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Swiss Federal Nuclear Safety Commission

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Regulatory Inspection Practices in Nuclear Installations

Part 1: Safety Requirements and Assessment

Recommendations to HSK

June 2002

KSA-Report

The Swiss Federal Nuclear Safety Commission (KSA) is an advisory body of the Swiss Federal Council and the Federal Department for Environment, Transport, Energy and Communication on matters of the safety of nuclear installations. In addition to commenting on licence applications, observing operation and participating in the preparation of codes of practice. KSA is concerned with fundamental questions on the safety of nuclear installations and on appraising their safety. KSA also writes and publishes its own reports.

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Summary

This report deals with the interface between the regulator and the operator of a nuclear installation (licensee), especially a nuclear power plant. Specifically, the types of regulatory requirement and the ways to assess safety are considered.

In the following, four types of safety requirements are looked at (chapter 3), namely:

- Requirements concerning specific features of the plant or plant operation
- Requirements concerning results of plant operation (performance)
- Requirements concerning risks of the plant
- Requirements concerning protection goals

In addition four ways to assess safety are differentiated (chapter 4), namely:

- Assessment by means of direct inspections/analyses by the regulator
- Assessment by means of inspections/analyses by the operator in the presence of the regulator
- Assessment by means of inspections/analyses by the operator; the regulator is not present, but takes notice of the results
- Assessment by means of verification by regulator of operator's work processes

The inspection practised in five countries is demonstrated in the light of six exemplary cases (chapter 6). The regulators of Switzerland, Germany, Finland, Sweden and the United States of America made a statement on their inspection actually practised. It is shown that regulatory requirements focus on specific features or on the operation of the plant, that is to say on specific requirements on technical systems and work processes. A further focus consists of the requirement concerning the performance of the installation. That means operational/performance indicators and only partially quantifiable safety indicators. Requirements for limiting values of acceptable plant-risks are not indicated in the exemplary cases. In most cases there are obligations to estimate the risk of events as a base to derive measures. Requirements concerning protection goals are deemed to be largely covered. Therefore, only a few cases are indicated, namely if none of the three other types of requirements are applied or if an additional safety barrier, in the sense of e.g. ALARA, is imposed.

All four ways of assessment are being used by the regulators. Since the operator is responsible for the safety of the installation, in many cases, he or his own expert inspects/analyses the plant himself. In important cases, inspections/analyses are done by the operator in the presence of the safety authority or its expert. Besides taking notice of the test results of the operator, the indicated cases show that the activities of the regulator are equally divided into inspecting the work processes of the operator and into direct inspections/analyses by the safety authority or by its expert. It appears that most regulators have diversified their inspection activities in order to look at safety aspects from different angles.

Recommendations to the Swiss Nuclear Safety Inspectorate (HSK) have been derived from the overview (ch. 7). The type of safety requirements as well as the ways of assessment should not be limited to one method. The inspection should be adapted to the installation, the specific case considered, and the experience. It should be periodically questioned and changed when appropriate. Besides the recommendations to mostly maintaining requirements concerning features of the plant or plant operation, emphasis should be put on development and use of safety indicators. In addition, probabilistic goals and risk-values should be established, and plant-specific risk-analyses should be further developed.

Contents

1 Introduction

The terms of reference for the functions of a regulatory authority are defined by the applicable law. In Switzerland this comprises the Atomic Energy Act (AtG) and the Supervision Ordinance:

- "The atomic installations and all possession of radioactive nuclear fuels and residues are subject to federal government supervision." (AtG art. 8, para. 1)
- "The Federal Council and its appointed agencies are authorised at any time in the exercise of their supervision to give whatever directions are necessary for the protection of persons and property or for safeguarding Switzerland's external security and its obligations undertaken under international law, and to oversee the observance of regulations and directions." (Federal law of 23 December 1959 on the peaceful uses of atomic energy, AtG: art. 8 Federal government supervision, para. 2)
- "The regulatory body in respect of nuclear safety and radiation protection is the Swiss Federal Nuclear Inspectorate (HSK). It makes its dispositions by order of the Federal Department of Energy." (Ordinance of 14 March 1983 concerning the Supervision of Nuclear Installations: art. 1 Supervisory authority)

The call for more transparency, the introduction of quality management, but also the plants' advancing age, liberalisation of the electricity market and social change are all reasons for re-examining the activities of a regulatory authority. The greater pressure on operators to reduce costs, for example, may lead them increasingly to question, even reject, measures aimed at preserving plant safety and security of operation. In such circumstances the watchful eye of the authorities is of ever growing importance.

It is expected of the authorities that in this situation they will continue to oversee Switzerland's nuclear installations efficiently and effectively. To this end, the authorities need to examine their ways of working hitherto, and where necessary seek out, evaluate and implement new forms of supervision.

This report deals with the interface between the regulatory authority and the operator of a nuclear installation. Attention is centred on the types of safety requirement and the ways of assessment; a broader viewpoint to include the evaluation and implementation of measures will be considered at a later date. The report is concerned on the one hand with different kinds of safety requirement (ch. 3) and, on the other, with different manners of assessment (ch. 4). The diverse nature of safety requirements and assessment gives rise to a great variety of possible combinations (ch. 5). These are practised mostly in a composite, rather than a pure form (ch. 6).

The findings presented here are intended to help in systematically defining and appraising the various combinations. They form the basis underlying the recommendations to the HSK in ch. 7.

2 Operator and regulator

The duties and responsibilities of operator and regulatory body must be clearly separated. The operator bears unreserved responsibility for the safe operation of his installation. As custodian of the public interest, the regulatory body must satisfy itself transparently by reference to laws, statutory orders, directives and guidelines that the operator meets this responsibility. It must take great care not to assume any part of the operator's responsibility. – There are signs that, owing to the pressure on costs referred to above, operators are tending to pass the burden of accountability for safety to the authorities. This tendency leads to conflicts of interest, and goes against the principle that the operator is accountable while the authorities check that the furnished evidence of accountability is correct.

It is assumed in the following that the regulatory body and the operator both have an effective quality management system (QMS):

– The regulatory body has a QMS which ensures that the safety requirements of the nuclear installations and also the elements of the control and inspection activity are defined, and that these are understood and suitably put into effect by the operator. This QMS also provides for the practical and formal basic and continuing training of the regulator's personnel.

– The operator has a QMS which provides the regulatory body with the information it needs to fulfil its supervisory mandate, and satisfies the requirements of IAEA SS 50-C/SG-Q "Quality Assurance for Safety in NPP and other Nuclear Installations".

According to IAEA SS 50-C/SG-Q, art. 105, the purpose of a QMS is to increase nuclear safety by continually improving the methods employed to achieve quality. On this premise, the regulator's supervisory activity can be assisted by the operator's QMS. The regulator has to make sure that the demanded proofs of safety are permanently recorded in the system, and that the information required in order to make an impartial check is available from the system when needed. Even with a good and safety-orientated QM system, tensions can occasionally arise between safety and cost-effectiveness. Regulatory bodies are thus necessary also in order to monitor (in a manner visible to the public) that the nuclear installations are built and operated safely first and foremost for the protection of people and the environment.

3 Types of safety requirement

A distinction is made in the following between four types of regulatory safety requirement ranging from specific measures to broad objectives:

(1) Requirements concerning specific features of the plant or of plant operation;

(2) Requirements concerning results of plant operation;

(3) Requirements concerning risks of the plant;

(4) Requirements concerning protection goals.

3.1 Features of the plant or plant operation (1)

The regulator imposes specific requirements on technical systems, operational processes, etc. (formal/prescriptive approach). These concern the execution and operation of the plant, including their incorporation in the technical specifications and the operator's operating manuals.

Advantages:

- Clear and understandable rules and regulations gives the operator clear and understandable instructions, makes enforcement easier for the regulator, clarifies the legal position and makes the regulator's work transparent to the public.
- Supervision is easily managed.

Drawbacks:

- Can seduce the operator into acting only according to the book, the regulator who drew up the instructions then takes on some of the operator's responsibility.
- Keeping the rules and regulations up to date is costly for the regulator; instruction details are often queried by operators.
- Less appropriate for areas not readily covered by rules and regulations, such as safety culture.
- Rigid requirements can hamper new technologies.

3.2 Results of plant operation (2)

Supervision based entirely on results (performance) relies on the results of operation, irrespective of how these came about individually. The regulator watches, for example, that prescribed indicators of operation and safety are adhered to, allowing the operator flexibility as to how he intends to achieve them. The regulator concentrates especially on aspects of the plant that contribute to poor results. Essential for this are measurable or calculable, informative indicators for assessing safety.

Advantages:

- Requirements are clear and easily understood.
- Gives the operator flexibility as to how he achieves results.

Drawbacks:

- A comprehensive set of operational and safety indicators and extensive monitoring are necessary so that shortcomings are quickly spotted and remedied.
- Less suitable for areas hard to define in terms of measurable parameters or objective criteria, such as safety culture or organisation.

