



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

REGULATORY GUIDE

Developing and Using Action Levels

G-228

March 2001

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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DEVELOPING AND USING ACTION LEVELS

1.0 PURPOSE

This regulatory guide is intended to help applicants for Canadian Nuclear Safety Commission (CNSC) licences develop action levels in accordance with paragraph 3(1)(f) of the *General Nuclear Safety and Control Regulations* and section 6 of the *Radiation Protection Regulations*.

2.0 SCOPE

This guide applies to all applications for a CNSC licence, other than an application for a licence to abandon. It describes how the licence applicant can develop action levels that provide for the radiation protection of workers and the public during the conduct of activities licensed by the CNSC. This document does not deal with action levels for the purpose of environmental protection at a uranium mine or mill.

3.0 BACKGROUND

3.1 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 *Nuclear Safety and Control Act* ("the Act") requires persons or organizations to be licensed by the CNSC for carrying 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.

3.2 Relevant legislation for this document

The following CNSC legislation is pertinent to an understanding of this regulatory guide:

- Paragraph 3(1)(f) of the *General Nuclear Safety and Control Regulations* which requires that an application for a CNSC licence contain "any proposed action level for the purpose of section 6 of the *Radiation Protection Regulations*."

- Subsection 4(a) of the *Radiation Protection Regulations* which states that:
“Every licensee shall implement a radiation protection program and shall, as part of that program,
 - (a) keep the amount of exposure to radon progeny and the effective dose and equivalent dose received by and committed to persons as low as reasonably achievable, social and economic factors being taken into account, through the implementation of
 - (i) management control over work practices,
 - (ii) personnel qualification and training,
 - (iii) control of occupational and public exposure to radiation, and
 - (iv) planning for unusual situations.”
- Subsection 6(1) of the *Radiation Protection Regulations* which defines an action level to be “a specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a licensee’s radiation protection program, and triggers a requirement for specific action to be taken.”
- Subsection 6(2) of the *Radiation Protection Regulations* which stipulates that:
“When a licensee becomes aware that an action level referred to in the licence for the purpose of this subsection has been reached, the licensee shall:
 - (a) conduct an investigation to establish the cause for reaching the action level;
 - (b) identify and take action to restore the effectiveness of the radiation protection program implemented in accordance with section 4; and
 - (c) notify the Commission within the period specified in the licence.”
- Subsection 4(1) of the *Uranium Mines and Mills Regulations* which defines an action level to be:
“A specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a licensee’s radiation protection program or environmental protection program, and triggers a requirement for specific action to be taken.”
- Subsection 4(2) of the *Uranium Mines and Mills Regulations* which stipulates that:
“An application for a licence in respect of a uranium mine or mill, other than a licence to abandon shall contain a code of practice that includes
 - (a) any action level that the applicant considers appropriate for the purpose of this subsection;
 - (b) a description of any action that the applicant will take if an action level is reached;
 - (c) the reporting procedures that will be followed if an action level is reached.”

3.3 The CNSC licensing process and action levels

The CNSC typically applies a phased process to its licensing of nuclear facilities and activities. For major facilities, this process begins with a consideration of the environmental impacts of the proposed project, and proceeds progressively through site preparation, construction, operation, decommissioning and abandonment phases.

The *Nuclear Safety and Control 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 judgement 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 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 an action level.

4.0 ACTION LEVELS FOR RADIATION PROTECTION

The *Radiation Protection Regulations* and the *Uranium Mines and Mills Regulations* contain different definitions of an "action level".

Under the *Radiation Protection Regulations*, an action level is defined to be "a specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a licensee's radiation protection program, and triggers a requirement for specific action to be taken."

However, under the *Uranium Mines and Mills Regulations*, an action level for a uranium mine or mill is "a specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a licensee's radiation protection program or environmental protection program, and triggers a requirement for specific action to be taken."

