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1. INTRODUCTION

1.1. The Office for Nuclear Regulation (ONR) has established its Safety Assessment Principles (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 dutyholders. 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.

2. PURPOSE AND SCOPE

2.1. The ONR has the responsibility for regulating the safety of nuclear installations in Great Britain. SAPs [1] provide a framework to guide regulatory decision-making in the nuclear permissioning process. They are supported by TAGs which further aid the decision-making process.

2.2. This TAG 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 should be applied throughout the entire facility lifecycle.

MS.2 The organisation should have the capability to secure and maintain the safety of its undertakings.

3. RELATIONSHIP TO LICENCE AND OTHER RELEVANT LEGISLATION

3.1. The Nuclear Site Licence Conditions (LC) [2] place legal requirements on the licensee to make and implement arrangements to ensure that safety is being managed adequately.

3.2. LC 14 is relevant to this TAG, as Human Factors Integration (HFI) is a good practice approach that should reflected in the arrangements for production of the safety case:

Licence Condition 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.

4. RELATIONSHIP TO SAPS, WENRA REFERENCE LEVELS AND IAEA SAFETY STANDARDS

SAPs

4.1. ONR's expectations concerning HFI are set out in a number of SAPs. The primary references are SAPs EHF.1and MS.2 cited in section 2 of this document.

WENRA Safety Reference Levels

4.2. 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) [3], 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.

Although no WENRA SRL refers explicitly to HFI, ONR considers that HFI is a good practice methodology that should be used to support the Safety Analysis Report (Issue N) and Plant Modifications (Issue Q).

IAEA Safety Standards

4.3. The IAEA Safety Standards (Requirements and Guides) were the benchmark for the revision of the SAPs in 2006 and are recognised by ONR as relevant good practice. They should therefore be consulted, where relevant, by the assessor as complimentary guidance, although it should be appreciated that they are design standards rather than regulatory standards.

4.4. The guidance in this TAG is also consistent with IAEA guidance:

SSR-2/1: Safety of Nuclear Power Plants: Design [4] 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……."

(This requirement is also repeated in SSG-2: Deterministic Safety Analysis for Nuclear Power Plant Specific Safety Guide [5])

"Verification and validation of aspects of human factors shall be included at appropriate stages to confirm that the design adequately accommodates all necessary operator actions."

NS-G-1.3 Instrumentation and Control Systems Important to Safety in Nuclear Power Plants [6] states:

"…….human factor processes should be integrated into the overall design process"

"Applicable human factor techniques include functional analysis, task analysis and workload analysis. These are used in the allocation of functions among humans and machines and in the design of the human–machine interface. Guidance on human factor engineering is available, in particular on anthropometrics, human error, design of user interfaces and various other related subjects. To take advantage of this knowledge, systematic attention should be paid to human factors."

"Applicable design principles or requirements for human factors should be observed to ensure compatibility with the users, comprehensibility and effectiveness of the human–

machine interface. The system design process should incorporate user group feedback and appropriate measures for verification and validation of the human–machine interface. The engineering programme for human factors should be included in the overall project plan. Analyses and findings in relation to human factors should be systematically documented in the course of the engineering design, following applicable engineering guides and references to human factors."

Other International Standards

The following International Standards are also relevant:

- BS EN ISO 6385:2004 Ergonomic Principles in the Design of Work Systems [7]
- BS EN ISO 11064 Ergonomic Design of Control Centres Parts 1-7 [8]
- BS EN ISO 9241 – 210:2010 Ergonomics of human-system interaction. Human-centred design for interactive systems [9]
- ISO/TR 18529:2000 Ergonomics of human-system interaction – Human-centred lifecycle process descriptions [10]

5. ADVICE TO ASSESSORS

Human Factors Integration

5.1. HFI is a good practice approach to the application of Human Factors (HF) to systems development. As a methodology it provides an organising framework to help ensure that all relevant HF issues are identified and addressed. In addition the HFI approach has a management strategy that aims for timely and appropriate integration of HF activities throughout the project.

5.2. 'Integration' means "…a combination of parts …that work well together..". Therefore HFI requires that HF is an integral part of a project, and is not carried out in isolation.

