Nuclear Regulation ISBN 92-64-02132-9

Nuclear Regulatory Review of Licensee Self-assessment (LSA)

NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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NUCLEAR ENERGY AGENCY

The OECD Nuclear Energy Agency (NEA) was established on 1st February 1958 under the name of the OEEC European Nuclear Energy Agency. It received its present designation on 20th April 1972, when Japan became its first non-European full Member. NEA membership today consists of 28 OECD Member countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, Norway, Portugal, Republic of Korea, Slovak Republic, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The Commission of the European Communities also takes part in the work of the Agency.

The mission of the NEA is:

- to assist its Member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as
- to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

FOREWORD

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international body made up of senior representatives from nuclear regulatory bodies. The Committee guides the NEA programme concerning the regulation, licensing and inspection of nuclear installations with respect to safety. It acts as a forum for the exchange of information and experience, and for the review of developments which could affect regulatory requirements.

This report was prepared based on input from the "Contact Network of Regulatory Experts" set up by the CNRA, with technical and secretarial assistance by Kurt Asmis, Barry Kaufer and Laure Geffroy. The Network mainly corresponded by e-mail, but also met on 19-20 September 2002 at NEA headquarters in Paris. Those attending the meeting were: Kurt Asmis, Bill Borchardt, Gerhard Feige, Rudolf Görtz, Barry Kaufer, Lyn Summers, Nobuo Tanaka and Jiri Vesely. The meeting proposed a draft report, which was circulated amongst all of the Network members. The other members of the Network included Albert Frischtnecht, Seija Suksi, András Tóth, Christer Viktorsson and Norio Watanabe.

The Network wishes to acknowledge the valuable contribution of Andrew Kadak, former President of Yankee Atomic and now Professor of Nuclear Engineering at the Massachusetts Institute of Technology, who provided a perspective from the licensee point of view.

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1. INTRODUCTION

Licensee self-assessment (LSA) was discussed at a number of CNRA meetings. In the summer of 2001 the CNRA membership was a sent a questionnaire on the subject that resulted in a report that was presented to the CNRA at the December 2001 meeting.

At the December 2001 meeting, the CNRA requested the Secretariat to follow up on answers given in the questionnaire with the assistance of the "Contact Network of Regulatory Experts", nominated by CNRA members. Specifically, the CNRA requested a report on LSA that was to include:

- definition of LSA, and
- a recommendation for a general response strategy to LSA by regulators.

The report as prepared is a short "principles" document that is intended to close the current effort on LSA.

The Network also discussed the relationship of quality assurance (QA) and periodic safety review (PSR) to LSA, but decided not to include these discussions in the document. The main difficulty in this area is that regulators have very different perspectives of QA. Many define QA as being a process of assuring that processes are adequate and being followed, while others think of QA as being total quality management (TQM). For the former the statement that QA is part of LSA is correct while for the latter LSA is an integral part of TQM.

2. WHAT IS LSA?

Description

LSA is described as all the activities that a licensee performs in order to identify opportunities for improvements.

The following elements amplify the compact description above:

- Helps organisations to find potential plant improvements, as well as policies, procedures and practises, which may be improved.
- Is an on-going process expected from a high reliability organisation.
- Assesses safety, quality and related issue performance against regulations, internal rules, industry standards, etc.
- Includes activities on and off site (offsite would include such entities as: corporate offices, engineering services, laboratory services, etc. that may be situated external to the site but provide services to the site).
- Should be performed by each level of management including the top management and individual workers.
- Should be a systematic and complete evaluation by the licensee of its technical, organisational, personnel and administrative arrangements.
- Should address declining performance.
- Results in improvement actions.

It is evident from the above definition and the amplifying bullets that LSA is part of the organisation's holistic management system, which must include other process elements. Particularly important elements are: a process

for choosing which identified potential improvements are to be taken forward for implementation and a process of project management for implementation of improvements.

LSA may be an integral part of a licensee's managed processes that is expected to bring an operating organisation to a higher level of performance in:

- safety;
- efficiency;
- economics.

Nuclear Safety Regulators expect the licensee to run an effective LSA programme, which shows the licensee's "priority to safety", as required, for example, by the Convention on Nuclear Safety.

3. REGULATORY APPROACHES TO LSA

Goal

An effective licensee self-assessment (LSA) programme should result in improved safety performance. In addition, the insights LSA produces and the potential for improvements in safety performance, commends it to regulators and offers to them the opportunity for increased regulatory effectiveness.

Strategy

In order to realise the goal, the regulatory body should seek evidence of:

- Management providing support and adequate funds.
- All the elements included under description in Section 2 are present.
- A formally defined and properly implemented process.
- The process operating on a written hierarchical basis and includes:
  - policies;
  - processes;
  - procedures.
- Appropriate and timely notification to the regulatory body to enhance the opportunities for regulatory oversight.
- Appropriate communication of results (e.g., public, regulatory body, licensee's staff).
- Delivery and implementation of improvements.
- Programme being subject to independent review.

Fulfilling the above, including satisfactory results of regulatory oversight, LSA may offer the opportunity for adjusting regulatory oversight.

4. RECOMMENDATIONS

This report attempts to answer the questions asked by CNRA in recent meetings. If the CNRA wishes to further explore this area then the TG has developed the following options:

- Seek industry views and experience through dialog with licensees and other appropriate organisations.

- Obtain input from other CNRA groups (e.g. Effectiveness Group, Performance Indicators (PI) Group, WGIP).

- Obtain input from other CSNI groups (e.g. SEGHOF).

- Explore ways that the regulatory body may review the licensee's LSA activities and programmes and judge adequacy.

Appendix A

SURVEY

1. Licensee self-assessment (LSA) can be defined in many different terms. Please provide brief description of what licensee self-assessment means.

