

TECHNICAL SAFETY
ASSESSMENT GUIDE

HUMAN AND
ORGANISATIONAL
FACTORS IN NUCLEAR
FACILITIES DESIGN
AND MODIFICATION
PROCESSES



FOREWORD

Since the beginning of EUROSAFE initiative (1999), IRSN, GRS and Bel V (former AVN) have pursued the objective to advance the harmonisation of nuclear safety in Europe by comparing their safety assessment methodologies. Based on a long standing experience of more than 40 years, in spite of different national nuclear safety regulatory backgrounds, they have developed practical methods to perform safety assessments that presented sufficient similarities to encourage them to persevere in building a collection of common best practices. The first version of their common Safety Assessment Guide was thus approved in 2004.

The general Safety Assessment Guide (SAG), and its specialized guides, the Technical Safety Assessment Guides (TSAG), have been written by the members of the European Technical Safety Organisations Network with progressive improvements brought by the new members of ETSON.

The SAG provides general principles such as safety assessment objectives or transparency and traceability of the process, and describes the general process for performing the safety assessment of nuclear installations. The goal of this SAG is to set down the harmonized methodology applied by ETSON organisations to ensure a common quality of safety assessment and to develop higher confidence in delivered safety assessments.

The TSAG series consists of specialized guides dedicated to specific technical domains of importance to the safety of nuclear installations. They provide an overview of the available practical knowledge gained by Technical Safety Organisations (TSO) in conducting safety assessments covering these main technical issues (use of operating experience feedback, assessment of human and organisational factors,

prevention of severe accidents, probabilistic safety assessment, etc.).

Each guide published by ETSON is updated according to the extension of experience gained as well as to the new requirements in nuclear safety.

The 2012 guides present the common views and practices of ETSON members:

- Bel V - Belgium
- GRS - Germany
- IRSN - France
- VTT - Finland
- UJV Rez - Czech Republic
- LEI - Lithuania
- VUJE - Slovakia
- PSI - Switzerland

With the contribution of ETSON associated members:

- SSTC - Ukraine
- JNES - Japan
- SEC NRS - Russia



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SCOPE

This document addresses the review and assessment to be done by regulatory bodies regarding human and organisational factors (HOF) during design and modifications of nuclear facilities.

Its primary goal is to provide some guidance for reviewers/assessors, with at least basic knowledge about HOF. This guidance relies as far as possible on practical experience considering safety assessment in the HOF field.

The document is structured as follows:

- chapter 2 reminds some fundamental concepts;
- chapter 3 presents an overview of HOF topics to be addressed during the design/modification process;
- chapter 4 addresses some important HOF topics to be reviewed and provides inputs for orienting the review.



FUNDAMENTAL CONCEPTS

2.1 Human and organisational factors: what is it (and what is it not)?

Human and organisational factors (HOF) cover several disciplines related to human and social sciences: psychology, sociology, ergonomics, anthropology, management sciences, etc.

and actions could be individual or collective, occur in a given context drawn by "working situations", and produce "effects" on these situations and so on safety. HOF covers the understanding of individuals' and groups' characteristics as well as situations characteristics.

Some of these characteristics, determining human activities, are listed in the figure 1 below.

This approach of safety, consisting in taking into account the man, the technology and the organisation is also known as the "MTO approach".

Considerations regarding intentional damage are out of the scope of this guide.

Figure 1
Scope of human and organisational factors.

A central topic is addressed by these disciplines: "human intentions, decisions and actions". These intentions, decisions



2.2

Tasks and safety relevant activities

A task is any action (including decision-making), the performance of which is required in a given situation in order to achieve a specified goal. A task is related to safety, if the achievement of the task goal leads or contributes to establish, to maintain or to re-establish a safe plant-state.

Activities range in specificity from general rules of conduct to concrete interactions with technical systems during operation including start-up and shutdown phases, testing, maintenance, repair, or plant modification activities, as well as abnormal or emergency situations.