5.3. The exact nature by which HFI is undertaken may vary between dutyholders and projects. Thisis to be expected although certain key elements (or commensurate activities) should always be evident and are discussed below. Similarly, the level of HFI should be align with the size of the project, and take account of the safety reliance on humans and the consequences of human error, together with the novelty and complexity of any new technology.

Human Factors Integration Methods

5.4. There are a number of recognised prescribed approaches to HFI developed by industry; for example see references 11 to 13. Inspectors should consider the application of such approaches in terms of their applicability for the context, breadth and depth of HFI delivery.

Human Factors / Human Performance / Organisational Factors

5.5. In recent years the term 'human performance' has evolved, and in some areas of the UK nuclear industry this term has been misinterpreted to mean something different than the widely recognised term 'human factors' or 'human and organisational factors'.

5.6. In the context of nuclear safety assessment, inspectors should probe a dutyholder's understanding and application of both HF and human performance, to ensure that any misinterpretation is not resulting in misapplication of the discipline and having an adverse safety outcome. Similarly, with reference to HFI, it is not helpful for an organisation to have separate disciplines of human performance and HF as this does not facilitate integration.

5.7. For clarity, ONR recognises and supports the Institute of Nuclear Power Operators (INPO) 'definition' of human performance – the avoidance of human error. Similarly the Organisation for Economic Co-operation and Development's (OECD) working group on risk and special experts group on human and organisational factors note that "…….the factors influencing human performance are known as human and organisational factors….(and)…human factors are task, individual and organisational characteristics influencing human performance", i.e. the terms are largely synonymous and have the same aims.

5.8. ONR has a Technical Position Statement titled 'Putting Human Performance in Context with Organisational and Human Factors' (Appendix 2). This provides ONR's perspective on the issue, our regulatory and safety concern, highlights international consensus and provides assessors with recommended 'lines to take'. Assessor interactions with dutyholders on this matter should be consistent with this Technical Position Statement.

The Human Factors Integration Plan (HFIP)

5.9. The assessor should ensure that a project specific HFIP is developed during the initial phases of the project. This is the key document that describes in detail how HF issues will be integrated and managed through the project. However the HFIP should be a living document that is able to evolve and reflect any changes over time relating to safety significant human actions.

5.10. The HFIP 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 accounted for.

5.11. The level of detail expected in the HFIP should be proportionate to the size of the project, and the safety significance of the human factors component of the project. An HFIP may be presented in a stand-alone form or may be contained within other project planning, scoping and management deliverables. Assessors should seek justification from the dutyholder for the level of HFI proposed for a project.

5.12. Assessors 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;
- A project organogram highlighting the position of the HF lead;
- The work breakdown structure of the HF analysis throughout the project (what HF analysis work is to done, at what level of detail, and when in the project);

- Integration of HF within the project plan. This should detail the key HF deliverables and show dependencies between discipline outputs;
- HF Suitably Qualified and Experienced Person (SQEP) resource requirements and how that resource will be managed;
- The HF standards to be applied;
- How assumptions, uncertainties and project issues and risks will be managed and resolved;
- How trade-offs between different discipline requirements will be managed and resolved;
- Hold points and design reviews and the expected HF contribution;
- Who has ownership of particular aspects of the work;
- Progress monitoring arrangements; and
- Reporting methods.

Concept of Operation

5.13. Assessors should ensure that for new facility build 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. Where an incomplete concept of operations is provided, assessors 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.

5.14. This document should provide the following basic details:

- A statement of the operational purpose of the system, and the operational requirements under all 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 and fault response situations.
- The staffing concept for the system and an indication of their required capabilities and responsibilities. This is also known as the 'target audience description'.
- The basic details of the working environment.

The Design Review Process

5.15. Depending on the size and complexity of a project, dutyholders may hold 'design reviews' [1].. Assessors should ensure that HF is represented at such reviews, and may request the output of the reviews as an input into the regulatory assessment process.

Validation and Verification

5.16. An appropriate validation and verification programme should be sought for the human factors elements of the project that aligns with general validation and verification activity on the project. The activity should be appropriate to the scope and safety significance of HF to the project.