Thus, the definition of an action level in the *Uranium Mines and Mills Regulations* encompasses both radiation protection and environmental protection. However, for the purposes of section 6 of the *Radiation Protection Regulations* and this guide, the two definitions are consistent.

5.0 UNDERSTANDING ACTION LEVELS

Action levels are designed to alert licensees before regulatory dose limits are reached. By definition, if an action level in a licence is reached, a loss of control of some part of the associated radiation protection program may have occurred, and specific action is required. The specified action under the *Radiation Protection Regulations* consists of establishing the cause for reaching the action level, restoring the effectiveness of the radiation protection program, and notifying the CNSC within the period specified in the licence.

Accordingly, CNSC licensees may use action levels to help them monitor and maintain the effectiveness of the radiation protection programs that they must implement under subsection 4(a) of the *Radiation Protection Regulations*. In particular, licensees may set action levels, and monitor related parameters, so as to provide for early warnings of any actual or potential losses of control of the parts of the radiation protection program to which the action levels apply; thereby maximizing their opportunities for follow-up investigations and any interventions that may be necessary in order to restore control. Where a radiation protection program consists of several parts, action levels may be appropriate for each or any part of the program.

Action levels may be expressed in terms of any parameters that, if reached, may indicate a loss of control of an associated part of the licensee's radiation protection program. Some examples of such parameters are:

- the quantity of radiation exposure or dose that an individual receives (“individual dose”),
- a radiation level within a work area (“ambient dose rate”),
- radioactivity per unit surface area (“surface contamination level”),
- an air-exchange rate in a work place (“ventilation rate”),
- a rate at which nuclear substances are released to the environment (“emission rate,” “discharge rate”), and
- a concentration or a quantity of a nuclear substance in a workplace or in an effluent (“concentration”, “loading”).

Action levels are typically site and facility specific. An action level at one facility could lie within the normal operating range of another facility. Over the lifetime of a facility or activity, an action level may be dynamic or static. That is, it may be revised upwards or downwards to accommodate the prevailing circumstances. For example, an action level for a new facility or activity may warrant refinement once significant operating experience is gained. Similarly, if conditions at a facility change (e.g., changes in geological conditions at a uranium mine), a related action level may also need to be changed.

All parts of a licensee's radiation protection program are considered to be under control when the radiation doses to persons as a consequence of the licensed activities are kept as low as reasonably achievable, social and economic factors being taken into account (ALARA), through the implementation of the measures specified in subsection 4(a) of the *Radiation Protection Regulations*.

Figure 1 on the next page illustrates, graphically, the typical relationship among a regulatory limit, the relevant action levels, and the maintenance of "the amount of exposure to radon progeny and the effective dose and equivalent dose received by and committed to persons as low as reasonably achievable, social and economic factors being taken into account."

