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| ONR Technical Assessment Guide  Human Factors Integration (HFI) |



ONR Technical Assessment Guide (TAG)

Human Factors Integration (HFI)

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Issue No.: 5

Publication Date: Mar-2023

Next Major Review Date: Mar-2026

Doc. Ref.: NS-TAST-GD-058

Record Ref. No.: 2020/127021

Table 1: Revision commentary

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| --- | --- |
| Issue No. | Description of Update(s) |
| 5 | Full review and update to reflect relevant good practice (RGP) including HFI activities in the safety assessment and design process. |

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# Introduction

1. ONR has established its [Safety Assessment Principles](http://www.onr.org.uk/saps/saps2014.pdf) (SAPs) [1] which apply to the assessment by ONR specialist inspectors of safety cases for nuclear facilities that may be operated by potential licensees, existing licensees, or other duty-holders. The principles presented in the SAPs are supported by a suite of guides to further assist ONR’s inspectors in their technical assessment work in support of making regulatory judgements and decisions. This technical assessment guide (TAG) is one of these guides.

# Purpose and Scope

1. The ONR has the responsibility for regulating the safety of nuclear installations in Great Britain. SAPs and supporting TAGs provide a framework to guide the regulatory decision-making processes.
2. This TAG represents the overarching principles of human factors integration and is therefore interlinked with all EHF SAPs. However, it is principally intended to provide guidance to aid Inspectors in the application of the following SAPs:

* EHF.1 - A systematic approach to integrating human factors within the design, assessment and management of systems and processes should be applied throughout the facility’s lifecycle.
* MS.2 - The organisation should have the capability to secure and maintain the safety of its undertakings.
* SC.3 - For each lifecycle stage, control of the hazard should be demonstrated by a valid safety case that takes into account the implications from previous stages and for future stages.

1. The principles of good HFI are relevant across all of ONR’s Purposes. However, the regulatory frameworks differ between transport, security, safeguards, nuclear safety and conventional health and safety. This HFI TAG predominantly addresses HFI relating to nuclear safety, though aspects may also be relevant to other Purposes. Further guidance on the consideration of HF aspects of security can be found in ONR’s SyAPs [2], in particular FSyP3 which addresses Human Performance, and its four supporting TAGs [3] [4] [5] [6].
2. As with all guidance, Inspectors should use their judgement and discretion in the depth and scope to which they apply the guidance provided in this TAG. Whilst this TAG describes some typical Human Factors Integration (HFI) aspects, it does not prescribe specific methods and approaches for implementing HFI. Inspectors should use their own knowledge and experience when considering the adequacy of a dutyholder’s approach.

# Relationship to Licence and other Relevant Legislation

1. The Nuclear Site Licence Conditions [7] place legal requirements on the licensee to make and implement arrangements to ensure that safety is being managed adequately.
2. Licence Condition (LC) 14 is relevant to this TAG, as HFI is a good practice approach that should be reflected in the arrangements for production of the safety case:

LC 14: Safety Documentation:

(1) Without prejudice to any other requirements of the conditions attached to this license the licensee shall make and implement adequate arrangements for the production and assessment of safety cases during the design, construction, manufacture, commissioning, operation and decommissioning phases of the installation.

1. The following LCs relate to the design of plant and equipment at different phases within the lifecycle:

* LC 19: Construction or installation of new plant
* LC 20: Modification to design of plant under construction
* LC21: Commissioning
* LC 22: Modification or experiment on existing plant.
* LC35: Decommissioning

HFI should be applied when these activities introduce new tasks or result in fundamental differences to the tasks that humans are required to perform.

LC 36: Organisational Capability is also relevant to this TAG since good HFI must be supported by adequate financial and human resources in order to undertake the HF analyses and integrate the findings with other disciplines across the licensee organisation.

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# Relationship to Safety Assessment Principles, WENRA Reference Levels, and IAEA Safety Standards and Guides

## SAPs and TAGs

1. ONR’s expectations concerning HFI are set out in a number of SAPs.   
   The primary references are SAPs EHF.1 and those cited in Section 2 of this document.
2. The other eleven HF-related (EHF) SAPs all link to the over-arching EHF1 and are supported by a series of HF TAGs which are also inter-related. The aim of this HFI TAG is not to replicate the detail in the other HF TAGs but to provide guidance on following aspects:

* Management of HFI
* Integration of HF aspects within the Design Assurance process
* Integration of HF aspects within the Safety Assessment process
* Common HFI approaches and tools

1. Given the linkage between HFI and the wider HF EHF SAPs and TAGs, it is important to note that this TAG interfaces with many other ONR TAGs, some of which provide additional context for HFI within their specific sub-topic areas. Although not intended to be fully comprehensive, a list of key TAG interfaces is outlined below:

* Design Safety Assurance (NS-TAST-GD-057) [8]
* Categorisation of Safety Functions and Classification of Structures, Systems and Components (NS-TAST-GD-094) [9]
* Allocation of Function Between Human and Engineered Systems (NS-TAST-GD-064) [10]
* Workplaces and Work Environment (NS-TAST-GD-062) [11]
* Human Machine Interface (NS-TAST-GD-059) [12]
* Human Reliability Assessment (NS-TAST-GD-063) [13]
* Staffing and Task Organisation (NS-TAST-GD-061) [14]
* Training and Personnel Competence (NS-TAST-GD-027) [15]
* Procedure Design and Administrative Controls (NS-TAST-GD-060) [16]
* Design Basis Assessment (NS-TAST-GD-006) [17]
* Probabilistic Safety Analysis (NS-TAST-GD-030) [18]
* Severe Accident Analysis (NS-TAST-GD-007) [19]
* Nuclear Lifting Operations (NS-TAST-GD-056) [20]
* Internal Hazards (NS-TAST-GD-014) [21]
* Periodic Safety Reviews (NS-TAST-GD-050) [22]

**Note**: The Human Reliability Assessment TAG [13] is also a high-level ‘umbrella’ overarching TAG focussing specifically on HF integration into the safety assessment process.

## WENRA Safety Reference Levels

1. The objective of the Western European Nuclear Regulators Association (WENRA) harmonization programme is to develop a common approach to nuclear safety in Europe by comparing national approaches to the application of International Atomic Energy Agency (IAEA) safety standards. Their Safety Reference Levels (SRL) [23], which are based on the IAEA safety standards, represent good practices in the WENRA member states and also represent a consensus view of the main requirements to be applied to ensure nuclear safety.
2. Issue LM4 (Emergency Operating Procedures and Severe Accident Management Guidelines) and Issue P2 (Periodic Safety Review) both specify the requirement to include human factors (HF). Issue E10.4 (Control Room) specifies that ergonomics considerations shall be taken into account in the design of a main control room. ONR considers that HFI represents Relevant Good Practice (RGP) and should also be used to support the Safety Analysis Report (Issue N) and Plant Modifications (Issue Q).

## IAEA Safety Standards

1. The IAEA Safety Standards (Requirements and Guides) were the benchmark for the revision of the SAPs in 2006 and 2014 and are recognised by ONR as RGP. They should therefore be consulted, where relevant, by the assessor as complementary guidance, although it should be appreciated that they are design standards rather than regulatory standards. The guidance in this TAG is also consistent with IAEA guidance.
2. SSR-2/1 - Safety of Nuclear Power Plants: Design Requirement 32 states:

“Systematic consideration of human factors, including the human-machine interface shall be included at an early stage in the design process for a nuclear power plant and shall continue throughout the entire process.” [24]

Paragraph 5.55 then states:

“The design shall support operating personnel in the fulfilment of their responsibilities and in the performance of their tasks and shall limit the likelihood and the effects of operating errors on safety. The design process shall give due consideration to plant layout and equipment layout, and to procedures, including procedures for maintenance and inspection, to facilitate interaction between the operating personnel and the plant, in all plant states.” [24]

“Verification and validation, including by the use of simulators, of features relating to human factors shall be included at appropriate stages to confirm that necessary actions by the operator have been identified and can be correctly performed.” [24]

1. SSG-51 - Human Factors Engineering in the Design of Nuclear Power Plants [25] outlines that the overall Human Factors Engineering (HFE) process can be divided into the following HFE activities across the design lifecycle:

* Programme management;
* Analysis;
* Design;
* Verification and validation;
* Implementation of the design;
* Human performance monitoring.

