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IAEA-TECDOC-1846

Regulatory Oversight of Human and Organizational Factors for Safety of Nuclear Installations

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REGULATORY OVERSIGHT OF HUMAN AND ORGANIZATIONAL FACTORS FOR SAFETY OF NUCLEAR INSTALLATIONS

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FOREWORD

Human and organizational factors (HOF) result from the interaction of humans, organizations and technology, and have a direct impact on safety. Regulatory bodies are responsible for exercising oversight of the safety of facilities and activities. However, there is currently no comprehensive report that addresses how to conduct regulatory oversight of HOF.

The importance of regulatory oversight of HOF has been discussed extensively at the international level. During a technical meeting on the topic in Vienna in December 2015, the participants agreed on the importance for a regulatory body to have a strategy for overseeing HOF in its regulatory functions. The participants also concluded that the development of an IAEA publication on the regulatory oversight of HOF was a priority to assist the Member States in strengthening their capability to exercise HOF oversight.

This publication addresses this need, and supports the efforts of the regulatory bodies in developing their respective HOF oversight programme. It defines HOF within a regulatory framework and describes their implementation. It also explores the various ways that a regulatory body can overcome the challenges it may face.

The IAEA wishes to acknowledge the efforts of the experts who participated in the technical meeting. The IAEA officer responsible for this publication was J.-R. Jubin of the Division of Nuclear Installation Safety.

CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

There are many factors which have influence, in a positive or adverse manner, on human performance in a given situation. Past nuclear accidents show the necessity to consider those factors, defined as human and organizational factors (HOF), as important contributors to the safety of nuclear installations. For example:

- The Three Mile Island accident demonstrated that the combination of different factors influences safety. The accident was initiated by a mechanical problem that was aggravated by several inappropriate actions carried by personnel who were not adequately trained and who were hindered by inadequate alarm systems;
- The Chernobyl nuclear power plant accident was caused by the interplay of different factors, including the lack of appropriate engineered safety features and deficiencies in the general safety and regulatory framework. Another important reason was that personnel omitted the operating rules and neglected nuclear safety because of clear deficiencies in safety culture;
- More recently, the nuclear safety community learned from the TEPCO Fukushima Daiichi nuclear power plant (NPP) accident that "with a systemic approach to safety that analyses the human, organizational and technical factors, an organization can be better prepared for an unexpected event" [1].

All these accidents highlight the importance of considering the entire system that contributes to the safety of a nuclear installation. Rather than separating HOF from the technical aspects, it is better to consider an integrated perspective and an effective systemic approach. Several IAEA safety standards take HOF into account to prevent failures and enhance safety. For instance:

- Principle 3 of the Fundamental Safety Principle, SF-1 [2] states in para 3.14 that, among others, "an important factor in a management system is the recognition of the entire range of interactions of individuals at all levels with technology and with organizations;"
- Requirement 5 of the Safety Requirements on Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, GSR Part 3 [3] in para 2.52 states that "the principal parties and other parties having specified responsibilities in relation to protection and safety, as appropriate, shall take into account human factors and shall support good performance and good practices to prevent human and organizational failures;"
- Requirement 4 of the Safety Requirements on Safety Assessment for Facilities and Activities, GSR Part 4 [4] in para 4.16 states that "This process requires that a systematic evaluation of all features of the facility or activity relevant to safety be carried out, and includes… (g) Assessment of human factor related aspects of the design and operation of the facility or the planning and conduct of the activity."

Regulatory oversight aims at providing assurance that all activities performed by a licensee throughout the lifetime of a facility, are carried out safely and meet the safety objectives and licence conditions. Principle 1 of the Fundamental Safety Principle SF-1 [2] states in para 3.6. "These responsibilities are to be fulfilled in accordance with applicable safety objectives and requirements as established or approved by the regulatory body, and their fulfilment is to be ensured through the implementation of the management system." The IAEA Safety Requirements GSR Part 1 (Rev. 1) on Governmental, Legal and Regulatory Framework for Safety [5] require regulatory bodies to exercise oversight on the safety of facilities and activities in conducting their regulatory functions, which includes the regulatory oversight of HOF. Considering that safety depends not only on the performance of the technology but also on the interactions between humans, technology and the organization, a regulatory body has to ensure that HOF are properly managed by the licensee to ensure their rightful contribution to safety.

It was noted at various international meetings[1,2] that there is a need to improve the regulatory oversight of capabilities of licensee provisions and practices in the area of HOF. The IAEA Integrated Regulatory Review Service conducted in Japan in 2007 revealed insufficient consideration of issues related to the management of safety and human performance by the regulatory body. The IAEA report on the TEPCO Fukushima Daiichi NPP accident [1] states in section 2.6 that the "basic assumption that the robustness of the technical design and existing measures would maintain and protect the safety of nuclear plants against postulated risks was developed, maintained and mutually reinforced among the main stakeholders[3] (…). As a result of the prevalent technical assumption (…), non-technical factors such as the associated infrastructure and cultural, human and organizational factors were not adequately assessed and strengthened (…)."

Para 4.3 of GSR Part 1 (Rev. 1) [5] states that: "The objective of regulatory functions is the verification and assessment of safety in compliance with regulatory requirements." The regulatory body is expected to conduct safety assessments, including integrated safety assessments, to get a better understanding of HOF-related issues, and to provide insights into trends and conclusions.

During the technical meeting organized in Vienna from 14 to 18 December 2015[4], participants discussed their respective experience in carrying out regulatory oversight of HOF. The participants concluded that a regulatory body needs to have a strategy for overseeing HOF as part of its regulatory functions. They added that there was a lack of practical guidance in this area. Consequently, the participants strongly believed that the development of an IAEA publication on the regulatory oversight of HOF was to be a priority.

1.2. OBJECTIVE

The objective of this publication is to support the development and implementation of a regulatory oversight programme that adequately takes HOF into account to oversee safety throughout the lifetime of nuclear installations.

1.3. SCOPE

This publication addresses the definition and implementation of a HOF oversight programme by the regulatory bodies for nuclear installations. It is intended for regulatory bodies and their technical support organizations (TSO). It may also be used by other organizations or individuals responsible for considering HOF to support human performance activities and programmes.

1.4. STRUCTURE

This TECDOC describes the essential concepts and terms used in the area of HOF. It intends to help the development of regulations and guides related to HOF, stressing the key role of the licensee's management system in establishing and maintaining conditions to support people at work. The publication depicts ways to verify compliance with regulatory requirements related to HOF, as well as ways to better understand HOF trends and conclusions, using an integrated safety assessment approach.

Section 2 explains what HOF are, the associated concepts and terms used, and the importance of managing them to positively influence human performance. Section 3 describes the recommended

[1] International Conference on Effective Nuclear Regulatory Systems: Transforming Experience into Regulatory Improvements, Ottawa, Canada, April 2013
[2] Sixth Review Meeting of Contracting Parties to the Convention on Nuclear Safety, Vienna, Austria, April 2014
[3] The license, the regulatory body and the public
[4] Technical Meeting on Regulatory Oversight of Human and Organizational Factors, Vienna, Austria, December 2015

way to develop regulations and what are the areas to be covered. It also describes a regulatory approach for HOF oversight and explains how this approach fits within a generic model of regulatory oversight. Section 4 provides guidance to develop, sustain and strengthen the regulatory oversight on HOF. This document also includes 6 Appendices and 2 Annexes.

2. HUMAN AND ORGANIZATIONAL FACTORS ESSENTIALS

2.1. INTRODUCTION

HOF essentials are relevant for all personnel having an impact on safety, irrespective of their role in the organization, e.g. workers, managers and contractors.

Sections 2.2 to 2.3 introduce important concepts and terms used. Section 2.4 explains how a dynamic environment influences human performance, while section 2.5 addresses the interaction of these factors in a complex system, referring to a systemic approach to safety. Section 2.6 describes how HOF fits within the management system. Section 2.7 discusses how various elements (e.g. safety culture, human reliability assessment) are considered part of HOF. Lastly, section 2.8 clarifies common misconceptions about what HOF are, and what they are not.

2.2. HUMAN AND ORGANIZATIONAL FACTORS

For the purpose of this TECDOC, based on existing IAEA publications and the discussions during the technical meeting held in December 2015, **HOF are defined as the factors which have influence, in a positive or adverse manner, on human performance in a given situation, keeping in mind that safety is the result of interaction of Human, Technology and Organization.**

HOF do not only refer to the individual and the organization as such, but also encompass contextual factors such as those related to the technology, the work environment and the task to be undertaken, i.e., all factors that can influence human performance, as well as their interactions with each other.

2.3. TASK AND ACTIVITY

An important distinction exists between the work that is prescribed (e.g. as specified in procedures under a management system), and what people do when actually carrying out their work, either individually or as a part of a team in a specific work situation. In general, many situations faced by personnel are different from the situations that were expected and planned. Reasons for those discrepancies usually include:

- The composition of the team is different from usual because a team member is absent;
- An experienced worker has to devote time to help a new worker;
- A tool prescribed by a procedure is not available;
- The working location is not accessible because of other, ongoing, work;
- Task interruption, due to other urgent work;
- An instrument is found to be past its calibration date while at the work location;
- A flange stud is found to be stripped when reassembling equipment;
- A novel task, which does not have a corresponding step-by-step procedure, is to be carried out following an event.

A ‘task’ is what people are expected to do as specified by procedures or by verbal instructions. A task is based on numerous assumptions such as: team composition; availability of equipment and tools; competence of workers; accessibility of work locations; and time schedule. An ‘activity’ is the actual situation faced by the worker. Differences between what a worker does, i.e. activity, and what a worker is expected to do, i.e. task, are often attributed to differences between the actual and expected situation.

This is an important distinction. The real-world activities and outcomes of work may be different from those expected by managers or what was intended by the designers of equipment or by authors of the procedures that are used to carry out the work. Even in situations where workers follow a prescribed task exactly, they have to cope with variations in the context of the specific situation, with deviations with respect to the anticipated task and decisions about how to proceed. As a result, workers may not be able to produce the expected results through strict adherence to the task-related documentation alone[5]. When faced with real-world activities, humans make the necessary adjustments to task prescriptions and to their individual perception and understanding of the actual situation to complete the work.

These inherent human characteristics of adaptability and flexibility are necessary for desirable outcomes, but workers also have to be competent to safely and effectively achieve the goals of the prescribed tasks by carrying out the real activities. Training is expected to provide the necessary technological knowledge and cover working methods, including the use of supporting and performance improvement tools (see section 2.5.3.3). The organization is to strive understanding gaps between tasks and activities and determine whether gaps are to be addressed to improve safety.

For nuclear safety, the focus is on tasks which affect or may affect safety, such as:

- The operation of nuclear installations;
- Surveillance, testing and maintenance of the structures, systems and components (SSCs)[6];
- Management of individuals carrying out safety-related tasks and their competence;
- Management of vendors, contractors and suppliers who supply items, products and services that may influence safety;
- Organizational changes.

The safety relevance of a task is not always obvious and needs to be carefully assessed in preparation for performing it.

2.4. HUMAN PERFORMANCE

As illustrated below in Figure 1, human performance usually refers to human activities[7] and to the results of these activities. This definition goes beyond the simple reference to human performance tools (see Section *2.5.3.3.*). This is important because the way that a worker carries out her/his work (the activities), and the outputs of the work performed (the results) are equally important to safety. It is possible that desirable results, which have positive value for the organization, could be produced by undesirable behaviours such as:

- Taking shortcuts to complete a task quickly;
- Achieving the task objective with excessive effort, resources or exposure to risk (good performance would then be achieved at a high human cost).

Therefore, even though the results achieved by an activity may be desirable for the task objective, there can be negative side effects on safety especially if there are deviations from the safe way to carry out the task.

[5] Industrial action known as 'work to rule' involves strict procedural adherence as a work slowdown or stoppage strategy, by doing nothing but what is written in job descriptions and work procedures.
[6] SSCs are those systems, structures and components necessary to fulfil the 'safety functions' [4].
[7] The term 'behaviour' is sometimes used instead of 'activity.' The term 'activity' is preferred because 'behaviour' can be considered in a restricted way as only relating to the directly observable aspects of the human activity.

Views of human performance have often considered only the negative impacts of personnel performance, such as human error. A broader view of human performance considers that personnel contribute positively to safety, since people can detect and mitigate adverse circumstances while carrying out their activities. This is important to maintain and improve safety across the whole range of potential work situations.

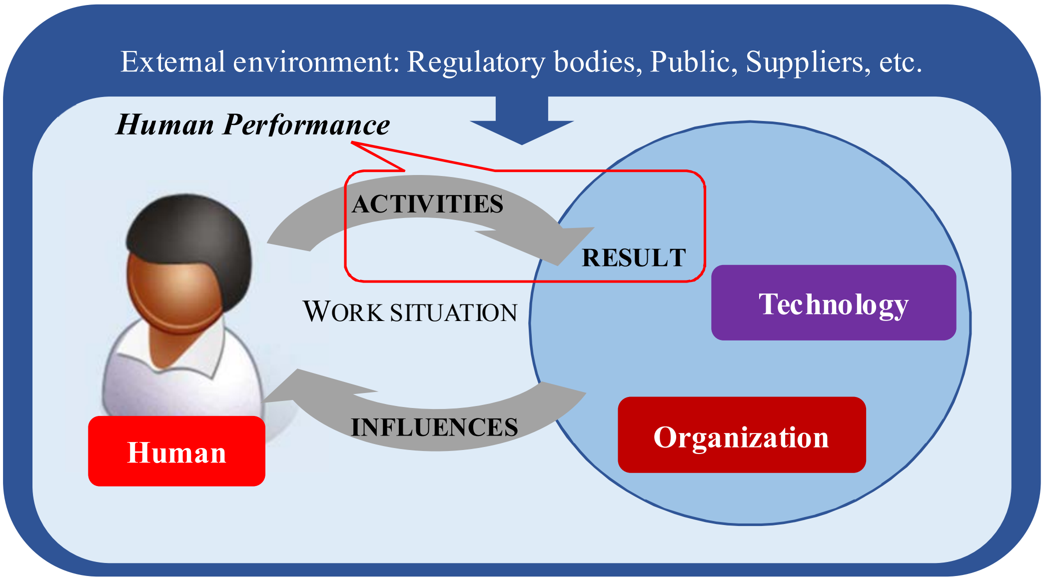

FIG. 1. Human performance, which refers to human activities and to the results of these activities, is influenced by various factors.

Achieving adequate human performance for infrequently performed tasks (e.g. during outages) or novel actions, under high mental workload, can be challenging. These were the types of challenging and stressful conditions experienced by TEPCO staff during the TEPCO Fukushima Daiichi NPP accident. Yet, the efforts made by personnel to mitigate the consequences, as well as to recover from the accident have relied, to a large extent, on the capabilities and adaptability of people to carry out work activities. It is important to realize that it is possible to devise human performance programmes that will help personnel to exhibit the best safety performance under difficult situations.