2. Do you have any requirements on licensees to perform self-assessment? If so please describe.

3. How does the regulatory body assess and inspect LSA programmes? Is it a systematic process?

4. How are the results from a licensee self-assessment evaluated and what steps are taken the regulatory body?

5. Does the regulator follow-up on corrective actions taken by the licensee as a result of LSA?

6. What "credit" if any is given to the licensee for performing an LSA (i.e., decreased inspections, etc.)?

7. Licensee self-assessment and periodic safety reviews:

   - If a periodic safety review (PSR) is performed in your country, are LSAs also performed?

   - What type of frequency is required for LSAs and how are they different from the PSR?

8. What other issues relating to licensee self-assessment would you like to see discussed by CNRA?

Appendix B

SUMMARY OF RESULTS

The results of the questionnaire proved a valuable basis for assessing member countries' views about licensee self-assessment. The preliminary analysis of the results clearly shows that while wide differences exist and there is basically no standard approaches taken. A majority of countries would welcome more information exchange by the CNRA, especially for the following issues:

- possibility of harmonisation of LSA programmes;
- best practices;
- value added (e.g., results achieved);
- performance metrics.

Discussion in these issues may be beneficial towards determining whether further international collaboration will help advance the topic as well as providing input to areas of regulatory challenges being reviewed by CNRA. Other areas CNRA may want to consider as further steps are:

- Identifying types of criteria useful to individual member countries.
- Establishing tools on implementing an LSA programme.
- Development of methods for assessing the effectiveness of LSA programmes.

The following sections provide a preliminary summary for each question. While it is difficult to attain exact commonalties by the responses received, it is possible to identify several major aspects from each area surveyed. It is important to note that in the following summaries, specific countries are referred to in many cases. These are used to provide examples and are not

meant to be inclusive. Other countries responding may also have like or similar requirements. The summaries are not intended to provide an in-depth review of the responses, but rather an overall perspective of the issues

Definition

While the wording differed in each case, the overall definitions provided were basically along the same lines. One good perspective was provided by the Netherlands, which stated that "LSA is a systematic evaluation by the licensee of all its technical, organisational, personnel and administrative arrangements in order to improve safety." A more general definition was offered in the US response, which stated, "LSA is generally defined as those activities conducted by licensees to monitor and evaluate various aspects of organisational performance."

The responses in themselves showed many differences in what regulators expect of an LSA and in consequence raised several additional issues in how LSA is defined, including:

- Is LSA a continuous process that covers activities over the lifetime of the plant (e.g. Czech Republic and Sweden), part of the QA system (e.g. Germany, Hungary and Switzerland), a one-time process or dependent entirely on the licensee?

- What specific area does an LSA cover (e.g. technical, organisational, operations, etc.) and what aspects should be looked at (e.g. non-conformances, areas of improvement, declining performance, etc.).

- Is LSA performed as a voluntary process (e.g. Japan) or a mandatory process? Should it be carried out by the licensee or an independent party contracted by the licensee.

The question that remains for CNRA to answer is whether there should be an internationally accepted definition of licensee self-assessment. A more thorough review of the IAEA standards and guidelines as well as the work performed by INSAG may be helpful in this area.

LSA Requirements

While not all countries have a specific legal requirement for LSA, the responses show that the most regulators have some type of standards, auditing

system or process set-up, most commonly associated with quality assurance (QA), which obligates (not necessarily legally) the licensee to have a self-assessment process. It is important to note, as pointed out by the UK response, that "the self-assessment process should be regarded as something different from a pure quality assurance programme in that one of its functions should be to check that at all times the plant is operated within the boundary conditions defined in its safety case."

Several countries (e.g. Sweden) have a continuous process supplemented by documenting and carrying out corrective actions. Other countries rely more on general requirements and pro-actively encourage licensees to conduct self-assessments.

Therefore some key elements are:

- While not all countries have a specific legal requirement for LSA, the responses show that the most regulators have some type of standards, auditing system or process set-up, most commonly associated with quality assurance (QA), which obligates (not necessarily legally) the licensee to have a self-assessment process.

- The responses show that while most countries do not have a legal requirement, per se, most expect the licensee to perform LSA and to monitor the results.

- Some countries require that LSAs plans be submitted for approval prior to implementing them.

Assessment and Inspection of LSA Programmes

A few countries (e.g. Australia, Czech Republic, Hungary) noted that they have programmes to assess LSAs while others (e.g. Finland, Hungary, Sweden, Switzerland, United States) regularly inspect specific aspects of licensees' assessments. Several countries (e.g. France, United States) pay special attention to ensure that corrective actions have been implemented.

Several mention the need for the regulator to remain completely independent in the LSA process. This is considered essential to allow the licensee to be able to fairly assess himself (e.g. it is noted that without this element the licensee may not be as thorough and frank and willing to make self-criticisms of his performance).

Evaluation and Regulatory Actions

Various timing (scheduling) and varying levels of degree are taken by regulatory bodies in evaluating LSAs. For example, Finland and the UK perform "spot" checks. Inspection results are used by Sweden (into the integrated safety assessment), Switzerland and as part of the US baseline inspection (selected) programme.

The Czech Republic, Japan and a few others receive results of LSAs performed. France receives a yearly report.

As noted above, results receive differing levels of review from. A few countries carry out checks to ensure that licensees have capability to perform LSA, but do perform detailed assessments of results. Several other countries evaluate the results as part of a larger assessment (e.g. Swedish integrated assessment programme, QM process in Switzerland, etc.).

Several countries (e.g. Netherlands, Japan, United States) note the need to ensure that appropriate corrective actions are implemented.

Corrective Actions as a result of LSA

The use of inspections is most frequently quoted as how regulators follow-up on the implementation of corrective actions found as a result of LSA. A few countries (e.g. Japan, Switzerland) have formalised processes through the periodic safety review or quality management systems.

Regulatory Credit for LSA

No country gives credit for LSA, with the exception that the US, under the revised Oversight programme, does recognise LSA during supplemental inspections (although this depends on the effectiveness of the LSA process) and Australia, which noted that satisfactory performance of LSA may lead to reduced regulatory surveillance.