1. SSG-39 - Design of Instrumentation and Control Systems Important to Safety in Nuclear Power Plants [26] now refers out to key parts of SSR 2/1 [24].
2. SSG-61 - Format and Content of the Safety Analysis Report for Nuclear Power Plants again refers out to SSR-2/1 and SSG-51 but does state:

“The HFE programme applies to all operational states and accident conditions and to all plant locations where such interactions are anticipated. The human factors engineering considerations presented in the safety analysis report should, as a minimum, cover the following:

1. The arrangements for the management of the human factors engineering programme, including the allocations of authority and oversight in the design process;
2. The human factors analysis methods that are applied;
3. The assumptions used in the choice of human–machine interface design, with account taken of human factors engineering;
4. Human factors verification and validation, including the identification and resolution of human factors engineering issues that are identified during the design stage and the assumptions made during analyses;
5. A description of how human–machine interface design has been implemented in the overall plant design;
6. A description of the strategy for monitoring human performance for safety critical tasks.” [27]

## Other International Standards

1. The following International Standards are also relevant:

* BS EN ISO 6385:2016 Ergonomic Principles in the Design of Work Systems [28].
* BS EN ISO 11064 Ergonomic Design of Control Centres Parts 1-7 [29].
* BS EN ISO 9241 – 210:2019 Ergonomics of Human-System Interaction. Human-centred design for interactive systems [30].
* ISO/TS 18152:2010 Ergonomics of human-system interaction — Specification for the process assessment of human-system issues [31]
* ISO 9241-220:2019 Ergonomics of human-system interaction — Part 220: Processes for enabling, executing and assessing human-centred design within organizations [32]

# Advice to Inspectors

## Introduction to Human Factors Integration

### Definition of Human Factors Integration

1. Human and Organisational Factors is the scientific study of the environmental, organisational and job factors, along with human and individual characteristics that influence performance. A significant proportion of accidents are attributed to or influenced by human error and organisational factors. The correct application of HF helps to match the capabilities of the human operator to the design and operation of the plant, optimising human performance and minimising the potential for human error.
2. Human Factors is a diverse and broad-ranging topic area. The term ‘Human Factors Integration’ describes the process of applying HF relevant good practice to systems development and implementation. As an approach, HFI provides a structured framework to help ensure that all relevant HF aspects are identified and addressed to support reliable task performance. To achieve this, any HFI methodology should include a management strategy that aims for timely and appropriate integration of HF activities into the design and safety case throughout the whole project lifecycle.
3. ‘Integration’ means “…a combination of parts …that work well together.”.   
   Therefore, HFI requires that HF is considered as an integral part of a project and should not be carried out in isolation.
4. Some industries define HF ‘domains’ or HF frameworks to structure and support the integration of HF across the project lifecycle. However, ONR recognises that the exact nature by which HFI is undertaken may vary and therefore this TAG does not attempt to align with any specific HFI model. Instead, the level of formal HFI should be proportionate to the size of the project and take account of:

* the safety reliance on humans;
* the consequences of human failure;
* the novelty and complexity of any new technology and the impact of this on the role of the human.

1. Certain key elements (or commensurate activities) should always be evident within a formal HFI approach, and these are discussed in greater detail in the subsequent sections.

### Terminology and Scope

1. Some industries use alternative terms for human factors e.g. ‘human engineering’, ‘ergonomics’ and ‘human element’. IAEA often use the term ‘human factors engineering’ (HFE). The scope and assessment boundaries of complimentary disciplines e.g. Leadership Management for Safety or Pre-Operations may also vary within different dutyholders therefore Inspectors should be cognisant of project roles and responsibilities.
2. Inspectors may also encounter the term ‘human performance’. Historically, some areas of the UK nuclear industry have used this term for programmes which were largely focussed on behaviours and the application of behavioural tools as a means to reduce the potential for error. ONR considers the term ‘human performance’ to be broadly synonymous with the term Human Factors (‘HF’) or ‘human and organisational factors’. As such, ONR considers behavioural approaches to be just one element of the systems approach required to minimise the potential for error and support reliable and effective task performance. Over time, the context and relevance of the term ‘human performance’ has evolved, and Appendix 1 provides ONR’s current perspective on where this topic area fits into the wider assessment of humans within organisations and safety systems.

## Management of Human Factors Integration

1. There are a number of recognised prescribed approaches to HFI developed by industry e.g. NUREG-0711 [33]. Inspectors should consider the application of such approaches in terms of their applicability for the context, breadth and depth of HFI delivery.

### HFI Across the Design and Safety Case Lifecycle

1. The level of evidence in support of HF integration should be proportionate to the size of the project, the safety significance of the HF component of the project and the human contribution to risk.
2. The timing of relevant HFI activities is of utmost importance to ensure any HF analyses inform the evolution of both the design and the safety case. Inspectors should ensure that HF activities align with the pace and maturity of engineering and safety analysis activities to ensure options are not foreclosed and the resulting human tasks can be reliably performed.
3. Paragraph 444 of the SAPs states

“Whilst human factors integration is expected throughout all design phases, for new designs, the majority of the human factors analysis should be undertaken during the Pre-Construction Safety Report (PCSR) stage in order to influence the design and inform the safety analysis. As the design progresses, human factors analysis should start to focus on verification of the human factors claims in the safety case.” [1]

This aspect is discussed further in Sections 5.3 and 5.4 of this TAG.

1. Inspectors should seek evidence of a feedback loop from the HF analyses back into the design and safety case processes to ensure that HF is not treated as a stand-alone activity.

### The Human Factors Integration Plan (HFIP)

1. The Inspector should ensure that a tailored plan for HF integration into a project is developed during the initial phases to ensure timely consideration of HF aspects and to ascertain the required level of HF resource and nature of activities to support the subsequent stages. The plan for HF integration may be presented in a stand-alone form commonly referred to as a Human Factors Integration Plan (HFIP) or may be contained within other project planning, scoping and management deliverables. Inspectors should seek justification from the dutyholder for the level of HFI proposed for a project.
2. The plan for HFI, whether a stand-alone document or integrated into the wider project plan, should describe in detail how HF aspects will be integrated and managed throughout the project. However the plan is presented, it should be regularly updated as the project moves through each stage of the design and safety case lifecycle, evolving to reflect any changes relating to safety significant human actions.
3. The HFIP or similar form of plan can potentially provide the basis for regulation of the HF aspects of a project and can provide assurance to assessors that HF issues are being adequately addressed.
4. Inspectors should ensure that the following information is captured in the HFIP:

* The strategy for integrating HF with other disciplines, including cross discipline working and communications within the project and with contractors;
* The scope of HF work to be undertaken and the nature of the HF analysis throughout the project (what HF analysis work is to be done, at what level of detail, and when in the project).
* The HF standards and methodologies to be applied (refer to Section 5.3 and 5.4).

### HFI Work Programme

1. It is important that Inspectors ensure that the implementation of the HFIP is actively monitored and that there is evidence to support this. Dutyholders should be able to provide an HF work programme which demonstrates the forward plan and timely delivery of HF activities. This should include, as appropriate:

* Hold points and design reviews and the expected timely HF contribution.
* The key HF deliverables and their integration within both the HF discipline and the overall project plan. This should detail dependencies between disciplines and their outputs.
* Resource requirements.
* Progress monitoring arrangements and
* Reporting methods.

### HFI Processes

1. Human factors interfaces with many other project disciplines and therefore the Inspector should seek evidence of how such a transverse topic will engage across multiple parallel workstreams, each with their own delivery processes. Dutyholders should be able to articulate, as appropriate:

* the interface with design and engineering pathways e.g. HF requirements capture, HF attendance at design reviews;
* the interface with the safety case development e.g. safety functional requirements or impact of design on human based safety claims (HBSCs);
* the interface with operations e.g. feed into training, procedures, design and implementation of administrative controls;
* how HF assumptions, uncertainties and project issues/ risks will be managed and resolved (with suitable governance);
* how trade-offs between different discipline requirements will be managed and resolved.

1. In interfacing with other project functions, it is important that human factors inputs and outputs are clearly communicated at an early stage to support effective and timely integration.