2.5. FACTORS THAT INFLUENCE HUMAN PERFORMANCE AT WORK

People perform activities in a context that is complex and evolving over time. This context contains a range of factors that influence human performance: human and organizational factors. Based on the Human, Technology and Organization (HTO) approach, referred to in IAEA Safety Requirement GSR Part 2 on Leadership and Management for Safety [6] in para 1.2., HOF can be categorized[8] as:

- Human-related factors;

[8] This is a way of categorizing the factors that influence human performance; there are other acceptable ways of grouping them.

– Technology-related factors;
– Organization-related factors.

Appendix I lists those categories with several examples of factors.

As depicted in Figure 1, the categories of factors are inter-related when they are considered in a work situation. For example, manually opening a valve is a relatively simple task, yet all categories of factors can play a part in influencing how the activities are carried out by the worker. Among others, HOF to be considered relate to:

– The worker's knowledge and competence to locate the correct valve, previous experience of this activity to know that there are tools that may be needed which are not identified in the procedure, and having sufficient strength, reach and fitness to successfully manipulate the valve. This knowledge and competence depends in turn on the organization's human resource management;
– The supervision and control of any related tasks that have to be completed before the valve can be safely opened, and the time pressure to complete the task that is perceived by the operator, perhaps due to low staffing levels and high production pressure;
– The ability of the organization to provide, on time and at the right place, individuals with usable written procedures for opening the valve, and needed personal protective equipment, such as breathing apparatus or heavy gloves, which slow the worker's activities;
– The work environment that could include the ambient lighting levels related to ease of reading the equipment tags and labels, successfully negotiating stairs or ladders without falling, and a noisy environment, where verbal communication is difficult, that could result in a misunderstood communication of other work in relation to the valve manipulation;
– The ergonomics considered in the design of the valve and in where it is located in the plant.

The following sub-sections further describe each of the categories of HOF.

2.5.1. Human-related factors

Human-related factors relate to the specific person in the work situation, and to the interactions with other people, such as working in teams or communicating information. As well, the general characteristics and limitations which apply to humans, influence human performance. Human-related factors include:

– Characteristics of humans in general, such as the limited capacity of human working memory, general consideration of human body size and strength, and the tendency of humans to use heuristics or shortcuts to minimize the effort to carry out an activity;
– Processes or internal states to the worker, when carrying out activities, such as maintaining situational awareness, maintaining an acceptable workload, or carrying out problem-solving and decision making;
– Cooperation and communication, such as the way a worker interacts with other people when working in a team, and when communicating or receiving information with other workers;
– The attributes of the specific worker who performs the activity, such as competencies (not only qualification) to perform the task, having the necessary strength and reach, or being unfit for duty due to illness or substance impairment.

2.5.2. Technology-related factors

Technology-related factors relate to the design features, usability and fitness for purpose of SSCs. These factors include:

– Accessibility of the equipment: The efforts required to access equipment may hinder calibration, maintenance, and create hazards for the workers;

- Automation: Automated systems modify the level of involvement of workers when conducting tasks. This can provide benefits in challenging and complex situations, by reducing workload, stress and fatigue that may otherwise lead to human errors. However, automation may decrease the level of awareness and understanding by the user about the system which, in turn, may lessen his/her ability to cope with unexpected events or recover from failures;
- Complexity: It may be difficult for workers to understand the functions of equipment, which may result in erroneous actions, especially in new, unusual, unfamiliar or infrequent situations;
- Human machine interface design, such as control room panels, local workstations or field equipment and tools, where those interfaces can hinder human performance if improperly matched to the task characteristics and demands.

2.5.3. Organization-related factors

2.5.3.1. Structure and management

An organization is composed of: a structure, which defines its framework, a set of interactions between the individuals and the groups that compose the organization, as well as cultures and collective identities that exist within it.

An organization's structure has to fit its actual situation by providing sufficient information processing and control while focusing employees on specific functions. It consists of written documentation, division of labour, the span of control and who reports to whom, the complexity or number of activities in the organization, the level in the hierarchy that has the authority to make decisions, the level of formal education and training of employees and the deployment of people. The characteristics of these elements are determined, in part, by the size of the organization or number of employees, the nature of the organization's production, the industry or environment that the organization functions, the purpose of the organization and its culture. The organizational structure is planned and implemented through organizational charts, headcounts in the various units, departments, etc. The organization chart is the visible representation of the underlying activities and processes in the organization. It shows the formal reporting relationships, grouping together of individuals into departments and design of system to ensure effective communication, coordination, interaction and integration of effort across departments.

Organization-related factors include:

- How the organization is managed to achieve its goals, regulatory compliance, productivity, sustainability and organizational learning (the management system);
- Characteristics that relate to the organizational structure and staffing, such as roles, responsibilities and authority, reporting lines, workforce composition;
- Policies, processes and programmes that relate to the organizations goals;
- The production and availability of artefacts that relate to management, such as procedures, guidance, job aids, visual management boards, newsletters, intranet, safety posters, records of meetings, performance indicators;
- Practices that are used to manage and supervise, including observation and coaching in the field, team meetings and discussions;
- The nature of the relationships (especially in terms of cooperation and / or conflict) that exist between employees, e.g. within a team;
- Cross-functional and interdisciplinary cooperation and teamwork;
- Conditions that enhance teamwork;
- Initiatives that are used to maintain and improve personnel engagement (e.g. incident reporting arrangements);

- Arrangements for personnel to raise suggestions and concerns, and their consideration and resolution at the appropriate level;
- The organizational culture (attitudes, beliefs, shared values and goals);
- Attributes such as leadership, trust, transparency, communication;
- Training carried out to ensure that individuals have the necessary competence to carry out their activities;
- Programme to assess and develop training.

Effective leadership is an essential factor for human performance. Requirement 2 of GSR Part 2 [6] mentions the key role of managers regarding leadership: "Managers shall demonstrate leadership for safety and commitment to safety." Managers at all levels need to use both a bottom-up and a top-down approach [7]. A manager, at all levels in the organization, provides the interface between the upper management level and the lower levels, down to workers in the field. He/she has the responsibility to facilitate the flow of information in both directions coherently with the decisions made, ensuring the clarity and relevance of information transmitted for its efficient and effective use. Also, a manager has the responsibility to facilitate the flow of information between the different units.

2.5.3.2. Work environment and infrastructure

Deficiencies in the environment of employees tend to disrupt their activities by introducing difficult work situations, distractions and hazards that need to be avoided while performing the work. These factors include:

- The physical infrastructure and workplace provisions, such as the signage relating to different units, housekeeping, access to washrooms, drinking water and food, ambient lighting, and the availability of tools and supplies;
- The characteristics of the specific workplace, such as cramped space for carrying out the activities, difficult access to the work location itself or working at heights, high noise levels that may impair communication, available table surface to spread out documents;
- The layout of the plant and associated buildings, including proximity of managers' offices to the plant, location of provisions such as the stores, personal protective equipment, washrooms and cafeteria, sufficient room to carry out maintenance tasks, and safe routes for workers;
- The situation at the specific time that the activities are carried out, such as other work being performed nearby, level of housekeeping, the presence of a chemical or radiation hazards, or severe weather for activities that take place outdoors;
- Security issues like access restrictions.

2.5.3.3. Task

Workers need to be provided with the necessary support to perform their work successfully. This support originates from the adequate design, planning, preparation, resourcing and control of the work. Task-related factors include:

- Documentation: rules, procedures, guides, notes, checklists, etc. These documents provide the information at the level of detail needed to carry out a task as prescribed. It is important to keep in mind that these instructions or guides may sometimes introduce confusion and mistakes. They cannot cover all the situations that an employee have to deal with while carrying out a task;
- Records, e.g. the results of a previous task, are often important parameters to consider for other tasks. Records need to be readable, complete, identifiable and easily retrievable;
- Tools and equipment necessary to perform a task, which are to be fit for purpose;

- Personal protective equipment, when protecting the workers, usually affects the way that the task is conducted and requires more time to complete it.

There are various activities that could be carried out on an individual basis to prevent error. These activities, sometime called human performance tools or error-free tools, are specific practices and approaches used when carrying out work with the intent of reducing human errors. They are mentioned in the Safety Guide on Application of the Management System for Nuclear Installations, GSG-3.5 [8]: "2.37. Individuals should be trained in how to recognize situations that are likely to give rise to errors, so that they can avoid making mistakes. In addition, there are various activities that could be carried out on an individual basis to prevent error."

Human performance tools include:

- Pre-job briefings, asking the questions: What are the critical steps? What situations associated with the work are likely to give rise to errors? What defences are in place to prevent unusual occurrences?
- Self-checks, which apply the STAR (Stop–Think–Act–Review) principle to task steps or outcomes;
- Peer checks, having a second individual check the intended action as it is carried out;
- Three-way communication by which a message is communicated from one individual to another. The individual receiving the message repeats the message to confirm a clear understanding and the originator acknowledges that the message has been correctly understood. This then closes the communication loop;
- Conservative decision making to be applied when there are no procedures in place or plans made for the activity.

Human performance tools are useful but are to be considered as an additional defence in preventing an error. Their use does not constitute a human performance programme.

As previously discussed in this publication, the variability and adaptability of humans is necessary to ensure safe operation of nuclear installations. This inherent human functioning can also lead to mistakes and errors. The idea that human errors can be totally eradicated is erroneous.

2.6. SYSTEMIC APPROACH TO SAFETY

A systemic approach relates to a system as a whole in which the interactions between technical, human and organizational factors are duly considered. It is related to the cross-cutting aspect of HOF, where virtually any component (hardware, software, business process, activity, etc.) is subjected to the combined effect of several human and organizational factors. The systemic approach is useful at any level of the organization (e.g., when looking at a single design modification, or when analysing a multi-unit event).

The approach taken to address nuclear safety has historically been to identify and analyse separately causes of events. While it is important to understand and regulate specific aspects of HOF, the consideration of a broad view of HOF in a systemic way is desirable because many factors influence human performance, and these factors are strongly inter-related, with changes in one factor triggering changes in other factors.

For example, an equipment modification (technology-related factors) may also require new competencies for the equipment maintainers (human-related factors). This could lead to recruiting staff with these competencies, or training existing workers (organization-related factors). This might also change the way that work is carried out and the procedures that describe it (organization-related factors). An approach that looks at HOF in a silo often does not consider the complex system of interacting factors.

Root cause analyses further illustrate the importance of a systemic approach. When something does not go as planned, the problem can often be traced back to an error made by a front-line worker. However, there are usually more than one root cause leading to an event, and those root causes often lie elsewhere in terms of HOF. Referring to a sequential approach, an accidental sequence is generally triggered by a human error but the event does occur because of latent/pre-existing failures in the system[9].

For example, the equipment design may unintentionally create an error-prone situation for the worker, or prevent the worker from carrying out a task to the required standard. Other factors may have contributed to the problem, such as a noisy work environment, which impaired communication or the work group culture may tolerate working without procedures in-hand for this task. Within this broader view, the front-line workers themselves are just a part of ensuring safe and effective work performance.

The examples above show why a facility with its operating organization is seen as a complex system of inter-related and interacting subsystems, embedded in an external regulatory, social, political and cultural environment. This whole system is undergoing a dynamic process of change and it has to adapt appropriately over time. A better understanding of the system requires taking into account its individual subsystems and their interactions but also the influences from the external environment of the system including the influence of the regulatory body. Within this approach, known as the systemic approach, humans are considered as a part of the overall system.

After the TEPCO Fukushima Daiichi NPP accident, questions were being asked about why it happened, what can be done to prevent it from happening anywhere again, and what can be done to mitigate the consequences if it did happen again. Analyses concluded that the causes of the accident were related to the inability of various organizations to detect the weaknesses in the overall system. As stated in the TEPCO Fukushima Daiichi NPP accident Summary Report [1], "…with a systemic approach to safety that analyses the human, organizational and technical factors, an organization can be better prepared for an unexpected event." Indeed, simultaneously considering human, organizational and technical aspects is critical for safety. This has been recognized in several IAEA publications, such as the IAEA Report on Human and Organizational Factors in Nuclear Safety in the Light of the Accident at the TEPCO Fukushima Daiichi Nuclear Power Plant [9].

The way that different HOF and technical factors interact and influence each other may be complex and evolve over time. Their combined influence on human performance may also vary over time. In addition, the nuclear facility is subject to numerous external influences, which may significantly influence its processes and performance, including the activities of the workers.

A phenomenon known as normalization of deviance is often found in complex systems and may have a negative impact on safety. For example, consider the case where the reliability of a system has not been demonstrated above a certain temperature. A known safe threshold value is established to operate the system, but staff decide to operate slightly above this threshold because it is easier for them. As no event occurs, staff develop the habit of operating slightly above the limit and establish a new baseline of 'normal' operation.

The way that the regulatory body oversees safety and interacts with the licensees has a major influence on the emphasis that the licensee places on the management of human performance. The analysis of the TEPCO Fukushima Daiichi NPP accident shows that the interrelationships between the perception and actions of stakeholders strongly impacted the way that safety was addressed by both the licensee and the regulatory body. The TEPCO Fukushima Daiichi NPP Accident Technical Volume 2/5 Safety Assessment [1] explains that "possible reactions from the

[9] System (a facility together with its operating organization) is sometimes called a Socio-Technical System.

public in terms of collective trust in safety had strongly influenced the way that risk management was carried out and lead to improper consideration of risks related to natural disasters by TEPCO."

2.7. MANAGEMENT SYSTEM

Establishing a management system, which values a systemic approach, is essential for defining and implementing adequate safety measures and for the fostering of a strong safety culture. The management system has to integrate all elements of management, including requirements for human performance, in the way that improves safety. According to Requirement 3 of GSR Part 2 [6] "Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety."

A management system is expected to provide provisions to coach, orient, direct, monitor, control, support and improve an organization and its performance when conducting its activities. It is a key tool to manage factors for them to positively influence performance at different levels of an organization:

- Organizational level: through the organization's policies, goals, strategies, plans and objectives for the organization, organizational structure, assignment of responsibilities and authorities and provisions fostering a strong culture for safety;
- Management level: with a focus on processes and the way that tasks are managed and accomplished within the organization. At this level, provisions, such as purpose, type of work and situation, responsibilities and required qualifications, and requirements, are set-up for managing tasks and the interactions among them;
- Individual level: by providing, among other things, work instructions and tools to conduct a task.

2.8. HUMAN AND ORGANIZATIONAL FACTORS-RELATED TERMS

This section discusses differences but also relations between HOF and other concepts dealing with human performance.