Safety relevant activities should be identified through cooperation between system designers, operation and maintenance specialists, HOF specialists, etc.

2.3

Human errors and hazards prevention during design

As it is suggested above, human performance is partly determined by the situation in which human activity takes place. One of the components of this situation is the technical system itself, resulting from a design process. So, the way the system is designed and in particular the way the risk of human errors is analysed and addressed during the design process will influence the future human performance once the system is in operation.

Occurrences of human errors provide an opportunity to learn about the conditions under which these errors occur. These conditions include technical factors, organisational factors, and personal factors. Learning from errors requires to analysing all aspects defining the tasks environment.

The likelihood of human errors can be (partly) anticipated and reduced by putting in place a set of barriers: technical provisions (automatisms, safeguard equipments, etc.), documents and procedures, training and qualification of people, organisational and managerial dispositions, etc. But, automation may also increase the likelihood of human errors if its impact on human performance is not adequately anticipated and assessed. In the same way, procedures may introduce ambiguity, and may induce human errors. Thus, the design of these barriers should result from an early integration of HOF analyses.

2.4

The contribution of organisational factors to safety

Organisation has to be considered as a “defence line” acting at each stage of the defence-in-depth approach.

An organisation is a set of human and technical elements structured to reach objectives. Its functioning is regulated by a set of formal and mandatory rules which define:

- the positions and organisational units, which constitute the organisational structure, and the tasks, which are allocated to these position and organisational units;
- qualifications required for personnel;
- the hierarchical relations between the various positions and organisational units and the other non-hierarchical relations such as the official channels for communication between organisational units;
- processes, *i.e.* steps, decisions and actions by which tasks have to be performed as well as process-schedules and relations between different processes (such as plant operation and maintenance);

■ equipment to be used for task performance and equipment design. Equipment comprises all work-aids, objects, man-machine interfaces, work-places and their environment.

valuable practical experience is available at this time within ETSON members.

Evaluating the efficiency of an organisation in supporting safe activities requires analysing *"How do people actually perform their tasks?"* That is why it is difficult to evaluate an organisation with a priori criteria, during the design process before the designed organisation actually operates. Such evaluations can be conducted (for example using experience feedback from similar designs and organisations), but their limitations should be clearly underlined in the assessment report, and they should be complemented when the designed organisation operates. This specific issue is addressed in chapter 4.8 of this document.

2.5

What about safety management and safety culture?

Organisational factors can be considered as a part of Safety Management System which can be viewed as an outcome of the system design process. Following the same idea, safety culture can be viewed as the product of a dynamic and reciprocal interaction between individual, organisational and job features. These aspects have to be continuously evaluated during operation.

However, they cannot be assessed (except from a formal perspective) during the design process. Because this SAG is focused on HOF integration in system design, safety management and safety culture are not covered by this SAG.

Although recent work focuses on safety culture of designers or of stakeholders involved during pre-operational phases (including regulators), the topic is not mature enough to be addressed here and no

3

OVERVIEW OF HOF RELATED ANALYSES WITHIN DESIGN PROCESSES

3.1 HOF integration - general principles and expectations

The need to integrate HOF analyses within design processes – from the starting phases of projects to the operation phases – is now a commonly recognized principle.

The main objective of such integration is to create the right conditions to minimize the risk of human errors during operation. This objective takes place within a preventive and anticipative approach, as it is briefly presented in the previous chapter.

Integration does not mean “to add independent HOF analyses to classical engineering activities”. It means HOF analyses must produce inputs to engineering analyses and deal with outputs from engineering analyses in order to orient the decisions taken for designing a new system or equipment, or for modifying existing ones.

This general principle generates the following basic requirements in order to be efficiently applied:

- HOF analyses need to understand and to take account of engineering constraints;
- HOF analyses need to produce applicable results for being used within the project life cycle;
- engineering practices and processes need to be adapted to be able to benefit from HOF analyses;
- these reciprocal adaptations between HOF and engineering could be achieved through the adaptation of tools, methods and practices supporting the analyses of both disciplines.