Several countries note that a strong and effective LSA programme by the licensee does enhance co-operation with the regulator in the overall evaluation process. For example, SKI maintains sort of minimum inspection and assessment program of all licensees. Strong confidence in a licensee's self-assessment process will mean less active activities in relation to that licensee.

Periodic safety review versus LSA

Most countries distinguish specific differences between PSR and LSA mainly that LSA is a continuous process and are performed more routinely while periodic safety reviews (PSRs) are 10-year overall assessments of the plant as to the current SOAR.

LSAs are also considered more or less to be a continuous process, although reporting is most often done at a fixed time (e.g. 1-year period). PSR are seen by some countries as a special case of LSA. Additionally LSA is perceived by some to be a more dynamic process continuously reactive to safety challenges.

Appendix C

COMPILATION OF RESPONSES TO SURVEY

1. Licensee self-assessment can be defined in many different terms. Please provide a brief description of what licensee self-assessment means.

Australia

Licensee self-assessment is the process by which the responsible safety approval body of the licensee satisfies itself that the particular conduct with any radiation or nuclear safety implications meets applicable safety and regulatory requirements. The *Responsible Safety Approval Body* means the licence holder's committee, group or individual with responsibility for ensuring the adequate safety review of an operation, procedure or experiment, and with the authority to approve the safe conduct of the reviewed modification, operation, procedure or experiment. See the ANSTO Licence Conditions Handbook available at http://www.arpansa.gov.au/pubs/ansto_hndbk.pdf.

Czech Republic

Licensee self-assessment covers all their activities during lifetime of NPP. It consists in assessment of operational and safety indicators:

- annual report with results of all activities;
- regular evaluation of all events;
- "Living" SAR (annually updated);
- internal questionnaire.

Finland

In the STUK's regulatory guides a reference is made to the IAEA Safety Series document Nn 50-C/S/SG-Q (Code and Safety Guide 5). This document gives a detailed view on "management self-assessment". ISO 9000 defines management review etc. which are, as well, elements of self-assessment.

According to this self-assessment means all assessments carried out by licensee according to some criteria. These criteria can be either made by licensee itself (focus usually on improving quality of single processes) or it can be made by some external organisation for example EFQM or MB criteria (focus usually on improving total quality of the organisation). Self-assessment helps organisation to find sectors and procedures, which need to be improved.

France

Self-assessment means an assessment by a special division of the corporate (EdF) which is distinct from the power plant staff, i.e. not in charge of its operation.

This assessment is dedicated to assess the performance with respect to safety, quality and related issues, based on regulation and internal rules. This assessment is mainly use for management purposes.

Utility self-assessment is conducted by EDF at three different levels:

- at the site level by the safety quality team which is independent from the operation team;
- at the corporate nuclear division level by inspection and reports;
- at the headquarter corporate level by the general safety inspectorate.

Germany

German regulations demand that licensees have to maintain an encompassing QA system. The scope of this QA system is outlined in KTA standard No. 1401. Accordingly, the licensee is to maintain a hierarchically independent quality management structure which is charged – amongst other duties – with internal and external (i.e. supplier) quality audits. Complementary to this "licensee-internal" self-assessment, the German licensees in 1998

initiated a national peer review programme of external assessments. The former as well as the latter can both be regarded as licensee self-assessments, as there is no direct involvement of the regulatory body. Should the peer review lead to insights that trigger the licensees' notification obligations the regulatory body would be involved.

Hungary

LSA according to regulatory code: "QA rules for NPPs" consists of management self-assessment and independent internal or external assessment.

Management self-assessment should be performed regularly on each level of the management including the top management to evaluate management processes, identify and eliminate their weaknesses and obstacles in achieving safety goals.

Independent self-assessment can be performed either by an internal organisation, independent of the assessed line organisation, or by an external organisation (e.g. QA-expert organisations, IAEA or WANO missions or the regulatory body itself).

The scope of independent self-assessment should cover every activity important for the safety.

Self-assessment of the subcontractors (persons and organisations) is not included in the regulatory code, but it is supposed to be performed according to internal QA-requirements of the utility.

Japan

Licensee self-assessment (LSA) can be defined as voluntary-based safety evaluation and action carried out by licensees that are authorised by the regulatory body. In Japan, typical examples are the executions of periodic safety reviews (PSR) and the implementation of accident management plans (AM).

Netherlands

A systematic evaluation by the licensee of all its technical, organisational, personnel and administrative arrangements in order to improve safety.

The evaluation may be initiated by the licensee himself or be a result of a requirement in the licence or a request of the RB.

Norway

LSA means the licensee's own assessment of the safety of the installations. It can be a part of the system for internal control or quality assurance of health, environment and safety.

Sweden

Licensee self-assessment or self-inspection that we prefer to call it in Sweden means for us all the activities that the licensee undertakes to establish goals and objectives as well as control and evaluate its actions to ensure safety is maintained and that all safety requirements are fulfilled.

Licensee self-assessment should be seen as a continuous process where each aspect of safe operation is continually evaluated to identify compliance and also where opportunities for improvement are taken into account. In the rest of the document the expression self-assessment is used in the sense mentioned above.

Switzerland

We are using the INSAG 12 Chapter 3.3.3 Self-Assessment: Self-assessment for all important activities at a nuclear plant ensures the involvement of personnel performing line functions in detecting problems concerning safety and performance and solving them.

Concerning the QA-Process, Management Self-assessment is described in IAEA Safety Series No. 50-C/G-Q "Quality Assurance" Guide 5: "Assessment of the Implementation of the Quality Assurance Programme". Other IAEA guidelines e.g. PROSPER exist (should replace the former ASSET self-assessment).

HSK relies heavily on the definitions mentioned in the above documents.

