

IAEA-TECDOC-1707

Regulatory Oversight of Safety Culture in Nuclear Installations



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REGULATORY OVERSIGHT OF
SAFETY CULTURE IN
NUCLEAR INSTALLATIONS

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INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2013

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FOREWORD

Experience across the international nuclear industry and in other technical fields over the past few decades has demonstrated the importance of a healthy safety culture in maintaining the safety of workers, the public and the environment. Both regulators and the nuclear industry recognize the need for licensees to develop a strong safety culture in order to support successful and sustainable nuclear safety performance. Progress over recent years can be observed in the rapid development of approaches to overseeing licensees' safety culture.

This publication follows on and complements earlier publications on safety culture, from the publication *Safety Culture* (Safety Series No. 75-INSAG-4 (1991)), published after the Chernobyl accident, to the more recently published *Safety Requirements on The Management System for Facilities and Activities* (IAEA Safety Standards Series No. GS-R-3 (2006)), which states that the management system is to be used to promote and support a strong safety culture.

A number of attempts have been made at both the international and national levels to establish practical approaches to regulatory oversight of safety culture. During 2010 and 2011, two projects were conducted by the IAEA under the scope of the Safe Nuclear Energy — Regional Excellence Programme within the Norwegian Cooperation Programme with Bulgaria and Romania. These projects were implemented at the Bulgarian and Romanian regulatory bodies. They encompassed the development of a specific process to oversee licensees' safety culture, and involved 30 experts from 17 countries and 22 organizations.

The IAEA continues to support Member States in the area of safety culture through its projects on safety management and capacity building. This publication addresses the basics of regulatory oversight of safety culture, describes the approaches currently implemented at several regulatory bodies around the world and, based on these examples, proposes a path to developing such a process. Accordingly, this publication provides practical guidance on developing and implementing strategies and processes for regulators to employ to monitor a licensee's safety culture in nuclear installations and in related activities. It is based on a compilation of state of the art international and national efforts.

The IAEA wishes to acknowledge the efforts of G. Rolina (France), who compiled the present publication. The IAEA officer responsible for this publication was A. Kerhoas of the Division of Nuclear Installation Safety.

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1. INTRODUCTION

1.1. BACKGROUND

In recent years, international discussions relating to regulatory oversight of safety culture have taken place at the following international events:

- The joint ANS–Nuclear Energy Agency “International Topical Meeting on Safety Culture in Nuclear Installations” (April 1995, Vienna, Austria);
- The IAEA “International Conference on Safety Culture in Nuclear Installations” (December 2002, Rio de Janeiro, Brazil);
- The IAEA Technical Meeting on “The Role of Governments and Regulators in Fostering a Strong Nuclear Safety Culture” (September 2003, Vienna, Austria);
- The OECD/Nuclear Energy Agency workshop on “How Regulatory Inspections Can Promote, or not Promote, Good Safety Culture” (May 2006, Toronto, Canada);
- The joint OECD/Nuclear Energy Agency–IAEA workshop on “Maintaining Oversight of Licensee Safety Culture-Methods and Approaches” (May 2007, Chester, UK);
- The 10th OECD/Nuclear Energy Agency International Nuclear Regulatory Inspection workshop on “Experience from Inspecting Safety Culture, Inspection Of Licensee Safety Management System, and Effectiveness Of Regulator Inspection Process” (May 2010, Amsterdam, Netherlands);
- The IAEA Technical Meeting on “Fostering a Positive Dialogue on Safety Culture between Regulators and Licensees” (February 2011, Vienna, Austria).
- The OECD/Nuclear Energy Agency workshop on “Oversight & Influencing Leadership & Managing for Safety, including Safety Culture: Regulatory Approaches” (September 2011, Chester, UK);

The most recent event at IAEA, in February 2011 was an opportunity for Member States to share several national initiatives undertaken to develop practical approaches to regulatory oversight of safety culture. In addition, during 2010 and 2011, two projects were conducted by the IAEA under the scope of the Regional Excellence Programme on Safe Nuclear Energy – Norwegian Cooperation Programme with Bulgaria and Romania. These projects have been implemented at the Bulgarian and Romanian regulatory bodies. They encompassed the development of a specific process to oversee licensees’ safety culture.

1.2. OBJECTIVE

The objective of this publication is to provide regulatory bodies with practical guidance, shared experience, and examples on how to establish their own regulatory oversight of safety culture.

Due to the nature of safety culture, the variety of nuclear installations and the different “governmental, legal and regulatory frameworks for safety” Ref. [1], several approaches are currently implemented around the world to oversee safety culture. The publication details these approaches and offers alternatives to regulatory bodies, pros and cons, and suggestions.

1.3. SCOPE

The guidance provided in this publication can be applied to the regulatory oversight of safety culture in all nuclear facilities and activities, including predisposal waste management facilities, throughout their full lifetime as well as during commissioning and decommissioning phases. It is intended to be useful to regulatory bodies, technical safety organizations or third-party organizations when developing and implementing approaches to oversee safety culture at any licensee’s organization.

1.4. STRUCTURE

This publication is comprised of four sections.

The current section introduces the objectives and scope of application of the document.

Section 2 presents fundamentals of safety culture and features of regulatory oversight of safety culture.

Section 3 describes approaches, which are currently implemented at several regulatory bodies around the world. These approaches are not exclusive to an individual regulator; they can be combined to enable effective regulatory oversight of safety culture.

Section 4 details a process applicable to any regulatory body’s organization, which may support the implementation of any approach, or combination of approaches.

Appendix 1 details main features of the safety culture concept.

Appendix 2 gives an example on convergent data collection, a concept previously defined in Section 4.

Annexes 1 to 5, available on CD-ROM, provide practical tools currently used by several Member States to perform their regulatory oversight of safety culture:

Annex 1 is the safety culture statement of policy developed by the American regulatory body (USNRC).

Annex 2 compiles the results of the questionnaire developed in the context of the IAEA Technical Meeting on “Fostering a Positive Dialogue on Safety Culture between Regulators and Licensees” (February 2011, Vienna, Austria).

Annex 3 describes the safety culture oversight process that has been implemented at the Bulgarian regulatory body (BNRA), under the scope of the Regional Excellence Programme on Safe Nuclear Energy.

Annex 4 details the training programme for regulatory oversight of safety culture, which has been performed at the Romanian regulatory body (CNCAN), under the scope of the Regional Excellence Programme on Safe Nuclear Energy.

Annex 5 presents the USNRC viewpoint on pros and cons of several safety culture data collection methods.

2. THE BASICS OF REGULATORY OVERSIGHT OF SAFETY CULTURE

Safety culture is a complex concept as revealed by its theoretical foundations and the variety of practical applications (See Section 2.1.). Due to this complexity, defining and implementing regulatory oversight of safety culture requires specific features to be considered (See Section 2.2.).

2.1. FUNDAMENTALS OF SAFETY CULTURE

Defining and implementing regulatory oversight of safety culture requires an understanding of the concepts used in this domain including organizational culture (See Section 2.1.1.) and Edgar Schein's multilevel model (See Section 2.1.2.). In this publication, the framework for safety culture is based on the five IAEA safety culture characteristics in Ref. [6] as shown in Figure 2. (See Section 2.1.3.).

2.1.1. Organizational culture

Organizational culture encompasses physical manifestations (behaviours, words, and symbols) as well as invisible aspects (norms, values, thoughts, feelings) that are shared by people in an organization and that control the way they interact with each other inside and outside the organization. Though there is no unanimously accepted definition of the culture of a group, the one given by Edgar Schein, organizational psychologist and management consultant defines culture in Ref. [2]: "Culture is a pattern of basic assumptions – invented, discovered or developed by a given group as it learns to cope with its problem of external adaptation (how to survive) and internal integration (how to stay together) – which have evolved over time and are handed down from one generation to the next."

Organizational culture is seldom homogeneous; sub-cultures exist in any group of significant size. Strengths and blind spots within a particular culture can be identified by interpreting what people say, the behaviours of leaders and staff, and other visible aspects (e.g. safety performance data, policies, standards of housekeeping and material condition, how incidents are investigated and how the findings are addressed, etc.).

Other features of the concept of organizational culture are discussed in Appendix 1 and further detailed in Ref. [3].

2.1.2. Schein's multilevel model for understanding organizational culture

Edgar Schein has developed a three-level model for understanding the culture of any organization. He has distinguished three levels, which go from the very visible (conscious) to the tacit and invisible (unconscious) ones: artefacts, espoused values and basic assumptions.

