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Physical Design

General Design Considerations: Human Factors

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Preface

This regulatory document is part of the CNSC's physical design series of regulatory documents, which also covers design of reactor facilities and uranium mines and mills. The full list of regulatory document series is included at the end of this document and can also be found on the CNSC's website.

Part A of REGDOC-2.5.1, *General Design Considerations: Human Factors,* sets out guidance for licensees and licence applicants in developing human factors engineering program planning documentation that demonstrates how human factors considerations are incorporated into activities licensed by the CNSC.

Part B sets out guidance for licensees and licence applicants in planning for human factors verification and validation activities.

This document supersedes guidance documents G-276, *Human Factors Engineering Program Plans,* and G-278, *Human Factors Verification and Validation Plans,* both published in June 2003.

Note: In 2013, the CNSC adopted a revised regulatory framework structure with a new system for naming and numbering regulatory documents. This document has been published as part of the CNSC's initiative to bring regulatory documents that were published before the current framework was adopted into the new system. The requirements and guidance in this document have not changed.

For information on the implementation of regulatory documents in the licensing basis, and on the graded approach, see REGDOC-3.5.3, *Regulatory Fundamentals.*

The words "shall" and "must" are used to express requirements to be satisfied by the licensee or licence applicant. "Should" is used to express guidance or that which is advised. "May" is used to express an option or that which is advised or permissible within the limits of this regulatory document. "Can" is used to express possibility or capability.

Nothing contained in this document is to be construed as relieving any licensee from any other pertinent requirements. It is the licensee's responsibility to identify and comply with all applicable regulations and licence conditions.

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General Design Considerations: Human Factors

1. Introduction

1.1 Purpose

Part A of this document is intended to assist licensees and licence applicants in developing human factors engineering program planning documentation that demonstrates how human factors considerations are incorporated into activities licensed by the CNSC. Such considerations help satisfy certain regulatory requirements by demonstrating that licensees and applicants have made adequate provision for health, safety and protection of the environment.

Part B of this document is intended to assist licensees and licence applicants in planning for human factors verification and validation activities. Such activities help satisfy certain regulatory requirements by demonstrating that licensees and applicants have made adequate provision for the protection of the environment and the health and safety of persons.

1.2 Scope

Part A of this guide describes the elements of effective human factors engineering program planning documentation for Class I nuclear facilities and uranium mines and mills.

A suggested documentation format is presented in this guide as a Human Factors Engineering Program Plan. However, submission of equivalent documentation that meets the objectives and intent of this guide is also acceptable. The CNSC will also consider the special circumstances of small business when assessing the human factors approach taken by applicants and licensees.

While a Plan, or equivalent documentation, is recommended to ensure the proper development, execution, management, and documentation of the human factors aspect of any licensable activity, it is not the intention of this guide to create unique human factors work methods or processes. Such processes should already be integrated into the normal project design process wherever possible.

Part B of this guide describes the elements of effective human factors verification and validation planning for Class I nuclear facilities and uranium mines and mills.

A suggested format for documenting these elements is presented in this guide as a Human Factors Validation and Verification Plan. However, submission of equivalent documentation that meets the objectives and intent of this guide is also acceptable.

The information provided in this guide in intended to be used in conjunction with CSA standard N290.12-14, *Human Factors in Design for Nuclear Power Plants* [1].[1]

[1] The standard is a requirement for nuclear power plants and may be used for guidance by other Class I nuclear facilities and uranium mines and mills.

1.3 Relevant legislation

Although the *Nuclear Safety and Control Act* (NSCA) and its regulations contain no explicit reference to "human factors", they include a number of general provisions that are intended to help assure that interfaces between humans and structures, equipment, or substances during licensed activities occur without unacceptable impacts on persons, the environment, or national security. Many of these provisions are synonymous with the application of common principles of human factors engineering.