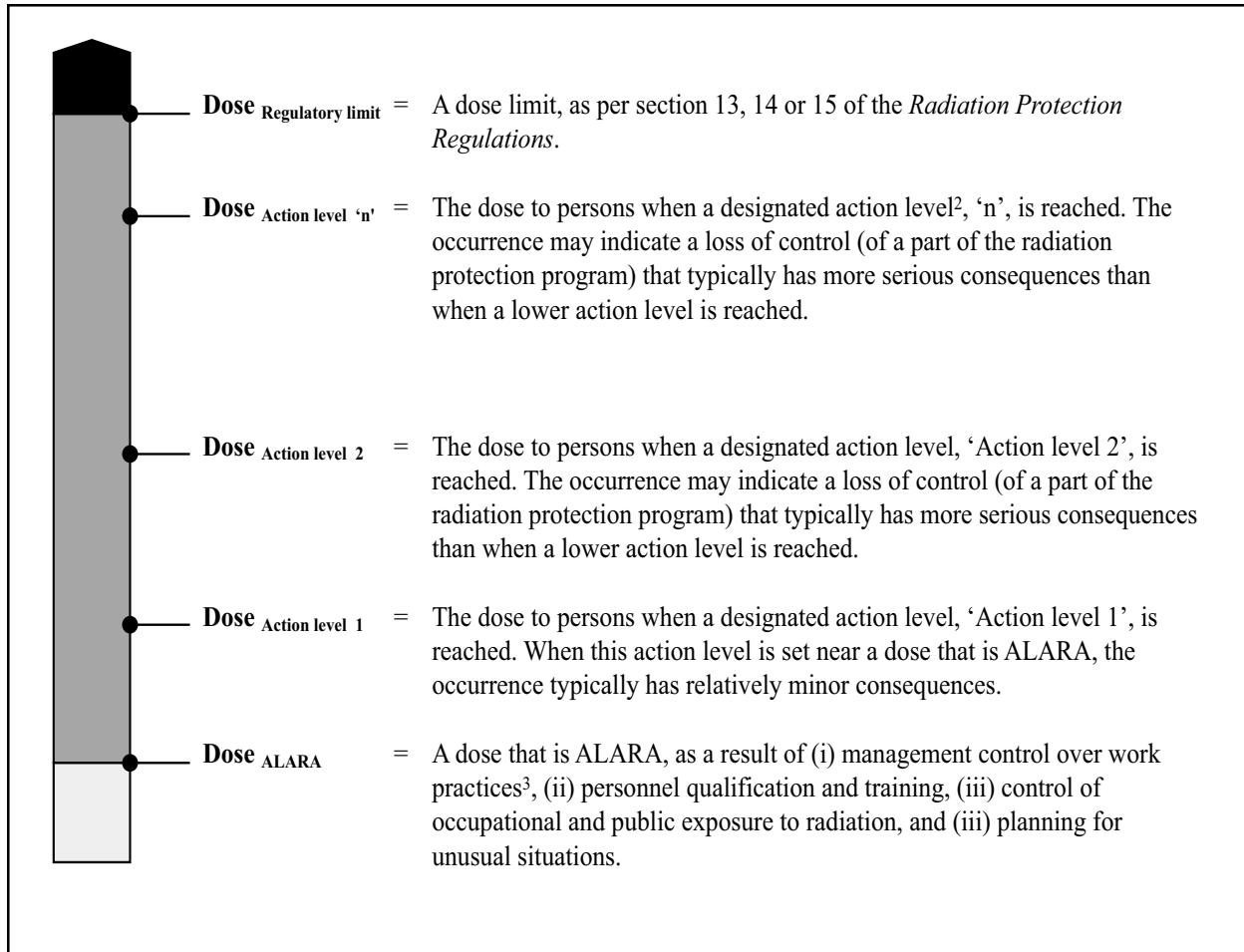
6.0 DEVELOPING, USING AND REVISING ACTION LEVELS

Typically, an action level for a nuclear facility or activity will be developed as part of the CNSC licensing process, in accordance with paragraph 3(1)(f) of the *General Nuclear Safety and Control Regulations*. However, some CNSC licensed activities may not warrant the use of action levels. Examples include some uses of fixed gauges, static eliminators or gas chromatography.

If it is to be useful and credible, an action level must be a meaningful indicator over a defined time period of the state of a radiation protection program. Accordingly, the action level must be measurable to accepted standards of accuracy.

Where possible, an action level for a nuclear facility should take into account the facility design and relevant operating experience. A licence applicant who lacks such experience, as in the case of new activities or operations, may be able to draw upon the experience of comparable designs and operations. To facilitate regulatory review of any proposed action level, the licence applicant should thoroughly and clearly explain the rationale for the level and its planned use.

Figure 1: An example of the typical relationship among regulatory limits, action levels and ALARA¹ doses



Notes

1. A radiation dose is ALARA if it is as low as reasonably achievable, social and economic factors being taken into account.
2. An action level may be expressed in units of radiation dose, or in any terms of any other parameter that could be indicative of a loss of control of a part of the associated radiation protection program.
3. Management control over work practices may, where appropriate, include levels for the routine release of liquid or gaseous effluents. Typically, such levels are set sufficiently low that control of the parts of the radiation protection program to keep doses ALARA state will not be jeopardized if these control levels are reached during normal operations.