2.8.1. Safety culture

Safety culture is defined as "*The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance"* [10]. This definition emphasizes that safety culture relates to attitudes of people, as well as to the more tangible physical items in the organization. It also relates to organizations and to individuals, and it requires that issues be given appropriate consideration, commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach which takes into account [6]:

- The safety significance and complexity of the organization, operation of the facility or conduct of the activity;
- The hazards and the magnitude of the potential impacts (risks) associated with the safety, health, environment, security, quality and economic elements of each facility or activity;
- The possible consequences for safety if a failure or an unanticipated event occurs or if an activity is inadequately planned or improperly carried out.

Safety culture influences human performance through the recognition that individuals in the organization have attitudes and beliefs that align themselves with espoused values within the organization. It is recognized that human performance influences safety culture as an outcome measure of safety performance. Safety culture is part of the wider culture of the organization, which exerts an influence on human performance, and it is therefore considered as an important factor.

2.8.2. Human factors engineering

Human factors engineering (HFE) acknowledges the importance of the interaction between humans and any technical systems and aims to improve this interaction. The IAEA Safety Glossary [10] defines HFE as "Engineering in which factors that could influence human performance and that could affect safety are understood and are considered, especially in the design and operation of facilities". This means that HFE actively and systematically considers the range of HOF that are relevant to the SSCs being designed. It applies the scientific body of knowledge concerning HOF and uses specific methods and techniques when designing systems and equipment, including modifications to the current facilities.

Applying HFE requires that designers have a sufficient knowledge and consideration of:

- Application of HOF-related science and methods to produce a design that satisfies the organizational, regulatory and users' requirements. At a minimum, this includes following human factors design guides, standards and design approaches;
- Recognition that design needs to be iterative, except in the simplest cases, to develop a product that meets usability requirements. The need for iteration also applies to the development of procedures, training, and organizational development;
- Recognition of the need for sufficient usability requirements analysis, usability testing in design, verification and validation.

Flaws and latent failures may be caused by human actions or failures to act during the planning and execution of an HFE programme. The systemic approach, considering the interactions of the HTO is to be applied in an integrated manner during the design process.

2.8.3. Human Reliability Analysis

Human Reliability Analysis (HRA) is a structured approach used to identify potential human failure events and to systematically estimate the probability of those events using data, models, or expert judgement [11]. Various HRA methods exist to calculate this likelihood. HRA is also a component of probabilistic safety assessment [12].

HRA is not always considered in relation to other activities related to HOF. HRA provides quantitative information about the probability of successful human performance, and it is expected to consider the influence of factors that shape human performance. HRA provides qualitative insights that help to understand the issues that create obstacles to achieve acceptable human performance. HRA can be used for decision making on further safety improvements. HRA considers the human failure events that can potentially occur during the activities. However, HRA is usually based on the description of the task rather than the consideration of what people actually do when carrying out their work (activity). Nevertheless, the output of the HRA is to be shared for the use of related HOF domains, such as procedure development and the development of training programmes.

Similarly, HRA is expected to consider HOF such as the usability of the equipment, the location and availability of the necessary tools and supplies, and the quality of procedures in relation to carrying out the safety-related human actions.

As just one example, the HOF body of knowledge, concerning the design of effective and usable procedures, can be used to improve the consideration of these factors in the HRA, and subsequently in the probabilistic safety assessment.

2.8.4. Resilience engineering

Resilience engineering is a model for safety management that focuses on how to successfully support people to cope with complexity, especially in stressful situations. The main feature of this paradigm is to consider human activities not as an initiator of failures which affect adversely safety, but as an asset introducing flexibility into rigid systems. The intention is to enhance human performance in a generic manner rather focusing on the reduction of the likelihood of human errors. Resilience engineering emphasizes that safety management needs to assume a proactive role in supporting the completion of work to an acceptable level of performance, rather than with error reduction programmes that only consider system protection from the unreliable, erratic and limited human components.

2.9. COMMON MISCONCEPTIONS ABOUT HOF

There are numerous misconceptions about HOF. When recognized, a misconception can usually be corrected by raising awareness and acquiring new knowledge about HOF. It is not possible to identify them all a priori. Nevertheless, below are listed some common misconceptions.

“HOF is just another name for safety culture.”

Both concepts, HOF and safety culture, are closely related, overlap and interact. HOF and safety culture can be assessed using similar techniques. However, HOF are based on identified factors that influence human performance while safety culture is concerned mostly with aspects of cultural and organizational processes.

“HOF-analysis is an overly complex and theoretical discipline”

HOF is often seen as a top-down view of the work, where complex and academic concepts are used for analysis or design. The reality is that the “theories” are based on hard science, where experiments, experience and observations of people at work have been used to derive objective facts. Here are a few examples:

- There are bio-mathematical models and empirically derived guidelines to design work schedules that will prevent fatigue from degrading operator performance [13];
- There are proven methods to objectively assess legibility, applicability and user-friendliness of procedures [14];
- There are validated methods for observation and analysis of work activities [15];
- There are well-established standards about design processes and design features of components that, when used appropriately, will yield designs that will support effective and efficient work activities of any kind [16].

Sometimes, it is not possible to give a clear-cut answer to a question. This is often due to an incomplete understanding of the situation, to the intrinsic variability and complexity of the situation, or, because there is insufficient science to provide a categorical opinion. This is not unique to HOF, however, and is also found in all traditional engineering disciplines. In those cases, the notion of engineering judgement is often appropriate. For HOF, applying engineering judgement means to consider the best available science, coupled with the best understanding of the situation, based on a structured and systemic analysis (and often requiring field observations), and then, well-considered answer can be provided.

"Nobody complains, so the design and the work situation are appropriate."

The achievement of a goal does not imply that the operator's effort is acceptable and that safety is maintained. Sometimes, the operator will incur an excessive workload that is unsustainable in the long run. Also, people will adapt to an inefficient and error-prone design. They manage to and maintain acceptable, short-term performance which can easily degenerate under more challenging situations if the conditions change. Past outcomes are not necessarily predictive of future performance, particularly in the case of degraded or unexpected situations.

"Opinions of the users were collected and a rationale was provided, so the design is validated."

Whereas verification considers "if the system has been built right," validation considers "if the right system has been built." From the perspective of human performance, validation considers variations of the question "can these users, with this equipment, procedures and training, carry out this task, in this environment, to the required standards of performance, effectiveness and safety?" From a regulatory perspective, validation confirms the degree to which the design, personnel and supporting provisions facilitate the achievement of operational and safety goals.

Validation has a specific meaning and is not achieved solely by collecting opinions. Validations are formal evaluations of a system or equipment under actual or simulated use to determine if a design solution achieves its pre-established design requirements when users carry out their tasks with or within it. It is necessary to carry out a rigorous, requirements-driven, validation, which includes human performance requirements, to ensure that a design is appropriate for its intended use.

"The designer knows the system in detail and will be in the best position to design a good operator (or maintainer) interface for it."

In the same way that a car driver differs from a mechanical (or electrical) engineer, a designer's understanding of the system differs from the operator's understanding. Further, the operator needs not only to know the individual system (which the designer does), but often and more importantly, about its interconnections with other aspects of the larger socio-technical systems. It is thus imperative that appropriate HOF-related processes and standards are used to develop a safe, effective and efficient design.

"If we tell the personnel to be careful, if we watch them closely and if we discipline those who make mistakes, we will improve safety."

Except for pathological or criminal situations, no individual decides that he or she "will not be careful today." Generally, people do what they consider to be the correct thing to do. It is rather because of the interconnections between various HOF that poor performance in one area (e.g. poorly designed procedures, which lead to higher workload, delay in the work, more pressure to get the work done, and which ultimately results in a human error) often leads to undesirable performance. The solution is to improve the system holistically, rather than to concentrate on a single "cause."

"There is one best way to design an organization and once it is well-designed, it will always work."

There is no single best way for an organization to be structured and managed, as there are many ways that an organization can achieve the desired performance and safety outcomes. Each organization has different characteristics, and so each will have ways of organizing, managing and working that are a good match with these characteristics. The organizational design cannot be static because the environment changes (e.g. regulations, economics and workforce). Therefore, the organization needs to be adapted to these external changes and to improve its performance through continuous improvement initiatives.

3. REGULATORY OVERSIGHT OF HUMAN AND ORGANIZATIONAL FACTORS

3.1. REGULATIONS AND GUIDES

The oversight of HOF is based on regulations and guides in which key requirements and guidance on HOF are clearly stated. Important areas to be considered for HOF-related oversight include:

- Leadership and management for safety (organizational structure, roles, responsibilities, organizational change, etc.);
- Management system;
- Operating experience;
- Human resources, e.g. staff recruitment, planning, qualification, training, fitness for duty;
- HFE;
- Procedures and task support;
- Procurement, supply chain and contractors;
- Working conditions.

The recommended way to develop regulations on HOF is to use a performance-based or goal-setting approach, rather than detailed and prescriptive regulations. The goal-setting approach promotes greater involvement by the licensee to determine how objectives and principles are applied, and to pursue continuous improvements. This provides more flexibility when carrying out more in-depth discussions between the regulatory body and the licensee. Appendix II provides examples of regulatory requirements using the IAEA Safety Requirements as a basis.

3.2. APPROACH FOR COMPLIANCE AND EVALUATION

A regulatory body has to regulate how licensees manage their work activities through their management systems. Requirement 13 of GSR Part 2 [6] states: “The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety.” The HOF perspective of work activities has been described in section 2.

The licensee’s management system drives and governs how the licensee defines and executes its business processes, therefore work activities. Its effectiveness is an essential consideration in compliance assessments and performance evaluations of HOF. The management system is the key tool by which the licensee establishes, manages, and improves its practices and outcomes, including those related to HOF. It is also the primary mechanism through which the HOF oversight programme is implemented and continuously improved.

The management system is expected to comprise arrangements to ensure that the licensee maintains an appropriate focus on HOF. The goal for the licensee, at all levels of the organization, is to understand the overall importance and usefulness of HOF. This can enable it to achieve its goals, from both a compliance and continuous improvement point of view. The regulatory body has to discuss these arrangements concerning HOF as part of the ongoing constructive and professional dialogue with the licensee.

Figure 2 shows:

1. The regulatory framework (top), which contains regulations and guidance to accomplish what the licensee is required to achieve regarding HOF, clearly stated and over the lifecycle of the nuclear installation;
2. The management system documentation (bottom left), which describe the ways that the licensee intends to meet regulations, through specifying the work tasks, as well as describing arrangements such as the organizational structure, infrastructure and task support provisions;
3. The actual activities performed (bottom right), arrangements and work outputs at the installation that need to be assessed, because what occurs in practice may not be the same as what is specified in the management system documentation.

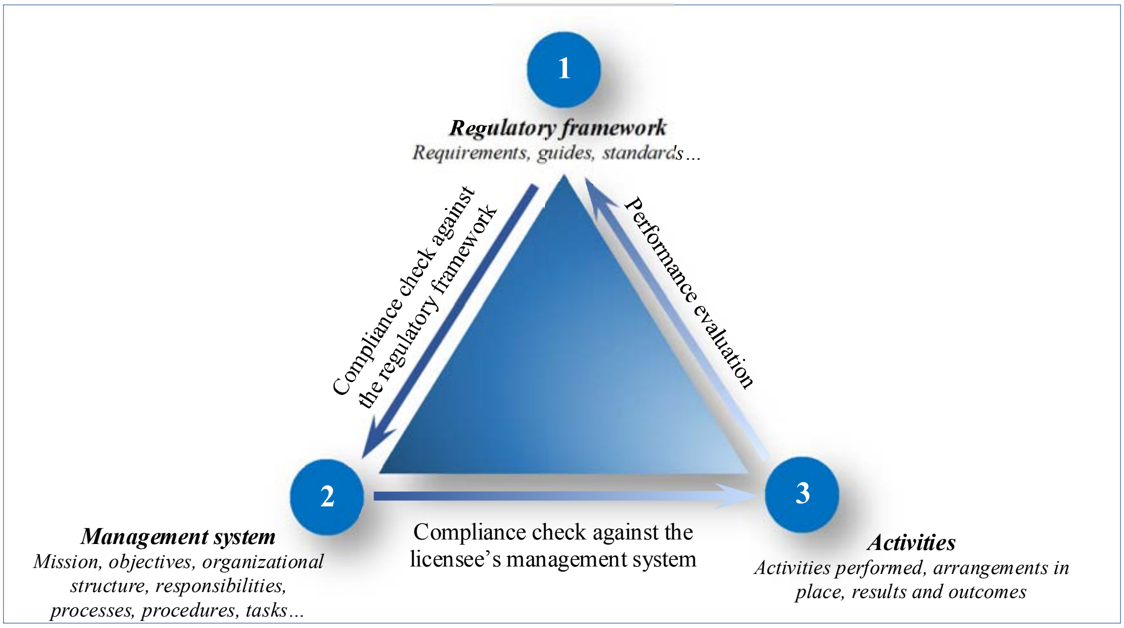

FIG. 2. Approach for compliance and evaluation - Reproduced courtesy of Claudia HUMBEL HAAG [17].

The compliance check and evaluation of HOF is expected to comprise:

1. The first compliance check {1-2}, to verify whether the documented management system complies with the regulatory framework. This does not indicate how the tasks are carried out in practice or how the arrangements are implemented;
2. The second compliance check {2-3}, to compare the actual work activities, the work results and the actual work situation against the documented management system. It assesses whether the work activities are carried out as prescribed in the management system documentation, whether the actual work situations exist as they are specified, and whether the outcomes of the activities are as anticipated;
3. The performance evaluation {3-1}, to assess how the activities and related results meet the regulatory requirements and expectations. Indeed, relying on simple compliance checks is insufficient for regulatory oversight of HOF. It is also necessary to understand how things

are really done, what works or does not work in the actual work situation and why the specified performance outcomes are achieved or not.

The compliance and evaluation activities of HOF are part of the regulatory body's oversight activities. It may be planned or reactive. The compliance assessment of the documented management system against the regulatory framework may be conducted as a desktop review. However, a performance evaluation of the actual work activities measured within the regulatory framework and the licensee's management system needs to be carried out at the installation.

3.3. REGULATORY OVERSIGHT MODEL

3.3.1. General

The regulatory oversight model, illustrated by Figure 3, describes a continuous process including planning and performing regulatory oversight activities. The process includes a detailed, organized and integrated assessment of information, obtained through various oversight activities, to provide an overview of HOF consideration, based on identified trends and early signs of weaknesses so that conclusions about licensee's safety performance can be drawn.

The oversight of HOF falls under the general regulatory oversight process. The HOF oversight deals with relevant information to promote improvements in managing HOF, to enhance human performance at work, and to improve the effectiveness of the management system of the licensee.