3.3 Plant risk (3)

Exclusively risk-based supervision relies on risk analyses and relevant experience. Regulatory inspection concentrates particularly on aspects of the plant with comparatively high elements of risk. This approach could, on the one hand, reduce instances of unnecessarily conservative design and, on the other, reveal cases where it is not conservative enough. Other risk variables besides the frequency of core damage must also be considered here.

Advantages:

- Risk analyses force operator and regulator to analyse systematically and thoroughly all factors that could be part of an accident chain.
- Risk analysis detects uncertainties and ranges.
- Quantified, traceable criteria are obtained for areas easily modelled and with a good database.
- Allows pinpointing of topics for instructions, inspections and discussions, hence making supervision easier.
- Gives the operator flexibility on how he achieves results.

Drawbacks:

- There is no guarantee that a risk analysis is complete.
- Some areas are poorly covered by today's risk analyses. Safety culture and organisation, for example, are not readily amenable to risk analysis.
- Risk analyses and appropriate modelling independently of the operator are costly for the regulator.

3.4 Protection goals (4)

Supervision based solely on protection goals aims at adhering to fundamental protection goals. – The overriding safety requirement of a nuclear installation is that people and environment are protected at all times. This gives rise to four basic protection goals that have to be attained when operating a nuclear power plant:

- control of radioactivity,
- cooling of the fuel assemblies,
- containment of radioactive materials,
- limitation and monitoring of radiation exposure.

Other objectives can be derived from these four basic protection goals.

Advantages:

- Focus on the crucial aspects of plant safety. Protection goals are evident and can be presented in a way the public understands.

– Criteria more detailed than frequency of core damage can easily be adhered to.

– Allows the operator flexibility as to how he achieves the protection goals.

Drawbacks:

– Heavy expense of assessing the operator's chosen ways of achieving the protection goals.

– Less suitable for areas such as safety culture and organisation.

4 Types of safety assessment

Considered below are four ways in which the regulator can assess whether the specified requirements are met:

(A) Assessment by means of inspections/analyses by the regulator;

(B) Assessment by means of inspections/analyses by the operator in the presence of the regulator;

(C) Assessment by means of inspections/analyses by the operator;

(D) Assessment by auditing the operator's work processes.

Note: "Assessment" denotes the verification with regard to safety of processes, results and protection goals by means of inspections conducted by the regulatory body or its experts. The formal verifications of processes and results of a QM system, so-called audits, for the purpose of having the QM system certified by an accredited agency and which have to be undertaken at regular intervals after certification, are not carried out by the regulatory authority and cannot completely replace the latter's verifications with regard to safety. They are not considered here. The following descriptions of the four ways of assessing safety are accompanied by examples of their respective advantages and drawbacks.

4.1 Inspections/analyses by the regulator (A)

The regulatory body itself monitors that requirements are met, using its own personnel or appointed experts, its own test equipment and its own analyses.

Advantages:

– Independent checks, promoting public confidence.

– The regulator's detailed knowledge on safety matters is maintained because of its activity.

Drawbacks:

– Large effort for regulator.

– Some checks are not possible without interfering in the plant, and consequently cannot be carried out by the regulator.

4.2 Inspections/analyses by the operator in the presence of the regulator (B)

The regulatory body monitors the adherence to requirements by means of inspections or analyses conducted by the operator in the regulator's presence.

Advantage:

– Lower effort than (A).

Drawbacks:

– Less impartial than (A), although this is partly compensated by the regulator's presence while the operator inspects/analyses.

– Regulator's activity is not always traceable.

4.3 Inspections/analyses by operator (C)

The regulatory body monitors the adherence to requirements by means of inspections or analyses conducted by the operator alone.

Advantage:

– Lower effort than (A) or (B).

– The operator remains fully accountable for the safety of his plant.

Drawback:

– Less impartial than (A) or (B).

– Difficult for the safety authorities to ensure inspections are carried out correctly.

4.4 Verification by regulator of operator's work processes (D)

The regulatory body monitors the operator's safety-relevant work processes. Purely process-based supervision would mean that only the processes described in the QM manual would be checked, and not the individual results. A prerequisite is a detailed description of the processes, including performance criteria.

Advantages:

– Transparency regarding duties and responsibilities.

– Insight into the operator's processes enables preventive action to be taken.

– The most suitable way of assessing aspects of safety culture and organisation.

– Can simplify supervision because no, or only special, findings have to be verified.

Drawbacks:

– Demands high standards of expertise and judgement from the regulator as systems and work processes must be known in detail. The regulator is not necessarily involved in technical problems.

– A well described work process is no guarantee that it will be properly executed.

5 Combination of safety requirements with ways of assessment

All kinds of safety requirements can be combined with any type of assessment. The ideal combination is likely to vary, depending on the facility being supervised. Also, changes may be made with time as experience is accumulated.

This is illustrated in the table below.

Types of safety assessment ▶ ▼ Types of safety requirement	**A** Direct inspections/analys-es by regulator	**B** Inspections/analyses by operator – regulator is present	**C** Inspections/analyses by operator – regulator is not present	**D** Verification of operator's work processes
1 Features of the plant or plant operation	(1A)	(1B)	(1C)	(1D)
2 Results of plant operation	(2A)	(2B)	(2C)	(2D)
3 Plant risk	(3A)	(3B)	(3C)	(3D)
4 Protection goals	(4A)	(4B)	(4C)	(4D)

Explanatory notes on the combinations and the respective boxes:

1 The regulatory body ascertains whether technical systems, operating procedures, etc. comply with prescribed requirements by

(1A) relying on its own on-site inspections or its own analyses conducted by itself or its appointed experts, and/or

(1B) relying on the operator's inspections/analyses conducted in the regulator's presence, and/or

(1C) relying on the operator's inspections/analyses conducted without the regulator being present, and/or

(1D) monitoring the operator's work processes.

2 The regulatory body ascertains whether operation takes place within preset ranges and values of safety indicators or of operating results, and concentrates on problematic areas in this regard.

(2A) to (2D) same as (1A) to (1D).

3 The regulatory body ascertains whether preset values of plant risk factors are maintained or not exceeded, and concentrates on areas where continually updated risk analyses indicate comparatively high risks.

(3A) to (3D) same as (1A) to (1D).

4 The regulatory body monitors the measures adopted to comply with preset protection goals and the results achieved.

(4A) to (4D) same as (1A) to (1D).

6 Examples of inspection practice

Some examples of representative activities are given below in order to allow the survey methods practised in different countries to be compared. The information was provided by the regulatory body of the country in question. In certain cases the allocation has been modified based on the provided description (these cases are denoted with [1]).

The examples are restricted to the *principal* stages of the supervisory process. In other words, for some stages, or as redundancy, other combinations of requirements and assessment are practised as well in most cases. The combinations follow the order (1A), (1B), etc., and do not indicate the sequence in time.

6.1 Switzerland (CH) [1]

6.1.1 Measuring, evaluation and reporting of the doses of plant personnel exposed to ionising radiation

(1A, 1C, 1D) An authorised personnel dosimetry laboratory is required for determining individual radiation exposure. The HSK uses outside experts to assess the operator's dosimetry lab, and issues its authorisation. Authorisation of a dosimetry lab also includes inspecting the process "measuring, evaluation and reporting of doses" with account taken of the regulatory requirements in Guideline HSK-R-12 "Dosimetry and reporting for radiation exposed personnel of nuclear installations and the Paul Scherrer Institute" (1997). The procedure is periodically monitored by HSK.

(2A) The HSK inspects work at the plant (dose planning, zoning, random sampling of dose rates). From the operator's reports it ascertains at a later date whether the measures adopted are effective, and verifies particular findings (e.g. personnel contaminations).

(2B) HSK takes part in the measurements as appropriate.

(2C) Measurement and evaluation are usually done by the operator without HSK being present.

(3D) HSK assesses those activities during which personnel can be exposed to elevated doses and hence to a greater health hazard. For these activities it inspects and monitors the operator's processes aimed at avoiding unnecessarily high doses and hence risks for the personnel (ALARA rules).

(4D) HSK orders the operator to set annual radiation protection goals. It assesses the operator's processes established for achieving the defined

[1] Assignment modified in order to fit activity description provided by the authority.

protection goals. These include the training in radiation protection of personnel working in controlled zones (ALARA rules).

The greatest contribution to safety is rendered by (1D), (3D).

6.1.2 Monitoring of aerosol emissions in the stack

(1A) The HSK inspects, or has experts inspect, the aerosol-measuring instruments, including sample collection and line routing, for compliance with requirements.

(1B) HSK is present on a spot-check basis at the function checks.

(1C) Normally, the operator conducts function checks without HSK being present.

(1D) HSK monitors the operator's work processes used to demonstrate proper functioning of the system for measuring aerosol emissions from the stack, and also the observance of regulatory requirements described in Guideline HSK-R-47 "Testing of radiation-measuring instruments" (1999).