- (1) **Artefacts.** The easiest level to observe is that of artefacts: what you see, hear and feel.
- (2) **Espoused values.** Espoused values are those values that are adopted and supported by a person or organization.
- (3) **Basic assumptions.** These lie at the deepest level of culture. They are fundamental beliefs that are so taken for granted that most people in a cultural group subscribe to them but not in a conscious way.

According to Schein, any organizational culture should be studied at these three levels, represented in FIG. 1. As illustrated by the iceberg metaphor, espoused values and basic assumptions represent larger areas of culture beneath the surface making them increasingly difficult to access.

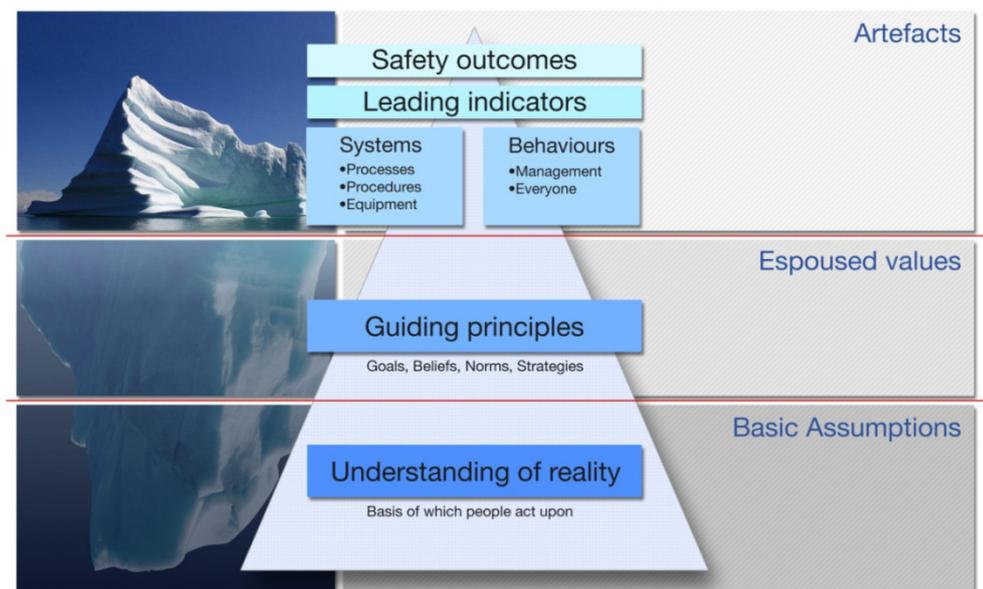


FIG. 1. The three levels of organizational culture.

More details and examples on these three levels are provided in Appendix 1.

2.1.3. IAEA definition and framework of safety culture

Safety culture is defined as “that assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance. This statement was carefully composed to emphasize that Safety Culture is attitudinal as well as structural, relates both to organizations and individuals, and concerns the requirement to match all safety issues with appropriate perceptions and action.” Ref. [4]

The influence of a management system on safety culture has been stated as a general requirement in Ref. [5]: “The management system shall be used to promote and support a strong safety culture by:

- Ensuring a common understanding of the key aspects of safety culture within the organization;
- Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;
- Reinforcing a learning and questioning attitude at all levels of the organization;
- Providing the means by which the organization continually seeks to develop and improve its safety culture.” (Para 2.5)

Broad agreement on five key characteristics of safety culture has gradually emerged in recent years and is documented in Refs. [6, 7]. These characteristics, as described in FIG. 2, provide a framework for developing a common understanding of the safety culture concept. The five characteristics are broken down into attributes that further describe important cultural aspects and provide a more detailed framework. Each of these are listed and described in Ref. [7].



FIG. 2. IAEA characteristics of a strong safety culture Ref. [7].

2.2. FEATURES OF REGULATORY OVERSIGHT OF SAFETY CULTURE

The objective of the regulatory oversight of safety culture, focused on a dynamic process, is to consider and address latent conditions that could lead to potential safety performance degradation at the licensees' nuclear installations. In sharing this proactive perspective with the licensee, actions can be then taken by the licensee to initiate improvements aiming at preventing the potential future performance degradation and to enhance overall safety at these installations.

Regulatory oversight of safety culture complements compliance-based control¹ with proactive control activities. Actually, with regards to safety culture², compliance-based control allows access to the upper levels of culture (artefacts) but not to the lower levels (espoused values and basic assumptions).

The role of the regulator with regards to safety culture is fully aligned with the responsibilities and functions of the regulatory body as stated in Ref. [1] and Ref. [9] (See Section 2.2.1.). International experience on this topic has led to identify three pillars (See Section 2.2.2.) and several high level good practices on which any regulatory oversight of safety culture should rely (See Section 2.2.3.). When implementing regulatory oversight of safety culture, the definition of regulatory requirements (See Section 2.2.4.) and the communication to the public (See Section 2.2.5.) are important aspects to be considered.

2.2.1. Role of the regulator

The first fundamental safety principle states that, “The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks” Ref. [8]. Therefore, licensees are expected to foster a strong safety culture in their organizations. The regulator ensures that the licensee properly discharges this prime responsibility for safety.

Reference [9] details the role of the regulatory body vis-à-vis the safety management system:

- “The regulatory body promotes an effective safety management system in the operating organization by ensuring that there is critical self-assessment and correction (described as self-regulation) and avoids acting in a manner that diminishes the responsibility for safety of the regulated organization.” (Para 15);
- “The regulator ensures that the operating organization has an effective self-regulating safety management system and the regulatory body monitors the effectiveness of the organization’s safety management system as part of its scrutiny of safety performance. It is thus important that the regulatory body or bodies maintain open channels of communication with operating organizations.” (Para 16);
- “The regulatory body monitors the performance of the organization and takes action if ever the safety management system becomes ineffective or the safety performance of the organization declines.” (Para 17).

The strong relationship between safety culture and management systems, as well as the complexity of accessing safety culture data for a regulatory body, entails a specific role of the regulatory body with regards to safety culture: to encourage the licensee to engage in safety culture. However, “in the event that unforeseen radiation risks are identified, whether or not

¹ “The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization.” Ref. [1] (Requirement 27).

² As stated in Ref. [1], safety culture is one aspect to be considered during inspections of activities and facilities (Requirement 29, Para 4.53).

they are due to non-compliances with regulatory requirements or authorization conditions, the regulatory body shall require the authorized party to take appropriate corrective actions to reduce the risks”. Ref. [1] (Para 4.59).

2.2.2. Pillars of regulatory oversight of safety culture

Continuously developing a common understanding of safety culture³ and establishing a positive dialogue⁴ with the licensee is of primary importance for performing effective regulatory oversight of safety culture. Therefore, regulatory oversight of safety culture is based on three pillars:

- (1) **Common understanding of safety culture.** The nature of safety culture is distinct from, and needs to be dealt with in a different manner than a compliance-based control. Its understanding is crucial in achieving a common language and framework that supports both the regulator and the licensee in their communications and promotion of the significance of safety culture in safety performance.
- (2) **Dialogue.** To gain a better understanding of safety culture, dialogue is necessary to share information, ideas and knowledge that is often qualitative. Dialogue enables the licensee and the regulator to have open discussion with respect to each other’s roles. Dialogue supports a more creative and constructive way to find solutions for continuous safety improvements.
- (3) **Continuousness.** Safety culture improvement needs continuous engagement of the licensee. Regulatory oversight of safety culture therefore ideally relies on a process during which the regulator continuously influences the engagement of the licensee.

2.2.3. High level good practices for regulatory oversight of safety culture

Because of the complexity of safety culture, as well as the sensitivity of this concept, the international community⁵ has identified the following high level good practices to be considered in order to effectively develop and implement regulatory oversight of safety culture:

- Avoid vague conclusions about a licensee’s safety culture as a whole, such as “safety culture is good or bad”.
- Use of a structured framework for safety culture oversight.
- Promote proactive approach in order to identify and influence the need to reinforce both individual and organizational behaviours for the continuous enhancement of nuclear safety.
- Encourage the development of an agreed policy document expressing the regulatory positions regarding the safety culture of the licensees (as an example, see Annex 1).

³ “The regulatory body shall foster mutual understanding and respect on the part of authorized parties through frank, open and yet formal relationships, providing constructive liaison on safety related issues.” Ref. [1] (Para 4.24.)