The way these basic requirements are implemented for a given project should be reviewed in the framework of an assessment.

Another set of requirements, derived from this general principle, concerns:

- project management: decision making processes need to be thought and need to be run so as they will be able to deal with multiple sources of inputs and constraints (engineering, HOF, economic considerations, etc.).

- time scheduling of the project: required time for each type of analysis needs to be correctly planned, mastered and coordinated, in particular to deal with the management of input/output interfaces between HOF and engineering activities and to reach a correct articulation of both.

- required competences of people involved in the project: on the one hand, HOF specialists need to be involved as soon as possible in the project, and on the other hand, the different stakeholders in the project need to be, at least, aware about the scope of HOF and the benefits that can be expected from HOF approaches.

The way these requirements are met should also be reviewed in the framework of an assessment.

3.2 HOF topics to be addressed through the design process

A design or modification process includes the following generic components¹ (figure 2 below):

In order to integrate HOF within this generic process, various activities are performed during the whole project life cycle, from the beginning to the operational phases, such as: task analysis, operating experience analysis, human reliability analysis (integrated in probabilistic safety analysis), staffing and staff qualification analysis, analyses of operation and maintenance activities, procedures design, etc.

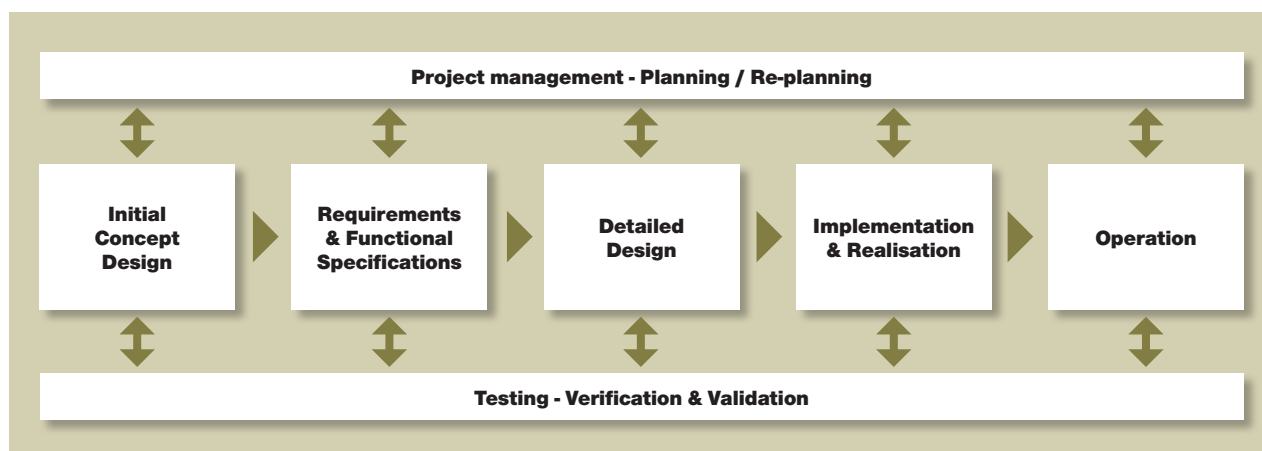
These HOF related analyses produce inputs for the generic components of the design process. Chapter 4 provides some guidance for reviewing how an applicant/licensee has taken into account HOF in addressing these subjects.

Evaluating how human and organisational factors have been taken into account induces:

1. to evaluate the technical, organisational and human barriers foreseen for making the socio-technical system efficient regarding its safety purpose;
2. to evaluate the methodological approaches put in place within the design process to manage and orient the design of these operational barriers.

In other words, it is important to review both the products of the design process (when available through mock-up or simulators, for

Figure 2 A generic design/ modification process.