Some examples of such generally applicable provisions can be found in the following paragraphs of the *General Nuclear Safety and Control Regulations*:

- Paragraph 3(1)(k). This provision states that an application for a licence shall contain [a description of] "the applicant's organizational management structure insofar as it may bear on the applicant's compliance with the Act and the regulations made under the Act, including the internal allocation of functions, responsibilities and authority".
- Subsection 3(1.1). The Commission or a designated officer authorized under paragraph 37(2)(c) of the Act, may require any other information that is necessary to enable the Commission or the designated officer to determine whether the applicant (i) is qualified to carry on the activity to be licensed, or (ii) will, in carrying on that activity, make adequate provision for the protection of the environment, [and] the health and safety of persons…"
- Paragraph 12(1)(a). This provision stipulates that "Every licensee shall ensure the presence of a sufficient number of qualified workers to carry on the licensed activity safely and in accordance with the Act, the regulations made under the Act and the licence".
- Paragraph 12(1)(c). The relevant portion of this provision states that "Every licensee shall take all reasonable precautions to protect the environment and the health and safety of persons …"

2. Background

2.1 Regulatory Framework

The CNSC is the federal agency that regulates the use of nuclear energy and materials to protect health, safety, security, and the environment, and to respect Canada's international commitments on the peaceful use of nuclear energy.

The CNSC operates under the NSCA. The NSCA requires persons or organizations to be licensed by the CNSC in order to carry out the activities referred to in Section 26 of the Act, unless otherwise exempted. The associated regulations stipulate prerequisites for CNSC licensing, and the obligations of licensees and workers.

The NSCA and its regulations contain several provisions that are intended to ensure that interfaces between humans and items involving nuclear substances, prescribed equipment, or nuclear facilities will occur without unacceptable impacts on persons, the environment, or national security.

2.2 CNSC Licensing Process

The CNSC applies a phased process to its licensing of nuclear facilities and activities. For major facilities, this process begins with an assessment of the environmental impacts of the proposed

project, and proceeds progressively through site preparation, construction, operation, decommissioning and abandonment phases.

The NSCA and its regulations require licence applicants to provide certain information at each licensing stage. The type and level of detail of this information will vary to accommodate the licensing stage and specific circumstances.

At all licensing stages, applications may incorporate, directly or by reference, new or previously submitted information, in accordance with legislated requirements and the best judgment of the applicant. An application that is submitted at one licensing stage can become a building block for the next stage. Upon receipt of an application that is complete, the CNSC reviews it to determine whether the applicant is qualified to carry on the proposed activity, and has made adequate provision for the protection of the environment, the health and safety of persons, and the maintenance of national security and the measures required to implement international obligations to which Canada has agreed. Safe and reliable human performance plays a major role in overall system safety. If satisfied, the CNSC may issue, renew, amend or replace a licence that contains relevant conditions. Typically, this licence will incorporate the applicant's undertakings, and will contain other conditions that the CNSC considers necessary, including a condition that incorporates or relates to human factors considerations or provisions.

Because safe and reliable human performance is essential in order to assure the overall safety of licensed facilities and activities, the CNSC, when determining whether licence applicants are qualified and have made adequate provision for health, safety and the environment, will consider whether the applicant has made adequate provision for human capabilities and limitations (human factors) as they relate to the safe conduct of the activity to be licensed.

Part A: Human Factors Engineering Program Plans

3. The human factors engineering program plan

As described in P-119, *Policy on Human Factors* [2], it is the policy of the CNSC to consider human factors in the nuclear facilities and activities licensed by the Commission.

A Human Factors Engineering Program Plan (HFEPP) documents the means by which human factors considerations are integrated into activities licensed by the CNSC. Human factors considerations are applicable during all licensing phases from design to decommissioning. Examples of licensable activities for which an HFEPP would be appropriate are the design of a new facility, significant modification to a human-machine interface, or decommissioning activities.

The HFEPP, or equivalent documentation, should describe the human factors considerations and activities that will be implemented to ensure that the system or licensable activity is designed and evaluated according to established human factors principles and practices. The technical elements described in the Plan should be supported by subsequent verification and validation activities for the resulting design (see Part B, Human Factors Verification and Validation Plans). For a given licensable activity, the applicant should demonstrate that each of the human factors technical elements (described in subsection 4.6.2, "Technical Elements for Review") has been addressed and either built into the Plan or deemed not applicable. If the licensee is uncertain about the need for, or the content of, an HFEPP, a preliminary outline may be submitted to the CNSC to initiate discussion. The need for, and the technical elements to be included in, an HFEPP would be established through discussion between the licensee and CNSC staff.

4. Elements of the human factors engineering program plan

An effective Human Factors Engineering Program Plan should include information about

- the goals of the plan,
- the scope of the plan,
- the background of the activity,
- criteria for determining areas of consideration
- human factors input,
- technical considerations, and
- processes and procedures.