⁴ “The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison.” Ref. [1] (Requirement 21)

⁵ During several recent international events such as the joint OECD/IAEA meeting in Chester in 2007 or the IAEA TM in February 2011 in Vienna (See section 1.1), those good practices were mainly discussed .

- Develop processes integrating an holistic approach promoting use of multiple data collection methods and data sources as well as rely on multidisciplinary teams. This is a way of increasing the reliability of outputs.
- Establish mechanisms for regulatory oversight of safety culture during the entire lifecycle of nuclear installations, including major technical or organizational changes (e.g. merging of companies and outsourcing).

2.2.4. Regulatory requirements on safety culture

With regards to safety culture, the regulatory body should develop general requirements and enforce them in order to ensure the authorized parties have properly considered these requirements. On the other hand, the regulatory body should avoid prescribing detailed level requirements. The regulatory body should not impose detailed requirements⁶, should not regulate safety culture as a whole, but may use the general requirement on management systems to address safety culture expectations⁷: “The management system shall be used to promote and support a strong safety culture by:

- Ensuring a common understanding of the key aspects of safety culture within the organization;
- Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;
- Reinforcing a learning and questioning attitude at all levels of the organization;
- Providing the means by which the organization continually seeks to develop and improve its safety culture.” Ref. [5] (Para 2.5)

Despite the fact that regulatory oversight of safety culture does not primarily aim at determining whether facilities comply with regulatory requirements or authorization conditions, the fulfillment of those general requirements on management system and safety culture is overseen by the regulatory body.

When developing requirements on safety culture, their potential impact on the safety of the facilities should be considered.

2.2.5. Communication with the public

As stated in Ref. [1], “the regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about (...) the processes and decisions of the regulatory body” (Requirement 36).

This communication can include the objectives of the regulatory oversight of safety culture.

⁶ “The regulatory body monitors the performance of the organization and takes action if ever the safety management system becomes ineffective or the safety performance of the organization declines. The regulatory body needs to be technically competent, and will be most effective if it works in a manner that is non-bureaucratic and avoids excessive detailed regulation. Furthermore, the regulatory body should not exercise direct control over the management of safety within the operating organization or impose detailed requirements on the form of the organization’s safety management system. This could be counterproductive by weakening the system of self-regulation and diminishing and diluting the responsibility for safety assumed by the operating organization.” Ref. [9] (Para 17)

⁷ One result of the questionnaire for the Technical Meeting on “Fostering a Positive Dialogue on Safety Culture between Regulators and Licensees” (February 2011, Vienna, Austria), was that several Member States use this general requirement. For more information, see Annex 2.

3. OVERSIGHT APPROACHES

An increasing number of regulators have developed an approach to safety culture oversight in recent years.

These approaches include the following: self-assessment review (See Section 3.1.), independent assessment review (See Section 3.2.), interaction with the licensee at a senior level (See Section 3.3.), focused safety culture on-site review (See Section 3.4.), oversight of management system (See Section 3.5.), and integration into regulatory activities (See Section 3.6.)⁸.

A key principle for the regulatory oversight of safety culture is to use multiple data collection methods and data sources (See Section 2.2.3.), regulatory bodies are encouraged to use not only one approach, but to select a combination of several approaches. The aspects to consider when selecting an approach are included in this publication (See Section 4.2.).

3.1. SELF-ASSESSMENT REVIEW

This approach involves utilizing the outputs (See Section 4.4.1) of a licensee's self-assessment of safety culture⁹. This may also include reviewing the process used by the licensee to conduct the self-assessment. The self-assessment may focus on safety culture or it may be part of a broader self-assessment.

The self-assessment can be proactively conducted by the licensee or enforced by the regulatory body.

Guidance for self-assessment of safety culture is provided in Ref. [7].

3.2. INDEPENDENT ASSESSMENT REVIEW

This approach involves utilizing the outputs (See Section 4.4.1) of an independent assessment of the licensee's safety culture. The independent assessment may focus on safety culture. It may be as well part of a broader assessment.

Here, it shall be understood that the independent assessment of the licensee's safety culture is conducted by an external independent organization. The licensee can request this assessment on its own initiative. The regulatory body can also request this assessment directly with an external organization or can make the request through the licensee.

Guidance for independent assessment of safety culture is provided in Ref. [7].

3.3. INTERACTION WITH THE LICENSEE AT A SENIOR LEVEL

This approach consists of meeting periodically or on an ad hoc basis with the senior management of the licensee, addressing safety culture aspects¹⁰. Those safety culture aspects may cover:

⁸ This set of approaches reflects the results of the joint OECD/Nuclear Energy Agency – IAEA workshop “Maintaining Oversight of Licensee Safety Culture-Methods and Approaches” (May 2007, Chester, UK) and of the questionnaire on “Experience from Overseeing Safety Culture”, developed in the context of the IAEA Technical Meeting on “Fostering a Positive Dialogue on Safety Culture between Regulators and Licensees” (February 2011, Vienna, Austria). For more information, see [Annex 2](#).

⁹ “Senior management and management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture.” Ref. [5] (Requirement 6.2)

¹⁰ “The regulatory body shall foster mutual understanding and respect on the part of authorized parties through frank, open and yet formal relationships providing constructive liaison on safety related issues.” Ref. [1] (Requirement 21, Para 4.24)

- Information related to the current safety culture programme;
- “Symptoms of a decline in safety culture” (Ref. [7], Para 2.29) identified by means of compliance-based approaches and/or following the analysis of a safety event;
- Additional means to foster safety culture which should be considered for future activities and programmes;
- Lessons learnt from major events in nuclear and other industries;
- Outputs of the regulatory oversight of safety culture.

3.4. FOCUSED SAFETY CULTURE ON-SITE REVIEW

This approach consists of conducting wide-ranging on-site review of the licensee’s safety culture. The review includes, where possible, all organizational functions and responsibilities.

This review may be triggered by specific circumstances such as occurrence of an event.

3.5. OVERSIGHT OF MANAGEMENT SYSTEM IMPLEMENTATION

Due to the strong relationship between a management system and safety culture, this approach is considered as a specific one, and not included as part of subsection 3.6.

As stated in Ref. [5], “the management system shall be used to promote and support a strong safety culture”. The management system can have an impact on safety culture by the way it provides organizational framework, which affects practices. Also compliance to the management system requirements may provide information on the licensee’s safety culture.

This approach utilizes the outputs of the regulatory oversight of the management system to provide information on the licensee’s safety culture.

3.6. INTEGRATION INTO REGULATORY ACTIVITIES

This approach consists of collecting safety culture information through routine and special regulatory activities¹¹, thus continuously providing a great amount of data related to the licensee’s safety culture.

¹¹ For a description of a process that supports such approach, see [Annex 3](#).

4. SAFETY CULTURE OVERSIGHT PROCESS (SCOP)

This section details the structured safety culture oversight process (SCOP) to support the implementation of one or more approaches to safety culture oversight. The SCOP is illustrated in FIG.3 and is composed of six phases. Each phase is detailed further in a dedicated subsection.