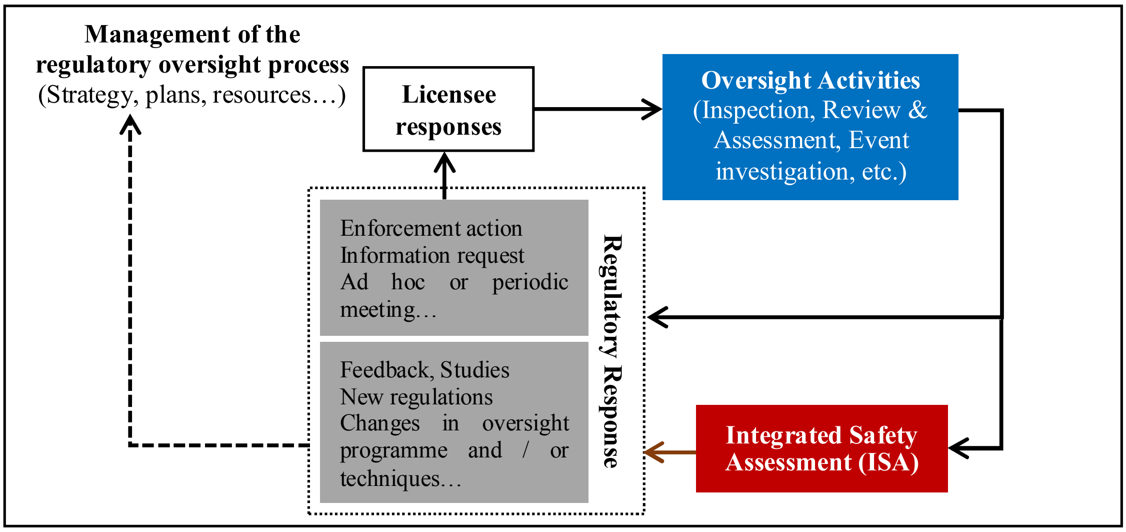

FIG. 3. Regulatory Oversight Model.

The regulatory oversight model comprises the following components:

- Management of the regulatory oversight process, which applies to and controls every aspect of the process;
- Oversight activities, which include inspections, reviews, assessments, as well as any other activity relevant to exercising oversight. The output of those activities may drive short term regulatory responses or actions, and are also inputs to the integrated safety assessment;

- Integrated Safety Assessment (ISA), which receives the inputs from various oversight activities and provides a more holistic, and typically longer term, assessment of the overall organization's performance;
- Regulatory responses and actions, which may be triggered by regulatory activities or by ISA;
- Licensee responses, which includes responses that the licensee will make as a result of the regulatory responses and actions.

These components are detailed in the next sections.

3.3.2. Management of the regulatory oversight process

The 'Management of the regulatory oversight process' covers: the strategy, plans, procedures, resources, schedule, tools and assessment methods of the regulatory body. The oversight includes both planned and ad hoc activities. To prepare for the HOF-related oversight activities, the regulatory body deals with two types of situations:

- Regular or planned (e.g. annual, safety case) oversight activities;
- Unexpected oversight activities to perform additional inspections or analyses in response to a specific problem or event which needs to be added to the regulatory oversight plan.

The strategy, focus, plan and schedule of oversight are updated periodically or as needed, based on the safety performance of the installations.

3.3.3. Oversight activities

The regulatory body conducts oversight activities according to the framework described in the section 'Management of the regulatory oversight process.' Information from inspections, review and assessment, event reporting and periodic reporting is assessed against the regulatory framework to determine compliance.

The output of this stage can be a series of compliance checks. It can also be the result of reviews and studies. In cases of non-compliance with regulatory requirements, the regulatory body defines the required regulatory action to address the issue (see GSR Part 1 (Rev. 1) [5] para 4.57). Evaluation of findings involves two parts:

- Compliance assessment, where the regulatory body understands the findings and verifies the compliance of the findings against the regulatory requirements to identify the non-compliances;
- A risk-informed and graded approach, which can be used to determine, based on their safety significance, those non-compliances to which the regulatory body responds immediately. Non-compliances and information can be retained to be used in the ISA.

To assist in evaluating the outcome of the regulatory activities, the regulatory body has to develop an analysis process. This process will include methods, guidelines and criteria to determine the appropriate regulatory response.

Some issues cannot be properly addressed solely through checking for non-compliance. Therefore, there is the need for collecting information over time and assessing it periodically, to identify trends, repeated occurrences and connections between the information that are of interest to the regulatory body. This is particularly useful for HOF considerations because it enables a systemic overview of a wide range of information. It also includes observations that can provide weak signals of problems even if, by themselves, they do not yet represent non-compliances but that may lead, if left unchecked, to gaps in the future. This type of information is normally used to perform for an ISA.

Appendix III describes techniques that could be used for gathering HOF-related information. The following sections discuss various oversight activities such as inspections, reviews and assessments, event analysis and thematic assessments.

3.3.3.1. Inspections

Regulatory inspections are important to gain insight into what occurs at the nuclear installation site, to formally collect observations and other information related to HOF and how they are considered in day-to-day activities on site. GS-G-1.3 [18] recommends: "4.17. The inspection programme of the regulatory body should include provision for direct monitoring of activities concerning SSCs, human factors significant to safety (performance of operating personnel, managerial attitudes), tests and other safety-related activities carried out by the operating organization." The collection of HOF-related data during inspections can use three main approaches, described as follows:

- Inspections related to the management system of the licensee can focus either on the entire system, i.e., several processes and their interactions, or be an in-depth review of a single safety-related process, such as maintenance, modifications, operating experience (OPEX), or emergency preparedness. These in-depth inspections are better performed by a multidisciplinary inspection team. Expertise in both HOF and the management system needs to be available in the team. As described in section 3.2 the management system is an essential consideration in the regulatory oversight of HOF;
- Inspections specifically dedicated to HOF, which aim to verify work carried out at the installation and how the licensee considers HOF, including improvement actions. These in-depth inspections need to involve HOF specialists;
- Other inspections, including those dedicated solely to the technology, can be valuable sources of HOF-related information. During these inspections, additional HOF-related information can be collected such as the accessibility of equipment, documents, tools used to conduct activities, competencies, communication and the presence of supervisors in the field. The advantages of this approach are that HOF-related information can be collected across the broad range of inspections. Inspectors can apply this approach, and the repeated, ongoing collection of information provides a considerable amount of data over time, which can be trended and analysed. Techniques for continually monitoring HOF during on-site inspections are presented in Appendix III.

Developing HOF inspection guides is an effective way to support inspectors especially in HOF area. The inspection guides (a description is provided in Appendix IV) facilitate the work of the inspectors and other regulatory body staff and help to systematize the inspections. A human and organizational factor (e.g. mental workload, legibility) is seldom inspected in isolation as numerous HOF affect the successful completion of tasks. A good way is to create inspection guides used for areas of oversight where HOF play an important role. Those areas often include:

- Procedures (operation, emergency, maintenance, etc.);
- Engineering design (especially for design projects that involve equipment that will be adjusted, maintained, operated);
- Minimum shift complement;
- Hours of work limits.

It is also possible to create combined inspection guides that can be used for HOF and other disciplines (e.g. management systems) when carrying out integrated or common inspections.

3.3.3.2. Review and assessment

Reviews and assessments are performed over the lifetime of nuclear installations. Requirement 25 of GSR Part 1 (Rev. 1) [5] states: "The regulatory body shall review and assess relevant information – whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere – to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization…" Reviews and assessments normally involve looking at three main types of document:

- Required submissions and reports by the licensee, which contain information pertaining to the conduct of licensed activities and facility status. These include: detailed event reports, studies, design reports, safety analyses, periodic performance reports, reports associated with the Periodic Safety Reviews, safety analysis reports and correspondence, self-assessments and safety performance indicators presented by the licensee;
- Documents from the licensee's management system, relevant to HOF considerations. These include policies and processes related to the management of the organization and its personnel, design processes, design guides, procedures for maintenance, operations and emergencies and action plans. The management system documentation describes how tasks are to be performed, provides expectations for what people are supposed to do, and contains requirements with which people has to comply when carrying out their work;
- Records and information, such as departmental plans, various types of reports (including non-reportable event records and analysis reports and internal audit reports), event trending summaries, training records, the results of licensee surveys, newsletters, meeting agendas and minutes, calibration records, maintenance records, verification and validation records for new or modified SSCs and changes in staffing.

The first step of any review and assessment activity is to determine the scope and goals of the review, the range of HOF to be considered, the criteria used for the assessment, the methods for quality assurance for the review and the composition of the team to carry out the work. It is essential that the review and assessment be performed by personnel with sufficient HOF competencies. The review and assessment can be conducted by individuals or by multidisciplinary teams.

Review and assessment of the documents involve an evaluation of the content's completeness, relevance and quality in order to identify whether the documents contain all required information and data for the regulatory body to perform the planned scope and depth of the review and assessment. If further information is needed, it is requested from the licensee.

The analysis of information needs to consider the strength and applicability of the rationale and justification of the statements and claims made by the licensee concerning HOF. The review of the documents may identify topics that are absent or insufficiently covered, the methodology used previously was not appropriate, or there was a lack of justification about processes and provisions. If further information or clarification is needed during the review and assessment, they are requested from the licensee.

3.3.3.3. Event analysis

Event analysis consists of identifying the causes leading to an event. As most events have HOF-related causes, a well carried out event analysis identifies the HOF involved in an event, thus enabling the licensee to explain the occurrence of the event and to prevent its recurrence. The regulatory body needs to develop its capability to consider HOF aspects of event analyses. Oversight related to event analyses includes the review, by the regulatory body, of the licensee's event analysis reports, as well as the independent event analyses performed by the regulatory body, in certain circumstances.

GS-G-3.5 [8] states that "2.36. When analysing events, consideration should be given to the possible influence of all these factors on human behaviour. These factors should also be considered when the purpose is to identify potential weaknesses in the interactions between individuals–technology–organization and to determine how to strengthen barriers or introduce new barriers to prevent human error. Ideally, interdisciplinary teams should carry out predictive and preventive analyses of these types of events. Such teams should include human behaviour competence, to analyse the individuals–technology–organization interactions from different perspectives to identify suitable barrier functions."[10]

The main aspects to which the regulatory body needs to pay attention are:

- Competencies of the licensee's analysis team concerning HOF and event analysis;
- Sufficient focus on relevant HOF for the event;
- The sufficiency of depth and completeness of the analysis, depending on actual or potential safety consequences of the event;
- Root causes concerning HOF, which need to go beyond the simple statement of human error;
- Schedules and resources devoted to carrying out the proposed corrective actions;
- Effectiveness of the corrective actions related to HOF.

The review of an event analysis report enables the regulatory body to draw conclusions about:

- The quality of the event analysis process of the licensee;
- Deficiencies in the way that the event analysis has considered HOF;
- Openness of the licensee towards the regulatory body;
- The commitment of management to organizational learning and to considerations of HOF;
- Deficiencies in the licensee's management system;
- Deficiencies related to the HOF elements (see 5 categories in section 3).

Event analysis is an important opportunity for the licensee to understand and improve HOF capabilities.

3.3.3.4. Thematic assessments

Thematic assessments can provide a more complete overview of HOF considerations, or can address a single topic or issue in greater depth than routine regulatory approaches allow. The regulatory body may decide to conduct a thematic assessment to address a specific topic or issue that requires more resources and time than for routine inspections, reviews and assessments or where specific HOF-related expertise is needed. Various HOF topics can be considered, such as safety management, OPEX, new plant design and management of competencies.

The regulatory body may contract external experts (e.g. TSO, consultants, research institutes) to perform research studies, or evaluations at the nuclear facility, and to obtain specific information concerning HOF. External experts may have specialized and extensive HOF-related knowledge of the topic of interest, which may not exist within the regulatory body. An external expert may be perceived as more neutral than the regulatory body, so that licensee personnel may show more openness to providing information. Openness may also be enhanced by confidentiality agreements, e.g. only aggregated, condensed or summarized information will be delivered to the regulatory body.

Two examples of thematic assessments are presented in Annex A.

[10] The concept of the 'Human, Technology and Organization' (HTO) is alluded to in section 2. Some publications state this same concept as the "Individual, Technology and Organization," where this is equivalent to HTO.

3.3.4. Integrated safety assessment

ISA is to be part of the overall regulatory review and assessment process. ISA is a specific approach to gather and integrate a wide range of HOF-related positive and negative information from the oversight activities (e.g. findings). It aims at identifying trends and early signs of weaknesses so that conclusions about the licensee's safety performance related to HOF can be drawn.

Requirement 26 of GSR Part 1 (Rev. 1) [5] states in para 4.46: "For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating installations, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach." GS-G-3.5 [8] states in para 6.54: "Trending should be used to identify categories of issues such as those associated with procedures, human performance and equipment. Trend coding can be used to assist in trend analysis, provided that it is applied consistently and in the knowledge that the number of trend codes is limited."

There are three stages in the ISA process:

1. **Information gathering:** The relevant information related to HOF that may be considered in the ISA, needs to be specified to collect and organize them. The results of the ISA depend highly on the input information, much of which can be provided by inspectors.

   To ensure that the ISA is effective, inspectors are to be encouraged to continuously collect and share HOF-related information. They need also be trained to use HOF-related data collection techniques (see Appendixes III and V). To make optimal use of the data collection and information gathering process, it is necessary to organize the HOF-related information as they are collected. It can be organized according to safety significance and coded, based on a suitable categorization (e.g. the three HOF categories mentioned earlier) or using the IRS coding[11] proposed by Appendix C of the IRS Guidelines [19] to facilitate information retrieval. This enables information from across the entire spectrum of HOF to be recorded and maintained in a database. An example of HOF oversight data gathering is provided in Appendix V.

2. **Assessment:** Information gathered across the entire range of regulatory topics and methods is assessed to identify trends, problems and conclusions regarding HOF-related issues. The assessment can be accomplished in different ways, but often starts at a broad level (e.g. the categories of HOF) with additional consideration of the more detailed HOF topics as well. Several views of the inter-relationships within the data are also examined, e.g. at the broad level of the HOF categories for the key domains in the regulatory framework related to HOF, such as HFE. This enables the patterns and influences within the data to be analysed in a systemic manner.

   Applying this systemic approach requires sufficient time to assess the information. Licensees may challenge the regulatory body's conclusions concerning HOF. However, gathering and assessing a broad range of information from oversight activities in conducting an ISA enables the regulatory body to draw robust conclusions, based on hard facts and converging evidence. HOF specialists have to be involved in the ISA because their specialized knowledge and expertise is normally required. Multidisciplinary assessments and discussions with colleagues are also necessary to understand the information inputs so that they can be properly coded.