The format presented in this guide is only a suggestion.

4.1 Goals of the plan

Provide concise statements about the objectives of the plan. The goals will normally be driven by the nature of the licensable activity. Goal definition early in development is vital to the Plan's effectiveness and validity.

4.2 Scope of the plan

The scope of the HFEPP should consider safety critical activities and hazardous interactions. It should also specify areas, systems and components involved, and the phases of the licensable

activity in which human factors engineering will be incorporated. Adequate justification for any exclusions should also be provided in this section and discussed in the "Criteria" section, as described in subsection 4.4.

The HFEPP should include documentation on any constraints, limitations, and assumptions that apply to the human factors work. These may relate to level of technology, resource limitations, time constraints, consistency and compatibility with existing design or operational features, or any other restrictions or requirements imposed on the project team or the Plan.

4.3 Background of the Activity

Provide a brief description of the licensable activity including purpose, scope, and time frames.

4.4 Criteria for Determining Areas of Consideration

Provide a description of the type of criteria that will be used to determine which aspects of the activity warrant human factors consideration. It is recommended that criteria be based on function, task importance, or risk, and that criteria statements be clear, concise, and objective.

4.4.1 Rationale

Indicate the rationale behind different levels of human factors effort, with an explanation of how such levels of effort reflect established criteria. Some examples of the types of decisions for which rationales would be helpful include:

- The human factors effort being limited to certain areas in a facility,
- Task analysis being restricted to selected tasks,
- The human factors effort being limited to certain project phases.

4.5 Human Factors Input

4.5.1 Roles and Responsibilities

Clearly define the role of any persons performing human factors work associated with the licensable activity for which the Plan is being prepared. Expand on that role definition with a statement about any part of the licensable activity which will require human factors involvement and input.

4.5.2 Training Needs

Familiarity with established human factors principles, benefits, techniques and guidelines is important to successful implementation of the HFEPP. If training in these matters is required by persons performing human factors work associated with the licensable activity, indicate those training needs and the plans for addressing them.

4.5.3 Related Groups

To varying degrees, the human factors elements addressed in the technical basis of the Plan will overlap and interface with other functions and disciplines within the licensable activity. Identify, at a high level, all groups that may be impacted by the Plan, and indicate how their input will be considered or incorporated.

4.6 Technical Considerations

Consideration should be given to the following technical aspects of the HFEPP:

- Technical basis of the plan
- Technical elements for review
- Methods for addressing the technical elements
- Intended tools
- Technical guides

4.6.1 Technical Basis of the plan

Clearly state the technical basis for the HFEPP, such as specific licence applicant's policies and procedures for human factors, regulatory documents, and industry documents such as consensus standards and guides.

4.6.2 Technical Elements for Review

The following technical elements should be included in the plan:

- **human-machine interface system:** any region or point at which a person interacts with a machine
- **human-machine allocation of function:** assigning system functions to human and machine agents (i.e., processes that are automated versus those that are manual)
- **human reliability:** addressing issues pertaining to the probability that an individual or group will adequately perform a given task at the appropriate time
- **job design:** determining how tasks will be grouped together and how work will be coordinated. This will include consideration of the operating states of the facility (i.e., shutdown, start-up, operation, etc.)
- **operating experience review:** the review and use of knowledge gained from nuclear industry operating experience to improve future performance
- **physical working environment:** the total physical environment within which a worker performs his or her tasks
- activities with potentially hazardous human interactions
- **procedures development:** the systematic process for the development of work instructions or instruction sets used to accomplish a given task
- **shift-work systems:** all of the schedules implemented in a given workplace to meet the requirements of a given plant or process
- **staffing:** for the purpose of the HFEPP, the process for determining numbers and placement of appropriate personnel for a given job
- **validation:** the process of determining the degree to which the human-machine system design and supporting mechanisms facilitate the achievement of overall safety and operational goals
- **verification:** the process of demonstrating that equipment and systems have been designed as specified and that adherence to human factors guidelines has been maintained

Provide justification for any omissions of the technical elements. It is expected that additional human factors issues may be identified and may warrant assessment on a case-by-case basis.

For the verification and validation processes, it is often appropriate to develop a separate plan. The CNSC recognizes that a Verification and Validation Plan cannot always be submitted concurrently with the Human Factors Engineering Program Plan. However, a commitment should be made in the HFEPP to submit a Verification and Validation Plan at a later date. For more information on Verification and Validation Plans see Part B, Human Factors Verification and Validation Plans.