(2A, 2C) The operator regularly removes the filters from the aerosol-measuring instruments, and evaluates them himself. HSK and the radiation-monitoring section of the Federal Health Department take the filters on a spot-check basis, and evaluate them independently.

(2C)[1] HSK and the operator together examine the results of measuring aerosol releases. This also provides an indication of the aerosol-measuring system's functional performance.

(3D) HSK ascertains whether the operator has established a procedure whereby the shift on duty can quickly and easily assess the risk of an elevated aerosol emission.

(4D) HSK ascertains annually whether the operator sets protection goals for emissions of radioactive substances to the environment, and how he achieves them.

The greatest contribution to safety is rendered by (1D), (2A), (3C).

6.1.3 Repair or replacement of a class 1 mechanical component

(1A) HSK checks the planned activity by reference to the application for an approval, and assesses the implications for the plant.

(1A)[1] Before giving clearance for cl. 1 components, HSK verifies that the cause of the damage has been correctly identified, and that repair or replacement will prevent the same damage occurring in future. This is achieved by analysing the component's behaviour in operation.

(1B) Where appropriate, HSK calls in SVTI to monitor the work on site (e.g. pressure testing with calibrated instruments, also weld testing) and receives notification from the operator and a report from SVTI.

(1C) The operator usually analyses the damage without the regulator being present, and submits an approval application for the repair or replacement in which he demonstrates compliance with the design requirements.

(1C)[1] The operator identifies the cause of the damage. He performs a review of the history of safety-relevant components, assesses the findings, and defines action to be taken as appropriate.

(1D) HSK monitors the operator's work processes applied for repairs or replacements, and also the observance of regulatory requirements described in Guideline HSK-R-05 "Supervisory procedures governing the construction of nuclear power plants: Mechanical equipment" (1990) and HSK-R-18 "Supervisory procedures governing the repair, modification and replacement of mechanical equipment in nuclear installations" (2000). It also verifies that the operator has a process that allows him to identify damage to mechanical components, and thence deduce suitable measures to prevent damage.

(3C) In the case of damage to safety-relevant active mechanical components, the operator determines what effect the damage has on the core damage frequency of the plant as a whole, and how the improvements/repairs influence the risk. HSK verifies these analyses.

(4A) If the design has been modified, HSK verifies that the protection goal (integrity of primary loop, hence cooling of fuel and containment of radioactive substances) can be achieved.

(4C) If the design has been modified, the operator verifies that the protection goals are achieved.

The greatest contribution to safety is rendered by (1A), (1B) and, where appropriate, (4A).

6.1.4 Evaluation of reportable events (e.g. exceeding a limit value)

(1D) HSK monitors the operator's work processes for reporting and evaluating events, and also the observance of regulatory requirements described in Guideline HSK-R-15 "Guideline concerning the operation of nuclear power plants" (1999). HSK verifies that the operator has a procedure for ensuring the feedback of experience from events at Swiss and foreign installations.

(1C, 2C) The operator evaluates the event, takes follow-up action and submits the event report to HSK.

(2A) By means of the event report, HSK examines the behaviour and diagnosis of the plant, and also the operator's actions, and assesses the appropriateness of the measures taken. If necessary, HSK interviews the people concerned on site, conducts inspections and verifies the implementation and subsequent effectiveness of the action taken or ordered. It ascertains whether similar events have occurred in the plant in question or in other plants.

(3D) HSK ascertains whether the operator has a procedure for assessing the risk significance of events.

(4A) HSK examines whether the event could have violated a protection goal.

(4D) HSK verifies that the operator takes steps after an event to check that the fundamental protection goals are attained.

The greatest contribution to safety is rendered by (1D), (2A).

6.1.5 Qualification / requalification of a shift supervisor

(1D) HSK monitors the operator's work processes for qualifying and requalifying shift supervisors (training and licensing) and adherence to them, and also observance of the regulatory requirements described in Guideline HSK-R-27 "Selection, training and examination of nuclear power plant staff requiring a licence" (1992).

(1C) The operator tests the qualifications of candidates on the occasions of hiring and training.

(1A, 1B) The licence examinations are conducted by the operator under the supervision of HSK. The examination procedure and examination results are adjudicated by HSK. The granting of licences is subject to the consent of HSK (veto).

(2C) Requalifications are conducted by the operator at intervals of at most two years. HSK must be notified in cases of unsatisfactory requalification.

The greatest contribution to safety is rendered by (1A), (1D).

6.1.6 Measuring and evaluation of safety culture aspects

(1D) HSK ascertains that the operator has defined the principles of safety culture and also suitable measures and processes for promoting and assessing it. The basic reference is KSA document "Safety culture in a nuclear installation; reflections on its assessment and promotion" (KSA 7/75; 1997).

(2A) HSK has methods for measuring and assessing safety culture, e.g. MOSAIK, and intends to establish safety indicators. It uses these methods to obtain its own picture of safety culture in action in the plants, and observes practical implementation of the results, e.g. training, safety culture campaigns, raising staff motivation, etc.

(2C) The operator usually measures and assesses safety culture himself, and informs the regulator. Under the new Guideline HSK-R-48 "Periodic safety review (PSR) of nuclear power plants" (2001), safety culture should be assessed every 10 years.

(2A)[1] HSK verifies that the operator achieves the safety-relevant yearly goals he has set, and that the management supports these goals.

(1D)[1] HSK verifies that the operator also takes steps to show the commitment of management in setting and achieving of safety-relevant yearly goals.

The greatest contribution to safety is rendered by (1D), (2A).

6.2 Germany (D) [2]

6.2.0 Remarks

Allocating the assessment activities to the four ways of assessment presented certain difficulties, as there is some flexibility for interpretation. For example, it is questionable whether in the case of regulatory inspection of an operator's evidence, assessment of type A or C applies, or both. Or whether assessment type D covers only extensive auditing or also random follow-up checks.

Attention is drawn to the fact that developments are in progress with the following aims (in addition to deterministic requirements):

- Make greater use of safety indicators for the early detection of trends,
- Integrate results of probabilistic analyses more fully into inspection and approval procedures,
- Integrate aspects of safety culture and safety management in the plants to a greater extent into regulatory inspection.

6.2.1 Measuring, evaluation and reporting of the doses of plantpersonnel exposed to ionising radiation

The regulatory requirements concerning measurement, evaluation and reporting of doses to personnel correspond to type 1. Detailed regulations exist which are implemented in operational rules and instructions. The following ways of assessment are practised:

(2A)[1] In parallel to the operator's dosimetry, radiation exposure is measured and evaluated by the regulator, using the regulator's dosimeters.

(1D) Observance of regulations and operational rules is regularly verified by random checks.

Regarding the acceptability of personnel exposure, in addition to regulatory limits (requirement of type 1), collective doses and dose distributions are used as indicators as well (requirements of type 2). Compliance is assessed in the following way:

(2C) The operator records the measurements, evaluates them, and reports to the regulator.

The greatest contribution to safety is rendered by (1D) and (2C).

6.2.2 Monitoring of aerosol emissions in the stack

The requirements concerning emission monitoring and instrumentation correspond to type 1. They are defined in specific standards. The following kinds of assessment are practised:

(1A) Compliance with requirements is assessed by the regulator when the instrumentation is introduced and with regard to the related procedures, including in-service tests, and also when modifications are made to the instrumentation or operating procedures.

In addition, the regulator periodically carries out check measurements. Compliance with emission limit values is also monitored by the reactor remote monitoring system, which automatically sends an alarm to the regulatory body.

(1B) The emission-monitoring systems and equipment are regularly inspected with the participation of experts appointed by the regulator.

Regarding the acceptability of emissions, in addition to regulatory limits (requirement of type 1), emission values are used as an indicator as well (requirement of type 2). Compliance is assessed in the following ways:

(2C)[1] The readings are passed to the regulator via the reactor remote monitoring

system, and regularly examined for trends.

(2C) The operator records the measurements, evaluates them, and reports to the regulator.

The greatest contribution to safety is rendered by (1A), (1B) and (2C).

6.2.3 Repair or replacement of a class 1 mechanical component

The safety requirements correspond to type 1. The component is subject to specific requirements. There are also detailed specifications for the procedure on replacement or repair. Assessment is performed as follows:

(1A) The operator's documents and records are examined by the regulator. In this process, appointed experts also use their own methods of analysis and calculation.

(1B) Previously defined tests are conducted in the presence of the regulator or its experts.

(1D) Observance of regulations and protection measures while carrying out the work are spot-checked by the regulator (work processes).

Since the surveillance measures cover different areas, (1A), (1B) and (1D) are necessary in order to ensure a high level of safety.

6.2.4 Evaluation of reportable events (e.g. exceeding a limit value)

The requirements concerning the evaluation and reporting of events are laid down in regulatory specifications and implemented in operational rules. They correspond to type 1. Aspects of achieving protection goals play an important role in analysing and categorising the events. Requirements of type 4 therefore underlie the safety requirements of type 1. Assessment is performed as follows:

(1C) Events are analysed by the operator, and the findings submitted to the regulator.

