IAEA TECDOC SERIES

IAEA-TECDOC-1895

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Safety Culture Practices for the Regulatory Body

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SAFETY CULTURE PRACTICES FOR THE REGULATORY BODY

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IAEA-TECDOC-1895

SAFETY CULTURE PRACTICES FOR THE REGULATORY BODY

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2020

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Printed by the IAEA in Austria
January 2020

IAEA Library Cataloguing in Publication Data

Names: International Atomic Energy Agency.
Title: Safety culture practices for the regulatory body / International Atomic Energy Agency.
Description: Vienna : International Atomic Energy Agency, 2020. | Series: IAEA TECDOC series, ISSN 1011–4289 ; no. 1895 | Includes bibliographical references.
Identifiers: IAEAL 20-01286 | ISBN 978–92–0–100520–5 (paperback : alk. paper) | ISBN 978–92–0–100620–2 (pdf)
Subjects: LCSH: Nuclear industry — Safety measures. | Independent regulatory commissions. | Industrial safety. | Safety.

FOREWORD

One of the statutory functions of the IAEA is to establish or adopt standards of safety and security for the protection of health, life, property and the environment in the development and application of nuclear technology for peaceful purposes.

IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment. Although not legally binding on them, Member States may adopt IAEA safety standards, at their own discretion, in conjunction with more detailed requirements consistent with national practice, for use in the regulation of nuclear facilities and activities.

This publication provides a summary of practices from Member States relating to the promotion of safety culture in the regulatory body as well as regulatory oversight of the safety culture of licensees. It also includes a consensus of some Member States on what safety culture means within their regulatory body.

The information provided will help regulatory bodies not only to verify but also to promote and enforce compliance with IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety. It is hoped that these practices will be helpful to regulatory bodies at all levels of experience and knowledge of safety culture.

The IAEA gratefully acknowledges the contributions of regulatory bodies in several Member States. The IAEA officers responsible for this publication were S. Magruder of the Division of Nuclear Installation Safety and O. Makarovska of the Division of Radiation, Transport and Waste Safety.

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1. INTRODUCTION

1.1. BACKGROUND

Over the past two decades, there has been increasing awareness of the significant contribution that organizational factors make to the safe operation of nuclear facilities and activities. The concept of safety culture, and its application in the nuclear industry, has evolved from the principles set out in the fundamental document IAEA Safety Series No. 75-INSAG-4 Safety Culture [1] to embrace recognition of the pivotal role of leadership and management for safety. This is reflected in the IAEA Safety Standards, GSR Part 2 Leadership and Management for Safety [2], published in 2016, and in the IAEA Safety Guides: GS-G-3.1 Application of Management System for Facilities and Activities [3], GS-G-3.5 The Management System for Nuclear Installations [4] and GSG-12 Organization, Management and Staffing of the Regulatory Body for Safety [5]. Initial efforts to define, understand and develop advice and guidance on nuclear safety culture focused on operators. However, there has been a growing appreciation that the activities of the regulatory body and the way that it engages with operators to maintain oversight of, and encourage, their safety cultures, makes a significant contribution to nuclear safety. Progress in addressing regulatory body safety culture has been made through meetings, conferences, and workshops to establish practical approaches for regulatory oversight of safety culture.

In light of the accident at the Fukushima Daiichi Nuclear Power Plant, the 2nd Extraordinary Meeting of Contracting Parties to the Convention on Nuclear Safety, held in August 2012, identified safety culture as one of the areas where improved regulatory processes were warranted. Also, the 3rd International Conference on Effective Nuclear Regulatory Systems (Ottawa, Canada, April 2013) focused on the key role of regulators in ensuring safety and security and The International Conference on Effective Nuclear Regulatory Systems Sustaining Improvements Globally (Vienna, Austria, April 2016) emphasized the importance of nuclear safety and security cultures. There was a widespread acknowledgement by senior regulators of the importance of, and a commitment to, safety culture. They stressed the need to take steps to strengthen programs and processes to continuously promote and improve their internal safety cultures. In addition, at the International Experts Meeting on Human and Organizational Factors in Nuclear Safety (IEM-5), held in May 2013, the importance of assessing and continuously improving the regulatory body's own safety culture was discussed.

The IAEA organized a Technical Meeting, in October 2014, that provided a forum for senior regulators to share their experience and disseminate knowledge about how safety performance can be improved through effective leadership, management for safety and safety culture. The meeting addressed how regulators integrate safety culture improvement programs into their daily activities, and how the senior management takes safety culture into consideration in its decision-making processes. A main outcome of this Technical Meeting was the recommendation to develop a technical document which describes regulatory processes, good practices, and work done by some Member States in this area.

1.2. OBJECTIVES

The objective of this publication is to provide practical guidance to regulatory bodies on promoting and assessing safety culture within their own organizations and providing regulatory oversight of licensees' safety culture activities. Practices from Member States are summarized and common challenges faced by regulatory bodies in implementing these practices are set out.

1.3. SCOPE

This document is intended for use by regulatory bodies responsible for regulating the safety of nuclear installations and related activities. Specifically, is to be used by senior management in sponsoring the conduct of safety culture self-assessment and by the regulatory staff involved in the safety culture self-assessment process.

Considerations on how to apply a graded approach depending on the specific characteristics of the organization are included. It must be noted that not all the practices included are applicable to every regulatory body, and relevance will depend upon national legal and regulatory frameworks.

1.4. STRUCTURE

This publication consists of three sections. The first section covers the background, objectives, scope and structure of the publication, the second section elaborates on safety culture in the regulatory body and the third section describes the regulatory oversight of licensee safety culture.

The annexes give practical examples of practices in different Member States.

2. SAFETY CULTURE IN THE REGULATORY BODY

The way in which a regulatory body conducts its activities will be apparent to, and influence, its licensees. It seems logical that if a regulatory body wishes to encourage a positive safety culture within a licensee, it has to be seen visibly to act in accordance with the principles that it advocates for the licensee. Although senior level conferences and other events have emphasized the need for nuclear regulatory body to take steps to sustain their own safety culture, there has not been a shared appreciation of what this means in practice. Section 2.1 of this report will clarify what safety culture means in the context of a regulatory body. This will provide a framework for a discussion of national practices that can be used to develop and sustain regulatory body safety culture which follows in Section 2.2. In Section 2.3, a set of 'challenge' questions is presented. These questions are intended to help the reader to reflect on what regulatory body is doing to sustain a positive safety culture within his/her own organization.

2.1. CONTEXT

In setting the context for this collection of regulatory practices it is important to be clear that, in this report, it is interpreted as the way in which individual and institutional attitudes, values, behaviours and processes impact on the effectiveness and efficiency of ***nuclear safety decisions and actions*** taken by the regulatory body. In other words, the practices do **not** relate to other matters, such as job satisfaction, working conditions etc., though a link between these different aspects is acknowledged.

All organizations across different industrial and business sectors, including nuclear licensees and regulatory bodies, are subject to external and internal factors that have the potential to affect the way that they work and take decisions. Some factors, and their potential to influence regulatory body decision-making and action, might include external and internal factors.

2.1.1. External factors

Although a regulatory body does not itself generate revenue from an operating nuclear power plant or other facility, its decisions on the adequacy of a licensee safety case have significant potential to affect the profitability and viability of the enterprise. For example, if the regulatory body seeks plant modifications that extend beyond what the licensee considers to be reasonably practicable; if the regulatory body considers that technical or organizational readiness to return from a plant outage has not been demonstrated; or if the regulatory body has not concluded its assessments at the point when the licensee wishes to restart. Pressure for a favorable decision might be brought to bear on the regulatory body from different stakeholders including the licensee and potentially government and the public if delivery of key services such as electricity supply or medical isotope production could be impaired. Conversely, national and local interest groups might press for overly conservative regulatory positions that do not represent a balanced safety position. The regulatory body needs to be resilient to such pressures and ensure that its expectations and position on the primacy of making the right safety decisions and actions are communicated clearly to staff and other stakeholders. Also, as noted below, adequate resources can have external, as well as internal origins.

2.1.2. Internal factors

A regulatory body needs to be adequately resourced with suitably qualified and experienced persons to take the right safety decisions and actions. All organizations, including regulatory bodies, can be subject to funding pressures which may impact upon the effectiveness with which they work. Some of the planning decisions on allocation of resources may be external and some internal; but funding pressure has potential to drive the wrong outcomes – for example by leading the regulatory body to curtail the depth of safety assessment, set unrealistic deadlines or use less experienced personnel or contractors.

A regulatory body has many different functions, such as technical, inspection, administrative, enforcement, policy etc. Effective working relationships within any organization can be difficult to secure, and a regulatory body is no different in this respect. Barriers to effective cross-section working can emerge for a range of reasons including territorial (e.g. 'this is my area'); personal career drivers (e.g. 'information is power'; 'this is a high-profile project that may earn me recognition'); lack of understanding ('my technical area is the most important') etc.

All aspects of individual behaviour that affect ways of working in other organizations are relevant to the regulatory body. Individual behaviours, as in any organization, may not be conducive to open, constructive discussion and decisions on nuclear safety matters. For example, people who are over-assertive or dismissive of alternative views could skew a regulatory decision. Individual staff members may be pressured – directly or tacitly – by their management or others to make judgements or to meet delivery deadlines which are not consistent with balanced or conservative decision-making. The question is whether the regulatory body leadership acknowledges the potential impact that inappropriate behaviours can have – not just on job satisfaction and attitudes, but also on nuclear safety decisions and actions.

A willingness to embrace constructive challenge is an acknowledged characteristic of a positive safety culture. Lack of challenge may compromise the quality of nuclear safety decision-making. There is ample evidence from different sectors, including nuclear safety regulation, showing that internal challenge is not always encouraged in practice, even where formal policies have been introduced. This may be a particular issue in more hierarchical organizations or societies, but individual behaviours, especially those of line management, can be a key enabler or blocker to constructive challenge.

A regulatory body needs to ensure that it learns from experience gathered both from within its own organization and from peers in the nuclear and other sectors. Without gathering, interpreting and reflecting on lessons learned, it cannot assure itself that it is working in the right way, with the right standards, approaches and behaviours to deliver its nuclear safety oversight role. A regulatory body needs to have the humility to acknowledge when it has got things wrong or when it can improve, and not seek to defend itself by deflecting responsibility.

The role of key policy and decision-makers in addressing these factors and working to promote and sustain a positive safety culture within the regulatory body is of paramount importance. A regulatory body leadership needs to set out its expectations regarding the primacy of effective and balanced nuclear safety decision-making and ensure that these are understood and met. This may not always be appreciated by senior leadership, especially where they have less experience in the nuclear industry. It is especially important, therefore, that leadership expectations for those individual and institutional attitudes, values, behaviours and processes that place an overriding priority on nuclear safety are formalized and documented in the regulatory body management system. A well-documented set of policies and processes alone is not sufficient, but it provides a basis for demonstrating expectations and leadership commitments. It is not clear that all regulatory bodies formalize commitments to behaviours and working practices in this way.

Some of these pressures and challenges to effective nuclear safety decision-making and action may be subtle, and the regulatory body may not have reflected on the potential impact that they can have on its nuclear safety decisions and actions. The practices considered in the section 2.2 do not address all these pressures and challenges but are drawn from the collective experience of those who participated in the Technical Meetings.

2.2. PRACTICES TO DEVELOP AND SUSTAIN REGULATORY BODY SAFETY CULTURE

The practices considered in the following sections are a summarized set of observations drawn from the collective experience of those who participated in the Technical Meetings.

Safety culture policy

A commitment to safety can be demonstrated powerfully through the published vision, mission, core values and policy statements of an organization. These statements usually form the top tier of the organizational management system and provide an enduring and powerful philosophy that underpins the way in which the organization operates ('the way we do things around here'). Organizations can reflect this in different ways, but a regulatory body might usefully consider whether it has taken appropriate steps to establish explicit principles on matters, such as:

- A commitment to nuclear safety as the overriding priority in decision-making and action;
- Establishing core values on matters such as mutual respect, integrity, aspiration to excellence, personal responsibility, behaviours, team-working etc.;
- A commitment to be a role model for industry;
- Encouraging a culture of constructive challenge;
- Transparency on regulatory decision-making and actions;
- Independence in decision-making;
- Continuous improvement and learning;
- Open communication with stakeholders.

2.2.1. Leadership and commitment

IAEA Safety Standards, GSR Part 2, Requirement 2, is explicit on the need for management to demonstrate leadership for, and commitment to, safety by establishing behavioural expectations and fostering a strong safety culture.

Demonstration by senior management of a commitment to develop and sustain a culture for safety is fundamental to establishing this culture within an organization. The Safety Culture within the regulatory body takes its strength from a visible Senior Management Commitment to establish and implement a strong safety culture in the organization. Commitment of senior management is reflected through their formulating vision, mission and policy statements which include safety culture, and by reflecting these in aspects, such as the regulatory body's strategic plans, organizational structures, resourcing and performance management processes. Visible commitment to 'lead by example' (i.e. to visibly show adherence to the advocated message) is a fundamental underpinning of the statements of policy and process.

Some examples of effective leadership commitment to securing a positive regulatory body safety culture offered by Member States included:

- Initiating a process to scrutinize, and improve regulatory body safety culture, led by senior leadership;
- Field presence of management, leading by example and demonstrating committed values;
- Setting goals and communicating expectations – for example, hosting regular, open, 2-way 'town-hall' type events (where staff are gathered together for communication events);
- Visible senior leadership commitment to learning and continual improvement – at all levels;
- Holding regulatory body management to account on their behaviours and the priority that they give to nuclear safety in their decisions and actions – for example, formalizing principles on management behaviours; incorporating as part of performance reviews;
- Establishing and visibly encouraging an open reporting culture;
- Appointing a safety culture working group and maintaining senior level oversight of its activities;

- Ensuring that incentive and reward schemes are balanced and signal/reinforce the priority given to nuclear safety;
- Seeking to understand the need for, and provide, resources, e.g. personnel, tools, organization to enable effective nuclear safety oversight;
- Encouraging the involvement of staff in decision-making to ensure diverse views are considered;
- Managing change in the organization to ensure safety focus is maintained (see, for example, approaches taken by a number of regulatory bodies to succession planning, knowledge capture and management of safety culture);
- Self-reflection – e.g. requiring all sections and the Executive Board to discuss how guiding principles for the organization are reflected in their work activities.

2.2.2. Promoting individuals' awareness of safety culture, plus their roles and responsibilities

IAEA Safety Standards, GSR Part 2, Requirement 12, refers to the need to foster a culture for safety and further emphasizes the role of leadership in advocating and supporting awareness of safety culture and individuals' own responsibilities and accountabilities. Examples of practices reported by Member States include the following:

- Workshops to reflect on safety culture in different departments within the regulatory body, and the regulatory body as a whole, involving licensee representatives to enable a shared diagnosis of safety culture and identify a vision and action plan;
- Leadership communications (e.g. 'town hall' meetings; monthly safety meetings; messages to staff about development of safety culture documents; newsletters emphasizing safety culture within the regulatory body; leadership attendance at staff information meetings to discuss safety culture);
- Training in safety culture (examples included specific training on organizational values and culture for new supervisors; training for site inspectors on leadership and management for safety; training for new inspectors on human and organizational factors and safety culture; part of Basic Professional Training Course; IAEA courses; online training course on safety culture; coaching; train the trainers to create safety culture champions; establishing communities of practice for safety culture);
- Active collaboration with IAEA, for example, to identify the need for and request training and workshops from IAEA;
- Factoring elements related to safety culture into feedback and appraisal processes (it was noted that although elements of safety culture may be reflected in annual appraisals etc., they may not be labelled with an explicit safety culture 'tag' – and that this might be worth doing to reinforce expectations*)*;
- Holding safety culture-related campaigns; issuing staff with safety culture cards to reinforce safety culture awareness; safety culture 'focus weeks' – hosted sessions/briefs; safety films; hosting visits by expert speakers; safety culture-themed diaries and calendars for staff;
- Development of internal safety culture principles, policy and guidance documents; safety culture establishing methodologies to oversee regulatory body own safety culture; integrating expectations for safety culture within the Integrated Management System; preparing guidance for oversight of safety culture and reinforcing relevance to regulatory body of safety culture; issuing booklets; intranet messages).

2.2.3. Promoting individual behaviours that place proper value on safety

An understanding of safety culture in the context of a regulatory body provides a basic platform for promoting suitable behaviours that place value on achieving the right nuclear safety outcomes, but some regulatory bodies have taken further steps to help support and deliver this. Examples include:

- Principles to encourage a questioning attitude at all levels: underpinned by formal processes for raising issues/concerns regardless of position in organization (backed up by management behaviours

that actively encourage rather than deter) – for example, 'open door' policies offering staff access to any level of management;

- Establishing a code of ethics setting out a general code of conduct and code of regulatory practice for all regulatory body staff;
- Formal processes to 'respect differences of opinion' and arrive at a considered outcome; introduction of 'shared space' to air issues; conflict resolution processes;
- Commitments to team working; formalizing arrangements to promote collaborative working across groups (e.g. cross-discipline inspections and project teams); safety culture surveys to peer review other groups' approaches to team working;
- Self-reflection; providing processes and training to encourage self-reflection; 360-degree assessments; annual reflection of how a regulatory body section or department meets regulatory body mission statement; self-review following safety culture training;
- Taking personal responsibility; ensuring a 'just culture' policy is in place; establishing a code of ethics; formalizing principles on good regulation covering (e.g. professionalism, integrity, honesty, respect);
- Promoting adherence to process but encouraging challenge, and taking action, where the process appears deficient; verification of inspection process, instituting internal and external audits;
- Reflecting on behaviours and their effect on the nuclear installation personnel;
- Establishing workshops to discuss what safety culture means in practice for individuals and the way they work.

2.2.4. Decision-making

A robust and resilient decision-making process that places nuclear safety outcomes at the heart of decision-making considerations is a fundamental characteristic of a positive regulatory body safety culture. Member States identified several examples to promote effective decision-making for safety:

- Formally stating that safety is the overriding priority over competing factors in decision-making – e.g. senior management statements; nuclear safety policy statements; formalizing principles on conservative decision-making;
- Enshrining the independence of the regulatory body's decision-making processes and decisions;
- Acknowledging that the role of regulator is to enable nuclear activities while ensuring safety;
- Avoiding conflicts of interest when using Technical Support Organization or other experts;
- Having a documented risk-informed decision-making process using established approaches (as low as reasonably practicable / as low as reasonably achievable (ALARP / ALARA), etc.));
- Using independent technical review teams to provide independent advice to the regulatory body on major technical matters;
- Formalising use of robust internal review processes for major regulatory decisions so that inputs to decision-maker can be subject to robust challenge;
- Open and transparent decision-making:
    - *External* – some countries consult, as well as inform the public and some do not; some countries publish safety assessment reports, and many countries publish regulatory guidance and procedures related to licensing to enable the public to understand how decisions are reached and to hold the regulatory body to account;
    - *Internal* – communicating decisions; providing a forum for discussion and expression of constructive challenge; briefing of regulatory body staff from other sections to promote awareness and a sense of 'one regulatory body'; acknowledge and seek to understand potential tension between project staff and technical staff with different roles and drivers.