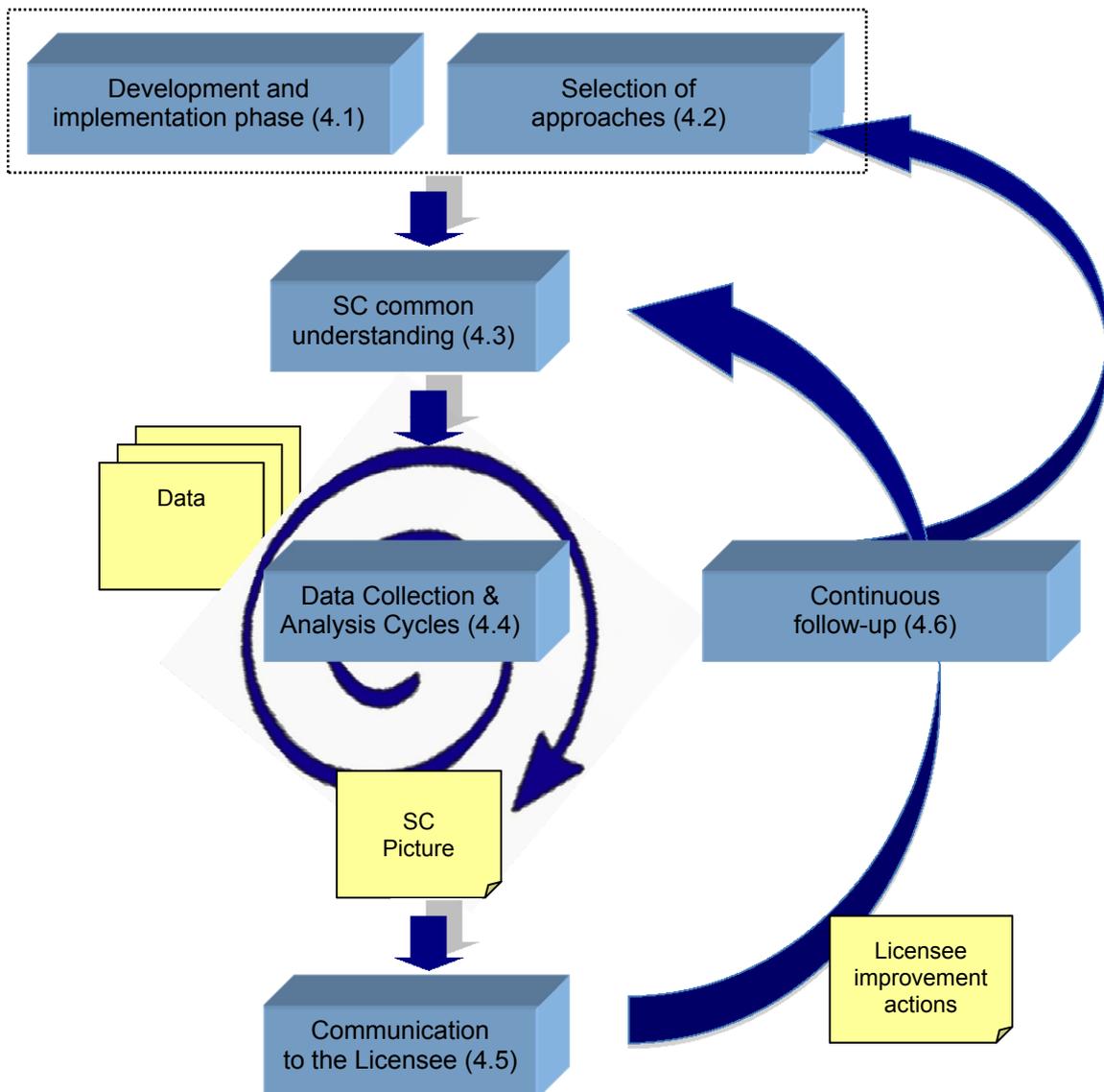


FIG. 3. Phases of the SCOP.

4.1. DEVELOPMENT AND IMPLEMENTATION PHASE

In preparing for the implementation of the safety culture oversight process, the regulatory body undertakes the following activities:

- Identify legal and regulatory requirements linked to safety culture oversight;
- Consider the IAEA requirements on process implementation Ref. [5];
- Define the type of facilities and activities for which the safety culture oversight process is applied. This should include all phases of life of the facilities;
- Ensure regulatory body's senior management is committed to implementing the SCOP;
- Ensure regulatory body's staff (including senior management) has a clear understanding of both safety culture and the regulator's role in the safety culture oversight process (See Section 2.2.1. and Section 4.3.);
- Provide proper interfaces to other regulatory activities which are relevant to safety culture oversight (e.g. operating experience analyses);
- Build up a project team in the regulatory body in charge of the implementation of the safety culture oversight process;
- Define the roles and responsibilities of the regulatory body's representatives involved in the regulatory oversight of safety culture. When outside organizations (such as technical support organizations) are involved in the process, their roles and responsibilities are also defined;
- Allocate the required resources, including qualified staff and tools;
- Develop any new policies, procedures, or framework for the regulatory oversight of safety culture, consistent with the existing regulatory requirements;
- Develop human and organizational factors expertise combining recruitment of specialists and training of current regulatory body staff (see Annex 4, as an example);
- Develop at all levels, regulatory competence in human and organizational factors and specific topics such as root cause analysis, communications skills, and how to gather and analyze the data;
- Communicate to the licensees the intention to initiate the safety culture oversight process (including matters such as goals of the process, concepts of safety culture);
- Define and implement measures for monitoring and enhancing the SCOP process.

4.2. SELECTION OF REGULATORY APPROACHES TO SAFETY CULTURE OVERSIGHT

The regulator uses a combination of as many of the approaches as appropriate depending on resources availability, nature of relations with the licensee, regulatory regime, and existing licensee approaches. For example, the "Integration into regulatory activities" would be carried out to give a time history at shallow depth; this would be combined with "Focused safety culture on-site visits" in order to give deeper understanding. Whereas the scope of an individual approach may be narrow, the adaptive combination of approaches should cover the licensee's total activities.

Four criteria may be used for selecting appropriate approaches, regarding accuracy of the outcomes (C1) and resources to engage (C2, C3, C4,):

C1: Accuracy of the resulting safety culture picture¹²;

C2: Regulator's workload (global effort);

C3: Involvement of regulator's senior management;

C4: Involvement of human and organizational factors and safety culture skills;

¹² The concept of "safety culture picture" is extended in 4.4.2.

Table 1 provides with guidance to assess each approach using above criteria graduated into three qualitative values: realistic, medium and limited for C1 and high, medium and low, for resources criteria. When needed, additional comments within brackets justify the value of the approach. This gives an insight into the pros and cons in using each approach.

TABLE 1. SELECTION CRITERIA FOR USING APPROACHES

Criteria	C1	C2	C3	C4
Approaches	Accuracy of SC ¹⁴ picture	Effort	Management involvement	HOF ¹⁵ & SC skills
Self-assessment Review (high experience and skills of the reviewers are assumed)	Medium	Low (depending on who initiates the self-assessment, regulator or licensee)	Low	Medium (to understand deliverables)
Independent assessment Review (high experience and skills of the reviewers are assumed)	Medium	Low	Low	Medium (to understand deliverables)
Interaction with the Licensee at Senior Level	Limited (however can support a shared understanding)	Medium	High	Medium
Focused Safety Culture On-Site Review	Realistic (gives depth in a moment of time)	High	Medium	High
Oversight of Management System Implementation	Medium (Reduced if only formal aspects are considered)	Low	Low	Medium
Integration into Regulatory Activities	Medium (when properly trended and analyzed)	Medium (after an intensive initial introduction)	Medium (with an intensive initial support)	Medium (specific training requirement and experience sharing)

¹⁴ Safety Culture

¹⁵ Human and Organizational Factors

4.3. DEVELOPMENT OF A COMMON UNDERSTANDING OF SAFETY CULTURE

The regulator creates opportunities to engage in a dialogue¹⁶ with licensees to ensure that the basic concepts of safety culture are shared and understood. This includes definitions (organizational culture, safety culture), framework (characteristics and attributes) and access to data.

4.4. DATA COLLECTION AND ANALYSIS CYCLES

The FIG.4 illustrates data collection and analysis phases and their respective outputs.

- **Data collection phase** (See Section 4.4.1.). Using data collection methods depending on the selected approach(es) to provide inputs;
- **Data analysis phase** (See Section 4.4.2.). Processing collected data in order to provide a safety culture picture of the organization.

This process is *iterative*: the safety culture picture is continuously enriched with new data being collected and analyzed.

4.4.1. Data collection phase

4.4.1.1. Data collection preparation

Before collecting data, the regulator selects, develops or refines a framework¹⁷ to support the data collection and data analysis phases.

Then, the methods for gathering data are selected, among:

- Observations;
- Interviews (individual or collective);
- Events review;
- Licensee's documents review;
- Regulator's documents review;
- Discussions (exchange with management);
- Others (questionnaires, surveys, third-party documents review, focus groups)

When selecting the method(s) for gathering data, pros and cons may be considered. One regulator's view of this is given in Annex 5.

4.4.1.2. Collecting data

The data collection phase aims at gathering inputs which can be analyzed to understand what really happens within the licensee's organization regarding potential safety culture weaknesses ; (i.e. combinations of facts, their context of occurrence and their sequence.)

¹⁶ "The regulatory body shall foster mutual understanding and respect on the part of authorized parties through frank, open and yet formal relationships, providing constructive liaison on safety related issues" Ref. [1] (Requirement 21, Para 4.24)

¹⁷ This framework can be the IAEA safety culture framework, but not necessarily. For example, it can be the list of technical areas of the facility. This framework will be useful for classifying and trending the data.