¹ For detailed information, see, for example: ISO (2010), Ergonomics of human-system interaction - Part 210: Human-centred design for interactive systems; USNRC NUREG 0711 rev. 2 (2004), Human Factors Engineering Programme Review

Model; EPRI (2004), Human Factors Guidance for Control Room and Digital Human-System Interface Design and Modification.

example) and the design process itself, in its methodological dimension (which gives confidence to the justifications of design choices presented by the licensee).

In the case of a plant modification, it is important to take into account, at an early stage in the design, the potential of the change on tasks required to operate, test, or maintain the plant². The scope of the HOF evaluation and the amount of effort dedicated to it would be graded, depending on the characteristics of the modification and its impact on human activities.

² For more information on the integration of HOF in modification process: NEA, "The Role of Human and Organisational Factors

in Nuclear Power Plant Modifications", OECD, CSNI Technical Opinion Paper n° 10 (2009)

4

MAIN HOF RELATED TOPICS TO BE REVIEWED

The following inputs are provided for the regulatory review in support to licensing of new plants or plant modifications. It might also be used in the frame of periodic safety reviews.

4.1 Task analysis

Task analysis or task modelling techniques are used during the design process to identify the functional requirements regarding the human activities. One of the main goals is to verify that performance requirements do not exceed human capabilities. In the context of making decisions on design, the application of these techniques should identify:

- human centred requirements like necessary knowledge, skills, fitness for duty, motivation and suitable measures to meet those requirements;
- requirements for suitable ergonomic layout of working areas, man-machine

interfaces, working tools, information sources;

- task allocation and task flow oriented requirements with consequences for e.g. staffing, team organisation, communication aspects and teamwork;
- environmental conditions that can hamper task completion, such as temperature, moisture, noise, dose rate, lack of visibility, etc.

Task analysis techniques are also useful to investigate given work situations and to provide inputs for simulating several options for those situations.

The scope of the task analysis should include:

- full range of plant operating modes, including start up, normal operations, abnormal and emergency operations, transient conditions, and low-power and shutdown conditions;

- selected representative and important tasks from the areas of operations, maintenance, test, inspection, and surveillance;
- considerations on automated functions such as execution of backup actions if the system fails;
- human actions and decisions that have been found to affect plant risk.

Reviewing the task analysis process and results documented by the applicant allows verifying that the design choices are justified by considerations on the feasibility and the efficiency of human actions and decisions.

SOME VALUABLE REFERENCES

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4.2

Use of operating experience

The use of operating experience feedback (OEF) by the applicant for design purpose has to be reviewed. OEF should relate to reported incidents as well as near misses and major accidents in high risk industries (not only nuclear).

Regarding HOF, the lessons learned from OEF should focus on human performance,

organisational efficiency, management practices for identifying issues or good practices on which design options may have an influence.

Both the process (of using OEF) and the results of this process (which elements of the OEF justify a given design option) should be reviewed.

Regarding the process, a particular attention should be put on resources and competences dedicated to collect and analyse OEF.

Another important point of the review should be the efficiency of the integration of lessons learned within design activities. This point raises classically some issues in terms of:

- management of interfaces between the departments managing OEF and design activities;
- management of scheduling (OEF use has to be scheduled in such a way, that any results will be available prior to any decision for which this result is needed);
- technical integration of operating skills, HOF skills and design skills;
- traceability and decision making issues.

SOME VALUABLE REFERENCES

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EUROPEAN SAFETY, RELIABILITY AND DATA ASSOCIATION, ESReDA working group on accident investigation, Guidelines for safety investigations of accidents, (2009). www.esreda.org

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tive consideration of human and organisational factors in event analysis and root cause analysis, (2010). www.oecd-nea.org/nsd/docs/2010/csni-r2010-8.pdf.

4.3 Design of control room and human system interactions

The objective of the control room and Human-System Interactions (HSI) design review is to assess whether operation means (control panels, mimic panel, documentation, etc.), the shift personnel organisation and the training ensure the shift personnel to operate in a safe, effective and efficient way.