2.2.5. Continual improvement and learning

As noted in the introduction to this section, a commitment to continual improvement, drawing on both internal and external learning, is an important element underpinning a positive regulatory body nuclear safety culture. Meeting participants reinforced this message and provided examples of practices designed to ensure that the regulatory body constantly strives for improvement. Ensuring that visible action plans are developed and committed to and led from the top was seen as key to success:

- A range of self-assessment activities are used. Some explicitly address safety culture, and some involve a broader review of the Integrated Management System, elements of which include safety culture. Self-assessment tools include questionnaires, checklists with opportunity to raise areas for improvement, self-reflection checklists, focus groups, interviews and observations. IAEA Safety Report No. 83 [6] guidance was applied in one country; proportionate application of this guidance is being considered by other countries. Some countries have put in place formal processes to commit to, and conduct, periodic self-assessment (i.e. conducting a safety culture and climate self-assessment every three years, and developing action plans on the basis of the findings; establishing an annual safety culture implementation programme);
- Independent reviews have been commissioned by some regulatory bodies; for example, a national research programme conducts independent assessment focusing on organizational factors and safety culture. It was noted that the Integrated Regulatory Review Service (IRRS) peer review missions can provide some insight from review of Integrated Management System self-assessment and peer advice; some countries hire independent specialist contractors to perform regulatory body surveys and assessments; some countries use internal reviews from different parts of the regulatory body;
- Learning from internal sources was referenced; some regulatory bodies have instituted formal knowledge management processes and appointed individuals to focus on delivering this so that regulatory experience is not lost;
- Post-project lessons-learned reviews, to identify what went well and potential for improvement, were cited by a number of meeting participants; periodic reviews of how sections of the regulatory body are working together and delivering their work were also mentioned;
- Examples of learning from external sources included joint workshop with licensees to discuss regulatory body safety culture; use of external safety culture experts to guide self-assessment; benchmarking against other high-reliability organizations (including other sectors outside nuclear, i.e. oil and gas, transportation) and other regulatory bodies; IAEA workshops and peer review services.

2.2.6. Management system

Meeting participants affirmed the need to ensure that, where practicable, the practices and approaches set out above are documented in the regulatory body management system. This not only sets out a framework and process but also provides an auditable basis against which the regulatory body can be held to account.

2.3. QUESTIONS TO CONSIDER FOR FOSTERING A SUSTAINABLE SAFETY CULTURE

This section draws upon the experience of the contributors to this report. They propose a set of questions that a regulatory body may ask itself to determine what other steps need to take to foster and sustain a positive culture for safety within its own organization. The following table lists the key questions related to safety culture characteristics and attributes like leadership, decision-making, enabling behavior and self-assessment. These are examples cuts across and are informed by the IAEA framework of characteristics and attributes of a strong safety culture [3] and [4].

Leadership	• Is there a clear vision and mission that is reflected in plans to deliver a vision for safety culture? • How do you know that you are planning or doing the right thing?

	• How do you ensure that there is sustained commitment of leadership to safety culture? • How is that commitment confirmed/sustained through all layers of leadership? • Is leadership holding organization and individuals to account (not accepting behaviour that could compromise effective nuclear safety decision-making or action and encouraging good behaviours)? • How do you persuade leaders to invest regulatory body resources in safety culture promotion when outcome measures can be difficult to define (i.e. to determine that investment in safety culture is beneficial)? • How does the regulatory body organize itself to promote and maintain safety culture? • How do you encourage, acknowledge and reward good safety behaviour?
Safety culture in decision-making	• How do you ensure that the bases for regulatory decisions/recommendations are communicated and understood by all parties? • How do you ensure that regulatory decisions/recommendations take into account contributions from all relevant parties (e.g. in a collaborative manner, without territorial issues)? • How do you enable an environment in which constructive challenge is embraced? • How do you ensure that regulatory body decision-making is not subject to inappropriate third-party influence? • How do you ensure that you have systems and processes in place to enable all of the above to happen in a consistent way?
Enabling behaviour for safety culture	• How do you secure shared awareness and understanding of what nuclear safety culture means for the regulatory body? • How do you 'operationalize' or 'make it happen' and embed in the Integrated Management System aspects such as safety culture principles, guidance, documentation, leadership communication etc.? • How do you obtain a consistent level of understanding amongst the whole regulatory body staff of the expectations on how they contribute to the safety culture of the regulatory body? • How do you ensure that the regulatory body has adequate capability and capacity to inform the regulatory body approach to promote and sustain safety culture? • How do you overcome scepticism of principles of organizational behaviour from regulatory body staff (e.g. 'win hearts and minds', overcome resistance to something new)?
Self-assessment	• How do you identify and then select the methodology for safety culture self-assessment that is suitable for your regulatory body? • How do you interpret and communicate the findings of the safety culture self-assessment (especially where they raise potentially difficult issues such as leadership for safety, how do you deal with sensitive matters)? • How do you ensure timely, honest and open feedback of output of safety culture self-assessment?

	• How do you turn the findings into identified opportunities for improvement? • How do you ensure that actions plans are put in place and properly implemented through to closure?

3. REGULATORY OVERSIGHT OF LICENSEE SAFETY CULTURE

This section considers the different roles that a regulatory body might have with regard to oversight of licensee safety culture which are generally limited to promotional activities although in some cases rely on enforcement. It then sets out some of the practices that Member States have identified with regard to preparing regulatory body staff to deliver regulatory oversight, and approaches to design and delivery of oversight activities.

3.1. THE ROLE OF THE REGULATOR

IAEA Safety Standards, GSR Part 2, requires individuals in the organization, from senior managers downwards, shall foster a strong safety culture. Therefore, the regulatory body can, be expected to take action to ensure that the licensee is taking suitable measures to foster and sustain its safety culture. This expectation is consistent with the findings of an IAEA International Experts Report on Human and Organizational Factors in Nuclear Safety in the Light of the Accident at the Fukushima Daiichi Nuclear Power Plant (21 – 24 May, 2013) [7].

The need for regulatory oversight has been reinforced at other senior level meetings, such as the 2nd Extraordinary Meeting of Contracting Parties to the Convention on Nuclear Safety, held in August 2012, which identified safety culture as one of the areas where regulatory processes have to be improved. Furthermore, an IAEA Report on Strengthening Nuclear Regulatory Effectiveness in the Light of the Accident at the Fukushima Daiichi Nuclear Power Plant (2014) stated that regulatory bodies should engage in ongoing dialogue with licensees to enhance the understanding of safety culture aspects and to seek licensees' commitment to perform self-assessments and independent peer assessments of safety culture on a regular basis.

Some countries place legal duties on licensees to sustain a positive safety culture within the national legislative system; some include explicit reference to safety culture within the regulatory framework or establish policy positions – for example by developing a guiding principle affirming the regulatory body's role in strengthening the safety culture of licensees; whereas regulatory bodies in other countries have less direct reference to safety culture. In any case, a regulatory body may promote safety culture by investigating and identifying culture-related root causes for non-compliance with procedures by licensee and asking for taking action to address them accordingly.

The following section summarizes practices adopted by member state regulatory bodies to help them prepare for oversight of licensee safety culture and then to deliver that oversight.

3.2. PREPARING REGULATORY BODY STAFF FOR REGULATORY OVERSIGHT

If regulatory oversight of safety culture is to be delivered in an informed and consistent way, training should be provided to those carrying out the oversight. Some, but not all, regulatory bodies take steps to prepare their staff to understand the bases for safety culture and approaches that can be taken to discharge regulatory oversight. Examples include:

- Formalising regulatory body expectations for regulatory oversight in processes and procedures;
- Communicating regulatory body expectations of its staff with regard to oversight of safety culture; this may include measures to ensure that staff have a shared understanding and are using a common language;

- Producing a safety culture knowledge map for the regulatory body, and establishing annual training course for volunteer inspectors;
- Designing a specific programme for training and formally qualifying safety culture specialist inspectors;
- Covering safety culture during induction training for new inspectors;
- Requiring all assigned inspectors to be trained on conducting safety culture inspections.

3.3. DESIGN AND DELIVERY OF REGULATORY OVERSIGHT

Subject to the national legal and regulatory regime, regulatory body oversight can be delivered in different ways.

- **Direct regulatory body monitoring** of licensee safety culture – e.g. through targeted interventions on aspects of safety culture, and by using different approaches including direct observation, questionnaires, surveys and interviews; some regulatory bodies review safety culture as a topic area within the management systems area;
- **Indirect regulatory body monitoring** – e.g. by gathering information as part of normal regulatory interaction and distilling safety culture-related intelligence to build a picture of licensee safety culture;
- **Oversight of licensee approaches** to fostering and sustaining a safety culture – e.g. though discussion with senior management about the actions they are taking and reviewing the documentary bases for licensee approaches;
- **Oversight of licensee self-assessment** activities and findings, and review of licensee action plans;
- Senior level interaction with licensees and other stakeholders to **encourage and advise** on safety culture matters.

It is not the purpose of this document to advocate which of these approaches, or combinations of approach, is most suitable. All are credible, and the selection of approach may depend on factors, such as national law and regulatory regime; regulatory body resource availability; and the regulatory body's view of the state and maturity of the safety culture within the licensee.

Some regulatory bodies have incorporated a consideration of safety culture into the periodic safety review process, and established review guidelines. Others have developed and formalised the methodology that is used in safety culture oversight. This can also include development of inspection guides for regulatory body staff. Some regulatory bodies have developed their own safety culture knowledge base and appointed safety culture specialists to design and contribute to licensee oversight activities; others rely on training given by experienced inspectors; whereas others use external contractors.

The benefits of documenting and sharing the regulatory body approach early with licensee senior management was emphasized as this provides a means for securing their understanding and commitment to support regulatory activities, as well as providing a means to signal the significance placed on this area by the regulatory body.

Emphasis was placed by some regulatory bodies on ensuring that the findings of safety culture oversight activities are shared with licensee senior management and those follow-up activities are programmed by the licensee and regulatory body. One example of acting on perceived safety culture shortcomings is one regulatory body's option to issue a 'formal' letter if there is evidence that licensee staff do not feel free to raise concerns without risk of negative personal consequences.

3.4. CHALLENGES

This section draws upon the experience of the meeting participants to identify a set of questions, or challenges, that a regulatory body can reflect upon when considering approaches to designing and delivering regulatory oversight of licensee safety culture:

- Do you have provisions in your national legislative and regulatory framework for safety culture oversight?
- Have you considered the approach that your regulatory body has to take (e.g. inspect; monitor licensee self-assessment; advise; encourage vs enforcement, etc.)?
- Do you train your staff in safety culture oversight? If not, how do you ensure that your regulatory body will adopt a consistent approach to safety culture oversight?
- Do you have formal and documented safety culture oversight principles and methodologies?
- What inspection guidance do you provide? How do you provide it?
- How do you select, train and equip inspectors to engage with licensee senior management? (not all Inspectors are necessarily capable of discussing these matters at senior levels)
- How do you make resources available to include coverage of safety culture oversight?
- How do you design oversight of safety culture such that it integrates with your other regulatory processes (e.g. how does it interact with ongoing inspection programmes, review and assessment plans etc.)?
- Over what time period do you collect data?
- What do you do with the data – how do you interpret it, reach conclusions and then engage with the licensee on the findings?
- Do you use the findings of safety culture oversight activities to identify your future regulatory body priority areas?
- How do you build relationships with the licensee at senior levels to ensure shared understanding of safety culture expectations and regulatory body approaches to oversight?
- How might you take enforcement action if you observe non-compliance with regulatory body safety culture expectations?
- How do you inform the public of your regulatory body approach to safety culture oversight?

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ANNEX I – EXAMPLES OF PRACTICES FROM JAPAN

I-1: PRACTICES TO DEVELOP AND SUSTAIN REGULATORY BODY CULTURE FOR NUCLEAR SAFETY IN THE REGULATORY BODY

a) Policy/Vision statements	・Policy statement - NRA's Core Values and Principles constitute five principles of activities and these are the important elements for fostering safety culture. Five principles include independent decision making, effective actions, open and transparent organization, continuous improvement and commitment etc. - The Statement on Nuclear Safety Culture constitutes eight principles taking due account of the lessons learned from at the TEPCO's Fukushima Daiichi NPP accident and is low order document of NRA's core values and principles. Eight principles include priority to safety, decision making taking into account for the risks etc.
b) Leadership and commitment	・Open reporting culture and provision of resources; The NRA has launched dialog among the chairman, commissioner, senior managers and staffs on trial base since 2017. The staffs can freely communicate with chairman and raise safety concerns etc. ・Encouraging the involvement of staff in decision-making; The Fukushima Daiichi NPP accident pointed out insufficient decision-making of the tsunami countermeasures by the regulatory body. It was a major factor that there was the issue of insularity and group-think. These lessons learned were reflected to the statement of nuclear safety culture.
c) Promoting individual awareness of safety culture, plus their roles and responsibilities	・Leadership communication; Management promotion office communicates to all staffs using email and intranet etc. for informing these safety culture activities. ・Training on safety culture; The NRA currently has operated safety culture training for new staffs, mid-carrier staffs and inspector. These training program constitute the lecture and group discussion using case studies. At the end of training program, the effectiveness of training is measured using questionnaires. ・Feedback and appraisal process; The NRA has developed questionnaires for safety culture self-assessment. The effectiveness of safety culture fostering activities are measured and assessed using safety culture questionnaires. ・Safety Culture-Related Campaigns; All NRA staffs have the individual card of NRA's core values and principles, and the statement on nuclear safety culture. Staffs can write down the card about what is safety culture of oneself.

	• Development of safety culture documents; The NRA has developed NRA's core values and principles, the statement on nuclear safety culture and draft guide of statement on safety culture.
d) Promoting individual behaviours that place proper value on safety	• Training and Principles to encourage a questioning attitude at all levels; The statement on safety culture of NRA includes questioning attitude. The NRA currently has operated safety culture training and these training program includes group discussion using case studies to give the opportunity for fostering organizational learning and questioning attitude. • Teamwork The NRA has conducted the survey of the questionnaires related to teamwork and trust to all stalls as the part of safety culture self-assessment for fostering the awareness. • Adherence to process Management promotion office of NRA carries out internal audit under management system.
e) Decision-making	• Safety as overriding priority over competing factors -The NRA is organized to separate the functions of regulation of the use of nuclear energy from those of promotion, and is required to independently implement its duties from neutral and fair perspectives based on its expertise. The NRA has developed NRA's core values and principles including independent decision-making on January 2013. -The NRA has developed the statement on nuclear safety culture including decision-making taking into account for the risk. • Conservative decision-making The NRA has developed the statement on nuclear safety culture including conservative decision-making for safety taking into account even the worst-case scenario. • Open and transparent decision-making -The NRA has developed the NRA's core values and principles including transparency and appropriate information disclosure on regulation in the decision making process. -The procedure of safety culture inspection by nuclear safety inspector is published to the public.
f) Continual improvement and learning	• Self-assessment Management Promotion Office of NRA has firstly developed the questionnaires for safety culture self-assessment in order to grasp the current status of safety culture and organizational climate of NRA and reflect the result to the developing action plan for fostering safety culture. Management Promotion Office of NRA carried out the safety culture questionnaires to all staffs in August 2016 using e-learning system. The staffs also could freely wrote down questionnaires sheet what they need to maintain or improve for safety culture as an alternative tool of interview and focus group discussion etc.

	・ Independent review IRRS mission provided suggestions of safety culture from review of IMS. Learning from For drastic improvement of nuclear regulatory organizations on the basis of the reflection and lessons learned from the Fukushima Daiichi NPS accident, the "Act for Establishment of the NRA" was enacted on 20 June 2012, and promulgated on 27 June 2012, founding the NRA as a new regulatory body. The NRA is currently striving to foster safety culture by developing several approaches.
g) Management system	・ Management system The objectives of the NRA Management System are to foster safety culture through effective leadership, and effectively integrating management elements such as quality, security as well as nuclear safety. Top management takes initiative to develop mid-term goal and annual strategic plan based on the Core Value and Principles of the NRA. Based on these goal and plan, each division head develops annual implementation plan including safety culture fostering activities.

I-2: REGULATORY OVERSIGHT

5.1 Introduction – Role of regulator (examples relating to legal powers, regulations, guidance on fundamental regulatory approach)	・What regulatory regime is empowered to do by law; The NRA requires licensee to establish systems for fostering safety culture (including involvement of top management).In other words, it is necessary to be clear that the system to foster organizational culture for developing, maintain and enhancing a sense of value, which gives the top priority to ensuring safety, is firmly established. Moreover, it is also necessary that involvement of top management is explicitly stated. ・Potential to inspect, influence, educate, enforce; -High-level meetings between chairman , commissioners of NRA and top managements of licensees related to safety culture for fostering nuclear safety (Licensee by licensee every month) -High-level meetings between commissioners of NRA and chief nuclear officer(CNO) of licensee about the issue related to nuclear regulation (Once in the two months)
5.2 Preparing for regulatory oversight	・Training RB staff in regulatory oversight approaches Nuclear safety inspector for safety culture inspection assigned by senior management of each region offices are required to be trained on safety culture for safety culture inspection. This training course constitutes the lecture and group exercise using case studies. ・Factoring safety culture oversight into regulatory activities Nuclear safety inspector implements annual safety culture inspection where results are published and used to define licensee program for next fiscal year. ・Developing and documenting formal approach/toolkit The NRA has developed guideline for confirmation/evaluation of licensee's efforts to prevent degradation of safety culture and organizational climate (safety culture guideline). ・Sharing approach with senior licensee leadership High-level meetings between chairman , commissioners of NRA and top managements of licensees related to safety culture for fostering nuclear safety (Every month)
5.3 Delivery of regulatory oversight	・How conduct of oversight activities is different for safety culture Nuclear Safety Inspector carries out observation and review to identify the item considered necessary to enhance licensee's efforts for next fiscal year during safety culture inspection. The detail oversight activities are as follows; -Nuclear Safety Inspector reviews the action plan for fostering safety culture, indicators of licensee's safety culture fostering activities, list of degradation indicators of safety culture. Nuclear Safety Inspector also reviews the results of these activities and measured indicators. -Nuclear Safety Inspector carries out observations through watching licensee's daily activities, records such as the

	licensee's meeting, the results of root cause analysis and trend analysis etc. and interview with the senior managers of headquarter office. ・<u>Reporting, sharing(internal, external) and acting on findings</u> - Nuclear Safety Inspector carries out safety culture inspection using comprehensive assessment sheet. Nuclear Safety Inspector summarizes comprehensive assessment sheet as the report at the end of the fiscal year. NRA headquarters staffs review the results reported by Nuclear Safety Inspector. The part of comprehensive assessment is uploaded on the NRA website. - Nuclear Safety Inspector confirms that licensee reflected improving measures suggested by inspection at the previous year to the action plan for fostering safety culture.