#### HF Issues and Assumptions Registers (HFIAR)

1. HFIARs are often used to collate and track progress on HF issues and assumptions relating to the design and/or safety case. These can exist at different levels across different project workstreams, design houses and the supply chain. Interpretation, integration and resolution of the HF issues within these registers is a recognised challenge.
2. The HFIARs are usually owned by the respective HF team but should interface with other project risk registers and issue trackers.
3. It is important that management of these registers is given suitable HF oversight and that issue closure is not delegated solely to a project management or delivery role since the impact of the HF issues may be lost.
4. Where issues are closed without full resolution, arrangements should be in place to feed the impact of any residual shortfalls into substantiation of both the design and human-based safety claims within the safety case. Similarly, if as the project matures, HF assumptions are not supported as expected the impact on the design substantiation and safety case analyses must be re-assessed.
5. Where licensees do not specifically use HFIARs, Inspectors should seek evidence of an alternative process for tracking HF issues to closure. Where such processes are used, Inspectors should consider whether they are suitably robust and whether they support effective integration and recognition of the importance of HF-related aspects.

#### Format of HF Deliverables

1. The output from the HFI process should be reported at key phases in the project lifecycle. The HFIP should link the HF work programme to specific deliverables.
2. ONR expects a proportionate level of HF evidence dependent on the safety importance, novelty and complexity of the activities. Therefore, it is for the licensee to determine whether this expectation should be satisfied by stand-alone HF documents or whether the design/ task substantiation should be integrated into engineering/ safety case deliverables as appropriate e.g. design substantiation reports or HAZANs.
3. Similarly, it is for the licensee to justify which discipline is best placed to collate the HF evidence into a documented format. ONR would expect any stand-alone, formal HF deliverable to be authored and reviewed by HF suitably qualified and experienced personnel (SQEP). However, in cases where the level of HF novelty and complexity is low (and there is considerable overlap with the competency of other disciplines) then the dutyholder may put forward a justification that it is proportionate to have the analysis undertaken and reported by a competent person from another relevant discipline. In such cases, there should be sufficient oversight of the approach and analysis, and peer review of the output provided by an HF SQEP. Inspectors should note that ONR ultimately expect dutyholders to ensure that personnel are competent for the activities they undertake that could impact safety.
4. It is important to note that licensees may draw on broader project evidence to support claims that human-related tasks can be reliably achieved e.g. CDM reviews, LOLER assessments. However, the dutyholder must justify that such evidence is both sufficient and timely to support the wider safety case development.
5. Design substantiation evidence should include, as appropriate, the following information:

* Changes since the previous design phase (philosophies, design changes etc).
* How the design meets identified HF requirements and aligns with relevant design standards.
* Any HF assumptions carried forward.
* Way forward and key areas of focus for HFI for the next phase of the project.

**Note**: Substantiation of human based safety claims is covered within the Human Reliability Assessment TAG [13].

### The Human Factors Team

1. For larger projects, the HFIP should also outline roles and responsibilities for delivery of the HF work. Typically, this should include:

* A project organisation chart highlighting the position and level of seniority of the HF Lead.
* An outline of HF SQEP resource requirements and how that resource will be managed.
* Who has ownership of particular aspects of the HF work.
* Management of contractors including how the dutyholder will ensure oversight as an intelligent customer (IC).

1. Inspectors should confirm that the HF team is embedded with the project team to ensure that HF has the appropriate focus and can direct and influence decision making on the project. For example, positioning the HF expertise solely in the safety case team is likely to limit their influence on the design decision-making process, and therefore it is usually appropriate to also have HF capability within the core engineering or design team.
2. Inspectors should ensure that the HF expertise has the appropriate authority and responsibility to ensure effective delivery and integration of the required HF work. It is generally expected that the HF Lead (or comparable) has an equivalent level of authority as other technical disciplines and is evidently included in the project’s design and assurance decision making processes.

#### Suitably Qualified and Experienced Resourcing for HF Activities

1. Para 2.15 of IAEA Safety Standard SSG-51 states that:

“The HFE programme should identify the relevant organizational requirements and competence requirements (e.g. qualifications, skills, knowledge and training) for personnel performing HFE activities”. [25]

1. Para 2.17 continues that:

“The HFE programme should specify that the design team have a member or members with HFE expertise.” [25]

1. All activities with the potential to impact safety should be undertaken by those who are suitably qualified and experienced to undertake the work effectively. Inspectors should be satisfied that the HF analysis is either directly carried out by, or suitably overseen by, individuals with an appropriate level of HF competence (depending on the risk importance of the task or design). Inspectors may consider requesting evidence from the dutyholder to demonstrate the HF competence of analysts supporting safety important work where such detail has not been provided as part of the HFIP or supporting materials.
2. Licensees will have their own arrangements for ensuring that staff undertaking HF activities which could impact safety are SQEP. HF, as with all technical disciplines, requires appropriate relevant academic qualifications along with experience commensurate with the seniority of the role.
3. Where a licensee chooses to contract out its HF work, an appropriate level of Intelligent Customer (IC) capability should be in place. Inspectors should ensure that the HF IC(s) has sufficient capability to adequately oversee the level of contractor support proposed and to assure the technical delivery of the HF scope. Inspectors may also choose to request SQEP statements/ assurances from the proposed contractor resource.
4. Due to current recognised constraints on HF expertise available in the UK, some licensees use HF contractors to perform an HF IC role providing oversight of HFI and review of HF deliverables. ONRs TAG on Licensee Use of Contractors and Intelligent Customer Capability [34] outlines the ONR expectation for the role of intelligent customer:

‘Principle 4: The licensee should maintain an ‘intelligent customer’ capability for all work carried out on its behalf by contractors that may impact upon nuclear safety.’

“…For example, if contractors are used to prepare a safety case, the licensee must be competent to ensure that the contractor is suitably qualified and experienced, follows an appropriate methodology, and uses the correct data and assumptions. The licensee should have sufficient knowledge to understand the limitations and implications of the analysis to its safety case; to question and challenge the contractor’s work; and to show that it has applied an appropriate degree of control and oversight in practice. The licensee should be able to lead the presentation of the safety case arguments. However, the licensee need not necessarily have the depth of knowledge required to undertake the detailed analysis itself.” [34]

1. Therefore, where an HF IC role is being performed by contractors rather licensee staff, Inspectors should ensure the licensee retains sufficient oversight and responsibility for the work undertaken. The Intelligent Customer TAG also states that:

“The licensee should be able to demonstrate that, within its core safety capability, it has a suitable and sufficient competence, resource and arrangements to understand where and when work is needed; specify requirements to carry out that work; understand and set suitable standards; supervise and control the work; and be able to review, evaluate and accept the work carried out on its behalf.” [34]

## Human Factors Integration into the Design Process

### Overview of HF in Design

1. Major projects usually use a phased or gated engineering process for design development. Some designs are novel and start with only an outline design objective whereas others are based on existing designs and technology.   
   Therefore, the design evolution process can vary between projects and between duty holders.
2. ONRs Design Safety Assurance TAG [8] highlights the importance of considering human factors throughout the design lifecycle. ONR’s Categorisation of Safety Functions and Classification of Structures, Systems and Components (SSCs) TAG [9] also includes a V-diagram which outlines that Safety Functional Requirements should be identified early in the design lifecycle.
3. SAP ECS.2 focuses on the application of classification to SSCs. However, paragraph 164 of the SAPs states that

“Where safety functions are delivered or supported by human action, these human actions should be identified and classified. It notes that the methods for classification should be analogous to those used for classifying SSCs. Therefore, systems and interfaces which support safety-important human based safety claims require a proportionate level of design substantiation.” [1]

1. This HFI TAG subsection has been written to broadly align with recognised design phases, but Inspectors should interpret the guidance based on factors such as the current project maturity, organisational structure, novelty and complexity, and the level of risk associated with an activity. Inspectors should not attempt to apply the guidance retrospectively to previous design phases.
2. Appendix 2 includes a summary table outlining design phases, associated phased safety case submissions and related HF considerations. This table is intended to support Inspectors by demonstrating the progressive approach to HFI and is not intended to be prescriptive or fully comprehensive.
3. The following aspects are common to all design phases and therefore have been described here rather than within individual sub-sections which focus on specific phases of design maturity.

#### Application of HF Standards, Good Practice & Recognised Methods

1. Inspectors should ensure that the HF analysis is consistent with relevant standards and good practices and applies recognised HF methods. Where novel or unfamiliar analysis methods are proposed by dutyholders, Inspectors should seek assurance of the provenance and validity of those methods to inform nuclear risk assessments and applications. Where ‘in-house’ standards and guides are proposed, Inspectors should determine their basis and assure themselves of their technical credibility.