5.17. Activities may range from verification against standards and good practice, and draw upon the output of any design reviews, to functional validation involving drawing walk-throughs, the use of mock-ups or simulators and the testing of HF aspects during wider project activities such as during a Factory Acceptance Test (FAT).

The Human Factors Team

5.18. Assessors should ensure 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, and therefore it is usually appropriate to also have a HF capability within the core engineering or design team.

5.19. Assessors should ensure that the HF expertise has the appropriate authority and responsibility to ensure effective delivery of the required HF work. It is generally expected that the HF manager (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

5.20. Assessors should be satisfied that the totality of the HF analysis is carried out by suitably qualified and experienced persons. Assessors may consider requesting SQEP statements from dutyholders where the analyst involved is not recognised, and such detail has not been provided as part of the HFIP or supporting materials.

5.21. Licensees will have their own arrangements for staff that are SQEP under LC 12 and in the HF area this should require a formally recognised and relevant academic qualification along with experience commensurate with the seniority of the role.

[1] 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.

5.22. Where a licensee chooses to contract out its HF work, an appropriate level of Intelligent Customer (IC) capability should be sought. Assessors should ensure that the HF IC(s) has sufficient capability to adequately oversee the level of contractor support proposed, to assure the technical delivery of the human factors scope. Assessors may also choose to request SQEP statements/assurances from the proposed contractor resource.

Standards, Good Practice & Recognised Methods

5.23. Assessors 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, assessors 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, assessors should determine their basis and assure themselves of their technical credibility.

6. REFERENCES

1 Safety Assessment Principles for Nuclear Facilities, 2006 Edition, Revision 1, Health and Safety Executive. www.hse.gov.uk/nuclear/saps/saps2006.pdf

2 Licence condition handbook. Office for Nuclear Regulation. October 2011. www.hse.gov.uk/nuclear/silicon.pdf

3 Western European Nuclear Regulators' Association. Reactor Harmonization Group. WENRA Reactor Reference Safety Levels. WENRA. January 2008. www.wenra.org.

4 INTERNATIONAL ATOMIC ENERGY AGENCY, Specific Safety Requirements: Safety of Nuclear Power Plants: Design, IAEA Safety Standards Series No. SSR-2/1, IAEA, Vienna (2012).

5 INTERNATIONAL ATOMIC ENERGY AGENCY, Specific Safety Guide: Deterministic Safety Analysis for Nuclear Power Plants, IAEA Safety Standards Series No. SSG-2, IAEA, Vienna (2010)

6 INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Guidance: Instrumentation and Control Systems Important to Safety in Nuclear Power Plants, IAEA Safety Standards Series No. NS-G-1.3, IAEA, Vienna (2002)

7 British Standards Institution, Ergonomic Principles in the Design of Work Systems, BS EN ISO 6385:2004

8 British Standards Institution, Ergonomic Design of Control Centres, Parts 1-7, BS EN ISO 11064

9 British Standards Institution, Ergonomics of human-system interaction. Human-centred design for interactive systems, BS EN ISO 9241 – 210:2010

10 International Organization for Standardization, Ergonomics of human-system interaction – Human-centred lifecycle process descriptions, ISO/TR 18529:2000