ANNEX II – EXAMPLES OF PRACTICES FROM REPUBLIC OF KOREA

II-1: PRACTICES TO DEVELOP AND SUSTAIN REGULATORY BODY CULTURE FOR NUCLEAR SAFETY IN THE REGULATORY BODY

a) Policy/Vision statements	• Nuclear Safety Policy Statement of Korean government include five principles of the regulation • KINS Mission Statement has six practice indicators including 'safety as the overriding priority' • KINS Code of Ethics consists of general code of conduct and code of regulatory practice • KINS Safety Culture Principles are composed of six principles and forty attributes
b) Leadership and commitment	• KINS Integrated Management System Chapter 2.6 describes the role and responsibility of management • KINS Safety Culture Management Procedure describes role of management and individuals • Each of the KINS Safety Culture Principles specifies duty of the management including leading by example, protection of the employees from undue pressure, commitment to learning environment • KINS president establish three-year leadership plan to strengthen core values
c) Promoting individual awareness of safety culture, plus their roles and responsibilities	• Conference, seminars, workshops, lectures, high-level meetings related to safety culture issues are held regularly • Dissemination of information and documents related to safety culture principles • Training program on safety culture oversight • On-line training course on safety culture and IMS • Internal safety culture survey
d) Promoting individual behaviours that place proper value on safety	• Nuclear Safety Policy Statement of Korean government include five principles of the regulation covering openness, clarity, reliability • KINS Code of Ethics consists of general code of conduct and code of regulatory practice including attitude, self-regulation, prevention of conflict of interest • KINS Safety Culture Principles specifies duty of individuals including questioning attitudes, interdepartmental mutual cooperation, active communication, demonstration of a leadership for safety • Differing professional opinions (DPO) procedure is used to foster constructive challenge • Reward to best cooperative staff • Assessment of cooperation between teams
e) Decision-making	• KINS Safety Culture Principles specify duty of individuals and management related to decision making. For example, staffs shall decide carefully and conservatively by considering any uncertainties having

	in mind that unexpected latent problems can exist on all issues. • KINS Executive Technical Advisors Group reviews and provides advice on major technical matters such as new reactor licensing report, regulation documents development, and policy issues. • Nuclear Safety Review Board reviews major technical decisions before finalization. • Result of regulatory decisions are published to public through Nuclear Safety Information Center(NSIC) homepage by law
f) Continual improvement and learning	• KINS Safety Culture Principles specify duty of individuals and management related to continuous improvement and expertise including knowledge management and lessons learned system • Targeted safety culture activities such as self-assessment, use of checklist, training programs within KINS are planned, conducted and assessed according to KINS Safety Culture Management Procedure • Benchmarking of international best practices such as US NRC DPO and 'lessons learned program', CLIs of French • KINS Safety Culture Principles are derived through benchmarking study on safety culture attributes of foreign regulatory authorities
g) Management system	• KINS Integrated Management System Chapter 6 details the measurement, evaluation, and improvement necessary to secure the relevance and effectiveness of the IMS • Internal Safety culture implementation program is planned, conducted, and monitored every year according to KINS Safety Culture Management Procedure

II-2: REGULATORY OVERSIGHT

Introduction – Role of regulator (examples relating to legal powers, regulations, guidance on fundamental regulatory approach)	• Promotion of safety consciousness among nuclear employees through promulgating safety charter, developing safety culture assessment tools and transferring them to licensee to encourage self-assessments, and conducting a few special inspection of safety culture on an ad hoc basis. • Consideration of safety culture into the periodic safety review process • Outreach activities such as joint workshops, education program for licensee operators, safety culture surveys, and sharing of good safety culture practices
Preparing for regulatory oversight	• Development of safety culture Knowledge map • Development of safety culture Oversight Process and Methodology • Development of safety culture Oversight Model and Components, and validation of the model • Development of regulatory oversight Guides and Procedures, e.g. safety culture Inspection Guides, Procedures for independent assessment of licensees' safety culture, etc. • Build-up of Safety Culture Database • Training course for Safety Culture Inspectors
Delivery of regulatory oversight	• Periodic review of matters related to licensee's organization, management system and safety culture according to IAEA SSG-25 • Pilot safety culture inspections to verify the feasibility and effectiveness of regulatory oversight • Top-management level dialogue addressing safety culture aspects • Regular information exchange meeting with safety culture officers of licensee

ANNEX III – EXAMPLES OF PRACTICES FROM INDONESIA

III-1. SAFETY CULTURE IN THE REGULATORY BODY

III-1.1. Basis

The Indonesia Nuclear Energy Act no. 10 of 1997 clearly stated that Nuclear Energy Regulatory Agency (BAPETEN) is the Nuclear Regulatory Body. This is the legal basis of BAPETEN to perform regulatory functions on the use of nuclear energy in Indonesia, including regulation, licensing, inspection and law enforcement. The Independent regulatory functions are stipulated in Article 4 and Article 14 of the Nuclear Energy Act no. 10 year 1997 which require the government to establish regulatory body that is reporting directly to the president and has responsibility to control nuclear energy utilization.

BAPETEN has stated in its vision to become a world class nuclear regulatory body and to achieve nuclear safety and security conditions and improve national competitiveness. BAPETEN shares a significant attention in the development and implementation of safety culture within the regulatory body. BAPETEN as regulatory body should provide a good example for the licensees related to the safety culture implementation.

In order to implement the vision concept in creating nuclear safety and security conditions, BAPETEN defines its mission to realize the national safety and security culture in accordance with the national personality and character. This mission is then elaborated in its objectives e.g. to reduce the nuclear incident rates in Indonesia by implementing nuclear safety and security culture for radiation workers, organizations and relevant stakeholders based on national personality.

III-1.2. Management Commitment and Safety Culture Policy

In the BAPETEN management system, the chairman of BAPETEN stated **management commitment** that the chairman of BAPETEN, together with the entire employees of BAPETEN, is willing to implement BAPETEN management system consistently in the nuclear regulatory control in order to assure safety, security, and safeguards in the use of nuclear energy in Indonesia

In order to foster the implementation of a good safety culture among BAPETEN or licensees, BAPETEN has released a Nuclear Safety Policy Statement initiated by BAPETEN Chairman in June 2000. The contents of the **safety culture policy statement** are the following:

- The purpose of the policy statement is to provide the framework for regulatory authority to manage the regulatory control of nuclear energy with due respect to safety, security, health of radiation workers, environmental protection and peaceful use and to improve the professionalism in nuclear regulatory activities by providing public information on the government basic policies regarding nuclear safety to achieve the ultimate goal of safe use of nuclear energy.
- The assurance of nuclear safety should be granted as first priority in nuclear energy utilization within organization of nuclear instalations and radiation facilities as well as individuals engaged in aspects of nuclear energy utilization. They should adhere to safety principles as top priority.
- People in nuclear fields should have more pro-active safety attitude in ensuring nuclear safety to obtain public trust and confidence for the sustainable development of nuclear energy utilization.
- Safety culture cannot be achived in a day, but rather it is secured through consistent regulatory practices, through clear and transparant rules and procedures, and uncompromised law enforcement activities.
- BAPETEN strives for effective regulations through the development of clear and transparant safety regulatory practices.
- In performing regulatory functions, BAPETEN should try to overcome public distrust and fear of nuclear activities.

- BAPETEN will actively encourage the achievement of expertise of regulatory activities in safety related assessments and reviews; and ensure the regulatory independence by minimizing any undue pressure and interference.
- The ultimate responsibility for safety of nuclear energy utilization rests solely on the licensees.

BAPETEN is currently preparing a new draft of Presidential Decree on National Policy and Strategy for Nuclear and Radiation Safety containing the definition of safety culture and the principles of a safety culture implementation.

III-1.3. Safety Culture Program

Implementation of BAPETEN safety culture has been written in BAPETEN management system, and the safety culture program also written in BAPETEN Strategic Planning for 2015-2019.

III-1.3.1. Safety Culture under the Integrated Management System

In order to provide protection to the public, workers and the environment, BAPETEN has implemented good governance through BAPETEN Integrated Management System. The scope of the BAPETEN Integrated Management System covers establishment and implementation of overall management requirements to be integrated in the regulatory process for nuclear energy utilization. It is applied through compliance with integrated of safety, health, environment, security, quality and economy. BAPETEN Integrated Management System manual combines the requirements of the IAEA GS-R-3 on Safety Requirements on The Management System for Facilities and Activities, ISO 9001: 2008 and ISO 9004: 2009.

To strengthen the implementation of BAPETEN-Integrated Management System and to improve BAPETEN performance and effectiveness, BAPETEN has set the organization values: Professionalism, Integrity, Independence, Openness and transparency, Excellence.

Safety Culture in BAPETEN is a part of the BAPETEN Integrated Management System implementation. It states that BAPETEN is fostering and supporting a strong safety and security culture, through the following measures:

a) Ensuring a common understanding of the main aspects of the safety and security culture in BAPETEN;
b) Supporting individuals and teams within the organization to complete their tasks safely and successfully taking into account the interaction between individuals, technology and organization in BAPETEN;
c) Strengthening the learning and questioning attitudes at all levels in BAPETEN;
d) Developing and improving the safety and security culture continuously.

The strategies to support and assess the safety and security culture will be described in detail in the BAPETEN Guidelines on Development of Safety and Security Culture. The Preparation of Guidelines for Safety Culture in BAPETEN will adopt some part of related IAEA management system documents which can be applied in BAPETEN. The references to be used are the IAEA GSR Part2, Safety Guide GS-G-3.1 on "Application of the Management System for Facilities and Activities" 2006 and GS-G-3.5 IAEA GS-G-3.5 "Management Systems for Nuclear Installations" 2009.

III-1.3.2. Promotion Strong Safety Culture within the National Nuclear Infrastructure

In accordance with IAEA GSR Part 1. Requirement 1 stated that in the national policy and strategy, account shall be taken of the promotion of leadership and management for safety, including safety culture, BAPETEN has commenced to develop a safety culture since 2000 after publishing BAPETEN Nuclear Safety Policy Statement.

The safety culture promotion activities for national nuclear stakeholder undertaken by BAPETEN are the following:

1. Providing socialization of The Guidance of Safety Culture Implementation published by BAPETEN in 2006.
2. Providing dissemination of the safety culture aspects contained in the regulation of nuclear safety regulations, both in the form of Government Regulations and BAPETEN Chairman Regulations.
3. Trainings on Nuclear Safety Culture for Nuclear Installation.
4. Promoting self-assessment and performing independent assessment of safety culture implementation for nuclear installation.
5. Trainings on Safety Culture to the Radiation Protection Officer for Radiation Facilities and disseminations of safety culture aspect to the licensees and public.
6. Workshop and seminar on the Safety Culture Implementation of Nuclear Installation. The objective is for sharing the results of self-assessment of licensee's safety culture and implementation.
7. Publishing a Book on 'Improving Our Safety Culture' for public.
8. Sharing knowledge related to various aspects of safety culture including:
   - Safety Leadership
   - Effective Safety Communication
   - Safety Culture Improvement
   - Safety Culture Self-Assessment
   - Behaviour Based Safety

III-1.3.3. Training for Senior Management and Staff

BAPETEN has training programs for senior management and staffs in their respective roles and responsibilities in its implementation to incorporate safety culture in the regulatory process. The training activities are:

- Nuclear Safety Culture lecture on Basic Professional Training Course on Nuclear Safety, for all new BAPETEN staff (4 hours)
- Training workshop on Safety Culture Implementation for nuclear installation (5 days)
- Safety Culture Implementation for nuclear safety inspectors (3 hour)
- Leadership and Management for Safety and Safety Culture for Managers (3 days)
- Workshop on Safety Culture Self-Assessment for Managers (4 days)
- Coaching for core team of safety culture implementation (10 X 2 hours)

III-1.3.4. Safety Culture Implementation Program

The Implementation of safety culture program in BAPETEN is part of the integrated management system commitment. One of our missions written in the BAPETEN strategic plan is the strengthening of the nuclear safety and security culture. Some safety culture implementation programs are as follow:

- Revision of Guidelines for BAPETEN Safety Culture Implementation
- Preparation and implementation of the Guidelines for Safety Culture Oversight
- Formulation and Implementation Guidelines Safety Culture Self-Assessment
- Community of Practices (COP) for Safety Culture Improvement
- Workshop and Training of Safety and Security Culture

III-2. CONTINUOUS IMPROVEMENT PROGRAM

III-2.1. Self-Assessment

BAPETEN perform the internal quality compliance evaluation as the self-assessment of BAPETEN Integrated Management System implementation. IRRS Mission gives the recommendation to BAPETEN to conduct self-assessment of safety culture implementation. To set up a safety culture self-assessment, BAPETEN has initiated to organize an IAEA workshop on Safety Culture Self-Assessment for Senior Management in May 2015, started to prepare the guidance for safety culture self-assessment, and coaching for core team of safety culture self-assessment.

III-2.2. Independent Assessment

Independent assessment on implementation of BAPETEN Integrated Management System has been performed by:

- Independent survey to license holders to know the effectiveness of BAPETEN as the Nuclear Regulatory Body.
- Independent assessment by IAEA IRRS mission in 2015. Recommendations for the safety culture Program are to implement the safety culture oversight, and perform BAPETEN safety culture self-assessment.

III-2.3. Benchmarking

Benchmarking for improvement of safety culture program have been carried out through technical visit to oil and gas company, electrical company, and sharing experience with other nuclear regulatory body during technical visit or other international meeting and seminar.

III-2.4. Implementation of action plan and follow-up

The implementation and follow-up of the self-assessment and independent assessment are:

- The follow-up of the IRRS Mission are preparing guidance and assessment of safety culture oversight to the license holder, preparing and assessment of safety culture self-assessment.
- The follow-up from the independent assessment of Integrated Management System Implementation, are preparing and reviewing several SOP, guidance, enhancing the knowledge, and optimized on-line Licensing process.

III-2.5. Challenges and Lessons Learned

Challenges and lessons learned from the safety culture implementation are the managers do not understand the importance of safety culture, as well as the budget constraints for socialization, training and other safety culture implementation programs.

III-3. REGULATORY OVERSIGHT

III-3.1. Basis

Base on the Indonesia Nuclear Energy Act no. 10 of 1997, the role of BAPETEN is to perform nuclear regulatory functions on the use of nuclear energy in Indonesia by developing nuclear regulation, licensing,

inspection and law enforcement. BAPETEN develop regulations and guidelines for implementation of safety culture, and perform dissemination to licensee and other stakeholders.

In accordance with the nuclear safety convention and Indonesia Government regulation, the prime responsibility for safety of nuclear energy utilization rests solely on the licensees. BAPETEN as the nuclear regulator ensure that the licensee properly discharges this prime responsibility for safety, including Safety management system and safety culture implementation through regulatory oversight. The scope of the inspection are safety of operation and maintanance program, radiation protection and environment, emergency preparedness and quality assurance or management system. BAPETEN inspection program does not cover a particular safety culture inspection. During auditing process of quality assurance program or safety management system, inspectors can put inquiries regarding safety culture implementation based on nuclear safety regulations as described in the regulatory framework.

III-3.2. Regulatory Framework

III-3.2.1. Regulatory requirements on safety culture

The basic framework for safety culture implementation is clearly stated in Nuclear Energy Act no. 10 of 1997. One of the objectives of regulatory functions is to increase legal awareness of nuclear energy utilization to develop safety culture (article 15, point d), while in the elucidation of article 15 it is stipulated that safety culture is a reflection of characteristics and attitudes in organizations and individuals that emphasize the importance of safety.

Article 5 of Government Regulation No. 33/2007 on the Safety of Ionizing Radiation and the Security of Radioactive Sources, states that Safety Culture is one part of the management requirements that must be realized in any nuclear energy utilization.

IAEA GS-R-3 on Safety Requirements on 'The Management System for Facilities and Activities', provides requirements to foster and support a strong safety culture through the development and reinforcement of good safety attitudes and behaviours in individuals and teams. These will enable them to carry out their tasks safely and provide the means by which the organization can continuously strive to develop and improve its safety culture. BAPETEN has adopted the GSR-3 by publishing BAPETEN Chairman Regulation (BCR) No. 4 /2010 on Management System for Nuclear Energy Facilities and Activities. The regulation mandates the licensees to conduct an independent assessment for the improvement of safety culture. Apart from that, management system should be implemented by the licensees to foster and support strong safety culture by:

a. Ensuring a common understanding of the key aspects of safety culture;
b. Providing a convenience to organizations and individuals to support the team in performing its task by considering the interaction between individuals, technology, and organization;
c. Cultivating attitudes of asking questions and learning at all levels of the organization; and
d. Providing a convenience to the organization to continuously develop and improve the safety culture.

To apply this regulation, BAPETEN also adopts by translating and enforcing IAEA document; IAEA Safety Guide GS-G-3.1 on Application of the Management System for Facilities and Activities 2006 and IAEA GS-G-3.5 on Management Systems for Nuclear Installations 2009.

III-3.2.2. High-level good practices for regulatory oversight of safety culture

BAPETEN develop guidance containing the mechanism and methodology for implementation of safety culture oversight, conduct training of safety culture oversight for inspector, dissemination of safety culture oversight to the licensee, and promote licensee safety culture self /independent assessment.

III-3.3. Promoting Safety Culture

Communication to promote safety culture has been performed at a high-level senior management of BAPETEN, with senior management of National Atomic Energy Agency (BATAN) as the licensee to present the results of the joint safety culture assessment of three research reactors in 2005. As a follow up, the chairman of BATAN give the instruction to each nuclear installation of BATAN to start to conduct safety culture self-assessment and improving their safety culture implementation.

High-level dialogue between senior manager of BAPETEN and senior manager of BATAN also conducted to communicate the nuclear safety condition include the results of inspections.

Communication between BAPETEN with all stakeholders including the licensee to discuss of nuclear and radiation safety also performed every year in the Regulatory Information Conference.

III-3.4. Oversight Process and Methodology

The scope of nuclear safety inspections are safety of operation, maintenance programs, radiation protection and environmental radiation safety, nuclear emergency preparedness programs and quality assurance programs. No specific safety culture oversight during our safety inspection. The recommendation of the IRRS mission to BAPETEN to conduct specific safety culture oversight activities to operator organization both for nuclear installation and radiation facilities. BAPETEN has conducted the assessment of safety culture oversight and develop the Guidance of Safety Culture Oversight implementation for BAPETEN Inspectors.

Based on the results of the assessment of safety culture oversight, nuclear installations licensee in BATAN is ready to receive the safety culture oversight from the BAPETEN inspector. In the final draft guidelines safety culture oversight, BAPETEN using the methodology of **'integration into regulatory activities'** for regular inspections. In this case the findings of the regular inspection as the data descriptive, and then for normative analysis using safety culture characteristics and attributes. Besides '**independent assessment**' methodology also is conducted once every five years simultaneously with the implementation of periodic safety review.

ANNEX IV – EXAMPLES OF PRACTICES FROM FINLAND

IV-1. SAFETY CULTURE IN THE REGULATORY BODY

The Radiation and Nuclear Safety Authority's (STUK) operations are based on the Act on Radiation and Nuclear Safety Authority. The first section of the Act defines STUK's mission and position: 'The Radiation and Nuclear Safety Authority operates under the Ministry of Social Affairs and Health with the purpose of preventing and limiting the adverse effects of radiation, controlling the safety of the use of radiation and nuclear energy, and engaging in associated research, education and communications.'

STUK has an independent role as a national regulator. In order to secure and maintain the independence, various arrangements have been taking place. E.g. the funding issues and substance matters are dealt with two different and separate ministries. As a safety authority it is vital for the STUK organization to be able to carry out its operations without substance steering coming from any external parties.

The mission of STUK is to protect people, society, and the environment and future generations from the harmful effects of radiation. The goal is to keep the radiation exposure of the Finnish population as low as reasonably achievable and the level of radiation safety as high as possible, while preventing radiation and nuclear accidents.

STUK's regulation operations are based on legislation, safety regulations and guidelines related to radiation and nuclear safety. STUK regulates nuclear power plants, other nuclear facilities, nuclear materials and final disposal of nuclear waste.

STUK regulates the use of radiation in health care, industry, research and training. STUK grants licenses for the use of radiation. For its part, STUK regulates the transport of radioactive substances. STUK maintains 24-hour emergency preparedness for nuclear accidents and other radiation hazard occurrences. If a radiation hazard occurs, STUK acts as the expert authority, co-operating with other authorities, organizations and experts. STUK monitors the presence of radiation in the environment round the clock.

Most of the radiation abs regulatory bodied by people comes from natural radiation. STUK monitors the presence of radon at workplaces and prepares regulations and instructions concerning radon at home. In addition to radon seepage from soil into indoor air, another factor exposing the Finnish population to a significant level of radiation is solar ultraviolet radiation. STUK also regulates the radiation safety of sunbeds, power lines, mobile phones and other devices that utilize radiation.

STUK operates openly, listens to people and engages in fruitful co-operation with other authorities, organizations and the entire society. Furthermore, an important part of STUK's operations is participation in international co-operation on radiation and nuclear safety.