Accordingly, the following steps for developing and using action levels may be helpful to licence applicants and licensees:

- From the design, identify those processes and activities that could result in doses to workers or the public.
- For activities and processes that could result in doses to workers or the public, identify the measurable parameters that will indicate, directly or indirectly, whether the radiation protection program is adequately controlled.
- On the basis of realistic assumptions, select appropriate action levels, expressed in terms of the appropriate parameters, for all key processes and activities.
- Incorporate use of the selected action levels into the proposed radiation protection program.
- Implement the radiation protection program and the associated action levels in accordance with the CNSC licence.
- As operating experience accumulates, revise action levels accordingly.

To revise an action level that is referred to in a licence, the licensee must obtain an appropriate licensing action from the CNSC. When applying for this action, the applicant should demonstrate that the proposed revision is appropriate for the purposes of section 6 of the *Radiation Protection Regulations* and any relevant requirements of the licence.

7.0 MONITORING

To serve as an effective indicator of a possible loss of control of a part of a radiation protection program, an action level must be supported by a monitoring program that can accurately detect when the action level is reached. Accordingly, licence applications that include any proposed action level should also describe the monitoring program that the applicant plans to implement in order to detect when the action level is reached.

Since the purpose of monitoring action levels is to provide timely warning of any potential or actual loss of control of part of the radiation protection program, a corresponding monitoring proposal should consist of an appropriate methodology and frequency of sampling or measurement. This selection of methodology and frequency will be influenced by case-specific factors, and should be commensurate with the probability and consequences of a loss of control of a part of the radiation protection program. For example, as the probability that regulatory dose limits could be approached or exceeded as a consequence of a loss of control of part of a radiation protection program increases, more rigorous action level monitoring programs may be appropriate.

When a proposal for monitoring an action level is accepted and incorporated into a CNSC licence, the licensee must ensure that the program is implemented and maintained in accordance with the licence.

8.0 RESPONDING WHEN AN ACTION LEVEL IS REACHED

When an action level referred to in a licence is reached, specific responses are required pursuant to subsection 6(2) of the *Radiation Protection Regulations*. The licensee must conduct an investigation to determine the cause, identify and take action to restore the effectiveness of the radiation protection program, and notify the CNSC within the time period specified in the licence.

Although an action level is not an enforceable dose limit, a failure to meet the above obligations would contravene the *Radiation Protection Regulations*, and would constitute an offence under the *Nuclear Safety and Control Act*.

The reaching of an action level could be due to any number of causes. An action level could be reached repeatedly as a consequence of chronic deficiencies in the associated radiation protection program. Ongoing occurrences could be triggered by a shift in normal operating conditions. Occasional or more frequent occurrences could be triggered by transient conditions that might not relate to a significant loss of control of the radiation protection program, or to a significant change in the radiation doses associated with normal operating conditions.

Accordingly, case-by-case assessments and commensurate remedies may be required in response to each situation where an action level is reached. The appropriate response will depend in part upon the results of the assessment, as well as any other relevant factor such as the hazards associated with the action level of concern.

The investigation that a licensee undertakes to determine why an action level referred to in a licence has been reached may need to first confirm whether the evidence (e.g., measurements, observations or calculations) that indicates that the action level has been reached is valid — i.e., whether the action level has indeed been reached.

Further to determining the cause for reaching an action level, the licensee must identify and take actions to restore the effectiveness of the radiation protection program. These actions should be appropriate to the circumstances and commensurate with the level of risk associated with the reaching of the action level. If the licensee cannot restore the effectiveness forthwith, the licensee should propose interim measures for CNSC consideration. The measures to restore the effectiveness of the radiation protection program, whether interim or final, should be based on credible experience, data or analyses, and should take into account the consequences of the loss of control.