[11] International Reporting System for Operating Experience

The assessment includes the review of trends and conclusions from previous ISAs and it is expected to check the effectiveness of the corrective actions carried out by the licensee. The effectiveness of previous regulatory responses to the licensee's corrective actions identified and continual improvements are also to be assessed. The conclusions aim at steering the oversight programme to initiate, adjust or set priorities for regulatory activities (e.g. planning inspections, focusing on specific topics).

3. **Reporting:** It is necessary to document all relevant results of the assessment to provide:
   - Details of the specific oversight activities that provided data for the ISA;
   - Descriptions of issues identified, including positive and negative performance;
   - Identification of the most significant issues;
   - Conclusions on the effectiveness of the licensee's previous corrective actions;
   - Conclusions on the effectiveness of previous regulatory oversight and responses;
   - Changes, trends and conclusions concerning HOF, including any relationships with technical regulatory domains;
   - Information to support the conclusions;
   - Recommendations for regulatory responses.

Appendix VI provides an integrated safety assessment case study.

3.3.5. Regulatory response

The objective of the regulatory response is to achieve an effective and sustainable change towards a desired outcome, to ensure compliance and improve safety through an improved consideration of HOF. Based on the results from its compliance assessment and evaluation, the regulatory body determines the appropriate level of response as stated by Requirement 26 of GSR Part 1 (Rev. 1) [5] in para "4.48. The regulatory body shall record the results and decisions deriving from reviews and assessments, and shall take appropriate action (including enforcement action) as necessary. The results of reviews and assessments shall be used as feedback information for the regulatory process."

There are three main types of regulatory responses directed towards the licensees:

- Enforcement actions;
- Requests for additional information for further regulatory assessment to gain understanding of an issue;
- Scheduling meetings with the licensee to discuss safety-related issues.

The objective of an enforcement action is to require a licensee to remedy non-compliances within a reasonable time period, to prevent their recurrence (see GSR Part 1 (Rev. 1) [5], 4.57). As stated in GSR Part 1 (Rev. 1) [5]: "4.55. Enforcement actions may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization. Regulatory enforcement may also entail prosecution, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance."

In addition, as stated in para 4.54 of GSR Part 1 (Rev. 1) [5] "The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach." The regulatory response considers other elements, such as the repetition of non-compliances, which may result in increasingly stringent enforcement action.

The way that the enforcement tools are used can have a significant impact on the relationship and liaison between the regulatory body and the licensees, especially if used inappropriately or unfairly. This has to be kept in mind when the regulatory body establishes and implements its enforcement policy, while still ensuring compliance with legislation and regulations to fulfil its legal responsibilities. It is vital to explain the rationale for any regulatory decision to ensure a mutual understanding between the licensee and the regulator of the HOF-related issue.

Responses directed internally to the regulatory body include future considerations of specific topics or issues, and improvements to the regulatory oversight programme, including:

- Additional inspections, reviews or studies to address specific issues and gaps;
- Specific consideration of key topics or issues in the future conduct of oversight activities;
- Changes to the regulatory strategy and priorities, both short term and long term;
- Changes to the planned regulatory oversight activities, e.g. resource allocation;
- Issue or revision of regulations and guides;
- Modification of the regulatory oversight methods and topics, tool development, training;
- Modifications to the ISA, such as the scope, frequency of data collection, information gathering methods, coding and analysis methods.

Another aspect of HOF oversight is that data and outcomes may concern individuals or groups of people. This may involve sensitive information and thus requires specific provisions for confidentiality. Therefore, while maintaining the independence of the regulatory body, it is important to develop a mutual understanding between the regulatory body and the licensee through a constructive and professional liaison, as specified by Requirement 21 of GSR Part 1 (Rev. 1) [5]: "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."

The key elements of the constructive liaison with the licensee are:

- Encouraging a clear and strong licensee senior management commitment to improve safety through HOF enhancements. This requires a clear communication of the strategy of the regulatory body for overseeing HOF;
- Developing a common understanding of the importance of HOF and its contribution to safety performance between the regulatory body and the licensee at all levels of the organization. This can be achieved through participation in joint training courses, workshops, and technical meetings;
- Seeking mutual understanding with the licensee on facts and evidence collected through different channels, including inspections and through discussions. It is important to demonstrate the reliability of the collected information and findings. This understanding will be facilitated by communicating any further information and explanations, constructively and transparently and focusing on areas for improvement. The credibility of the regulatory body's HOF resources will contribute strongly to this understanding;
- Giving feedback to the licensee about HOF activities carried out by the regulatory body as part of the ISA, as well as in day-to-day regulatory activities. This feedback is provided to different levels of the licensee's organization, depending on the safety significance of the findings;
- Discussing continuous improvement about HOF-related issues with the licensee. The licensee has to identify the specific problem-resolution approaches related to the regulatory conclusions concerning HOF. The regulatory body has to follow-up on the implementation of the actions to check their effectiveness. Feedback is to be given to the licensee about the sufficiency and effectiveness of its improvement programme.

A key means to ensure a constructive dialogue is to have regular meetings to discuss the results of regulatory oversight, such as the ISAs or to discuss the progress on current corrective actions. Non-routine meetings can also be arranged:

– In relation to issues that arise, such as changes proposed by the licensee in staffing, shift-work or the organization;
– To promote good practices and to share national or international experiences;
– To present and discuss changes to the regulatory framework and approaches This may include providing information about proposed or new regulations or guidance, or changes to regulatory processes and approaches, such as requirements for reporting, or organizational changes in the regulatory body.

Relevant information arising from meetings has to be recorded. Other information shared in the form of presentations and other documents provided by the licensee, as well as meeting notes taken by the staff of the regulatory body, can be valuable for further use by the regulatory body, such as for the next new ISA.

3.3.6. Licensee responses

To maintain the independence of the regulator, the licensee is always accountable to propose corrective actions to address the issues raised by the regulatory body.

The effectiveness of a licensee response needs to be followed up or even controlled in the subsequent oversight stages. In this regard, Requirement 31 of GSR Part 1 (Rev. 1) [5] states in para 4.56 that: "At each significant step in the enforcement process, the regulatory body shall identify and document the nature of non-compliances and the period of time allowed for correcting them, and shall communicate this information in writing to the authorized party."

To ensure its sustainability, the licensee's response needs to be reflected as appropriate within the licensee's management system. The lessons learned from this step need to be fed back to the licensee and the regulatory body through a continuous improvement loop.

4. DEVELOPING REGULATORY OVERSIGHT OF OF HUMAN AND ORGANIZATIONAL FACTORS

4.1. CHALLENGES

HOF have become more important to safety because the context in which nuclear installations operate has been changing. This change is due to higher safety level expectations, a higher competitive market, long term operation and communications pressure. It is thus necessary for a regulatory body to develop its capabilities to oversee HOF and to consider changing or adapting its own organization, for example, by establishing a HOF-dedicated team or making other provisions to consider HOF in its regulatory activities.

Developing and implementing regulatory HOF oversight activities requires time, effort and resources, especially at an early stage when the regulatory capabilities in this area are limited. It is important that these oversight activities be integrated into the overall regulatory programme. Several challenges could be encountered by the regulatory body to achieve this integration, including:
– The culture of the regulatory body may be biased towards technology at the expense of HOF, due to beliefs that the robustness and quality of technology are sufficient to protect the safety of nuclear installations against risks;
– Resistance to change at all levels of the organization in considering HOF, in a systematic manner, for safety oversight. Consideration of HOF could impact the organization's functions, and its way of working and managing regulatory activities. This could call managerial practices into question, leading, in turn, to resistance to change;
– A lack of understanding or misconceptions about HOF, making it difficult to identify and achieve goals;

- Limitation of resources. Defining and implementing HOF regulatory activities will require resources and expertise, which may be found internally (through reallocation of resources), externally or both. The content and scope of the oversight activities and programme is to be realistic considering the resources and expected competencies available for HOF;
- The relationship between regulatory bodies and licensees based only on enforcement practices without real constructive and professional dialogue on a deeper level and a mutual understanding of safety is not conducive to effective HOF oversight;
- A framework for the regulatory oversight of HOF is not in place, or shortcomings in regulatory requirements, guides, process, tools and criteria regarding HOF. Some framework pieces may exist to address certain aspects of HOF but are usually scattered, fragmented and too general.

These challenges are sources of potential failure for establishing an effective regulatory HOF oversight. They need to be anticipated and carefully addressed, for example through the development and implementation of a dedicated project. Defining and implementing the necessary HOF oversight infrastructure, as well as successfully dealing with the previous challenges, will allow the regulatory body to discharge its responsibilities effectively and efficiently.

4.2. SENIOR MANAGEMENT COMMITMENT

Requirement 2 of GSR Part 2 [6] states "3.1 The senior management of the organization shall demonstrate leadership for safety by: (a) Establishing, advocating and adhering to an organizational approach to safety that stipulates that, as an overriding priority, issues relating to protection and safety receive the attention warranted by their significance; (b) Acknowledging that safety encompasses interactions between people, technology and the organization…"

It is essential that the senior management of the regulatory body supports the project for establishing, implementing, promoting and sustaining a successful HOF oversight programme. Visible senior management engagement is vital to overcome the challenges listed in section 4.1. Key commitments required from senior management are:

- Foster a positive attitude towards HOF within the organization;
- Openly promote the regulatory oversight of HOF and communicate that message on a regular basis;
- Endorse the goals and objectives associated with the project;
- Allocate adequate resources to the project;
- When endorsed, support and follow-up on the project's implementation;
- Assess the progress and make decisions to resolve problems hindering the successful implementation;
- Ensure internal, and if applicable, external cooperation within the organization.

4.3. MANAGEMENT

4.3.1. Responsibilities

Because of the cross-cutting nature of HOF oversight, the project of developing regulatory oversight of HOF needs to be managed by a senior manager who will be accountable and have the appropriate authority and responsibility for the entire project. She/he reports regularly to senior management about the progress made, difficulties faced, and discussions of future steps, including upcoming senior management involvement.

4.3.2. Management system

Requirement 6 of GSR Part 2 [6] states "(4.8.) The management system shall be developed, applied and continuously improved. It shall be aligned with the safety goals of the organization." Likewise "(4.13.) Provision shall be made in the management system to identify any changes (including organizational changes and the cumulative effects of minor changes) that could have significant implications for safety and to ensure that they are appropriately analysed."

The project and the HOF regulatory oversight programme have to be covered by the management system to ensure their regular assessment and the application of lessons learned. The oversight techniques, including data collection specifically related to HOF, need to be documented to ensure consistency of approaches in the regulatory activities conducted by different individuals and for different installations.

Any organizational or managerial change has to be effectively managed and, when appropriate, reflected in changes to the management system of the regulatory body.

4.3.3. Communication

Communication is an important component of any successful project. It can prevent misunderstandings and mitigate problems, including those related to culture, management and organizational changes. Communication is initiated as soon as possible, at the latest when establishing the project management team. Communication is addressed through the project plan and covers relations with external organizations which support or are expected to support the regulatory oversight of HOF. It is important to identify the communication goals and objectives, the communication mechanisms, the responsibilities for communication in the project plan, as well as the milestone events to be communicated.

Communication means meaningful two-way interactions and exchange of information between key parties, with fair and reasonable opportunities to discuss their views [20]. The project team needs to listen and understand the concerns, issues and questions raised and address them in a manner that is responsible and transparent.

The regulatory body's staff and licensees are two key target groups:

1. Regulatory staff - They are to be included in interactive communications. An awareness campaign on HOF is one of the first steps for developing a common understanding of HOF while eliminating misconceptions, especially among the managers at all levels of the organization (See section 2.9). It is important to keep the staff informed about the progress of the project. The communication of the goals and objectives, endorsed by the senior management, will give a clear direction to the whole organization. Managers, especially those having direct responsibility to regulate safety, constitute the first communication target group. They will eventually be responsible for implementing the HOF oversight programme and for introducing necessary changes in the overall oversight system. Beyond the proper consideration of HOF in their own team, the managers will help to ensure good communication and interactions between the different parts of the organization. Relations between people or even between departments may be difficult because of different backgrounds and sometimes even culture. Misunderstandings may happen between technical staff and HOF specialists. Yet, effective cooperation is critical since the HOF oversight is multidisciplinary and requires true collaboration between all staff across the organization. Specific attention is to be paid to the direct contributors overseeing HOF, such as the inspectors and reviewers.
2. Licensee - The regulatory body needs to inform the licensee about its intentions regarding HOF oversight. There needs to be constructive dialogue between the regulatory body and the licensee throughout the project and beyond. The main aim of this constructive liaison

is to foster a mutual understanding about HOF and its place in all safety-related activities. At an early stage in the project, a meeting has to be organized to share background information and discuss the establishment of a licensee's programme, to ensure the suitable consideration of HOF and their contribution to safety.

4.4. STAFFING AND COMPETENCIES

4.4.1. Competencies and resources

Appropriate resources and competencies are necessary to properly develop and to ensure effective regulatory oversight of HOF. Requirement 9 of GSR Part 2 [6] states: "4.21. Senior management shall make arrangements to ensure that the organization has in-house, or maintains access to, the full range of competences and the resources necessary to conduct its activities and to discharge its responsibilities for ensuring safety at each stage in the lifetime of the facility or activity, and during an emergency response."

The development of competencies in HOF is a priority, given the specifications of the topic and the frequently limited competencies available in the regulatory body. The purpose of a project plan is to ensure coherence between competency development and other project activities. Competencies have to be acquired progressively, in accordance with and to support the project progress using opportunities at national or international levels. Several years may be needed for a staff member to acquire the level of specialized competence required. Further, HOF specialists need also to be fluent in the terminology used in the nuclear domain to facilitate cooperation within the organizations.

The project manager is normally supported by a multidisciplinary project team. Its composition is determined, based on the HOF oversight objectives, available resources, competencies and maturity of the regulatory body with respect to HOF. The project team members need to be provided with relevant training for the team to have the adequate competencies. Other required support is to be identified and, when necessary, solicited by the project team.

It is advisable to identify existing staff members interested in HOF, as they can often offer support for the project design and its implementation, and can help to resolve cultural and organizational resistance. These interested staff will represent key players who provide feedback and experience for the successful implementation of the entire project.

As described in Table 1, the HOF-related competence to be expected for different positions within the regulatory body might be categorized into four levels:

1. Elementary: General sensitization about HOF and their key importance to safety;
2. Basic: General competence about the key aspects of the HOF approach and how the regulatory body oversees them, including the key features of an oversight programme;
3. Medium: Sufficient competence, including good understanding of regulatory policies and requirements as well as supporting safety guides, to conduct routine activities, including:
    - Capability to use tools and guidance, e.g. for collecting, analysing and making recommendations about HOF-related data;
    - Overall evaluation of HOF contributors to reported events;
    - Contribution for drafting regulations and safety guides;
    - Sufficient expertise to evaluate support provided by external experts.
4. High: Competence required to carry out detailed analysis (e.g. detailed event analysis, review and assessment of safety analysis reports, ISAs), and to conduct HOF-focused inspections. For this level of competence, the regulatory body may decide to request external support.