In particular, it has to be assessed whether the safety-related functions and tasks allocation between the operation means and the shift personnel, and between the shift members, allow the team to reach its operating goals without threatening safety and with an acceptable individual workload for each member of the operation team.

Moreover, the review should cover the design process methodology as well as the design choices.

The review process should start in the early phases of design and not only when the applicant/licensee performs the validation phase of control-room and HSI. The review should be performed at several steps of the design process from the basic design (general principles for Human System interactions) to the validation design once the plant is operated. Classically the applicant/licensee is recommended to refine the design via an iterative process, using an evaluation method which is more and more realistic and representative of the future socio-technical system.

Experiments on software simulators constitute the most commonly accepted technique for supporting such evaluations. As simulator time is very often a scarce resource, these

experiments have to be thoroughly prepared. For example, procedures should be checked (by crossing a technical view with a HOF view) before being evaluated on simulator.

At each design step, the reviewer should assess whether the design choices are relevant and sufficient, regarding the regulatory requirements, the state of the art in HOF domain and the existing operating experience. Then, if a modification has been designed without evident reference to any operating experience and its usability is doubtful, the design process of the procedures should be investigated: the requirements analysis and Verification & Validation (V&V) activities of the design process should be questioned.

In terms of review process, two main stages have to be distinguished, depending on the inputs provided by the applicant/licensee:

- the review should firstly rely on documents, and if available, from static and/or dynamic mock-up provided by the applicant/licensee. At this stage, the review should address the design methodology and the first directing principles of design.
- once the design solutions become more and more detailed, significant phases of evaluation and validation using a full scale simulator should be carried-out on the full socio-technical system (equipment, documentation, organisation, etc.) according to the V&V strategy implemented by the applicant/licensee. At this stage, the review should address the capability of the retained technical and organisational solutions to support safe operation.

SOME VALUABLE REFERENCES

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ROUSE, W.B., Design for Success: a Human-centered approach to Designing Successful Products and Systems. New-York, Wiley, (1991).

4.4 Design of maintenance activities

Maintenance activities cover what is done to prevent equipment failures, including periodic testing and equipment surveillance (preventive maintenance) or to fix out of order equipment (corrective maintenance). Specific requirements regarding HOF should address maintenance aspects of the new system or equipment during the design process.

The goal is on the one hand to facilitate future maintenance activities by anticipating possible human errors and, on the other hand, to make systems or equipment "maintenance-error tolerant". The objective underlying the assessment of this topic is to evaluate whether these aspects have adequately been addressed during the design process.

When a new system or equipment is being designed, maintenance activities should be anticipated as soon as possible by the

applicant/licensee. This anticipation should focus on HOF aspects regarding:

- the global maintenance programme and the maintenance strategies underlining it;
- the functions and the characteristics of the system/equipment to be monitored, maintained, inspected, etc., including active and passive systems;
- the required activities for the "re-qualification" (post-maintenance testing) of the system or the equipment before putting it on operation;
- the means (tools, procedures, organisational aspects, etc.) provided to the maintenance crews for planning, preparing, executing and controlling maintenance activities;
- the accessibility constraints of the equipment in case of local repairing and visiting actions, including radiation protection considerations as well as health and personal security aspects;
- the way the equipment is locally identified, labelled, tagged, marked;
- the technical and organisational dispositions foreseen for managing spare parts;
- and more generally, all the technical and organisational needs induced by maintenance activities requiring human interventions, coming from manufacturers requirements or from previous operating experience feedback on same or similar systems or equipment.

For all of these elements the applicant/licensee should justify to which extent the design choices contribute to reducing maintenance error occurrences, to offering opportunities for detecting maintenance errors, or to mitigating such errors, following a defence-in-depth approach.