#### HF Attendance at Design Reviews

1. Depending on the size and complexity of a project, dutyholders may hold “design reviews”. Design reviews are recognised in systems engineering as a governance mechanism. They are multi-disciplinary and can be held at defined stages of a project. They aim to verify that the design is correct, complete (for that design stage), satisfies requirements and adheres to standards. They also provide a mechanism for confirming resolution of outstanding issues and trade-offs, reviewing resources and scheduling. Ultimately, they formally approve the project to proceed to the next stage. Inspectors should ensure that HF is appropriately represented at such reviews and may request the output of the reviews as an input into the regulatory assessment process.

#### HF Verification & Validation (V&V) of the Design

1. ONRs Design Safety Assurance TAG states:

“Design verification is the process to confirm that each stage of the design is confirmed as correct against the requirements from the previous stage.” [8]

1. For HF, this can be split into two types:

* HF design verification being an assessment of the design against the project specified HFE design standards.
* HF task verification being an assessment of the design to confirm that the items required to support effective task performance are present and functional.

1. The TAG continues:

“Design validation ensures that the overall intent of the design is achieved. It also prevents failure of the design intent by incremental deviation or dilution.” [8]

1. Together, verification and validation activities form an important part of the design and safety analysis process, as they provide the evidence to demonstrate that the design is safe and operable for the full scope of its intended use. It also minimises design foreclosure risk due to the continuous HF testing of the design.
2. Inspectors should confirm that HF V&V activities are carried out proportionally (taking a risk-informed graded approach). V & V activities should be undertaken throughout the design process, from concept to final demonstration, and should address plant and equipment design where there is reliance on the operator to deliver or maintain safety functions. This is unlikely to be limited solely to the main control room, or to specific HF topics areas such as human machine interfaces (HMI).

### HF Considerations During Concept Design

1. This section identifies some common HF-related activities and methodologies used by major projects during the concept design phase which can be instrumental in supporting effective HFI. This list is not intended to be exhaustive or prescriptive since approaches may vary across licensees and projects. Inspectors should ensure that HF is appropriately considered and proportionately integrated during the early stages of any design process.

#### Concept of Operation

1. Inspectors should ensure that for new build facilities and larger scale projects, the dutyholder has provided a “concept of operations”. A basic concept of operations should be developed at the beginning of the project and refined as further detail is available.
2. This document should provide the following basic details:

* A statement of the operational purpose of the system, and the operational requirements under all conditions (normal operations, faults and accident conditions). This will highlight the functions to be performed by the system and how the system is operating to achieve those functions.
* A consideration of the command-and-control philosophy – how is the system intended to be operated during normal operations, faults and accident conditions.
* The outline staffing concept for the system and an indication of their required roles and responsibilities.
* The basic details of the working environment.

1. Where an incomplete concept of operations is provided, Inspectors should ensure that the dutyholder has arrangements in place for the development and monitoring of the document and has made provision for managing assumptions cited in the document.
2. Where dutyholders do not produce a separate concept of operations deliverable, Inspectors should ensure that human-related system design and process assumptions are suitably captured and documented e.g. via a Basis of Design engineering deliverable (BOD). This will ensure such HF-related assumptions can be reviewed and tested at each subsequent design phase.

#### Early Human Factors Analysis (EHFA)

1. This describes the process of conducting an initial high-level HF analysis to identify HF issues and their relative importance for a given system or facility. This activity should be completed as early as possible in order to gain a high-level understanding of the human activities within a system and to develop a proportionate strategy for HFI. Where available, use of OPEX from similar plants or human tasks can inform the process.
2. The EHFA should inform the initial project HFIP and aims to de-risk the project by ensuring HF resources and effort are suitably targeted to develop a more detailed understanding of the human tasks as the design and safety case mature.
3. Inspectors should note that EHFA can be a formal or an informal process depending on the size, novelty and complexity of the project.

#### HF in Optioneering

1. ONRs Design Safety Assurance TAG [8] provides guidance on optioneering within the design safety assurance process.
2. An optioneering process is sometimes used by dutyholders to inform decision-making and ALARP justifications associated with Allocation of Function (i.e. the division of roles between humans and equipment [10]). Where this is the case, Inspectors should seek evidence that HF has been appropriately considered within that optioneering process.
3. This may be achieved via specific HF criteria used alongside engineering, project and safety criteria. Any HF criteria should be assigned an appropriate weighting that is proportionate to the human contribution to risk. Alternatively, HF aspects may be considered within the wider definition of engineering optioneering criteria. Either way, it is important to consider issues such as:

* Level of task complexity.
* Task durations (impacting dose / exposure).
* Human reliability (error potential).
* Maintainability.
* Recoverability under fault conditions.
* Decommissioning.

#### Target Audience Description (TAD)

1. New build projects typically produce a Target Audience Description (TAD) document. This provides a valuable source of information to inform the design process.
2. A TAD should outline user requirements and define the intended user demographic for the facility or equipment being designed. It should describe behavioural, psychological and physiological characteristics of the users and any limitations of facility staff.
3. Typically, the TAD will include:

* Anthropometric data for the identified user population (body dimensions).
* Additional dimensions to accommodate PPE.
* Physical abilities if required for specific roles e.g. mobility assumptions, eyesight, hearing, physical strength.
* Cognitive abilities.
* Accessibility requirements.

1. Inspectors should note that for legacy facilities, this type of information is unlikely to have been specified or documented. However, since the UK demographic has generally increased in size over time, the impact of changes in the user population should be considered during any plant modifications and design of replacement facilities.

#### HMI Style Guides

1. ONRs HMI TAG contains the following expectation:

“An HMI style guide, or similar document, based on agreed HMI requirements and specifications should be developed by the dutyholder to demonstrate the philosophy and underlying principles for the HMI and the integration of these requirements and specifications into the design. The style guide defines the design and interaction principles in the HMI design”. [12]

1. This document provides a single point of reference for HMI design across all control rooms, software-based systems, hard-wired panels and physical local-to-plant controls for a given facility. By outlining common expectations early in the design of new build facilities, this reduces the likelihood of operators and maintainers being forced to navigate divergent or conflicting designs and thus reduces the potential for human error.
2. The HMI TAG provides further guidance on this topic, but an HMI style guide would typically include information such as:

* Types of HMI/ controls e.g. input devices, valves.
* Ergonomic factors e.g. Maximum human force and dexterity expectations, location /physical positioning of HMIs for the user population, dimensions of controls.
* HMI layout.
* Conventions on use of colour e.g. alarm coding and labelling.
* Visibility - text size, viewing distances etc.

1. Inspectors should note that achieving such design consistency can be difficult when incorporating legacy systems or COTS equipment and therefore dutyholders may choose an alternative approach to interface design management and ultimately confirming the suitability of HMIs.

#### Alarm Philosophy

1. It is important to consider alarm architecture and requirements early on in the design. Although this topic may be led by the Control & Instrumentation specialism, Inspectors should confirm how the needs of the end user have been captured within the early alarm design process in order to avoid design foreclosure and ineffective indications in support of HBSCs.
2. ONRs HMI TAG contains a section on alarms:

“Inspectors may consider whether:The dutyholder has an alarm design and management strategy document, which includes an overall philosophy for the design and management of alarm systems”. [12]

1. Alarm philosophies should outline a consistent approach to providing the end user with the required system information. This may include information such as:

* Whether an alarm should be hard-wired or software based.
* Whether an alarm should be presented visually or audibly (or both) and the design characteristics of each alarm type with an associated meaning.
* Alarm prioritisation frameworks.
* Locations for alarm presentation and an associated control philosophy e.g. between main control room and back-up control room, or local-to-plant indications vs main control room.
* The alarm management functionality available to the end user e.g. silence, acknowledge, clear, cancel.

1. The HMI TAG also notes that “ONR recognise The Engineering Equipment & Materials Users' Association (EEMUA) 191 guide [35] as relevant good practice for alarm design and management. Inspectors are referred to this reference for comprehensive guidance on the design, implementation and assessment of alarm systems”.
2. Although there may not be a specific HF deliverable associated with alarm design and management, Inspectors should ensure the alarm systems have considered end user capabilities and meet the safety functional requirements for operator response.

### HF Considerations During Detailed Design

#### Detailed HF Requirements Capture

1. Inspectors should ensure that the HF output from the concept design phase is fed into the detailed design requirements capture process. This is important to inform equipment specifications, a suitable layout and access arrangements for operations and maintenance. It is recognised however, that it can be difficult to derive HF requirements before the detailed engineering design is frozen and the safety case is suitably mature. Therefore, if there are HBSCs identified by this stage, ONR expects the dutyholder to minimise the potential for future design shortfalls that would undermine their substantiations by including:

* Human access dimensions to support maintenance tasks.
* Human capacity and capabilities of the end user demographic (as described in the Target Audience Description).
* Required environmental conditions (lighting, noise, temperature, etc) to support the task.
* Adherence to specific HF design standards where applicable.