TABLE 1. MINIMUM LEVEL OF COMPETENCE ACCORDING TO THE REGULATORY STAFF ROLE

	Competence level	1. Elementary	2. Basic	3. Medium	4. High
Typical Roles	***Senior manager***	*X*	*X*		
	Technical line manager	*X*	*X*	*X*	
	HOF specialist	*X*	*X*	*X*	*X*
	Non-HOF reviewer	*X*	*X*		
	Inspector	*X*	*X*	*X*	
	Legal expert	*X*			
	Other staff	*When relevant*			
Examples of means for capacity building		Communication campaign	Training and refresher courses	Training programme, including on-job trainings Practical experience	Training and Education programme (advance degree) Practical experience

There are specific competencies required for using HOF-related methods and techniques (e.g. interviews, observations, assessments, analysis). Therefore, a sufficient background and experience in human and social sciences is desirable.

4.4.2. External support

Requirement 20 of GSR Part 1 (Rev. 1) [5] states "The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities."

In the area of HOF, external experts (e.g. TSO, consultants or universities) are sometimes needed. An advantage to using them is that they may have specialized and extensive HOF-related knowledge which might not exist within the regulatory body. On the other hand, some external experts, such as consultants or universities, might not have enough knowledge of the licensee's organization, or the relevant competencies required in nuclear technology, to provide useful information and analysis. Also, external experts might not understand the regulatory policies and approaches, or responsibilities and regulatory constraints, to provide useful results for the regulatory body.

External experts can be used to develop the regulatory competence in specific areas and, where relevant, support the regulatory HOF oversight programme itself. However, the level of involvement of the external experts to oversee HOF has to be relevant and clearly defined.

Whatever the level of involvement of external experts, "the regulatory body should maintain its status as an 'intelligent customer' for all work carried out on its behalf by external experts" as expressed in para 4.6 of GSG-4 [21]. The regulatory body needs to have sufficient expertise in-house, to provide adequate management, supervision, oversight and evaluation of the work of the provider of external expert support.

4.4.3. Organization

Requirement 16 of GSR Part 1 (Rev. 1) [5] states that: "The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities."

The regulatory body may need to adapt its organization, to maximize the best use of its resources, and to improve its performance for overseeing HOF. Some regulatory bodies have established a dedicated team specialized in HOF and other directly-related issues, such as the management of safety and the assessment of safety culture. Others have allocated experts to already established groups within their organization.

It may be necessary to carry out a needs analysis to determine the support needed for HOF in the regulatory body, and to determine if a change to the organization's functions is warranted. The implementation of this change follows the provisions of the change management process as part of the management system, to assure that any new organizational function will be understood and accepted by staff, and will contribute positively to the organization. Provisions are to be made to improve the integration of the regulatory oversight of HOF in regulatory activities.

4.5. PROJECT PLAN DEVELOPMENT

The development of HOF oversight capabilities may take several years. It will be stepwise and build on its successes and failures over time.

4.5.1. Taking stock of the current situation

The first step for developing HOF oversight capabilities is to determine the current situation regarding the oversight of HOF. The evaluation of the current situation needs to cover:

- Available competencies[12] and resources;
- Regulatory framework: regulations, guides and standards in place;
- Internal arrangements and associated support (database, guidance, procedures);
- Possible external support for the regulatory body;
- Activities already conducted by the licensee for dealing with HOF;
- The existing regulatory experience and previously identified critical HOF issues.

4.5.2. Goals and objectives

In line with the overall goals, senior management has to determine specific goals to be achieved during a specified period of time (usually years) to oversee HOF. These goals and associated priorities are determined by considering the current situation and anticipated demands, e.g.:

- Licensing for a new nuclear installation or the renewal of a license, or a periodic safety review;
- Transition from one stage of a lifetime of a nuclear installation to another (e.g. operation to decommissioning);
- External demands, such as the need to provide the public or government with responses to specific issues.

Resulting goals could be:

- Encouraging the licensee to progress in area of HOF;
- Examining a HOF topic more in-depth, with respect to a specific safety concern;
- Getting a more comprehensive picture of HOF considerations for a specific licensee process (e.g. operation, maintenance);
- Showing and demonstrating the feasibility and importance of HOF considerations to the licensee, (e.g. when performing root cause analyses of events).

The HOF oversight goals are to be converted into practical objectives within a project plan. It is important to include in the project plan a realistic timetable as well as the needed resources and responsibilities. Annex B provides an example project plan. The project plan addresses:

[12] The management of regulatory competencies are guided by the IAEA Safety Reports Series No.79 Managing Regulatory Body Competence [22], and the technical Report, IAEA-TECDOC-1757, Methodology for Systematic Assessment of Regulatory Competence Needs [23].

- Internal and external competence and resources. A critical aspect of the project is the ability to build capacity as required by the project. Throughout the project, the available competencies and resources have to be sufficient for at least the short term objectives;
- Organizational change of the regulatory body. It may be decided to re-organize and allocate resources dedicated to HOF by establishing, e.g. a team dedicated to HOF as cross-cutting resource and support within the regulatory body;
- Communication activities and liaison with the licensees: An ongoing activity which starts at an early stage of the project;
- Regulatory framework (cf. section 3). Appropriate regulatory objectives have to be in place. They could be adjusted and completed over time when necessary;
- Internal arrangements and associated support. Guidance and tools are to be prepared on time with the support of competent staff and the involvement of the users, to facilitate the examination of the HOF area in an efficient way. For example, there could be a need to develop check-lists, templates or other aids to assist inspectors during inspections;
- HOF oversight topics. The oversight topics are to be based on the established goals, the existing regulatory experience and any pre-identified critical HOF issues. These topics will be normally covered by the regulatory framework;
- Methods of oversight. For each selected topic, the regulatory body identifies the relevant methods (see section 3) to be used in a complementary manner for effective oversight of the selected topic and to determine the actual performance of the licensee in its management of HOF for this particular topic.

For example, when a facility is to move to another stage of its lifetime (e.g. from construction to commissioning and then operation) the licensee has to ensure that a high level of safety is achieved through the effective management and control of necessary changes of its organization. The regulatory body is to oversee those changes. That includes among others, the management of competence by the licensee through its training and qualification process. In this case, the regulatory body wants to be sure the personnel are suitably qualified and competent to be able to adapt to the transitional state and the future stage of the lifetime of the facility. For this purpose, it may review and assess the adequacy of the licensee’s training process and organization, and the documented results of the training (e.g. certificates). This can be complemented with insights on inspections to verify if, for example, employees are able to explain a process within their area of expertise, or whether other employees explain the same process differently, disagree or have difficulties finding relevant documents.

4.6. PROJECT IMPLEMENTATION AND FOLLOW-UP

Adequate resources are to be available for the proper implementation of the plan. Competences need to be developed progressively and in line with the status of the plan’s implementation. In addition, specific guidance, such as inspection guides described in section 3.3.31, can be developed that contributes to a common understanding about HOF among the staff.

Regular communications with the relevant staff is crucial. Due consideration of their feedback will be beneficial to facilitate the plan’s implementation, and to maintain their motivation for the success of the project.

Regular discussions are to be held with licensees during and after learning periods to discuss areas for improvement. These discussions will provide opportunities to solicit and gather feedback from licensees to further improve HOF oversight. Similarly, constant dialogue with the appropriate external stakeholders is crucial for effective oversight of HOF. New regulations related to HOF need to be discussed with the licensee, keeping in mind that the final decision rests with the regulatory body.

For a new oversight activity, a pilot with a learning period of 6-12 months is suggested.

A limited set of performance indicators could be established to evaluate the project progresses and associated outcome, and will help making decisions related to the project.

4.7. PROJECT REVIEW AND IMPROVEMENT

Requirement 13 of GSR Part 2 [6] states: "The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance…" Therefore, the project is to be monitored and evaluated to identify successes, lessons to be learned and areas for potential improvements in all components of the project, e.g. regulations, activity management, oversight mechanisms and practical methods, competencies. To ensure that improvements lead to risk reduction, HOF oversight needs to be tailored in accordance with a graded approach.

Feedback from regulatory staff is encouraged. Feedback is also expected from the licensees as part of the constructive liaison between them and the regulatory body. Benchmarking with other national and international groups is encouraged. External reviews can also be conducted with support from other regulatory bodies, and will provide valuable inputs from their experience[13] [24].

[13] CNSC, the Canadian regulatory body, successfully organized an externally conducted review to gather feedback on the licensees' implementation of the guide 'G-323 Minimum Staff Complement'.

Appendix I

LIST OF HUMAN AND ORGANIZATIONAL FACTORS

It is rarely the case that individual HOF (e.g. workload, working memory) are assessed as part of the regulatory oversight. Rather, regulatory areas where HOF are especially important (e.g. operating procedures, design, minimum shift complement) are assessed from a HOF point of view. Table I.1. provides a subset of HOF (left column), grouped by the categories described in section 2. Table I.1. lists a few typical regulatory areas where they can be evaluated. The number of regulatory areas is normally substantially higher, and depends, to an extent, on the policies and practices of the regulatory body.

TABLE I.1. TYPICAL REGULATORY AREAS WHERE HOF CAN BE EVALUATED

Examples of regulatory areas of interest	**Procedures**	**Human Factors in Design**	**Minimum Shift Complement**	**Operating Experience**
1. Human-related factors				
Basic assumptions, values, ethics, attitudes				X
Limited capacity human working memory				X
Workload experienced (underload and overload)	X	X	X	X
Questioning attitude, complacency	X			X
Stress response effects	X	X	X	X
Team working, social skills	X		X	X
Communication skills	X		X	X
Qualifications, experience	X	X	X	
Competence, knowledge, familiarity with a task and the environment	X	X	X	X
Literacy, numeracy	X	X		X
Fitness for duty: Fatigue, illness, physical fitness, anxiety, stress, influence of drugs and alcohol	X		X	X
Physical characteristics: Anthropometry, reach, strength		X		X
Vision: visual acuity, colour vision	X	X		X
2. Technology-related factors				
Accessibility to hardware and its components e.g. maintenance		X		X
Hidden or transparent system response		X		X
Unexpected equipment conditions	X	X		X
Reliability of equipment		X		X
Error-recovery provisions in equipment and systems	X	X		X
Complexity, fragility, size of systems and equipment	X	X		X
User interface design and layout (control room)	X	X		X
User interface design and layout (field systems and equipment)	X	X		X
User interface design (tools)	X	X		X
Redundancy of indication	X	X		X
Out-of-service alarm and warning systems	X	X		X

TABLE I.1 (Cont.)

Examples of regulatory areas of interest	Procedures	Human Factors in Design	Minimum Shift Complement	Operating Experience
3. Organization-related factors				
Leadership and management for safety				X
Management system (mainly effectiveness)	X	X	X	X
Collective values, organizational culture,				X
Organizational structure, vertical and horizontal (e.g. for addressing cross-cutting projects within the organization)				X
Accountability, responsibility and authority (prescribed and perceived)				X
Level of involvement of individuals in decision making				X
Career planning, promotion system, types of contracts				X
Planning, timely provision and availability of resources in the context of the opportunities and constraints				X
Time pressure (perceived)	X		X	X
Time pressure (actual)	X		X	X
Production pressure			X	X
Rewards / incentives –just culture				X
Discipline / punishments				X
Management of process performance				X
Staffing provisions (sufficient qualified and competent staff)			X	X
Fitness for duty policy and its implementation			X	X
Knowledge retention				X
Staff retention				X
Management of personnel workload, availability of possible additional support			X	X
Clarity and coherence of objectives for individual and team			X	X
Information management and knowledge management				X
Management and supervision of activities, results evaluation and monitoring performance				X
Non-conformance reporting by personnel				X
Understanding and accommodation of individual work styles and competencies				X
Training and education, including refresher and enhancement, competence programs			X	X
Communication between shifts for operation, maintenance, fuel handling, security, stores etc.			X	X
Open and effective communication, cooperation and team working			X	X
Night shift, back shift or recent shift change			X	X
Peer pressure, group cohesiveness, trust among work group			X	X
Social interaction, working atmosphere			X	X
Arrangements in place to promote feedback from individuals on safety concerns			X	X
External forces (regulator, market, economy, political)				X

TABLE I.1 (Cont.)

Examples of regulatory areas of interest	Procedures	Human Factors in Design	Minimum Shift Complement	Operating Experience
Factors related to work environment and infrastructure				
Location of workplace	X	X		X
Dimensions and other features of workplace (e.g. sufficient space, confined working entry)		X		X
Distractions and interruptions		X		X
Task hazards and/or workplace characteristics: heat, cold, vibration, noise, chemical, radiation		X		X
Ambient temperature, lighting, noise, humidity, high winds, precipitation		X		X
Housekeeping				X
Facilities for workers: toilets, drinking water, locker rooms, etc.		X		X
Other ongoing activities in the surroundings				X
Factors related to tasks				
Task features: Sequences, idle time, excessive allocated time, length, complexity, repetitive, monotonous	X		X	X
Multiple and/or simultaneous tasks	X		X	X
Requirements and success criteria	X			X
Documents (Guidance, procedures, instructions, guides, notes, check-lists, plans, etc.): Accurate, relevant, usability, clear, appropriate, coherent, right level of details, availability, up-to-date	X			X
Availability and clarity of records and data: results from previous activities, measurement, operational parameters				X
Availability and quality of tools and supplies to be used		X		X
Level and frequency of reporting, administrative burden, paperwork				X
Number of individual required to perform the task			X	X
Use of personal protective equipment	X	X		X

Appendix II

EXAMPLES OF REGULATORY REQUIREMENTS

To develop regulatory requirements and guidance on HOF, an initial review of existing national regulations is important because HOF-related regulatory requirements and associated guidance are often found across several documents. For example, some work environment-related factors (e.g. heat, vibration, lighting, and noise) can be found in the regulations on occupational safety, whereas technology-related factors (e.g. engineering design of SSCs) can be covered by dedicated technical regulations for nuclear installations.