Typically, the greater the radiation hazards that result when an action level is reached, the more immediate, complex or rigorous will be the measures to restore the effectiveness of the radiation protection program.

In addition to the above responses when an action level is reached, paragraph 6(2)(c) of the *Radiation Protection Regulations* requires the licensee to notify the CNSC within the period specified in the licence. This period will take into account the consequences of reaching the action level. The greater the radiation hazards when an action level is reached, the shorter the specified notification period is likely to be. Accordingly, the specified period for notifying the CNSC when an action level referred to in a licence is reached will typically be longer (*i.e.* days, weeks or months) than the immediate notification required pursuant to paragraph 16(a) of the *Radiation Protection Regulations* when the licensee becomes aware that a dose limit may have been exceeded.

9.0 EXAMPLES OF THE USE OF ACTION LEVELS

In the past, some operators of nuclear facilities, and some persons engaged in nuclear activities, used various indicators of radiation dose to monitor, control and assure that their radiation protection programs were effective. Traditionally, these dose indicators were arrived at on the basis of facility-specific or industry experience. In some cases, these indicators were used in the same way that action levels are to be used under the current regulations. In other situations, the uses of such indicators were not expressly linked to any loss of control of a radiation protection program, and consequently were a form of the “management control over work practices” that is referred to in paragraph 4(a)(i) of the *Radiation Protection Regulations*. In still other situations, licensees used a combination of the two approaches.

Some examples of the historical and current application of dose indicators follow:

- **Uranium mines and mills**

Under the former *Uranium and Thorium Mining Regulations*, the operators of uranium mines and mills used dose indicators that were also termed “action levels” to help assure the radiation safety of workers, on-site personnel and the public. The use of these action levels differed from that envisaged under section 6 of the *Radiation Protection Regulations*, in that their application was not limited to situations involving a possible loss of control of a radiation protection program. Instead, they were used as administrative mechanisms to track and control radiation doses at much lower levels.

Under the current *Uranium Mines and Mills Regulations*, applications for licences shall include a “code of practice” that contains any action level that the applicant considers appropriate, as well as the proposed responses and reporting procedures if a proposed action level is reached.

At a given mine or mill, different action levels may be needed for different operations. Accordingly, any action level and related responses contained in a proposed code of practice should be tailored to the specific situation and its needs.

- **Medical and research institutions**

Medical and research institutions commonly use open sources of radiation. To address the possibility of significant intakes of nuclear substances during such uses, the associated radiation protection programs may require that certain actions be taken if the results of precautionary monitoring to screen for significant intakes of radionuclides reach specific levels.

For example, some medical and research institutions that use radioiodine in their operations have in the past adopted criteria for taking remedial actions in response to the results of thyroid monitoring programs. When these results reached or exceeded defined criteria, specified responses were implemented. Typically, these responses consisted of such actions as repeating the thyroid counting procedure to verify the initial result, performing supplementary bioassays on co-workers, or implementing interim measures to prevent further exposure of the workers until the cause was identified and remedied.

- **Radioisotope use**

In licences that authorized radioisotope use, the former Atomic Energy Control Board (now the Canadian Nuclear Safety Commission) routinely included conditions that obliged the licensee to carry out certain actions if specified surface contamination criteria were reached or exceeded. Further, if preventative and confirmatory monitoring indicated that a surface was radioactively contaminated in excess of a predetermined criterion, the licensee was typically required to decontaminate the affected work surfaces to an acceptable level.

The above use of contamination criteria was an integral part of the licensee’s radiation protection program, and the associated contamination criteria served a purpose similar to that of action levels under the existing regulations. Accordingly, some applicants for licences under the *Nuclear Safety and Control Act* and regulations may choose to propose the use of action levels that are expressed in terms of surface contamination levels.

Thus, under the *Nuclear Safety and Control Act* and regulations, licensees may continue to use a combination of action levels and management controls to help keep radiation doses below regulatory limits, and as low as reasonably achievable, social and economic factors being taken into account.