United Kingdom

Licensee self-assessment from the UK standpoint means that the licensee has an effective process for uncovering both non-compliances and potential areas for improvement which it operates on its own behalf, and without dependence on the external regulator. Implicit in this is that having discovered non-compliances and areas for improvement, the licensee has effective means for rectifying the situation, both in relation to the particular non-compliance which has been discovered, and also in order to reduce the chances of non-compliance in this and related areas in the future.

United States

In the U.S., licensee self-assessment is generally defined as those activities conducted by licensees to monitor and evaluate various aspects of organisational performance. In a broad sense, self-assessment activities include those required by NRC regulations, such as periodic quality assurance audits, as well as those that are voluntary, such as those directed at improving safety or economic performance. Self-assessments may also be performed to address declining performance trends or as necessary to assess the extent of condition of identified issues. Self-assessment can take many forms and be performed by various levels throughout the organisation from top management through line management and down to individual workers.

2. Do you have any requirements on licensees to perform self-assessment? If so please describe.

Australia

The Standard Licence Conditions for Particular Conducts at Controlled Facilities (research reactor, spent fuel storage facilities) operated by ANSTO, Section 4.1.1 specifies the following condition: *12 Safety Approval.* The licence holder must maintain current approvals by the licence holder's responsible safety approval body for all dealings and conducts authorised under a facility licence. See Internet document (question 1) for further details.

Czech Republic

General requirements for assessment of licensee activities are in Atomic Act No.:18/97 Coll. which requires in *Article 17* "General Obligations of Licensees" to "assess in a systematic and comprehensive manner the fulfilment of conditions set in Article 4, from the aspect of the current level of science and technology, and ensure that the assessment results are put into practice" and in *Article 18* "Obligations from the Aspect of Nuclear Safety, Radiation Protection, Physical Protection and Emergency Preparedness" to "monitor, measure, **evaluate**, verify and record values, parameters and facts with an impact on nuclear safety, radiation protection, physical protection and emergency preparedness, to the extent laid down in an implementing regulations". Concrete requirements (see question No.1) are done by the SÚJB Letters and decisions.

Finland

The Decision of the State Council sets the general criteria of quality management. The YVL-guides issued by STUK supplement these criteria's. In our YVL-guides (rules) there are some requirements for licensees quality assurance. In YVL 1.4 (Quality Assurance for Nuclear Power Plants 20.9.1991) there are requirements for licensees quality assurance programs and in YVL 1.9 (Quality assurance during operation of nuclear power plant 13.11.1991) there are requirements for QA during operation, LSA can be an element in licensees quality assurance programme.

France

The French "quality" order (August 1984) requires, in its article 9, a continuous surveillance action supplemented by corrective actions. Self-assessment shall also be performed when specifics problems arise.

Germany

LSA is not explicitly called for in the German regulations. However, the German nuclear (KTA) standard No. 1401 explicitly stipulates that "... the licensee is responsible for planning, conducting and auditing the effectiveness of QA measures..." And further: "The licensee has to assure that all companies involved in QA matters – which means the licensee proper, his contractors and subcontractors – plan and realise QA according to the rules laid down in this

standard". Further: "...persons charged with installation and auditing of the QA system must be empowered to ... control adherence to predefined QA measures. These persons must not belong to the personnel named under subtitle a) [i.e. personnel charged with planning, design, procurement, production, and installation of items, erection of buildings, start-up of plant, and operation of plant]."

Based on this requirement, the regulatory authorities demand that the licensee submit QM documents – i.e. QM handbook and, to the authorities' discretion, yearly schedules for the audits.

Hungary

The regulatory code: "QA-rules for NPP-s" requires performing LSA according to IAEA safety code: 50-C-Q (1996). The "QA-rules" are actually an adopted version of the IAEA code.

Japan

Basically, yes. The requirements are not legal ones but are to be followed by licensees. Licensees submit their plans on the self-assessment and then, the Nuclear and Industrial Safety Agency (NISA) of METI approves the plans. If licensees change the plans, they need to re-submit the revised plans and NISA reviews them.

Netherlands

Yes, stated in the licence (see introduction).

Norway

The NRPA requires that the system for internal control is kept updated. This should be a continuous process.

Sweden

According to SKI's regulation SKIFS 98:1 (available on www.ski.se):

- The licensee shall maintain an efficient and effective self-assessment programme including a two-step safety review system, a primary and an independent as well as a clear safety strategy, total quality management system encompassing all activities important to safety and a solid decision-making system.

- The safety of nuclear facility shall be continuously analysed and assessed in a systematic manner. Any need for safety improvement measures, engineering as well as organisational, which arise as a result of such analyses and assessment, shall be documented in a safety programme. The programme shall be updated on an annual basis.

Thus, self-assessment is not seen as some isolated effort by the licensee such as PSR or internal or external peer-reviews. Such efforts are done in Sweden also, but for us self-assessment means the continuous process referred to above.

Switzerland

HSK required the compliance of the Licensees QA-Programmes with 50-C/G-Q. In this context Management Self Assessment of the Licensees is part of it, Safety Performance Indicators and other operating results have to be considered. The IAEA PROSPER Guideline may also be used in the special area of operating experience feedback.

In regular Management Meetings HSK discusses the NPPs annual goals and their achievement. Deviations from goals are also part of the discussions.

A regular formal self-assessment process is not established yet at Swiss NPPs.

United Kingdom

For many years the UK has sought to persuade licensees to have their own departments, separate from the operational management at licensed sites, and in general reporting to a headquarters department, which could carry out surveillance and compliance checking activities on any matters affecting safety.

There is, however no legal requirement for such a department except in general terms by virtue of a licence condition which requires the licensee to have adequate quality assurance arrangements. The self-assessment process should be regarded as something different from a pure quality assurance programme in that one of its functions should be to check that at all times the plant is operated within the boundary conditions defined in its safety case. In its pure sense, quality assurance can amount to merely a process of checking compliance with documented procedures, which may themselves be incomplete, inadequate or unsafe.

