

**THE CANADIAN NUCLEAR SAFETY COMMISSION
COMPLIANCE PROGRAM**

AN OVERVIEW

Published by the
Atomic Energy Control Board
May 2000



Atomic Energy
Control Board

Commission de contrôle
de l'énergie atomique

Canada

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PREFACE

This information document (INFO-0713) was prepared to accompany the draft regulatory policy C-211, *The CNSC Compliance Policy*, during its public consultation period.

The intent of the information document is to provide background and context to the compliance policy, on the one hand, and the CNSC Compliance Program, on the other hand. It provides an overview of the components of the program, and highlights how the CNSC will implement the program.

Comments received during the public consultation period will be taken into consideration during the revision of the compliance policy. This may also result in changes to the compliance program.

While the compliance policy was developed under the existing regulatory regime, its application, as well as the implementation of the CNSC Compliance Program, is based on the new Nuclear Safety and Control Act which will soon come into force.

1. Introduction

1.1. About this document

This document provides general information about the compliance program being developed for the future Canadian Nuclear Safety Commission (CNSC). The intent of this document is to provide background and context for the CNSC Compliance Program, to provide an overview of its components, and to highlight how the CNSC will implement the program.

1.2. About the Canadian nuclear regulatory system

At present, the legal basis for the control of the nuclear regulatory system in Canada is the Atomic Energy Control Act. Soon, a new act, the Nuclear Safety and Control Act (NSCA), will come into force and replace the Atomic Energy Control Act. The CNSC Compliance Program will be based on the new act.

The NSCA serves two key functions: it provides the legal framework for the control of nuclear technology in Canada, and it establishes the Canadian Nuclear Safety Commission as the regulatory body that exercises the administrative controls described in the NSCA.

The basic element of control is the prohibition of specified activities associated with nuclear technology, unless authorized by a licence. This control element allows the CNSC to impose strict rules on persons who perform an activity that involves nuclear technology. All prohibited activities are itemized in the NSCA. The CNSC administers and enforces the act and is given a comprehensive set of powers to do so.

2. The CNSC regulatory program

The NSCA designates the CNSC to regulate activities associated with nuclear technology. The goals of the regulations are to prevent unreasonable risks and to ensure conformity with the measures of control and international obligations to which Canada has agreed.

According to paragraph 9(a) of the Nuclear Safety and Control Act, the Commission's regulatory object is

- a) to regulate the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information in order to
 - i) prevent unreasonable risk, to the environment and to the health and safety of persons, associated with that development, production, possession or use,
 - ii) prevent unreasonable risk, to national security associated with that development, production, possession or use, and
 - iii) achieve conformity with measures of control and international obligations to which Canada has agreed;

Figure 1: The regulatory object of the Canadian Nuclear Safety Commission

To achieve its regulatory objective, the CNSC will develop regulatory rules that must be followed by persons who desire to perform a specific activity. The CNSC will also undertake activities aimed at achieving maximum compliance with these rules.

Figure 2 illustrates the CNSC regulatory program. Each of the program's components is described below.

2.1. Regulatory framework

The regulatory framework is composed of tools used by the CNSC to control persons who perform activities associated with nuclear technology. The framework also includes the processes that establish and maintain these tools.

The legislative basis of the control system is a set of legal requirements. These requirements are found in a hierarchy of legal documents: the NSCA, regulations, licences, certificates, and authorizations¹. Only requirements found in these documents, or in an order, are legally binding.

In some cases, the legislation is very prescriptive; therefore, meeting the conditions for compliance is fairly straightforward. In other cases, the legislation is more performance-based, thus requiring interpretation of how compliance is to be achieved. To the extent possible, CNSC policies, standards, and guides will provide an interpretation of how compliance with a legal requirement can be achieved. These documents can also be used for the purpose of verifying compliance with a legal requirement.