(1A) The reports and analyses submitted by the operator are examined by the regulator and appointed experts.

(1D) The recording of events and procedures applied by the operator for their analyses are subjected to random checks.

Events below the reporting threshold, disturbances and near-events are also analysed by the operator (e.g. by means of HF analysis). The requirements for this are of type 2. The number of reportable events and the number of reportable events with comparable causes are used as an indicator. The assessment carried out corresponds to:

(1D)[1] The regulatory body examines the procedures and interviews the people responsible.

(2C) The operator evaluates the events, disturbances and near-events.

The greatest contribution to safety is rendered by (1C) and (1A).

6.2.5 Qualification / requalification of a shift supervisor

The requirements for the licensing of a shift supervisor and for the necessary

training are defined in detail. They are of type 1. Assessment practice is as follows:

(1A)[1] From interviews with the shift supervisor during inspection visits, the regulator gains an insight into his technical expertise and safety-oriented attitude.

(1B)[1] The regulatory body takes part at the oral basic examination and the plant-specific specialist examination.

(1C) As evidence of the prior qualifications for licensing and of the necessary expertise, the operator submits documentation to the regulatory body, which is examined.

The stated types of assessment (1A) and (1C) relate to different areas.

6.2.6 Measuring and evaluation of safety culture aspects

The safety requirements are of type 2. It is broadly left to the operator as to how he promotes, measures and evaluates the safety culture in his plant. If indicators or signs (factors contributing to events, quality of documentation, impressions gained on inspection visits, etc.) point to a weakness, the operator is asked to investigate these cases more in depth. Assessment is done as follows:

(2A) Indicators and signs are watched for by the regulator, independently of the operator.

(2C) The operators conduct peer reviews and audits.

The aim is assessment as (2D), since this is expected to contribute more to safety.

6.3 Finland (FIN) [3]

6.3.0 General

In general, Finnish regulatory requirement system consists of all types 1 to 4 presented on the previous page. For example, the basis of the Finnish regulatory system has been built to fulfil the four elementary protection goals given under number 4, notably control of the reactivity, cooling of the fuel, confinement of radioactive material, limitation and control of radiation exposure. In order to meet these protection goals quite stringent regulatory requirements have been issued for some areas in the legislation and in the YVL Guides (YVL Guides are rules an individual licensee or any other organisation concerned shall comply with, unless STUK has been presented with some other acceptable procedure or solution by which the safety level set forth in the YVL Guides is achieved). In some areas, the control of the fulfilment of some regulatory requirements is based on the performance of the plant. Nowadays, also risk insights are being increasingly utilised to use and focus regulatory resources to risk significant areas.

6.3.1 Measuring, evaluation and reporting of the doses of plant personnel exposed to ionizing radiation

The regulatory requirement concerning the measuring equipment and instrumentation corresponds to type 1 in that the equipment and instrumentation have to be manufactured and installed according to given regulatory requirements in a specific YVL Guide. The following ways to assess measuring equipment and instrumentation are practised:

(1A) The regulatory authority tests randomly whether the measuring instrumentation functions according to its specified design.

(1D) The regulatory body inspects as a part of its periodic inspection programme the work processes of the operator to prove the proper function of the measuring equipment and instrumentation.

The regulatory requirement concerning the evaluation and reporting of doses corresponds mostly to type 2, the amount of doses being a performance indicator. Reporting requirements related to radiation doses are specified in YVL Guides. The following ways to assess doses are practised:

(2A) The regulatory authority performs random dose tests using plants' dosimeters irradiated at an independent laboratory.

(2C) The operator conducts regular tests, measures the doses and sends the results to the regulatory authority.

(1D)[1] The regulatory body inspects as a part of its periodic inspection programme the work process of the operator used to measure and evaluate the doses.

The most important contributions to safety come from the activities (1D) and (2C).

6.3.2 Monitoring of aerosol emissions (in the stack)

The regulatory requirement concerning the monitoring equipment and instrumentation corresponds to type 1 in that the equipment and instrumentation have to be manufactured and installed according to given regulatory requirements in a specific YVL Guide. The following ways to assess are practised:

(1D) The regulatory body inspects as a part of its periodic inspection programme the work processes of the operator to prove the proper function of the measuring equipment and instrumentation.

The regulatory requirement concerning the acceptable emissions corresponds mostly to type 2, the amount of aerosols released being a performance indicator. The following ways to assess are practised:

(2C) The operator measures the aerosols released and sends the results to the regulatory authority.

(1D)[1] The regulatory body inspects as a part of its periodic inspection programme the work process of the operator used to measure the aerosol emissions.

The most important contributions to safety come from the activities (1D) and (2C).

6.3.3 Repair or replacement of a class 1 mechanical component

The regulatory requirement concerning the repair of a class 1 mechanical component corresponds to type 1 in that the general requirements for the repairs and their inspections are given in YVL Guides. The following ways to assess are practised:

(1A) Operator has to submit necessary documents (repair plans) to the regulatory body for approval. Regulatory body performs inspections after repairs.

(1C) Operator performs inspections and tests and sends the results of inspections and operability verification tests to the regulatory body.

(1D) The regulatory body inspects as a part of its periodic inspection programme operator's work processes related to maintenance of mechanical components.

The most important contributions to safety come from the activities (1A) and (1C).

6.3.4 Evaluation of reportable events (e.g. exceeding a limiting value)

The regulatory requirements concerning the evaluation of reportable events correspond to type 1. Regulatory requirements give regulations on what types of events need to be reported to the regulatory body and what elements of event evaluation reports have to cover. However, regulatory requirements do not specify the investigation or evaluation method (root cause analysis method) to be used. The following ways to assess are practised:

(1A) All event reports are evaluated by the regulatory body. In a specific case, regulatory body performs own independent event investigations and evaluations.

(1C, 2C)[1] Operator performs own event evaluations and sends the results to the regulatory body in a form of event reports and operating experience feedback report.

(1D) The regulatory body inspects as a part of its periodic inspection programme operator's work process related to the event evaluation and operating experience feedback in general

The most important contribution to safety come from the activities (1A) and (1C).

6.3.5 Qualification / requalification of a shift supervisor

The regulatory requirement concerning the qualification/requalification of all shift operators (turbine and reactor operators and shift supervisor) corresponds to type 1 in that the scope of training, written and oral examinations of shift operators has to be performed according to given regulatory requirements in specific YVL Guides. The following ways to assess are practised:

(1B) Operator performs written and oral examinations of all shift operators in the presence of the regulatory body.

(1C) Operator performs own assessments on the performance of the operators during simulator training.

(1D) The regulatory body inspects the work processes of the operator to prove the proper shift operators qualification.

The most important contribution to safety come from the activities (1B) and (1C).

6.3.6 Measuring and evaluation of safety culture aspects

Measuring and evaluation of safety culture aspects is mainly based on the assessment of the performance of the operator. There are no specific requirements for operators to measure and evaluate safety culture aspects, only to have and maintain high safety culture. Some characteristics of good safety culture have been presented in YVL guides. Taking this into account the regulatory requirement in this issue corresponds mostly to type 2. The following ways of assessment are practised:

(2A) Safety culture aspects are mainly evaluated during periodic inspections and event inspections by the regulatory body. The results of safety culture observations are reported separately within the regulatory body. Also external experts have been used to assess and to develop methods to assess safety culture aspects at operators.

(2A)[1] Regulatory body assesses safety culture aspects as a cross cutting issue through the whole periodic inspection programme.

(2C) Operators make own self-assessments on their safety culture aspects.

The most important contribution to safety comes from the activity (2A).

6.4 Sweden (S) [4]

6.4.1 Measuring, evaluation and reporting of the doses of plant personnel exposed to ionising radiation

The regulatory requirement concerning the equipment for measuring dose to personnel corresponds to type 1 in that the laboratory performing the measurements has to be authorised by the regulatory authority. The instrumentation has to be calibrated and there should be a written instruction for both use and calibration for each instrument and measuring equipment used.

The following ways to assess are practiced:

(1C) The operator performs inspections and analyses without the safety authority present. Results are reported to the regulatory authority on a regular basis.

(1D) The safety authority inspects and analyses the operator's work processes. The operator should have a written description of the full process for measuring, evaluation and reporting personnel doses.

The regulatory requirement concerning reporting of doses corresponds mostly to type 2. The operator reports the doses to a national database in a way prescribed by the regulatory authority.

The following ways to assess are practiced:

(2C) Evaluation and reporting of doses are performed by the operator without the safety authority present.

(1D)[1] The safety authority requires the process of evaluation of measuring data and reporting of doses to be fully described in written documents.

SKI prefers not to grade. – The most important contribution to safety comes from more than one activity.

6.4.2 Monitoring of aerosol emissions in the stack

The regulatory requirement concerning the monitoring equipment corresponds to type 1 in that the equipment should have a measuring standard to fulfil detection limits given by the safety authority. There should be a written instruction for both use and calibration for each instrument and measuring equipment used.