More generally, organisational aspects related to maintenance have to be presented with sufficient details. At minimum, the following aspects have to be considered by the reviewer:

- the management of interfaces between operation and maintenance teams should be described by the applicant/licensee, as well as the way maintenance activities are planned, prepared, executed and controlled. This point has to be reviewed with regard for data coming from operating experience;
- specific organisational dispositions for managing outages (when most of maintenance activities occur) should also be described. In particular, the way time pressure is taken into account and managed has to be reviewed;
- from an organisational point of view, the strategies and the practical dispositions set-up to take into account radiation protection and security of workers has to be reviewed in accordance with regulatory requirements.

As a potential limitation, the relevance of the review will depend on the moment when the review is performed regarding the state of advance of the design process with the applicant/licensee. For a valuable review, providing a reasonable degree of confidence of the conclusions, it is preferable to start from data coming from a "detailed design" phase. Thus, the review should be based on sufficient details for the future system/equipment with a relevant level of justification of the design choices and a comprehensive view of the targeted future situations, in terms of human and organisational activities for maintenance.

Another potential pitfall is the way the applicant/licensee translates its HOF analyses in requirements for the vendors who will construct the future system/equipment. Experience has shown that it is important to monitor the entire chain of the system/equipment design and production and to verify that requirements are correctly integrated at each step. This particular aspect of the review may raise difficulties and depends on the ability of the reviewer to get access to data concerning the contractual relations of the applicant/licensee with vendors.

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REASON, J. AND HOBBS, A., *Managing Maintenance Error - A Practical Guide*, Ashgate Publishing Company: Hampshire, (2003).

4.5 Procedures design

Procedure design review addresses two objectives:

- it has to be shown to which extent procedures support reliable performance of safety-related tasks by personnel. It has to be checked how well contents and layout of information presented by procedures are adapted to the needs, abilities, and performance limits of personnel in the areas of information processing and information understanding, memory, decision making, action planning and action execution. These aspects have to be considered in addition to the analyses and evaluations of the technical correctness of procedures.

- it has also to be checked to what extent the procedure design process includes all the steps by which human and organisational factors will be adequately implemented in the procedures.

The review should address the following kinds of procedure:

- permanent and temporary procedures for the interaction of personnel with safety-related systems during normal and emergency operation (including start-up and shutdown phases, inspection, testing, maintenance, repair) or plant modification tasks in the main control room, emergency control room, and on the shop-floor-level of the plant.
- permanent instructions for the checks to be performed during shift-turnovers and by rounds-men as a means of detecting and (or) preventing safety-relevant non-conformities and deviations of plant status.
- guidance for selecting procedures which are required in a given situation (such as decision trees guiding the selection of the appropriate procedures to be carried out, if a safety goal is violated).
- permanent procedures for fighting fire, flooding, and similar events which threaten plant safety.

The reviewer should check the procedures design process, the procedures content, and their layout regarding ergonomics considerations.

Regarding the procedures design process, the following elements should be reviewed:

- task analysis for identifying required human actions and decisions, factors shaping performance of these actions, possible human errors with their impact on plant safety, and means of error-detection, error-prevention or error-mitigation;
- design process, content and application of the writer's guide for procedures;

- verification and validation of procedures from a technical point of view;
- test of procedure usability and reliable performance by personnel in charge of the tasks covered by the procedure;
- check, if procedure requires specific training and (or) changes of team organisation.

Regarding the content and the layout of procedures, the focus should be put on main issues, such as:

- the consistency of the procedure with the requirements of the licensee organisation regarding tasks and responsibilities of work-team members;
- an appropriate level of guidance according to the expected skills of personnel using the procedure;
- an appropriate level of detail according to the expected situation (stressing factors for instance) and the expected performance of the task the procedure supports;
- means for keeping track of the progress of procedure execution;
- an appropriate structure to support correct and quick orientations through the procedure;
- a good homogeneity of presentation between procedures;
- an appropriate material that supports usability: factors to be considered are handling with protective clothing (gloves) or protection against degraded readability due to humidity or dirt.