#### Workspace Design & Layout

1. This topic links to ONRs TAG on Workplaces and Work Environment [11] and SAP ELO.1 (Access) [1].
2. Projects usually hold phased design reviews which consider layout, control room design, access for maintenance and inspection, etc. These can focus on individual rooms, systems or buildings and may involve review against engineering layout rules. Inspectors should ensure that human requirements (for example, for space, viewing angles, access etc) are included within these reviews and are captured to ensure preservation of them during the construction and installation phases. Although inclusion of HF SQEPs at design reviews is desirable, dutyholders will often prioritise attendance based on the risk-importance of the equipment within scope for each review session. Inspectors should ensure a proportionate approach is taken and confirm that human requirements are given suitable consideration. Whilst operations and maintenance staff bring valuable expertise to the review process they should not be provided as a blanket substitute for HF expertise within the design review process.
3. Modern design methods include the use of CAD Modelling and virtual reality labs. These have a high level of face validity and often show mannequins or human representations interacting with the design. Inspectors should confirm whether these representations adequately reflect the characteristics of the user population (as outlined in the TAD). If not, alternative evidence should be sought that the design aligns with HF RGP and is fit for purpose. Often, the CAD mannequins are ‘standard’ not scalable, thus creating a false visual impression. Therefore, Inspectors should ensure appropriate drawings/methods showing dimensions are also utilised for design reviews and design substantiation.

#### Define Environmental Conditions to Support Human Tasks

1. This topic links to ONRs TAG on Workplaces and Work Environment [11].
2. Building lighting design, noise management and temperature management often fall under the remit of other technical disciplines within a major project. However, environmental conditions are an important Performance Shaping Factor (PSF) that should be managed as part of the task design process. This is key to supporting tasks important to safety, thus ensuring safety functions can be successfully delivered.
3. Industry guidance on lighting (e.g. from CIBSE) outlines lighting levels for different types of work area within typical buildings. Since HF specialists usually have a more detailed understanding of the task demands associated with each room/ location, it is important to consider whether these ‘generic’ lighting levels support the required human actions claimed within the safety case. Inspectors should seek evidence that the task requirements have been included within the lighting design process. Although additional/ mobile task lighting may be appropriate for infrequent tasks e.g. inspection or maintenance, its use should be justified for routine activities.
4. The Noise Regulations 2005 [36] require employers to prevent or reduce risks to health and safety from exposure to noise at work. Dutyholders must take specific action at certain ‘action values’. These relate to:

* the levels of exposure to noise of employees averaged over a working day or week; and
* the maximum noise (peak sound pressure) to which employees are exposed in a working day.

There are also levels of noise exposure which must not be exceeded (‘exposure limit values’).

1. Therefore, it is a legal requirement to manage noise levels and their sources as part of the overall design process. However, noise is also a PSF which affects human reliability on a task and effectiveness of communications. Therefore noise impact should form part of the HFI process. This may be via setting target noise levels for a given location associated with one or more HBSCs or, for larger projects, via a review of the proposed noise management plan produced by specialist engineers. Inspectors should seek evidence that the HFI process has considered noise levels and the impact on task performance, provision of PPE and communication abilities.
2. Temperature range requirements may be driven by equipment design tolerances and process requirements. These can form part of the limits and conditions of the safety case. Temperature is also a PSF that can impact human reliability. Inspectors should seek evidence that the HFI process has identified scenarios where either high or low temperatures could negatively impact actions important to safety and that HF have engaged in a multidisciplinary approach to resolve any concerns. As well as operational tasks, Inspectors should consider:

* Maintenance and inspection activities,
* Fault response tasks,
* Severe accident response,
* Recovery actions.

#### Task Design

1. This activity should define the nature of the human task, the equipment and tooling required, outline procedures/ instructions, expected levels of competence, level of supervision, etc. At the detailed design stage, the maturity of both the design and the safety case matures and therefore the level of task understanding also increases proportionately.
2. In order to verify the task design, techniques such as desk top walk-through of procedures, use of mock-ups/ prototypes or virtual reality modelling may be employed.
3. For detailed guidance on HMI design, procedures and administrative controls, training, staffing and HRA, Inspectors should refer to the targeted HF TAGs outlined in Section 4.

### HF Considerations During Implementation / Construction

1. Construction activities are typically associated with civil engineering, structural integrity and conventional health and safety specialisms. HF interfaces include human reliability on installation and inspection tasks, but these typically only require specialist HF assessment where there are significant nuclear safety implications.
2. However, during the construction and equipment installation phase of a project, it is important to ensure that the HF requirements and assumptions from earlier design phases are retained during construction and fit-out activities.
3. In order to preserve space for human tasks e.g. maintenance and tooling, it is important to ensure that this information is captured and translated into contractors work instructions and verification processes that are conducted on site e.g. configuration management and controls. The Inspectors should seek evidence of how HFI feeds into the on-site construction and installation activities to ensure that the as-built design will support the HBSCs.
4. It is important to note that not all changes begin at concept design. This implementation phase may also represent the ‘starting point’ for some changes on existing facilities where the as-built design remains the same.
5. The implementation phase also covers activities such as further procedure development, training roll-out, detailed staffing arrangements. The design of these aspects is an iterative process from concept design onwards but must be frozen at this stage in order to implement the arrangements and support validation activities. Further guidance on each sub-topic can be found in the HF TAGs listed in Section 4.

### HF Considerations During Test and Commissioning

1. This phase typically includes factory acceptance tests (FATs), site acceptance tests (SATs) and inactive commissioning of equipment and systems. Whole system active commissioning will typically be undertaken once sufficient design confidence has been gained via these earlier phases. Inspectors should seek evidence of consideration of HF requirements throughout these activities.
2. HF requirements and assumptions should feed into acceptance criteria, to test and confirm that the implemented design performs as expected in the real world and supports the human to fulfil their claimed role.
3. ONRs TAG on Design Safety Assurance states:

“Design validation ensures that the overall intent of the design is achieved. It also prevents failure of the design intent by incremental deviation or dilution.” [8]

“The commissioning process should confirm the assumptions made and requirements identified through the design process.” [8]

1. HF validation is an assessment of the safety and operability of the design, with the aim of demonstrating that it is fit for its intended use and meets the needs of the user. This typically involves testing the design with real users in real-world or simulated environments (from basic mock-ups to full-scope simulation) to ensure that it is safe and operable.
2. Factory Acceptance Tests (FAT) are a good opportunity to confirm the as-built or manufactured design aligns with HF requirements. Other activities may range from plant walk-downs, field trials and simulator testing. These provide good opportunities to confirm that HBSCs can be achieved in practice e.g. local to plant actions.
3. Commissioning activities relate not only to the equipment, but also to personnel and associated safety management arrangements to demonstrate that the safety function can be delivered in-line with the safety case expectations. See Section 5.4.5 Test and Commissioning Procedures in the Procedures and Administrative Controls TAG [16].
4. Validation of environmental conditions is often undertaken by other specialists, but the output should be communicated to HF to allow confirmation that the assumed PSFs have been achieved. However, please note that some HF aspects e.g. validation of environmental conditions and alarm management cannot be fully confirmed until all parts of the system come together.

#### Integrated System Validation (ISV)

1. This specific form of design validation is typically used for new build nuclear power plants and relates to the holistic confirmation of the design process. This is often used to confirm that a fully manned new main control room can support safe operation through application of the new procedures and processes. Integrated System Validation can also have significant benefits for plants and facilities more generally across the nuclear sector and its application should be considered in a risk informed and proportionate way.
2. SSG-51 outlines expectation for HF V&V and states that

“Validation of the integrated system, comprising hardware, software, procedures and humans, should be performed before the design is finalized, so that enough time is available to make changes to the design before the plant becomes operational.” [25]

1. For ISV trials the objective is to verify that the frozen design passes a series of performance-based tests (e.g. success, time, cognitive workload, situational awareness, etc.) and that the integrated system design   
   (i.e., hardware, software, procedures and personnel elements) supports the safe operation of the plant. Testing should be done against the full range of scenarios that the system will be expected to operate in.
2. Section 11.4.3 of NUREG-0711 [33] also provides guidance on ISV trials:

“…the objective of the ISV review is to verify that the applicant validated, using performance-based tests, that the integrated system design (i.e., hardware, software, procedures and personnel elements) supports the safe operation of the plant. The scenarios for ISV should be performed using a simulator, or other suitable representation of the system, to determine the complete design’s adequacy to support safe operations. Validation should be performed after the resolution of all significant human engineering deficiencies identified in verification reviews.” [33]

1. Since formal ISV trials involve considerable effort and expense and are typically reserved for major new build projects, many Inspectors may not be aware of modern standards expectations for this topic area. ISV has been included in this updated TAG to raise awareness of the complexity involved and to direct Inspectors to liaise with HF specialist Inspectors.