The following way to assess is practiced:

(1D) The safety authority inspects and analyses the operator's work processes. The operator should have a written description of the full process for measuring, evaluation and reporting aerosol emissions.

The regulatory requirement concerning the acceptable emissions corresponds mostly to type 2, the amount of aerosols released being a performance indicator.

The following ways to assess are practiced:

(2A) The regulatory authority measures samples of the aerosol filters and takes note of the results sent by the operator.

(2C) The operator measures the aerosol released and sends the results to the regulatory authority.

(1D)[1] The safety authority requires the process of evaluation of measuring data and reporting of emissions to be fully described in written documents.

SKI prefers not to grade. – The most important contribution to safety comes from more than one activity.

6.4.3 Repair or replacement of a class 1 mechanical component

The regulatory requirements concerning the repair of class 1 mechanical components correspond to type 1.

(1C) The regulatory requirements for repair of class 1 mechanical component are given in the regulation SKIFS 2000:2 "The Swedish Nuclear Power Inspectorate's Regulations concerning Mechanical Components". According to these regulations repairs shall be performed according to a repair programme that has been qualified for its purpose. The licensee is responsible for preparing the programme including all necessary analyses and demonstrations of the effectiveness of chosen repair methods and procedures.

(1C) The repair programme has to be reviewed by an independent (third party) inspection body, who also shall supervise practical qualification exercises to demonstrate the effectiveness. This independent inspection body shall be accredited for its tasks.

(1D) SKI inspects on a sample basis, and as a part of its inspection programme, the licensee's organisations and work processes for plant modifications including repair activities. SKI also assists the Swedish Accreditation Board (SWEDAC) in their assessments of accredited inspection bodies.

SKI prefers not to grade. – The most important contribution to safety comes from more than one activity.

6.4.4 Evaluation of reportable events (e.g. exceeding a limiting value)

Regulatory requirement: Events that have occurred and conditions that are detected and are important to safety shall be investigated in a systematic manner and classified according to the significance of the event by the licensees.

Type (1C) and (1D): LER´s in Sweden are reported to SKI, according to reporting demands in the regulation SKIFS 1998:1 "The Swedish Nuclear Power Inspectorate's Regulations concerning Safety in Certain Nuclear Facilities". These demands are divided into three groups:

cat 1. Events require start-up permission from SKI. Reporting time is 7 days.

cat 2. Ordinary LER reports to SKI. Time to report is 30 days.

cat 3. Cat 3 events are reported to SKI once a year, and have to be documented in the workorder system of the plants or in other equal documentation system.

Type (2A) and (3A): The reports are evaluated at SKI in the following manner:

consequences of failures are judged against the affected safety barriers and the defence-in-depth principles,

general safety impact of faulty function, system, component judged against the regulations in SKIFS 1998:1,

impact/deviations in maintenance and testing procedures component judged against the regulations in SKIFS 1998:1,

impact of possible dependencies on components judged against the regulations in SKIFS 1998:1,

collection of data for internal safety indicator systems,

lesson learned at plant,

domestic generic issues.

SKI prefers not to grade. – The most important contribution to safety comes from more than one activity.

6.4.5 Qualification / requalification of a shift supervisor

The regulatory requirements concerning the competence of operations personnel correspond to *type 1 and are process-based* in that basic provisions are required such as systematic analyses of competence requirements, and competence evaluation against the competence requirements with established criteria for acceptable performance; an authorisation shall be issued by the licensee for each

position for max three years; retraining is required every year – part of it in a full-scale simulator etc.

The requirements and general recommendations concerning their application are part of the The Swedish Nuclear Power Inspectorate Regulatory Code SKIFS 2000:1 "The Swedish Nuclear Power Inspectorate´s Regulations concerning the Competence of Operations Personnel at Reactor Facilities". The regulations have been translated into English and can be found on www.ski.se.

The following ways to assess are practiced:

(1A) Direct inspections by the safety authority in that samples may be taken in order to assess the quality of the process and its outcome as part of an inspection.

(1C) Inspections/analyses by the operator; the safety authority is not present. It is a requirement in SKIFS 2000:1 that the application, effectiveness and suitability of the system for training and competence evaluation of the operations personnel shall continuously be investigated by the licensee´s quality assurance function.

(1D) Inspections/analyses of the operator´s work processes by the safety authority.

SKI prefers not to grade. – The most important contribution to safety comes from more than one activity.

6.4.6 Measuring and evaluation of safety culture aspects

The regulation is indirect in that the regulation SKIFS 1998:1, type 1 process-based, addresses processes and aspects which are seen as necessary although not sufficient for safety culture enhancement (such as requirements to continuously develop safety, to learn from experience, and ensure working conditions supporting safe behaviour).

The following ways to assess are practiced:

(1D) Inspections/analyses of the operator´s work processes by the safety authority.

(2C)[1] Inspections/analyses by the operator; the safety authority is not present.

SKI prefers not to grade. – The most important contribution to safety comes from more than one activity.

6.5 United States of America (US) [5]

6.5.1 Measuring, evaluation, and reporting of the doses of plant personnel exposed to ionizing radiation

The regulatory requirement concerning the measurement, evaluation, and reporting of radiation worker doses correspond to type 1. The U.S. NRC has specific regulations on the acceptable methods of measuring, evaluating, and reporting the dose to radiation workers.

The U.S. NRC assesses the safety requirements in the following ways:

(1B) Qualified U.S. NRC inspectors periodically observe the licensee perform the operation/analyses.

(1C) The licensee routinely performs the operation/analyses without the U.S. NRC inspector present. The data/results of the licensee's operation/analyses are periodically inspected by the U.S. NRC inspector.

The regulatory requirement concerning the acceptable radiation dose to plant workers correspond to type 2, the amount of radioactive effluent released is compared to a regulatory standard.

The U.S. NRC assesses compliance with the regulatory standard in the following ways:

(2B) Qualified U.S. NRC inspectors periodically observe the licensee perform the operation/analyses.

(2C) The licensee routinely performs the operation/analyses without the U.S. NRC inspector present. The data/results of the licensee's operation/analyses are periodically reported to the U.S. NRC for inspection.

6.5.2 Monitoring of aerosol emissions (in the stack)

The regulatory requirement concerning the radiological effluent monitoring equipment corresponds to type 1 in that the instrumentation has to be specified according to a given standard.

The U.S. NRC assesses the safety requirements in the following ways:

(1B) Qualified U.S. NRC inspectors periodically observe the licensee perform the operation/analyses.

(1C) The licensee routinely performs the operation/analyses without the U.S. NRC inspector present. The data/results of the licensee's operation/analyses are periodically inspected by the U.S. NCR for inspector.

The regulatory requirement concerning the acceptable radiological effluent emissions correspond to type 2, the amount of radioactive effluent released is compared to a regulatory standard.

The U.S. NRC assesses compliance with the regulatory standard in the following ways:

(2B) Qualified U.S. NRC inspectors periodically observe the licensee perform the operation/analyses.

(2C) The licensee routinely performs the operation/analyses without the U.S. NRC inspector present. The data/results of the licensee's operation/analyses are periodically reported to the U.S. NRC for inspection.

6.5.3 Repair or replacement of a class 1 mechanical component

The regulatory requirements for the repair of an American Society of Mechanical Engineers (ASME) Code Class 1 mechanical component are specified in Title 10 to the Code of Federal Regulations (10 CFR) Part 50, Section 50.55a, "Codes and

standards." The regulations in 10 CFR 50.55a require, in part, for operating nuclear power plants that ASME Code Class 1, 2, and 3 components and their supports meet the requirements set forth in Section XI of the ASME Boiler and Pressure Vessel Code (1995 Edition up to and including the 1996 Addenda). More specifically, Article IWA-4000 of the ASME Code, Section XI provides requirements for the repair of ASME Code Class 1, 2, and 3 pressure-retaining components and their supports (including appurtenances, subassemblies, and parts of a component) by welding, brazing, or metal removal. The Code requirements and, therefore, the regulatory requirements for the repair of Class 1, 2, and 3 pressure-boundary components and their supports are the same. The regulatory requirements for the repair of Class 1 mechanical equipment are implemented as follows:

(1A, 1C, 1D)[1] The utility has the full responsibility for preparing the necessary documentation (repair plans) for the Class 1 repair in accordance with the ASME Code. The utility is not required to submit the documentation to the NRC unless the repair does not meet ASME Code requirements. If the repair plan does not meet the ASME Code, then NRC must review and approve the alternative repair plan before the repair can be performed. The utility is required to use a third-party accredited inspection organization to inspect the repair. The utility is required to notify the third-party inspection organization prior to starting a repair. The utility is required to keep documentation of all repairs of Class 1 mechanical equipment at the plant site. The documentation is subject to inspection by the NRC.