For that purpose, the regulator:

- assigns an individual or a team to compile the evidences;
- integrates data collection methods;
- uses multidisciplinary teams;
- collects data through several iterations;
- considers all levels of the licensee's organization.

An illustration of how to connect the various inputs is given in [Appendix 2](#).

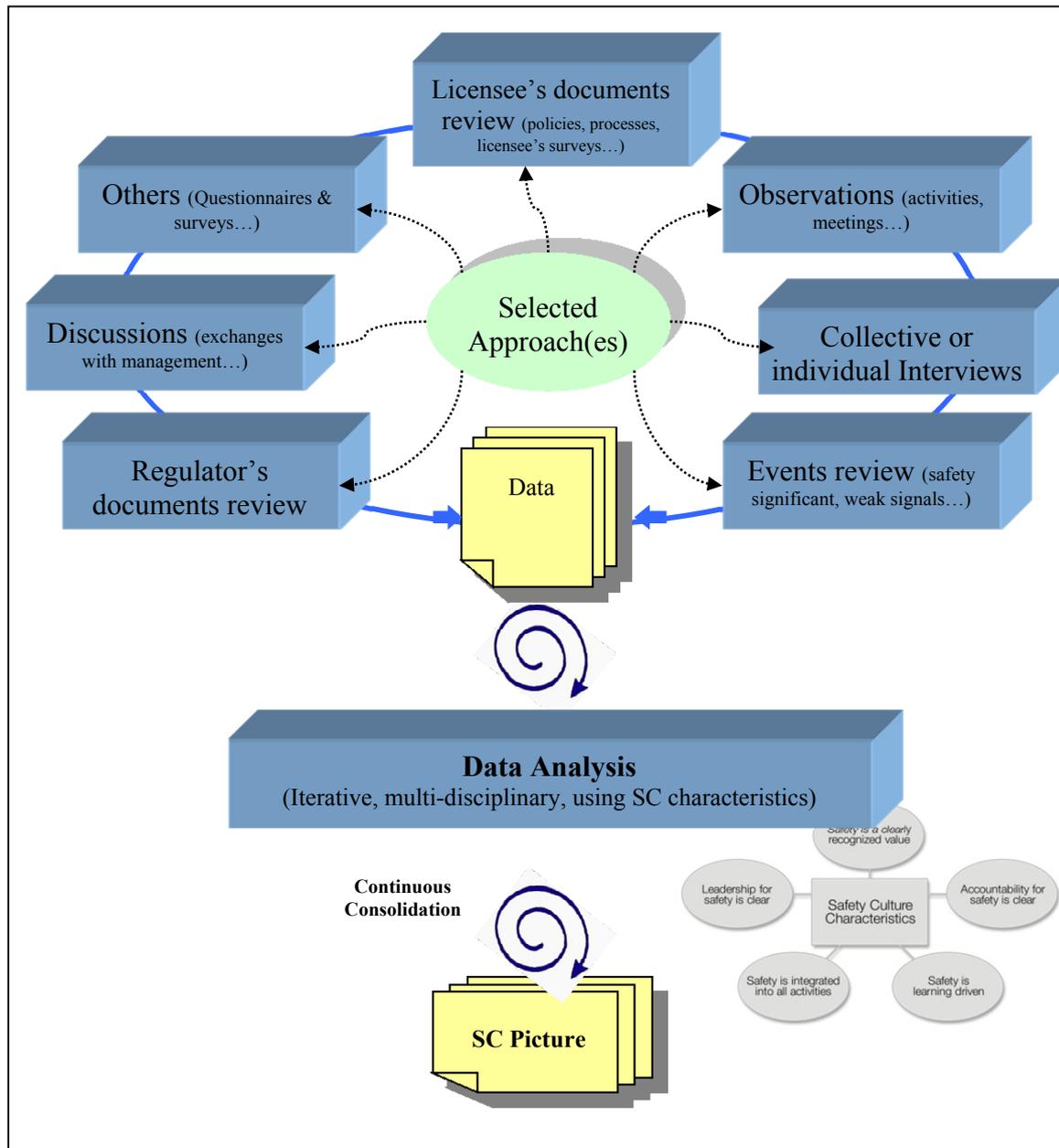


FIG. 4. Overview of data collection and analysis cycles.

While conducting observations, interviews, or reviewing documentation, the following principles are followed:

- keep an open mind;
- maintain a questioning attitude and consider the credibility of sources;
- gather data on as many safety culture attributes as possible;
- keep detailed notes and records;
- look for examples of both strong and weak performance (balanced approach);
- stick to the facts and consider the context of their occurrence.

4.4.2. Data analysis phase

The aim of data analysis is to build a safety culture picture based on the inputs collected.

The safety culture picture is a representation of the regulator's understanding of a licensee's safety culture at a given moment in time. It is a set of interpreted data regarding the organizational practices and the priority of safety within these practices. These data belong to the three levels of safety culture: artefacts, espoused values and basic assumptions (see Section 2.1.). The picture is a summary that represents a given perspective on the safety culture data collected and analysed against a framework such as the IAEA characteristics and attributes outlined in Ref. [7]. According to the three pillars, the safety culture picture is elaborated on agreed, shared and mutual understanding of safety culture concepts, definition and framework between the regulator and the licensee. Therefore, this picture constitutes a good basis for discussion with licensees and leads the licensee to engage in practical improvement actions.

The analysis comprises:

- classifying the inputs against the framework previously selected;
- identifying a need for additional data collection to confirm the first assumptions;
- understanding the actual reasons for the actions collected in the facts (e.g. "what were the intended actions?" and "what was actually done?");
- questioning the collected facts with regards to the past;
- looking for medium to long term trends.

The analysis requires iterations: it is rare that a single pass through the analysis phase generates a reliable safety culture picture. Several cycles may be necessary to ensure enough data to support the analysis.

The analysis requires multi-disciplinary teams. A variety of expertise (technical, human and organizational factors, regulations) are necessary to build a reliable safety culture picture. The analysis could be carried out by a committee in which experts and senior managers of different units of the regulatory body are represented.

These two considerations (iterations and multi-disciplinary teams) are introduced to protect against bias inherent to the multiple sources of data.

When analyzing the data, special consideration of the following aspects is necessary:

- Where apparent conflicting evidence is collected in the process, the conflict needs to be examined and may usually be resolved by looking at the root of the culture or interpretation of the data; actually, experience shows that an apparent conflict is often not a conflict when subject to a deeper review at the assumption level (see 2.1.2);
- During or immediately following organizational change, some of the data may be chaotic.

Building a safety culture picture is a continuous activity, accordingly, the regulator should communicate to the licensee about this picture on a periodic or an ad hoc basis.

4.5. COMMUNICATION WITH THE LICENSEE

A positive dialogue between executives of the regulator and the licensee is beneficial to increasing the emphasis of safety culture within the licensee's organization.

The safety culture picture developed is presented for discussion to the licensee during meeting on a periodic or an ad hoc basis.

The objective of the meeting is to reach agreement on next steps, including a common definition and implementation of possible meeting actions. It is important to capture opportunities for improvement and the corresponding commitments of the licensees for follow-up.

The senior management of the regulatory body is actively involved in the communication related to the safety culture oversight process.

As licensees have the prime responsibility and means for fostering safety culture, particular attention is given to the message that the regulatory body wants to convey to the senior management of the licensee.

4.6. CONTINUOUS FOLLOW-UP

The communication phase leads the licensee to engage in "improvement actions" (see FIG. 4) on the basis of the safety culture picture.

These "improvement actions" could be discussed with the regulator.

These actions may impact the safety culture picture. In order to understand these effects and to update his understanding of the new picture (See Section 4.3.), the regulator identifies complementary data to be collected during the next cycle of collection and analysis (See Section 4.4.).

When relevant the regulator may consider opportunities for continual improvement through revisiting the preparatory phases (See Section 4.1. and Section 4.2.).

Appendix 1

SOME MAIN FEATURES OF THE CONCEPT OF CULTURE

The following contents are taken from Ref. [3], wherein the concept of culture is explained in more detail.