## Human Factors Integration into the Safety Assessment

1. For a new facility or a major modification to a facility, safety cases go through a number of stages to reflect the lifecycle of the facility under consideration. Typically, safety cases are completed at early design (preliminary safety report), during detailed design (pre-construction safety report) during installation and testing (pre-commissioning safety report) and then updated during the operational lifetime of the facility (periodic reviews of safety). Safety cases are also typically completed prior to the end of operations and ahead of decommissioning.
2. It is important that human factors considerations are addressed proportionately in the safety assessments undertaken at each stage of the facility lifecycle in order that the human contribution to safety is fully identified, understood, designed for and substantiated. ONR’s Human Reliability Analysis TAG [13] provides detailed guidance on human factors assessment activities and methods that should be employed proportionately in order to do this. Inspectors should confirm that a licensee has an appropriate programme of human factors activities planned and integrated in the safety case development process at each stage of the facility lifecycle.
3. HF should be proportionately integrated into all aspects of the safety assessments that underpin the safety case including human tasks conducted as part of:

* Normal operations e.g. operational tasks, maintenance tasks, criticality management, security arrangements, transport, safeguards arrangements.
* Fault response and recovery.
* Severe accident response.
* Emergency response e.g. incident management, evacuation, casualty handling, stakeholder communications.

1. HF assessments are required to support the range of safety and fault analysis methodologies used in the development of a safety case including Design Basis Analysis (DBA), Probabilistic Safety Analysis (PSA), Severe Accident Analysis (SAA) Internal and External Hazard analysis, and dose assessments. Appendix 3 provides guidance on the requirements for HF assessment in relation to the principal safety and fault analysis methodologies and identifies the key HF interfaces with these methodologies.
2. Proportionate integration of HF into the safety assessments underpinning the safety case will occur throughout the design and safety case lifecycle, with evidence to support the safety case claims and arguments being developed in an iterative manner. Inspectors should ensure that licensees’ safety case processes reflect the need for the inclusion and integration of human factors assessment in all aspects of the safety case and fault analysis.
3. The depth and rigour of the human factors analysis required should be proportionate to the safety importance of the human actions claimed, e.g. as indicated by the class assigned to the human action. SAP ECS.2 reinforces this expectation in paragraph 164 stating that:

“Where safety functions are delivered or supported by human action, these human actions should be identified and classified on the basis of those functions and their significance to safety (see Principle EHF. 3).   
The methods used for determining the classification should be analogous to those used for classifying structures, systems and components….” [1].

1. Other factors that should be borne in mind when considering the adequacy of the plan for HF assessment in support of the safety and fault analyses includes the complexity of the human actions required, the novelty of the actions or the equipment and interfaces the operator must interact with in order to complete the action to deliver the safety function.
2. Typical human factors assessment activities at each stage of the safety case development lifecycle are outlined below. Inspectors should seek confidence that an adequate programme of HF assessment work is planned at each stage of the safety case lifecycle and should ensure these are integrated with the safety and fault analyses and engineering design development as outlined below.
3. Inspectors should seek confidence that a suitably comprehensive package of HF support is provided to support the full range of safety and fault analysis methodologies used in the safety case. Inspectors should ensure the timing of the HF analysis and presentation of the results so that it can impact the engineering design and the claims structure in the safety case in a meaningful way.
4. Inspectors should be sensitive to the risk of silo working where different specialisms undertake their own assessments in parallel but little effective integration across the assessment disciplines takes place, resulting in a disjointed set of safety case arguments and evidence being produced.

### HF Safety Case Considerations at the Preliminary Safety Report Stage

1. The example table in Appendix 2 shows that typically, initial safety functional requirements should be identified at this early phase of a project. These are sometime referred to as demand safety functional requirements (DSFRs).   
   At this stage initial decisions may be made about whether safety functional requirements will be met by passive or active engineered systems, or by human action and associated administrative controls (in accordance with SAP EKP.5 [1]). HF SQEPs should be involved in these allocation of function decisions either via attendance at early optioneering and HAZID meetings or by review of outputs from these initial assessments in order to make a preliminary judgement on the feasibility of the operator tasks required to meet the safety functional requirements.
2. Whilst it is unlikely, at this stage, that details of how the safety functional requirement will be delivered and the relevant PSFs will be available, HF should be able to give an initial view on the appropriateness of allocations of safety functions to operators, by comparing the likely task demands with human capabilities and limitations.
3. Inspectors should consider the adequacy of the dutyholders approach to the allocation of safety functions between engineered and human systems and the role of HF SQEPs in arriving at these allocations. The Allocation of Function between Human and Engineering Systems TAG [10] provides detailed guidance on allocation of function between human and engineered systems.

### HF Safety Case Considerations at the Pre-Construction Safety Case Stage

1. The example table in Appendix 2 shows that the detailed design phase aligns with an increase in safety case maturity and further analysis of human-related claims. At this stage of the safety case development significant HF support to the safety and fault analyses should be expected. This may involve a number of HF activities including:

* Identification of initiating event human errors via attendance and review of detailed HAZID activities such as HAZOPs (including human HAZOPS), FMEAs, OPEX reviews.
* Derivation or review of initiating event frequencies for operator error induced initiating events for use in DBA and PSA.
* Review of unmitigated consequence calculations where these make claims on operator evacuation or reduced operator occupancy times (particularly where these could impact the design basis region of assessed faults).
* Detailed allocation of function to determine the appropriateness of safety measures where these rely wholly on operator action to achieve safety functions or where human actions are required to initiate engineered systems or otherwise support engineered delivery of safety functions. This should be undertaken in support of fault sequence modelling in the DBA, PSA and SAA.
* Support to the classification of SSCs and operator actions that deliver safety functions.
* Analysis of tasks that provide or support the delivery of safety functions to provide detailed engineering and operational design requirements for in-feed to engineering and operational design teams.
* Collection and presentation of evidence to substantiate the feasibility and reliability of human actions important to safety. At the detailed design stage this will use evidence from detailed task analyses, HF design confirmation activities etc. to demonstrate confidence that the safety function can be delivered.
* Derivation of Human Error Probabilities (HEPs) for use in the PSA modelling (once the task design and analysis is sufficiently mature to apply the quantification techniques).
* Assessment of the impact of human error dependency where deterministic or probabilistic fault sequences claim more than one operator action in response to an initiating fault.

1. Where safety and fault analyses make claims on human action it should not simply be assumed that such claims will be underwritten by the HF analysis, rather there should be a mechanism in place to check that initial allocation of safety functions to operator actions are achievable and these should be revised, either in terms the nature of the claim or the means by which the safety function is delivered, where the intended allocation is not supported by HF assessment. Inspectors should seek evidence of an iterative approach to the development of the safety and fault analyses e.g. seeking examples of where changes are made to the claims and arguments used arising from the results of HF and other assessments.

### HF Safety Case Considerations at the Pre-Commissioning Safety Case Stage

1. The example table in Appendix 2 shows that at the pre-commissioning safety case stage HF task verification and further substantiation of HBSCs should now be undertaken. The broad aims of HF activities during this phase are to confirm design assumptions, confirm performance shaping factors and to update the relevant human error analyses.
2. This may involve a number of HF activities including:

* Review of the as built plant to confirm any assumptions made about the installed engineering design and workspaces made in the earlier HF assessments are supported to ensure local-to-plant actions can be undertaken with suitable reliability.
* Review of in-situ environmental conditions e.g. noise, temperature, lighting.
* Review of Operating Instructions and other operational documentation used to support operators to deliver the safety functions.
* Review of training to ensure any assumptions made in the HF substantiations completed at detailed design are met, e.g. the content and adequacy of training material and processes.
* Assessment of the workload associated with operator tasks across a range of normal and fault operations to establish that the staffing design supports reliable operations.
* Identification of a programme of commissioning tests to demonstrate human delivery of safety functions. This is most likely to cover human actions with a high safety classification or where novel and complex safety actions are required to be performed by operators. Whilst the results of these tests may not be available at the time the pre-commissioning safety case is submitted, a route to resolve any HF issues arising from the commissioning test should be documented in the HFIP produced at this design and safety case stage.   
  By the PCmSR, HBSCs should be fully substantiated and the designs should be validated.
* Refinement of HEPs used in the safety and fault analyses may be undertaken at this point once design assumptions used to drive HEP estimates at early stages of the HF analysis are confirmed or otherwise. Refinement of HEPs is likely to be driven by an understanding of the risk importance of particular human failure events or fault sequence cut sets.

