Canada's Nuclear Regulator

Proposal to Amend the Class II Nuclear Facilities and Prescribed Equipment Regulations

Discussion Paper DIS-22-01

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Preface

Discussion papers play an important role in the selection and development of the regulatory framework and regulatory program of the Canadian Nuclear Safety Commission (CNSC). They are used to solicit early public feedback on CNSC policies or approaches.

The use of discussion papers early in the regulatory process underlines the CNSC's commitment to a transparent consultation process. The CNSC analyzes and considers preliminary feedback when determining the type and nature of requirements and guidance to issue.

Discussion papers are made available for public comment for a specified period of time. At the end of the first comment period, CNSC staff review all public input, which is then posted for feedback on the CNSC website for a second round of consultation.

The CNSC considers all feedback received from this consultation process in determining its regulatory approach.

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Executive Summary

The Canadian Nuclear Safety Commission (CNSC) has identified considerations for a potential revision of the *Class II Nuclear Facilities and Prescribed Equipment Regulations* (C2NFPER). If revised, the new version would supersede the existing C2NFPER, dated 2000 (last substantially amended in May 2010). This discussion paper is being issued to provide information and solicit feedback on these considerations.

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.

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 are outlined. These considerations include:

- 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 approach to licensing in order to allow for different licensing approaches between 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 the information to be submitted to the CNSC in support of a licence or certificate application)

The purpose of this discussion paper is to gather feedback from licensees, proponents, the Canadian public, Indigenous peoples, and other stakeholders on these considerations. All feedback received during this consultation will inform the CNSC’s approach in moving forward with these regulatory considerations for potential amendments. Once this preliminary consultation is complete, the CNSC will finalize its analysis. Stakeholders will have further opportunity to comment on a more formal proposal for the changes being considered during the *Canada Gazette, Part I*, pre-publication process.

We would appreciate stakeholders’ special attention to any potential impacts on their operating and administrative costs that the considerations for potential changes discussed in this document may have.

The CNSC will proceed with a cost–benefit analysis (CBA) when this preliminary consultation is completed and its findings analyzed.[1]

[1] A CBA is a structured approach to identifying and considering the economic, environmental and social effects of a regulatory proposal. The CBA identifies and measures the positive and negative impact of regulatory proposals so that decision makers can determine the best course of action.

Proposal to Amend the Class II Nuclear Facilities and Prescribed Equipment Regulations

1. Introduction

The Canadian Nuclear Safety Commission (CNSC) regulates the use of nuclear energy and materials to protect the health, safety and security of Canadians and the environment, and to implement Canada's international commitments on the peaceful use of nuclear energy.

In Canada, Class II nuclear facilities and prescribed equipment are regulated in accordance with the *Class II Nuclear Facilities and Prescribed Equipment Regulations* (C2NFPER), under the *Nuclear Safety and Control Act* (NSCA). With a few exceptions, all Class II prescribed equipment must be certified and licensed by the CNSC before any of these devices can be used in Canada. The C2NFPER (in conjunction with the *General Nuclear Safety and Control Regulations*, or GNSCR) set out the requirements all applicants must meet before such a certificate or licence is issued. In addition, the C2NFPER include requirements to ensure that effective measures are put in place in all Class II nuclear facilities to protect workers and members of the public from unintended exposure to radiation.

During the most recent substantial amendment to the C2NFPER, in May 2010, requirements for the certification of radiation safety officers (RSOs) at Class II facilities were added, as this was necessary to ensure proper oversight of these facilities, which can vary broadly in terms of size and complexity.

Lastly, the C2NFPER contain requirements for the records that must be kept and retained when Class II prescribed equipment is operated or serviced.

The C2NFPER are currently supported by several CNSC regulatory documents (REGDOCs) that provide guidance on how licensees and applicants may meet regulatory requirements. Three of these regulatory documents would be directly affected by the changes proposed in this document. They are:

- REGDOC-1.4.1, *Licence Application Guide: Class II Nuclear Facilities and Prescribed Equipment*, published 2021
- REGDOC-1.5.1, *Application Guide: Certification of Radiation Devices or Class II Prescribed Equipment*, published 2020
- REGDOC-2.2.3, *Personnel Certification: Radiation Safety Officers*, published 2014

Impacts to the above mentioned regulatory documents are currently under analysis. A separate discussion paper outlining these changes may be communicated at a later date.