1. Persons must seek authorization from the CNSC before entering a security area where nuclear material is present.

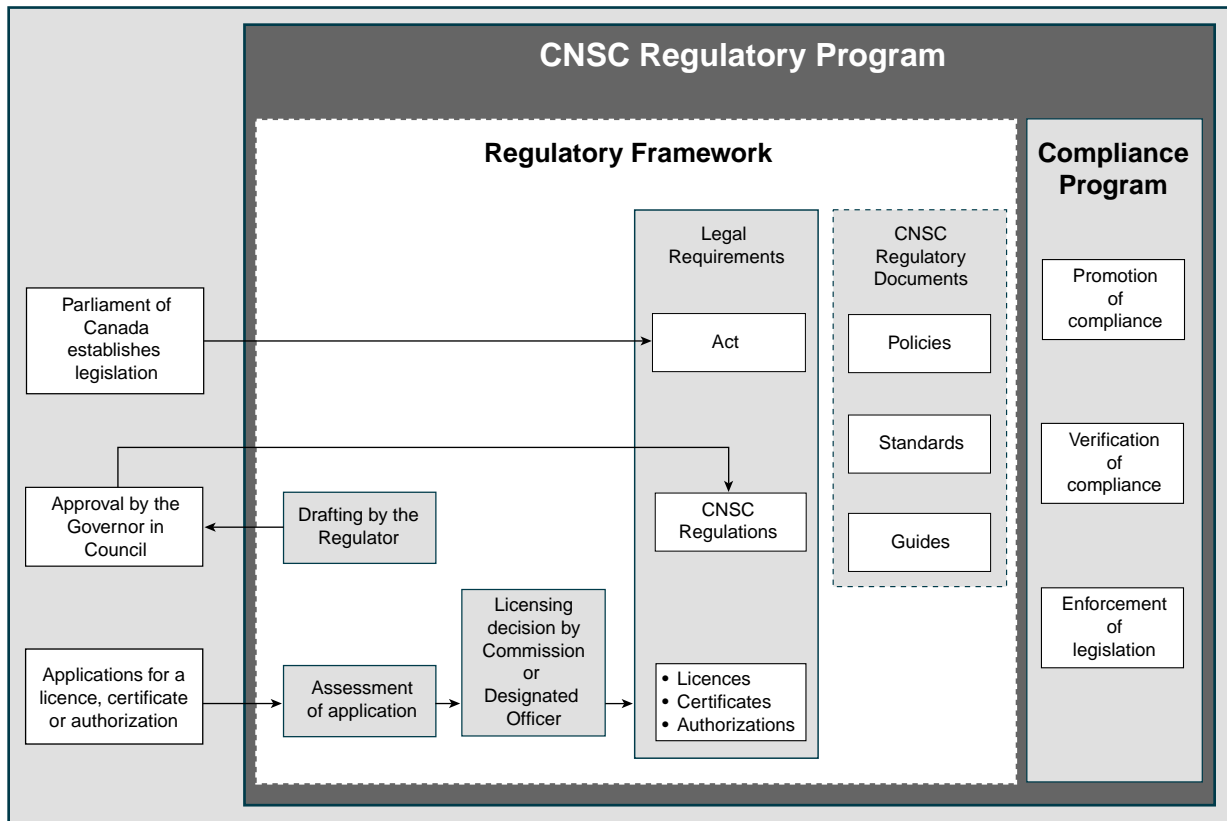


Figure 2: CNSC Regulatory Program

2.1.1. Nuclear Safety and Control Act

The NSCA is legislation passed by the Parliament of Canada. The powers and obligations specified in the act are particularly important for the compliance program. Features of the act that are of greatest importance to the compliance program are summarized below.

Powers of the Commission

The NSCA provides the Commission with a broad range of powers, including the power to

- make regulations;
- grant exemptions, for any activity, person, or material, from the application of any portion of the act or the regulations;
- authorize a person, by virtue of a licence, to perform any activity that would otherwise be prohibited by the act;
- include any condition in a licence; and
- renew, suspend, amend, revoke, or replace, on its own motion (such as when enforcing specific requirements), any licence, provided that this is done in the manner prescribed by regulation.

The act allows the Commission to delegate some of its licensing powers to designated officers and provides powers to inspectors for the purpose of verifying compliance with the legislation.

The act also allows inspectors and authorized designated officers to order measures to be taken to correct unacceptable situations. Orders are legally binding.

