**What We Heard Report: DIS-22-01**

DIS-22-01 Proposal to Amend the C2NFPER

## Preamble

The Canadian Nuclear Safety Commission (CNSC) uses discussion papers, information sessions and workshops to better understand the potential impacts of its proposed regulations, amendments to existing regulations and/or approaches when updating regulatory requirements and guidance.

## Introduction

The CNSC has identified considerations for potential amendments to the [*Class II Nuclear Facilities and Prescribed Equipment Regulations*](https://laws-lois.justice.gc.ca/eng/regulations/sor-2000-205/FullText.html) (C2NFPER). The C2NFPER were first published in 2000, and were last substantially amended in May 2010.

The CNSC was mindful of the following goals while performing this regulatory review:

* Modernize the C2NFPER to reflect the latest technological changes, and where possible, strive to create technology-neutral regulations.
* Incorporate the operational experience gained since the last regulatory review in performing licensing and compliance verification activities involving Class II prescribed equipment.
* Allow for flexibility while still ensuring safety.
* Reduce regulatory burden through streamlining and removal of duplicate requirements, where they exist.
* Ensure that the C2NFPER are logical and align with existing good practices, where they exist.
* Make the C2NFPER easier to understand and use for all stakeholders.

## Discussion paper

In 2022, the CNSC issued a discussion paper entitled “DIS-22-01, Proposal to Amend the Class II Nuclear Facilities and Prescribed Equipment Regulations”. DIS-22-01 was published on [Let’s Talk Nuclear Safety](http://www.letstalknuclearsafety.ca) (an e-consultation platform) from August 16 to November 14, 2022. In addition to the general need to harmonize and modernize the C2NFPER in light of the evolution of the CNSC's regulatory framework over the past 20 years, several specific considerations for changes were outlined. These considerations included, but were not limited to:

* Regulation of all particle accelerators (including high-energy accelerators currently regulated as Class IB facilities) under the Class II regime
* Regulation of Class II prescribed equipment that is intended to be operated outside a shielded facility, and clarification of the term “Class II nuclear facility” as it pertains to the C2NFPER
* Introduction of a two-stream licensing process to allow different approaches for mass-produced “standard” Class II equipment/facilities and unique “non-standard” Class II equipment/facilities
* A shift towards generic, outcome-based radiation protection safety system requirements, with guidance on how these requirements should be implemented contained in an associated regulatory document
* Introduction of provisions allowing for the amendment and expiry of certificates issued to Class II radiation safety officers (RSOs), and for the recertification of RSOs
* Changes to the activities that may be carried out without a CNSC licence, and changes to existing exemptions from equipment and personnel (RSO) certification
* Ease-of-use changes to many sections of the C2NFPER, such as re-ordering and grouping to better reflect how these sections are actually used by stakeholders (in particular those sections that detail information to be submitted to the CNSC in support of a licence or certificate application)

During the consultation period, there were 551 visitors to the e-consultation webpage from various stakeholders who hold CNSC licences and/or certificates. In total, 218 comments were received. These numbers represent a new record for engagement on CNSC’s e-consultation website.

## Workshops

On September 12-13 2022, CNSC staff held consultation sessions in English and French with over 100 participants in attendance. All attendees were stakeholders who currently hold CNSC licences and/or certificates. During these sessions the following items were presented:

* Regulatory background of the C2NFPER
* Impetus and goals for the regulatory review
* A high-level description of the proposed regulatory changes
* A description of the project’s current place in the regulatory change process
* Desired outcomes of the regulatory review

In addition to the workshop above, two information sessions were held in January 2024, one in English and one in French. These sessions were aimed primarily at members of the general public, as well as Indigenous groups. In total, more than 100 people attended these two sessions. Although most attendees were stakeholders who currently hold CNSC licences and/or certificates, approximately 10-15 attendees were representatives of Indigenous groups, or members of the public. The material presented was largely the same as that presented at the September 2022 workshops in terms of major themes, but with minor changes to better suit the intended audience.

All consultation sessions provided an opportunity to discuss the proposed changes and their potential impacts and will help inform the proposed regulations and guidance.

## Summary of Stakeholder Comments

Overall, most of the comments received during the consultation period were supportive of the proposed changes to the C2NFPER. Stakeholders expressed support for the proposed two-stream approach for licensing of standard vs non-standard facilities, the shift towards non-prescriptive regulations wherever possible, and allowing the amendment of RSO certificates.