In order to carry out its oversight tasks in an effective manner STUK has developed an organizational structure (Chart 1) that supports the nuclear reactor regulation and the nuclear waste and material regulation. These two activities are organized into separate departments in order to ensure the adequate independence from other STUK operations.

The Nuclear reactor regulation and the Nuclear Waste and Material Regulation departments carry out all oversight actions related to nuclear power plants. Both departments have their own directors and management teams. The department heads report directly to STUK's Director General.

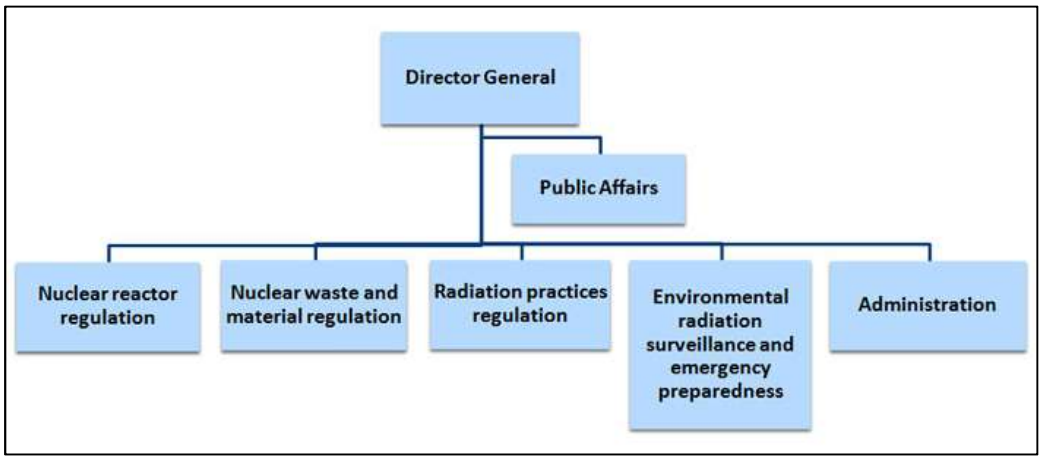

FIG. IV-1: Chart 1 - Organization Structure

The Nuclear reactor regulation and the Nuclear Waste and Material Regulation departments carry out all oversight actions related to the use of nuclear energy in Finland. Both departments have their own directors and management teams. The department heads report directly to STUK's Director General. All discipline specialists, the inspectors, are divided into specific teams each with their own areas of responsibilities. These teams carry out all inspection duties within the technical area of the discipline. The inspections and other oversight activities are often carried out in specific inspection teams that acquire needed competences from the discipline teams.

IV-1.1. Safety culture framework in STUK

The theoretical framework for STUK's Safety Culture has been influenced by various models. The first of them is the IAEA model that defines the Safety Culture Characteristics as follows: *Leadership for safety is clear, Safety is a clearly recognized value, Accountability for safety is clear, Safety is learning driven, Safety is integrated into all activities*.

The second source for the STUK's safety culture framework has been the DISC (Design for integrated safety culture) model, created by VTT (Technical Research Centre of Finland Ltd). VTT is a Technical Support Organization with a strong track record in the safety culture research.

The DISC model presents e.g. the fundamentals of the safety culture and the organizational functions necessary to develop a good safety culture (Chart 2). (e.g. http://www.vtt.fi/inf/pdf/technology/2015/T222.pdf)

FIG. IV-2: Chart 2 - The DISC Model Overview (VTT: Oedewald, Reiman, Pietikäinen)

The importance of the regulator's own, strong safety culture is vital for all aspects of regulatory safety culture. Therefore, the regulatory organization shall develop and maintain its own safety culture in an organized and planned manner.

STUK has established its Safety Culture Program with various policies procedures and other activities to support and promote the culture for safety: e.g. STUK has developed its Policy on Safety and Security, Quality Manual for the regulatory departments that highlight the importance of safety culture. In addition, the development of Quality Manual, STUK has developed its Integrated Management System that integrates safety culture elements into processes of entire organization.

IV-1.2. Policies related to Safety Culture

STUK has adopted a systemic approach to safety. The systemic approach means that the people (individuals), technology and organization are considered as a complex and dynamic system where all parts interact with each other. The safety factors or outcomes are not to be evaluated (or achieved) by focusing on the individual parts of the system, but also by understanding the interactions between them. Consequently, every policy, practice, process and procedure of a Nuclear Regulator should pay attention to the safety factors related to them.

STUK has multiple policies and procedures that effect on safety culture. The Safety and Quality Policy states the mission and goals of STUK organization. In addition, it describes the core values and the overall policies of the STUK organization. These fundamental items concern the entire STUK organization, not only the Department of Nuclear Reactor Regulation. Besides the Safety and Quality Policy, STUK has several other policies (e.g. the Information Security Policy and Personnel Policy) that have a direct impact on the Organizational Safety and also for the Culture for Safety.

The STUK's Quality Manual includes various items that have a direct impact on organizational safety culture in STUK. The Quality Manual e.g. presents the operating principles of the STUK organization. The Nuclear Reactor Regulation department has its own internal Nuclear Safety Regulation Guides. These guides (and the related procedures) e.g. set the requirements and the framework for the nuclear oversight activities in STUK. All internal guidance effects on the organizational culture and therefore they have a direct link with STUK's culture for safety.

IV-1.3. Safety Culture Program

The policies presented earlier in this document describe fundamental elements for the safety culture program in STUK. Besides the safety and security specific policies, safety and security elements are integrated in the guides and the requirements steering the operations of the Nuclear Reactor Regulation department. The Safety Culture Program in STUK consists of various procedures and development activities. The different kinds of training activities have an important role in safety culture development. In addition to training, Self-assessment and evaluation activities play a key role in the Safety Culture Program.

Training and other development activities are an important part of STUK's Safety Culture Program. Training events target different aspects of the topic area e.g. essentials of safety culture, case study -workshops, discussions, self-study materials etc. In addition to the safety culture specific training events there are numerous training events where safety, safety culture and other matters related to 3S (Safety, Security and Safeguards) are included. Nuclear Safety factors and systemic safety are to be considered whenever the training events and their contents are planned in STUK.

Self-assessments are an important part of STUK's Safety Culture Program. The self-assessments are conducted regularly and they are supplemented by other evaluations focused on the STUK organizational factors. If needed, the self-assessments are carried out with the support of an external support organization. IAEA methodology is utilized in the process of conducting the self-assessments on safety culture.

IV-1.3.1. Safety culture in the processes under the Integrated Management System

STUK's has developed an integrated management system that includes all regulatory activities. The Integrated Management System forms a coherent structure that supports, guides, regulates and steers the organization in its operations. As described earlier, STUK has adopted a systemic approach to safety. This approach applies to the Integrated Management System as well. The various elements related to safety culture and other safety and security related factors and activities are an integrated part of the system.

Safety culture has its own processes but virtually all processes and procedures have some 3S content to them. Consequently, all activities shall follow the Integrated Management System descriptions and therefore the Integrated Management System of STUK is viewed as one of the key support structures and tools for the safety culture development.

IV-1.3.2. Training for senior management and staff

STUK's training system consists of training programs that are formed around the specific topic areas (Picture 1). One of the training programs is about safety culture. The Safety Culture Training Program aim to promote and develop safety culture among the STUK staff by e.g. providing information and opportunities to reflect on the topic. The Safety culture training activities are offered to all of the inspectors and the staff on nuclear regulatory departments but they are open for all STUK personnel.

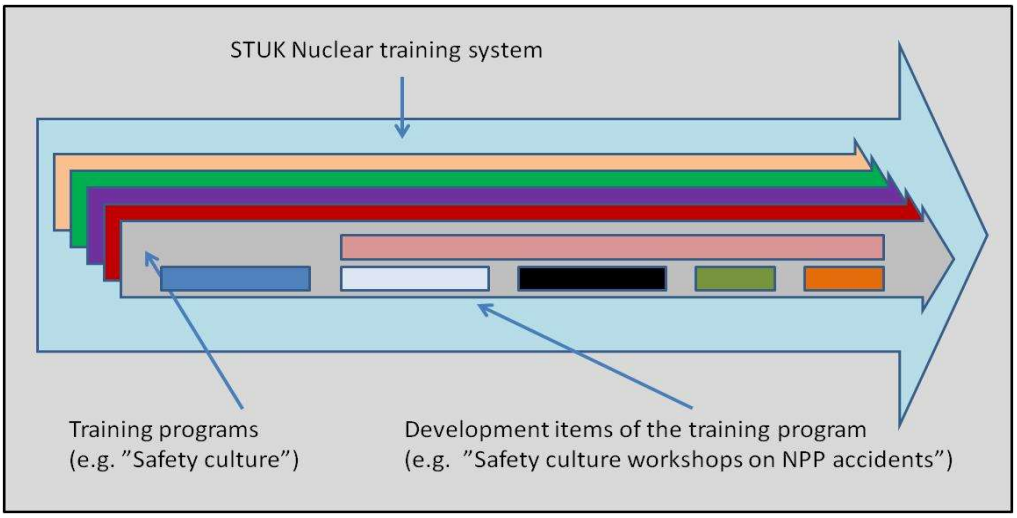

FIG. IV-3: Picture 1 - Basic Structure of STUK's Nuclear Training System

In addition to the general training, there are specific training and development activities for STUK's senior management and the supervisors. The leadership and management training includes safety culture elements. The leadership training is currently under revision and the updated training will be launched in 2016. The Leadership for Safety Program will encompass the understanding of the essence of leadership in STUK, the development of personal managerial and leadership competences, the knowledge of managerial role and related tasks and requirements in STUK and the understanding the linkage between leadership and the culture for safety. The Leadership for Safety Program consists of training and development activities on personal and group levels. The program will include development elements for managers, directors and management teams.

The systemic approach to safety is adopted in the development and maintenance of STUK's nuclear training system. Besides the specific safety culture training, the safety culture (and safety factors in general) is incorporated into various topic areas and training programs (Picture 2). Importance of having an awareness for 3S and safety culture - even when the training is predominantly focused on e.g. plant technology - is highlighted. Training is one of the ways to promote the safety culture as an integral part of regulator's everyday activities.

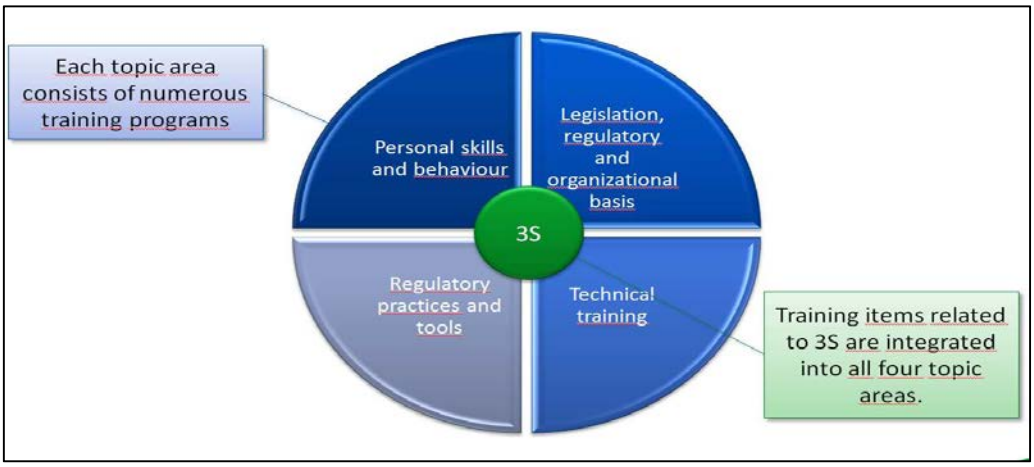

FIG. IV-4: Picture 2 - Main topic areas of nuclear training in STUK

The main topic areas of STUK's Nuclear Training System are divided into four categories. The categories are adopted from the SARCoN (Systematic Assessment of Regulatory Competence Needs) methodology. The SARCoN divides the competence needs of a nuclear regulator into four areas: Legislation, regulatory and organizational basis, Regulatory practices and tools, Technical competences and Personal skills and behavior. These four areas include variety of training elements for various target groups - from a newcomer to a senior experts.

STUK carries out self-assessments regularly. In times, these activities are directed to the safety culture activities. For further information see Part 4. of this document.

IV-2. CONTINUOUS IMPROVEMENT

STUK's mission is to protect people, society, and the environment and future generations from the adverse effects of radiation. The mission requires strong competence and understanding of complex phenomenon. Continuous improvement is an integral part of STUK's Integrated Management System. Majority of the Integrated Management System processes and procedures contain elements that strive to support continuous improvement throughout the organization - the improvements take place on all levels of organizational activities.

STUK's core values – expertise, openness, courage and co-operation - highlight the importance of competence and continuous improvement. STUK's choices, statements and solutions are based on shared high-quality expertise and scientific knowledge. STUK's operations are open and honest in all transactions with stakeholders, citizens and STUK's staff. Perceived problems and one's own opinions are presented without hesitation. Responsibility is assumed for implemented solutions. Errors and mistakes are fixed. Co-operation within STUK is based on collegiality, inclusion and mutual respect. Stakeholders are included in the preparation of matters. None of this would work without a strong strives for continuous improvement.

STUK strives for continuous improvement in numerous ways. The training activities (described briefly in part 3) are an important factor when developing the capacity within the staff. Besides the education and training methods, STUK utilizes self-assessments, independent assessments and various surveys to evaluate and asses its level of maturity and status in different areas and activities.

IV-2.1. Self-Assessments

STUK carries out self-assessments and internal audits on regular basis as part of its normal operations. These activities are targeted to all areas and activities of the organization. The activities follow the careful planning and they are carried out in accordance with the Integrated Management System procedures and processes. The self-assessment and internal audit programs are executed through annual action plans. The actions are carried out by specifically assembled audit and assessment teams each with their own targets, plans and reporting duties.

Self-assessment and internal audits are steered by the office of quality management. The program is divided into annual actions plans. The input for the planning is gathered from the operational environment as well as from the previous assessments (follow-ups). The self-assessment activities are described in detail in STUK's Integrated Management System.

The self-assessment and audit program includes the STUK's safety culture. The safety culture self-assessments are carried out periodically. Once the results are reported, the evaluation of results will lead into development plans and programs. The self-assessments are part of the Safety Culture Program as they are an important method for evaluating the status of the safety culture and a vital source of input for further development.

The senior management have an important role e.g. in the evaluation of the results and in putting development plans and actions in place. Besides the safety culture self-assessments, STUK's senior management has an active role as the drivers of continuous improvement. The senior management reviews the work and the

progress of different areas of the organization regularly. The management reviews are a useful method to steer the development and continuous improvement in STUK. They present the general view of the current development work and highlight the needs for further development. E.g. on Nuclear Reactor Regulation department management reviews are carried out twice a year. In addition to the department level, management reviews are carried out annually on STUK level.

IV-2.2. Independent Assessment

In addition to internal audits, self-assessments and internal inspections, independent assessments are conducted regularly. Independent assessments are conducted for various reasons e.g. to gain expert views from external parties. The information and understanding acquired through independent assessments is turned into development plans and programs. Therefore, the independent assessments are an important part of continuous improvement in STUK.

STUK is an active participant in multiple national research programs (e.g. SAFIR Finland). Many of the research programs include research projects that carry out assessments in the participating organizations (e.g. SAFEX - Expert work in safety critical environment). Majority of the research programs are nuclear specific or targeted to the safety critical industries. The results of the assessments are evaluated and reviewed in co-operation with the research teams in order to establish better understanding of the results and potential development needs. The results are also reviewed and discussed among the STUK staff in order to share the knowledge.

In addition to e.g. the research programs concerning entire Finnish nuclear industry, STUK has carried out its own extensive independent assessments. The assessments are conducted by external experts. The assessments focus on the operational areas that need to be improved or that are chosen – for some reason - to be under further revision. The research activities and assessments are contracted between the independent party and STUK and the results are reported once the research has been carried out. Research and assessment findings are carefully evaluated in an open manner. The STUK staff is invited to take part into the process. The external and independent assessments are regularly utilized to supplement the STUK's internal assessment and inspection activities. Their overall goal is not to highlight the weak spots of the regulatory organization, but highlight the need and opportunities for continuous improvement.

IV-2.3. Resources and implementation plan

Continuous improvement is integrated part of STUK's Integrated Management System. Need for improvement is highlighted in all levels of the system. The improvement actions planned and then are placed into the annual action plans on department level. Consequently, the needed resources are reserved for the chosen development work packages. The resource and implementation plan includes all of the needed resources whether they are people (working time), new tools, monetary elements etc.

The adequate resourcing for development and continuous improvements require a clear overall planning process. Prioritization of development actions is often needed. Therefore, the quality of overall strategy and operational planning on all levels of the STUK organization is important.

IV-3. REGULATORY OVERSIGHT

IV-3.1. Basis

The basis for the regulatory oversight on safety culture is in regulator's own safety culture. It is difficult to carry out regulatory oversight activities if the regulator itself fails to establish and understand the phenomena or its own strong culture for safety. The basis for the safety culture in STUK is in STUK's own safety culture program. In addition to the understanding of the safety culture as phenomena, concrete regulatory and procedures tools are needed. In Finland the YVL guides set basic requirement level for the safety culture of any licensee organization. STUK's Integrated Management System describes the conventions, the processes,

the practices and the methods for the safety culture oversight work. In addition to the basis and the regulatory framework, continuous dialogue is needed between all parties of Finnish nuclear industry.

IV-3.2. Regulatory framework

The regulatory activities in Finnish nuclear industry are based on the Nuclear Energy Act, the Nuclear Energy Decree, the Government Decrees, YVL Guides issued by STUK and finally by various Codes and Standards. The regulatory framework for the safety culture is based on the legislation. The Government Decree 733/2008, 28§ states e.g. the following:

> 'When designing, constructing, operating and decommissioning a nuclear power plant, a good safety culture shall be maintained. --- The decisions and activities of the management of all organizations participating in the abovementioned activities shall reflect its commitment to safety-promoting operating methods and solutions. --- Personnel shall be motivated to perform responsible work and an open working atmosphere shall be promoted in the working community to encourage the identification, reporting and elimination of factors endangering safety. --- Personnel shall be given the opportunity to contribute to the continuous enhancement of safety.'

The YVL guides issued by STUK present various requirements for safety culture. E.g. the YVL guide A.3 sets requirements for the management system of a licensee: 'The management system shall support positive characteristics of the organizational culture that promote safety'. However, the YVL guides do not present the specific structures or required levels for 'a good safety culture'. The guidance promotes the need for e.g. procedures and activities that tend to support the healthy culture for safety. Oversight activities focus on evaluating how well these activities have succeeded.

Further information regarding the Finnish requirements for Management system and safety culture is found in the YVL guide A.3. The legislation, the decrees and the YVL guides form the basic framework for all oversight of safety culture in the Finnish nuclear licensee and applicant organizations. (e.g. http://plus.edilex.fi/stuklex/en/lainsaadanto/saannosto/YVLA-3)

The guidance for the regulatory and oversight work on safety culture is presented in the specific YTV guides that set the requirements for all nuclear regulatory activities in Finland. Within the YTV guides, the requirements for oversight of the organizational factors are also specified. The specification of the safety culture oversight guidance is one of the current development areas in Finland. The general approach to the regulatory oversight of safety culture highlights the importance of the general view which can only be achieved through effective cooperation between the inspectors of the different disciplines. This cooperation can be supported by the Integrated Management System and various inspection tools.

IV-3.3. Promoting Safety Culture (dialogue)

As a safety regulator, STUK promotes safety culture continuously in all of its actions. Whether it is the licensee organization, Technical Support Organization or other interest group, STUK aim to include safety and safety culture elements into the dialogue. Even when interacting with the non-nuclear organizations or such, STUK aim to highlight the importance of safety factors in the dialogue. Also, it is important for STUK to learn from other organizations' experiences and therefore promoting a dialogue on safety culture is important for the STUK's own safety culture development.

