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**NUCLEAR ENERGY AGENCY
COMMITTEE ON NUCLEAR REGULATORY ACTIVITIES**

**NEA/CNRA/R(2010)5
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**10th International Nuclear Regulatory Workshop on Experience from Inspecting Safety Culture,
Inspection of Licensee Safety Management System, and Effectiveness of Regulator Inspection Process**

Workshop Proceedings

Hosted by the Ministry of Housing, Spatial Planning and the Environment VROM Inspectorate

**Amsterdam, the Netherlands
17 – 19 May 2010**

English text only

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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.

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“The Committee on Nuclear Regulatory Activities (CNRA) shall be responsible for the programme of the Agency concerning the regulation, licensing and inspection of nuclear installations with regard to safety. The Committee shall constitute a forum for the effective exchange of safety-relevant information and experience among regulatory organisations. To the extent appropriate, the Committee shall review developments which could affect regulatory requirements with the objective of providing members with an understanding of the motivation for new regulatory requirements under consideration and an opportunity to offer suggestions that might improve them and assist in the development of a common understanding among member countries. In particular it shall review current management strategies and safety management practices and operating experiences at nuclear facilities with a view to disseminating lessons learnt. In accordance with the NEA Strategic Plan for 2011-2016 and the Joint CSNI/CNRA Strategic Plan and Mandates for 2011-2016, the Committee shall promote co-operation among member countries to use the feedback from experience to develop measures to ensure high standards of safety, to further enhance efficiency and effectiveness in the regulatory process and to maintain adequate infrastructure and competence in the nuclear safety field.

The Committee shall promote transparency of nuclear safety work and open public communication. The Committee shall maintain an oversight of all NEA work that may impinge on the development of effective and efficient regulation.

The Committee shall focus primarily on the regulatory aspects of existing power reactors, other nuclear installations and the construction of new power reactors; it may also consider the regulatory implications of new designs of power reactors and other types of nuclear installations. Furthermore it shall examine any other matters referred to it by the Steering Committee. The Committee shall collaborate with, and assist, as appropriate, other international organisations for co-operation among regulators and consider, upon request, issues raised by these organisations. The Committee shall organise its own activities. It may sponsor specialist meetings and working groups to further its objectives.

In implementing its programme the Committee shall establish co-operative mechanisms with the Committee on the Safety of Nuclear Installations in order to work with that Committee on matters of common interest, avoiding unnecessary duplications. The Committee shall also co-operate with the Committee on Radiation Protection and Public Health and the Radioactive Waste Management Committee on matters of common interest.”

ABSTRACT

The NEA Committee on Nuclear Regulatory Activities (CNRA) believes that an essential factor in ensuring the safety of nuclear installations is the continuing exchange and analysis of technical information and data. To facilitate this exchange, the Committee established working groups and groups of experts in specialised topics. The Working Group on Inspection Practices (WGIP) was formed in 1990 with the mandate "... to concentrate on the conduct of inspections and how the effectiveness of inspections could be evaluated..."

These proceedings cover the 10th International Workshop held by WGIP on regulatory inspection activities.

The focus of this workshop was regulatory inspection activities in 3 main areas:

- Experience from Inspecting Safety Culture.
- Inspection of Licensee Safety Management System.
- Effectiveness of Regulator Inspection Process.

FOREWORD

The main purpose of the inspection practices workshops is to provide a forum of exchange of information on the regulatory inspection activities. Participants have the opportunity to meet with their counterparts from other countries and organisations to discuss contemporary issues on the selected topics. They develop conclusions regarding these issues and identify methods to help improve their own inspection programmes.

The NEA Committee on Nuclear Regulatory Activities (CNRA) believes that safety inspections are a major element in the regulatory authority's efforts to ensure the continued safe operation of nuclear facilities. Considering the importance of these issues, the Committee established the Working Group on Inspection Practices (WGIP) in 1990. The purpose of WGIP is to facilitate the exchange of information and experience related to regulatory safety inspections between CNRA Member countries. This workshop, which is the tenth in a series, along with many other activities performed by the working group, is directed towards this goal. The consensus from participants at previous workshops, noted that the value of meeting with people from other inspection organisations was one of the most important achievements.

The focus of this workshop was regulatory inspection activities in three topic areas:

- Experience from Inspecting Safety Culture.
- Inspection of Licensee Safety Management System.
- Effectiveness of Regulator Inspection Process.

Members of Organising Committee wish to acknowledge the excellent planning and arrangements made by the staff of the hosting organisation, the Ministry of Housing, Spatial Planning and the Environment VROM Inspectorate- Department of Nuclear Safety, Security and Safeguards. Special appreciation is given to Dr. Piet Müskens and Mr. Kees des Bouvrie of the host organisation and Mr. Steve Lewis, Chairman of WGIP and Workshop Chairman.

Special acknowledgement is given to the members of WGIP who worked as facilitators and recorders for each of the topics.

TABLE OF CONTENTS

ABSTRACT	5
FOREWORD.....	7
1. EXECUTIVE SUMMARY	11
2. ORGANISATION / OVERVIEW OF WORKSHOP	13
2.1 Planning	13
2.2 Location	13
2.3 Topic Introductions	13
2.4 Announcement	14
2.5 Pre-Workshop	14
2.6 Overview of Workshop.....	14
3. OPENING SESSION.....	17
3.1 Welcoming Remarks.....	17
3.2 Experience from Inspecting Safety Culture	17
3.3 Inspection of the Licensee Safety Management System.....	19
3.4 Effectiveness of Regulator Inspection Process	23
4. DISCUSSION GROUPS – SUMMARY OF RESULTS	29
4.1 Experience from Inspecting Safety Culture	29
4.2 Inspection of the Licensee Safety Management System.....	32
4.3 Effectiveness of Regulator Inspection Processes	37
5. CLOSING PLENARY SESSION	41
5.1 Presentation of Topics.....	41
5.2 Closing Remarks	41
6. CONCLUSIONS	43
6.1 General Workshop Conclusions.....	43
6.2 Conclusions and Commendable Inspection Practices	43
7. EVALUATION	47
7.1 Evaluation Form.....	47
7.2 Suggested Future Topics	52
APPENDIX 1 LIST OF PARTICIPANTS	53
APPENDIX 2 PREVIOUS WORKSHOPS.....	55

1. EXECUTIVE SUMMARY

The main objectives of the WGIP workshop are enabling inspectors to meet with inspectors from other organisations, to exchange information regarding regulatory inspection practices, to discuss the selected topics, to discuss current inspection issues and to develop conclusions and commendable practices (if possible) on the selected topics.

As part of the registration form, participants were asked to provide answers to a questionnaire describing practices within their own countries on the various topics for inclusion as pre-workshop information. The complete compilation of questionnaire responses is contained in the appendix (separate report) to this document.

Approximately sixty (60) participants from twenty (20) different countries and one international organisation took part in the workshop (Appendix 1). Additionally, the Civil Aviation Authority for the Netherlands participated in this workshop. Participating countries included: Belgium, Bulgaria, Canada, Czech Republic, Finland, France, Germany, Hungary, Japan, Korea, Lithuania, Mexico, the Netherlands, Slovakia, Spain, Sweden, Switzerland, United Arab Emirates, the United Kingdom and the United States.

Six discussion groups were established for the working group sessions. The members of each group were chosen to support a diversity of views for each of the topics. Discussions groups met for three separate sessions to review the various topics. The exchange of ideas and opinions between participants was active and the groups formulated conclusions on the various issues selected for the discussion topics.

The evaluation of the workshop results are based on questionnaire responses received from the participants at the closing of the workshop. The evaluation showed that as in the past workshops, the highest value perceived, was in meeting and exchanging information with inspectors from other organisations. Responses also showed that the format selected was highly favoured and that more workshops of this type are supported in the future.

The results of the evaluation also reflected that participants in exchanging information are provided a unique opportunity to “calibrate” their own inspection methods against those from other countries. While exchanging inspection practices and learning new ideas are part of the main objectives, this opportunity to recognise and understand commonalities and differences is equally important.

Overall discussions between the various participants both in discussion group sessions and throughout the workshop were extensive and meaningful. Ideas and practices regarding regulatory inspection activities were exchanged and it can be foreseen that these ideas will provide improved expertise when being applied in the future. Based on follow-up discussions, WGIP members agreed that:

The workshops on regulatory inspection practices held by the CNRA Working Group on Inspection Practices, continue to provide a unique opportunity for inspectors and inspection managers of nuclear power plants to meet and share and exchange information.

The main conclusions consist of list of commendable practices for each topic that were developed by the discussions groups. Additionally, the participants agreed that the participation by the aviation regulatory body of the Netherlands provided additional depth and insights into the discussions. The workshop results are provided in Section 6.

2. ORGANISATION / OVERVIEW OF WORKSHOP

2.1 Planning

Preliminary planning for this workshop, the tenth in a series, of international workshops on regulatory inspection activities began following the conclusion of the previous workshop in Helsinki, Finland in June 2008. The WGIP members reviewed comments and suggestions made at previous workshops and considered and discussed ways to improve the format of the workshop. Formal planning started following the approval by the CNRA at its annual meeting in December 2008.

2.2 Location

The workshop was hosted by the Ministry of Housing, Spatial Planning and the Environment VROM Inspectorate- Department of Nuclear Safety, Security and Safeguards, in Amsterdam, the Netherlands, 17 – 19 May 2010.

2.3 Topic Introductions

Participants at the last workshop held in June 2008 [NEA/CNRA/R(2010)1/2] suggested numerous topics for discussion at a future workshop. The working group considered these topics and also reviewed various proposals on other topics. A list of topics were developed and proposed to the CNRA. A consensus and the approval of the topics to be addressed were reached at the June 2009 CNRA meeting. The members of the workshop committee further defined the issues to be discussed under each of these topics as summarised in the following paragraphs:

2.3.1 Experience from Inspecting Safety Culture

Given the work that has been previously performed by WGIP at its Toronto 2006 workshop and by the Working Group of Human and Organisational Factors (WGHOF) and its workshop at Chester 2007, this workshop will give regulatory inspectors an opportunity to share their own experience regarding internationally practised approaches for the assessment of licensees safety culture by a process of inspecting some attributes of the behaviour of nuclear power plant (NPP) management and staff. The workshop should also compile the initial knowledge and qualification requirements for inspectors to assess NPPs, as well as further development of necessary skills for experienced inspectors. In addition, the workshop should evaluate methods to incorporate the findings of the inspectors into the overall assessment of plant performance.

2.3.2 Inspection of the Licensee Safety Management System

In 2001, the WGIP members recognized that there is a spectrum of approaches that may be appropriate for use by a regulatory authority when it assesses the effectiveness of a licensee in managing safety related issues [NEA/CNRA/R(2001)9]. Since then, the inspection methodologies and programs have been evolving and experiences in the inspection of the management system have been gained.