4.6.3 Methods for Addressing the Technical Elements

Describe the methods and techniques that will be used to address each of the technical elements for review. Examples of methods and techniques might include:

- functional analysis
- task analysis
- human error analysis
- timeline analysis
- physical demands analysis
- verification and validation activities
- communications analysis

Provide a statement for each method, indicating how the output from each analysis and activity will be used. For example: “Task analysis data is used as input to the specification of human-machine interface features”.

4.6.4 Intended Tools

Indicate the human factors facilities, equipment and tools that will be used to support the licensable activity. These may include such items as

- simulators,
- laboratories,
- software packages,
- mock-ups, and
- usability trials

4.6.5 Technical Guides

During development of the detailed design phase of a licensable activity, it is expected that various human factors guides will be used to address such topics as

- alarm annunciation;
- abbreviations and acronyms;
- panel device selection and layout; and
- colour usage.

Whether guidelines are developed specifically for the licensable activity to standardize operational practices and conventions, or selected from applicable published material, they should be relevant to the current facility and activity, level of technology, and user population. In addition, all guides should be comprehensive and up to date.

4.7 Processes and Procedures

4.7.1 General

To ensure consistency across the various work elements of the HFEPP, identify the steps required for its implementation.

4.7.2 Timelines

On a timeline, plot the work activities related to human factors to show their place within the project development cycle for the activity to be licensed. Reference to the master project schedule may be appropriate if it incorporates information relevant to the purposes of the timeline.

4.7.3 Documentation

Specify how human factors data will be incorporated into the existing design documentation structure for the project (i.e., activity to be licensed). For large projects, a document hierarchy diagram should be included to illustrate this incorporation.

4.7.4 Disposition of Human Factors Issues

Determine a reasonable method for recording, categorizing, tracking, and responding to the issues and recommendations that arise during implementation of the plan. Development of the processes and procedures for this aspect of the plan should take into account the ultimate goals of the human factors work, as well as any anticipated limitations to those goals.

Provide a description of how tracking of unanticipated human factors issues will be conducted to ensure consideration in development of future HFEPP. It is anticipated that project groups affected by the recommendations arising from the human factors work may, at times, disagree with those recommendations. The process for resolving differences of opinion that might be generated by human factors issues should include an explanation of the authority structure to clarify how and by whom final decisions are to be made.

4.7.5 CNSC Contact

Include a proposal for maintaining contact with CNSC staff during plan implementation, listing proposed submissions supporting the Plan, meetings to discuss progress of the plan, and communications processes.

Part B: Human Factors Verification and Validation Plans

5. Verification and validation of human factors

One way to demonstrate the extent to which human factors have been considered in activities licensed by the CNSC, and the effectiveness of that consideration, is through verification and validation activities.

A Verification and Validation Plan documents the set of activities within a specific project (i.e., licensable activity), that will be carried out to demonstrate that the human factors considerations of the project design conform to accepted human factors design principles. This will ensure that the project design enables personnel to perform their tasks safely and to meet operational goals.

A Verification and Validation Plan usually supports an HFEPP. For more information on HFEPP, see Part A, Human Factors Engineering Program Plans. The Verification and Validation Plan may be included as part of the HFEPP or as a separate plan. The intent is not to create documentation, but to ensure that verification and validation activities are similarly planned and recorded.

6. Elements of the verification and validation plan

An effective Verification and Validation plan includes comprehensive information about:

- the basis and objectives of the plan,
- verification of design, and
- validation of design.

6.1 Basis and Objectives of the plan

The basis for the Verification and Validation Plan depends on its objectives. In order to facilitate review by CNSC staff, the Plan should provide clear definitions of the basis and objectives in the Plan, including scope and background information.

6.1.1 Scope and objectives

This section of the Verification and Validation Plan should reflect the overall scope and objectives of the project. General considerations for this section should include:

- impacted facility areas (e.g., main control rooms, instrument rooms, secondary control rooms, field actions)
- human-machine interface systems and components involved
- allocation of function (i.e., to humans, to automated systems, and between team members)
- the design phase at which the Verification and Validation Plan will be implemented

6.1.2 Background Information

This section should describe relevant background information about the design, such as any previous Verification and Validation Plans that have been completed or review activities that have already taken place.