11 Ministry of Defence, Human Factors Integration for Defence Systems, Joint Services Publication: 912, Version 2i, 2013

12 US Nuclear Regulatory Commission, Human Factors Engineering Program Review Model, NUREG 0711, Rev 3, 2012

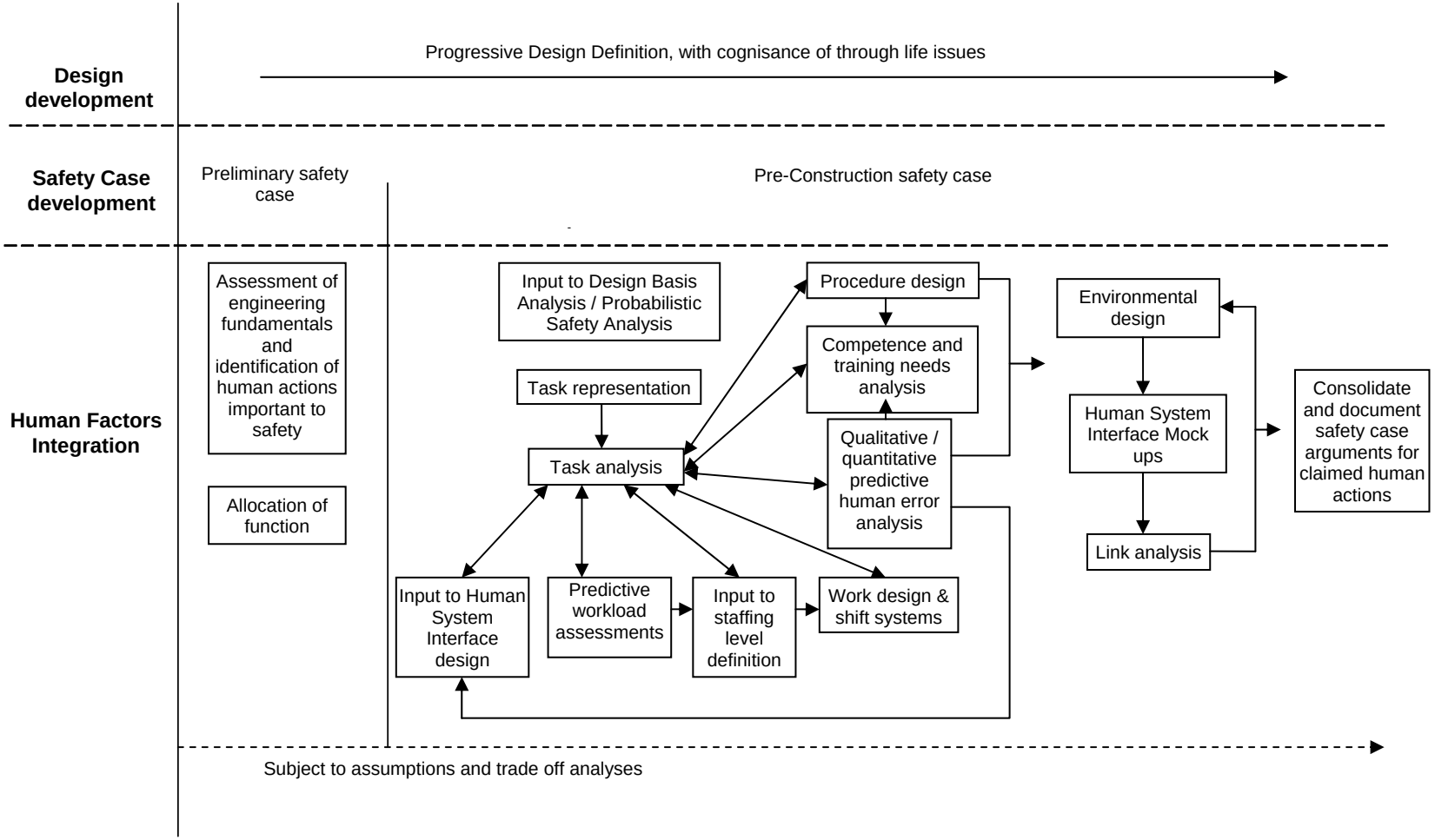
13 Ministry of Defence, Human Factors for Designers of Systems, Part 0: Human Factors Integration, Defence Standard 00-250, Issue 1, 2008