STUK has a strong and independent role as a regulatory organization in Finland. This role enables STUK to be an active party within the Finnish nuclear industry and in the discussions taking place in the industry. However, the strong regulatory role requires strong competence to be able to argument and point out factors with relevant safety culture or organizational influence. STUK's ability to act as an independent and strong regulator and still maintain the healthy dialogue is important for the long-time development of national safety culture in Finland. The dialogue and general discussion regarding the safety culture must take place all the time – not just when something is clearly going into wrong direction. Promoting the dialogue on safety culture in nuclear organizations is therefore one of the key tasks of STUK.

IV-3.4. Oversight Process and Methodology

Regulatory oversight of safety culture is a network activity that needs to be coordinated. On one hand, the oversight process and methodology must pay attention to details and specific indicators (e.g. procedures specified in the YVL guides), but on the other hand the oversight work must include extensive and broad-scaled observation of different contexts and relations. The safe culture oversight activities are steered by the big picture formed by the regulator as well as the assessment of the licensee activities.

In STUK the responsibility for safety culture oversight process and methodology is appointed to the Office of *Organizations and Management Systems of the Nuclear Reactor Regulation Department*. The team is responsible for developing the process, the methodology needed and the tools for safety culture oversight. The process for maintaining the understanding of the status of safety culture in each licensee organizations is steered by this this office. However, observation of safety culture and organizational related factors is a task of all STUK inspectors – within relation to their own area of expertise.

In 2012, STUK started the systematic use of the 'KOTKA' database to collect inspection findings indicating to different aspects of safety culture from the operating nuclear power plants. The findings collected in KOTKA databases were analyzed by STUK inspectors (once a year) and reported in an annual report.

Recently, STUK has developed a modernized database ('HAKE') for collecting inspection findings from nuclear facilities under construction and in operation - as well as from all other the activities under STUK oversight. Other sources of information are also used to provide input to the database, including analysis of operating events.

HAKE tool allows to STUK to collect the findings, analyze them, prepare reports with the results of the analysis, plan future inspections and identify corrective actions to ensure feedback from the inspection findings. The tool enhances the transparency between technical disciplines significantly. Consequently, it supports the regulatory organization to create and maintain an intact general view on the licensee organization and its various operations.

Specific software and methods are used to extract the elements relevant to safety culture from HAKE. The results of this extraction will be discussed by a group of experts three times a year and any identified safety culture issues are reflected in feedback actions. In order to further strengthen its internal competences and identification of safety culture issues (and actions), STUK has hired a senior expert in the area of safety culture. In addition, analysis of the findings by external experts (typically VTT) is frequently used. The safety culture findings and expert reports have a significant steering effect on the inspection program planning of the following years.

By training and educating its inspectors to observe safety culture and organizational factors, and by collecting, evaluating, discussing and reporting safety culture issues from all regulatory oversight areas STUK aim to establish a coherent picture of licensee organizations and their culture for safety. This is an area where coordination, cooperation and continuous improvement are needed all the time.

ANNEX V – EXAMPLES OF PRACTICES FROM FRANCE

In France the Regulatory Body is the Nuclear Safety Authority (ASN), an independent administrative authority created by the Law on Transparency and Nuclear Security (2006).

This paper presents the safety culture approach within ASN. According to the structure proposed by the IAEA, it addresses the safety culture policy, the safety culture program, continuous improvement, self-assessment and regulatory oversight.

V-1. SAFETY CULTURE IN THE REGULATORY BODY

V-1.1. Basis

Consideration and development of safety culture in the French regulatory body is based on the one hand on the European regulatory framework applicable to each EU Member States and, on the other hand, on the recommendations of the IAEA. These basis are developed in the two following sections.

V-1.1.1. IAEA Basis

The General Safety Requirements on Governmental, Legal and Regulatory Framework for Safety (GSR part 1) that apply to regulatory bodies specify some recommendations related to safety culture in the regulatory body such as the need for the Regulatory Body to implement a management system that promote and support a good safety culture.

V-1.1.2. European Basis

The European Directive 2009/71/Euratom, revised on July 8th, 2014 (EU Directive 2014/87/Euratom) establishing a community framework for nuclear safety of nuclear installations, defines requirements related to safety culture in its articles 5 and 8.

Article 5 requires EU Member States to implement an independent regulatory body that, in particular, employs a staff in appropriate number having qualifications, experience and expertise necessary to perform its obligations.

Article 8 requires the regulatory body to:

- Implement a management system aiming to promote and strengthen safety culture and allowing the ability to adopt a questioning attitude on the effective implementation of relevant principles and practices regarding nuclear safety and to report in due time on safety issues;
- Take provisions related to training.

The revised directive adds, in its Article 8, a section (Article 8ter) related to safety culture.

In particular, Member States shall ensure that the regulatory body and the licensees take measures allowing to promote and strengthen an effective safety culture. These measures include:

- Management systems which give due priority to nuclear safety and that promote at all levels of staff and of managers, the ability to question the effective application of safety relevant principles and practices and to report timely on safety issues;
- Arrangements implemented by the licensee to record, evaluate and document any significant experience gained in the frame of internal and external operation in terms of safety;
- The requirement for the licensee to notify the competent regulatory authority the events that may impact nuclear safety;
- Provisions for education and training.

V-1.1.3. French Basis

There are no specific requirements related to safety culture for the regulatory body in the French general regulations.

Arrangements with regards to safety culture in the Regulatory Body appear in the following documents (see sections below):

- ASN's Rules of Procedure, that transpose the European Directive establishing a Community framework for nuclear safety of nuclear installations and that have been endorsed by an order of the ministry of environment;
- ASN's management system.

In addition to these documents, as regards the questioning attitude which is one of the most important behaviour in safety culture, a Law of 16 April 2013 protects employees who, in good faith, have launched a warning for a fact or a particular action, since ignorance of this information seems to him to pose a serious risk to public health or to the environment.

V-1.2. Safety Culture Policy

Safety culture is, with the defence in depth principle, one of the two cornerstones of nuclear safety.

ASN's policy is defined in ASN's Rules of Procedure that have been endorsed by a ministerial order of the ministry of Environment and the safety culture policy is part of this general policy. It relies on:

- The achievement of all the missions of the regulatory body as defined in the law in accordance with the four core values of ASN that are described below;
- The development of a management system that maintains and develops rigour and individual and collective, skills for all ASN's staff;
- The definition of a quality approach within the management system that includes provisions for continuous improvement of ASN's operation and effectiveness of ASN's action;
- The organisation every ten years of a self-assessment and of IAEA peer reviews;
- The definition of appropriate human resources for individual and collective skills.

The four core values of ASN include:

1 - Competence:

This value is achieved through:

- Qualified teams with competence in the technical, legal, management and communication fields;
- Adequate number of competent staff to deal with the activities and topics regulated, with a graded approach.

Such a value requires adequate financial resources as a significant part of ASN's resources is spent on staff training activities.

2 - Independence:

The law establishes ASN as an independent administrative authority and this status guarantees ASN's freedom of judgment, action and expression.

3 - Rigour:

The level of professional rigour required by ASN for its staff is comparable to the level that ASN requires for all the licensees and this contributes both to its credibility and to its legitimacy.

4 - Transparency:

Transparency is a value promoted by the law. This law gives to ASN a mission in informing the public.

In particular, the objective for ASN, as regards transparency, is the obligation of exemplary nature of its actions in terms of safety. This includes the obligation of neutrality in all ASN's positions and the need to correctly deal with all files and topics in order to be able to report to stakeholders.

Transparency also includes public consultation on all draft regulatory documents and regular information of local information committees constituted near regulatory body each nuclear site. Transparency also aims to avoid complacency.

These four-core value are essential to ensure efficient, impartial, legitimate and credible regulation, recognized by the public and regarded internationally as a benchmark for good practice.

V-1.3. Safety Culture Program

Nuclear and radiation safety is the core business of the Regulatory Body and safety culture, as one of the nuclear safety cornerstones, is part of this core business.

The development of safety culture within ASN comprises:

- An adequate education and training for all ASN's staff. Each new member of ASN follows, when joining ASN, an initial training before being designated as inspector in its field of competence;
- A strong leadership;
- An interrogative attitude;
- A transparent reporting.

V-1.3.1. Safety culture in the processes under the Integrated Management System

ASN's Rules of Procedure specify that the Director General shall create and operate a management system that:

- Maintains and develops, within ASN staff, rigour and individual and collective skills;
- Sets the rules for operating and organising the services;
- Includes provisions for continuous improvement of ASN's operation;
- Relies on simple, clear and accessible documentation.

For increasing effectiveness and promoting the safety culture in its own teams and those of nuclear licensees, and for supporting its actions aimed at improving nuclear safety and radiation protection, ASN applies a quality approach based on the international standards for nuclear safety authorities and management systems (GSR-Part 1 and GS-R-3 from the IAEA), the ISO 9001 standard concerning the quality management system, and the ISO 17020 standard concerning inspection. Without looking for an accreditation or a certification according to these standards, but to ensure that its management system is always relevant, ASN decided to benefit from an evaluation by its peers with regard to IAEA safety standards (IRRS mission), at least every 10 years.

The purpose of this approach is to maintain and improve the rigor and individual and collective skills in the ASN core values, whilst making its action proportionate to the safety risks.

The integrated management system of ASN includes three main types of processes: management processes, business core processes and support processes (see Figure 1 below).

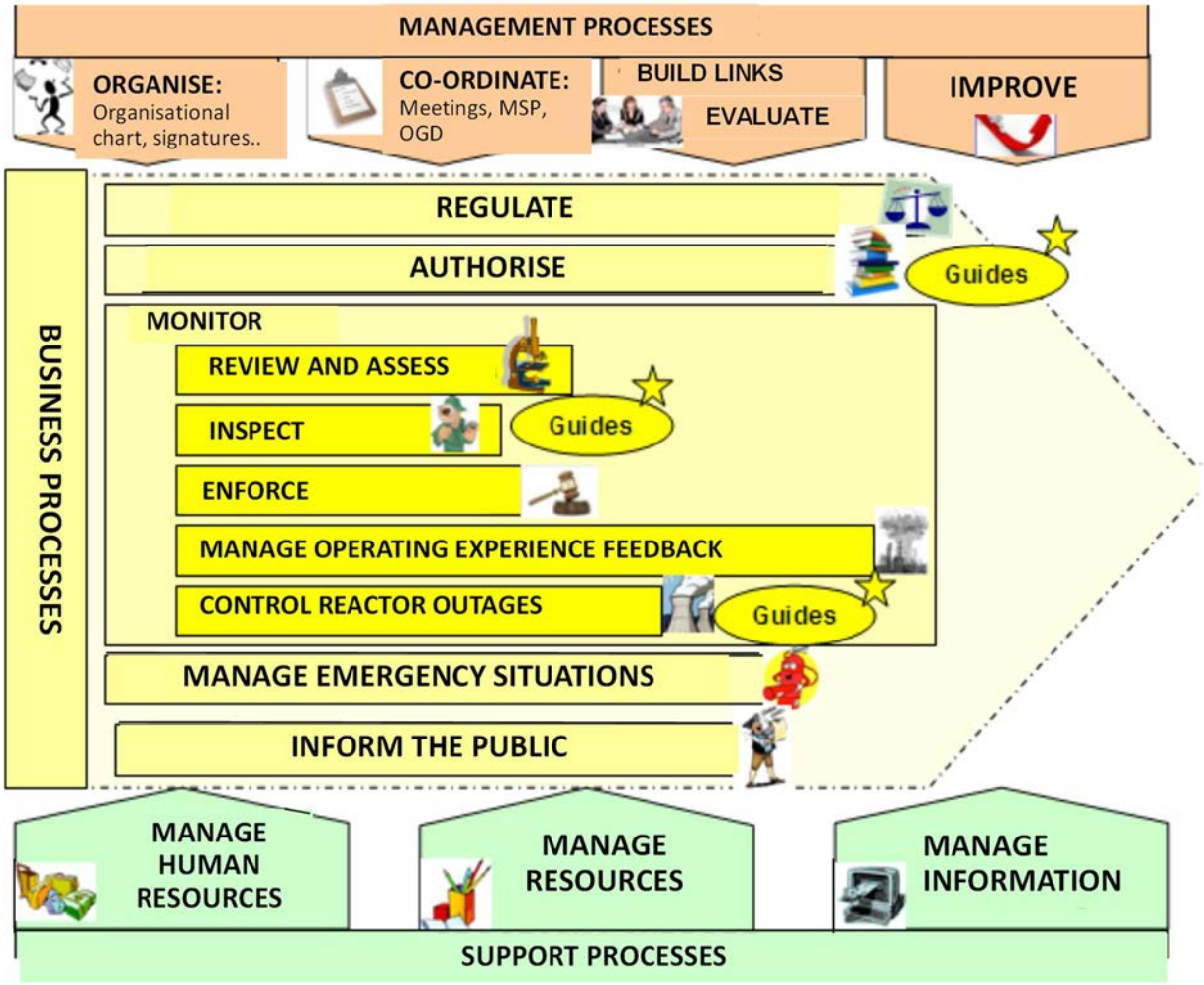

FIG. V-1: Processes of ASN's management system

In ASN's management system there is no specific process on safety culture, insofar as safety culture is more or less linked to all the processes of the management system. The views of ASN as regards safety culture aspects in the different processes of the management system is detailed below for each main core process.

V-1.3.1.1. Consideration of safety culture in the management processes

Process 'Organise': this process provides a clear definition of the organisation: job descriptions, responsibilities, authorities, organisation charts, organisation notes and signature delegation rules. The robustness and clarity of the organisation is a basis for safety culture.

Process 'Co-ordinate': the objective of the process is to set up means of exchanges in the form of seminars or networks and meetings in order to increase collective effectiveness, challenge viewpoints. The sharing of practices makes alive safety culture.

Process 'Build links': various relationships with external institutions or organisations (local, national and international institutions, foreign safety authorities…) contribute to the enhancement of safety culture by external questions on ASN practices and decisions.

Process ‘Improve’: ASN has implemented reviews and assessment tools including self-assessment that allow the questioning of practices (questioning attitude). The improvement loop, described below in Figure 3, helps enhance safety culture.

V-1.3.1.2. Consideration of safety culture in the support processes

Process ‘Manage Human Resources’: the goal of the process is to provide the regulatory body with competent staff in adequate number in technical, regulatory and organisational areas. ASN has defined a set of training courses to have a competent staff in all inspections fields. This set includes an initial training for each new staff member and additional actions that supplement this initial training. All these actions help to provide ASN staff a good safety culture for the achievement of its daily work and for the assessment of safety culture of the licensees during inspections.

Process ‘Manage Resources’: the definition of effective and appropriate means contributes to provide to ASN staff members a good work environment and to increase its efficiency, which is an important element of safety culture.

Process ‘Manage Information’: rigour in the management of all information received and transmitted in order to ensure its monitoring and its traceability contributes to the effectiveness of the global action of ASN and as a consequence to safety culture.

V-1.3.1.3. Consideration of safety culture in the business processes

Process ‘Regulate’: the establishment of regulation is one of the mission of ASN. The goal of the process is to set up a clear and comprehensive regulatory framework. ASN regularly checks the relevance of regulations to improve the safety of nuclear facilities (proposal of evolution of regulations, drafting decisions and guides as needed). This is part of the questioning attitude.

Process ‘Authorise’: the licensing regime is governed by procedures that are adapted to the type of facilities given the wide range of different nuclear facilities. These procedures are also part of the improvement process and the examination of operators’ requests requires the expertise of inspectors.

Process ‘Monitor’: the analysis of the results of the inspections performed annually (operating experience feedback, analysis of significant events, nuclear power plants site evaluation…) for the definition of the coming inspection programme needs a questioning attitude.

Process ‘Manage Emergency Situations’: to prepare for a potential emergency situation and because an accident remains always possible, ASN regularly contributes to national crisis exercises.

Process ‘Inform the Public’: public information about ASN actions contribute to transparency on nuclear safety and also to the development of safety culture and its improvement by highlighting potential issues in terms of safety and of safety culture.

V-1.3.2. Training senior management and staff

There is no specific training on safety culture for ASN staff. As for the management system, safety culture is part of the whole training provided to the staff all along its position in ASN.

When joining ASN, each new staff member shall follow on arrival an initial training before obtaining its inspector status. This initial training is the same for all staff members. Although some technical training may be waived considering the professional experience, training related to the organization of ASN, the regulatory framework or inspection practice are always mandatory.

This training is part of the Process ‘manage human resources. The whole training for inspectors includes:

- An initial training of several months (about 6 month) spread over 1 year. This initial training comprises mainly a theoretical training but also some field training (e.g. observing meetings or inspection, spending a week at a regional office…). The theoretical part is based on courses and seminars on technical topics related to inspector's activities and on general topics such as inspection practices, management of safety or communication;
- An on-the-job training mainly based on mentoring to provide professional experience for the performance of ASN's missions. In particular, this aims at having a mindset oriented at:
    - understanding the safety relevance of an item (proposed plant modification, modification of technical specifications, reported event, inspection finding…);
    - understanding the various viewpoints (licensee, Technical Support Organization, colleagues…) in support of various options with their advantages/drawbacks and uncertainties, being able to challenge them;
    - preparing ASN decision on a topic with the corresponding supporting safety arguments;
- A continuous training that supplement the initial training on specific activities not required for the certification.

The inspector status is obtained after the initial training (e.g after the first year within ASN) based on a formal training completion report, line manager evaluation and ASN Inspector Committee review.

This whole training is the opportunity of dialogue between trainees and trainers on all topics and in particular on nuclear safety.

V-1.3.3. Self-Assessment

As there is no specific safety culture programme, there is no specific self-assessment for the safety culture programme.

Nevertheless, a self-assessment is performed for the evaluation of the practices according to the 'improve' process of the management system.

V-2. CONTINUOUS IMPROVEMENT

V-2.1. Basis

According to ASN's Rules of Procedure, the Director General shall create and operate a management system that, in particular, include provisions for continuous improvement of ASN's operation.

These provisions include processes to improve ASN's efficiency and to verify that objectives have been achieved and that requirements have been met in order to promote a safety and radiation protection culture within its departments that is commensurate to the risks and hazards.

These tools for continuous improvement of ASN's efficiency consist of self-assessment, internal audits, reviews that are parts of the 'improve' process of the management system and are described in the sections below.

V-2.2. Self-Assessment

The self-assessment is the first step of the continuous improvement process and its objective is to verify the compliance of the organization and the operation of the department with the requirements of the organisation manual (process organisation).

In ASN, this self-assessment is based on self-assessment grids to evaluate practices with respect to the requirements defined in the national baseline aiming at identifying and then implementing the improvement actions.

V-2.3. Complementary Assessment

In addition to the self-assessment performed within each ASN department, complementary assessment is also performed:

Internal cross-audits: A multi-annual planning of cross-audits is established by the quality manager of ASN. The auditors, constituting the audit teams, are chosen among ASN senior staff who volunteered to perform such audits. To create the auditing team, the selection process takes into account the need to ensure a good representation of ASN entities and a good coverage of activities processed by the audited department. Audits help identify gaps in the quality framework and areas for improvement, but also to highlight and promote good practices.

Each department of ASN is audited every four years.

Performance indicators: ASN's action is quantitatively measured through indicators that are specific to each process. These indicators are reported to ASN Commission and the DG Office and are subject to regular monitoring.