6.5.4 Evaluation of reportable events (e.g. exceeding a limiting value)

(1C, 2A, 2C) [1] There are two relatively rare types of reportable events (exceedance of a Safety Limit and occurrence of an earthquake in excess of the Operating Basis Earthquake) where the reactor operator (licensee) must shutdown the reactor and obtain approval of the regulatory authority (NRC) before restarting. – For other types of reportable events the reactor operator must submit a report of the event to the regulatory authority, including a description of the causes and corrective actions taken. The regulatory authority then reviews the event to determine if further action is warranted.

(2B) A few of these other types of reportable events (such as safety system functional failures) are also used as performance indicators. This usage is Type 2 (the regulatory authority bases its activities on the results of plant operation) Assessment Method B (inspection/analyses by the operator in the presence of the safety authority or its experts).

6.5.5 Qualification / requalification of a shift supervisor

6.5.5.1 OPERATOR QUALIFICATION - INITIAL LICENSING

Title 10, Part 55, of the *Code of Federal Regulations* (10 CFR 55) requires individuals who manipulate the controls of a nuclear facility (or direct these manipulations, such as a shift supervisor) to be licensed by the NRC. The actual licensing of an individual (as an operator or supervisor) is composed of several steps. The key NRC action steps are discussed below, including the approximate NRC assessment method and type of regulatory requirement (Remark: Operator

licensing and requalification are unique NRC processes, and are significantly different from other types of NRC inspections. Assigning regulatory requirements and assessment methods per the present classification scheme was often difficult for operator licensing and requalification.) Note that the operating experience and training of license applicants is performed by the facility operator. Applicable references for initial operator licensing are: 10 CFR 55 and NUREG-1021, "Operator Licensing Examination Standards for Power Reactors", Revision 8, Supplement 1.

Generic Fundamentals Examination (GFE): The GFE is a 100 question, multiple choice examination, prepared by a contractor and approved by the NRC's IOHS staff. This exam contains questions at a fundamental, non-plant specific level, associated with generic plant components, reactor theory, and thermodynamics. The GFE is typically taken shortly after the applicant begins his formal license training. There are two versions of the GFE, one version for boiling water reactors, and one version for pressurized water reactors. This exam is administered by the facility operators, graded by a contractor, and the final results approved by IOHS.

License Application and NRC Review: Each individual must complete two forms to apply for a license: Form NRC-398, "Personal Qualification Statement – Licensee" AND Form NRC-396, "Certification of Medical Examination by Facility Licensee." By completing and signing these two forms, the facility operator and the license applicant are certifying to the NRC that all education, training, operating experience, and medical requirements are satisfied for being licensed. These forms are typically forwarded to the appropriate NRC Regional Office (Philadelphia, Atlanta, Chicago, or Dallas) 30 days prior to the NRC plant-specific examination.

NRC plant-specific examination: If the license applicant has satisfactorily completed the GFE, and his application forms (396 and 398) are satisfactory, then the NRC will allow the license applicant to take the NRC plant-specific examination. The NRC plant-specific examination consists of a 100 question, multiple choice written test, and an operating test. The operating test, primarily performed on a plant-specific control room simulator, requires applicants to perform individual tasks and participate in crew-based dynamic simulator scenarios. The plant-specific written and operating tests are typically prepared by the facility operator and approved by the NRC. However, on occasion, these tests are prepared by the NRC, with an accuracy check performed by the facility operator. NRC written exams are typically administered by the facility operator, with an NRC Examiner available to answer any facility operator questions that may occur during the exam. NRC operating tests are ALWAYS administered by NRC Examiners. Although the facility operator will set up and run the simulator to support the exam, NRC Examiners are solely responsible for evaluating applicant performance during NRC operating tests. NRC written exams are typically graded by the facility operator, and the grading is checked by an NRC Examiner. NRC operating tests are ALWAYS graded by NRC Examiners. – The NRC plant-specific examination covers the remaining required 10 CFR 55 exam topics not covered by the GFE. In addition, the plant-specific exam is required to include an examination of risk significant topics. Therefore, the NRC plant-specific examination includes both a formal/prescriptive approach to regulation, and risk insights.

If a license applicant (1) performs satisfactorily on the GFE, (2) possesses satisfactory personal qualifications (398 form), (3) is in satisfactory health (396 form), and (4) performs satisfactorily on the plant-specific exam, then the NRC will issue the applicant a license.

The activities correspond to (1A, 1C)[1].

6.5.5.2 OPERATOR REQUALIFICATION

10 CFR 55 requires licensed operators to participate in an NRC-approved, facility operator administered requalification program. Facility requalification programs consist of various forms of instruction (e.g., classroom, control room simulator), and various forms of examination, including a required annual operating test, and a required biennial written examination. All licensed operator requalification programs are administered by facility operators. The NRC periodically monitors and inspects the facility operator requalification programs, including: a quarterly observation of requalification training activities, by the on-site NRC Resident Inspector; A yearly review of examination pass/fail rates; a detailed biennial review by NRC specialists/examiners. Applicable references for licensed operator requalification are: 10 CFR 55 and NRC Inspection Procedure Attachment 71111.11, "Licensed Operator Requalification Program".

Most of the operator requalification program is performed by the facility operator, without the presence of the NRC. However, a portion of the requalification program is performed in the presence of the NRC, and all aspects of the requalification program, including the work processes, are subject to NRC inspection. The majority of the NRC's requalification inspection activities focus on the facility operator's performance of prescriptive requirements, contained in 10 CFR 55 and the facility operator's requalification training process documents. However, concerning exam pass/fail rates, the NRC is primarily interested in the results and not necessarily the process. When selecting sample areas to inspect within the licensed operator requalification process, a risk-informed, performance-based regulatory approach should be considered in which risk insights, engineering analysis and judgment, including the principle of defense-in-depth and the incorporation of safety margins, and performance history are used.

Biennial NRC Requalification Inspection: Approximately every two years, the NRC performs a detailed inspection of facility operators' requalification programs, utilizing NRC Examiners and/or training specialists. This detailed inspection is scheduled to correlate with when each facility operator will be administering the annual requalification operating test and biennial requalification written examination. The primary activities of this NRC inspection include: Review the facility's operating history; Review the facility operator's requalification examinations; Review the facility operator's administration of requalification examinations; Review the facility operator's training feedback system; Review the facility operator's remedial training program; Review conformance with operator license conditions.

The activities correspond to (1A, 1B, 1C, 1D, 2C)[1].

6.5.6 Measuring and Evaluation of Safety Culture Aspects

In the United States, safety culture is thought to be a "cross-cutting" issue that can effect multiple aspects of a facilities performance. The NRC does not have specific regulations regarding safety culture, but assesses safety culture through performance in other areas. – The NRC does not have specific performance indicators for measuring safety culture; however, assesses safety culture by monitoring the number of allegations to the NRC by plant employees and during periodic inspections of licensee problem identification and resolution programs. Safety culture may or may not be assessed by individual operators. Some operators have developed specific performance metrics in this area.

The activities correspond to (1D, 2A, $2C_{part.}$)[1].

6.6 Overview of results

Printed bold and underlined are those combinations which in the view of the regulatory bodies concerned render the greatest contribution to safety.

6.6.1 Measuring, evaluation and reporting of the doses of plant personnel exposed to ionising radiation

Types of safety assessment ▶ / ▼ Types of safety requirement	**A** Direct inspections/analyses by regulator	**B** Inspections/analyses by operator – regulator is present	**C** Inspections/analyses by operator – regulator is not present	**D** Verification of operator's work processes
1 Features of the plant or plant operation	(CH) (FIN)	(US)	(CH) (S) (US)	**(CH)** **(D)** (S) **(FIN)**
2 Results of plant operation	(CH) (D) (FIN)	(CH) (US)	(CH) **(D)** (S) **(FIN)** (US)	
3 Plant risk				**(CH)**
4 Protection goals				(CH)

6.6.2 Monitoring of aerosol emissions in the stack

Types of safety assessment ▶ / ▼ Types of safety requirement	**A** Direct inspections/analyses by regulator	**B** Inspections/analyses by operator – regulator is present	**C** Inspections/analyses by operator – regulator is not present	**D** Verification of operator's work processes
1 Features of the plant or plant operation	(CH) **(D)**	(CH) **(D)** (US)	(CH) (US)	**(CH)** (S) **(FIN)**
2 Results of plant operation	**(CH)** (S)	(US)	**(CH)** **(D)** (S) **(FIN)** (US)	
3 Plant risk				(CH)
4 Protection goals				(CH)

6.6.3 Repair or replacement of a class 1 mechanical component

Types of safety assessment ▶ / ▼ Types of requirement	**A** Direct inspections/analyses by regulator	**B** Inspections/analyses by operator – regulator is present	**C** Inspections/analyses by operator – regulator is not present	**D** Verification of operator's work processes
1 Features of the plant or plant operation	**(CH)** **(D)** **(FIN)** (US)	**(CH)** **(D)**	(CH) (S) **(FIN)** (US)	(CH) (D) (S) (FIN) (US)
2 Results of plant operation				
3 Plant risk			(CH)	
4 Protection goals	($CH_{teilweise}$)		($CH_{teilweise}$)	

S (1C): Supervised and approved by a third party accredited control organisation.