Obligations of the Commission

The act imposes certain obligations on the CNSC that must be taken into account when designing the regulatory program, most notably the following:

- The Commission may not issue a licence unless, in the opinion of the Commission, the applicant is qualified and will make adequate provisions for preventing unreasonable risk in performing an activity that would be otherwise prohibited. This obligation sets the scope of the licensing requirements. (See section 2.1.3, “Licences, certificates, and authorizations,” below.)
- The act imposes rules on the CNSC for ensuring that persons affected by regulatory decisions are given the opportunity to be heard, and that their views are taken into account by the Commission.

Obligations of persons

The act imposes obligations on persons involved in nuclear technology. Most significant is the prohibition of activities named in the act, which stipulates that no person shall, except in accordance with a licence, perform any of the named activities.

The NSCA also imposes obligations on persons by identifying circumstances that constitute an offence.

2.1.2. CNSC regulations

The Commission may make regulations under the act; however, it is constrained by both the NSCA and federal government policy when making and modifying regulations:

- The act stipulates which regulations can be made by the Commission, with the approval of the Governor in Council, and which regulations can be made by the Governor in Council itself. All regulations must be consistent with the purpose of the NSCA.
- Regulations must comply with federal government policy and assessing the need for regulations, including an analysis of the costs and benefits of modifying regulations, and on the need to consult with the affected public.

Figure 3 contains a list of regulations that are proposed to come into force with the new act. These proposed regulations have been issued in draft form for public scrutiny and have since been revised to incorporate the comments received. They will soon be submitted to the Governor in Council for final approval.

- 
- *Class I Nuclear Facilities Regulations*
 - *Class II Nuclear Facilities and Prescribed Equipment Regulations*
 - *General Nuclear Safety and Control Regulations*
 - *Nuclear Non-Proliferation Import and Export Control Regulations*
 - *Nuclear Security Regulations*
 - *Nuclear Substances and Radiation Devices Regulations*
 - *Packaging and Transport of Nuclear Substances Regulations*
 - *Radiation Protection Regulations*
 - *Uranium Mines and Mills Regulations*
 - *Canadian Nuclear Safety Commission Rules of Procedure*

Figure 3: CNSC regulations

In general, the regulations specify the exemptions that have been made by the CNSC, what constitutes prescribed equipment and prescribed information, and what information that an application for a licence shall contain.

Of particular importance to the compliance program are the requirements that specify the obligations of licensees, workers, transport carriers, and other regulated persons, concerning the protection of the environment, the health and safety of persons and of national security, and concerning achieving conformity with measures of control and international obligations to which Canada has agreed.

2.1.3. Licences, certificates, and authorizations

Licences, certificates, and authorizations serve as permissions, and are provided by the Commission or a designated officer. Certificates are used, for example, to certify packages for the transportation of nuclear substances, or to certify persons to perform certain activities. Authorizations for entering a security area where nuclear material is present can be provided to persons.

The majority of permissions issued by the CNSC are in the form of licences. Concerning licences, the act imposes on the Commission an important obligation that establishes the basis of regulatory control. This obligation is stated in subsection 24 (4) of the act, as follows:

“No licence may be issued, renewed, amended, or replaced unless, in the opinion of the Commission, the applicant

- a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and
- b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.”

It is important to note that the act gives the Commission considerable latitude in deciding the level of qualification that a licence applicant is required to possess, as well as what constitutes an “adequate provision” of safety.

The licensing process comprises three elements:

- application for a licence;
- assessment of the application; and
- a decision by the Commission or an authorized designated officer.

Application for a licence

Applications should demonstrate that the person is, and will remain, qualified to perform the activity the licence will authorize, and that the person will make adequate provisions for the protection of the environment, the health and safety of persons, the maintenance of national security, and for implementing international obligations to which Canada has agreed. The CNSC regulations identify the minimum information that is required in an application for a licence. The Commission may require more information for specific classes of licences.

Assessment of an application

The CNSC reviews the licence application and assesses its adequacy. This review leads to a staff recommendation to the Commission or to the designated officer on whether to issue a licence.

The review consists of the following components:

- verification that the information required by regulation has been provided; and
- review of the qualifications of the applicant and the adequacy of the provisions taken as measured against assessment criteria. Policies, standards, guides, and expert judgment are used as assessment criteria. Conclusions reached by CNSC staff are documented and form the basis for the recommendation to the Commission, or to the designated officer.