1. Inspectors should gain confidence that the programme of HF work planned to support commissioning of the plant will provide the necessary evidence to close gaps in the substantiation evidence available at the previous safety case stages. Inspectors should be content that a route for the closure of any outstanding HF issues and assumptions relevant to the safety case has been identified by the licensee and that this extends to any post commissioning changes to the task design or safety case (necessitated as a result of commissioning tests, whether these arise at inactive or active commissioning).

### HF Safety Case Considerations at the Periodic Review of Safety Stage

1. IAEA SSG-25 [37] provides guidance on periodic safety reviews. Under this framework, human factors falls predominantly under ‘Safety Factor 12’.
2. The example table in Appendix 2 outlines some typical HF activities during the operations stage broadly aiming to review relevant historical data, identify any changes to HBSCs within the safety case, identify and assess changes to performance shaping factors and identify changes in HF RGP.
3. This may involve a number of HF activities including:

* Reviews of OPEX and event data to determine the extent to which human factors shortfalls are responsible for recorded incidents and events, how these reflect on the substantiations for actions important to safety, whether remedial actions have been required and have been successful and whether these have resulted in updates to substantiation evidence.
* Review of the extent of change of HBSCs during the review period to understand whether there is increased reliance on operators for safety and to ensure any new HBSCs are underpinned by suitable HF assessment and evidence.
* Review of substantiation evidence against extant plant condition, operational support materials such as training and procedures, organisational design, staffing and workload to evaluate whether they remain an accurate reflection of plant conditions and to identify shortfalls where remedial actions are required in order that the human contribution to safety can be delivered as required by the safety case.
* Review of current safety case evidence against changes in modern standards and HF RGP in order to determine if gaps against RGP exist, the extent of their impact on the safety case claims and arguments and the need for additional human factors assessment to support the safety case. Where RGP has changed since the production of the safety case, or where the safety case covers a legacy facility which is not supported by a modern standards human factors safety justification, the size of the delta to RGP should be assessed and a risk-informed and proportionate programme of HF safety assessment should be undertaken to secure any necessary improvements.

1. As with any project phase, Inspectors should seek confidence that an adequate programme of HF review and assessment activities is proposed either within a standalone HFIP or in the wider licensee’s PRS project planning. Inspectors also should seek evidence that any HF reviews undertaken have:

* identified routes to close any shortfalls and
* included appropriate mechanisms for raising issues.

1. Non-HF disciplines involved in the PRS process may be best suited to address such shortfalls e.g. concerns about plant conditions or organisational arrangements that might impact on the operators’ ability to reliably perform safety-important actions. Therefore once again, HF assessments should not be conducted in isolation.

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# Glossary and Abbreviations

AoF Allocation of Function

BOD Basis of Design (document)

BS British Standard

CAD Computer-Aided Design

CDM Construction (Design & Management) Regulations 2015

CIBSE Chartered Institute of Building Services Engineers

COTS Commercial Off The Shelf

DBA Design Basis Analysis

DSFR Demand Safety Functional Requirement

EEMUA Engineering Equipment & Materials Users' Association

EHFA Early Human Factors Assessment

FAT Factory Acceptance Test

FMEA Failure Modes and Effects Analysis

HAZAN Hazard Analysis (report)

HAZOP Hazard and Operability Study

HBSC Human Based Safety Claim

HEP Human Error Probability

HF Human Factors

HFE Human Factors Engineering

HFI Human Factors Integration

HFIAR Human Factors Issues and Assumptions Register

HFIP Human Factors Integration Plan

HTA Hierarchical Task Analysis

HMI Human Machine Interface

HRA Human Reliability Assessment

HU ‘Human performance’

IAEA International Atomic Energy Agency

IC Intelligent Customer

ISV Integrated System Validation

LC Licence Condition

LOLER Lifting Operations and Lifting Equipment Regulations 1998

ONR Office for Nuclear Regulation

OPEX Operational Experience

PCSR Pre-Construction Safety Report

PCmSR Pre-Commissioning Safety Report

POSR Pre-Operational Safety Report

PPE Personal Protective Equipment

PRS Periodic Review of Safety

PSA Probabilistic Safety Analysis

PSF Performance Shaping Factor

PSR Preliminary Safety Report

RGP Relevant Good Practice

SAA Severe Accident Analysis

SAP Safety Assessment Principle (ONR)

SAT Site Acceptance Test

SFR Safety Functional Requirement

SQEP Suitably Qualified and Experienced Person

SRL Safety Reference Level (WENRA)

SSC Structures, systems and components

TAD Target Audience Description

TAG Technical Assessment Guide(s)

UK United Kingdom

V&V Verification and Validation

VR Virtual Reality

WENRA Western European Nuclear Regulators’ Association

# Appendix 1 – Putting Human Performance in Context with Organisational and Human Factors

**Background**

1. The term ‘human performance’ (HU) has become widespread in the UK nuclear industry. Historically, ONR has had concerns that the industry was interpreting the term too narrowly with a focus on individual behaviours rather than the wider human and organisational factors that underpin effective human performance. When initially introduced activities under the HU banner were commonly not linked to other relevant work streams, and in some instances, there was a misconception that HF is ‘about safety cases’ and HU is “about behaviours”.
2. ONR’s initial experience was that the primary focus of HU within licensees was aimed at implementing a suite of HU ‘tools’, with the intention of reducing human error. These were initially targeted at front line workers and in some instances were also extended to ‘knowledge workers’. ONR considers these tools to have merit. However, they do not focus on the underlying organisational and systemic factors that give rise to the symptoms of poor performance and therefore are limited in their ability to deliver lasting improvements.
3. ONR recognise that the delivery of resilient organisational performance requires a holistic approach, with the integrated application of knowledge and skills across the field of human and organisational factors. This is supported by IAEA who in NG-T.2.7 (‘Managing human performance to improve nuclear facility operation’ [38]) note that the individual, processes, and the organisation all play a role in human performance improvement.

**Safety Importance**

1. Underlying organisational factors are proven causes of major accidents/events and for risk to be managed effectively, systematic organisational weaknesses need to be identified and understood.
2. A significant percentage of individual human errors ultimately have a systemic cause, and these should be addressed in an holistic and integrated way. A narrow approach to HU will have limited benefits.
3. When an organisation does not see a reduction in human error-based events following implementation of a HU initiative, there can be a tendency to increase the focus on individual accountability rather than recognising the need for a holistic and integrated approach to human and organisational factors. This focus on individual accountability can be counterproductive as it can contribute to moving an organisation towards a blame culture and it fails to address the underlying factors.

**Application of HU Tools**

1. ONR recognises that considered application of HU tools has merit in supporting reliable individual and organisational performance. However, it should be noted that they represent only a relatively small part of the work required to support effective human performance. It is important that licensees understand this bigger picture and are able to articulate the breadth of human and organisational work required to support effective performance and how their HU initiatives fit into this.
2. Appendix 2 demonstrates that HU tools may be of limited value during the early phases of the design process where HF techniques are more applicable. However, HU programmes can provide useful sources of OPEX which can be fed into the design process and inform the safety case development.
3. HU tools are most effectively applied from the construction and implementation phases of a project onwards and can usefully be linked to other relevant workstreams which together support effective human performance.
4. It is important that HU tools are applied in a considered and measured way. Not all tools are appropriate in every circumstance, and over-application can in some instances undermine their use and effectiveness.