SOME VALUABLE REFERENCES

IEEE Std 1023, Guide for the application of human factors engineering to systems, equipment, and facilities of nuclear power generating stations, (1988).

HWANG, F.-H., HWANG, S.-L., Design and evaluation of computerized operating

procedures in nuclear power plants, *Ergonomics* volume 46, issue 1-3, (2003).

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SALVENDY, G., *Handbook of Human Factors and Ergonomics*, 3. Ed., New York: Wiley, (2006).

4.6 Staffing, qualification and training

In order to achieve and maintain a high level of safety, nuclear facilities are required to be staffed with an adequate number of sufficiently qualified and experienced personnel. To establish and maintain a high level of competence, appropriate staff training and qualification programmes should be in place. These programmes should be kept under regular review by the licensee to ensure that staff competence is sustained.

The objective of the staffing and personnel qualification regulatory review is to verify that the requirements for the number and qualifications of personnel (plant staff and contractors) have been systematically analysed and identified and that this analysis includes a thorough understanding of the implications of organisational design, technology (section 4.3) and task requirements (section 4.1). Compliance of staffing and qualification requirements with all relevant regulatory requirements should also be assessed. Staffing levels are also an important consideration when plant modifications are designed that affect the role or tasks

of personnel and are potentially significant to plant safety.

The objective of the training programme regulatory review is to verify that training and retraining programmes are established for all personnel fulfilling safety functions that enable them to perform their duties safely and efficiently. Furthermore compliance of training programmes with relevant regulatory requirements or guidance should be assessed. In case of plant modifications the regulatory review should focus on the impact of these modifications on the training programmes.

The following elements should be provided by the applicant/licensee as input for the assessment:

- a description of the methodological approach used for identifying the requirements regarding the number, the qualification and the training programme of personnel;
- organisational information regarding the overall structure for operate and maintain the plant, the extent to which maintenance and support activities are outsourced to contractors, etc.
- information related to specific positions: the minimum number of persons to be assigned to common or duplicated positions (e.g. technicians), the positions for which licenses are required, the proposed means of assigning shift responsibility for implementing radiation protection and fire programmes, etc.
- staff qualification requirements such as: education, initial training and experience requirements for each management, operating, technical and maintenance position category in the operating organisation;
- a description of the qualification process for licensed staff;
- a description of formal training programmes important to safety.

The review of a new plant will entail a more comprehensive and detailed assessment than the review of individual modifications of existing plant (be them technical or organisational). Review of plant modifications will be more limited in scope and focus mainly on the impact of the modification on previously justified staffing levels and on currently accepted qualification and training programmes.

In a general view, the scope of the review should focus on:

- fitness for duty: internal factors used for selecting candidates such as skills, motivations or physical and psychological aspects (e.g. health and impact of stressors) should be considered;
- staffing: the review should address components such as requirements for minimum shift complement, presence of licensed operators in the control room, requirements regarding engineering expertise onsite at all times. Total manpower available should be sufficient to avoid the routine use of overtime for plant staff that performs safety-related functions;
- qualification: the reviewer should check whether qualification programmes comply with regulatory requirements and guidance and whether formal qualification of plant staff relies on an evaluation of the individuals' knowledge and skills;
- training: the review should address the scope and content of training programmes (initial and retraining), as well as the pedagogic facilities used as support for training and examinations (simulators, computer based training, etc.) and the extent to which a systematic approach to training development has been implemented.

Regarding the process, the staffing analysis is expected to be iterative, the basis of which is modified through the analysis of the other HOF items (operating experience review, functional requirements analysis, task analysis, HRA, HSI design and procedure development). Staffing

level analysis and justification will to a large extent be based on the experience available to the applicant/licensee with operation of similar nuclear facilities and on regulatory requirements and guidance. Issues to be addressed in the analysis are therefore operational problems and strengths resulting from the organisation and corresponding staffing levels in similar or predecessor plants. Issues identified during training (development) such as crew coordination concerns should also be addressed.