In contrast, commenters expressed concern with some of the proposed changes, such as the removal of the requirement for a patient viewing system in cancer treatment bunkers, the inclusion of the “related components, systems and equipment” in the definition of a Class II facility, and the periodic recertification of Class II RSOs.

Moving forward, the CNSC plans to proceed with many of the proposed changes where there is stakeholder support. For the proposed changes that generated concern, CNSC is reviewing the comments and may implement some of the suggested improvements/changes provided by commenters. Stakeholders will continue to have opportunities to provide feedback throughout the regulation making process.

The following is a summary of the comments received from stakeholders, using the same section numbering as that found in CNSC Discussion Paper DIS-22-01.

## Section 4.1.1.1: Equipment regulated under the C2NFPER.

Stakeholders expressed general agreement with the proposal to regulate all particle accelerators which produce nuclear energy under the Class II regulatory umbrella. Commenters agreed that removing the current 50 MeV threshold to be considered Class II prescribed equipment would remove barriers to innovation and allow for a more familiar licensing process. There were, however, some questions surrounding a lower-energy regulatory limit, as well as applicability to a situation where a licensee may have mixed Class II and Class I activities (such as producing > 1015 Bq of a nuclear substance). There is currently no lower-energy regulatory limit expressed in the regulations, and this is not expected to change. The Nuclear Safety and Control Act (NSCA) provides the following definition of nuclear energy:

*“Nuclear energy means any form of energy released in the course of nuclear fission or nuclear fusion or of any other nuclear transmutation.”*

In short, when particles or energy originate from the nucleus, it is considered “nuclear”, and is therefore regulated by the CNSC. Energy/particles originating from the electron shell are not regulated by the CNSC.

With respect to licensees performing mixed Class II/Class I activities, these situations can be assessed on a case-by-case basis to ensure the highest level of safety, and to determine the best licensing approach.

Currently, the CNSC intends to proceed with this proposed change.

## Section 4.1.1.2: Add a definition for “medical accelerator”.

Stakeholder feedback generally suggested this proposed change was not necessary, and that current regulatory requirements were sufficient for the effective regulation of medical accelerators. As such, CNSC has decided not to proceed with this proposed change.

## Section 4.1.1.3: Add definitions for mobile and portable prescribed equipment, which are not typically operated in shielded, fixed facilities.

Stakeholders were in favour of this proposed change, however comments indicated that guidance would be required from CNSC to better define what is meant by “portable” or “mobile” prescribed equipment. CNSC intends to proceed with this proposed change, and will ensure that the definitions for these types of equipment are not ambiguous. In addition to defining these types of equipment directly in the Regulations, CNSC may also document regulatory expectations in a future regulatory document.

## Section 4.1.2.1: Define a Class II facility as one that includes Class II prescribed equipment fixed in place inside a shielded room or other enclosure, as well as its related components, systems and equipment.

This proposed change generated a significant number of comments from stakeholders. Upon closer examination of the text in DIS-22-01, the description of the proposed change may have been insufficient to communicate the desired result. The text in the discussion paper could have been interpreted to mean the entire building containing Class II prescribed equipment, including drywall, electrical wiring, plumbing, etc., would be classified as a Class II facility. Instead, the intent of the proposed change was to only include areas and components which are directly related to the facility and required for the safe operation of the radiation-emitting equipment, such as:

* User-installed safety systems external to the prescribed equipment (e.g. last-person-out switches, emergency stop devices)
* Beam limiting devices external to the prescribed equipment
* Shielding external to the prescribed equipment
* Transfer lines/systems for radioactive isotopes produced by the prescribed equipment
* Holding tanks or other containment systems for radioactive isotopes produced by the prescribed equipment
* Ventilation systems, if necessary for ozone or other airborne hazards generated by the prescribed equipment, e.g. exhaust stacks
* Hot cells or fume hoods where radioactive isotopes produced by the prescribed equipment are handled.

While CNSC does intend to proceed with this proposed change, the points made by commenters are well-taken, and will inform the final regulatory proposal.

## Section 4.2.1.1: Two-stream approach to licensing.

Stakeholder response to this proposed change was positive, however commenters had questions surrounding the implementation, particularly how an applicant or licensee would choose a particular stream, or whether the CNSC would impose which stream applicants and licenses would follow.