Inspections are performed which cover the most important elements of the management system like the establishment and the basis of the management system, responsibilities and documentation, policy and

resources, process implementation and continuous improvement. Inspections, meetings and indicators are used to evaluate the overall effectiveness of the management system as to ensure the safety of the plant.

The objective of this workshop topic is to share and discuss different approaches and practices as well as to identify commendable practices for the regulatory inspection of licensee's management systems and of processes within these management systems.

2.3.3 *Effectiveness of Regulator Inspection Processes*

As an essential part of their mission, the regulatory bodies must carry out inspections of the NPPs. The inspections are designed to verify that the licensees operate their facilities in a safe manner, in accordance with design/licensing basis, and regulatory requirements are met (e.g., laws, regulations standards).

While findings are identified and corrected on routine basis, there is a challenge on how the regulator determines whether the inspection program is effective in maintaining and improving the safety of the plant. Therefore, it is important for the regulatory bodies to have a tool for the periodical assess and measure of the effectiveness of their inspection process and programs. This may be accomplished by the regulatory body through various self-assessment processes or by other means such as third-party independent evaluations, and taking into account all the stakeholders.

2.4 *Announcement*

The workshop announcement was transmitted in the fall of 2009. As part of the registration form, participants were asked to provide answers to a questionnaire describing practices within their own countries on the various topics for inclusion as pre-workshop information. The results were transmitted to participants one month in advance of the workshop.

2.5 *Pre-Workshop*

2.5.1 *Facilitator Training*

Prior to the start of the workshop, facilitators and recorders attended a pre-workshop meeting. Mr. Steve Lewis reviewed the general objectives of the workshop and outlined the various characteristics required of a good facilitator. He noted the importance of their role in guiding the group and the methods required to manage an effective discussion.

2.5.2 *Reception*

A reception was held following delegate registration at the workshop hotel. Participants were given the opportunity to socialise and exchange information in an informal setting in order to familiarise themselves with each other. Dr. Piet Müskens, Director, VROM Inspectorate - Department of Nuclear Safety, Security and Safeguards made welcoming remarks to the participants to the workshop.

2.6 *Overview of Workshop*

The format of the workshop used a process, which was first utilised in 1992 at Chattanooga and has evolved over the continuing series of workshops. Following an opening session to establish the context of the discussions, participants were divided into six smaller groups for detailed discussion on the workshop topics. A closing session was held to review the results of the discussions and commendable practices that have been derived.

Based on the success of the last workshop and in order to continue improving the exchange of information and assist participants in their preparation WGIP members volunteered to compile and analyse the responses to these questionnaires as well as act as lead facilitators during the workshop. A compilation

of these papers is produced as Appendix to these proceedings, and were used as background material for the group discussions.

2.6.1 Opening Session

Following the welcoming remarks from the host country, the opening session included a brief introduction of workshop objectives by the Chairman and presentation of the three workshop topics including the results of the survey.

2.6.2 Group Sessions

The participants in each of the six discussion groups were decided on to provide a diversity group of background, opinion, and region. A major consideration was the participant's pre-selected preferred topic. Three half-day sessions of group discussions were held. A facilitator and recorder worked with each group to stimulate and encourage discussions. The summary of the discussions and results are provided in Section 4.

2.6.3 Presentations by Host Country Representatives

Presentations were given by Mr. Mark Damman, from the Borssele NPP, Mr. Rob van der Stad from the Nuclear Research & consultancy Group (NRG), and Mr. Hok Goei from the ministry of aviation inspections. Mr Hok Goei presented *Measuring Safety Culture in Aviation Maintenance Organisations*. Mr. Rob van der Stad presented *The repair of degraded areas in the primary cooling lines of the HFR Research Reactor*. Mr. Mark Damman presented *Improving Safety Culture and Human Performance from the Borssele NPP Experience*.

2.6.4 Closing Session

Following the completion of the group discussions, facilitators and recorders met and developed a set of conclusions based on the discussions. One facilitator from each topic presented the conclusions and recommendations that were developed by their respective groups. A question and response period followed each topic. Following the presentations, an open panel discussion was held on the results of the workshop.

3. OPENING SESSION

3.1 Welcoming Remarks

Mr. Steve Lewis, NII and Chair of the WGIP welcomed participants to the 10th WGIP international workshop on nuclear regulatory inspection activities. He noted the importance and relevance of this type of workshop and the excellent opportunity it presented to both inspectors from OECD Member countries and non-member countries to meet and exchange information on important contemporary issues. The daily work of regulatory inspectors depends on their own individual national culture, national legal framework and national nuclear regulations. He provided the overall objectives of the workshop and introduced the two introductory speakers.

Mr. Piet Müskens, Director-Inspector of the VROM-Inspectorate-KFD, Department of Safety Security Safeguards and Radiation, welcomed the participants to the Netherlands. He provided an overview of the Netherlands's regulatory authority and future activities.

Mr. Uichiro Yoshimura, NEA Deputy Director in charge of Safety and Regulation, spoke on the success of the WGIP workshop series. He noted that the success is based on the collaborative efforts of the experts that actively participate in the workshops and the responsiveness of the working group to address emergent challenges to the regulators.

Ms. Diane Jackson, NEA technical secretariat, and Mr. Lewis presented the main objectives of the workshop, basic information on the set-up of the programme, the expected products and different roles of the facilitators, recorders and participants.

An opening presentation was given on each of the workshop topics. The presentations included an overview of the topic, an assessment of the country responses from the pre-workshop questionnaire, and provided additional questions for discussion based on the questionnaire responses. In total, 16 countries answered the pre-workshop questionnaires. In addition to the answers from the nuclear regulatory bodies, a response from the Civil Aviation Authority for the Netherlands was received. The presentations were developed and given by Mr. Timothy Kobetz (Experience from Inspecting Safety Culture), Dr. Walter Glöckle (Inspection of the Licensee Safety Management System), and Mr. Julio Crespo (Effectiveness of Regulator Inspection Processes).

3.2 Experience from Inspecting Safety Culture

Mr. Kobetz provided an introduction to the topic based on the responses to the questionnaire. He discussed the 2006 WGIP workshop [Ref: NEA/CNRA/R(2007)1/2] on this topic and the major changes in the evolution of safety culture for the regulatory bodies since that workshop. The presentation included insights that were gained from reviewing the responses and answered the three following main questions: What did the question responses tell us? What else did the responses identify? What other questions should we be asking? He provided common responses to each question and discussed the working group's ideas when they formulated the question.

Summarising the responses, Mr. Kobetz presented the following slides:

Question 1

In the absence of regulatory requirements how does your regulatory body convey its expectations regarding the importance of safety culture on nuclear safety and the promotion of its use, (e.g., the content of a safety culture program and the need to be proactive) to operators/licensees?

- Management Meetings with Operators/Licensees.
- Regulatory Requirements.
- Regulatory Expectations.

Question 2

How does your agency inspect against its expectations for operators/licensees (e.g., routine inspections, special inspections, inspection criteria) in lieu of its inspections against regulatory requirements?

- A Combination of Routine and Event Follow-up Inspections.
- Information Developed by Experts External to the Nuclear Industry.
- A few Regulatory Bodies do not Inspect Safety Culture.

Question 3

How does your inspection program convey to operators/licensees that the agency's expectations for the implementation of a safety culture programme have or have not been met (e.g., management meetings, documentation of inspection findings, enforcement or regulatory actions)?

- The Majority of Regulatory Bodies Communicate during Routine Management Meetings.
- Several Regulatory Bodies use Inspection Reports to Communicate Findings.

Question 4

How does your agency train its inspectors in the inspection of safety culture (e.g., does it use experts educated in this area, and/or does it train its inspectors)?

- Use of In-House Specialists/Experts.
- General Training.
- Experience Gained through International Sources (NEA, IAEA).

Question 5

How does your agency avoid subjectivity and maintain consistency during inspections of safety culture?

- Subjectivity is Always More or Less Present.
- The Regulatory Body Management Review Process.
- The use of Multiple Inspectors.
- Gathering Information over an Extended Period.

Question 6

How does your agency fairly communicate findings in the area of safety culture to external stakeholders (e.g., other operator/licensees and the general public) to ensure its findings are not mischaracterized or taken out of context?

- A combination of Public and Non-Public Meetings.
- Written Public Reports.

Question 7

How does your agency assess the effect of safety culture on decision making process of operators/licensees (e.g., performing maintenance or equipment testing in a plant configuration that meets technical specifications and regulatory requirements but reduces the margin of safety)?

- Routine Measurements.
- Evaluate the Effectiveness on Safety.
- Many do not Evaluate.

Question 8

What have been the outcomes and findings associated with your inspection of the operators/licensees safety culture?

- Resulted in Improvement to Plant Operations.
- Impacts on New Builds.
- Used to Confirm Safe Performance.
- Switched from Reactive to Proactive Safety Strategy.

Question 9

What would you like to learn regarding the inspection of safety culture from the workshop?

- What has been the Experience of Other Countries?
- How do you Incorporate Safety Culture into the Evaluation of Every Day Operations?
- What are the Expectations of other Regulatory Bodies?
- What are the Attributes of a Strong Safety Culture?

3.3 Inspection of the Licensee Safety Management System

Dr. Glöckle provided an introduction to the topic based on the responses to the questionnaire. In most of the countries, requirements are in place or just in preparation which postulate – in accordance with the IAEA safety standard GS-R-3 - an (integrated) management system. Safety management should be integrated in the management system in such a way that safety issues have overriding priority.

In this paper, the term “management system” is used for an integrated management system which integrates safety management into the licensee management system.

Different approaches are used by regulators in inspecting the management system of the licensee. On one hand, audits of processes such as management of modifications, staff training or control of documents are inspected. On the other hand, licensee’s activities are checked by routine inspections, and management system aspects are addressed by going in depth into the cause of inspection findings.

Dr. Glöckle pointed out that the responses from the questionnaire as well as the information and experiences in the responses provided a good basis to commence discussions in the smaller groups. He formulated questions that emerged from the evaluation of the responses and he invited all participants to bring in their personal opinions, questions and experience into the group discussion.

Summarizing the responses, Dr. Glöckle presented the following slides:

Introduction and stimulus for the group discussions

- questions in the questionnaire,
- evaluation of the answers,
- resulting additional questions.

Question 1. Requirements

Legal/regulatory requirement for a MS

In most countries a requirement **exists**:

- general requirement which covers the issue,
- general reference to IAEA safety standards (e.g. GS-R-3),
- specific requirement (e.g. regulatory guide, technical standard).

In some countries a specific requirement is **in preparation**.

Establishing requirements for a MS

Which experience have we gained from the evolution of the old **quality assurance programme** requirements to the more modern **management system** requirements?

What do we prefer: detailed requirements or a few general requirements?

Regulatory approval of MS documents

- most countries : no,
- some countries : general description,
- some countries : top level documents,
- few countries : all MS documents.