As mentioned in the Executive Summary, one of the goals of this review is to modernize the C2NFPER and make them more flexible and adaptable to ever-changing technologies, while still ensuring safety. With this in mind, a general shift towards higher level, less prescriptive regulatory requirements may be expected, with specific details of how these requirements should be implemented contained in a CNSC regulatory document. If this proposed strategy is accepted, one or more new regulatory documents may be developed in concert with the C2NFPER to provide specific guidance for the safety of Class II facilities, with the content being informed, in part, by this review process.

2. Scope

The considerations for potential amendments to the C2NFPER will affect the following groups or individuals:

- all licensees who currently hold a Class II licence
- all holders of certificates for Class II prescribed equipment
- those individuals certified as RSOs under the current C2NFPER
- holders of Class IB licences who operate particle accelerators

No amendments to the NSCA, the GNSCR or other regulations are proposed as part of this project.

3. Pre-Consultation Activities to Date

No formal pre-consultation activities have been performed to date. Operational experience gathered while performing certification, licensing and compliance activities involving Class II facilities and prescribed equipment, as well as informal discussions with stakeholders since the last time the C2NFPER were amended, have informed the considerations for potential amendments in this discussion paper. The intent of this discussion paper is to serve as the opening of formal consultation with stakeholders for the potential amendment of the C2NFPER.

4. Considerations for Potential Amendments to the Regulations

4.1 Interpretation and definitions

This section describes the changes being proposed to definitions of terms as they apply to the C2NFPER, including the definition of Class II prescribed equipment and of a Class II facility. This will impact the scope of equipment and facilities that are encompassed by the C2NFPER.

Details of the proposed changes and the reasoning for each are presented below.

4.1.1 Equipment regulated under the C2NFPER

It is proposed to change the definition of Class II prescribed equipment, as well as add new definitions for equipment that is or will be encompassed by the C2NFPER.

4.1.1.1 Proposed change: Revise the definition of Class II prescribed equipment to include *all* particle accelerators capable of producing nuclear energy, with no explicit upper or lower limit on beam energy.

Reasoning: Under the current definitions in the C2NFPER, any particle accelerator designed to operate with a beam energy of less than 50 million electron volts (MeV) is regulated as Class II

prescribed equipment.[2] Conversely, any accelerator designed to operate at energies higher than this limit automatically falls under the Class I regulatory regime.

While the beam energies of accelerators that would be captured by this proposal may be one or two orders of magnitude higher than those currently regulated under the C2NFPER, this increase in beam energy does not translate to a proportional increase in radiological risk. Many such accelerators operate with a very low beam current, so while the accelerated particles may have a higher energy when compared to accelerators currently licensed under the C2NFPER, there are usually not as many particles accelerated in a given time. Because of this, the overall radiological risk due to prompt radiation from these accelerators is similar to that presented by accelerators currently licensed under the Class II regime.

As mentioned earlier, any accelerator currently producing a beam with an energy greater than 50 MeV is licensed as a Class I facility in Canada. Other examples of Class I facilities include nuclear fission power reactors and processing facilities for nuclear fuel products, such as uranium. Some of these facilities require stringent containment facilities and processes in order to prevent unauthorized or unintended releases to the environment. Accelerators, however, regardless of operating energy, do not have these same containment risks since no radiation is produced unless the accelerator is actively powered by electricity. Material that may be activated by the accelerator beam will only remain in such a state for a time period on the order of months or at most a few years before it returns to background radiation levels. By comparison, waste products from the aforementioned examples of other Class I facilities may have a considerably longer lifetime.

The complexity of other Class I facilities is related to the potential risk and can include multiple redundant systems to provide safety and security under almost any condition. In addition, there tends to be an understandably high level of interest from the public in such facilities due to the risks that may be posed in the to the public and the environment. The level of complexity of the systems for any accelerator are less complex and there is little risk of releases to the public or the environment.