If the licence is issued based on the recommendations of CNSC staff, the documented staff assessment becomes important for the compliance program, because many of the assessment criteria serve as the foundation for compliance criteria.

Decision

The conclusions reached by staff in the assessment phase are communicated to the Commission, or to the designated officer.

An applicant may make representations either to the Commission or to the relevant designated officer. Applicants may clarify, supplement, or correct the information held by CNSC staff. The decision makers are guided but not bound, by staff recommendations. After the decision is made, it is communicated to the relevant persons.

2.2. CNSC Compliance Program

The goal of the CNSC Compliance Program is to secure compliance with regulatory requirements in order to maximize the effect of the regulatory program on the control of nuclear technology.

The highest levels of compliance are achieved when regulated persons are themselves motivated to meet the regulatory requirements. The CNSC Compliance Program strives to provide this motivation through a judicious balance between proactive incentives to encourage compliance and reactive control measures to compel compliance. The incentives and measures are these:

- promotional activities to encourage compliance;
- verification activities to assess the actual level of compliance; and
- graduated enforcement actions in cases of non-compliance.

2.2.1. Promotion of compliance

The goal of promotion activities is to maximize compliance levels by strengthening the factors that encourage compliance and mitigating those that hinder compliance. Compliance promotion encompasses the following types of activities.

Communication activities

Such activities include informing the regulated community of the rationale behind the regulatory regime, and disseminating information to regulated areas about regulatory requirements and standards (e.g. educational material targeted at a specific audience). The CNSC may also make public the results of verification activities and information about significant enforcement actions taken against a regulated person.

Consultation activities

Such activities include consulting with regulated areas through an established process in order to design realistic and achievable requirements and standards. Consultation activities have two purposes: they convey the message that the CNSC respects the views of the regulated community, and they help to develop a sense of responsibility with respect to compliance. Proposed modifications to regulations, licences, and standards will be sent out for the appropriate consultation.

2.2.2. Verification of compliance

Information gathered through verification activities confirms whether the risks associated with nuclear technology are limited to reasonable levels and whether applicable international control measures are effectively implemented. In addition, compliance is more likely to be achieved when the activities of regulated persons are subject to verification.

Compliance verification will be performed through such activities as inspections, audits, and assessment of submitted information. The criteria that will be used to assess compliance may be derived from:

- legal requirements;
- CNSC policies, standards, or guides that clarify how the Commission intends to apply the legal requirements;
- information, supplied by licensees to the Commission, that defines how the licensees intend to meet the legal requirements in performing the licensed activity; or
- expert judgment of CNSC staff.

In all cases, the compliance criteria will be linked to specific legal requirements.

In many cases, CNSC staff will verify, through audits, that licensees abide by their programs, which will have been assessed as adequate by the Commission during the licensing process.

Owing to the large scope and volume of potential verification activities, such activities will be prioritized based on considerations such as these:

- risks to the environment, to the health and safety of persons, and to national security;
- implementation of international control measures to which Canada has agreed; and
- the compliance record of the regulated person.

2.2.3. Enforcement

Enforcement actions are an important part of compliance, as they re-establish compliance and act as a deterrent against non-compliance. Consistently applied enforcement actions also encourage prompt identification and correction of items of non-compliance.

The enforcement actions available to the CNSC are these:

- *Verbal or written notice*: Notifying a regulated person, verbally or in writing, of a non-compliance situation. The notice does not detail the remedial action to be taken. The CNSC internally records verbal notices.
- *Compliance discussion*: Discussing solutions to a non-compliance situation with the regulated person.
- *Warning*: A written notice of non-compliance with a clear statement of the expected remedial action.
- *Increased regulatory scrutiny*: Increasing reporting requirements and inspection frequency, for example.
- *Publicity*: Publicizing instances of non-compliance and of the enforcement measures taken by the CNSC in the CNSC newsletter or in community newspapers, for example.
- *Issuance of an order*: Prescribing remedial action to be taken. An order is issued by an inspector or an authorized designated officer based on the criteria set out in section 35 of the Act; it is legally binding, and it can be enforced in a court of law.
- *Licensing action*: Amending a licence or deciding to suspend part of a licence, for example.
- *Revocation of personal certification*.
- *Prosecution*.
- *Revocation or suspension of a licence*.