United States

Criterion XVIII of Appendix B to 10 CFR Part 50, requires licensees to establish a comprehensive system of audits to verify compliance with all aspects of the quality assurance programme and to verify the programme's effectiveness for safety-related equipment. Other NRC regulations are more specific to the plant support areas of emergency preparedness, security, and radiation protection. For example, Criterion IV to Appendix E of 10 CFR Part 50 requires licensees to conduct periodic drills and critiques of the emergency response plans. Also,10CFR20.11.1 requires that licensees periodically review the radiation protection programme and its implementation. Requirements regarding the conduct of security audits are contained in 10CFR Part 73.55.

The NRC has also encouraged licensees to conduct self-assessments to determine the extent of performance problems once risk significant performance issues have been identified. The NRC's revised reactor oversight process assumes that licensees will perform such self-assessments, which will then be reviewed by NRC inspectors. The depth and breadth. of the safety assessments should correspond to the risk significance and complexity of the identified performance issues.

3. How does the regulatory body assess and inspect LSA programmes? Is it a systematic process?

Australia

A systematic process for regulatory assessment of the LSA programmes has been introduced via the ANSTO Licence Conditions Handbook Section 4.1.1 Standard Licence Conditions for Particular Conducts at Controlled Facilities. These include requirements for periodic and annual reporting by the licensee to the regulator (conditions 22, 23), licensee safety management arrangements (conditions

10 to 15), assessment and reporting of abnormal occurrences, incidents and accidents (18, 19) and modifications and relevant changes (24 to 29, particularly condition 25 requiring adequate review). The ARPANS Act and Regulations (available at http://www.arpansa.gov.au/reg_fun.htm#acts) establish an inspection system by which the regulatory body may conduct inspections to ascertain compliance with the conditions related to the LSA programmes.

Czech Republic

The Regulatory Body (SÚJB) regularly assess LSA programme in this process:

- Annually – during the common meeting with licensee – the operational indicators are:
  - annual report of licensee;
  - the "Living" SAR.

- Monthly – evaluation of events on common event commission meeting – it is ever subject of regular inspection with conclusions in monthly protocols.

Finland

STUK does not have any separate assessment or inspection specified for LSA-programmes, but these are assessed and inspected as a part of assessment or inspection of licensees QA.

LSAs are also inspected in our periodic inspection programme. It contains 16 different inspections and one of those is Safety Management. This is a regular inspection and it is carried out once in two years.

France

French regulator does not systematically assess and inspect LSA programmes.

Regulatory body checks that all necessary corrective actions are implemented.

The regulator remains independent and does not interfere with LSA in order not to disturb the internal process of the operator.

Germany

As stated before, regulatory authorities have the licensees submit their QM handbooks and pertaining documentation. And as LSA procedures (i.e., internal audits and supplier audits) are integral part of the QM system, they are assessed by the regulatory authorities. The national peer review programme being a complementary and voluntary effort of the German licensees, it is not assessed or supervised by the authorities.

Hungary

Assessment and inspection of LSA by the RB is a systematic process. According to inspection procedure of HAEA NSD: N ° 3.2.1 – "Inspection of QA-system of the Licensee" an inspection of the top management's self-assessment should be performed by the head of NSD once a year. The performance of independent LSA (including follow-up of the corrective actions) should be performed by the inspection department permanently and evaluated once a year.

Japan

As mentioned above, NISA reviews and approves the LSA programmes submitted by licensees in consideration of the necessity of changes in design and/or operating procedures. When doing that, if necessary, the advisory committee of NISA is consulted. Also, NISA reports the review results to the Nuclear Safety Commission (NSC). The assessment of the LSA programmes is conducted in the systematic process through the review by the standing committee of NISA.

Netherlands

NPP Borssele has developed and described a system of "main-processes" in which all organisational aspects, communications and responsibilities are described to perform a "main-process" in an adequate manner.

At the 2-yearly assessment this scheme is used. Before starting the assessment the set-up, including special subjects must be approved by the RB.

At the 10-yearly assessment it is very important that at the start of the real evaluation there is agreement between licensee and RB on the inventory of

issues to be addressed as well as on the current licensing basis in which the current requirements and knowledge on nuclear safety are collected.

Norway

The LSA programmes are reviewed during the licensing process and followed up at ordinary inspections.

Sweden

One of the main components in SKI's regulatory strategy is the requirement of the licensee to maintain a self-assessment programme to control compliance with regulations. SKI oversight focuses mainly on the activities of the licensees in this respect, and SKI shall convince itself that the licensees have full control with regard to safety of plant processes as well as of organisational processes. Moreover, SKI shall supervise that the licensee's self-assessment:

- Is organised in an effective manner with sufficient staff and competence and that there are clear responsibilities and delegation/authorisation.

- Is conducted with sufficient quality supported by well-suited procedures, methods and tools.

The detailed content of SKI's oversight programme is decided in an annual budget and planning process. In many of the SKI oversight efforts and especially in the inspection activities, the quality of the licensees' self-assessment programme is reviewed and thus constitutes an important factor. Also, SKI reviews a sample of those notified modifications that SKI considers are of special importance to safety. This concerns technical as well as organisational modifications.

Switzerland

HSK regularly inspects the QA processes of the Licensees. The Self-Assessment Process will be part of these inspections. Reportable events or other Non-conformances may also trigger an inspection on self-assessment.

United Kingdom

The NII does carry out checks to ensure that the licensee has both adequate staff and systems for performing the licensee self-assessment process described in answers 1 and 2 above. There is however a general policy of not looking closely at the detailed results of specific self-assessment checks and investigations. The same applies to QA audits carried out by the licensee. The reasons for this are to allow the licensee to be absolutely frank in making self criticisms. If these were examined too closely by the NII, the general view is that the thoroughness and frankness of these reports would quickly become degraded: they would become sanitised and would lose their value.