Given that accelerators operating at any energy do not present these complexities, it is reasonable that the licensing regime for accelerators also be reduced in complexity, and all accelerators, regardless of beam power, be regulated under the Class II regime. This would lead to a simplified licensing model for existing Class IB-licensed accelerators, such as TRIUMF and CLS,[3] as well as for facilities that are expected to come to Canada in the future, such as proton radiotherapy accelerators. Note that while the licensing process may be simplified, it will still be commensurate with the risks involved in constructing, operating and decommissioning these types of facilities.

[2] Note that at the time the C2NFPER were originally drafted, the value of 50 MeV was chosen as a convenient boundary between the majority of accelerators then in operation that had a maximum beam energy in the range of 25–35 MeV, and the only high-energy accelerator then in operation (TRIUMF), which was operating at energies of approximately 500 MeV. Since that time, evolution in the field has led us to re-examine this limit, as described in section 4.1.1.1.

[3] TRIUMF (TRI-University Meson Facility): a facility located in Vancouver, BC, operating several research accelerators with beam energies of up to 500 MeV.
CLS (Canadian Light Source): a synchrotron facility located in Saskatoon, SK.

4.1.1.2 Proposed change: Add a definition for "medical accelerator".

Reasoning: This change is being proposed in order to allow for separate requirements for medical accelerators and other accelerator types that are not used on humans. Medical accelerators, or particle accelerators that are used for radiotherapeutic treatment of humans, are often operated in environments that are generally accessible to the public, in contrast with other accelerators, which are usually operated in industrial or research settings that are only accessible to trained licensee staff. Because of this, facilities operating medical accelerators have different factors to take into consideration in their design and operations.

Specific proposed differences with non-medical accelerators include different testing frequencies for safety systems, accommodation for non-isocentric designs, and requirements for independent radiation monitors. These are discussed in greater detail in later sections of this discussion paper.

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

Reasoning: When the C2NFPER were originally conceived, Class II prescribed equipment was typically operated only within shielded structures. However, the growth in the use of accelerators over the past several years (especially in the industrial sector) has resulted in innovations that see accelerators being operated outside shielded facilities, in a mobile or portable configuration.4 The current C2NFPER do not include definitions for mobile or portable Class II prescribed equipment, nor do they include the regulatory requirements necessary to regulate these types of equipment. While mobile and portable prescribed equipment have been operating in Canada for several years, regulation of these types of equipment has been achieved largely through licence conditions created specifically for them. The proposed new regulatory definitions for mobile and portable prescribed equipment will allow the introduction of a set of specific requirements for these types of equipment in order to incorporate an equivalent level of safety to the safety systems currently required for fixed facilities. Providing the necessary distinction between fixed facilities and stand-alone mobile/portable prescribed equipment will allow for the prescription of specific and tailored requirements for the aforementioned activities and facilities (see section 4.2.3.1 for these proposed requirements). This subdivision will better target the requirements applicable to each situation and eliminate the need for exemptions to accommodate both categories under one set of regulations. This should serve to provide clarity and reduce confusion among applicants and licensees.

4.1.2 Facilities regulated under the C2NFPER

The current definition of a Class II facility does not include the components, systems, shielding, and so on that typically comprise a Class II facility, only the Class II prescribed equipment.

[4] For the purposes of the C2NFPER, a mobile accelerator is one that is typically moved using a truck or other machinery, while a portable accelerator is one that can be moved by the operator without the assistance of machinery.

4.1.2.1 Proposed change: 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.

Reasoning: The current definition of a Class II facility ("a facility that includes Class II prescribed equipment") does not include the fact that the purpose of the facility walls, ceiling, and so on is to shield those outside the facility from irradiation. Moreover, such facilities contain not only Class II prescribed equipment, but also other directly related systems and components that should be included as part of the regulated envelope (e.g., safety-related systems such as entrance interlocks and emergency power-off devices). Given that such sub-systems and components are already being implemented by current licensees and that their operation is verified during CNSC compliance verification activities, adopting the proposed definition of a Class II facility will serve to align the C2NFPER with current practices. Doing so (concurrent with adopting the proposed addition of definitions for mobile/portable accelerators) will also allow for proper segregation between Class II prescribed equipment that is operated inside a shielded facility and equipment that is not.