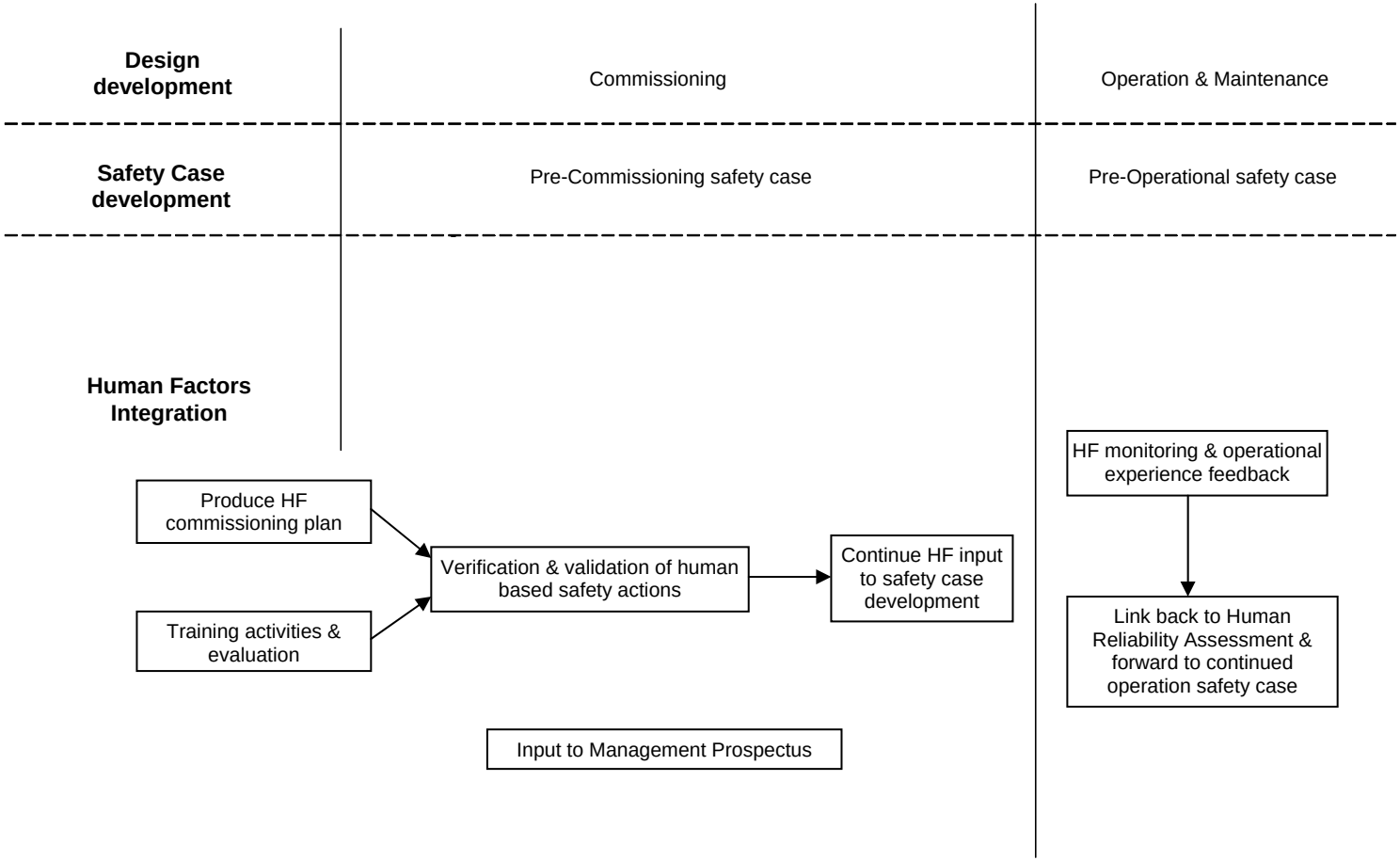
7. GLOSSARY AND ABBREVIATIONS

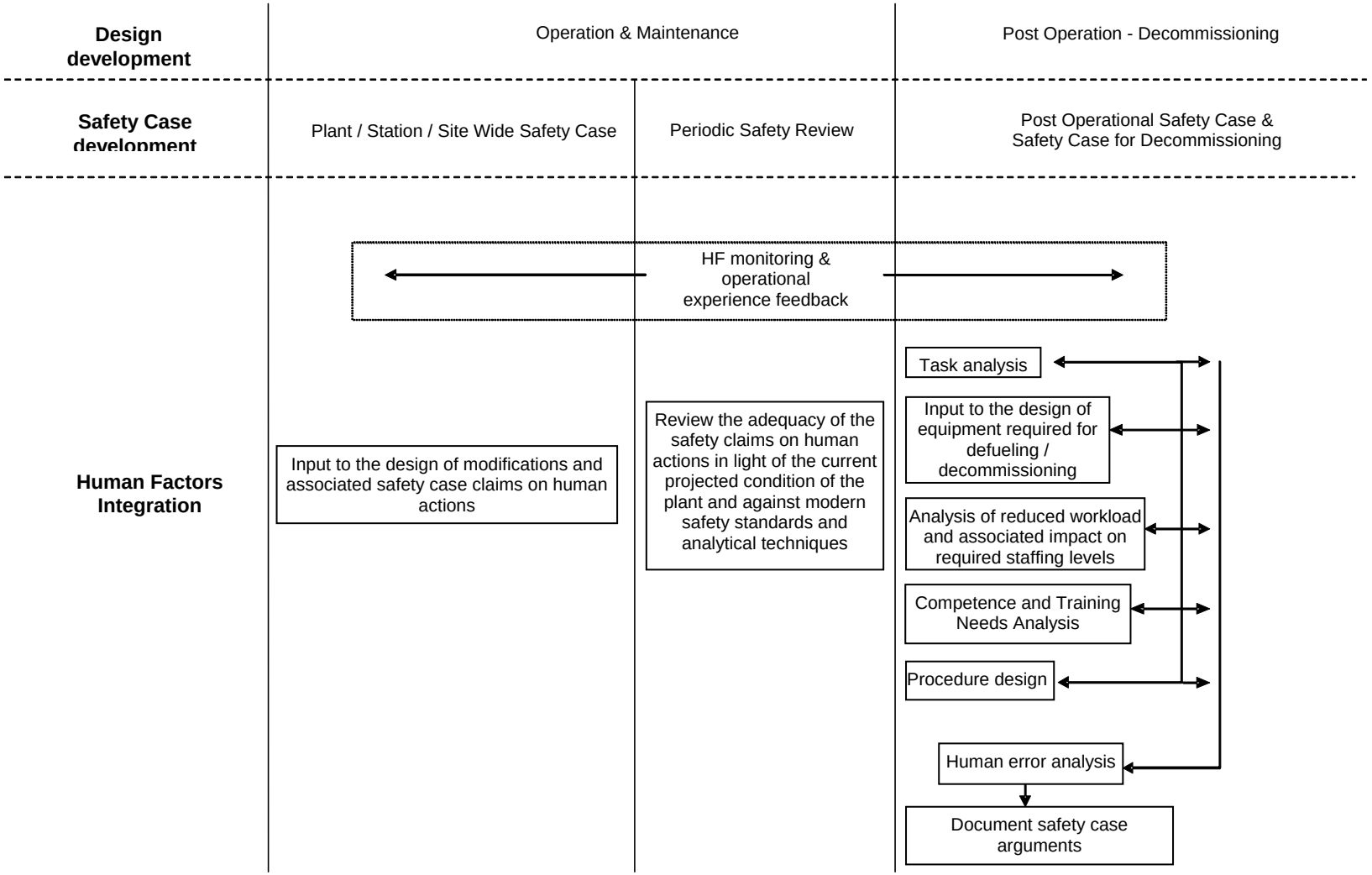
DBA	Design Basis Analysis
FAT	Factory Acceptance Test
HF	Human Factors
HFI	Human Factors Integration
HFIP	Human Factors Integration Plan
HU	Human Performance
IAEA	International Atomic Energy Agency
IC	Intelligent Customer
INPO	Institute of Nuclear Power Operations
LC	Licence Condition
MIT	Massachusetts Institute of Technology
OECD	Organisation for Economic Co-operation and Development
ONR	Office for Nuclear Regulation
PSA	Probabilistic Safety Analysis
SAP	Safety Assessment Principle (ONR)
SQEP	Suitably Qualified and Experienced Person
SRL	Safety Reference Level (WENRA)
TAG	Technical Assessment Guide(s)
WENRA	Western European Nuclear Regulators' Association

8. APPENDIX 1

Human Factors Integration Process Flow Diagram




Design development
Commissioning
Operation & Maintenance
Safety Case development
Pre-Commissioning safety case
Pre-Operational safety case
Human Factors Integration
Produce HF commissioning plan
Training activities & evaluation
Verification & validation of human based safety actions
Continue HF input to safety case development
HF monitoring & operational experience feedback
Link back to Human Reliability Assessment & forward to continued operation safety case
Input to Management Prospectus