**Considerations for Inspectors**

1. In the context of nuclear safety assessment, Inspectors should probe a licensee’s understanding and application of both HF and HU, to ensure that there is a clear understanding of what each can contribute
2. Inspectors should check the scope and nature of HU, HF and organisational factors work being undertaken by licensees and challenge if the organisational and systemic factors are not being adequately addressed.
3. Where possible, Inspectors should promote integrated approaches towards HU, HF and organisational factors as a coherent model for achieving resilient organisational performance.
4. ONR should check if licensees have clear definitions of the SQEP criteria for those undertaking Human and Organisation Factors work, including those for HU specialists. This is important to ensure that practitioners only undertake safety important activities for which they are suitably qualified and experienced.
5. Inspectors should ensure that where events occur the systemic causes are appropriately identified rather than simply blaming the individual and their application of HU tools.
6. Where Inspectors are concerned that there is an over reliance on the application of HU tools and individual accountability, they should seek advice and guidance from specialist Inspectors from the Human and Organisational Capability specialism.

# Appendix 2 – Overview of Design Phases, Safety Case Submissions and Related HF Considerations

| System Maturity Phase | Problem Definition /Concept Design | Detailed Design/ Design Freeze | Implementation/ Construction | Test and Commissioning | Operations |
| --- | --- | --- | --- | --- | --- |
| Staged Safety Submission | PSR | PCSR |  | PCmSR | PRS |
| **HF Topics** | * Review of OPEX * EHFA * Early Optioneering (Initial AoF) * Target Audience Description * Concept of Ops * Functional Specification (Ops) * Alarm philosophy * HMI Style Guide | * Application of HF RGP via requirements * Workplace design & layout * Environmental conditions defined * Detailed optioneering * AoF justification * Task Design * HMI Design * Alarm Architecture * Procedure Design * Identification and design of Admin Controls * Staffing concept including shift patterns * Identify Training Needs | * Verification[[1]](#footnote-2) of HF requirements * Task Verification * Further development of Procedures * Further development of Admin Controls * Staffing arrangements * Training development | * Validation[[2]](#footnote-3) of HF Requirements * Validation of workspace layout * Validation of environmental conditions * Validation of tasks & admin controls * Alarm Management * Validation of procedures * Workload assessment | * Review of HF RGP * Data collection & event reporting * Ongoing training & competence management * Review of Procedures * Change management |
| **Example Processes to Consider for HFI** | * Review of HF RGP and standards * Safety Functional Requirements specification * Substantiation (feasibility) * High level task analysis | * HF RGP into design specifications * Detailed task analysis and HRA processes – HTA, timelines, link analysis * Error identification * Timely input into design reviews * Mock-ups/ VR / prototyping * Training Needs Analysis * Human HAZOP | * Compliance with Standards * Training Programme * Procedure writing Programme * Timely alignment with construction activities | * Plant walkdowns * Field trials * ISV trials * Timely alignment with commissioning activities * Data collection to feed into HRA processes | * Introduction of new tasks * Change in Equipment Designs * Change in Staffing Concept * Ageing & Degradation – impact on maintenance & inspection tasks |
| **Human Performance Focus** | OPEX input | Task Input | Human Performance – construction/ installation tasks | Human Performance – commissioning tasks | Human Performance - Ops |

**Notes:**

ONR recognises that many designs are based on existing processes rather than ‘blue sky thinking’. Therefore, some projects will not include all of the system maturity phases outlined here.

The ONR SAPs highlight the need to consider decommissioning early in the project lifecycle. Therefore, this table has not listed this as a separate system maturity phase.

The HF topics listed will persist throughout the project lifecycle and are presented in this table to indicate the point at which they should be considered for maximum effect, thus avoiding design foreclosure in the later phases of system maturity. However, Inspectors must be cognisant of each project context when considering which HF topics are relevant and the timing of HFI activities.

# Appendix 3 – HF Integration with Safety Case Methodologies

1. HF assessments are required to support the range of safety and fault analysis methodologies used in the development of a safety case including Design Basis Analysis (DBA), Probabilistic Safety Analysis (PSA), Severe Accident Analysis (SAA), Internal and External Hazard analysis and dose assessments. This Appendix provides guidance on the requirements for HF assessment in relation to the principal safety and fault analysis methodologies and identifies the key HF interfaces with these methodologies.

**Design Basis Analysis (DBA)**

1. ONR’s TAG on DBA states:

“DBA has a role to play in identifying human actions which are important for the delivery of safety functions. LC 24 is important for ensuring human based safety claims made and set out in the safety case are achieved on the plant” [17]

1. DBA requires identification of the role of human error in initiation event frequencies plus substantiation of the level of reliability for HBSCs claimed to protect or mitigate against fault sequences. DBA should also ensure any claims on required operator occupancy and response times are underpinned by a suitable task analysis.
2. The following sources of information may be considered by Inspectors:

* Fault Schedule / Fault & Protection Schedule
* Fault sequence progression diagrams
* Transient analyses (for power plants)
* HAZAN reports

1. It is important to discuss any supporting analyses with an Inspector from the Fault Studies specialism to ensure the wider safety case context of the HBSCs identified is fully understood.

**Probabilistic Safety Analysis (PSA)**

1. ONRs TAG on PSA outlines the expectation that the probabilistic safety analysis should include various type of modelling, including accident sequence and system modelling, human reliability analysis, dependence analysis and classification of accident sequences into plant damage states [18].
2. Para 653 supporting SAP FA.13 also states:

“The PSA should account for contributions to the risk including, but not necessarily restricted to:

(a) random individual component failures;

(e) pre-fault human errors (e.g. misalignments and miscalibrations);

(f) human errors that lead to initiating faults (see Principle EHF.3);

(g) human errors during the course of fault sequences, including those required for repair or recovery actions (see Principle EHF.5); and

(h) potential dependencies between separate human activities (either by the same or by different operators).”

1. Inspectors should ensure that any HBSCs identified within the detailed fault and event trees are captured as part of human reliability assessment work.
2. Inspectors should ensure that any human error quantification techniques employed in support of the PSA are justified by the licensee to be both aligned with RGP and also relevant to the context in which they are applied.
3. It is important that the risk significance of HBSCs are understood in order to drive a proportionate level of HF substantiation. This can be examined via cut set analysis, importance analysis and sensitivity analysis.

**Hazard Analyses**

*External Hazards*

1. External hazards include consideration of ‘Human-induced external events’ e.g. aircraft impact. Typically, the HF specialism does not get involved in assessing the likelihood or consequences of such events since there are established methodologies for doing so.
2. However, HF aspects should be considered when assessing the expected response following external events (including their impact on human performance) e.g. response times.

*Internal Hazards*

1. ONRs Internal Hazards TAG states that:

“Where operator actions play a role in preventing or mitigating the consequences of flood scenarios, for example, by isolating the flood source / paths, then the feasibility of performing the required actions under the hazard conditions is a matter for consideration by Human Factors and / or Radiological Protection specialists in conjunction with Internal Hazards. Inspectors should ensure that the safety case assumptions and calculations (such as, available response times, flood levels) are compatible with the release scenarios and proposed actions (for example, deploying defences, closure of flood doors etc.).” [21]

1. Typically, human error should be considered as an initiating event when considering dropped loads and other impact damage. Therefore, the Inspector should ensure that HBSC identified within the hazard analysis studies have been captured and a proportionate level of HF analysis has been applied.

**Severe Accident Analysis (SAA) and Emergency Response**

1. ONRs TAG on SAA states that:

“The SAA should use deterministic methods to demonstrate that the safety functions are achieved by features implemented in the design, combined with measures that can be implemented through human actions and administrative controls described in procedures and/or accident management guideline.” [19]

“…the term ‘severe accident safety measures’ here is intended to include SSCs and associated human actions, which either individually or in combination, prevent escalation of severe accidents and/or mitigate the consequences.” [19]

1. Therefore, Inspectors should seek evidence of a proportionate assessment of measures implemented through human actions and administrative controls including:

* Evacuation routes and claimed muster and evacuation times
* Human actions that support the delivery of any active measures and mobile equipment to site
* Command and control and decision-making frameworks.

1. Further guidance on how to recognise dependency between human actions and how to assess the associated impact is provided in the HRA TAG [13]

**Radiological Protection**

1. Although the assessment of radiological risks is undertaken by radiological protection specialists, any analysis should align with the findings of corresponding HF analysis. Typical interfaces include:

* Task durations underpinning exposure times.
* Occupancy assumptions and timescales.
* Impact of shielding requirements on task design and human reliability.

1. “Design verification is the process to confirm that each stage of the design is confirmed as correct against the requirements from the previous stage.” [8] [↑](#footnote-ref-2)
2. “Design validation ensures that the overall intent of the design is achieved. It also prevents failure of the design intent by incremental deviation or dilution.” [8] [↑](#footnote-ref-3)