4.2 Licensing of Class II facilities and prescribed equipment

This section describes the changes being proposed to those parts of the C2NFPER that pertain to the information that must be submitted as part of an application for a licence to construct, operate, service or decommission Class II facilities or prescribed equipment. Proposed changes to exemptions from licensing, as well as a new approach for licensing unique, one-of-a-kind facilities, are also discussed.

Details of the proposed changes and the reasoning for each are presented below.

4.2.1 Two-stream approach to licensing

For the purposes of this discussion paper, the CNSC defines a "standard" facility as one that typically incorporates mass-produced and established equipment designs, while a "non-standard" facility would be one that does not meet that definition (i.e., unique facilities that are only constructed once).

4.2.1.1 Proposed change: Design the C2NFPER in such a way that standard facilities would continue to follow the approach used throughout the current regulations. Non-standard facilities, however, would follow an approach similar to that currently used for Class I facilities, where broad, high-level safety and security requirements are in place and a licence conditions handbook (which describes in detail how the licensee will conduct its operations in a safe and secure manner) is developed and incorporated into the licensing basis. Furthermore, it is proposed that equipment licensed under the non-standard stream would be exempt from certification (see section 4.3.1.2 for details).

Reasoning: The prescriptive nature of the requirements included throughout the current C2NFPER, which are intended mostly for established, mass-produced designs, may not be best suited for all facilities if the proposal to regulate all particle accelerators under the Class II umbrella (as described in section 4.1.1.1 of this paper) is accepted. The advantage of such an approach is to allow for novel or innovative designs to be incorporated into Class II facilities where prescriptive regulations may not be applicable or may lead to unnecessary burden, while still providing sufficient regulatory oversight.

Other regulatory texts have incorporated such two-stream approaches with success.[5]

4.2.2 Construction licences

Several changes are being proposed to section 3 of the current C2NFPER, which deals with the information to be provided in support of an application to construct a Class II facility. Changes being proposed include ensuring that safety and security are "designed in" to the facility during construction, aligning the way radiological workload is calculated/reported with existing practices, and other changes resulting from lessons learned from operational experience gained in licensing the construction of Class II facilities since the last regulatory review.

It should be noted that the requirements in section 3 pertain only to Class II facilities and not to Class II prescribed equipment operated outside a shielded facility since, in such a case, there is no facility to construct.

In addition to the specific proposed changes outlined below, it is also proposed that section 3 be re-organized or re-ordered so as to group related items where possible. It is hoped this will make the C2NFPER easier for stakeholders to use and implement.

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

Reasoning: The radiological workload (a measure of the total radiation used by a nuclear facility over a period of time, usually 1 year) is one of the vital parameters that must be examined when ensuring that the facility's shielding is adequate to protect those outside the facility from unintended irradiation. Although the C2NFPER currently require this only for teletherapy machines,[6] this information is in fact needed for all Class II facilities, and indeed, this information is currently being submitted for all construction licence applications. Making this change would align the C2NFPER with current practices.

4.2.2.2 Proposed change: 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).

Reasoning: For the evaluation of the facility's proposed shielding, it is not necessary to know the specific proposed uses of the Class II prescribed equipment, only the total annual usage/workload. Operational experience has shown that CNSC staff do not use this information when evaluating construction licences, meaning that requiring licence applicants to estimate the breakdown of workload into these specific use cases is an unnecessary regulatory burden. In fact, the most recent edition of REGDOC-1.4.1 requests only the total workload for construction licence applications, and while it reminds applicants to take into account workload from all

[5] One example is the *Safe Food for Canadians Regulations* (SOR/2018-108), wherein specific requirements are prescribed for certain food categories and generic requirements apply to foods that do not fall within those specific categories. Another example is the proposed *Clean Fuel Standard*, which will separate various categories of fuels into distinct classes, each of which having slightly different regulatory requirements.