The details of the two-stream approach to licensing (where there is a “standard” stream for mass-produced or non-unique facilities, and a “non-standard” stream for unique facilities which will only be constructed once) are not yet fully defined.

The intent of this proposed change is to allow the licensee and CNSC to utilize the stream which best meets the requirements of both the licensee and the CNSC. It is expected that licensees currently operating unique facilities would not be required to switch to the “non-standard” stream (or vice versa) if the current arrangement is satisfactory for both the licensee and the CNSC. The most likely implementation of this proposed change would be that the licensee would request the stream they wish to use, and this request will be subject to CNSC approval before proceeding. Any decisions made by CNSC with regards to which stream is chosen would be based on the risks and benefits of proceeding with either stream. Practically speaking, it is expected that any decision respecting which stream to choose would involve several proactive discussions between CNSC and the applicant to determine the best path forward.

While the exact process surrounding the implementation does not yet exist, CNSC does intend to proceed with this proposed change, with detailed guidance being developed and made available to licensees/applicants prior to implementation.

## Section 4.2.2.1: Require radiological workload and beam-related parameters (where applicable) for all Class II prescribed equipment, not only teletherapy machines.

Stakeholders expressed overwhelming agreement with this proposed change. CNSC intends to proceed with the regulatory amendment.

## Section 4.2.2.2: Remove the requirement to provide the anticipated number of hours per week that the Class II facility will be operated for specific uses (treatment, dosimetry, servicing or research).

Stakeholders expressed overwhelming agreement with this proposed change. CNSC intends to proceed with the regulatory amendment.

## Section 4.2.2.3: (When applying for a licence to construct) Remove the current requirement to provide the proposed responsibilities of and training program for workers during the operation of the facility.

Stakeholders expressed overwhelming agreement with this proposed change. CNSC intends to proceed with the regulatory amendment.

## Section 4.2.2.4: (When applying for a licence to construct) Clarify that a description must be provided of all safety systems that are required under section 15 of the C2NFPER.

Stakeholders expressed overwhelming agreement with this proposed change, however some comments requested further information as to the level of detail required when describing the safety systems. Section C.2 of CNSC REGDOC 1.4.1 describes the current level of detail required for the descriptions of safety systems which will be installed, and it is expected that a similar level of detail will be available in future guidance, which will be issued concurrently with the amended Regulations.

CNSC intends to proceed with the regulatory amendment.

## Section 4.2.2.5: Add a requirement for panoramic, wet source storage gamma irradiators (pool-type irradiators) to adhere to ANSI standard N43.10 in the design of these types of facilities.

Stakeholders overwhelmingly disagreed with the need to incorporate standards in the Regulations, such as ANSI N43.10. Following review of other standards which may apply to Class II facilities (such as CSA N286), CNSC agrees that incorporating such standards into regulations will reduce flexibility and will not result in a net benefit to the CNSC or its stakeholders. If necessary, such standards can continue to be imposed through licence conditions which are specific to the licensed activity.

This proposed change will be removed from consideration.

## Section 4.2.2.6: (When applying for a licence to construct) Add a requirement that the proposed method of disposing of Class II prescribed equipment (and any activated components or materials) be provided with the preliminary decommissioning plan.

Stakeholders expressed general agreement with this proposed change, however commenters expressed concern that the proposed method of disposal may change during the lifetime of the equipment. The intent of this proposed change is to ensure that applicants have in place a plan (during the construction phase) for disposal of the equipment at the eventual end of life. CNSC understands that the plan may need to be amended from time to time as conditions warrant.

CNSC intends to proceed with the regulatory amendment, and will take into account the concerns expressed above.

## Section 4.2.3.1: (When applying for a licence to operate) Add information to be submitted in support of an application for a licence to operate Class II prescribed equipment that will be operated outside a shielded facility.

Stakeholders expressed general agreement with this proposed change, however there appeared to be some confusion among certain commenters who were of the impression that the proposed changes (such as per-shift radiation doses) applied to licensees operating in fixed facilities. The proposed changes in this section of DIS-22-01 are intended only for Class II prescribed equipment operating outside of shielded facilities (i.e. “mobile” or “portable” prescribed equipment).

CNSC intends to proceed with the regulatory amendment, but will clarify any ambiguity surrounding the applicability of the proposed change.