Notices, compliance discussions, and warnings are administrative measures that are mainly used to re-establish compliance. However, the decision to pursue more severe enforcement actions will be based on the effectiveness of these approaches. For situations in which the safety or

regulatory impact is significant, orders or licensing actions may be used. Orders and licencing actions are legally binding in the sense that the act makes it an offence to fail to comply with them.

Increased regulatory scrutiny, publicity, and prosecution are measures that also signify serious regulatory concern and that may deter future non-compliance by the offender and others. Revocation of personal certification and revocation or suspension of a licence are measures that may be used when the Commission judges that a regulated person no longer meets the conditions for carrying out the activity authorized by the CNSC.

Additional circumstances may exist under which the enforcement actions described above can be used.

The CNSC will use a graduated approach commensurate with risk or regulatory significance in choosing which enforcement action to use. Initially, depending on several factors, the CNSC will seek to use the least severe enforcement action considered likely to achieve the desired outcome. Subsequently, depending on the effectiveness of the initial action, the CNSC may use enforcement measures of increasing severity. The CNSC recognizes that situations will arise in which it is appropriate to use one of the more severe enforcement measures (e.g. prosecution) as an initial response.

3. Implementation

3.1. Structure

The program is based on a policy that formally establishes and communicates the corporate approach to compliance. The policy describes how the CNSC will strive to maximize the level of compliance with regulatory requirements for persons regulated by the CNSC.

The CNSC compliance policy is implemented through a program that applies to all licensees and integrates all elements of compliance. Management of the CNSC Compliance Program is the responsibility of a program authority who is accountable for program effectiveness and consistency of application among all affected CNSC groups.

At the operational level, responsibility for implementation of the program is shared among the various CNSC service lines and technical groups that manage specific technical programs. (The service lines and technical programs are listed in Figure 4.)

3.1.1. Service lines

CNSC service lines are units of the CNSC organization that carry out the activities needed to regulate a given type of nuclear technology application. Compliance activities in the areas of promotion, verification, and enforcement are implemented through each of the service lines.

3.1.2. Technical programs

Technical programs are centres of expertise associated with specific nuclear technology specialities. Technical programs are administered by in-house CNSC technical experts who comprise the various technical groups. More than one technical program may fall under the responsibility of a given technical group. Technical programs provide specialized information to the service lines and help to ensure that compliance with regulatory requirements is approached in a consistent manner by all service lines.

| Services Lines | Technical Programs |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">• Dosimetry Services• Imports and Exports• Irradiators• Non-Power Reactors• Nuclear Fuel Facilities• Nuclear Research and Test Establishments• Nuclear Substance Processing Facilities• Nuclear Substances and Radiation Devices• Packaging and Transport of Nuclear Substances• Particle Accelerators• Power Reactors• Safeguards• Uranium Mines and Mills• Waste Management Facilities | <ul style="list-style-type: none">• Criticality Safety• Decommissioning• Emergency Preparedness• Environmental Protection• Event Analysis and Investigations• Examination and Certification• Fire Protection• Geoscience• Human Factors• Laboratory Services• Quality Management• Radiation Protection• Safety Analysis• Security• Structural Integrity• System and Component Performance• Training Program Evaluation |

Figure 4: CNSC Service Lines and Technical Programs

3.2. Work planning and control

Work that falls under the compliance program will be planned and monitored. Adjustments to the plan will be justified and recorded. During planning, the compliance history of the licensee will be taken into account when deciding whether to increase the level of scrutiny to be applied.

Work will be performed by each service line and technical group in accordance with written procedures; results will be recorded by each service line and technical group. At the end of each year, the work that was done and the adjustments that were made to the plan will be analysed to determine whether any adjustment in the planning process is necessary. Finally, an annual report will be provided to the program authority integrating and summarizing the results of the compliance program.

3.3. Review of program effectiveness

Review of program effectiveness involves an assessment of past work to ensure that staff obtain the benefits of any lessons learned, and to avoid practices that are found to be cumbersome or inefficient. While the program will be continuously monitored and assessed by the program authority and other senior executives of the CNSC, a more comprehensive review will be conducted every five years. This review will include analysis of the information generated during the previous five years from all sources. It will involve soliciting staff input on how the program can be improved.