[6] In the current C2NFPER, a teletherapy machine is defined as "a device that is designed to deliver controlled doses of radiation in a collimated beam for therapeutic purposes."

specific uses, it does not ask that the applicant break workload down into those categories. Making this change would serve to align the C2NFPER with current practices.

4.2.2.3 Proposed change: Remove the current requirement to provide the proposed responsibilities of and training program for workers during the operation of the facility.

Reasoning: Construction licence applications are generally received from applicants early in the facility's lifetime, while planning for construction is still occurring. At this point in time, the exact make and model of the prescribed equipment that will eventually be used may not yet be known. Because of this it is difficult, or sometimes impossible, for applicants to provide a description of the responsibilities and training program during eventual operation of the facility. In addition, there is a duplicate requirement for this information under paragraph 4(s) of the current C2NFPER, which specifies the information to be provided in support of a licence to operate. As this requirement already exists, and it is more logical to provide it when the applicant will actually have the information, the proposal is to remove this requirement when applying for a construction licence, and only seek the information prior to issuing an operating licence.

4.2.2.4 Proposed change: Clarify that a description must be provided of all safety systems that are required under section 15 of the C2NFPER.

Reasoning: Section 15 of the C2NFPER prescribes the radiation protection safety systems that must be incorporated into all Class II facilities. In order to ensure that the facility will comply with section 15, the CNSC must verify that all of these safety systems will be incorporated into the facility at the time that it is built. Currently, paragraph 3(d) of the C2NFPER requires a description of measures to control access and of other safety-related features, which is vague and bears no connection to the systems prescribed by section 15. Making this change would remove ambiguity for licence applicants, and would not result in increased regulatory burden since this information is already requested for construction licence applications in REGDOC-1.4.1.[7]

4.2.2.5 Proposed change: Add a requirement for panoramic, wet source storage gamma irradiators (pool-type irradiators) to adhere to ANSI standard N43.10[8] in the design of these types of facilities.

Reasoning: This requirement already exists as a licence condition that is currently attached to all pool-type irradiator licences issued in Canada. The proposal is simply to move this requirement from the licence condition to the C2NFPER. Implementation of this change would not result in extra regulatory burden for licensees and could negate the need for the current licence condition. All existing facilities of this type are already compliant with this standard.

[7] Note that in REGDOC-1.4.1, section 15 of the C2NFPER is referenced as the source of the regulatory requirements for providing this information. Since this information should be provided prior to construction to ensure that safety is built in to the design, the requirement should be in section 3, which lays out the information to be submitted in support of a licence to construct a Class II facility.

[8] ANSI N43.10, *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*.

4.2.2.6 Proposed change: 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.

Reasoning: The disposal method of Class II prescribed equipment is required in order to allow for "cradle-to-grave" tracking. The main intent of this change is to ensure that nuclear substances that are/were contained in Class II prescribed equipment are disposed of in a safe and secure manner, or transferred to an entity who is authorized to possess such material (in accordance with IAEA Safety Standard SSR-5, *Disposal of Radioactive Waste*). If this is not done, nuclear substances could end up in an uncontrolled situation, such as being disposed of in regular trash, or possibly used for unlawful purposes. Components or materials (e.g., shielding) that may have become activated by the Class II prescribed equipment should also be properly disposed of in order to protect the environment and any members of the public who may come into contact with such components or material following disposal.

While the main intent of the change is the control and security of nuclear substances, it is also important to ensure that other Class II prescribed equipment does not end up in a situation where it may be operated by unlicensed entities, creating a safety hazard for workers and the public as proper shielding, safety systems, and so on may not be in place. Because of this, the disposal method is required for all Class II prescribed equipment, including that which is currently exempt from requiring a decommissioning licence (for example, brachytherapy afterloaders).

4.2.3 Operation licences

Several changes are being proposed to section 4 of the current C2NFPER, which deals with the information to be provided in support of an application to operate a Class II facility. Changes being proposed include the addition of Class II–specific licensing requirements for prescribed equipment being operated outside a shielded facility, aligning the way radiological workload is calculated/reported with existing practices, and adding requirements for the methods/frequencies of testing safety systems.