6.6.4 Evaluation of reportable events (e.g. exceeding a limit value)

Types of safety assessment ▶ / ▼ Types of safety requirement	**A** Direct inspections/analyses by regulator	**B** Inspections/analyses by operator – regulator is present	**C** Inspections/analyses by operator – regulator is not present	**D** Verification of operator's work processes
1 Features of the plant or plant operation	**(D)** **(FIN)**		(CH) **(D)** (S) **(FIN)** (US)	**(CH)** (D) (S) (FIN)
2 Results of plant operation	**(CH)** (S) (US)	(US)	(CH) (D) (FIN) (US)	
3 Plant risk	(S)			(CH)
4 Protection goals	(CH) (S)			(CH)

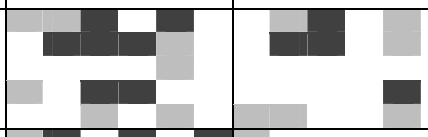
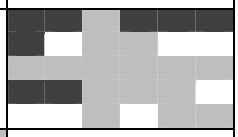
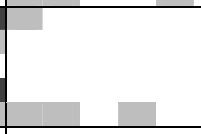
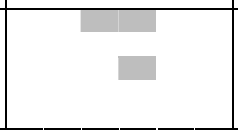
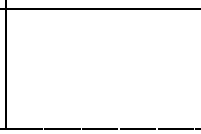
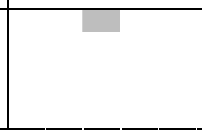
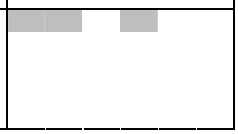
6.6.5 Qualification / requalification of a shift supervisor

Types of safety assessment ▶ / ▼ Types of safety requirement	**A** Direct inspections/analyses by regulator	**B** Inspections/analyses by operator – regulator is present	**C** Inspections/analyses by operator – regulator is not present	**D** Verification of operator's work processes
1 Features of the plant or plant operation	**(CH)** (D) (S) (US)	(CH) (D) **(FIN)** (US)	(CH) (D) (S) **(FIN)** (US)	**(CH)** (S) (FIN) (US)
2 Results of plant operation			(CH) (US)	
3 Plant risk				
4 Protection goals				

6.6.6 Measuring and evaluation of safety culture aspects

Types of safety assessment ► / ▼ Types of safety requirement	**A** Direct inspections/analyses by regulator	**B** Inspections/analyses by operator – regulator is present	**C** Inspections/analyses by operator – regulator is not present	**D** Verification of operator's work processes
1 Features of the plant or plant operation				**(CH)** (S) (US)
2 Results of plant operation	**(CH)** (D) **(FIN)** (US)		(CH) (D) (S) (FIN) (USteilweise)	(Dgeplant)
3 Plant risk				
4 Protection goals				

6.6.7 Synoptic table

Types of safety assessment ► / ▼ Types of safety requirement	**A** Direct inspections/analyses by regulator	**B** Inspections/analyses by operator – regulator is present	**C** Inspections/analyses by operator – regulator is not present	**D** Verification of operator's work processes
1 Features of the plant or plant operation				
2 Results of plant operation				
3 Plant risk				
4 Protection goals				

The synoptic table contains the information from all five countries for all six examples. Boxes are shown white in the table if a country has not mentioned this combination. Boxes are shown grey if a country mentioned the combination. Boxes are black if in the view of the regulatory body of a country this combination renders the greatest contribution to safety.

The practices adopted by the regulatory bodies of five countries are summarised here in terms of six examples of representative inspection activities. The regulatory bodies of Switzerland, Germany, Finland, Sweden and the USA provided information on their methods. It was found that the main focus of regulatory requirements is on features of the plant or plant operation; in other words, specific requirements to be met by technical systems and work processes. Another focus is on requirements concerning certain performance results, attention here being on performance indicators, and only partly on quantifiable indicators of safety. Requirements regarding limit values for accepted plant risks are scarcely considered at the plants in question; with most of the cases mentioned, it is a matter of obligations to estimate the risks of events, and from this derive any action to be taken. Requirements relating to protection goals are evidently felt to be largely covered by the requirements concerning features of

operation, and are therefore given in only a few instances, namely when none of the three other types of requirement is assessed, or if an additional safety barrier such as ALARA, for example, is to be applied.

The regulatory authorities use all four ways of assessment. In order to meet his responsibility for safety, the operator does much of the inspection himself or with his experts. In important cases, the regulator or its experts are present. Besides taking note of the operator's test results, the work of the regulators in the examples considered is spread roughly equally between inspecting the operator's work processes and conducting tests themselves or through their experts. It appears that most regulators have diversified their inspection activities in order to look at as many safety aspects as possible from different angles.

7 Recommendations by KSA to HSK

7.1 Introduction

As in the preceding chapters, the following recommendations relate to the interface between HSK as safety authority and the operator of a nuclear installation, in particular of a nuclear power plant, and not to the entire field of regulatory inspection. Of interest here is, on the one hand, the manner of establishing the regulatory requirements regarding safety (extremes: setting of protection goals or prescribing specific requirements of technical systems, procedures, etc.) and, on the other, the manner of regulatory inspection (extremes verification of work processes or verification of results obtained).

7.1.1 General principles

The following principles apply generally:

- HSK must reach its own conclusions about the plant's safety; it must therefore be thoroughly familiar with the plant and its operation.
- HSK should impose on the operator as little as possible, but as much as necessary.
- HSK should restrict itself to safety-relevant areas.
- HSK must not assume any of the operator's responsibility.
- HSK may take over work of common interest regarding safety, provided it is not plant-specific.
- HSK must be a competent interlocutor for the operator in matters of safety.
- HSK must ensure that its personnel are well trained in all safety-relevant areas.

7.1.2 Principles on the combination of safety requirements and ways of assessment

The following principles are recommended concerning the types of safety requirements and ways of assessment:

- HSK must not limit itself one-sidedly to one type of safety requirement or one way of assessment. HSK can obtain a full picture of all aspects of safety

only if it defines several safety requirements for specific safety matters, and carries out its assessments in a variety of ways.

- To make the best use of its resources, HSK should periodically review the type of safety requirement and manner and frequency of inspection, and change them if necessary.
- HSK's criteria for defining the safety requirement and assessment are:
  - results obtained by the operator;
  - evaluation of safety indicators;
  - knowledge gained from events in the surveyed plant and from other domestic and foreign plants;
  - the contribution to risk of a wrong action or failure of a system or component, taking account not only of the contribution to core damage frequency (CDF), but also the consequences of other disturbances such as exceeding a dose limit.

7.2 Types of safety requirement

7.2.1 Features of the plant or plant operation

It is essential that the requirements to be met by specified deterministic features of the plant and its operation are satisfied in accordance with the international state of the art, in particular

- to ensure a multi-level system of protection (defence in depth)
- and by defining important key safety-relevant factors.

These deterministic features are laid down in legislation and HSK's guidelines, and also in foreign and international regulations designated by HSK. These provide the operator with legal safeguards, HSK with the framework in which it performs its regulatory role, and the public with transparency.

HSK should endeavour to have the most important deterministic features and requirements formulated in ordinances, as is largely the case in the field of radiation protection.

7.2.2 Results of plant operation

The targeted safety-relevant operating results should be set down in the form of safety indicators. A value for each safety indicator should be defined, together with a permitted bandwidth for this value. If values are outside the band, action must be taken. The measured values are to be evaluated as follows:

- identification of trends, in order to be able to react in an early stage on emerging weaknesses;
- determination of priorities and intensity of regulatory inspection.

HSK should pursue its work on drawing up a full set of safety indicators. The resulting document should be clearly laid out and formulated, discussed with the parties concerned, and published as a guideline.

7.2.3 Plant risk

In addition to deterministic requirements, probabilistic objectives should be set as well. A prerequisite are plant-specific risk analyses (PSA). Core damage frequency and the release of large amounts of radioactive substances to the environment should be considered as particular risk elements. Risk analyses are mathematical models that should comply with the latest technical advances and reflect as closely as possible the plants' actual conditions. Since the scope of the model and the input data are subject to some uncertainty, the findings of a PSA should be used only as an additional decision base, supplementing the deterministic requirements and other inspection criteria. When setting probabilistic goals, attention should be paid on the variation (delta) rather than the absolute values.