6.2 Verification of Design

An outline should be provided of the approach that will be used to conduct human factors design verification. Typically, this activity will involve a comparison of each human-machine system component against appropriate human factors principles, guidelines, and standards.

6.3 Validation of Design

Information should be provided about the following elements of the validation process:

- Approach
- Location
- Techniques and Tools
- Participants
- Participant Training
- Performance Measurement in Validation
- Data Collection and Analysis

6.3.1 Approach

Provide an outline of the approach that will be used to conduct validation of the integrated systems associated with the design.

6.3.2 Location

Identify the location of the validation trials.

6.3.3 Techniques and Tools

Validation of integrated systems is accomplished by evaluating task accomplishment using appropriate validation tools. Tabletop analysis, walk-throughs using comprehensive drawings, photographs, prototypes, mock-ups, full-scale simulators, or other techniques appropriate to the nature of the project may be used.

6.3.4 Participants

Identify the participants by job type (i.e., operator, engineer, shift supervisor) who will be involved in the validation exercises. The number of participants should be indicated.

6.3.5 Participant Training

It is expected that some training of participants will be necessary. Provide information about the level and nature of training that will be provided.

6.3.6 Performance Measurement in Validation

Clearly state the technical basis for performance measures and acceptance criteria.

i) Performance Measures
Present a general discussion of the categories of performance measures that will be used for validation activities (e.g., time, accuracy, frequency, amount achieved or accomplished, etc.).

ii) Acceptance Criteria
For both objective and subjective performance measures, include clear statements of how acceptance criteria relevant to those measures will be derived.

6.3.7 Data Collection and Analysis

Effective validation requires appropriate collection and analysis of data. Describe the data collection methods that will be used and how the results will be analyzed.

Glossary

For definitions of terms used in this document, see REGDOC-3.6, *Glossary of CNSC Terminology*, which includes terms and definitions used in the *Nuclear Safety and Control Act* (NSCA) and the regulations made under it, and in CNSC regulatory documents and other publications. REGDOC-3.6 is provided for reference and information.

validation
The process of determining the degree to which the human-machine system design and supporting mechanisms facilitate the achievement of overall safety and operational goals.

verification
The process of demonstrating that equipment and system have been designed as specified, and that adherence to human factors guidelines has been maintained.

References

1. CSA Group, CSA 290.12-14, *Human Factors in Design for Nuclear Power Plants*, Toronto, 2014.
2. Canadian Nuclear Safety Commission, Regulatory Policy P-119, *Policy on Human Factors*, October 2000.

Additional Information

The following documents are not referenced in this regulatory document but contain information that may be useful to the reader:

- CNSC, REGDOC-2.5.2, *Design of Reactor Facilities: Nuclear Power Plants*, 2014.
- CSA Group, CSA N290.12-14, *Human factors in design for nuclear power plants*, 2014 (revised 2015).
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CNSC Regulatory Document Series

Facilities and activities within the nuclear sector in Canada are regulated by the CNSC. In addition to the *Nuclear Safety and Control Act* and associated regulations, these facilities and activities may also be required to comply with other regulatory instruments such as regulatory documents or standards.

CNSC regulatory documents are classified under the following categories and series:

1.0 Regulated facilities and activities

Series 1.1 Reactor facilities
1.2 Class IB facilities
1.3 Uranium mines and mills
1.4 Class II facilities
1.5 Certification of prescribed equipment
1.6 Nuclear substances and radiation devices

2.0 Safety and control areas

Series 2.1 Management system
2.2 Human performance management
2.3 Operating performance
2.4 Safety analysis
2.5 Physical design
2.6 Fitness for service
2.7 Radiation protection
2.8 Conventional health and safety
2.9 Environmental protection
2.10 Emergency management and fire protection
2.11 Waste management
2.12 Security
2.13 Safeguards and non-proliferation
2.14 Packaging and transport

3.0 Other regulatory areas

Series 3.1 Reporting requirements
3.2 Public and Aboriginal engagement
3.3 Financial guarantees
3.4 Commission proceedings
3.5 CNSC processes and practices
3.6 Glossary of CNSC terminology

Note: The regulatory document series may be adjusted periodically by the CNSC. Each regulatory document series listed above may contain multiple regulatory documents. Visit the CNSC's website for the latest list of regulatory documents.