Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

REGULATORY GUIDE

# Human Factors Verification and Validation Plans

G-278

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Canada

# REGULATORY DOCUMENTS

The Canadian Nuclear Safety Commission (CNSC) operates within a legal framework that includes law and supporting regulatory documents. Law includes such legally enforceable instruments as acts, regulations, licences and orders. Regulatory documents such as policies, standards, guides, notices, procedures and information documents support and provide further information on these legally enforceable instruments. Together, law and regulatory documents form the framework for the regulatory activities of the CNSC.

The main classes of regulatory documents developed by the CNSC are:

**Regulatory policy:** a document that describes the philosophy, principles and fundamental factors used by the CNSC in its regulatory program.

**Regulatory standard:** a document that is suitable for use in compliance assessment and describes rules, characteristics or practices which the CNSC accepts as meeting the regulatory requirements.

**Regulatory guide:** a document that provides guidance or describes characteristics or practices that the CNSC recommends for meeting regulatory requirements or improving administrative effectiveness.

**Regulatory notice:** a document that provides case-specific guidance or information to alert licensees and others about significant health, safety or compliance issues that should be acted upon in a timely manner.

**Regulatory procedure:** a document that describes work processes that the CNSC follows to administer the regulatory requirements for which it is responsible.

Document types such as regulatory policies, standards, guides, notices and procedures do not create legally enforceable requirements. They support regulatory requirements found in regulations, licences and other legally enforceable instruments. However, where appropriate, a regulatory document may be made into a legally enforceable requirement by incorporation in a CNSC regulation, a licence or other legally enforceable instrument made pursuant to the *Nuclear Safety and Control Act*.

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# HUMAN FACTORS VERIFICATION AND VALIDATION PLANS

## 1.0 PURPOSE

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.

## 2.0 SCOPE

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 CNSC Regulatory Guide G-276, *Human Factors Engineering Program Plans*.

## 3.0 DEFINITIONS

For the purpose of this guide:

- "human factors" means factors that influence human performance as it relates to the safety of a nuclear facility or activity over all phases, including design, construction, commissioning, operation, maintenance, and decommissioning.
- "verification" means the process of demonstrating that equipment and system have been designed as specified, and that adherence to human factors guidelines has been maintained.
- "validation" means 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.

## 4.0 BACKGROUND

### 4.1 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 Nuclear Safety Control Act (NSC Act, Act). The Act 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.

## 4.2 CNSC Licensing Process

The CNSC typically 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 NSC Act and 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 staff 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. 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.

## 4.3 Legislative Basis

Although the NSC Act and its regulations contain no explicit references to "human factors", they contain 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 and the environment. 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(n). The relevant portion of this provision states that an application for a licence shall contain, "at the request of the Commission, any other information that is necessary to enable the Commission to determine whether the applicant (i) is qualified to carry on the activity to be licensed or (ii) will, in carrying our 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 and the licence"
- Paragraph 12(1)(c). The relevant portion of this paragraph states that "Every licensee shall take all reasonable precautions to protect the environment and the health and safety of persons…"

## 5.0 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 a Human Factors Engineering Program Plan (HFEPP). For more information on HFEPP, see CNSC Regulatory Guide G-276, *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.

## 6.0 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.

## REFERENCES


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