hold Point Strategy

The nuclear site licensees have processes which require hold points throughout the design, construction and commissioning cycle. These hold points will be developed in a clear programme along with schedules and quality documents which ensure that all relevant checks and controls have been met before a hold point can be released. The process for hold point clearance will have a high level of control and supervision by the licensee. Internal governance and oversight arrangements are also expected to ensure that an internal independent challenge function confirms that the work necessary to clear a hold point has been completed to an adequate standard.

In addition using the nuclear site licence it is common for ONR to place hold points or to select a subset of the licensees hold points. Generally ONR will have a small number of hold points placed at the start of the project, with options to increase the number of hold points if the performance of the licensee requires this.

B. Expectation on licensees (includes control of non-conformances)

The licensee is responsible for safety.

The nuclear site license has 36 standard conditions which encompass design, construction, commissioning, modification, operation, maintenance and decommissioning activities. One condition of the licence is that the licensee makes adequate arrangements to ensure that they procure equipment and services that are of sufficient quality. The responsibility for defining the standards and expectations for control of design, manufacture, commissioning, etc lies with the nuclear site licensee. ONR inspections consider the licence compliance arrangements.

Control of non-conformances

In accordance with arrangements made under the nuclear site licence the licensee will have robust controls for the control of modifications, change control and non-conformances which arise during the

design, manufacture, construction, and commissioning phases. These arrangements will ensure that the safety significance of deviations is considered with increasingly robust controls in place for higher category components or deviations. These arrangements will be controlled by the licensee and will be expected to be mirrored in main suppliers and contractors. The arrangements will be inspected and reviewed by the licensees internal oversight function.

As part of ONRs' inspection processes we would generally request oversight of significant non-conformances. The licence compliance arrangements include reporting of deviations from expected condition – for major deviations, these are reported directly to ONR.

C. Regulatory review of Design Documentation (RB/IO, safety class)

ONR fulfils its regulatory duties through inspection of licence compliance, and inspection and assessment of the adequacy of safety cases throughout all stages of life of nuclear facilities.

As there are expected to be new NPPs constructed in the UK, ONR has set up a division with the express purpose of considering the generic design of potential new plant. Certain aspects of the design are being examined in some detail, with ONR advising whether the proposals are likely to result in a design or operational plant that is licensable. The oversight process is known as Generic Design Assessment (GDA), and involves ONR and the Environment Agency.

At the end of the GDA process, the Regulators will decide if the proposed designs are acceptable for build in the UK. The GDA process is based on sampling of the design.

The GDA process is separate from nuclear site licensing. Following completion of GDA, issues requiring further regulatory assessment and resolution within the licensing and permissioning regime may include:

- site-specific aspects not covered by the generic site envelope;
- other site-specific aspects;
- any other changes to the design or safety documentation since GDA;
- assessment of the licence applicant's organisation;
- consideration of any exclusions in ONR's statement of Design Acceptance

In general there is no independent design verification required, but in some cases ONR would look for independent design verification, specifically when it is a code requirement. However, for those components that form a principal means of ensuring nuclear safety, such as the Reactor Pressure vessel, other principal NSSS components, or the concrete containment structures, the licensee is expected to contract an Independent Third party (normally the ITPIA) to undertake independent design review, verification and certification. ONR may also commission independent design verification.

D. Regulatory inspections of structures and components (RB/IO, safety class, during manufacture/post manufacture/installation/commissioning)

In general, the principle of goal setting regulation expects the licensee to have full control and supervision of the supply chain and all activities which contribute to nuclear safety. The licensees' arrangements should ensure that adequate oversight is in place to procure components qualified to standards defined in specifications and presented in the Pre Construction Safety Report (PCSR). ONR will inspect aspects of these arrangements on a sampling basis taking account of safety significance, degree of complexity, novelty, feedback from UK or international experience, etc.

For those components that form a principal means of ensuring nuclear safety ONR would normally sample inspect quality management systems and arrangements of the licensee and the supply chain. In addition, for critical phases of manufacture and commissioning, ONR may choose to deploy specialist inspectors to inspect and witness specific activities, such as forging, welding, heat treatment, non-destructive testing, the leak testing of the Prestressed Concrete Containment vessel, etc.

ND may choose to inspect the licensee's arrangements for control of quality of materials supplied for example in the manufacture of concrete, or quality of steel provided to site. The licensees will create arrangements for construction inspection and ONR inspections will sample arrangements to confirm they are adequate and are being complied with.

E. Authorisation of IOs

Third party organisations are used to support both the regulator and licensee's activities to secure licence compliance.

ONR does not license or authorise bodies other than operators of plant. Some third parties are accredited by the UK Accreditation Service (UKAS) e.g. individuals performing auditing or surveying functions. UKAS also provides an accreditation service to organisations such as laboratories or testing companies that perform tests in accordance with standard procedures. Other organisations may be accredited through different organisations, for example, Lloyd's Register Quality Assurance may provide accreditation against the quality assurance management system ISO 9001.

Third Party Organisations are selected by ONR via their procurement process which includes assessment of their capability in the particular topic that they are to service. The organisation must have suitably qualified and experienced personnel to provide the appropriate standard of support. Third Party Organisations are expected to have suitable Quality Management systems.

The regulator, licensee (or prospective licensee, purchaser) would normally place contracts with inspection organisations. Considerable care is invested on the part of ONR and the Third Party organisations to avoid conflict of interests, which may occur where the Third Party Organisation could be seen to be providing specialist assistance to ONR while being engaged by the licensee on a related activity.

F. Use of Management System Audits/Focused Audits

ONR engages with prospective nuclear site licensees as they develop management arrangements in the build up to nuclear site licence application. Further inspection of leadership and management for safety, including audit and inspection is undertaken once a site licence application is received and before a licence is granted. Management system and quality audits continue once an organisation receives a nuclear site licence.

Inspection of quality management arrangements of licensees and of the supply chain are undertaken by ONR, with supply chain auditing a key element of the licensees' arrangements for control and supervision of the supply chain.

Appendix 5

International standards that define general requirements for conformity assessment bodies in the accreditation process

- EN ISO/IEC 17011, Conformity assessment. General requirements for accreditation bodies accrediting conformity assessment bodies
- EN ISO/IEC 17020, General criteria for the operation of various types of bodies performing inspection
- EN ISO/IEC 17021, Conformity assessment. Requirements for bodies providing audit and certification of management systems
- EN ISO/IEC 17024, Conformity assessment. General requirements for bodies operating certification of persons
- EN ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- EN 45011, General requirements for bodies operating product certification systems