A regulatory approval of a modification in a MS document is necessary if the document is approved and if the modification is safety significant.

Question 2. Regulatory Inspections

Regulatory inspections of the MS

- are carried out in all countries with different focus:
 - management system,
 - top level management,

- special topics,
- results from other audits and reviews.
- mostly by mixed teams of specialists and site inspectors.

Inspector qualification in the field of the MS

- common feature:
 - general qualification programme for inspectors,
 - use of team inspections for qualification (coaching, mentoring, experience exchange etc.).
- additionally:
 - commercial courses (e.g. for ISO 9001 audits),
 - IAEA workshops and courses,
 - internal training courses,
 - detailed *inspection guidelines*.

Question 3. Inspection Issues

Inspection of important elements of the MS

Most countries address the elements important for the management **system**, but in a different way:

- audit type inspections,
- inspections to technical issues and analyzing the reasons of findings in the area of the MS,
- interview/discussion with the site director and the department heads.

What are the advantages of certified/registered systems?

Inspection of safety important processes

Different approaches:

- checking special processes of the ms like management of modifications, training, suppliers etc.;
- checking activities within the routine inspection programme and going in depth if there are findings.

To which extent should an inspector know the written processes of the operator and check if the activities are done in accordance with these processes?

Inspection of safety important processes

Inspecting processes or inspecting operational results and performance – what are the advantages and disadvantages?

Is it feasible to reduce the inspection effort in fields where good processes are in place?

Inspection of the effectiveness of the MS

Different types of information are used:

- results from audits and special inspections,
- interviews, discussions, results of the licensee's own reviews and evaluations,
- indicators of the regulator and the licensee,
- evaluations of weaknesses found in the usual inspections,
- trends.

What are the experiences with the different methods?

Question 4. Inspection Criteria

Inspection criteria

Compliance, conformity, accordance with:

- regulatory body's requirements,
- codes, standards (nat. standards, ISO 9001, GS-R-3),
- MS documents (MS manual, process documents etc.),
- general expectations (safety orientation, promotion of safety, improvements, messages of the management etc.),
- requirements from specific inspection procedures (dependent on the issue that is being inspected).

Integrated management system

Distraction from safety orientation is avoided by:

- independence and safety orientation of the reg. body,
- goals, guidelines and training for the inspectors,
- preparation of the inspection (clear expectations, checklists etc.).

But: How can an inspector check if the licensee has an **integrated** MS with a proper integration?

Question 5. Inspection experience

Inspection experience

Differences regarding the status of the ms in the NPP:

- implementation of a new integrated MS,
- improvement of the existing quality management system.

Regulatory bodies have inspected the licensees' MS

- on a regular basis with dedicated inspections,
- with special in-depth inspections,
- within their routine inspection programme.

Important issues for the regulatory body

- to develop a common understanding and terminology between reg. body and licensees,
- to address the importance of the MS and support the operator's activities,
- to concentrate on main points and avoid focussing on details,
- to upgrade the guides and improve the reg. oversight,
- to develop criteria for the evaluation of the effectiveness of the MS.

Question 6. Other important issues

- What is meant by "integrated management system" and why is such a MS important?
- What can we learn from management systems of different licensees?
- What can we learn from major events from other industries about organisational culture, senior management behaviour etc.?
- How can an operator come to a MS which is graded according the safety significance of the activities?
- What skills and what training of inspectors are advantageous for inspecting MS?

3.4 Effectiveness of Regulator Inspection Process

Mr. Crespo provided an introduction to the topic based on the responses to the questionnaire which was distributed to all participants in advance of the workshop. In his presentation the questions and a selection of answers given by the different countries were listed. Mr. Crespo also suggested a definition for "effectiveness of regulatory inspection" to be further discussed by the participants. He also compared his ideas with earlier documents published by NEA and IAEA.

The responses provided by the participants in advance of the workshop gave a variety of further ideas, questions and proposals for further consideration in the discussion groups.

Summarizing the responses and the additional issues raised, Mr. Crespo presented the following information and slides:

Objective

The objective for this task is to find a suitable way for the Regulatory Bodies of measuring the effectiveness of the regulatory inspections in their process and programs of inspection.

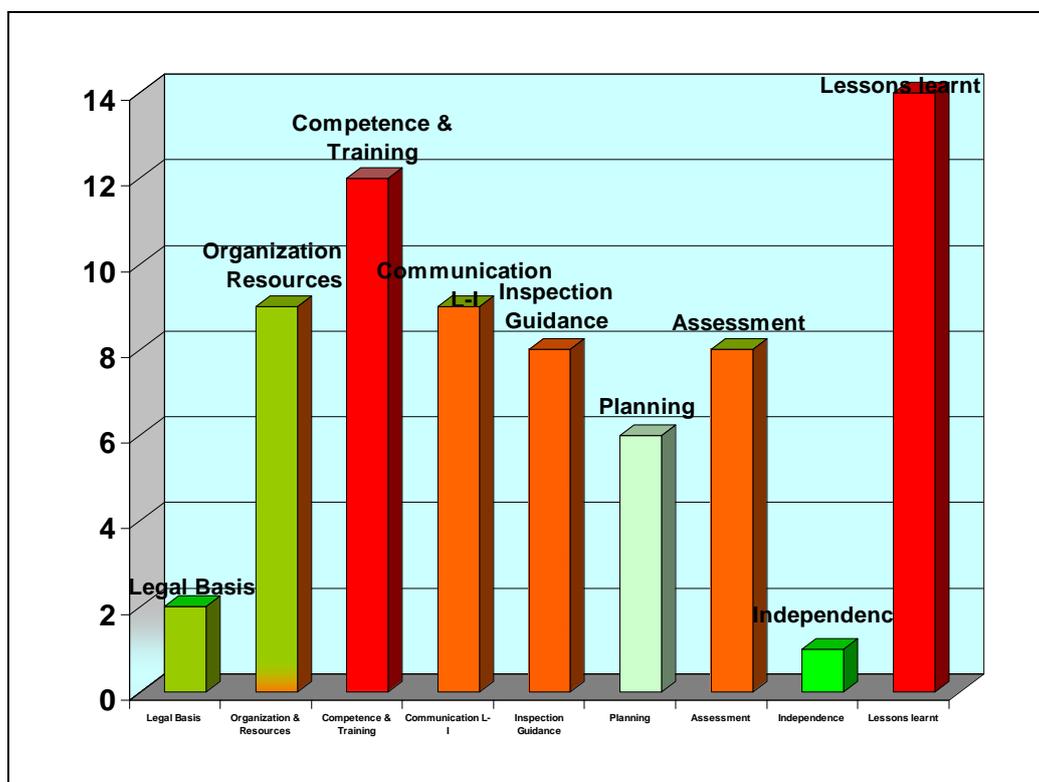
Background

- Improving Regulatory Effectiveness. NEA/CNRA/R(2001)3. January 2001.
- The Effectiveness of Nuclear Regulatory Inspection. NEA/CNRA/R(2001)7. October 2001.
- Direct Indicators of Nuclear Regulatory Efficiency and Effectiveness. NEA. ISBN 92-64-02061-6. 2004.

The following chart was presented as an overview of the key areas identified by country.

	Legal Basis	Organisation & Resources	Competence & Training	Communication Licensee-Insp.	Inspection Guidance	Planning Performance Reports	Assessment Follow-up Corrective. A.	RB Independence	Lessons learnt
Belgium		X	X		X		X		X
Czech Rep.	X	X	X	X	X	X	X		X
Finland			X				X		X
France		X	X		X	X	X		X
Germany									
Hungary	X	X	X	X	X	X	X	X	X
Japan			X		X				X
Rep. Korea							X		X
Mexico			X	X	X	X	X		X
Netherlands VROM		X			X				
Netherlands CAA		X	X	X	X	X			X
Slovak Rep.									X
Spain			X	X		X	X		X
Sweden			X		X	X	X		X
Switzerland		X		X					
U.K.		X	X	X					X
U.S.A.		X	X		X				

Considering the items in the following graph as key elements for the inspection process, the responding countries identified on which items that they felt a need for improvements in their respective RB.



How does your effectiveness review incorporate lessons learned both from your own country and internationally?

- Operating Experience. Analysis of incidents/events.
- Establishing priorities & Recommending changes to the baseline inspection program.
- Systematic review of findings. Track of results. Internal meetings and meetings with the Licensees.
- Management System. Effectiveness of processes. e.g., EFQM; ISO; GSR3
- Annual reports and relevant indicators.
- Benchmarking.
- Other NEA working groups: Working Group on Operating Experience (WGOE); Working Group on Human and Organisational Factors (WGHOE)

Follow-on question for discussion: How to incorporate lessons learned into the inspection process in a systematic and integrated manner?

Examples of recent challenges or improvements, performed or planned by your RB, related to the elements that support the process of inspection, included in the previous question.

- Changes in the legal framework of RB - New Atomic Act
- Major changes in the RB organisation - Restructuration of nuclear authority. Integration of Agencies
- IAEA Integrated Regulatory Review Service (IRRS) missions.

Changes in the inspection process:

- Site/Resident inspectors.
- Integrate OE into the inspection and assessment process.
- Systematic inspection plan and its review. New inspection system. Graded inspection system.
- Improvement of the inspection planning.
- Inspection system for the maintenance.
- Evaluation of safety Culture.
- Moving to electronic communication and database format.
- Increased communication with the Licensee.
- Transparency.

What are the tools used by your RB to review the procedures, program, planning, and effectiveness of the inspection process? Examples: Indicators, Internal/ External audits, IRRS missions, and Self-Assessments.

- Internal audits, as part as the RB management system.
- Other than IRRS, only a few countries have external audits.
- Most, but not all the countries have yet had an IRRS mission.
- A few countries have implemented a formal method for the Self-assessments of the inspection process, that, in a very schematic form, it could be understood as periodic reviews of how inspections are conducted, their findings evaluated, including its safety significance, and what are the subsequent actions taken by the Regulatory Body.

The tool most used by RBs are the indicators. Some countries use indirect indicators. (Licensee Performance).

What part of your organisation is responsible for these reviews?

- Staff. Auditors.
- Inspection /Assessment Branch chiefs.
- Project Managers.

Discussion Point: Not all countries have established a process to integrate in the inspection process the feedback from the Top Management of the Regulatory Body.

How is feedback considered in the effectiveness review? These may include: licensees, external stakeholders, RB staff.

- Audit Reports.
- Follow-up and degree of achievement of the action plan.
- Management meetings with Licensees and RB staff.
- Feedback through internal and external Surveys.
- Performance indicators. PDCA process.
- Involvement of licensees in the RB inspection program.

Other important issues, related to inspection, which you would like to discuss during the workshop.

- Kind of indicators and confidence in them to accurately inform.
- How to be as effective as possible with limited resources.
- Upgrade of training methods.

Discussion Point: Definition of the effectiveness of RB inspection. How to measure it?