United States

The NRC evaluates licensee self-assessments as part of its baseline inspection programme that is implemented at all facilities and during supplemental inspections performed in response to risk significant performance issues. In the baseline programme, selected licensee self-assessments are reviewed during periodic inspections of licensee problem identification and corrective action programmes.[1] The focus of these inspections is to verify that when safety issues are identified during self-assessments, they are appropriately evaluated, prioritised, and corrected. The results of the licensee's self-assessments are also compared against NRC inspection findings to see whether the licensee and the NRC have a common understanding of problem areas. In the emergency preparedness area, licensee critiques of emergency drills are reviewed in an annual baseline inspection.[2]

NRC supplemental inspections are focused on a licensee's assessment of specific performance issues. Specific supplemental inspection procedures have been developed that are implemented based upon the safety significance and nature of the identified issue.[3] The supplemental inspection procedures are listed in the NRC's Assessment Action Matrix.[4]

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1. NRC Inspection Procedure 71152, "Identification and Resolution of Problems".

2. NRC Inspection Procedure 71114.01, "Exercise Evaluation" and 71114.06, "Drill Evaluation".

3. NRC Inspection Procedures 95001, "Inspection for One or Two White Inputs in a Strategic Performance Area"; Ip 95002, "Inspection for One Degraded Cornerstone or Any Three White Inputs in a Strategic Performance Area"; and Ip 95003,

The ability of a licensee to perform effective self-assessments is also a criteria that is used in determining what, if any, additional regulatory actions are necessary should a significant safety issue be identified. These additional actions could range from additional inspections, orders, or ultimately, shutdown of the facility.

4. How are the results from a licensee self-assessment evaluated and what steps are taken the regulatory body?

Australia

Results of the LSA are routinely reviewed against the relevant licence conditions, regulatory assessment principles (http://www.arpansa.gov.au/ass_ info.-htm#RAPs), and codes and standards, and the results notified to the Licensee. For assessment of modifications that will have significant implications for safety (defined as a "relevant change" for which ARPANS Regulation 51 applies), prior approval of the CEO of ARPANSA is required before the modification is undertaken; that is, the LSA in such cases requires formal approval of the regulator.

Czech Republic

The results from LSA are compared with results and conclusions of the Regulatory Body.

The "Living" SAR is evaluated and the Regulatory Body requires to correct identified discrepancies (scope of modifications, their impact on nuclear safety etc.).

As regards evaluation of events the SÚJB assesses the root causes analyses and accepted remedial measures. Requirements of the SÚJB are set in month protocols (legal document in accordance with Atomic Act) from common event commissioning meetings.

"Supplemental Inspection for Repetitive Degraded Cornerstone, Multiple Degraded Cornerstone, Multiple Yellow Inputs, or One Red Input".

4. NRC Inspection Manual Chapter 0305, "Operating Reactor Assessment Program." Exhibit 5.

Finland

The results of LSAs are assessed as spot-check – licensees deliver partially their self-assessment documents for information to STUK.

France

The utility provides information excerpts from its LSA in its yearly reports but does not provide extensive LSA results reports. The regulatory body takes into account the conclusions of the operators in addition to the observations made during its own inspections when elaborating the final judgement of the ASN on each NPP.

Germany

See answer to question 1.

Hungary

The managers' self-assessment shall be documented and the documents are to be presented during the inspection. A broad set of questions is elaborated for evaluation of management self-assessment.

The independent assessment results are to be submitted to RB in quarterly and in yearly reports according to safety guide 1.24 – "Periodical reporting requirements of NPPs". The Licensees' safety performance evaluation programme, which shall include the LSA evaluation criteria, is under preparation.

Japan

The documents describing the results of LSA are submitted to the regulatory body. NISA carries out the comprehensive review of the results, focusing on the implementation of adequate preventive/corrective actions, the incorporation of the state-of-the-art technologies, etc., to ensure that the plant safety has been improved.

Netherlands

A final concept of the 2-yearly assessment (must be ready within 4 months after assessment period) is evaluated by several experts within the RB. The presented subjects, conclusions and actions to be taken are analysed in order to check that:

- all relevant subjects are dealt with;
- the right conclusions are reached; and
- the proposed actions will be effective.

During a meeting with the licensee the comments on the final concept are presented and discussed. After corrections the final report is presented and a formal reaction of the RB will be given.

Norway

The licensee is obliged to take the evaluation into account and implement necessary.

Sweden

Results from the licensees' self-assessment activities are fed into SKI's integrated safety assessment of the licensees and will thus influence the oversight plan.

Switzerland

In the same manner as other inspection results, deviations to expected results will become an open issue. Details are formulated in the regulatory QM process.

United Kingdom

See the answer to 3 above.

United States

As stated above, the NRC reviews selected licensee self-assessments as part of the baseline inspection programme to ensure that issues identified during the self-assessments are entered into the licensee's corrective action programme, prioritised, and that appropriate corrective actions are taken to prevent recurrence and restore compliance with NRC regulations. The results of these NRC inspection reports are documented and made publicly available. Should significant weaknesses be identified during an NRC inspection of a licensee self-assessment, the NRC may decide to take additional enforcement actions or conduct additional inspections as necessary to ensure that the corrective actions are taken to prevent recurrence. Weaknesses identified during supplemental inspections are similarly followed up to ensure that appropriate corrective actions are taken

5. Does the regulator follow-up on corrective actions taken by the licensee as a result of LSA?

Australia

Corrective actions are expected to be reported by the licensee under the periodic reporting requirements of the Licence Conditions Handbook. If ARPANSA is not satisfied with the actions undertaken, then follow-up action, inspection or audits are conducted.

Czech Republic

The SÚJB follows-up the corrective actions that have impact on nuclear safety or radiation protection mainly their fulfilment in prescribed terms by protocols.

Finland

STUK does not take prescriptive role if the licensee has found deficiencies in its LSA and it is apparent that the licensee will take the corrective actions. On the other hand if the issue is significant or STUK has made some inspection remarks on the same things, are the corrective actions naturally followed up by STUK.

France

The follow-up by the regulator of operator's corrective actions is mainly performed through inspection by spot-checking.