## Section 4.2.3.2: (When applying for a licence to operate) Require radiological workload and beam-related parameters (where applicable) for all Class II prescribed equipment operating in a shielded facility, not only teletherapy machines; in addition, remove the stipulation that workload must be tracked on a weekly basis and in units of grays measured at a distance of 1 m.

Similar in scope to Section 4.2.2.1, stakeholders expressed overwhelming agreement with this proposed change. CNSC intends to proceed with the regulatory amendment.

## Section 4.2.3.3: (When applying for a licence to operate) Require applicants to submit the proposed methods and frequency for testing the safety systems set out in section 15 of the C2NFPER, as well as any installed security systems.

Stakeholders expressed general agreement with this proposed change, however many commenters expressed concern that CNSC would impose the methods and frequencies of testing of safety/security systems in the Regulations.

The methods/frequencies for testing of safety/security systems will not be defined in the Regulations, rather it would likely be addressed in a related CNSC REGDOC. However, CNSC does anticipate specifying minimum acceptable standards for testing of safety systems (frequency/method). Development and determination of such standards would be carried out in consultation with stakeholders. Alternatively, CNSC may define a framework for analyzing the minimum or best-practice methods/frequencies for the testing of safety systems. With respect to security systems, guidance from CNSC REGDOC 2.12.3 may be referenced or incorporated.

Commenters also suggested that CNSC develop an official definition of “safety systems” in the context of Class II prescribed equipment and facilities, in order to remove ambiguity. This suggestion is under consideration.

Additionally, although not directly related to this proposed change, commenters separately suggested that it should be incumbent upon equipment vendors to provide a method of testing equipment safety systems/interlocks in a manner that will not cause potential damage to the equipment. This suggestion is also under consideration.

CNSC intends to proceed with the regulatory amendment, but without specifying or imposing the nominal method or frequency in the amended Regulations. If any minimum standards for testing of safety/security system methods/frequencies are developed, this will be done in consultation with stakeholders.

## Section 4.2.3.4: (When applying for a licence to operate) Provide details of the disposal method for all Class II prescribed equipment to be removed from an operating licence, including mobile/portable Class II prescribed equipment.

Similar in scope to Section 4.2.2.6, stakeholders expressed agreement with this proposed change, with the understanding that the disposal method may change during the lifetime of the equipment. CNSC intends to proceed with the regulatory amendment.

## Section 4.2.4.1: Ensure decommissioning activities are performed only by (or under the supervision of) persons or entities who hold a valid CNSC servicing licence.

Stakeholders expressed general disagreement with the proposed change to require a servicing licence when decommissioning a Class II facility. CNSC acknowledges that section 4.2.4.1 of the discussion was inaccurate in stating that a service license would be required for dismantling a *facility*. Currently, the CNSC does not expect individuals dismantling a facility that is free of prescribed equipment and nuclear materials to possess a Class II servicing licence. To be clear, the proposal is to require a servicing licence when dismantling Class II prescribed equipment only.

Since dismantling is listed in the definition of servicing in the C2NFPER, any individuals or organizations who wish to dismantle Class II prescribed equipment must perform these activities under a servicing licence.

CNSC intends to proceed with the regulatory amendment, with the clarification that a servicing licence is only required when dismantling and decommissioning Class II prescribed equipment (as opposed to a facility). Additionally, CNSC may investigate the possibility of issuing consolidated “decommissioning and servicing” licences, a solution which could be implemented using licensing tools already available to CNSC. Given the confusion due to the erroneous wording in DIS-22-01, further stakeholder consultation on this subject may be required.

## Section 4.2.5.1: Add a requirement to provide a description of the methods and/or equipment that will be used to ensure safety during servicing operations (e.g., defining circumstances or dose levels that require workers to “back out” of a situation, or steps to take when a situation arises that is not covered by standard servicing procedures); conversely, remove the requirement for applicants to submit their standard procedures and/or equipment for performing servicing (a table of contents of such standard procedures may be requested instead).

Stakeholders expressed general agreement with this proposed change, however some licensees who hold development licences or “non-standard” licences expressed concern that standard servicing procedures may still be under development when applying for a licence to service, thus making it difficult to submit a table of contents. CNSC is aware of this possibility, and it is expected that in such situations, the licensee will instead submit the description of the methods and/or equipment that will be used to ensure safety during servicing operations (which is also part of this proposed change).