Design development
Operation & Maintenance
Post Operation - Decommissioning
Safety Case development
Plant / Station / Site Wide Safety Case
Periodic Safety Review
Post Operational Safety Case & Safety Case for Decommissioning
HF monitoring & operational experience feedback
Human Factors Integration
Input to the design of modifications and associated safety case claims on human actions
Review the adequacy of the safety claims on human actions in light of the current projected condition of the plant and against modern safety standards and analytical techniques
Task analysis
Input to the design of equipment required for defueling / decommissioning
Analysis of reduced workload and associated impact on required staffing levels
Competence and Training Needs Analysis
Procedure design
Human error analysis
Document safety case arguments

9. APPENDIX 2

Putting 'Human Performance' in Context with Organisational and Human Factors

The Problem

In recent years the term 'human performance' (HU) has become more widespread in the UK nuclear industry. ONR considers that the industry is interpreting the term too narrowly. HU is not being applied in the wider context of organizational performance, taking into account human and organisational factors. Activities under the HU banner are not being linked to other relevant work streams. Licensees do not appear to be recognising that 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.

In particular, HU and HF are usually treated as unrelated topics and with different teams of people. There is a common misconception across industry that HF is 'about safety cases' and HU is 'about behaviours'. Additionally, although licensees usually have specific SQEP criteria for HF specialists, the requirements for HU specialists seem to be less clearly defined.

ONR's experience is that the primary focus of HU within licensees has been aimed at implementing a suite of HU 'tools' at the individual front line worker and team leader level, with the intention of reducing human error. These tools have merit but are limited in their ability to deliver lasting improvements because they do not focus on the underlying organisational factors that give rise to the symptoms of poor performance.

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. This can be counter-productive as it can contribute to moving an organisation towards a blame culture and it fails to address the underlying factors.

Regulatory Interest / Safety Concern

- Underlying organisational factors are proven causes of major accidents/events. For risks to be managed effectively, systemic organisational weaknesses need to be identified and understood.

- A narrow approach to HU will have limited benefits. A significant percentage of individual human errors ultimately have a systemic cause.

- A narrow approach can have negative effects such as fostering a blame culture.

International Consensus

INPO

The INPO strategic approach to human performance emphasises that reducing error and managing (organisational) defences will lead to zero events. Inherent to this strategy is a need for increased focus on the conditions that lead to error and failure of organisational defences/barriers. INPO emphasise that use of HU tools should not be the sole strategy against human error risk. A common problem identified by INPO is that managers believe the worker is the sole source of variance in performance. The INPO guidance 'Excellence in Human Performance' highlights the

need to identify and eliminate the organisational weaknesses that create conditions for human error. The guide states that leaders should focus attention and energy on preventing recurrence of organisational weaknesses that create conditions to provoke error and weaken defences. INPO has started to look at how to apply the concepts of organisational resilience.

IAEA

IAEA TECDOC 1204 emphasises that integration of organisational factors, human and equipment performance are needed for effective plant performance. It defines human performance as: the behaviour of people in a system with a focus on understanding the general behaviour of people within the system, rather than on the behaviour of any one individual.

OECD/NEA

OECD's Working Group on Human and Organisational Factors has stated that "…….the factors influencing human performance are known as human and organisational factors….(and)…human factors are task, individual and organisational characteristics influencing human performance." i.e. HF forms an integral part of organisational and individual performance.

MIT

The Massachusetts Institute of Technology (MIT) is developing the concepts of system dynamics and archetypes for organisational safety. This work, by leaders in the field (e.g. Nancy Leveson, Karen Marais), recognises the complexity of modern socio-technical systems and the potential downsides of fixing the symptom rather than underlying problem. MIT emphasise that, to improve safety in the long term, the fundamental problem or organisational deficiency that is causing the symptom must be identified.

LINES TO TAKE

- ONR should promote more actively an integrated approach towards HU, HF and organisational factors as a coherent model for achieving resilient organisational performance.

- Currently, the term 'human performance' is too narrowly understood and applied. Where a licensee uses the term ONR should check understanding and question if the wider context is recognised.

- ONR should check if licensees have clear definitions of the SQEP criteria for HU specialists.

- Existing HU tools have merit in supporting reliable individual and organisational performance. However they are only a relatively small part of what is required to address the issues that can affect performance.

January 2010