Many people use the word “culture” to explain a variety of phenomena, but as each tends to adopt a slightly different perspective, there is no unanimously accepted definition. Definitions of culture vary in complexity. One of the simplest is: “*The way that we do things around here*”. Although simple, this definition is not of much practical use to anyone interested in analyzing culture. Perhaps the most inclusive definition is: “*Culture is the human-made part of the environment.*” *This definition reminds us that the ecology shapes the cultures that emerge in it, and in turn culture shapes particular kinds of behaviours.*

Currently one of the most widely accepted definitions of culture is that given by Edgar Schein¹⁸. Schein’s definition includes the key characteristics of culture. First, culture emerges in adaptive interactions. Second, culture consists of shared elements (shared language, and the opportunity to interact). Third, culture is transmitted across time periods and generations (modern communications results in cultural diffusion in films and television).

Culture is to society what memory is to individuals. Culture includes traditions that reflect “What has worked in the past”. It also encompasses the way people have learned to look at their environment and themselves, and their unstated assumptions about the way the world is and the way people should act.

The biggest risk in working with culture is to oversimplify it and ignore several aspects that matter. These are:

- (1) ***Culture is deep.*** If you treat it as a superficial phenomenon, if you assume that you can manipulate it and change it at will, you are sure to fail. Culture controls you more than you control culture. As you learn what works, you develop beliefs and assumptions that eventually drop out of awareness and become tacit rules on how to do things, how to think about things, and how to feel.
- (2) ***Culture is broad.*** As a group learns to survive in its environment, it learns about all aspects of its external and internal relationships. Deciphering culture can be an endless task. If you do not have a specific focus or reason for wanting to understand culture, you will find it frustrating.
- (3) ***Culture is stable.*** People want to hold on to their cultural assumptions because culture provides meaning, and makes life predictable. Humans do not like chaotic, unpredictable situations. Any prospective cultural change creates great anxiety and resistance to change. If you want to change some elements of your culture, you must recognize that you are tackling some of the most stable parts of your life.

¹⁸ See 2.1.1. in this publication.

Schein's three levels of culture are extensively defined in Ref. [3], from where the following text has been extracted:

- (1) **Artefacts.** The easiest level to observe is that of artefacts: what you see, hear and feel. Entering an organization, the most obvious artefact is the architecture and design of the building. Is the space where people work open, partitioned by half walls or in private offices? Other aspects of layout, such as the number of executive dining rooms, washrooms, or reserved parking spaces also indicate the importance attached to hierarchy and status. These may be reinforced by artefacts such as cars, and office furniture that send clear messages regarding ranking order. At the level of artefacts, culture is very clear and has immediate emotional impact. But you do not really know why each organization is constructed as it is, or why people are behaving as they are. It is difficult to decipher what is going on. You have to move to the next level of culture.
- (2) **Espoused values.** Espoused values are those values that are adopted and supported by a person or organization. Information about espoused values can be obtained by asking questions about the things that you observe or feel. Espoused values are those values that people say that they support. Values are preferred states about the way things should be. Examples of espoused values often quoted in organizations are, equality of opportunity, teamwork, empowering employees, safety is a priority etc. These values are not uncommon in organizations, even those having completely different physical layouts and working styles. Should you spend a longer time in an organization you will often become aware of inconsistencies between some of the espoused values and the visible behaviour. For example, an organization may espouse "teamwork" as a value but has a reward system that is highly competitive and individualistic. It may espouse that "safety is a priority" but employees take risks to meet production targets. What these inconsistencies tell you is that a deeper level of thought and perception is driving the behaviour. The deeper levels may or may not be consistent with the values espoused by the organization. If you are to understand the culture, you must decipher what is going on at the deeper level, and establish what are the basic assumptions.
- (3) **Basic assumptions.** These lie at the deepest level of culture. They are fundamental beliefs that are so taken for granted that most people in a cultural group subscribe to them but not in a conscious way. To understand any culture you must unearth these basic assumptions that are operating. These basic assumptions will reflect many of the deeper assumptions of the national culture but are not exclusively determined by the national culture. In the case of an organization they will also reflect its history, the values, beliefs and assumptions of the founders and the key leaders who have made it successful.

Appendix 2

AN EXAMPLE OF DATA COLLECTION

This case study illustrates the way collection methods can be combined. Each provides data that is not directly usable for analyzing cultural aspects or for taking regulatory actions. Combining different sources of data using a framework allows for a more complete safety culture picture.

When building the safety culture picture, if the analysis raises any issue, it is important to seek to understand “*why*” the issue exists, not just “*what exists*”. As is the case in a “Root Cause Analysis” approach, the question “*why?*” is asked continuously until the resolution is outside the scope/ability of the organization responsible for corrective action. This principle justifies the necessary iterations between data collection and data analysis stages.

To illustrate this principle and the kind of pitfalls it tends to resolve, one can consider the following example: “Non-compliance with procedures” may be an observable fact and may relate to several safety culture characteristics and attributes:

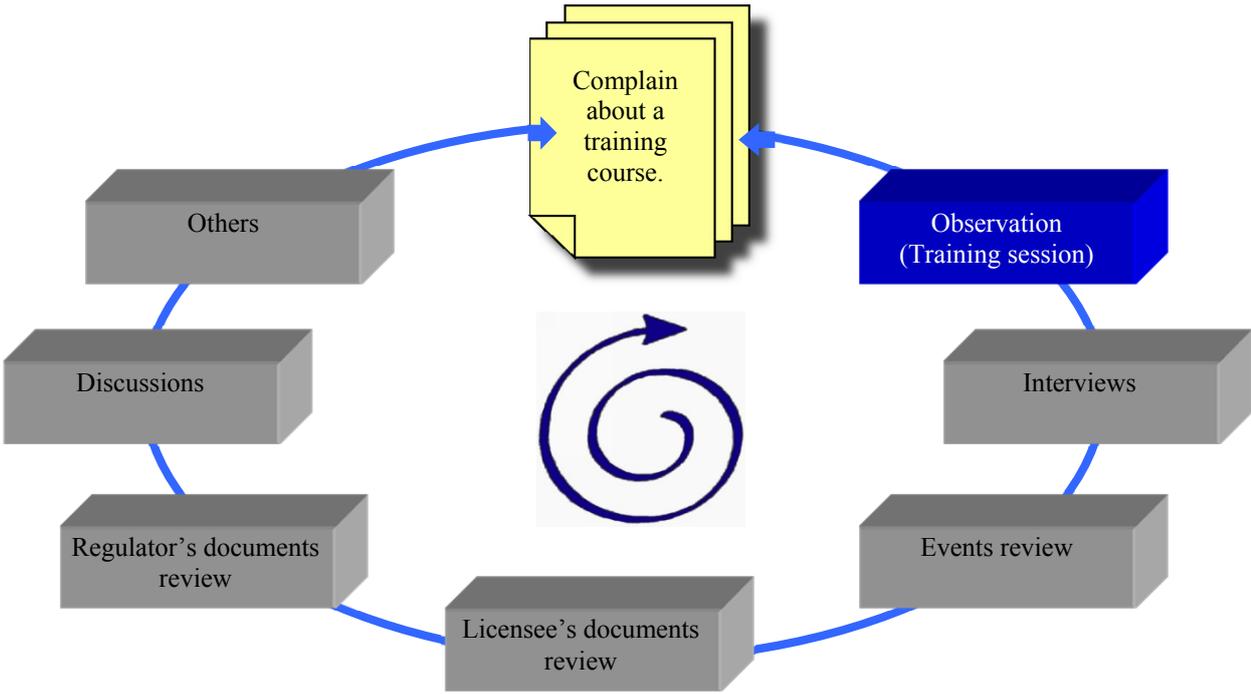
- Inadequate procedures due to: inadequate procedure revision program; lack of resources to update procedures; failure to allocate suitably qualified and experienced staff to update procedures; timeliness of revision program; reluctance of staff to report procedure inaccuracies; etc.
- Lack of management/supervisory oversight: procedure use expectations not fully communicated; no management observation in field; etc.
- No “ownership” of safety by plant personnel: complacency; inadequate training; etc.