An inspection system is effective when the results of audits and indicators are consistent with the main mission of their Regulatory Body, getting nuclear facilities operated by operators safely, Therefore an inspection process is effective when its contribution to promote and enhance the safety of the plant is measurable.

- Management System/ Safety Culture / Risk / Transparency.

Discussion Point: Could your RB clearly identify any safety performance improvement or positive performance trend in NPPs, attributable to the RB' inspection?

4. DISCUSSION GROUPS – SUMMARY OF RESULTS

4.1 Experience from Inspecting Safety Culture

4.1.1 Discussion Groups

<u>Group 1</u>	<u>Group 2</u>
<ul style="list-style-type: none"> • Kobetz, Mr. Timothy, Nuclear Regulatory Commission , USA * • Veselý, Mr. Jirí State, Offico for Nuclear safety SÚJB, CZECH REPUBLIC * • Van den Berghe, Mr. Yves, Bel V, BELGIUM * • Akiyama, Mr. Takao, Nuclear Safety Commission of Japan, JAPAN • Edland, Dr. Anne, Swedish Radiation Safety Authority, SWEDEN • Holopainen, Ms. Milka, Radiation and Nuclear Safety Authority, FINLAND • Fassmann, Dr. Werner, Gesellschaft für Anlagen- und Reaktorsicherheit (GRS), GERMANY • Gil - Montes, Mr. Benito, Consejo de Seguridad Nuclear, SPAIN • Arends, Mr. Patrick, VROM-Inspectorate/ KFD, THE NETHERLANDS • Axelsson, Mr. Lars, Federal Authority for Nuclear Regulation (FANR), UAE • Kerhoas, Ms. Anne, IAEA, AUSTRIA 	<ul style="list-style-type: none"> • Veyret, Mr. Olivier, French nuclear safety authority (ASN), FRANCE * • Gutierrez, Mr. Luis Miguel, CNSNS, MEXICO * • Idehaag, Mr. Klas, SSM, SWEDEN * • Müskens, Dr. Piet, VROM-Inspectorate Department for Nuclear Safety Security Safeguards and Radiation, THE NETHERLANDS • Moore, Mr. Michael, UK Nuclear Installations Inspectorate, UNITED KINGDOM • Mr. Goei, Hok, Inspectie Verkeer en Waterstaat, THE NETHERLANDS • Aspelund, Ms. Anna , Radiation and Nuclear Safety Authority, FINLAND • Kern, Dr. Axel, Ministry of the Environment Baden-Württemberg, GERMANY • Ishii, Mr. Yoichi, Japan Nuclear Energy Safety Organisation, JAPAN • Frischknecht, Dr. Albert, Swiss Federal Nuclear Safety Inspectorate ENSI, SWITZERLAND • Yankova, Ms. Neli, Bulgarian Nuclear Regulatory Agency, BULGARIA
* WGIP members	

4.1.2 Group Discussions

The group noted that licensees and regulators should have a common understanding of safety culture and determined that the 37 Attributes of Safety Culture developed by IAEA served as a good basis for countries to establish a definition for safety culture. The overarching aspects as defined by IAEA are:

- Ensuring a common understanding of the key aspects of safety culture within the organisation.
- Providing the means by which the organisation supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organisation.

- Reinforcing a learning and questioning attitude at all levels of the organisation.
- Providing the means by which the organisation continually seeks to develop and improve its safety culture.

The group identified that a strong safety culture is an observable attitude, not just a regulatory compliance.

The workshop participants found the following areas should be considered when inspecting the safety culture of licensees.

Considerations for conveying expectations for safety culture to licensees

Expectations should be established with licensees through a combination of proactive interactions including frequent communications with the licensees and industry and collaboration on methodologies and guideline development.

Considerations for inspecting against those expectations in an objective and consistent manner

There are two basic methods to inspect safety culture. First, through the continuous gathering and evaluation of data, and second, through periodic focused inspections. The preparations and process for safety culture inspections are similar to other safety inspections and should be established in accordance with the regulatory body's programs.

Considerations for communicating inspection findings to licensees, other stakeholders, and between regulatory agencies

The communication of inspection findings should be effectively communicated with applicable stakeholders in accordance with established procedures of the regulatory body. Examples of communication methods and suggestions include:

- Communications with licensees
 - Inspection exit meetings.
 - Issue inspection reports.
 - Inspection reports are made available to other licensees.
 - Management meetings.
 - Website postings.
 - Routine or annual assessment meetings (on a variety of topics).
 - Generic communications.
 - Communicate "real time" to licensee management from inspectors.
- Communications with external stakeholders
 - Safety culture is sometimes difficult to understand by the general public (need to avoid confusing plant safety with safety culture).
 - Proactive outreach or seminars to discuss current events and issues to the public.
 - Meetings with the licensee that are open to the public.
 - The more the public understands the better.
 - Open communications from the inspectors.
 - Communication plans to have a common voice.

- The exchange of information between different regulatory bodies
 - Report weaknesses and root causes in safety culture to other countries.
 - Improve the skills and competence in safety culture for those individuals or groups that analyse and report event issues internationally.

Considerations for training inspectors to assess safety culture

As with the inspection of other areas of nuclear plant safety, the inspection staff must be well trained. This can be accomplished in a number of ways including:

- Knowledge transfer within the regulatory agency and with cooperation with IAEA and other international organisations.
- Relying on specialists both internal and external (and should provide additional training as necessary).
- Networking within regulatory agencies and externally with international organisations.
- Training guidelines on safety culture for general inspectors (e.g., interviewing techniques specific for safety culture, use of current evaluation tools, recording and reporting safety culture findings).

What have been the outcomes and findings of safety culture inspections?

Most countries have only recently started to assess licensee safety culture. As such, a large amount of specific inspection findings does not currently exist. However, the group acknowledged that early inspection experience has found that safety culture assessments have led to licensee improvement programmes that resulted in the overall enhancement to plant safety.

What else should regulators consider?

The group identified that the internal safety culture established by the regulatory body was important to maintain a strong safety culture within the nuclear industry. Regulators should have a strong sense of safety culture that encourages employees to speak freely and raise safety concerns. It is important that the inspectors maintain a questioning attitude and objectivity. Regulatory bodies should consider performing periodic self-assessments of their internal safety culture. Regulatory body leaders set the tone for their agency and should set an example of a strong safety culture.

Regulatory bodies should also maintain an awareness of labour issues that may be occurring at licensees and monitor the impact of those issues on plant safety.

4.2 Inspection of the Licensee Safety Management System

4.2.1 Discussion Groups

GROUP 1	GROUP 2
<ul style="list-style-type: none"> • Gloeckle, Dr. Walter, Umweltministerium Baden-Württemberg, GERMANY* • Kupila, Mr. Jukka, Radiation and Nuclear Safety Authority, FINLAND* • Schneider, Dr. Matthias, Federal Office for Radiation Protection, GERMANY • Al Hammadi, Mr. Rashid, Federal Authority for Nuclear Regulation (FANR), UAE • Jones, Mr. Kenneth, Canadian Nuclear Safety Commission, CANADA • Zwart, Mr. Klaas, Inspectie Verkeer en Waterstaat, THE NETHERLANDS • Wertelaers, Ms. Anna, Federal Agency for Nuclear Control, BELGIUM • Barjegard, Mrs. Anna, Swedish Radiation Safety Authority, SWEDEN 	<ul style="list-style-type: none"> • Valpy, Mr. Burton, Canadian Nuclear Safety Commission, CANADA* • Fichtinger, Mr. Gyula, HAEA NSD, HUNGARY* • Yamamoto, Mr. Yoshihiro, Japan Nuclear Energy Safety Organisation, JAPAN* • Des Bouvrie, Kees, VROM, The Netherlands* • Treier, Dr. Clemens, TÜV SÜD, Energietechnik GmbH, GERMANY • Harvey, Mr. Paul, HSE/Nuclear Installations Inspectorate, UNITED KINGDOM • Pezet, Mr. Stéphane, French Nuclear Safety Authority, FRANCE • De Santos, Mr. Alejandro, NUCLEAR SAFETY COUNCIL, SPAIN
<p>* WGIP Members</p>	

4.2.2 Group Discussions

Both discussion groups exchanged the participants' own inspection experiences. They discussed questions and challenges from their practical work. They recorded opinions, observations and practices worth communicating in the regulatory community. At the end of the three half-day discussion group meetings, the two groups joined to exchange their results. Although the starting point of the two groups was different, they addressed similar subjects and came to comparable conclusions. Areas which were discussed only in one group or in more detail in one group, the other group concurred with the results presented.

The two groups had a consistent view on management systems and focus areas for a regulatory body. They had a strong consensus on important areas for regulatory attention.

Introductory Remarks

Management system is the term to use. Adjectives such as *integrated* or *safety* tend to focus management away from having one management system. It is one business, therefore only one management system for the business. For a nuclear business, safety must be integrated into the management system.

Licensees and regulators need to understand the extent of change from *Quality Management* to a *Management System*. It is much more than changing the name. It is a transition to a system based on processes which integrates different perspectives and standards and focuses on the root causes of problems.

Such a transition cannot be made from one day to another. It has to be organised and managed by the licensee. Regulators need to be patient in licensees managing the transition to a management system.

The purpose of the discussion groups was neither to draft a requirement paper comparable to GS-R-3 nor to come up with a comprehensive paper about regulatory oversight of management systems (for this purpose an IAEA TecDoc is in preparation). The purpose was rather emphasizing special important aspects for regulatory bodies.

Regulatory Requirements

In several countries regulatory requirements for a management system are in preparation. In discussing the level of prescription, the IAEA requirement GS-R-3 was found adequate. The following commendable practice was identified:

Regulatory requirements in the field of the management system should be not too prescriptive, in order to:

- allow responsibility / flexibility to the operator,
- be open for innovation and improvements,
- allow integration of different management system aspects, and
- have the “big picture.”

Regulatory Expectations

Apart from requirements and standards clear expectations are applied for inspecting management systems. Such expectations are:

- The management system finds and corrects (or starts to correct) the root causes of problems before the regulator identifies them (e.g., compare inspection results with licensee’s audit results, problem identification and corrective actions).
- A comprehensive set of feedback processes (e.g., internal audit, performance indicators, self assessments, assessment of individual programs, and periodic assessment of the management system conducted by senior management) are used for improvement.
- The actions are tracked by management and missed deadlines are held accountable.
- The licensee has defined expectations for nuclear safety and a plan or programme to implement those expectations.
- Performance indicators for nuclear safety are applied, reviewed and changed in case of changing conditions or problems.
- The licensee seeks good practices inside and outside of the industry.
- The management system should have a process for managing changes to the management system, organisational structure and resources.
- The licensee needs to define the human resource requirements including potential weaknesses/vulnerabilities (e.g., shortage of expertise, age profile of the work force, recruitment difficulties).
- Resource issues should be reported to the highest levels of facility and corporate management, including to the Board level.