Germany

The regulatory authorities are obliged to oversee any corrective actions taken by the licensee, provided this action is in any way safety-relevant.

Hungary

See Point 3.

Japan

Yes. NISA carries out follow-up activities on corrective actions taken by the licensees within the review of the results of licensees' PSR and on-site inspection, and requests licensees to take relevant measures if necessary.

Netherlands

Twice a year a special inspection takes place to check the progress of the corrective actions and to verify that a corrective action is completed.

Norway

If corrective actions are substantial, they are followed up by the NRPA.

Sweden

The corrective action programmes of the licensees are important and form a part of the basis for SKI assessment of the safety work at the plants. In relation to incidents and discovered plant deficiencies, for example, SKI reviews carefully the corrective actions proposed by the licensees and the corresponding internal safety review of these actions.

Switzerland

There are formalised ways how open issues have to be closed in the regulatory QM process. Normally it requires a written confirmation of the licensee that the deviation is solved, sometimes a regulatory inspection will also be performed.

United Kingdom

As stated above, the NII does not scrutinise the follow up on specific corrective actions undertaken by the licensee. The exception to this might be if the NII carried out an inspection or audit of its own, revealing a substantial degree of non-compliance. In such a case, the NII inspectors might well ask to examine the results of the licensee's self-assessment process on the same topic to understand why the licensee had not uncovered and rectified the non-compliances before these were discovered by the NII.

United States

During the baseline inspection of problem identification and corrective action programmes, selected issues are reviewed to ensure that the licensee has implemented planned corrective actions. The issues reviewed included a sample taken from licensee self-assessment activities. During supplemental inspections conducted for risk significant issues, the NRC ensures that the licensee has established a method for evaluating the effectiveness of the corrective actions.

6. What "credit" if any is given to the licensee for performing an LSA (i.e., decreased inspections, etc.)?

Australia

ARPANSA sees the satisfactory performance of LSA as an indicator of good safety culture and good safety management arrangements. This is likely to lead to the reduction of regulatory surveillance activities (such as inspections).

Czech Republic

The regulatory body does not give any "credit". The inspection activities are planned among others mainly based on results and conclusions of previous SÚJB inspections.

Finland

STUK doesn't give the licensee any credit for performing an LSA.

France

There is currently no use of LSA to modify the French regulatory supervision programme.

Germany

Inspections and also the PSRs are scheduled subject to the plant license (and possible amendments thereto) or subject to general legal or regulatory requirements. These schedules are legally binding and are not subject to trade-offs due to LSAs.

Hungary

There is no direct credit for performing LSA, but LSA is one of 12-15 topics of integrated team-inspections. These inspections are performed 4 times a year. It means LSA can be inspected once in 3-4 years, but the frequency of each topic's inspection depends on satisfaction of the RB in that area.

Japan

No such credit is given to the licensee at present.

Netherlands

No credit is given when the licensee has drawn up a self-assessment.

Norway

No special credit is given for performing an LSA.

Sweden

SKI maintains sort of minimum inspection and assessment programme of all licensees. Strong confidence in a licensee's self-assessment process, will mean less active activities in relation to that licensee. Less resources will be directed to supervision and inspection and a smaller sample of all the technical and organisational modifications that the licensee notifies will be reviewed by SKI.

Switzerland

Not yet defined. But it seems clear that such important activities have to be taken into account in the regulatory inspection strategy.

United Kingdom

There is a degree of co-operation between the self-assessment programmes run by the licensee and the inspection and audit programmes conducted by the NII. The objective of such co-operation is to try to cover different topics on team inspections and audits, rather than have a situation where the licensee uses its own self-assessment resources to "clean up" the topic area which the NII has said it intends to check, before the regulator makes those checks. It is however not easy to persuade the licensee to co-operate in this idealised fashion, and to work properly it depends on the general confidence of the licensee's staff and the pressures they are under to avoid the regulator discovering non-compliances.

United States

In the past, the NRC has given "credit" to licensees for self-assessment activities and has decreased inspection accordingly.[5] The NRC's revised reactor oversight process now in effect does not allow substitution of licensee self-assessments for baseline inspections as the baseline inspection programme was developed with the assumption that it would be implemented equally at all

5. NRC Inspection Procedure 40501, "Licensee Self-assessments Related to Team Inspections" provides guidance for evaluating a licensee's self-assessment in lieu of an NRC team inspection.

facilities. The revised oversight process does however recognise licensee self-assessments during supplemental inspections, and emphasises that if licensee's do not do effective self-assessments, the NRC may do additional inspections as necessary to determine the cause and prevent recurrence of risk significant performance issues. As a future action, the NRC has committed to explore the possibility of using licensee self-assessments in lieu of NRC inspections in selected areas.

7. Licensee self-assessment and periodic safety reviews

- **If a periodic safety review (PSR) is performed in your country, are LSAs also performed?**

- **What type of frequency is required for LSAs and how are they different from the PSR?**

Australia

LSAs are performed routinely. Safety reviews have recently been undertaken as part of the initial licensing of ANSTO facilities under the ARPANS Act 1999. See, for example, the safety evaluation report for ANSTO's HIFAR research reactor, available at http://www.arpansa.gov.au/hifar_lic_app.htm#ser.

Czech Republic

The periodic safety reviews are performed in ten years period. The requirement for periodicity of PSR is done as condition in permission for operation of NPP.

The LSA is performed (see above) some parts of LSA are given by SÚJB (see question No.2).

The LSA frequency is not required but practically the LSA frequency is month (events evaluation) and annual (Living SAR, annual report). The LSA is continual process with conclusions for the nearest future (with fix terms of fulfilling), PSR evaluates and analyses impact on nuclear safety and radiation protection in ten year periodicity without concrete conclusions for future.

Finland

PSR is performed in Finland. In PSR there is a part dealing with the quality management at licensees, but self assessment is not specially mentioned in the review.