Management System General Reviews: The annual review process of the ASN management system is based on a series of reviews, on the one hand at the local level under the responsibility of each department head and on the other hand at the national level in which the process owners and the network of quality correspondents take part, in order to prepare the review meeting chaired by the ASN Director General. A block diagram of this process is presented below in Figure 2. The department review reporting deadline is the 31st July each year. The general review usually takes place at the beginning of the last quarter of the year, and its conclusions are included in a general review report.

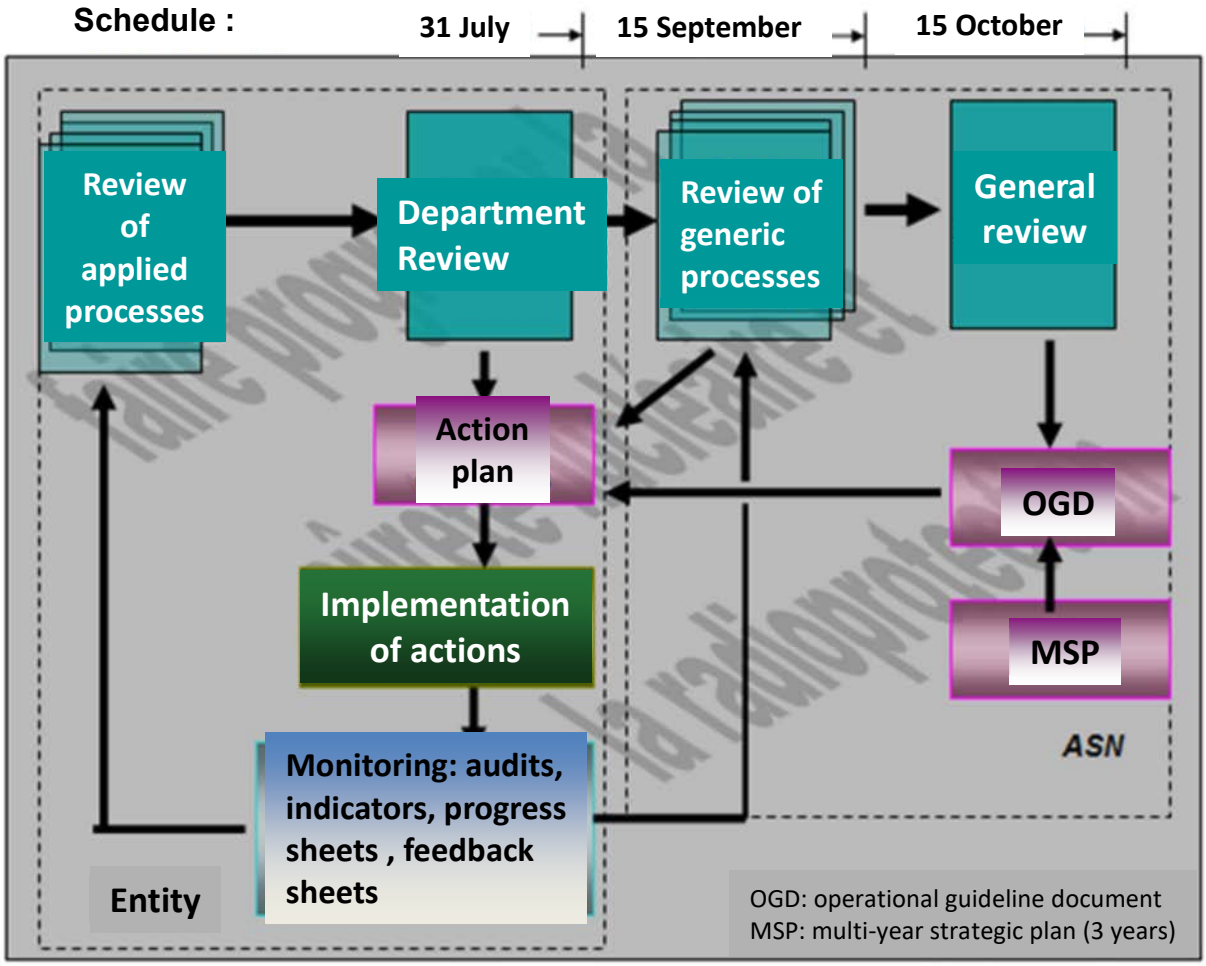

FIG. V-2: Diagram of ASN's Annual Review Process

The suggestions for improvement collected during these exercises are generally used to revise the operational guideline document (OGD) and the department action plan.

Other inputs for improvements

The improvement sheets: The objective of improvement sheets is to report and solve any significant deviation in the implementation of the management system or implement the improvements. They are available to all ASN'S employees.

The feedback sheets: the objective of feedback sheets is to collect the needs and expectations of in-house or external persons in order to identify areas for improvement and increase their satisfaction.

For findings that are of major importance, relevant sheets are regularly reviewed by the ASN Quality Manager and the management committee (executive committee and heads of ASN's Departments).

V-2.4. Resources and implementation plan

The implementation of continuous improvement is performed through an improvement loop based on a Act – Plan – Do – Check process. Figure 3 below gives an overview of this continuous improvement loop process.

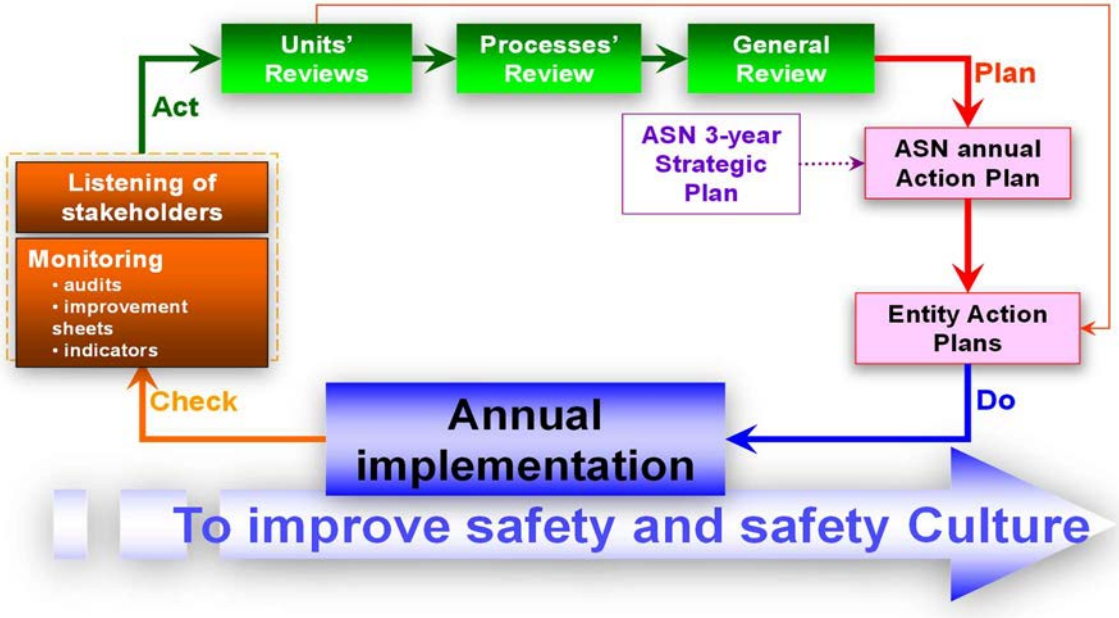

FIG. V-3: Continuous Improvement Loop Within the Management System

The improvement loop is based on several reviews, first at the level of a department of ASN. They feed the annual action plan of ASN that also takes into account the objectives of the 3 years strategic plan defined by the board of commissioners for the definition of the next annual department action plan.

One of the goals of this annual process is to improve each year nuclear safety and safety culture in the daily action of ASN.

V-3. REGULATORY OVERSIGHT

V-3.1. Basis

The basis for the regulatory oversight of the French regulatory body is provided by the Law on Transparency and Nuclear Security.

In its title II, this Law creates the French Nuclear Safety Authority (ASN) as an independent administrative authority for the control of nuclear safety and radiation protection and for public information in these fields.

The control of nuclear installations is required by the Law and is one of the missions of ASN defined in the Law that are:

- To establish regulations and guides and give opinion on ministerial orders and decrees;
- To license nuclear activities and facilities;
- To control nuclear installations (BNIs) with nomination of inspectors among its members;
- To contribute to informing the public;

- To assist the government, in its expertise field, for the management of radiological emergencies;
- To provide permanent monitoring, as regards radiation protection, on the national territory.

The oversight of nuclear facilities is therefore mandatory and constitutes a major activity of the regulatory body in France.

V-3.2. Regulatory framework

The regulatory framework for the oversight of nuclear installations in France, founded by the law, relies on the Ministerial Order of February 7, 2012 setting the general rules applicable for basic nuclear installations (BNIs[1]) taken in accordance with the Law on Transparency and nuclear security and with the Decree of November 2, 2007 defining the applicable procedures for the authorisations of basic nuclear installations. This decree is an enforcement decree of the Law.

The ministerial order consists of several titles dealing with the following topics:

- Organisation and responsibilities of the licensee;
- Licensee's management system;
- Nuclear safety demonstration;
- Control of detrimental effects and impact on public health and the environment;
- Pressure equipment specifically designed for nuclear installations;
- Waste management;
- Preparation and management of emergency situations.

Safety culture is requested in the two first topics as for example in the:

- Oversight of external contractors;
- Policy in terms of protection of the interests which includes safety: the policy states in particular the priority given to the protection of the interests and the permanent search for improved arrangements for the protection of those interests;
- Control of the performance of activities important for safety.

In addition to this ministerial Order, ASN also establishes regulatory decisions (regulatory binding) and guides (non-regulatory binding) to supplement and clarify the general rules as well as to explain the regulation.

As regulatory binding documents, the decisions constitute with the Law, Decree and Ministerial order the basis for the regulatory oversight.

[1] A basic nuclear installation is a nuclear facility that meets criteria such as for example the activity of radioactive materials handled inside the facility, the category of radioactive materials and the energy of the particles for an accelerator. These criteria are defined in an enforcement Decree of the Law on transparency and nuclear security. Basic nuclear installations include nuclear power plants and research reactors as well as other facilities (laboratories, storages, accelerators…) meeting the criteria.

V-3.3. Promoting Safety Culture (dialogue)

ASN and licensees top management are in continuous dialogue on strategic issues. Such issues include management and organization of the licensees, which are topics that have clear connection with safety culture.

In addition, and in order to prepare its decisions, ASN can call on the opinions and recommendations of 7 Advisory Committees of Experts (ACE), with expertise in the areas of reactors, waste, nuclear pressure equipment, medical exposure, occupational radiation protection, transport, and nuclear laboratories and plants. The ACEs comprise experts appointed by ASN for their individual competence.

The consultation of the advisory committees is decided by ASN, considering the significance of the topic. For example, the advisory committee on reactors is regularly and periodically consulted on the organisation and on the management of safety of the licensees as well as on the operating experience feedback of the licensees. Such consultations allow a new questioning of some analysis performed or of some practices. On this basis, ASN may request the licensees to develop new methodologies or implement new practices to address safety culture failures that have been highlighted by the advisory expert committee.

The consultation of an advisory committee of experts contributes to a good quality of decision taken by the regulatory body through an appropriate consideration of the stakes, the consultation of competent persons, the formalisation of difficult issues and the transparency of the process.

V-3.4. Oversight Process and Methodology

As the control of nuclear installations is one of ASN's mission, the oversight process is a specific process within the management system.

In France, the licensee has the prime responsibility for the safety of its facilities and activities. This responsibility cannot be delegated and the licensee is required to ensure permanent control of its facilities and activities. The mission of ASN is to ensure that the licensees comply with the regulations and with the license conditions.

The oversight process includes 5 sub-processes (inspections, control of reactors outages, enforcement, management of operating experience feedback and the evaluation of the site) that are described below.

a. Inspection

Every year, ASN draws up a programme of inspections organised according to the type or field of the facilities and activities being inspected (nuclear safety, radiation protection, pressure equipment, audits of approved organisations and laboratories). For each field, inspectors are designated by ASN Chairman, based on training and competence criteria ranging from the status of qualified inspector to senior inspector.

The inspection programme, restricted to ASN and its Technical Support Organization (IRSN) identifies the facilities, the activities and the topics concerned. It is set up using a methodical approach based on a regular review of the high-risk activities or topics defined by the ASN departments according to a graded approach. It is updated in the light of the periodic safety reviews outcomes, lessons learned from previous inspections and significant events. The implementation of this programme is checked monthly, to ensure regular implementation over the year.

ASN conducts different kinds of inspections: routine inspections (one day on-site, two inspectors), review inspections which take place over several days (up to one week one-site) and involve about ten inspectors, reactive inspections following significant events, inspections with sampling designed to ensure the conformity of discharges, worksite inspections. Except for the unannounced inspections (about 20% of the annual program), the licensee is informed beforehand of the date and the topic of the inspection.

Inspections, except review inspections, are performed by a minimum team of two ASN inspectors with the potential contribution of a member of the technical support office.

Several inspections topics are defined to check the compliance of operators' practices with the regulations and with its commitments to ASN. As for the processes of the management system, safety culture is not a specific inspection topic as safety culture is linked to all inspections topics.

Safety culture is assessed as part of the following nuclear power plant topical inspections:

- Organisation and responsibility of the licensee (management system and organisation, feedback experience process, activities performed by external contractors…);
- Operation;
- Status of the confinement barriers;
- Prevention and management of hazards, emergency preparedness and response;
- Status of systems, structures and components (maintenance, operation and modifications);
- Radiation protection (organisation, radioactive sources management, work in controlled areas);
- Environment protection;
- Significant events follow-up;
- Labour inspections.

Whatever the type of facility inspected, after each inspection, a follow-up letter is drafted by the pilot inspector. This letter includes a short synthesis of the inspection and the corrective actions requested to the operator; requests for clarification may also be used in order to challenge or verify inappropriate operating modes. The follow-up letter is sent to the licensee within a targeted 3 weeks period by the ASN department responsible for inspecting the facility and is posted on the ASN website. An internal inspection report is also drafted within the same timeframe. This report is only for ASN's internal use and includes findings on safety culture of the licensees. Once the licensee reply to the follow-up letter has been received, after the licensee's reply review by the responsible department, the inspection is either being closed or if needed, additional information is requested to the licensee. Significant licensee's commitments are monitored by ASN.

The results of all inspections as well as the occurrence of significant events are analysed by ASN. These analyses may highlight safety culture shortfalls.

This whole process contributes to public information and transparency on nuclear safety. It also contributes to the development of safety culture and its improvement by highlighting shortcomings and raising licensee's upper management awareness on these shortcomings.

b. Control of reactor outages

For nuclear power plant, reactor outage phases lasting more than 10 days, either for refuelling only or for significant maintenance or plant upgrade, are subject to specific ASN oversight framed, within ASN management system, by a 'reactor outage' sub-process. For an outage, EDF draws up a programme for the inspection or maintenance of systems and other activities (modification…) that are envisaged. ASN reviews this programme on the basis of national and local maintenance 'codes' established by EDF. For each outage, an 'outage inspector' from the competent regional division is identified from among the qualified inspectors. He is more specifically tasked with overseeing the outage and updating the ASN internal 'reactor outage' sheet on the basis of information sent by the licensee, he results of post-maintenance qualification checks and tests carried out. In the light of these elements, at the end of the outage, ASN will decide to authorise (or not) the reactor to be restarted (the transition of the reactor coolant water to 110°C, and then the reactor criticality).

During the outage, inspectors shall be particularly watchful on the following points:

- the pressure on stakeholders in order to carry out activities in the shortest time to restart the reactor as soon as possible;
- a regulatory body rations as for example repair - maintenance versus a fast restart of the reactor.

Once the reactor has reached its rated power level, the ASN regional office issues an information notice posted on the ASN website. Two months after reactor criticality, the regional office drafts an outage report.

c. Enforcement

In situations where the licensee does not comply with the legally binding provisions or when its facility presents an imminent and confirmed risk without the licensee taking appropriate remedial action, ASN may take enforcement actions, as foreseen by the legislations and regulations, graded according to the gravity of the situation.

Administrative enforcement actions are proposed by the qualified inspector, decided on by the ASN Commission with respect to nuclear safety or radiotherapy, by the Director and Deputy Directors with respect to other matters. They can take the form of an official letter, followed by formal notice, suspension of activity, submission of a bond corresponding to the cost of the work to be done, or the decision to have the work performed at the expense of the licensee. Each formal notice is rigorously monitored and compliance is checked at expiration date.

At the same time as the administrative action, the inspectors can issue an official report to the prosecutor, who may decide to initiate prosecution.

An ASN notice and the guidelines associated with the enforcement process propose a structured framework to ensure an impartial decision is reached that is proportionate to the deviation observed and consistent between the inspectors.

d. Management of operating experience feedback

The licensee has to report quickly to ASN any significant event it identifies, according to criteria established by ASN. This significant event notification describes the event and the preventive and corrective measures taken to mitigate the consequences and the reoccurrence of the event and, as applicable, proposes a rating on the INES or ASN/SFRO scale.

The ASN department or regional office confirm the significance of the event and determine whether the event is generic. As necessary, ASN informs the other competent administrations.

For events with high actual or potential consequences (INES level INES $\geq$ 2 or ASN-SFRO $\geq$ 3) a press release is posted on the ASN website.

No later than 2 months following the notification of the event, the licensee sends a significant event report. This report contains an in-depth analysis of the conditions in which the event occurred and proposes measures to prevent it recurrence. Once the measures taken or proposed are considered to be satisfactory, ASN closes the significant event file.

In this process, as regards safety culture, ASN monitors:

1. transparency: in particular on the identification, reporting and analysis of deviations and of significant events, definition and implementation of corrective actions to avoid the recurrence of the deviation and of the significant event;
2. the dynamics of continuous improvement of the licensees.

e. Evaluation

In order to determine an overall level of safety or radiation protection of the facilities and activities inspected, general evaluations of a type of activity (e.g. radiotherapy) or of a site (site with several nuclear power plants) are performed. The main objectives are to identify best practices and areas for improvement in nuclear safety and radiation protection and to compile relevant data, as objective as possible, for reporting and communicating to the stakeholders.

The list of topics and activities adopted for year N is chosen when preparing the inspection programme for year N. An operational framework document is drafted by the competent department. This may consist simply, some years, in updates of indicators filled out following each inspection, or a more thorough assessment based on findings during inspections, review of significant events, reactor outages, exchanges with the licensee…. In year N+1, ASN departments produce a summary of the elements based on those transmitted by the regional offices concerning year N.

In this evaluation, comments on safety culture, transparency, consideration of operating experience feedback are formalised for each topic.

V-4. CONCLUSION

Safety culture in the regulatory body is an important issue in order to perform an efficient and credible control.

Safety culture within the regulator includes two parts:

- consideration of safety culture within the regulatory body itself, in particular in its management system for the realisation of its daily activities;
- the capability of all inspectors to assess safety culture of operators and licensees.

Safety culture arrangements are supported by ASN's Rules of Procedure and ASN's management system in order to comply with the requirements of the European Directive and with the IAEA recommendations.

Practices developed by the regulatory body (ASN) as regards safety culture cover:

- Inspections, feedback analysis of inspections and of reported significant events that contribute to safety culture improvement;
- Continuous improvement and feedback analysis of the management system;
- Strong training for ASN staff, in particular for inspectors;
- Issuance of in-house guidelines.

All processes of the management system include practices or attitudes related to safety culture insofar as safety culture is linked to each process and therefore a specific safety culture process has not been considered necessary.