As there was wide agreement from stakeholders with this part of the proposed change, CNSC intends to proceed with the regulatory amendment.

## Section 4.2.6.1: Remove the exemption from licensing for the operation of a Class II facility that includes a geophysical well logging accelerator.

CNSC received no comments from stakeholders for this proposed change. While CNSC intends to proceed with the regulatory change at this time, more focused outreach on the proposed regulatory changes will be directed at licensees who currently hold licences to operate geophysical well logging accelerators.

## Section 4.2.6.2: Add an exemption from licensing for the import and export of Class II prescribed equipment that does not contain a nuclear substance.

Stakeholders expressed overwhelming agreement with this proposed change. Additionally, CNSC received a suggestion that by changing the definition of Class II prescribed equipment in section 1 of the C2NFPER to include equipment that “contains” rather than “uses” a nuclear substance, it may be possible to repeal section 9 entirely. CNSC is currently investigating this possibility and will provide further updates going forward.

Although the exact implementation is unknown at this time, CNSC intends to proceed with amending either section 9 or section 1 of the C2NFPER to exempt the import and export of Class II prescribed equipment which does not contain a nuclear substance from licensing.

## Section 4.3.1.1: Remove the exemption for certification based solely on the fact that the equipment will be used for scientific research.

Stakeholders expressed overwhelming agreement with this proposed change. Some commenters did wish to clarify that the requirement for deciding when certification would be necessary should depend on the quantity of equipment to be licensed in Canada, rather than worldwide. As the CNSC only certifies/licences equipment and facilities in Canada, it is expected that a single installation of equipment that is mass produced outside of Canada would still be treated as “unique”. Note however that if the CNSC feels it is likely that this equipment will be used more widely inside Canada, it may still decide to pursue certification.

CNSC intends to proceed with the regulatory amendment.

## Section 4.3.1.2: Add an exemption from certification for equipment or facilities that are to be licensed under the “non-standard” licensing stream (i.e., unique equipment/facility that is only constructed once).

Stakeholders expressed overwhelming agreement with this proposed change. Similar to the proposed change in section 4.3.1.1, some commenters did wish to clarify that the requirement for deciding when certification would be necessary should depend on the quantity of equipment to be licensed in Canada, rather than worldwide. As the CNSC only certifies/licences equipment and facilities in Canada, it is expected that a single installation of equipment that is mass produced outside of Canada would still be treated as “unique”. Note however that if the CNSC feels it is likely that this equipment will be used more widely inside Canada, it may still decide to pursue certification.

CNSC intends to proceed with the regulatory amendment.

## Section 4.3.2.1: (When applying for Class II prescribed equipment certification) Add a requirement to provide the proposed method for securing Class II prescribed equipment that contains a nuclear substance.

Stakeholders expressed general agreement with this proposed change, however some comments were received requesting information as to how this proposed change would affect currently certified/installed equipment and renewals of certificates for currently certified equipment. At this time, CNSC has not finalized how this change will impact existing equipment, however it is expected that such equipment will be exempted under a grandfather clause if the certificate holder has not modified the design to include a method of securing the equipment. In all cases, it will still be incumbent upon the end user to ensure that Class II prescribed equipment containing nuclear substances is secured in accordance with the requirements of the Nuclear Security Regulations and/or CNSC REGDOC 2.12.3.

CNSC intends to proceed with the regulatory amendment, while further examining how making this change will affect currently certified equipment.

## Section 4.3.2.2: (When applying for Class II prescribed equipment certification) Add a requirement to provide a description of the proposed safety interlock system that will prevent/halt unintended irradiation.

Stakeholders expressed general agreement with this proposed change. Some commenters mentioned that providing descriptions of the interlocks would increase regulatory burden, however this information is already currently required in sections C.2 and C.8 of CNSC REGDOC 1.5.1, which is the regulatory document providing guidance for applicants wishing to certify Class II prescribed equipment. Therefore, there will be no additional burden on applicants – this proposed change only codifies existing practices into the Regulations.

Other comments were received regarding the connection of such equipment-based interlock systems to facility-based actuators, and the fact that each facility is different, and in some cases where Class II prescribed equipment is operated outside a shielded facility, there may be no facility at all. The intent of this proposal is to ensure that interlock circuits and logic built into the equipment itself performs as expected when activated using facility safety systems, and “fails safe” if the internal interlock circuit is not operating as expected. There is no expectation that applicants for Class II prescribed equipment certificates will be required to describe potential safety systems installed by eventual users of the equipment in their facilities. All Class II prescribed equipment, whether operated within a facility or in a mobile/portable configuration outside of a facility, already incorporates such interlocks, and will continue to do so going forward.