Commendable Practice:

For inspecting the management system, inspectors should have clear expectations of the characteristics that a “good” management system should show.

Grading in the Management System

A very general requirement of the management system is that it should be graded according the safety significance of the activities. The discussion groups found that grading in the management system is not well-defined up to now. The common view was that the licensee should have a process, e.g. the process for managing technical and organisational changes, in which grading is applied using defined criteria. Since inspection effort by regulators often depends on the safety significance of an activity, the licensee may tend to use criteria and levels leading to a low degree of safety significance for the activities. Thus the following commendable practice was formulated:

Licensees should have a process (e.g., a change process) and criteria for grading the safety significance of activities. The regulator should look at the application of the grading to check that the grading is not too low.

Allocation of Inspection Effort

In discussing the possibilities to allocate inspection effort by using knowledge of the management system and the performance of processes the following common view was attained:

It is reasonable to reduce inspection effort on management system processes if there is confidence in the processes. However, defined criteria are needed.

In case of poor performance, inspection efforts should be increased.

An option for reducing the overall inspection effort is to direct a certain amount of the inspection effort in a different area, e.g. focus attention on attitudes and understanding of senior licensee managers using the management system.

Certification or registration to ISO 9001 should not automatically lead to reduced regulatory attention/inspection. This is just one of the factors to take into account when allocating regulatory effort.

Focus on Top Management

The senior management has a prominent role for the implementation and continuous improvement of the management system. Therefore many regulatory bodies meet with the licensee’s top management on the plant level and on the corporate level. Depending on the subject, both informal communication and specific inspection methods are applied. To obtain information about the management system the talks, discussions or interviews should or could address

- interactions between the corporate level and the plant level,
- strategies, where the organisation is heading (e.g. subcontracting, planned lifetime),
- future investment strategy and budget,
- top management’s views on safety level, safety culture etc.,
- top management’s responsibility for the management system (the top management “owns” the management system),
- changes in the management system and reasons why the changes are being made,
- lessons learnt from major events in nuclear and other industries (e.g. petrochemical),
- major findings, review of the past performance,
- major projects important for resource planning of the regulatory body,
- expectations of the regulatory body (in order to promote, stimulate, motivate, push in the expected direction).

Commendable Practice:

The regulatory body should have discussions, interviews, and routine meetings with the licensee's top management, both on the facility level and on the corporate level.

Inspecting Key Aspects

In the discussion groups, an exchange of experiences took place. The practices of inspecting management system elements and processes are comparable in general but different in the details. It was recognized that special key elements are subject of the regulatory inspections in many countries. It is assumed that from information to such key aspects a conclusion to the entire management system could be drawn. The following commendable practice was ascertained:

By inspecting key aspects of the management system, the regulatory body can ascertain a well-founded impression of the effectiveness of the management system.

Examples for such key aspects are:

- safety policy and scope of the management system
- closed plan-do-check-act (PDCA) cycles
- management system effectiveness: self-assessments, reviews (a comparison of inspection findings to the licensee's own self assessment results is helpful)
- documentation structure of the management system (including the integration of requirements from other areas, such as ISO 14001 and ASME)
- use of information for improvements (including the evaluation of safety performance indicators)
- human and organisational factors (e.g. leadership, management walk downs, human performance program)
- management of (organisational) changes

Effectiveness of the Management System

A challenging question is: How can the regulatory body "measure" the effectiveness of the licensee's management system? The discussions concluded in the commendable practice:

The regulatory body should "measure" the effectiveness of the MS

- by evaluating inspection results
- by looking at the recurrence of findings
- by looking at the recurrence of contributing factors to events
- by examining the licensee's own evaluation on achievements of goals
- by evaluating safety performance indicators (trends)
- by observing if the staff members have the appropriate knowledge / awareness of the management system according to their hierarchical level within the licensee's organisation.

Additional Items for Consideration

From the discussions some additional points were noted:

- Regulators need to understand the difference between "promotion" and compliance. Initial contact between the regulator and the licensee requires "promotion" (i.e., a period of time to allow for an explanation and understanding of the new regulatory requirement and its associated regulatory expectations). Compliance verification through inspection should only begin after the licensee has had the time to understand and implement the requirement.

- Regulators must consider the adequacy of both the programmes/processes (e.g., process design, process owner) and the outcomes/findings.
- World Association of Nuclear Operators (WANO) and Institute of Nuclear Power Operations (INPO) can have a strong influence on the licensee. Regulators have to be prepared for potential conflict between the WANO/INPO approach and the regulatory expectations. A common problem identified among licensees is overly complicated processes and associated procedures. Such overly complicated processes are cumbersome for effective implementation of the management system and difficult for understanding and inspecting the system.
- Regulators should identify the stakeholders affecting the licensee and understand their level of influence on the licensee.
- A potential challenge for the regulator is that the licensee may have a management system that is integrated, but the regulatory regime is not. The regulator may have to deal with conflicting requirements of expectations: e.g. the nuclear regulatory requirements may be different from the occupational health and safety regulatory requirements.
- There is a difficulty in taking enforcement action on management system failures. No regulatory body has shutdown a plant directly due to management system failures. Licensees have taken action on their own. The problem for the regulator is in making a case that management system failures can have a direct and predictable impact on safety. However, management system failures do lead to major events (e.g., Davis Besse vessel head corrosion).
- A culture change is required in both licensees and regulators. A focus on the root causes of problems is necessary, rather than fixing individual problems.

Knowledge in the Regulatory Body

Considering the necessary knowledge for the inspection of the licensee's management system one has to distinguish the knowledge, skills and abilities of the individual inspectors from the organisational knowledge and competence of the regulatory body. The discussion resulted in the common view:

The regulatory body should have:

- specialists (or specialist inspectors) in organisational factors and management systems,
- a process for getting specialist's assistance,
- a culture where generalists are willing to ask for assistance, and
- an awareness of good practice in other industries.

The regulator's personnel should have a common interpretation of the regulatory expectations for management systems.

The regulator's personnel need to know when to apply promotional effort instead of compliance effort.

Inspectors and specialists need to have some knowledge of the licensee's financial system and pressures.

Inspectors need to understand:

- how management systems are developed and implemented,
- the audit process,
- the root cause analysis at an appropriate level, and
- wider issues affecting the function of the management system like leadership, culture of the licensee organisation, human performance.

Inspectors need the usual soft skills for inspections of the management system.

4.3 Effectiveness of Regulator Inspection Processes

4.3.1 Discussion Groups

GROUP 1	GROUP 2
<ul style="list-style-type: none"> • Crespo, Mr. Julio , Nuclear safety council (CSN), SPAIN* • Barras, Mr. Pierre, Bel V, BELGIUM* • Chung, Dr. Dae-Wook, KINS, R. OF KOREA* • Bencat, Dr. Mikulas, UJD, SR SLOVAKIA* • Koch, Mr. Werner, Kernfysische Dienst (KFD), THE NETHERLANDS • Jansen, Mr. Kees, Ministry of VROM, THE NETHERLANDS • Smith, Mr. Gavin, Health and Safety Executive, UNITED KINGDOM • Schlögl, Mr. Frank, TÜV SÜD Industrie Service GmbH, GERMANY • Fraysse, Ms. Aline, French Nuclear Safety Authority, FRANCE • Koizumi, Mr. Hiroyoshi, Nuclear Energy Safety Organisation, JAPAN 	<ul style="list-style-type: none"> • Fierz, Mr. Hans Rudolf, Federal Nuclear Safety Inspectorate, SWITZERLAND* • Klonk, Dr. Hartmut, Bundesamt für Strahlenschutz, GERMANY* • Jansen, Mr. Rob, VROM-Inspectorate/KFD, THE NETHERLANDS • Johnson, Ms. Andrea, US Nuclear Regulatory Commission, USA • Emrich, Dr. Hansjörg, Hessisches Umweltministerium, GERMAN • Sunabacka-Starck, Mrs. Ann-Mari, Radiation and Nuclear Safety Authority, FINLAND • Schrauben, Mr. Manfred, Federal Agency for Nuclear Control, BELGIUM • Wassink, Mr. Carel, Inspectie Verkeer en Waterstaat, THE NETHERLANDS • Yoshimura, Uichiro (1-day), NEA, FRANCE
* WGIP Members	

4.3.2 Group Discussions

The presentation given at the Opening Session summarized a review of the information given by the participants before the workshop (issued as a separate Appendix to the Proceedings). The presentation also addressed additional questions, which were derived from the responses and were used by both groups to trigger the discussion during the breakout sessions.

Group 1 participants started the discussions looking for an acceptable definition of the effectiveness of RB inspection. They agreed on a common understanding for such a definition. Different approaches were discussed whether the regulatory inspector should assure that safety is maintained or should give incentives to improve safety. In the following session, the group members focused their attention trying to identify feasible direct indicators for the effectiveness of the RB inspection. The group members also discussed various aspects of how to improve the effectiveness of regulatory inspection, in particular, issues related to the inspectors themselves. Finally the group concentrated in other aspects of the subject, concluding with a global view towards the effectiveness of the RB inspection.

Group 2 focused on discussing the different elements influencing the effectiveness of the regulatory inspection process. Extensive discussions were held about how to increase the effectiveness of the regulator inspection process. Inspection indicators were discussed, but doubts were raised about their suitability and feasibility. Furthermore, it was emphasised that the inspectors should be integrated in a team with a common strategy and have the full support of their organisation. Subjectivity should be avoided, consistency should be maintained. Continuous improvements in the inspection process are necessary. The regulatory body should be a learning organisation. Audits, self-assessments, trainings, and a strong international collaboration are elements to achieve this goal.

Group 2 also discussed how to inspect and contribute to improvements on the licensee's safety performance. Solely, inspecting for compliance does not identify the practiced operational safety performance and cannot reveal any degradation. Licensee's safety management and safety culture ensures good operational safety performance by adding appropriate operational safety margins. Related regulatory inspection can give additional incentive for such improvements. By this, regulatory inspection is effective.

The facilitators of both groups recognized that the two groups focussed their discussion on completely different issues related to the topic, but with a potential to combine these issues to an integrated view. At the end of the breakout sessions, the members of the two groups met to explain their results and mutually comment on the conclusions. Both groups accepted the conclusions derived from the different approaches. For similar conclusions of both groups, a common language was accepted. Both groups agreed that their conclusions complement each other in a perfect way and could be easily combined.

The combined conclusions from the discussions of the working group sessions were summarized in the closing plenary session covering the following discussion areas:

- Definition of the RB effectiveness inspection process
- Elements to establish the effectiveness of the regulatory inspection process
- Direct effectiveness inspection indicators
- Others tools
- Global view towards the effectiveness of RB inspection

1. Definition of the RB effectiveness inspection process.

RB inspection process is effective when:

- the results of inspections are consistent with the RB mission, and
- the inspection findings are communicated and recognized by the licensee,

This influences the activities of the licensee to ensure the safe operation of the plant.