ANNEX VI – EXAMPLES OF PRACTICES FROM CANADA

VI-1. PRACTICES TO DEVELOP AND SUSTAIN REGULATORY BODY CULTURE FOR NUCLEAR SAFETY IN THE REGULATORY BODY

a) Policy/Vision statements	• CNSC incorporates its commitment to safety culture within the management system manual. CNSC does not have a standalone policy statement to demonstrate the commitment to safety culture. However, our definition of Safety Culture at the CNSC and the principles we respect are continuously reinstated and communicated through many communication methods such as town hall meetings. • CNSC's core values are defined, documented and communicated through MSM and other means such as posters. • Our Approach to Stakeholder Engagement and open communications are explained in section 2.9 of the Management System Manual.

b) Leadership and commitment	• Management System Manual:
	  o President commitment
	  o Executive Committee commitment
	• The commitment to be a role model for the industry is demonstrated through the CNSC's Strategic planning framework.
	• Responsibility to maintain a good Safety Culture at CNSC is delegated to the Senior Vice President and Chief Regulatory Operations Officer. He oversees the effectiveness of CNSC's Safety Culture by appointing a Safety Culture Working Group (SCWG).
	• Conducting short but frequent staff meetings to share information. (Top down and bottom up). Mandatory requirement from the President.
	• Field presence of management is achieved through management participating in divisional and directorate meetings to encourage staff to raise any concerns, discuss issues and provide explanations to questions.
	• Provide resources, e.g. personnel, tools, organization to enable effective nuclear safety oversight. Examples are risk informed resource planning, compliance planning, initiative such as establishing capability for nuclear safety project
	• CNSC is managing change in the organization to ensure focus on safety is maintained through activities such as succession planning, knowledge capture, pre-retirement transition policy.
	• Continuous learning environment.

c) Promoting individual awareness of safety culture, plus their roles and responsibilities	• CNSC Safety culture presentations • CNSC's Key behavioural competencies • Clarity on the roles and responsibilities between Regulatory Operations Branch and Technical Support

	Branch • Safety culture blitz week • Safety culture booths during CNSC wide functions such as year-end event, security awareness week, etc. • Article in internal bi-weekly communications such as Synergy article.
d) Promoting individual behaviours that place proper value on safety	• CNSC Values and Expected Behaviours • CNSC encourages a culture of constructive challenge by providing many different mechanisms so that staff can utilize the mechanism comfortable for them. Examples of mechanisms are: o Open door policy o Non-concurrence process o Differences of Professional Opinions process • Adherence to procedures to ensure safety are added as part of each employee's performance contract and reviewed during the performance reviews. • CNSC's training programs such as Regulatory Operations Training Program and Inspector Training and Qualification Programs ensure that training needs for all employees involved in the regulatory work are adequately identified and provided with required training to ensure safety. • Respectful Workplace Policy • CNSC conduct self-assessments of our process to assure that our processes and activities meet our safety objectives.
e) Decision-making	• CNSC Value and Ethics Code. This Code identifies our core values and expected behaviours, and the principles we will apply in our decisions and actions. • CNSC's Policy on Science in a Regulatory Environment • CNSC's Policy - Risk informed regulatory approach. • CNSC's Risk Informed Regulatory Decision-making process • CNSC's commitment to transparency on regulatory decision-making and actions are achieved through many mechanisms. These mechanisms are explained in detail in section 2.9 of the Management System Manual. Some examples are: o Participant Funding Program o Aboriginal Consultation Process o Consultation Process • Independence in decision-making is explained in the Management System Manual page 1of 38 • Senior Management Committee meetings are open to all staff to attend and learn about the decisions and how they are made. Minutes are shared with all staff.
f) Continual improvement and learning	• Improving how we manage for safety is clearly explained in section 8.0 of the Management System

	Manual. • Operational Experience (OpEx) process to learn and share lessons learned from international community. • Harmonized Plan – CNSC's Continuous improvement program. This program brings all improvement ideas together to analyse, select and prioritize organizational improvement so that resources can be better utilized to achieve CNSC's goals to be the best Nuclear Regulator. This program also includes monitoring, reporting and bring closure to all action plans. This is the mechanism utilized to strengthen CNSC's Management System and Safety Culture. • Peer reviews by third party organizations and experts. (Examples are: IRRS review, reviews by expert consultants) • Participation in domestic and international conferences. • All actions raised are documented, monitored, reported and closed. CNSC uses tools such as Action Tracking Tool (RIB/BIR), Management Action Plan, etc. • CNSC also utilizes the mechanisms such as surveys and focus groups to learn about the effectiveness of CNSC's safety culture.
g) Management system	• CNSC's Management System is clearly described in the attached Management System Manual (Attachment #1). • CNSC's Management System is continuously monitored and improved through conducting internal management reviews and reviews by third party experts such as IRRS review. • CNSC's Management System is also reviewed through internal audit program to confirm that we meet our safety objectives.

VI-2. REGULATORY OVERSIGHT

Introduction – Role of regulator (examples relating to legal powers, regulations, guidance on fundamental regulatory approach)	• Role of CNSC relating to legal powers, regulations, guidance and fundamental regulatory approach are explained in the Management System Manual / section 2.0. • CNSC includes explicit reference to safety culture within the regulatory framework. It is assessed as a topic area within the assessment of Management System Safety and Control Area (SCA). CNSC assesses licensee's performance against 14 SCAs.
Preparing for regulatory oversight	• CNSC is currently in the process of issuing a Regulatory Document (REGDOC 2.1.2) that will provide clarity on the requirements for the implementation of licensee's safety culture. • CNSC inspectors are trained and qualified through Inspector Training and Qualification Program. Inspection of safety culture is covered as on of the specific area under the Management System as part of this training program.
Design and delivery of regulatory oversight	• Safety culture is assessed as one of the topic area under the Management System. CNSC utilizes staff review guides and inspection guides for assessing the licensee's safety culture. • Findings are communicated to licensees and the commission as part of the overall Management System safety and control area. • CNSC also utilize the annual Regulatory Oversight Reports to communicate any safety culture related information.

ANNEX VII – EXAMPLES OF PRACTICES FROM THE UNITED STATES

VII-1. SAFETY CULTURE IN THE REGULATORY BODY

VII-1.1 Context

The U.S. Nuclear Regulatory Commission's (NRC's) mission is to license and regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment. Given this safety and security mission, the NRC recognizes the importance of maintaining its own positive safety culture and the need to continuously seek to improve its internal organizational effectiveness. The NRC strives to create an environment where everyone—technical and nontechnical employees—understand that their behaviors and attitudes play a critical role in ensuring that we create a work environment that focuses on safety and security and is conducive to raising all concerns and issues.

VII-1.2 Practices to develop and sustain regulatory body culture for nuclear safety

a) The NRC's Safety Culture

The NRC fosters an environment in which all employees reflect the NRC's values by adhering to the "Principles of Good Regulation" and demonstrating a positive safety culture to support the NRC's mission to protect public health and safety and the environment. The NRC culture includes a system of shared values, beliefs, and behaviors that demonstrate our collective commitment to emphasize safety as the overriding priority in our regulatory decisionmaking and that recognizes the important role each employee plays in the NRC's success. The NRC is committed to creating and sustaining a positive work environment to ensure that the agency remains a model regulator.

b) Leadership and Commitment

The NRC strives to establish and maintain an environment that encourages all employees and contractors to promptly speak up and share concerns and differing views without fear of negative consequences. Diverse views, alternative approaches, critical thinking, collaborative problem solving, unbiased evaluations, and honest feedback are encouraged, recognized, and valued. Trust, respect, and open communication promote a positive work environment that maximizes the potential of all individuals and improves our regulatory decisionmaking.

The free and open exchange of views or ideas conducted in a nonthreatening environment provides the ideal forum where concerns and alternative views can be considered and addressed in an efficient and timely manner that improves decisionmaking and supports the agency's safety and security mission. NRC employees understand that everyone has a role in safety and that we are all responsible for promoting a strong safety culture and achieving our mission.

In 2014, the NRC's Executive Director for Operations established Project Aim 2020 in coordination with the Chief Financial Officer to enhance the agency's ability to plan and execute its mission while adapting to a dynamic environment promptly and effectively. Senior leadership identified key strategies addressing people, planning, and processes to transform the agency and improve the effectiveness, efficiency, and agility of the NRC. The NRC expects the successful implementation of these strategies to play a key role in helping the agency to accomplish its safety and security mission more effectively and efficiently while operating with fewer resources while the agency contracts during the next several years.

c) Promoting Individual Awareness of Safety Culture

The NRC provides senior leaders, managers, and supervisors with the necessary communication tools to create an environment in which employees feel comfortable speaking up and raising concerns. The NRC provides leaders with practical guides, self-assessments, action planning tools, and other key resources conducive to open and effective communication, respect, and trust.

Executive leadership seminars focus on key areas of safety culture such as crucial conversations, trust, leadership, maintaining civility, conflict management, and understanding the role of leaders in creating and maintaining safety culture.

All new supervisors attend a course on the agency's values and organizational culture (including safety culture and differing views processes), and the staff is encouraged to attend. The staff is also encouraged to take online training on the differing views processes.

d) Promoting Individual Behaviors that Place Proper Value on Safety

The NRC's Open Door Policy supports and allows any employee to initiate a meeting with an NRC manager or supervisor, including a Commissioner or the Chairman of the NRC, to discuss any matter of concern to the employee. An employee may request an Open Door meeting directly with the selected manager or supervisor without the approval of the intermediate management. Note: It may be inappropriate for any of the Commissioners to meet with an employee and discuss his or her issues if those issues relate to an ongoing proceeding in which the Commission has an adjudicatory role.

The Non-Concurrence Process (NCP) promotes discussion and consideration of differing views on draft documents, provides a nonconcurrence option (an option to disagree) for individuals with concerns who had a role in creating or reviewing draft documents, and provides a uniform approach for processing nonconcurrence. Employees may choose to use the NCP and not concur on any part of a document undergoing review. The process allows employees to document their concerns early in the decisionmaking process and to have their concerns responded to by NRC management and attached to proposed staff positions or other documents to be forwarded with the position as it moves through the management approval chain.

The Differing Views Opinion Program (DPO) is a formal process that all NRC employees and contractors can use to have their differing views on established positions considered by appropriate office directors and regional administrators. A DPO is a difference of opinion that is developed in

the free and open discussion of technical, legal, or policy issues that have been formally submitted, screened in an independent review by a panel, and accepted in the formal DPO Program. The DPO can involve a broad range of concerns as long as they are directly related to the agency's mission and are no longer currently under staff review.

e) Decisionmaking

The NRC establishes a strong safety culture that does the following: encourages all employees to reflect the organizational values; supports an environment (encompassing the entire staff) in which administrative and corporate support personnel and members of the technical and legal staff work together for mutual benefit and achievement of a common goal; encourages collaborative problem solving and decisionmaking; values diverse views, alternative approaches, critical thinking, unbiased evaluations, and honest feedback on how decisions are made; and encourages trust, respect, and open communication to foster and promote a positive work environment in which employees are comfortable speaking up and sharing concerns and differing views without fear of negative consequences

Decisionmaking at the NRC entails gathering facts and soliciting diverse viewpoints of those involved in the process. The decisionmaker considers as many viewpoints as practical and critically assesses the merits of each position to make the most informed and sound decision. Once the responsible person or organizational unit makes a decision, the decision should be explained and implemented accordingly. NRC leadership retains final decisionmaking authority and accountability.

As an independent regulatory agency, the NRC conducts its regulatory activities as openly as possible with meaningful stakeholder involvement. The NRC considers public involvement in and information about its activities to be a cornerstone of strong, fair regulation of the nuclear industry. The NRC recognizes the public's interest in the proper regulation of nuclear activities and provides opportunities for citizens to be heard. For that reason, the agency is committed to giving the public opportunities to participate meaningfully in the NRC's decisionmaking process.

f) Continuous Improvement and Learning

Benchmarking allows the NRC to learn more about current practices used by other regulatory agencies and high-reliability organizations to define, advance, and evaluate their safety culture and differing views processes and programs. In turn, the NRC can use these insights to improve practices and programs in safety culture.

Since 1998, the NRC's Office of the Inspector General has conducted the Safety Culture and Climate Survey (SCCS) every 3 years. The SCCS objectives are to (1) measure the NRC's safety culture and climate to identify areas of strength and opportunities for improvement, (2) compare the results of the SCCS against the survey results reported previously, (3) provide, where practical, benchmarks for the findings against other similar organizations and high-performing companies, and (4) understand the key drivers to engagement.

The annual Federal Employee Viewpoint Survey (FEVS) is a tool administered electronically by the Office of Personnel Management to Federal agencies and departments to measure employees' perceptions of whether, and to what extent, conditions characterizing successful organizations are present in their agencies. The survey results provide valuable insight into the challenges that the agency's leaders face in ensuring that the Federal Government has an effective civilian workforce.

The NRC uses the results from both the annual FEVS and the SCCS to develop action plans. The NRC asks each office and region to create an action plan that identifies two to three action items that will help to improve or sustain a positive work environment. Each year, the offices and regions use the new FEVS data to refine and recalibrate their action plans to ensure that action items reflect necessary changes or improvements. In addition, the NRC creates several action items for the agency as a whole because they apply to all staff members. The NRC reassesses these agencywide action items yearly.

VII-2 REGULATORY OVERSIGHT OF LICENSEE SAFETY CULTURE

VII-2.1 The Role of the Regulator

The NRC recognizes that it is important for all organizations performing or overseeing regulated activities to establish and maintain a positive safety culture. The NRC's approach to safety culture is based on the premise that licensees bear the primary responsibility for safety. The NRC provides oversight of safety culture through expectations detailed in policy statements and the oversight processes.

Beginning in 1989, the NRC published the first of three policy statements about safety culture at nuclear power plants. The first policy statement describes the Commission's expectations for the conduct of operations in control rooms. The NRC published the second policy statement in 1996 to establish the Commission's expectation for maintaining a safety-conscious work environment (SCWE) in which workers are able to raise nuclear safety concerns without fear of retaliation. Finally, the NRC published the third policy statement, the Safety Culture Policy Statement (SCPS), in 2011 to establish the Commission's expectations for licensees to maintain a strong safety culture.

The SCPS sets forth the Commission's expectation that individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. The SCPS is not a regulation. It applies to all licensees; certificate holders; permit holders; authorization holders; holders of quality assurance program approvals; vendors and suppliers of safety-related components; and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. In addition, the Commission encourages the Agreement States (States that assume regulatory authority over their own use of certain nuclear materials), their licensees, and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture within their regulated communities.

The NRC staff develops outreach materials that can be used to educate stakeholders about safety culture and the NRC's SCPS. These materials include brochures, posters, Safety Culture Case Studies, "Safety Culture Trait Talk," and "Safety Culture Journey." As part of ongoing outreach activities, the NRC staff makes presentations at meetings and conferences in a variety of industry forums to share information with stakeholders about the SCPS and participates in international and interagency efforts on safety culture.

VII-2.2 Preparing the regulatory body staff for regulatory oversight

With insights gained during the development of the SCPS, the Office of Nuclear Reactor Regulation, along with the Institute of Nuclear Power Operations and Nuclear Energy Institute, hosted a series of public workshops beginning in December 2011 to discuss the idea of a safety culture common language. The intent of this initiative, as requested by the industry, was to align terminology between the NRC's inspection and assessment processes within the Reactor Oversight Process (ROP) and the industry's assessment process. The common language initiative identified 10 traits of a healthy safety culture (the 9 traits from the SCPS plus a 10th trait, decisionmaking), 40 aspects included under those traits, and numerous examples for each aspect. These common language traits and aspects have been incorporated under the three cross-cutting areas of the ROP.

The NRC provides training to inspectors and other experienced staff to become qualified as safety culture assessors for safety culture assessments under Inspection Procedure (IP) 95003. This qualification requires a firm understanding of both safety culture and inspection skills and is an essential part of the NRC's oversight of safety culture. Qualification as a safety culture assessor requires the completion of a variety of activities, each of which is designed to help gather information or practice a skill that may be important during safety culture assessments.

VII-2.3 DESIGN AND DELIVERY OF REGULATORY OVERSIGHT

The Reactor Oversight Process (ROP) is the NRC's program for assessing the performance of operating commercial nuclear power reactors. In 2004, the NRC took steps within the ROP to strengthen the agency's ability to detect potential safety culture weaknesses during inspections and performance assessments. In 2006, the NRC included guidance and procedures for inspecting and assessing aspects of licensees' safety culture in the ROP. In 2014, the NRC revised the ROP based on the common language initiative, which was informed by the SCPS. The NRC's approach to safety culture is based on the premise that licensees bear the primary responsibility for safety. The ROP is the NRC's program for assessing the performance of operating commercial nuclear power reactors. The ROP uses inputs from performance indicators and inspection findings to develop conclusions about a licensee's safety performance. Performance is evaluated systematically and continuously through planned inspections and mid-year and end-of-year assessment meetings.

The Construction Oversight Process (cROP) for new reactors was based on the ROP assessment program methodology, including the use of safety culture traits and cross-cutting issues. NRO revised the construction oversight process to provide guidance in assessing the safety culture of a construction site. These procedures provide NRC inspectors with guidance on how to assess the

safety culture at a construction site with escalating levels of efforts commensurate with the significance of a site's performance decline. The supplemental inspection procedures also give NRC inspectors the tools to communicate safety culture issues to stakeholders.

The Commission describes a safety conscious work environment (SCWE) as a work environment in which employees are encouraged to raise safety concerns and concerns are promptly reviewed, given the proper priority based on their potential safety significance, and appropriately resolved with timely feedback to the originator of the concerns and to other employees as appropriate. Unlawful adverse actions taken against an employee for raising safety concerns or perceptions that such actions have been taken may create a "chilling effect" on the employee or other workers who may wish to raise concerns (i.e., the employees may not feel that they are free to raise concerns without fear of retaliation). If the NRC is concerned about the licensee's awareness of, or efforts to address a known chilled work environment, the agency may issue a chilling effect letter (CEL). A CEL is a public way for the NRC to communicate with the licensee, the public, and the licensee's employees. The intent of such action is, in part, to prompt the licensee to act to mitigate the chilling effect that the discriminatory act or other event has caused.

The NRC's Enforcement Policy ensures, through appropriate enforcement action against a licensee or licensee contractor (and, when warranted, against the individual personally responsible for the act of discrimination), that adverse employment actions taken against licensee or contractor employees for raising safety concerns do not have a chilling effect on the individual or others who may wish to report safety concerns. The NRC vigorously pursues actions against licensees or licensee contractors who discriminate against their employees for raising nuclear safety concerns.

Through the identification of cross-cutting issues, safety culture assessments in supplemental inspections, or findings of discrimination or chilling effect, the NRC typically documents the concerns publicly, and the licensee responds to the concerns with planned corrective actions. The NRC may also use its Alternative Dispute Resolution (ADR) Program to resolve discrimination and wrongdoing cases or other specific cases subject to enforcement action through mediation rather than through the NRC's traditional enforcement processes.