Further development of provisions, or revision of existing provisions, can profit from the application of the IAEA safety standards. The following main HOF topics provide an initial orientation:

- **Leadership and management for safety**: Leadership in safety matters has to be demonstrated at the highest levels in an organization (see SF-1 [2] para 3.12). Those requirements contain the expectations and demands on leaders, principles for effective leadership, how safety is taken into account in the decision making at different levels of the management, and the evaluation of the commitment regarding safety, etc. [6]. Managers are required to support and encourage trust, collaboration, consultation and communication in order to foster a culture for safety (see GSR Part 2 [6], para 5.2). Specific requirements include:
  - The licensee has to develop, apply and continuously improve a management system, aligned with the safety goals of the organization. Requirement 6 of GSR Part 2 [6] states "The management system shall integrate its elements, including safety, health, environmental, security, quality, human and organizational-factors, societal and economic elements, so that safety is not compromised." The management system is documented.
  - The licensee has to establish a process to evaluate regularly the effectiveness of its management system. This evaluation is based on independent assessments and self-assessments of the management system (see Requirement 13 of GSR Part 2 [6]).
- **Organizational structure, roles and responsibilities:** The licensee retains the prime responsibility for safety throughout the lifetime of facilities and activities, and this responsibility cannot be delegated (see SF-1 [2] para 3.5). The requirements on organizational structure, roles and responsibilities include establishing and documenting the structure of the operating organization and the functions, roles and responsibilities of its personnel (see SSR-2/2 (Rev. 1) [25], para 3.8). Specific requirements include:
  - The licensee has to establish and document the structure of the operating organization and the functions, roles and responsibilities of its personnel. Functional responsibilities, lines of authority, and lines of internal and external communication for the safe operation of a nuclear installation are clearly specified (see Requirement 6 of GSR Part 2 [6] and Requirement 1 of SSR-2/2 (Rev. 1) [25]).
- **Organizational Change**: Changes, that might be of importance to safety, including the cumulative effects of minor changes have to be managed by the licensee (see GSR Part 2 [6] para 4.13 and SSR-2/2 (Rev. 1) [25] para 3.9). Poorly managed changes may create unnecessarily large and prolonged uncertainties about future responsibilities and even job security among key technical staff [26]. Specific requirements include:
  - The licensee has to make and implement arrangements to identify any changes, including organizational changes and the cumulative effects of minor changes, that

could have significant implications for safety and to ensure that they are appropriately analysed (see Requirement 6 of GSR Part 2 [6]).

- **Management system**: The licensee has to develop, apply and continuously improve a management system, aligned with the safety goals of the organization. GSR Part 2 [6], GS-G-3.1 [27], and GS-G-3.5 [8] contain detailed requirements and recommendations.
  - **Documentation:** The documents and records of the management system are to be controlled, usable, readable, clearly identified and readily available at the point of use (see GSR Part 2 [6], Requirement 8; GS-G-3.5 [8], attribute (c), p. 104).
- **Operating experience**: The operating organization has to establish and implement a programme to report, collect, screen, analyse, trend, document and communicate OPEX at the plant in a systematic way (see SSR-2/2 (Rev. 1) [25] para 5.27). Part of this programme is a sub-process of notification of the regulatory body. Analysing HOF as contributors for events and near misses and learning from these events is important because it provides knowledge and opportunities to improve the design, the management and / or the operation and prevent (similar) future events (see NS-G-2.11 [28] para 2.3).
- **Human resources**: The operating organization is staffed with competent managers and sufficient qualified personnel for the safe operation of the plant (see SSR-2/2 (Rev. 1) [25] requirement 4) who are duly aware of the technical and administrative requirements for safety and are motivated to adopt a positive attitude to safety [29]. The operating organization ensures that all activities that may affect safety are performed by suitably qualified and competent persons (SSR-2/2 (Rev. 1) [25] requirement 7). This involves also assuring the competence of contractor personnel [30]. Specific requirements include:
  - **Staff recruitment and planning**: The qualifications and number of the personnel are adequate. The recruitment and selection policy of the operating organization are directed at retaining competent personnel to cover all aspects of safe operation. A long term staffing plan aligned to the long term objectives of the operating organization are developed in anticipation of the future needs of the operating organization for personnel and skills (see SSR-2/2 (Rev. 1) [25] para 3.11, 3.12).
  - **Qualification and training**: The management of the operating organization is responsible for defining the qualification and competence requirements, for identifying the need for training, for establishing a training programme for initial and continuing training including periodic confirmation of the competence and refresher training, etc. (see SSR-2/2 (Rev. 1) [25] para 4.16-4.24)
  - **Fitness for duty**: A staff health policy is instituted and maintained by the operating organization to ensure the fitness for duty of personnel carrying out any safety-related activities including management. Important issues are minimizing conditions causing stress, setting restrictions on overtime and requirements for rest breaks and prohibiting alcohol consumption and drug abuse (see SSR-2/2 (Rev. 1) [25] para 3.13).
  - The licensee ensures that all activities that may affect safety are performed by a sufficient number of suitably qualified and competent persons, fit for duty [25].
- **Human factors engineering (HFE)**: When designing human machine interfaces, e.g. control room panels and mobile devices, HFE and ergonomic considerations are to be implemented for both:
  - The design of a new installation (see SSR-2/1 (Rev. 1) [31] para 5.53-5.61);
  - Modifications of existing installations (see SSR-2/2 (Rev. 1) [25] para 4.40, 7.1, 7.9).

Using a structured HFE approach for the design of human-machine interface (HMI) supports effective and safe performance of operators. It supports the provision of clear displays and audible signals for those parameters that are important to safety (see NS-R-5 (Rev. 1) [32] para 6.15) and the anticipation of foreseeable human errors which have to be taken into account (see NS-R-5 (Rev. 1) [32] para 6.16). HFE involves analysing consequences of the design (modifications) on human tasks and performance.

Specific requirements include:

- Systematic consideration of human factors is included at an early stage in the design process for a nuclear installation and is continued throughout the lifetime of the nuclear installations (see Requirement 32 of SSR-2/1 (Rev. 1) [31]).
- Adequate arrangements are made and implemented, including in the design of installations to support personnel in the fulfilment of their responsibilities and in the performance of their tasks, and limit the likelihood and the effects of errors on safety (see Requirement 32 (5.55.) of SSR-2/1 (Rev. 1) [31]).
- Safety assessment submitted to the regulatory body addresses the human interactions with the facilities and it is determined whether the procedures and safety measures that are provided for all normal operational activities, in particular those that are necessary for implementation of the operational limits and conditions, and those that are required for responding to anticipated operational occurrences and to accident conditions, ensure an adequate level of safety (see Requirement 11 of GSR Part 4 [4]).

- **Procurement, supply chain and contractors**: The organization put into place arrangements with vendors, contractors and suppliers for specifying, monitoring and managing the supply to it of items, products and services that maintain safety (see GSR Part 2 [6], para 4.33-4.36). The organization has a clear understanding and knowledge of the product or service being supplied (i.e., being called the "informed customer capability" in GSR Part 2 [6] para 4.34 and further specified in NP-T-3.21 [33]). The management system includes arrangements for qualification, selection, evaluation, procurement and oversight of the supply chain (see GSR Part 2 [6] para 4.35).
- **Working conditions**: They significantly influence human performance at work. Licensee's senior management determines the resources (e.g. infrastructure, working environment, and material and financial resources) necessary to carry out the activities safely and provides them (see GSR Part 2 [6], req. 9). In GS-G-3.5 [9], good working conditions are specified, among others, as:
  - Optimal shift schedules (see GS-G-3.5 [9], attribute (g), p. 104);
  - Conducive physical working environment, e.g. provision of equipment and tools including response equipment, and guarding and signposting of hazards (see GS-G-3.5 [9], attribute (g), p. 104);
  - Addressing the individuals' needs with regard to the ergonomics and the effectiveness of their working environment (see GS-G-3.5 [9], attribute (g), p. 104);
  - Excellent housekeeping and material conditions (see GS-G-3.5 [9], attribute (i), p. 104, and SSR 2/2 [24] para 7.12).
  - The licensee makes and implements arrangements to identify and control aspects of the work environment and tasks to be undertaken by individuals that influence human performance and the effectiveness and fitness of personnel for duty [25].

Appendix III

TECHNIQUES THAT CAN BE USED FOR GATHERING DATA

This appendix describes techniques that are useful to collect HOF-related data when carrying out oversight activities (e.g. inspections, reviews and assessments). The appendix draws attention also to specific information to be considered when those techniques are used.

At times, HOF might be considered subjective, as information might have been derived from data gathered through interviews and observations. While different techniques are often used, reliable data can be obtained when a) the techniques are used correctly, b) the data is obtained through repeated application of the techniques (e.g. interviews, observations) to other individual, and c) the data is correlated with other data, such as physical parameters, documents, reports, etc. The following paragraphs describe key aspects for using common HOF data collection techniques to ensure that they will yield rigorous information.

1. Interviews

Interviews are widely used for many kinds of regulatory data collection activities. For HOF-related data collection, the following characteristics have to be kept in mind.

Interviews can be:

- Structured – with questions largely pre-defined and with a clear goal. Those are especially useful when trying to confirm an hypothesis, or to collect data about a well-defined issue;
- Semi-structured – with many questions pre-defined and with one or more clear goals, with an opportunity to elaborate on the subject matter through additional questions;
- Open – with perhaps a few warm up questions (e.g. what is your position here, for how long) and then questions being asked to explore a situation.

For data collection, interviews can provide either objective (e.g. how many times did this happen last week?) or subjective (e.g. please describe the morale in the team) information.

Information is validated by interviewing several people, at the same or at different levels in the organization, depending on what is required. The information can also be confirmed through other facts or findings produced using other techniques such as observations and documents review.

When conducted properly, interviews provide valuable and reliable HOF-related data.

2. Observations

In many cases, observations are a good way to gather data in work situations (e.g. procedure use and adherence, maintenance activities). Observations are used to gather facts about the performance of activities in real work situations.

There are several aspects to be considered when considering using observations:

- It takes specific training and preparation to carry out effective observations for collecting HOF-related data. Casually looking at a worker doing a job yields minimally useful data.
- Successful observation sessions are prepared. As a minimum:
    - The worker is made aware that the HOF observer is interested on information on the tasks and not on the worker. Agreement is sought from the licensee’s management before carrying out observations.

- The HOF observer is familiar as possible with the situation to be observed, as well as with the task itself and any supporting documentation. For instance, when observing the use of and adherence to procedures, the observer has read the procedure in advance and familiarized him/herself with the work site and followed the execution of the work while observing, line by line, how the procedure is being used. When observing maintenance work, the observer is familiar with the task itself, any supporting documentation, (e.g. work order, procedure) as well as with the licensee and regulatory expectations. The observer ensures that the observations are carried out in a way that they will be representative of a realistic task execution.
- Extreme care is to be taken to avoid interfering with the worker's performance (e.g. interrupting the worker to ask questions while he/she is actively engaged in carrying out the activity), to avoid creating safety hazards. Furthermore, interferences may reduce and even render the data collected irrelevant or invalid.
- The HOF observer collects data on the work environment, as well, for a given set of observations (e.g. lighting is sufficient, clearance around the equipment, local situations that might affect how the work was carried out, how were deviations from the procedure or from licensee/regulatory body's expectations handled).

- It is best to limit the number of observers to one or two.
- Well-executed observations are one of the most powerful for collecting HOF-related data. They interfere minimally with the work done, can be relatively unbiased and may provide a level of understanding that other techniques do not provide.

3. **Review of documents and records**

Document and record reviews can be used to collect HOF-related information on:

- How tasks is to be performed;
- How procedures are used;
- How the management system complies with regulatory requirements;
- How licensee personnel have carried out various tasks (e.g. operations, maintenance, engineering).

Examples of documents and records that may be reviewed include: plant data, shift logs, training records, minutes of safety meetings, self-assessments, audit reports, event investigations, lists of open actions (e.g. maintenance, corrective actions), and safety performance indicators.

It is often useful to compare the results from document and record reviews with the results from other techniques. It is also important that the reviewer has a sufficient amount of HOF knowledge and competence to identify the relevant HOF information and meaningfully integrate the results.

4. **Surveys**

Surveys can be used to collect quantitative HOF data, but their use requires specialized knowledge from the personnel creating the survey, as well as analysing the results. There are good commercially-available surveys that may be suitable for the organization's specific needs. A common example of survey use is self-assessment.

Appendix IV

INSPECTION GUIDES

Human and organizational factors (e.g. decision making, workload) are seldom inspected in isolation as there are numerous HOF that affect the successful completion of tasks by licensee staff. A more frequent and more comprehensive way to assess HOF is to look at areas of regulatory oversight where HOF play an important role. Areas of regulatory oversight may be defined differently depending on the regulatory body but often include:

- Technical procedures (e.g. maintenance, testing);
- Emergency operating procedures;
- Engineering design (especially for design projects that involve equipment that will be adjusted, maintained, operated);
- Minimum shift complement;
- Hours of work limits.

It is possible to create combined inspection guides that can be used for HOF and other disciplines (e.g. management systems) when carrying out integrated or common inspections. Having inspection guides supports the inspectors in their work, and improves consistency of inspection findings that meet regulatory requirements. Inspection guides can be developed to suit the needs of the various disciplines in the regulatory staff. Table IV.1 shows the type of content that has been found useful in inspection guides. Table IV.2. describes an example of checklist for specific aspects of an inspection.

TABLE IV.1. TYPE OF CONTENT OF INSPECTION GUIDES

Typical sections in a guide	**Specific content and description**
Authorization page and versioning	Inspection guides are issued, controlled and authorized by the proper authorities. They are to be continuously improved based on lessons learned during their use. Therefore, the names and signatures of the author(s), reviewer(s) and authority(ies) are to be provided. Each version has a unique version number.
Prerequisites	Useful reminder of steps to complete prior to carrying out the inspection. Examples: - Is a letter announcing the inspection required? - Are there health and safety steps (e.g. radiological refresher, confined space training) required for the inspection staff? - Check last record of inspection and follow-up actions; - Ensure that the inspectors are using the latest revision of the inspection guide; - Ensure that the licensee documents that will be examined (e.g. procedures) are the latest approved versions.
Suggested approach to conduct this type of inspection	This is a description of how to best conduct this inspection. Typical points addressed include: - What is the scope of the inspection? It is not always desired to apply all of an inspection guide. Sometimes, using a subset makes sense; - Are specialized HOF personnel required? In several instances, non-specialized personnel can apply an inspection guide without having a HOF expert on board; - Are documents required from the licensee beforehand or are they examined on-site? - What are the most critical parts of the inspection and what are good ways to go about them?