2. Elements to establish the effectiveness of the regulatory inspection process.

- The participants noted the definition given in the document "Improving Regulatory Effectiveness" (NEA/CNRA/R(2001)3), stating that a regulatory body is effective when it assures that an acceptable level of safety is being maintained. Expanding this approach, most participants agreed that inspectors should aim for continuous improvement in safety of the plant.
- Participants agreed that the review of operating experience and feedback for safety improvement measures in a systematic and comprehensive way is regarded a strong element to improve the effectiveness of the RB inspection process.
- The regulatory body should strive to be up to date with international state of the art of regulation. Therefore, they should adequately follow up and update their inspection programmes.
- The regulatory inspection programme is based and developed from the established Vision, Mission, Policy, and Strategy of the RB.
- The regulatory body should be a learning organisation, with established PDCA cycle. Therefore RB competence could be improved by self assessment, external missions like IRRS, and incorporating feedback from the licensee and other RB staff.

- The regulatory body needs effective inspectors. Contributing to this their Qualifications, Experience, Competence, Training, Motivation, Questioning attitude, need appropriate development with Management support and oversight.
- Positive and consistent RB management support and oversight as well as working in a team have the potential to improve the experience, knowledge, motivation, training, behaviours of RB inspectors.
- It is necessary to have constructive and professional communication between the licensee and RB inspectors with a balanced attitude regarding the necessary distance and appropriate closeness for mutual understanding and respect.
- Regulatory inspectors should have the ability to fully integrate inspection findings in order to reveal deficiencies in the licensee's organisation or processes.
- The rotation of site inspectors among different sites and/or different licensees prevents too much familiarity with the licensee, and thus, contributes to the effectiveness of RB inspection.

3. Direct effectiveness inspection indicators.

Group members identified four direct indicators to review inspection effectiveness. During the closing plenary session it was highlighted that there was a great difficulty in identifying these indicators and care must be taken about their suitability, feasibility and contribution to indeed measure the effectiveness of RB inspections.

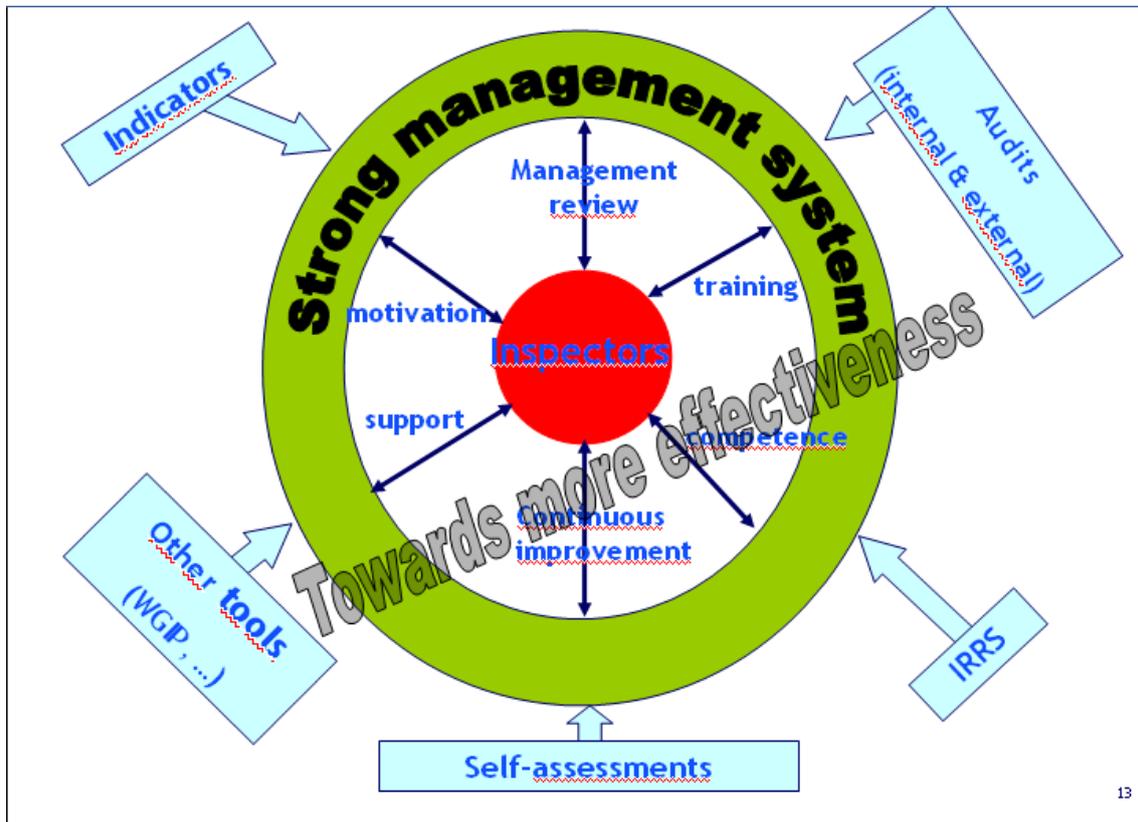
- **Repetitive inspection findings.** Participants considered that repetitive findings could address to persistent shortfalls and an attitude to "not making a difference." Therefore it could be recognized as an indicator of lack of effectiveness.
- **No relevant findings over a cycle of inspection programs.** Group members agreed that if regulatory inspection does not reveal any relevant finding during a time of 5 or more years, this could indicate the need to modify the regulatory inspection program or process.
- **Self revealed issues.** This kind of issue was defined as those problems that are not identified before it happens, neither by the inspection of the licensees nor by the regulatory body inspection. A negative trend in this area could indicate a lack of effectiveness in RB inspection.
- **RB reactive inspection** – An increase in the inspection effort devoted to reactive inspection may indicate a weakness in the regulatory inspection process.

4. Other Tools to improve the effectiveness of the inspection.

- International cross inspection
- Bench marking
- International workshops
- Exchange of experience and lessons learned in CNRA, WGIP, ...
- Interaction with non-nuclear regulatory bodies.

5. Global view towards the effectiveness of RB inspection.

Group members developed a visual image demonstrating their vision of, not only how to measure the effectiveness of the RB inspection, but also how to contribute in setting the direction towards an increased effectiveness of regulatory bodies.



5. CLOSING PLENARY SESSION

5.1 Presentation of Topics

A presentation on each of the workshop topics was made by the facilitators. Each presentation was followed by general questions and comments from the floor. Each of the groups developed a set of conclusions or commendable inspection practices based on their discussions.

“Commendable practices” are extracts from the topics, which were discussed by the workshop participants and were thought to be reference for member countries. These are neither international standards nor guidelines. Each country should determine inspection practices, considering its own historical, social and cultural backgrounds and the commendable practices can be useful reference when each country improves its inspection practices.

5.2 Closing Remarks

Mr. Lewis remarked on the success of the discussions. His impression was that there had been full and frank exchanges of views both during the plenary and break-out discussion sessions. He also noted that the informal sessions provided many additional opportunities for bilateral exchanges.

Discussions on the Workshop topics have shown that:

- These workshops for inspectors continue to provide a unique environment in which inspectors can exchange information on current issues to gain insights and to also validate their own processes.
- The topics were well developed and the participants were well prepared and made important contributions.
- The development of both commendable inspection practices and the development of new challenges to be faced were successful and participants and their national organisations would hopefully benefit from the insights gained.

In closing the work, Mr. Lewis thanked VROM for hosting and in particular, Mr. Kees des Bouvrie, the WGIP member who co-ordinated all the organisation efforts of the workshop. Mr. Lewis also thanked Ms. Diane Jackson (OECD/NEA secretariat) for her service to the Working Group on Inspection Practices, which included support from NEA, all organisational aspects for the groups programme of work and for the group meetings and workshops.

In concluding, Mr. Lewis thanked all the workshop participants, facilitators and recorders remarking that without their contributions, hard work, dedication and commitment the Workshop would not have been a success.

6. CONCLUSIONS

6.1 General Workshop Conclusions

The following conclusions emerged from the workshop (Note - These conclusions and the accompanying commendable practices are based on workshop discussions and do not reflect a consensus NEA opinion. Nevertheless, they can be utilised as a general benchmark for basic comparisons of those issues which inspectors from participating countries share).

The following subsections provide a listing of the commendable inspection practices that evolved from the various group discussions.

6.2 Conclusions and Commendable Inspection Practices

6.2.1 *Experience from Inspecting Safety Culture*

The groups agreed that the following conclusions and commendable inspection practices are important to monitoring and evaluating the safety culture of licensees:

- Regulatory safety culture inspections programmes are a useful tool to proactively promote the importance of strong licensee safety culture.
- Regulators and licensees need to strive towards a common understanding of the definition of safety culture.
- Licensee employees need to buy in to the safety culture programmes.
- It is important to continually communicate with licensees on safety culture matters.
- Safety culture should be continuously evaluated.
- It is important to clearly communicate safety culture inspection findings to licensees, stakeholders, and other regulatory bodies (in accordance with local frameworks).
- Safety culture training for general inspectors is important.
- Licensees should implement safety culture improvement programmes and regulators should monitor the programmes for effectiveness.
- Regulators should demonstrate a strong sense of safety culture.

6.2.2 *Inspection of the Licensee Safety Management System*

The groups agreed that the following conclusions and commendable inspection practices are important to the inspection of licensee management systems:

1. For inspecting the management system, inspectors should have clear expectations of the characteristics that a “good” management system should show.

2. Regulatory requirements in the field of the management system should be not too prescriptive, in order to:

- allow responsibility / flexibility to the operator,
- be open for innovation and improvements,
- allow integration of different management system aspects, and
- have the “big picture.”

3. Licensees should have a process (e.g., a change process) and criteria for grading the safety significance of activities. The regulator should look at the application of the grading to check that the grading is not too low.

4. The regulatory body should have discussions, interviews, and routine meetings with the licensee’s top management, both on the facility level and on the corporate level.

5. By inspecting key aspects of the management system, the regulatory body can ascertain a well-founded impression of the effectiveness of the management system.

6. The regulatory body should “measure” the effectiveness of the MS

- by evaluating inspection results,
- by looking at the recurrence of findings,
- by looking at the recurrence of contributing factors to events,
- by examining the licensee’s own evaluation on achievements of goals,
- by evaluating safety performance indicators (trends),
- by observing if the staff members have the appropriate knowledge / awareness of the management, system according to their hierarchical level within the licensee’s organisation.