KSA recommends to apply PSA for the following uses and, where appropriate, to define corresponding standard (or routine) values:

- To determine risk by means of state-of-the-art PSA methods standardised at least for Swiss plants. Standard (or routine) values are to be defined, plant-specific if necessary. Action to be taken according to results obtained, taking into account pre-defined criteria.
- For deciding on retrofits when risk can be reduced at reasonable expense, even below defined standard values (ALARA principle). The effort started by HSK on proposing criteria should be continued with priority, and discussed on a broad basis with those involved. The results should be issued in a guideline.
- To verify the effectiveness and appropriateness of existing requirements and safety measures. If no risk reduction can be demonstrated and if other criteria, such as defence in depth, are not violated, an existing requirement or safety measure can be abandoned. First the relevant provisions in ordinances, guidelines, etc. must be revised.
- To optimise safety measures in order to reduce risk at the same costs, or reduce costs at the same risk.
- In setting priorities for ageing surveillance and for regulatory inspections.
- As an aid in deciding whether operation can continue on the failure of safety equipment or measures, provided actions are not prescribed in the technical specifications.
- For evaluating events regarding risk increase (precursor analysis) and checking if the PSA model or individual input parameters need to be extended or corrected.
- To observe the risk pattern over a calendar year or overhaul period for analysing trends or checking that the set annual or downtime risk goals have been achieved.
- For regularly revising the PSA in order to reach a better match between the model and the actual plant conditions, for periodic adaptions to the latest state of the art or, case by case, to important new knowledge. Input parameters, in particular component data, must also take ageing into account.

7.2.4 Protection goals

Where no requirements have been defined in the form of plant and operational features or of risk values, the fundamental or derived protection goals should be used directly as safety requirements at the HSK/operator interface. Compliance with the protection goals must always be demonstrated by the operator and verified by HSK whenever modifications to the plant could have an influence on these protection goals. Protection goals also play an important role in actions taken in the case of beyond-design events.

7.3 Types of assessment

HSK should employ all types of assessment in its regulatory activities. Only in this way it is possible to identify and evaluate all aspects of plant safety. The following paragraphs give some suggestions concerning the choice and application of the four types of assessment.

7.3.1 Assessment by means of HSK inspections / analyses

HSK should carry out its own inspections/analyses only as far as no direct responsibility for the plant is involved. Inspections/analyses should be restricted to most significant parameters, in particular to those related to pronounced public interest (for example, emissions), or in certain cases, when they fulfil the purpose of maintaining specialist expertise.

7.3.2 Inspections / analyses by operator with HSK present

Inspections crucial to safety should be conducted in the presence of HSK or its experts (examples: personnel licensing examinations, in-service testing of safety-class pressurised mechanical components). For other important inspections, the frequency of HSK's attendance depends on the risk related to a test result, experience from and quality of earlier tests, the rating of relevant safety indicators and the training benefits gained for HSK personnel.

7.3.3 Inspections / analyses by operator

The findings of inspections/analyses by the operator should be reported to HSK or its experts, who should verify them critically.

7.3.4 Assessment by HSK of operator's work processes

HSK should place great emphasis on scrutinising the operator's safety-relevant work processes with regard to suitability and effectiveness (examples: nature and frequency of function tests on safety systems or of in-service tests on structures, sequence and test steps when starting up the plant). An auditable QM system with appropriate work instructions is a prerequisite. Regulatory assessments are made by reference to written records supplemented by interviews with those concerned and random observation of processes in action. The decision on which processes to inspect lies with HSK and depends on, among other things, the risk involved, the findings of previous inspections and the rating of relevant safety indicators. This kind of assessment requires both technical

expertise and QM skills; the HSK personnel engaged in this work must be trained accordingly.

7.4 Comments to the examples of inspection practice

The tables in Section 6.6 are limited to six examples of inspection activity. Each of the responding regulatory authorities filled out several boxes for each subject, i.e. in each case numerous types of requirement are specified, and/or numerous ways of assessment practised. The intensity in absolute terms with which the respective inspection activities are carried out is not evident from the tables, but their relative significance can be seen, if only roughly, by indicating the activities considered most important.

The following can be deduced from the tables:

(1) Measuring, evaluation and reporting of the doses of plant personnel exposed to ionising radiation

The majority of the regulators see the main focus of their activity in inspecting and analysing the operator's work processes; for the Swedish authority, this is its only inspection activity for this example of inspection activity. (1D)

Germany, Finland (and presumably also Sweden) see a major contribution to safety in the measuring of doses by the operator. (2C)

Switzerland, Finland and Germany also carry out their own dose measurements, the first two on a random basis, while Germany conducts full official measurements with separate TLDs. (2A)

Switzerland approves the dosimetry laboratory, Finland mentions only random checks to verify the reliability of the measuring equipment, while Germany and Sweden make no reference to this aspect. (1A)

Switzerland is the only authority to mention the setting of annual radiation protection goals and surveillance of the optimisation of activities with elevated dosage, this last as major focus. (3D, 4D)

Recommendation to HSK:

– As regards intensity of inspection for this subject, Switzerland clearly tops the list (possibly with Germany). Current practice should essentially be continued; the efforts made in Switzerland have proved worthwhile. The effort and necessity of activity (2B) "participation in operator's measurements" could perhaps be reviewed.

(2) Monitoring of aerosol emissions

The majority of authorities filled out boxes (1D) and (2C), most of them as a major focus.

Boxes (1A), (1C) and (2A) are filled out by Switzerland and only one additional country.

Only Switzerland filled out boxes (3D) and (4D). Other countries may practise similar activities as well but did not indicate because they did not deem it a principal stage of the supervisory process.

Sweden filling out box (2A) (regulatory random measurement of aerosol filters) is surprising, as inspection there is otherwise restricted to processes (1D).

Recommendation to HSK:

– Following the unmeasured release of aerosols from Mühleberg in 1986, close attention was paid to this measurement in Swiss NPPs. The entries in the various boxes show that this still seems to be justified, although the total effort should no longer be high.

(3) Repair or replacement of a class 1 mechanical component

The manufacture, testing and repair of pressure-retaining structures are subject to strict formal regulations in all countries.

In the USA, the ASME is authorised to certify the involved companies and people generically for the processes concerned, hence boxes (1D) and (1C) are filled out.

In Europe, the operatives have to be licensed by the officially recognised organisation specifically for the work in question (1D). The work is done under the supervision of the operator and usually also the regulator or its experts (1C, 1B). Except for Sweden, before the work is done, the regulatory body checks that the planned action is appropriate as regards overall safety (1A), for example the decision for repair or replacement.

The operator may, or in Switzerland must, make an assessment of risk to justify his decision on execution, nature and timing of the repair (3C).

Recommendations to HSK:

– The current practice should be continued, with attention paid to developing and maintaining the technical expertise both of HSK and of its experts.

– The ability to determine in detail the risk represented by damaged mechanical components should be further refined and nurtured.

(4) Evaluation of reportable events

In all countries, the operator's instructions on what to do in case of events are checked by the regulator to verify that they exist and comply with requirements (1D). This is presumably also true in the USA, although it is not explicitly mentioned.

In all countries, events are evaluated by the operator (1C, 2C if set safety indicators are concerned).

In all countries, the event reports are examined by the regulator and further evaluated, e.g. for conformity with assumptions in the safety analysis, to establish its own indicators, etc. (1A; where appropriate 2A, 3A, 4A), insofar as indicators, risk or protection goals are to be applied as prescribed yardsticks.

Recommendations to HSK:

- The activities stated by HSK should be expanded. In particular, HSK should set up a database and maintain systematic documentation on all events in Swiss NPPs, and on relevant events in NPPs abroad. The events should be coded, for example according to IRS (Incident Reporting System of the IAEA/NEA) or WANO.
- Where safety-related equipment is concerned, HSK should in each case assess the added risk caused by the event, i.e. request (and verify) appropriate analyses by the operator, or carry them out itself (3A).

(5) Qualification / requalification of a shift supervisor

It is assumed that the operator's processes are examined in all countries (1D, not explicitly stated in the case of Germany).

Shift supervisors are licensed in Switzerland and the USA, but not in Sweden, where the quality and results of the operator's qualification process is subject to random inspection only.

Recommendations to HSK:

- The shift supervisor is a key factor in the plant's safety. His knowledge and skills must therefore be tested regularly. Swiss practice conforms largely to that in most other countries. There is no necessity for radical changes. Regarding qualification, HSK must verify that knowledge and skills are comprehensive. With regard to requalification, HSK should review the process regularly and verify that criteria are defined, review the requalification reports and make its own observations.
- Practical experience shows that mistakes frequently occur when assessments have to be made quickly during plant operation. The reason for this, beside incomplete or unclear instructions, is often a poor overall view of the circumstances crucial to the situation in question. Care must be taken to ensure that shift supervisors, and picket engineers as well, are informed about events that occurred in their own and in comparable plants elsewhere, and about how they were dealt with.

(6) Measuring and evaluation of safety culture aspects

Switzerland, Sweden and the USA inspect the operator's documents with regard to the processes applied for assessing safety culture (1D). Germany plans to assess the processes practised (2D).

In all considered countries, assessment is done by the operator (2C) and – except in Sweden – also separately by the regulator (2A), the latter being seen as important by Switzerland and Finland.

Recommendations to HSK:

- HSK should encourage the development and use of indicators for safety culture.
- HSK should continue to use and refine the method of situative analysis for assessing safety culture.

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