TABLE IV.1. (Continued)

Typical sections in a guide	Specific content and description
Checklist – process definition	Depending on the regulatory approach, it may be useful to have a portion of an inspection guide dedicated to ensuring that the process that is examined is: - Well-defined; - Documented; - Has all of its implementation documents signed off and current and licensee personnel know where to find them. That the implementation documents are sound and well-written. For example, if examining technical or emergency operating procedures, is a writer's guide available, and if so, does it meet regulatory requirements?
Checklist - implementation	Inspections typically look at how things are implemented. Depending on the process that is being inspected, typical implementation criteria could include: - Is the actual design implemented as specified in the design document? This normally requires going and looking at the installed equipment in the field; - Are personnel trained on using the new design or the procedures? A good way to check this is to ask a sample of users directly, in addition to checking the training records; - Are the procedures (technical, administrative or emergency) used as written? This often requires observing how the procedures are used, either in the field or during training exercises.
Checklist – record checking	When visiting the site to perform the inspection, it is often useful to include records checking. Depending on the topic being inspected, the following types of records are suitable inspection items: - Training records; - Low-level event reports; - Testing procedures (if they are used to collect information); - Attendance records (if inspecting hours of work limits).
Sample interview questions	Often, there will be semi-formal, or even formal, interviews with licensee staff. It may be useful to collect some sample interview questions. However, those sample questions are to only be used as guides and are not to constrain the inspection, additional questions may be asked if needed, as long as those additional questions do not exceed the scope of the inspection).

TABLE IV.2. EXAMPLE OF CHECKLIST FOR SPECIFIC ASPECTS OF AN INSPECTION

The table below describes an example of checklist for specific aspects of an inspection. While each checklist will be different, the following format is often useful for each checklist (this is an example for inspecting emergency operating procedures).

Regulatory criteria	Licensee management system reference	Expected outputs - What needs to be verified	Inspection activity - How to perform the activity or check	Result(s)
Requirement related to documents and records of management system	Licensee's implementation of the requirement in their management system	Procedures are written based on a writer's guide that takes into account human performance considerations for the format and organization of procedures	Select a sample of emergency operating procedures and compare these procedures to the licensee's writer's guide	Is the licensee in compliance or not with some comments to facilitate the writing of the inspection report

Appendix V

EXAMPLE OF HOF OVERSIGHT DATA GATHERING

1. Recording HOF during oversight activities

The basic idea is to use different types of oversight activities continuously as a source of information about HOF. The HOF-related information can be categorized, for instance using the HOF categories described in section 2.4 and sub-topics (see also table in Appendix 1):

1. Human-related factors, e.g. competence, seizing of leadership functions, adherence to obligations;
2. Technology-related factors, e.g. accessibility, complexity of equipment;
3. Organizational-related factors, e.g. leadership, workload, training programme, interaction with authorities, housekeeping, quality of written documents.

The regulatory staff collect data for a limited number of areas during each regulatory activity (which may include a technical inspection) as well as during any other interaction with the licensee. These data have to be organized; the use of a database to record and organize the data will be helpful.

In an annual evaluation of the collected data, trends that are attributable to HOF as an early warning instrument of declines in performance can be derived. The more data points are available, the higher the probability to find systematic effects, not only “noise” and random aspects. Hence, the data have to be interpreted with caution because the amount of evidence may be too weak to draw strong conclusions. This information can be useful for the ISA.

2. Example focusing on leadership

Leadership can be assessed by looking at the following areas:

1. Creating working conditions, e.g. communicating corporate objectives, creating best possible prerequisites of task performance, fostering staff development;
2. Personnel management, e.g. giving clear targets, monitoring and evaluating the task execution;
3. Dealing with errors and improvements, e.g. investigating errors in a proper and fair manner, developing and making provisions;
4. Appreciation and sanctioning, e.g. fostering desired behaviour, counteracting undesired behaviour;
5. Social behaviour, e.g. fostering good working atmosphere.

Information can be collected by using different approaches:

a. During any inspection (e.g. technical inspections);
b. During an inspection dedicated to leadership: This approach requires a certain amount of resources and the involvement of HOF-experts.

Appendix VI

INTEGRATED SAFETY ASSESSMENT CASE STUDY

(Fictitious scenario)

Suppose that a regulator has just performed various oversight activities in the last year for a licensee. These oversight activities can be summarized in accordance with the different oversight tools:

- Inspections on Maintenance and on the Management system;
- Review of licensee's OPEX analysis results and the measures taken;
- Feedback from inspectors;
- Document review of licensee's request for the approval of a design upgrade for a safety system.

During information **gathering** at the regulatory body all HOF relevant information need to be extracted from the oversight results. This requires that the person who is gathering the information has access to the final oversight results and have sufficient HOF competence. The HOF relevant information needs to be systematically and continuously captured in an appropriate form (e.g. database). Looking at the example, the following HOF relevant information was captured from each of the following oversight activities:

- *Maintenance inspection:* The provision of procedures was incomplete; the maintenance personnel needed to carry out the work under time pressure, personnel training status cannot be verified.
- *Management system inspection:* The roles and responsibilities of the people involved in the OPEX process are not clear especially where organizational interfaces are concerned, licensee has taken a lot of improvement measures without finalization. There is no self-assessment process in corrective actions programme. Same finding was also made during other inspections.
- *Review of licensee's OPEX analysis:* Most of the remedial actions just recommend "be more careful," the corrective actions taken are not directly linked to the actual situation in the organization. The root causes identified are most frequently associated with equipment failures.
- *Feedback from inspectors*: Reporting of a lot of minor events: lack of leadership, demoralization of people in the field. However, management seems to consider the situation is going well.
- *Document review of design upgrade request:* The information provided is disjointed, the application of the graded approach is missing and licensee is not responsive to a follow-up information request.

Assuming that the HOF relevant information gathering was done, the next step is the **assessment** of the information with the aim to identify commonalities for HOF considering the overall organization. This can also require looking at the original oversight documents (inspection reports, event reports). It might be useful to discuss with either inspectors, technical specialists or other personnel familiar with HOF to better understand the information. Also, information coming from previous years ISA is to be considered in the assessment.

With respect to the given example the regulator identified the following commonalities for HOF concerning the overall organization:

- Deficiency in the effectiveness of the management system (unclear strategy/objectives/processes, poor implementation of the Management system at all levels of the organization);

- Overall the performance of the problem identification and corrective action programme does not meet the regulatory expectations.

The **reporting** of the results from the integrated safety assessment are then used externally to contribute to the overall licensee status in the annual report published by the regulator. The results are also used internally to:

- Help plan the following year' regulatory HOF oversight activities (e.g. increase regulatory oversight on the OPEX process);
- Improve the guidance provided to the licensees regarding regulatory requirements on the HOF competencies of the staff carrying out OPEX analysis and identifying remedial actions;
- Send feedback to the licensee and require that they develop a corrective action plan;
- Consider the possibility of annual follow-up meetings with the licensee.

The results are also stored in a report that will be used when carrying out next year's ISA.

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Annex A

EXAMPLES OF THEMATIC ASSESSMENTS

Thematic assessment is one oversight activity where influence of HOF on safety can be examined in-depth by the regulatory body and its Technical Support Organization (TSO). In France, for example, such safety evaluations are performed by the Institut de radio-protection et de sûreté nucléaire (IRSN, TSO) upon request by the Autorité de sûreté nucléaire (ASN, Regulatory Body). The following are two examples of HOF thematic assessments.

Assessment of the EDF (Electricité de France Safety Management System, by IRSN (2006-2008) [1]

In 2006, IRSN provided conclusions and recommendations on the management for safety in NPPs. The main questions were about:

- Priority given to safety in the daily trade-offs made at NPPs;
- Meaningfulness of safety for operators faced with frequent evolutions of the managerial and organizational contexts;
- Organizational measures taken by the licensee to continuously improve safety.

After a preliminary analysis and definition of the assessment strategy, it was decided to focus the assessment on "decision-making processes." The assessment was conducted through a series of safety analyses carried out at national level (headquarter and central support department) and at on-site level (NPPs) to evaluate decision making practices in different situations, such as:

- Real time decision making during outages;
- Support provided by the headquarters to the plants to solve technical problems;
- Definition and use of indicators, as decision-support tools for managers, for managing safety;
- Processes for performing internal safety assessments and use of the results of them for improving safety;
- A posteriori analyses of decision making processes implemented by the licensee as an experience feedback tool;
- Identification of licensee staff mental representations of safety used when operating the plant. The goal was to determine the influence of the organizational and managerial context on these representations.

Data was collected from documents reviews, as well as from about 150 interviews and 35 days of observations. This data collection might help identifying strengths and weaknesses when examining decision making processes.

Issues were identified in the following areas:

- Authority balance between the shift operation team and the outage project team;
- Real time decision making capabilities of plant managers;
- Lessons learned from the analyses of decision making processes;
- Management of cultural changes.

Conclusions were also made regarding the effectiveness of the management system, the priority given to safety, the meaning of safety used by operation staff and the continuous improvement approach. As a regulatory response, ASN used these conclusions as a basis to request the operating organization EDF (Electricité de France) to improve its practices in this area.

From a methodological point of view, a lesson learned from this thematic assessment was that it is possible to examine decision making processes as they are implemented in “real life” and not only as they are documented within the management system. These documents highlighted again that the gaps and differences exist between what is planned in documentation and what is actually implemented.

This comprehensive thematic assessment was effective to:

– Complement compliance verification in a deeper manner;
– Assess the effectiveness of the safety management system to support operational safety management in real time situations;
– Obtain data on beliefs, values, representations and more generally all ‘hidden aspects’ composing HOF and safety culture.

In addition, it shows that safety culture is not only a concept used to explain errors committed by individuals, but it can be examined from the organizational and managerial context contribution to its construction, and from the effects the culture of an organization produces, in particular on daily decisions.

Assessment of the EDF control over contracted operations, performed by IRSN (2013-2015) [2]

The French NPP licensee outsources approximately 80 % of the maintenance activities. The volume of outsourced operations will be increasing in upcoming years due to, among other, the NPP safety improvements to take into account lessons learned from the TEPCO Fukushima Daiichi NPP accident and to extend the operating lifetime of NPPs beyond 40 years.

Consequently, the regulatory body requested its TSO to assess the measures implemented by the licensee to control the risks associated with outsourced maintenance activities. The following aspects were covered by the assessment:

– Ability of the licensee to ensure contractors are aware of safety issues then act upon appropriately;
– Contractors’ responsibility for safety and their responses for taking appropriate technical actions;
– Contractors’ communication with the licensee on operating experiences.

For assessing the organizational measures implemented by the licensee, IRSN focused on the relationship between the licensee and their contractors and how this relationship positively or adversely affected the compliance with safety requirements.

As a preliminary step, IRSN met members of local information commissions[14] and environmental protection organizations to discuss and identify their concerns, including as regards the quality of contractors’ surveillance and the time constraints undergone by the workers.

IRSN then examined the licensee's measures for carrying out maintenance operations by focusing on their actual effects on the activity of persons who had to apply them “in the field.” In particular, IRSN looked at the adjustments and solutions implemented by workers when encountering difficulties in applying these measures. Moreover, IRSN analysed the way for identifying and processing OPEXs stemming from the contracted operation.

To this end, IRSN visited three nuclear power plants during outages, conducted more than 160 interviews and observed 40 maintenance operations. Systematically, IRSN interviewed both employees of the licensee (project managers, monitoring managers, purchasers, etc.) and contractors. This mirror approach of the assessment process was useful for addressing both

[14] Local liaison commissions are organized in France to facilitate communication and dialogue with the ‘local’ public.

contributions of the licensee and their contractors in the overall control of risks related to contracted operations.

Globally, IRSN's assessment showed that the licensee implemented a set of technical and organizational measures that did contribute to the safety of contracted operations.

Areas for improvement included:

- The ability of contractors to perform operations that impact safety;
- The balance between workload and available resources;
- Risk assessment approach;
- Licensee's monitoring of contracted operations;
- Collect and use of OPEX from contracted works.

As a regulatory response, based on the IRSN's conclusions, ASN formulated requests for improvement to the attention of EDF.

REFERENCES TO THE ANNEX A

[1] Safety Management in a competitiveness context, Jean-Marie Rousseau (IRSN), Eurosafe, Paris, 2008.

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Annex B

EXAMPLE OF A PROJECT PLAN

Project Outcome: Development and implementation of regulatory HOF oversight programme

Goal 1: To increase competencies of key staff at Medium level
Goal 2: To establish an in-house training programme for the regulatory capability sustainability
Goal 3: To recruit a HOF specialist
Goal 4: To establish a comprehensive HOF programme

TABLE B.1. EXAMPLE OF A PROJECT PLAN

Objectives		**Responsibility**	**Resources (staff- weeks)**	**External support**
Obj. 1	**Managing the project**			
Task 1.1	*Assignment of the project manager*	*Chairperson*	*<1*	
Task 1.2	*Initial communication with all staff*	*Seniors*	*1*	
Task 1.3	*Constitution of the project team*	*Project manager*	*5*	
Task 1.4	*Drafting of the initial project plan*	*Project manager*	*5*	
Task 1.5	*Participating in HOF-related meeting*	*Project manager*		*Yes*
Task 1.6	*Initial discussion with licensees*	*Seniors*	*6*	
Task 1.7	*Periodically review the project*	*Project manager*	*12*	
Obj. 2	**Increasing the awareness among staff about the importance of HOF for safety**			
Task 2.1	*Organization of workshop with Managers*	*Project manager*	*6*	*Yes*
Task 2.2	*Organization of 2 days awareness course*	*HR department*	*12*	*Yes*
Task 2.3	*Regular information to the staff through the managers*	*Project manager*	*10*	
Obj. 3	**Taking stock of the current situation**			
Task 3.1	*Review of existing HOF-related regulations and guides*	*Project Team* *Tech. department*	*4*	
Task 3.2	*Identification of existing internal arrangements related to HOF (Guide, tools...)*	*Project Team*	*3*	
Task 3.3	*Identification of existing competences and resources and HOF issues already overseen*	*Directors*	*3*	
Task 3.4	*Review of external resources*	*Project Team*	*6*	*Yes*
Task 3.5	*Finalization of conclusions on the current situation*	*Project Team*	*5*	
Task 3.6	*Revision of the project plan*	*Project Team*	*2*	
Obj. 4	**Capacity building in HOF**			
Task 4.1	*Organization a training course for project team and some key staff*	*HR department*	*6*	*Yes*
Task 4.2	*Recruitment of a HOF Specialist*	*HR department*	*6*	*Yes*
Task 4.3	*Identification of the competence and training needs*	*HR department*		
Task 4.3	*Implementation of training programme*	*HR department*		*Yes*
	Development of internal guidance and tools			
Obj. 5	**Event analysis**			
	etc.			
Obj. 6	**Completing regulatory requirements**			
	etc.			

ABBREVIATIONS

ASN	Autorité de sûreté nucléaire
EDF	Electricité de France
HOF	human and organizational factors
HFE	human factors engineering
HRA	human reliability analysis
HTO	human, technology and organization
HMI	human-machine interface
IRSN	Institut de radioprotection et de sûreté nucléaire
ISA	integrated safety assessment
NPP	nuclear power plant
OPEX	operating experience
PSA	probabilistic safety assessment
SSCS	structures, systems and components
SARCON	systematic assessment of the regulatory competence needs
TEPCO	Tokyo Electric Power Company
TSO	technical support organizations

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