6.2.3 Effectiveness of Regulator Inspection Processes

Both Groups agreed on the conclusions as reported in Section 5. They did not explicitly formulate commendable practices. In summarizing the conclusions, the following conclusions can be regarded as the participants’ view:

1. RB inspection process is effective when the results of inspections are consistent with the RB mission, and the inspection findings are communicated and recognized by the licensee. This influences the activities of the licensee to ensure or improve the safe operation of the plant.
2. Review of operating experience and feedback for safety improvement measures in a systematic and comprehensive way is a strong element to improve the effectiveness of the RB inspection process.
3. The regulatory bodies need to be up to date with international state of the art of regulation. Therefore they adequately follow up and update their inspection programmes.
4. The regulatory body is a learning organisation. Its competence is improved by self assessment, external missions like IRRS, and incorporating feedback from the licensee and other RB staff.
5. Effective regulatory inspectors develop their qualifications, experience, competence, training, motivation, questioning attitude by working in a team and with strong management support.
6. Regulatory inspectors have good communication with the inspected licensee having a balanced attitude regarding necessary distance and appropriate closeness for mutual understanding and respect.

7. Rotation of site inspectors across different sites and/or different licensees can contribute to the effectiveness of RB inspection.
8. Direct indicators to review or measure regulatory inspection effectiveness should be taken with care about their suitability and feasibility. Such indicators may include repetitive inspection findings, no relevant findings over a cycle of inspection programs, self revealed issues, inspection effort devoted to reactive inspection.
9. Regulatory inspection effectiveness can be supported by bench marking, international cross inspections, experience exchange and interaction with non-nuclear regulatory bodies.

7. EVALUATION

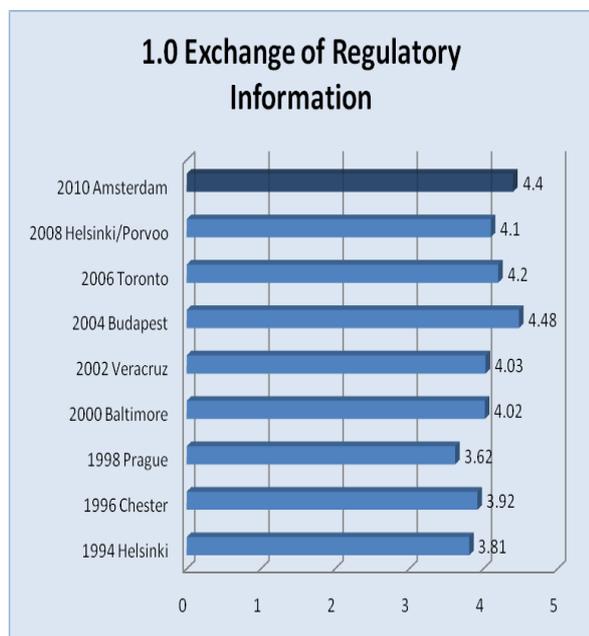
7.1 Evaluation Form

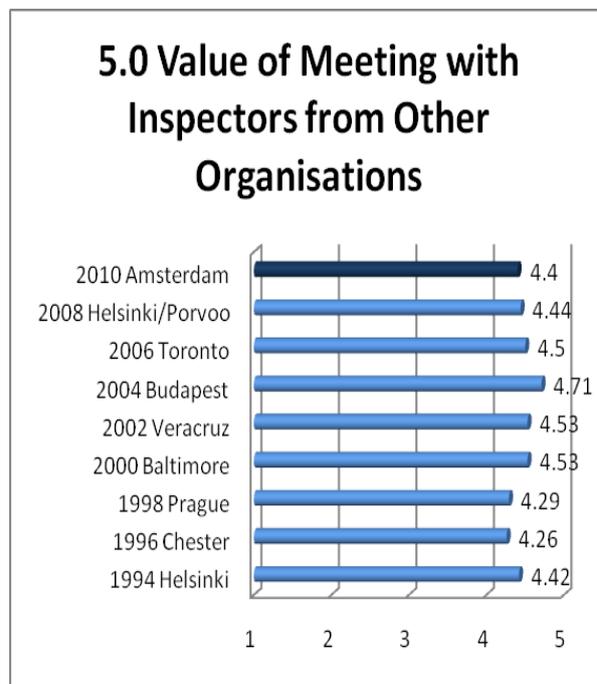
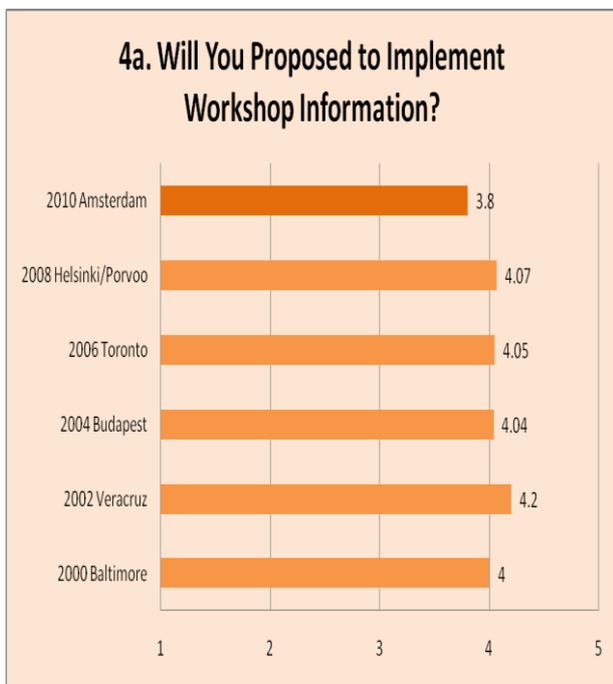
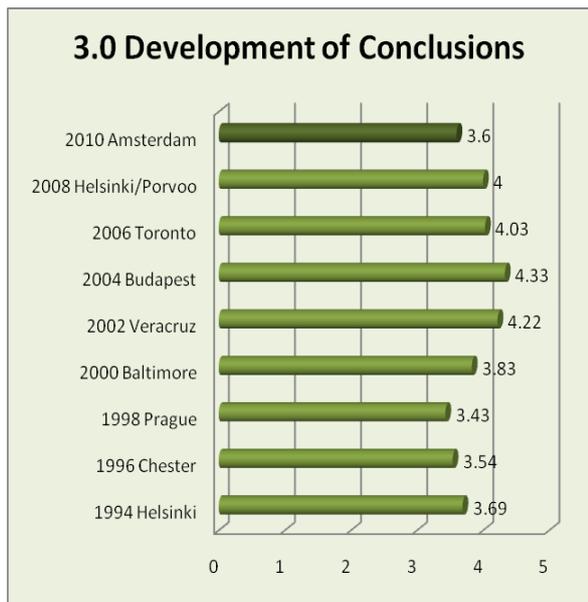
All participants at the workshop were requested to complete an evaluation form. The results of this questionnaire summarised below, are utilised by WGIP in setting up future workshops and to look at key issues for in the programme of work over the next few years. Of the 60 total participants 43 responses were received.

The evaluation form, which was similar to ones issued at previous workshops, asked questions in 4 areas: general - workshop objectives, workshop format, workshop topics and future workshops. Participants were asked to rate the various questions on a scale of 1 to 5 (with 1 being a low (poor) score and 5 being a high (excellent) score). Results are provided in the following charts (which also reflect scores from the previous workshops - for comparison purposes) along with a brief written summary.

7.1.1 General

Each of the following charts depicts a specific objective of the workshop and the participant's responses on how well they were met.

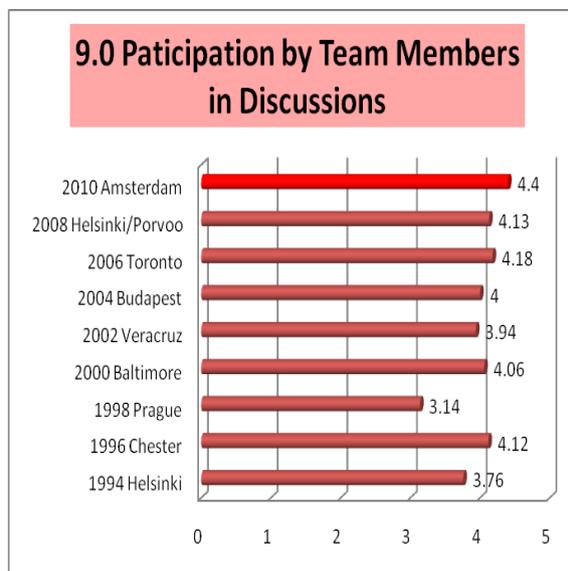
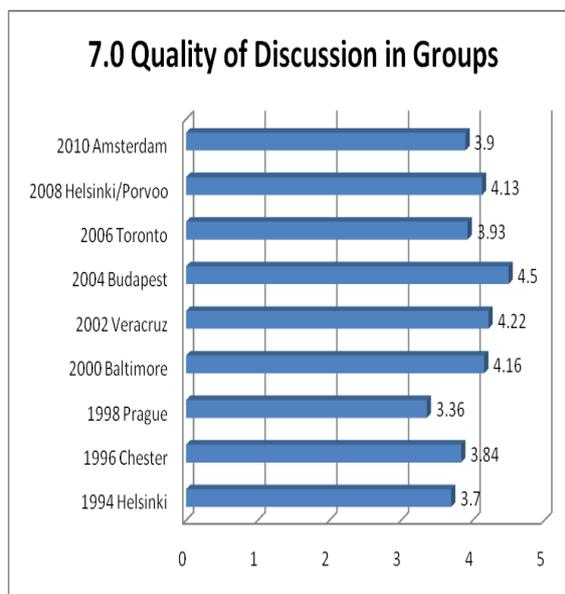


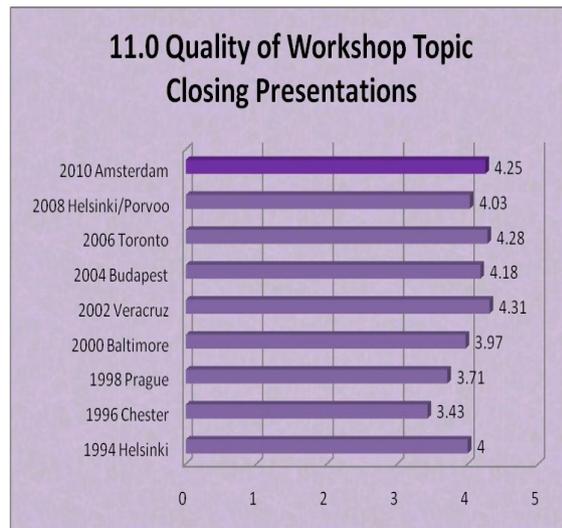
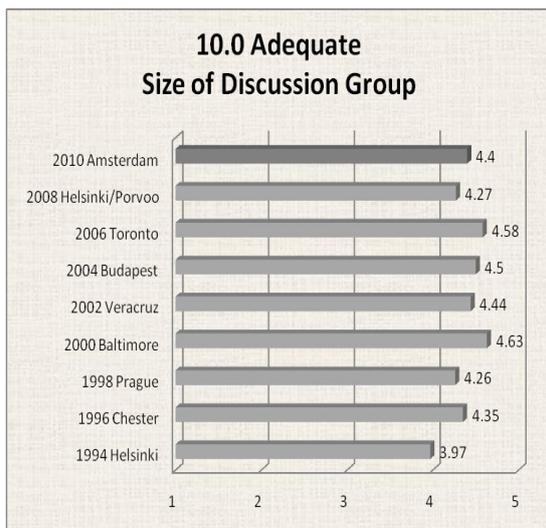


The results for the quality of information exchange and the discussion was very high. These are important indicators for the level of participation. The response for Questions 3, 4 and 4a, are lower than previous workshops. However, this is a reflection of the level of difficulty of the topics chosen for this workshop and also the maturity of the topics. Both safety culture and safety management require softer skills and few regulatory bodies have regulations for straight-forward inspection implementation. Additionally, the topic of effectiveness of the regulatory inspection process is a self-assessment topic, and not an inspection method. As such, it is expected that this would influence the results of this question. However, it should not be inferred that this topic was not supported. On the contrary, as seen in Question 12, the effectiveness of the regulatory inspection process was rated the highest among the workshop topics.