CNSC intends to proceed with the regulatory amendment.

## Section 4.4.1.1: Replace the current prescriptive requirements with outcome-based requirements.

Stakeholders expressed general agreement with this proposed change, however many comments were received expressing concern that an area radiation monitor and irradiation state indicators would be required inside the radiation area, neither of which are currently required by the C2NFPER.

The text of the proposed change in DIS-22-01 states that “*There must be a method of determining whether radiation is present within the controlled area and of displaying this fact both within and outside the defined area*”. CNSC wishes to clarify that an independent area monitor may not be required to determine if radiation is present; instead, if the prescribed equipment produces a signal that indicates when radiation is present, and this signal is used to indicate the status outside the controlled area, then this will satisfy the requirement. CNSC acknowledges that the wording in the discussion paper may not have been clear on this point, and will either clarify the proposed language, or develop guidance to ensure the intent is clear to licence applicants.

With regards to the proposal to include an irradiation state indicator inside of the radiation area, this proposal is based on operational experience (i.e. people being in the room when radiation was turned on, and only becoming aware of the fact due to already existing warning lights which were installed within the bunker, even though they are not currently required by regulations). While several current licensees already incorporate such indicators within the radiation area, CNSC understands that this is not universal, and that installation of such systems would introduce a new burden on some licensees. CNSC will continue to examine whether the benefit of these new requirements outweigh the cost to stakeholders of implementing them, and further consultation with the licensed community may be required.

With respect to the general approach of switching to performance-based regulations, there was overwhelming agreement from stakeholders, therefore CNSC intends to proceed with this aspect of the regulatory amendment.

## Section 4.4.2.1: Make section 15 applicable to Class II prescribed equipment operated outside a shielded facility.

Stakeholders expressed general agreement with this proposed change, however some questions were received which asked how the requirements in section 15 of the C2NFPER would apply to mobile/portable equipment, when section 15 is clearly written with fixed facilities in mind.

Given the current lack of requirements for mobile/portable equipment in the C2NFPER, the requirements are instead applied via binding conditions which are added to each licence for these types of equipment. The proposal is to add these requirements to section 15, or if necessary, create a new section in the Regulations for these requirements. Therefore, the proposal is not necessarily to impose the requirements of section 15 on mobile/portable equipment, but rather to add the requirements (currently applied via licence conditions) to the Regulations. CNSC acknowledges that the wording in the discussion paper may not have been clear on this point, and will ensure that clarity is added when drafting the regulations to ensure there is no ambiguity for requirements of fixed versus mobile/portable equipment.

CNSC intends to proceed with the regulatory amendment.

## Section 4.4.2.2: Allow licensees to propose and implement alternative or additional safety precautions in the event of a failure of an installed and approved safety system.

Stakeholders expressed general agreement with this proposed change, however there was some confusion due to the wording in the discussion paper. To be clear, CNSC is proposing to only *temporarily* allow alternative or additional safety precautions in the event of a failure of an installed and approved safety system, for a minimal amount of time while the safety system is being repaired/replaced, and restored to the systems specified in the licence. Any longer-term change to a safety system would require proper assessment by CNSC, and an amendment to the licensing basis. Additionally, it should be clarified that this proposed change would only apply when the failure of a safety system will impact the operation of a facility that is used for human therapeutic purposes.

CNSC is continuing to explore the implications of proceeding with this regulatory amendment.

## Section 4.4.2.3: Add a requirement that licensees must test all installed safety systems on a regular basis.

Similar to Section 4.2.3.3, stakeholders expressed general agreement with this proposed change, however many commenters were concerned that the CNSC would impose the methods and frequencies of testing of safety/security systems in the Regulations.

As stated in Section 4.2.3.3., the methods/frequencies for testing of safety/security systems will not be defined in the Regulations, rather it would likely be addressed in a related CNSC REGDOC Such a REGDOC would likely contain minimum acceptable standards, as well as best practices and guidance, for the frequency/method of testing of safety/security systems. Development and determination of such standards would be carried out in consultation with stakeholders. Alternatively, CNSC may define a framework for analyzing the minimum or best-practice methods/frequencies for testing of safety systems.