Staffing levels and qualification of onsite technical support and maintenance groups will depend on the applicant/licensee's headquarters staffing, the division of effort between onsite and offsite personnel and the extent to which the applicant/licensee relies on contractors to perform maintenance and other support activities. These aspects should therefore be carefully considered in the assessment. It should be verified that sufficient managerial depth is available to provide qualified backup if a manager is absent. The reviewer verifies that the number of shift crews determined by the licensee allows the plant staff involved to follow the minimum required retraining programme.

Sufficient people should have received training prior to initial fuel loading to ensure that applicable limiting conditions for operation with respect to minimum shift complement can be met and excessive planned overtime for supervisory personnel during the start-up phase can be avoided.

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4.7 Probabilistic Assessment of Human Behaviour

Probabilistic Safety Assessment (PSA) is increasingly used in many countries, in a complementary manner to the traditional deterministic analysis, as part of the decision making process to assess the level of safety of nuclear power plants and to support various risk-informed applications.

PSA provides a comprehensive, structured approach to identify accident scenarios and deriving numerical estimates of risks. The reliability experience, mainly derived from operational experience of all safety relevant

features of the plant, are brought together, compared and evaluated.

Human performance may substantially influence the reliability and safety level of all safety relevant components of the plant. Therefore human reliability analysis (HRA) constitutes an important part of PSA.

For performing the review, the applicant should provide a detailed description of the methodology used for HRA including HRA procedures, the scope of tasks to be considered, the tasks classification according to cognitive aspects, a task model for considered situations, a description of human errors modes and probabilities.

In order to perform an HRA many different methodologies are available. Even within the ETSON member organisations differences in the treatment of specific HRA aspects are observable. Those will not be detailed here.

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4.8

Assessing the organisational dimension

Adopting a MTO approach in design means the designers define a new “working situation” including the human activities (M), the technical system (T), and organisational elements (O). The design choices made for each of these three dimensions have impacts on the two others.

Usually safety reports from licensees/applicants include a description of these organisational elements. Most of national regulators, over the world, require such a description. They could include organisational charts, roles and responsibilities, staffing level and qualification, etc.

The issue is *“how to evaluate the relevance of these elements, and on the basis of which criteria the assessors decide whether or not these elements are adequate to comply with safety requirements?”*

The challenge is double, given that:

- the “perfect organisation” for managing safety does not exist. A multiple choice is open, one best model of organisation is an illusion (known as the myth of “one best way” in sociology);
- there is a gap between the formal description of the organisation and the way an organisation functions in reality. The actors of the organisation constantly adapt and manage the established rules in order to perform the tasks allocated to them. But, as a product of the design process, only a formal description is available for assessment.

In this context, assessing organisational elements from written documents and before the plant is in operation becomes a challenging task. The only source of data useable for such an assessment is provided by operational feedback and mainly the

organisational aspects of it, in addition to generic rules of organising work coming from (for most of them) quality approaches.

Whatever the quality of the evaluation, it will never provide the absolute guarantee that the presented organisation will ensure safe operation.

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4.9

Human factors in verification and validation

The objectives of verification and validation (V&V) evaluations are presented in the NUREG 0711 as: *“comprehensively determine that the design conforms to human factors engineering design principles and that it enables plant personnel to successfully perform their tasks to achieve plant safety and other operational goals”*.

V&V evaluations have to be performed iteratively throughout the design process. One important aspect of these evaluations is the use of ergonomic validation techniques, which concern essentially the design of human-system interfaces (see 4.3) and procedures (see 4.5).

The reviewer should verify that the applicant/licensee has correctly implemented the main principles of these techniques: iteration, evaluations on simulators if applicable, use of experience feedback for identifying relevant scenarios of work, involvement of end-users, etc.

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