7.1.2 Workshop Format

This part of the questionnaire looked at how effective each of the sessions was. The main objective of this question focuses on the way sessions are conducted. The responses provide key information to WGIP in their preparation and planning for future workshops.

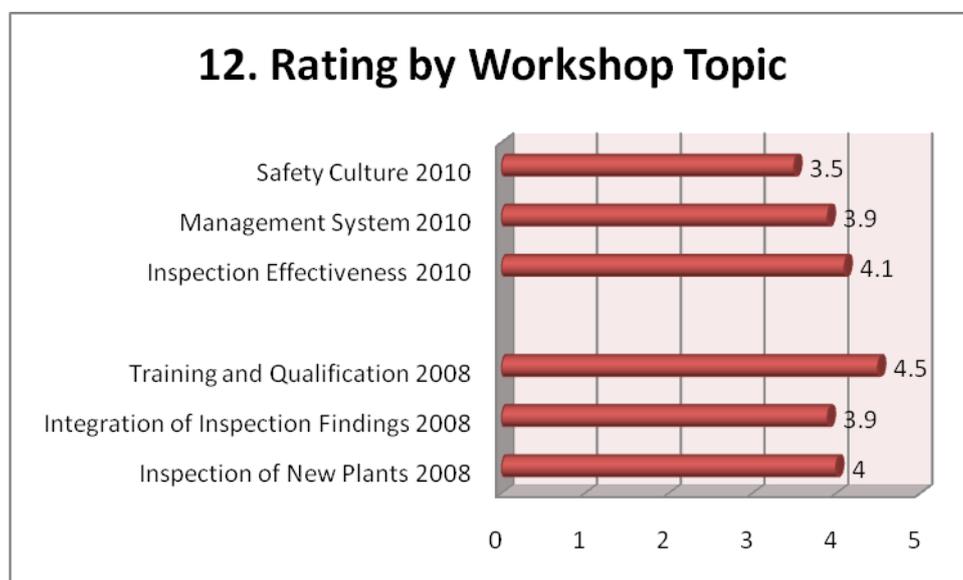




The results are with a similar range to other WGIP workshops. They confirm that WGIP members are efficient in preparing and running the workshop. The success of each workshop is dependent on good preparation by the WGIP and co-ordination between the facilitators and recorders for each topic. As discussed in previous proceedings, social interaction outside the workshop sessions clearly enhances the discussions.

7.1.3 Workshop Topics

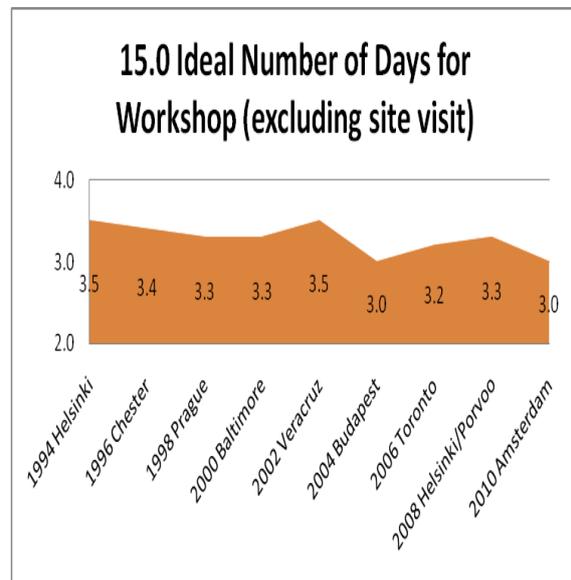
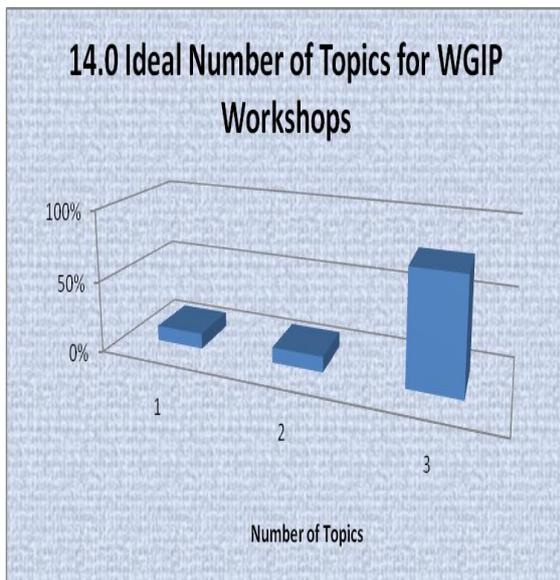
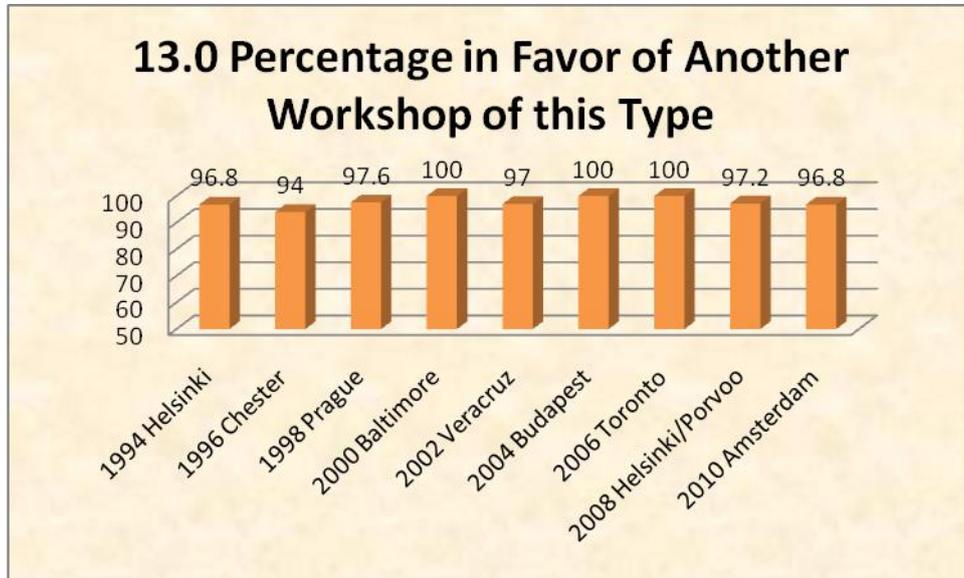
In order to assess how well the topics have been addressed, participants are asked to give a rating on whether they perceived the topics were covered adequately.



Workshop participants were generally satisfied with the selection of topics and how they were addressed. The scores recorded were similar to past workshops and the importance of the regulatory body's assessment of the effectiveness of the inspection programme is clearly depicted. The relatively lower score for Safety Culture reflects the difficulty of the topic for inspection.

7.1.4 Future Workshops

While Section 7.3 looks at the way workshop sessions are conducted, this section provides a perspective of the type of format, the overall value of having workshops and how they can be bettered.



Workshop participants who responded clearly supported future workshops. The results show that most participants also agree with the existing format regarding the number of topics and the length of the workshop.

7.2 Suggested Future Topics

Participants were asked to provide their input on potential future topics. Over 25 topics were listed in the responses. While no specific analysis was applied to the results, WGIP and the CNRA will evaluate these and use them in proposing topics for future workshops. Some of more frequently mentioned topics (randomly listed not prioritised) were as follows:

- Safety Risk Management (2)
- Safety Culture (SC) assessment of RB/ Safety Culture of the RB
- Safety Culture
- Safety Management (SM)
- Blending SM System (SMS) and SC assessment methodologies
- Special Aspects of SMS: maintenance, knowledge management, data collection
- Incorporating Operating Experience into the Inspection Process
- Long Term Operation
- License Renewal
- Operational Safety Assessment
- Use of Inspection Results
- Relationship between regulator and operator
- Performance Indicators
- Management: Analysis tools and indicators
- Inspection of adequacy of the NPP's Organisation
- Inspection of adequacy of the NPP's resources for safety measures
- Roll of RB and technical support organisation (TSO) in Nuclear Regulation
- Decision making

Additional Comments Received

- Very well organised
- Groups too large; Groups should be a max of 6 – 7
- Several definitions of Nuclear Safety exist – WGIP should explore and have one clear definition
- SC workshop did not cover “Experiences”
- Close collaboration between WGIP and WGHOE on SC and SM would be beneficial
- Some participants in this workshop should participate in IAEA workshop in January 2011 to continue international collaboration on SC

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APPENDIX 2. PREVIOUS WGIP WORKSHOPS

Year	Date	Country	City	Publication Number
1992	30August -4 Sept.	United States	Chattanooga	NEA/CNRA/R(92)3
1994	22-27 May	Finland	Helsinki	NEA/CNRA/R(94)4 and OECD/GD(95)14
1996	19-24 May	United Kingdom	Chester	NEA/CNRA/R(97)1 and OECD/GD(97)62
1998	07-12 June	Czech Republic	Prague	NEA/CNRA/R(99)2
2000	14-19 May	United States	Baltimore	NEA/CNRA/R(2001)4 and NEA/CNRA/R(2001)5
2002	28 April -03 May	Mexico	Veracruz	NEA/CNRA/R(2003)1 and NEA/CNRA/R(2003)2
2004	25-30 April	Hungary	Visegrad	NEA/CNRA/R(2005)4 and NEA/CNRA/R(2005)5
2006	30 April -05 May	Canada	Toronto	NEA/CNRA/R(2007)1 and NEA/CNRA/R(2007)2
2008	02-06 June	Finland	Helsinki (Porvoo)	NEA/CNRA/R(2010)1 and NEA/CNRA/R(2010)2
2010	16-20 May	The Netherlands	Amsterdam	NEA/CNRA/R(2010)5 and NEA/CNRA/R(2010)6