Data collection is not a “one-shot” activity. Data is not just gathered; it is built progressively from several iterations. An illustration of such process is described hereafter:

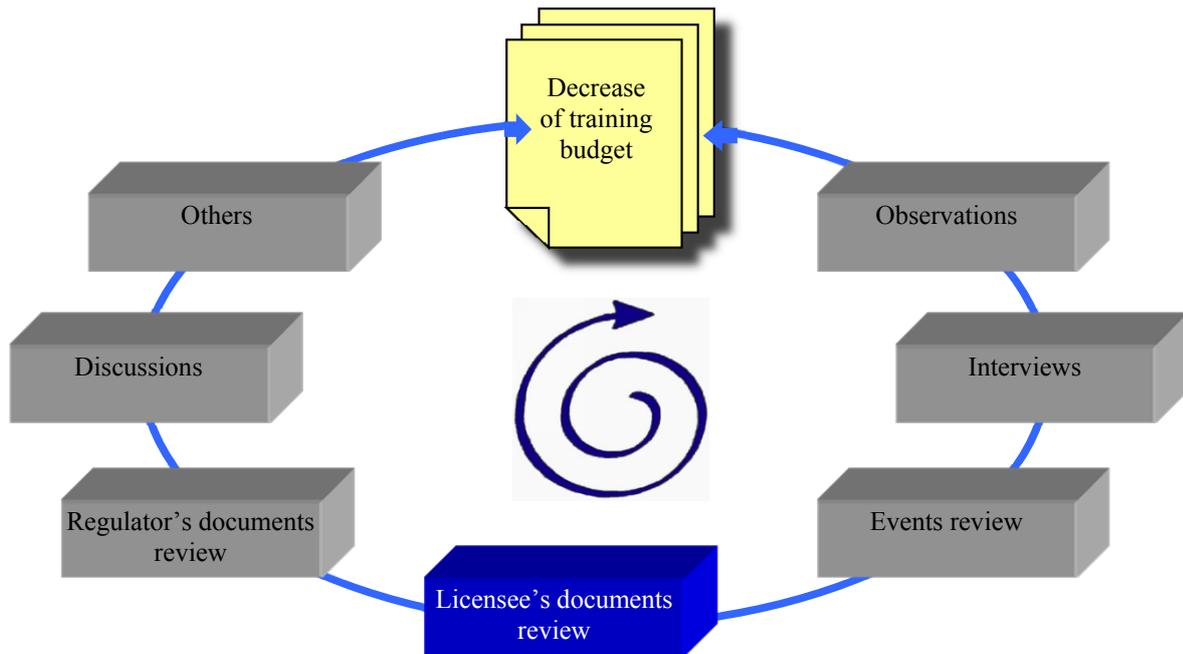
This short example illustrates the way collection methods could be mixed. Each of the methods provides data not directly usable for analyzing cultural aspects or for taking regulation actions. The links between gathered information made by combining different sources of data provide a more complete picture.

The “stories” are reconstructed by linking isolated facts in sequences that make sense regarding safety management. A collection of such stories can provide inputs to understand cultural aspects of the way the organization and people at all levels of the hierarchy pay attention to safety.

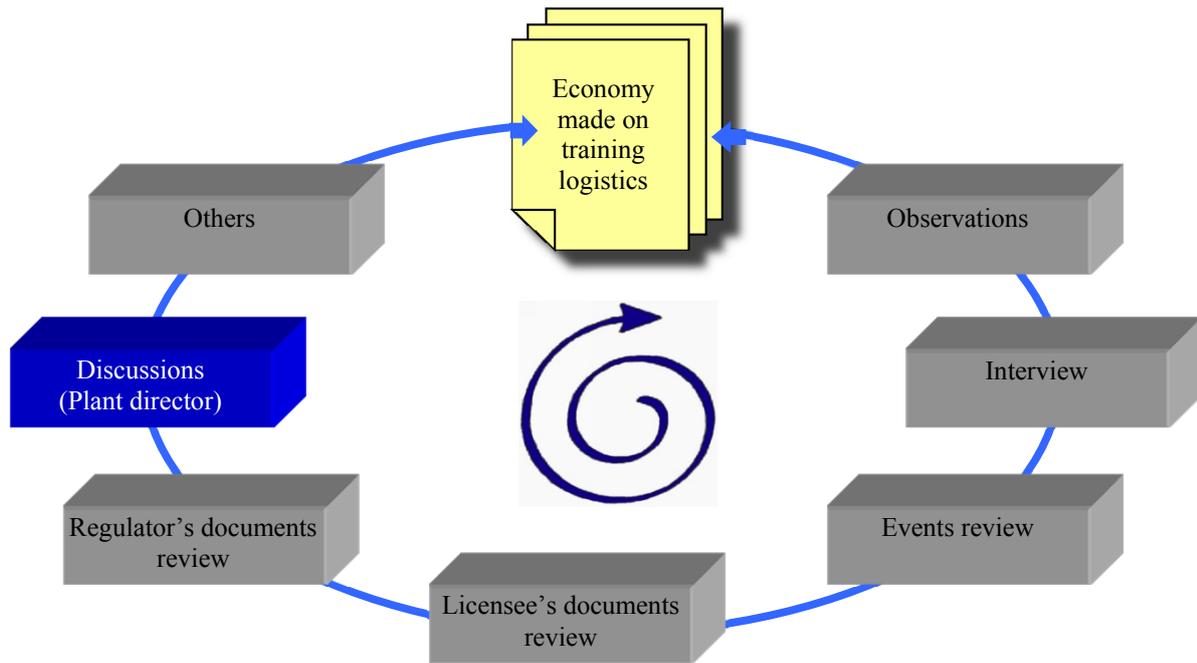
- (1) A training management inspection is performed.
A training session is observed.
Some trainees complain about a lack of hardcopy training materials.
The trainer explains that the printer is out of order and will be replaced in few weeks.
This fact is reported, however, it is not sufficient to trigger a regulatory action.



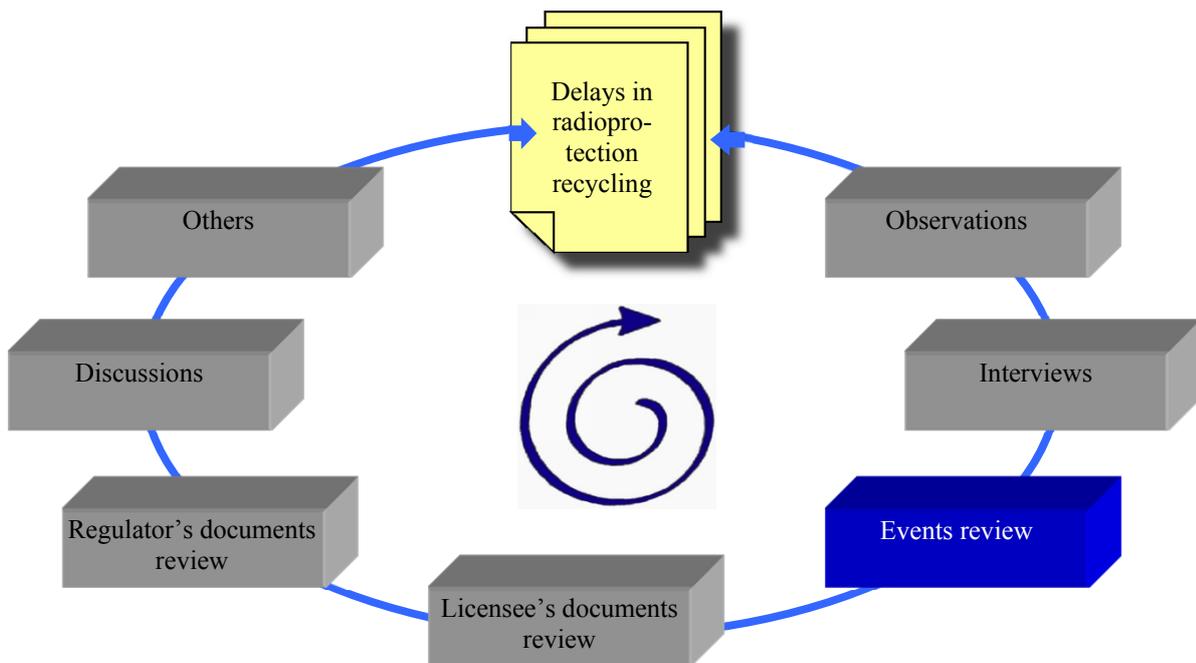
- (2) By reading a licensee report, it is discovered that the training budget has decreased from 20% compared to the previous year. This fact triggers a concern, but there is no regulation stipulating that the training budget has to be maintained or increased over time. It is decided to meet with plant senior management to clarify this point.