We do not have any rules about the frequency of LSA. Licensees in Finland do self assessment on a regular basis and in most cases the frequency is once a year.

France

Yes both PSR and LSA are performed in France.

What type of frequency is required for LSAs and how are they different from the PSR?

PSR is generic and concerns all of the plants from the same series.

As mentioned in answer to question 3, the utility uses different processes for the safety assessment of its NPPs:

- A continuous assessment process is performed on each NPP by the Safety Quality Team which reports to the plant manager.
- Annual reports from the General Inspectorate and the safety inspectorate of the power division synthesizing the main findings of their inspections.
- Global Safety Assessments which are extensive assessments lasting two weeks performed on each NPP every three years.

Germany

In Germany, PSRs have been performed in the 1990s and are to be repeated every ten years. PSRs are conducted complementary to continuous plant supervision to get an entire view of the plants safety including the results of deterministic and probabilistic analyses and operational experience. LSAs are not part of PSR but the information collected in a PSR by the licensee provides insights to him on his own performance. LSAs in the form of internal and supplier audits are scheduled according to the licensee's QM system (which is submitted to the regulatory authorities, as explained under no. 3); LSAs in the

form of national peer reviews are a voluntary effort of the licensees and are, presently, rather in some test phase.

Hungary

LSA and PSR: the PSR is itself a LSA in a broader sense, the RB reviews it only. The scope of a PSR is in accordance with the safety guide No. 50-SG-D12 of IAEA. It does not include an explicit form of LSA as defined in point No.1., though, some elements of LSA are mentioned there. The most important difference appears in frequency of both processes: PSRs are performed once in 10 years, LSA is to be performed at least once a year. The organisational structure of the utility changes relatively often and the safety performance requirements increase permanently that's why the frequency of the PSR seems to be too low for the LSA.

Japan

As mentioned above, PSR is being performed within LSAs.

What type of frequency is required for LSAs and how are they different from PSR?

NISA requests licensees to perform Periodic Safety Reviews for their respective nuclear power plants at fixed intervals (approximately every ten years). In the PSRs, the core damage frequency (CDF) for power operation is updated according to the current status of the plant system configurations. Also, the importance of safety equipment and/or postulated initiating events is examined based on the updated CDF.

Netherlands

In the opinion of the KFD the PSR is a very important part of the LSA. However other self-assessments e.g. initiated by the licensee himself, exist. In the LSA also the assessment of efficiency and cost reduction are taken into account.

In the Netherlands we have two types of LSA; one with a frequency of 2 year (reference: the existing licence) and another with a frequency of 10 year (reference "new insights"; see also the introduction).

Other self-assessments than PSR are mainly not bound to a prescribed frequency or follow frequencies that are specified in the licensee's QA system.

Norway

Yes, the licensee has to submit a report on the status of the installations every third year. This is quite close to a PSR and contains the licensee's assessment of the installations.

Sweden

Both periodic safety reviews, PSRs and licensee self-assessments are performed in Sweden. PSRs are performed every 10-years. Licensee self-assessments, however, are seen as the basis for safety at the nuclear installations and constitute the continuous day to day safety work of the licensee under the supervision toe SKI, as said above.

Switzerland

LSA is a short term problem solving or performance enhancement process, to maintain safety in reaction on operating results as deviations, new operating experience or changing external impacts.

PSR is a periodically self-assessment of the plant against the state of the art and how to close the gaps. Switzerland requires a 10 years period for PSRs.

What type of frequency is required for LSAs and how are they different from the PSR?

On PSR See above.

LSAs in the context of QM are expected to be done periodically or in reaction to internal or external triggers (e.g. declining of performance indicators, etc.).

United Kingdom

Under the definitions described in answers 1 and 2 above, it will be clear that the licensee's self-assessment process is quite distinct from the periodic

safety review process. In the UK, periodic safety reviews are required every ten years whereas the self-assessment process is seen as a continuous process undertaken by a department within the licensee, which is permanently dedicated to this task.

United States

Periodic safety reviews are not performed in the U.S.

8. What other issues relating to Licensee Self-assessment would you like to see discussed by CNRA?

Australia

None at this time

Czech Republic

- tools for implementing of regular LSA and requirements for LSA range
- ways for enforcement of LSA results

Finland

It might be useful to have a common position on LSAs – what things should be included in it and should there be a standard for LSAs. It might also be interesting to discuss if there is need or possibility to harmonise LSAs.

France

None at this time.

Germany

An in-depth discussion of experiences gained so far in the field of "LSA and de-regulation" might be interesting provided countries requiring LSA can

offer input. Furthermore, it might be interesting whether countries have reduced plant inspections and introduced LSA instead and what are the experiences.

Hungary

It seems to be important to discuss about criteria of LSA in comparison with regulatory requirements. (To what extent can the RB encourage or motivate utilities to aim at results, higher than prescribed in legal or regulatory requirements? A typical example: the utilities obviously are in a position to have much lower radioactive emission than prescribed in regulatory requirements.)

Another opened question: Is it worth for the utilities to establish and maintain a QA or quality excellence system, which could be certified according to requirements of an internationally approved, independent of the nuclear industry standard? (It could be useful to have a certificate of utility's QA-system from an independent expert organisation outside of the nuclear society when discussing with anti-nuclear organisations or with people who just doubt of declarations from the "nuclear lobby".)

Japan

There is no particular item at present.

Sweden

It would be good to get an international definition/understanding of the term licensee self-assessment in order to facilitate communication internationally and foster mutual understanding. Once this is done, CNRA could discuss pros and cons with various ways to inspect these programmes. It could also be discussed in what way and extent direct regulatory control could be replaced with regulatory requirements on licensee self-assessment.

Switzerland

United Kingdom

United States

We would like to discuss whether any countries have experience with regard to the development of performance metrics for assessing the effectiveness of licensee self-assessment programmes.

OECD PUBLICATIONS, 2 rue André-Pascal, 75775 PARIS CEDEX 16
Printed in France.