ANNEX VIII – EXAMPLES OF PRACTICES FROM SWITZERLAND

VIII - 1: PRACTICES TO DEVELOP AND SUSTAIN REGULATORY BODY CULTURE FOR NUCLEAR SAFETY IN THE REGUALTORY BODY

a) Policy/Vision statements	**1. Mission Statement ENSI [VIII-1]:** "We strengthen safety" ENSI operates in an environment that sets the highest requirements for supervision. ENSI is well aware that successful supervisory work depends not only on the technical qualifications of each and every employee, but also on their values and their ability to work constructively together. To achieve these objectives, ENSI has drawn up a Mission Statement. The motto for the Mission Statement is: We strengthen safety, and it answers the following questions: Who are we? How do we carry out supervision? How do we act? How do we manage? The Safety Culture statements out of the Mission Statement are: **1.1 Guiding principle 1: We are the independent supervisory authority for Switzerland's nuclear plants.** 1.1.1 "As the supervisory authority, we carry out the statutory mandate of protecting people and the environment from the hazards related to the peaceful use of nuclear energy." 1.1.2 We are the centre of competence for the assessment of nuclear safety in Switzerland. We base our decisions on the latest developments in science and technology. 1.1.3 Our guidelines and requirements aim to ensure a high standard of safety for the nuclear plants. They are clear and easily understandable for the parties we supervise. 1.1.4 "We are a reliable point of contact for the general public, the authorities and the parties we supervise. We provide information that is easy to understand, well founded and up to date **1.2. Guiding principle 2: We strengthen nuclear safety through our supervisory work.**

	1.2.1 “In carrying out our supervisory work, we are vigilant, autonomous and independent. We implement our decisions consistently. 1.2.2 „We assess the overall picture of safety at Switzerland’s nuclear plants, and we constantly endeavour to improve our supervisory work 1.2.3 “Through our supervision, we strengthen the safety culture of the supervised parties, and we encourage them to take responsibility for their own actions 1.2.4 “The relationships we cultivate with the supervised parties are based on professionalism and constructive dialogue” **1.3 Guiding principle 3: We work as a team** 1.3.1 ”Individual responsibility and mutual respect are hallmarks of our work” 1.3.2 We provide mutual support, we work together on an interdisciplinary basis and we create a motivation environment. 1.3.3 “We analyse ourselves and our activities. Differences are addressed openly and resolved jointly.” 1.3.4 „We act with integrity, openness and reliability.” **1.4 Guiding Principle 4: We set an example** 1.4.1 “We are aware of our function as a role model, and we perform that function.” 1.4.2 We take an active and professional approach to management, and we resolve issues through teamwork. 1.4.3 “We are responsible for our decisions and our team.” 1.4.4 We recruit staff with technical expertise, regardless of their age, gender and attitudes to nuclear energy, and we ensure that all our employees continue to develop their technical skills.
b) Leadership and commitment	**2.1 Safety culture values, “Project Oversight Culture (ENSI’s Safety Culture) [VIII-2]:** The ENSI board supported by the ENSI management launched a broad-based process designed to scrutinise and improve ENSI’s safety culture in 2011.

	The large-scale project, called "Oversight Culture", involved all of the authority's employees, and it was completed three years later in 2014. The findings obtained were converted into measures, some of which have already been realised and others scheduled for implementation in the coming years. Even though the project as such is over, the identified processes remain alive and will continue to influence ENSI's work in the future. The Director General presented regularly as the "sponsor" of the project, the progress of the internal project and he emphasized the importance of the issue. Now, after the end of the project, he still informs the staff about the implemented measures. The implementation and continuation of the measures of the project are agenda items in the retreat meetings of the management. **2.2 Staff information events:** The Director General personally informs the staff regularly about news, special events, important decisions, outcome of the board meetings, etc…. The staff has the opportunity to ask questions. **2.3 Director General's personal talk:** The Director General invited employees to a 30 min talk. (The employee could choose the topic). **2.4 Staff council:** ENSI has a staff council consisting of 5 staff members. They meet the management board regularly to discuss the issues of the staff to find solutions. **2.5 Self-reflection of the mission statement [VIII-2]:** ENSI made a self-reflection of its mission statement on all levels. Every section and the executive board at ENSI discussed the guiding principles of the mission statement. They reflected on the meaning of the principles for their daily work and on possible/necessary improvements in their own and others' practices. **2.6 Staff involvement in decision-making [VIII-2]:** With regard to important regulatory decisions the Director General convenes an internal meeting for technical and organisational aspects with the broad participation of the sections for the purpose of finalizing the decision.
c) Promoting individual awareness of safety culture, plus their roles and responsibilities	**3.1 Analysing the safety culture - Project "Oversight Culture" [VIII-2]:** ENSI's project whose subject was the reflection about its own safety culture and whose aim was to

	start an ongoing reflection process within ENSI, was performed in three phases over three years. The goal of Phase 1 of the project on Oversight Culture was to describe the "actual condition", i.e. ENSI's current safety culture (at the time of the analysis). As a basis, a multidisciplinary project team first sought to characterise ENSI's safety culture on the basis of three specific examples from ENSI's oversight practice. For each chosen example, members of the project team conducted interviews and surveys with the ENSI employees involved in the relevant example and other staff members. Based on the analysis of these surveys, the project team elaborated 33 hypotheses about ENSI's safety culture. In the course of six all-day, department-specific workshops, employees in all ENSI departments reflected on the safety culture in their section, in their department, and at ENSI as a whole. The hypotheses were presented to them in the form of a questionnaire for verification or falsification. Moreover, a workshop was organised with representatives from the supervised parties in order to elicit their perception with respect to the impact of ENSI's safety culture on their safety culture and compare it with ENSI's self-image. Three key aspects that characterised ENSI's safety culture emerged from the Phase 1 activities: -Oversight philosophy and practice: What is "good oversight"? -Collaboration and communication within ENSI: How do we work together (in and between sections, departments, hierarchical levels)? -Oversight role vs. public role: How do oversight and public relations depend on and influence each other? On the basis of the results of phase 1, then, phases 2 and 3, were dedicated to developing a vision about the safety culture to strive for and the compilation of a new Mission Statement (phase 2), as well as to the formulation of practical measures in order to implement the formulated vision (phase 3). **3.2 One hour for safety [VIII-2]:** For the purpose of promoting reciprocal knowledge and overarching collaboration within ENSI, a monthly lecture series aimed at all ENSI employees, called "One hour for safety", was

	institutionalised as one of the measures of the "Oversight Culture Project". In this regard, two half-hour lectures are normally given, in connection with which (1) an ENSI section introduces itself and explains its tasks, and (2) an ENSI employee reports on a technical issue from his or her work. Alternatively, the hour can be used as a forum for mutual reflection and discussion about oversight issues. **3.3 HOF and Safety Culture Course for new inspectors and other employees:** A 2 day training course was established and is hold by ENSI employees from the "Human and Organizational Factors" Section. The three topics are: • organisation of nuclear installations "Human and Organizational Factors HOF" • the supervisory authority's safety culture "ENSI's Project on Oversight Culture" • foundations of safety culture "ENSI's Approach to Oversight of Safety Culture" **3.4 Feedback training [VIII-2]:** To strengthen social skills, which in addition to technical competence, are also indispensable for professional oversight, ENSI did a feedback training for all employees. **3.5 Role and mandate of ENSI [VIII-3]**: ENSI specified its understanding of its mandate and role in its Mission Statement in 2014. It put the Mission Statement under the motto "We strengthen safety", implying that the regulatory body has a role that goes beyond the mere establishment of regulations and assurance of compliance with them by the licensees. As a concretion of this motto, ENSI states as a guiding principle: "We strengthen nuclear safety through our supervisory work" as well as, "Through our supervision, we strengthen the safety culture of the supervised parties, and we encourage them to take responsibility for their own actions", envisaging an active role in the promotion of nuclear safety culture and fostering the sense of responsibility by the licensees.
d) Promoting individual behaviours that place proper value on safety	**4.1 Cross-departmental workshops World Café "Project Oversight Culture" [VIII-2]:** On the basis of Phase I the project team elaborated a proposal for a description of the desired safety culture ("target") and asked all ENSI

	employees to register for one of five possible dates for a workshop. The goals of the workshops were to: • encourage a broad discussion in ENSI about the desired safety culture • consolidate the proposed "target" • collect ideas for measures for implementing the "target" • practice self-reflection about the safety culture, and • promote and practice cross-sectional and hierarchy-spanning collaboration in ENSI. **4.2 Implementing Measures "Project Oversight Culture" [VIII-2]:** On the basis of Phase 2 in Phase 3 the project team elaborated a proposal for a package of measures for implementing the "target" regarding the safety culture and the new ENSI Mission Statement [1]. The project team elaborated the following fundamental principles that were to be supported by the package of measures: "Good oversight" is based on a high degree of competence and professionalism on the part of ENSI employees, on overarching collaboration, and on a well-founded framework for oversight, with "good oversight" being geared toward the motto of strengthening nuclear safety as defined in the ENSI Mission Statement [1]. **4.3 Cross-section groups for oversight on the licensees:** ENSI does inspections and other oversight activities in cross-discipline teams for a better cross-section collaboration. **4.4 Self-reflection of the mission statement [VIII-2]** **4.5 One hour for safety [VIII-2]** **4.6 Feedback training [VIII-2]**
e) Decision-making	**5.1 Priority for nuclear safety:** Article 1 of the ENSI Act (ENSIG) stipulates that ENSI shall be managed according to economic and business principles. According to the message concerning ENSIG, this should ensure that resources are used economically, and costs and benefits should be in reasonable proportion (which means that efficiency is addressed). However, nuclear safety must be given priority over financial aspects in performing the mandate [VIII-4] **5.2 Independence of the regulatory body:**

	Article 1 of the ENSI Act (ENSIG) stipulates that ENSI organises itself independently and keeps its own account. Article 18 of the ENSI Act (ENSIG) stipulates that ENSI carries out its supervisory work independently and autonomously and that ENSI is subject to supervision by the Federal Council; the latter decides about the formal approval of the actions of the ENSI Board. **5.3 Independence statement:** ENSI wrote an independence statement [VIII-5]. This covers different aspects of the independence of the regulatory body, such as organisational independence, financial independence and personnel independence, independence in oversight and research activities and in choosing experts. **5.4 Technical Safety Forum:** A technical safety forum has been set up and is chaired by ENSI under the auspices of the sectoral plan for deep geological repositories. The sectoral plan specifies how sites for deep geological radwaste repositories are to be selected in Switzerland. The main purposes of the technical safety forum are to receive, discuss and answer questions from the public about technical safety aspects. These questions may be submitted by members of the public, communes, and regions containing sites, organisations, cantons and communities in neighbouring countries that are affected. The questions and answers are posted on the Internet after replies have been given. **5.5 Technical Forum on Nuclear Power Plants (TFK):** The technical forum on nuclear power plants (TFK) provides ENSI with a platform where questions raised by the general public on the safety of Swiss nuclear power plants can be discussed. Comments on safety issues are made by members of this permanent body, who include representatives of communes, cantons, non-governmental organisations, nuclear power plant operators/Licensees and the authorities involved. **5.6 Code of Conduct:** ENSI's code of conduct, which describes the desired behaviour is compulsory for the whole staff, management and board. **5.7 Staff information events** **5.8 Staff involvement in decision-making** **5.9 Oversight Practices in the Integrated Management System**

f) Continual improvement and learning	**6.1 Self-reflection "Project Oversight Culture" methods and approach [VIII-2]:** The goal of ENSI's project was to initialise and institutionalise a process of self-reflection within ENSI on its own safety culture. The project was designed on the basis of a participative approach. All ENSI employees were actively involved in all phases on a repeated basis. The project was designed and implemented in three phases over three years: analysis, assessment, and implementation. The goal of Phase 1 (analysis) was to describe the "actual condition", i.e. ENSI's current safety culture (at the time of the analysis). Activities Phase 1 • Interviews about three specific examples form oversight • Written survey of the sections and departments not involved in the examples • Evaluation of the interviews and the survey • Elaboration of hypotheses about ENSI's safety culture by the project team • 6 Workshops with all employees to reflect about the safety culture in the own organisational unit and in ENSI as a whole. • Workshop with the supervised parties to elicit their view on ENSI's safety culture and its effect on their own safety culture. Phase 2 (assessment) followed from and built on Phase 1. It was designed to elaborate a normative determination and description of the safety culture sought by ENSI and to clarify the existing need for action. Activities Phase 2 • Discussion and approval of the proposal on the "target" for safety culture by the project team • 5 cross-departmental workshops to include the majority of ENSI's staff: Discussion and enhancement of the proposal on the "target" for safety culture; identification of need for action and formulation of initial measures proposals • Completion of "target" by the project team • Integration of results from the "Oversight Culture" project in ENSI's Mission Statement Phase 3 (implementation), served to elaborate a package of measures for implementing the "target" elaborated in Phase

	2 and the identified need for action. Using the results from Phases 1 and 2, the project team elaborated a proposal for a package of measures for implementing the target regarding the safety culture and the new ENSI Mission Statement. This was submitted to the ENSI executive Board and ENSI employees in several iterations, revised, and then approved by the Executive Board in the fall of 2014. However, in order to achieve a permanent change, the process has to be continuously carried on. **6.2 Workshop with the supervised parties "Project Oversight Culture":** ENSI's self-reflection about its own safety culture does not constitute an end in itself but rather should serve the continual improvement of oversight in the service of the safety of the supervised nuclear installations. In their daily routine, the supervised parties are constantly confronted with ENSI's safety culture, since the latter substantially influences the basic conditions under which they have to go about their daily business, their specific activities, their deployment of resources, and ultimately their safety culture and the safety of their installations. For this reason, in connection with a project by the supervisory authority on its own safety culture, it is indispensable to take into account the perception of the supervised parties with respect to the effect on this very safety culture. Accordingly, at the end of Phase 1, an all-day workshop was conducted with representatives from the supervised parties. The aim of this workshop was a juxtaposition of the self-image elaborated by ENSI about its own safety culture with the external image of the supervised parties. The following issues were discussed: - How do the supervised parties experience ENSI's safety culture? - What effect does ENSI's oversight have on the safety (culture) of the supervised parties? **6.3 Directorate meetings in nuclear facilities:** The executive management of the regulatory body holds annual meetings with the executive management of the nuclear facilities. One issue on the agenda is the feedback of the licensees concerning ENSI's oversight activities and safety culture. **6.4 Learning from other regulatory bodies**: ENSI actively participates in international activities where experience on

	issues related to the regulatory body's safety culture are exchanged and discussed. **6.5 One hour for safety** **6.6 Feedback training**
g) Management system	**7.1 Management System:** ENSI has a comprehensive, process-oriented management system designed to optimise internal processes and continuously improve efficiency. The Management Handbook (MHB) is divided into four sections that mirror product categories: • Management Processes • Processes for the Assessment of Facilities • Processes for Surveillance of Operations • Support Processes. The Main Process "Management" provides the basis for all ENSI activities. The aims of the Process are the proper fulfilment of its statutory remit as a regulatory body, its successful management based on the objectives and key parameters of ENSI and systematic improvements to tools and processes. The mission statement is reflected in the main process and to achieve a common understanding of the key safety culture aspects within the organization safety culture is explicitly addressed in the process "Management". Some further safety culture issues which are anchored in ENSI's Management Handbook are: • Regulatory Basis • Oversight Practices • Communication • Improvement • Decision-making

Introduction – Role of regulator (examples relating to legal powers, regulations, guidance on fundamental regulatory approach)	**Oversight principles [VIII-6]:** With respect to safety culture, ENSI bases its oversight on the following principles: • The responsibility for safety is borne by the operator of a nuclear installation. The supervisory authority verifies whether the operator is meeting its responsibility for safety. For this purpose, it gathers the information required in order to obtain a realistic overall picture of the nuclear installation as a human-technology-organisational system [VIII-4] • If the supervisory authority finds that the operator is not meeting its responsibility for safety in full, it implements supervisory and enforcement measures. As is the case with nuclear safety in general, ENSI is unwilling and unable to make an across-the-board statement about the safety culture of the operators of nuclear installations. It can, however, make statements about specific safety-related facts and circumstances insofar as they can be accessed and assessed **Role and mandate of ENSI [VIII-3]:** ENSI specified its understanding of its mandate and role in its Mission Statement in 2014. It put the Mission Statement under the motto "We strengthen safety", implying that the regulatory body has a role that goes beyond the mere establishment of regulations and assurance of compliance with them by the licensees. As a concretion of this motto, ENSI states as a guiding principle: "We strengthen nuclear safety through our supervisory work" as well as, "Through our supervision, we strengthen the safety culture of the supervised parties, and we encourage them to take responsibility for their own actions", envisaging an active role in the promotion of nuclear safety culture and fostering the sense of responsibility by the licensees. As regards safety culture in nuclear installations, ENSI's supervisory activities should be targeted at the following objectives [6]: • Exerting a positive influence on the safety of the nuclear installations • Exerting a positive influence on the safety culture of the supervised organisations • Encouragement of the operators to take responsibility for their own actions

	• Avoiding anything which makes it more difficult for operators to meet their responsibility for nuclear safety • Promoting overall conditions that are suitable for these purposes **Methods for oversight of safety culture in nuclear installations [VIII-6]:** In accordance with the Integrated Oversight approach [VIII-4], ENSI supervises the safety-related issues in a nuclear installation graded according to their importance for nuclear safety. There are variances in the extent to which the supervisory authority can address these safety-related issues. Accordingly, different methods of access are required for the oversight of different parts of the safety culture content [6] **The following ENSI guidelines contain specific requirements on safety culture in nuclear installations [VIII-6]**: • Guideline ENSI-G07: The Organisation of Nuclear Installations Measures for the purpose of observing, assessing and fostering a good safety culture must be incorporated in the management system. It is necessary to promote a working atmosphere that encourages trust, cooperation and open communication, and one, which attaches value to the communication of problems. Consideration must be given to cultural aspects in connection with the organisation's own staff and third-party personnel, and efforts shall be made to encourage a positive development of the culture in the nuclear installation [7]. • Guideline ENSI-B02: Requirements for periodic reporting by nuclear installations As part of the periodic reporting, the programme and measures to foster a good safety culture shall be presented; alongside a comparison of the measures to foster a good safety culture shall be presented, alongside a comparison of the measures implemented with the expectations [8]. • Guideline ENSI-A03: Periodic safety reviews of nuclear power plants As part of the periodic safety review, aspects of the safety culture shall be described and assessed, especially as regards measures to foster safety awareness and to implement a learning organisation [VIII-9].

	• Guideline ENSI-B10: Basic training, recurrent training and continuing education of personnel in nuclear installations The operator has to provide measures in the initial training programme, in the recurrent training programme and in the continuing education programme which in particular promote the workers' individual, methodical and social competence (soft skills). The personnel have to be continuously made aware of the significance of their tasks and activities, learning from experience as well as of the consequences that errors may have on safety [VIII-10].
Preparing RB staff for regulatory oversight	**HOF and Safety Culture Course for new inspectors and other employees:** A 2 day training course was established and is hold by ENSI employees from the "Human and Organizational Factors" Section. The three topics are: • organisation of nuclear installations "Human and Organizational Factors HOF" • the supervisory authority's safety culture "ENSI's Project on Oversight Culture" • foundations of safety culture "ENSI's Approach to Oversight of Safety Culture"
Design and delivery of regulatory oversight	**Specialist discussion promoting a dialogue on safety culture [VIII-6]:** ENSI addresses values and ideologies of which the members of the operating organization are not or only partially aware, so access to them is generally difficult. Such aspects cannot be measured or assessed, so they are not covered by conventional supervisory methods (such as inspections). In these areas, ENSI makes use of specialist discussions at regular intervals (approximately 3 years or on the need and on the installation's hazard potential) aimed specifically at encouraging dialogue about safety culture; the objective here is to prompt operators to reflect on the hidden aspects of their safety culture. The issues to be covered in a specialist discussion promoting a dialogue on safety culture are defined on a case-by-case basis. One of the sources ENSI makes use of, are the characteristics of a good safety culture as described in [VIII-6]. Questions regarding safety culture arise also from the systematic safety assessment or from day-to-day oversight. Specialist discussions of this sort are also triggered by the ongoing development of scientific and technical knowledge in the field of

	safety culture or by experience gained in other nuclear installations or other industries. The specialist discussions comprise two parts with an interval of several weeks between them: Part 1: discussion about the defined question regarding the safety culture and record of the discussion Part 2: presentation of the findings and hypotheses drawn up by ENSI in the interim, on the basis of the recordings of part 1, but without formal assessments; discussion about these findings and hypothese

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ISBN 978–92–0–100520–5
ISSN 1011–4289