CNSC intends to proceed with the regulatory amendment.

## Section 4.4.2.4: Remove explicit exemptions for brachytherapy remote afterloaders that incorporate pure beta emitters as their only nuclear substances, and for facilities that include particle accelerators used for geophysical logging.

Stakeholders expressed overwhelming agreement with the proposal to remove explicit exemptions for brachytherapy remote afterloaders that incorporate pure beta emitters as their only nuclear substances. CNSC intends to proceed with the regulatory amendment.

With respect to the proposal to remove explicit exemptions for facilities that include particle accelerators used for geophysical logging, there were no comments received. While CNSC intends to proceed with the regulatory amendment, more focused outreach on the proposed regulatory changes will be directed at licensees who currently hold licences to operate geophysical well logging accelerators.

## Section 4.4.2.5: Remove the requirement for a patient viewing system.

Stakeholders expressed overwhelming disagreement with this proposed change.

Currently, the Regulations only require viewing systems in Class II facilities which are used on humans. The purpose of these viewing systems is to ensure that patients do not move after being accurately positioned on the treatment table by facility staff to receive radiation therapy, and to monitor the patient’s health during treatment. As both purposes are related to patient health, it was the opinion of the CNSC that such viewing systems were beyond the scope of the CNSC’s mandate.

However, based on the feedback received and further internal discussions, CNSC has decided not to proceed with this proposed regulatory amendment.

## Section 4.5.1.1: Require that every licensee who operates or services a Class II facility or Class II prescribed equipment appoint a radiation safety officer who has been certified by the CNSC.

This proposed change included two parts:

1. Change the current subsection 15.01(1) of the C2NFPER to include operators of Class II prescribed equipment (not just facilities)
2. Remove/repeal section 15.12

With respect to item (a), CNSC did not receive any comments. CNSC intends to proceed with this part of the regulatory amendment.

With respect to item (b), some commenters mentioned that requiring separate certification for persons who had already been designated/certified under section 9 of the Class I Nuclear Facility Regulations would result in additional regulatory burden. While the CNSC acknowledges the potential for additional burden on some licensees who operate both Class I and Class II facilities, CNSC feels that this is justified since the RSOs at such facilities must be able to understand and apply regulations specific to the Class II facility/equipment, and such knowledge cannot be assumed based on the current certification process under section 9 of the Class I Regulations. Additionally, some commenters suggested that the certification process for Class II RSOs could be incorporated into the certification process under section 9 of the Class I Regulations, however questions arose around the situation where candidates may fail to achieve the minimum score on the Class II portion, which could lead to an overall failure to achieve certification for both the Class II and Class I facilities.

While CNSC is still examining the details of implementation, CNSC intends to proceed with this part of the regulatory amendment.

## Section 4.5.2.1: Add a provision under which certificates issued to Class II radiation safety officers will expire after a certain period, to be defined by the CNSC. Consequently, a clause that will require periodic recertification of a Class II RSO will also be added.

Stakeholders expressed a great deal of concern with this proposed change.

CNSC acknowledges and appreciates the concern around the proposal to require periodic recertification of RSOs. Most comments received were not necessarily in opposition to the idea of recertification, but were rather requesting and suggesting details as to how RSO recertification would proceed, practically speaking.

When the discussion paper DIS-22-01 was written (and when the stakeholder workshop was held in autumn of 2022), CNSC had not yet devised details of the proposed program for recertifying RSOs. The comments received in response to the discussion paper and during the workshop have provided CNSC with several possible approaches for recertification, which may be incorporated as part of this regulatory change. Such suggestions include:

* Implementing a “points” or “credit” system, through which RSOs would need to maintain a certain number of credits over the certification period to maintain currency. RSOs could potentially receive credits for certain activities related to radiation safety, such as (but not limited to):
	+ Attending radiation-safety-related training or conferences
	+ Authoring or co-authoring radiation-safety-related publications
	+ Performing radiation-safety-related activities, such as internal audits of their own licensed activities, safety audits of other facilities, etc.
	+ Performing radiation-safety-related outreach to the general public or other bodies external to their organization
	+ Membership or participation in organizations such as the Canadian Radiation Protection Association (CRPA), Canadian Organization of Medical Physicists (COMP), etc.
	+ Authoring and/or maintaining radiation-safety-related policies or procedures;
* Recognizing the accreditation (or similar) of other radiation safety related bodies (e.g. CRPA(R));
* Linking the requirement for recertification to inspection results for the facility(ies) for which the RSO is responsible;
* Aligning the “breadth” of the recertification with the usetype (i.e. risk-based);
* Implementing a short, focused quiz, rather than the current examination structure;
* Incorporating RSO assessment into the compliance verification process;
* Incorporation of a “renewal” system rather than a recertification (i.e., renewal would be implied, with assessment of the RSO’s performance/qualifications during the certification period, similar to how CNSC licences are renewed).

While the intent is to proceed with the regulatory amendment, the CNSC will take all of these suggestions into consideration when devising the draft regulations and any associated guidance documents. The CNSC will continue to consult with stakeholders to ensure that if the proposal for RSO recertification is incorporated, the adopted method will take into consideration the practical implementation as well as the potential regulatory burden of such a change.

## Section 4.5.2.2: Add language allowing the amendment of certificates issued to Class II radiation safety officers.

Stakeholders expressed overwhelming agreement with this proposed change. CNSC intends to proceed with the regulatory amendment.

## Section 4.6.1.1: Remove the relationship between record retention period and licence expiry.

Stakeholders expressed overwhelming agreement with this proposed change. CNSC intends to proceed with the regulatory amendment.

## Section 4.6.2.1: Changes relating to records of servicing of Class II prescribed equipment.

Stakeholders expressed overwhelming agreement with this proposed change. Some commenters had questions surrounding records requirements when servicing is performed by Canadian organizations outside of Canada. For clarity, records of servicing performed in other countries falls under the retention requirements of the Regulator in the country where servicing is performed. For servicing provided to Canadian licensees, whether the organization is headquartered in Canada or internationally, the records must be retained by the servicing provider and a copy must be given to the equipment owner.

CNSC intends to proceed with the regulatory amendment.

## Regulation of Nuclear Fusion

The discussion paper, DIS-22-01, did not provide a detailed proposal for the regulation of nuclear fusion facilities under the C2NFPER. CNSC recognizes that there is a near-term need to provide regulatory certainty regarding the CNSC’s approach to regulating fusion. CNSC will publish a position paper, followed by a discussion paper, to articulate its intended approach on regulating fusion.

## Next steps

The CNSC will develop a proposed regulatory amendment package that considers all feedback received. This includes a detailed Regulatory Impact Analysis Statement (RIAS), which is an evidence-based, non-technical synthesis of expected impacts of a proposed regulation. The RIAS and the text of the proposed regulations are expected to be published in the *Canada Gazette, Part I*, which serves as a tool for further consultation between the Government of Canada and Canadians.

The C2NFPER are supported by regulatory documents which provide clarity on how to meet requirements specified in the regulations.

## Acronyms

CNSC Canadian Nuclear Safety Commission

CSA Canadian Standards Association

RSO Radiation Safety Officer

NSCA Nuclear Safety and Control Act

C2NFPER Class II Nuclear Facility and Prescribed Equipment Regulations

REGDOC CNSC Regulatory Document

ANSI American National Standards Institute

RIAS Regulatory Impact Analysis Statement

MeV Mega electron volt

Bq Becquerel

## References

1. Canadian Nuclear Safety Commission (CNSC), *DIS-22-01 Proposal to Amend the Class II Nuclear Facilities and Prescribed Equipment Regulations*, Ottawa, Canada, 2022.
2. CNSC REGDOC 1.4.1: *Licence Application Guide: Class II Nuclear Facilities and Prescribed Equipment*, Ottawa, Canada, 2021
3. CNSC REGDOC 1.5.1: *Application Guide: Certification of Radiation Devices or Class II Prescribed Equipment*, Ottawa, Canada, 2020
4. CNSC REGDOC 2.12.3: *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material*, Ottawa, Canada, 2020
5. ANSI/HPS N43.10-2019: *Safe Design and Use of Panoramic, Dry Source Storage (Category II), Self-Contained, Wet Source Storage (Category III), and Panoramic, Wet Source Storage (Category IV) Gamma Irradiators*, American National Standards Institute, 2019
6. CSA N286: *Management Systems Requirements for Nuclear Facilities*, CSA Group, 2022