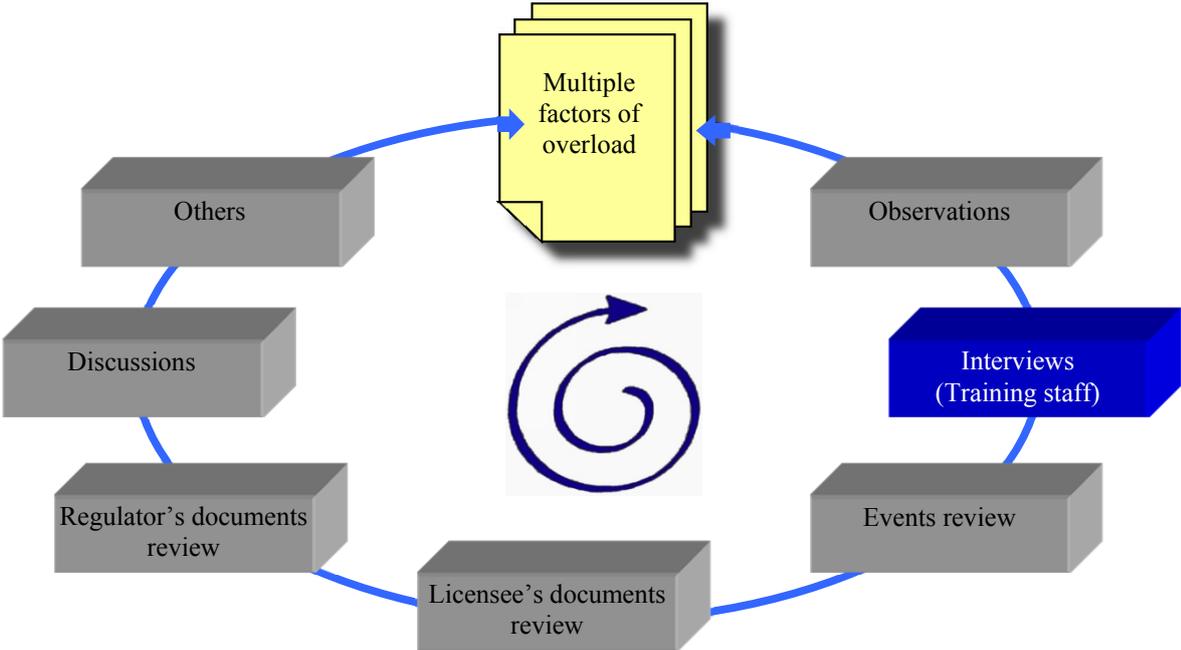
- (3) The plant director is consulted about this fact. It is said that the impact of this decrease has been analyzed and managed. The director shows meeting minutes that confirm the decision and the various people participating in it. In fact, only logistics aspects of training courses have been affected by this decrease and no additional complaints are have been recorded



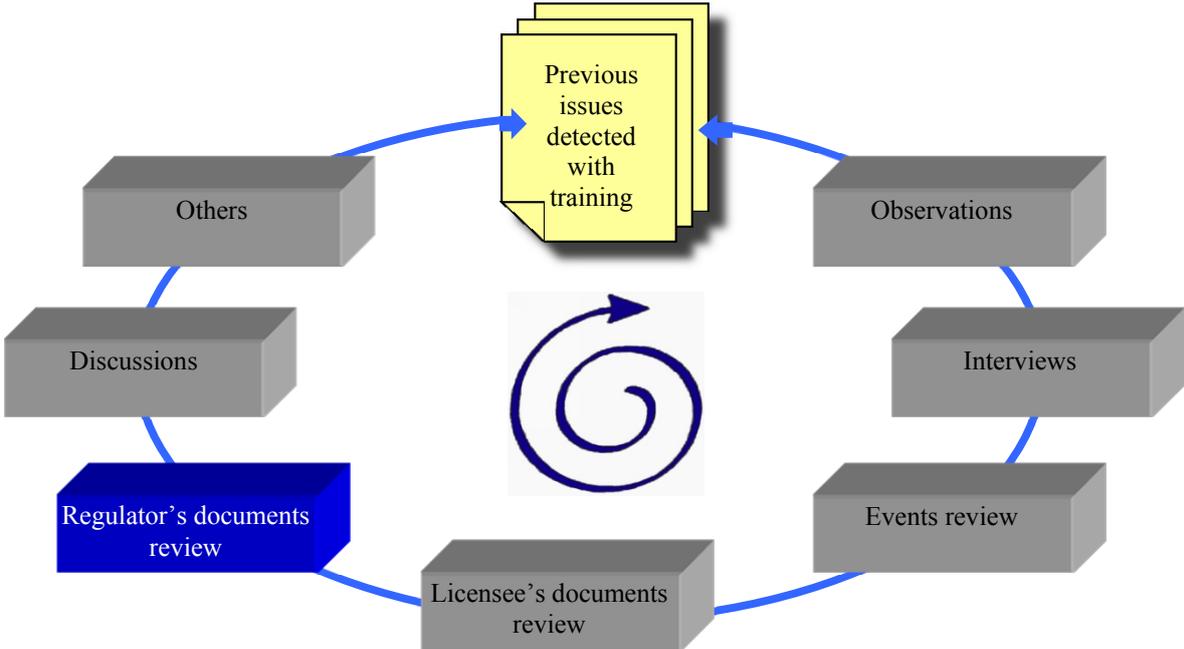
- (4) Alerted by other concerns regarding training, some related events from a few months before are examined: two show errors made by operators. Their radioprotection recycling was delayed. This was not the direct cause of the events; however, this fact is linked to others training issues. It is decided to interview training staff.



(5) Interviews of training staff reveal an overload due to multiple factors: New courses to develop following recent modifications of the installation; Implementation of new quality insurance procedures; recent retirement of 2 administrative personnel, not replaced; A high rate of absenteeism.



(6) By consulting the previous regulator’s annual report it is stated that concerns have already been raised about the training management system. The issue was reported as a “problem of quality of training”. The licensee reacted to this issue by setting up new quality assurance procedures. This was correctly reported and updated within the current corrective action plans.



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ANNEXES

Annexes 1 to 5, available on CD-ROM, provide with practical tools currently used by several Member States to perform their regulatory oversight of safety culture:

- Annex 1 is the safety culture statement of policy developed by the American regulatory body (USNRC).
- Annex 2 compiles the results of the questionnaire developed in the context of the IAEA Technical Meeting on “Fostering a Positive Dialogue on Safety Culture between Regulators and Licensees” (February 2011, Vienna, Austria).
- Annex 3 describes the safety culture oversight process that has been implemented at the Bulgarian regulatory body (BNRA), under the scope of the Regional Excellence Programme on Safe Nuclear Energy.
- Annex 4 details the training programme for regulatory oversight of safety culture, which has been performed at the Romanian regulatory body (CNCAN), under the scope of the Regional Excellence Programme on Safe Nuclear Energy.
- Annex 5 presents the USNRC viewpoint on pros and cons of several safety culture data collection methods.

GLOSSARY

SCOP: The safety culture oversight process is the specific process that supports regulatory oversight of safety culture.

The following terms are extracted from Ref. [10]:

event. In the context of the reporting and analysis of events, an event is any occurrence unintended by the operator, including operating error, equipment failure or other mishap, and deliberate action on the part of others, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

facilities and activities. A general term encompassing nuclear facilities, uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources.

independent assessment. Assessments such as audits or surveillances carried out to determine the extent to which the requirements for the management system are fulfilled, to evaluate the effectiveness of the management system and to identify opportunities for improvement. They can be conducted by or on behalf of the organization itself for internal purposes, by interested parties such as customers and regulators (or by other persons on their behalf), or by external independent organizations. This definition applies in management systems and related fields.

lifetime. The period during which an authorized facility is used for its intended purpose, until decommissioning or closure

management system. A set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective way. The management system integrates all elements of an organization into one coherent system to enable all of the organization's objectives to be achieved. These elements include the structure, resources and processes. Personnel, equipment and organizational culture as well as the documented policies and processes are parts of the management system. The organization's processes have to address the totality of the requirements on the organization as established in, for example, IAEA safety standards and other international codes and standards.

nuclear installation. A nuclear fuel fabrication plant, research reactor (including subcritical and critical assemblies), nuclear power plant, spent fuel storage facility, enrichment plant or reprocessing facility.

self-assessment. A routine and continuing process conducted by senior management and management at other levels to evaluate the effectiveness of performance in all areas of their responsibility.

senior management means the person who, or group of people which, directs, controls and assesses an organization at the highest level.

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