Changes being proposed are mostly a result of lessons learned from operational experience gained in licensing the operation of Class II facilities and prescribed equipment since the last regulatory review, and are also intended to accommodate new technologies that have appeared during this same period.

In addition to the specific proposed changes outlined below, it is also proposed that section 4 be re-organized or re-ordered so as to group related items where possible. It is hoped this will make the C2NFPER easier for stakeholders to use and implement – for example, those operating mobile/portable prescribed equipment, whose requirements are very different from those operating in a shielded facility.

4.2.3.1 Proposed change: 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. Some proposed examples of information to be required include:

- a description of how the applicant will prevent entry to the area where the prescribed equipment is being operated
- a description of the warning signage and the policy for posting it
- copies of operating/emergency procedures when using the Class II prescribed equipment
- description of any irradiation state indicators, and policies for their use
- description of the policy for use of calibrated, alarming dosimeters

- description of any proposed weekly or per-shift radiation dose limits to be imposed, and the policy for verifying these doses

Note that this proposed list should not be considered exhaustive and that items may be added or removed following consultation.

Reasoning: As previously described in section 4.1.1.3 of this paper, the proposal is to add definitions for mobile and portable prescribed equipment. If that proposal is accepted, licensing requirements for these types of equipment will need to be added to the C2NFPER. Currently, the only licensing requirements that may be applied to mobile/portable Class II prescribed equipment are those specified in section 3 of the *General Nuclear Safety and Control Regulations* (which pertain to all licences issued by the CNSC), while items specific to Class II prescribed equipment are regulated through the use of licence conditions that are attached to licences for these types of equipment.

Amending the C2NFPER to include licensing requirements for mobile/portable prescribed equipment will result in a path towards licensing that is more clearly defined for stakeholders. Given the existing requirements of the GNSCR and the aforementioned licence conditions, it is not expected that making this change will result in additional regulatory burden for licensees.

4.2.3.2 Proposed change: 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.

Reasoning: The reasoning for requiring radiological workload for all facilities (not just those housing a teletherapy machine) was previously discussed in section 4.2.2.1 of this discussion paper and will not be repeated here.

The current C2NFPER specify that workload must be tracked on a weekly basis, and that the only acceptable unit for measuring and reporting workload is grays, measured at a distance of 1 m. In actuality, workload is typically logged in real time as the equipment is operating, or immediately following operation, and reported to the CNSC annually (or on request from an inspector).

Logical or meaningful units for measuring/tracking workload vary among equipment types (e.g., total annual production in becquerels for isotope production and processing facilities), so the proposal is to remove the specific requirement to record workload in grays. This is already the case for many types of existing Class II facilities, so making this change would align the C2NFPER with existing practices and would not result in extra regulatory burden for licensees.

4.2.3.3 Proposed change: 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.

Reasoning: The C2NFPER currently specify the safety systems that must be installed in a Class II facility. However, there is no regulatory requirement stipulating that they must be tested periodically in order to confirm that they are functioning as expected. Systems such as emergency stop devices, or search buttons that force users to verify that the facility is clear prior to irradiation, are essential in ensuring the safety of workers (and in the case of medical applications, the public). Therefore, demonstrating ongoing functionality on a regular basis is critical to ensuring safety.

It should be noted that although there is currently no regulatory requirement to perform these tests, most licensees are already doing so in accordance with accepted industry best practices[9] since it is an obvious safety best practice. In addition, CNSC inspection criteria include the requirement to verify testing of installed safety systems. The regulatory instrument currently being applied to ensure performance of this testing is paragraph 12(1)(c) of the *General Nuclear Safety and Control Regulations*, a non-specific regulation that essentially states that all licensees must carry out all licensed activities in a safe manner. However, operational experience gained over the past 20 years has shown that failing to perform testing of safety systems is one of the most common non-compliances found during inspections of Class II licensees. It is hoped that adding a specific and transparent regulatory requirement for this testing will decrease instances of failing to test required safety systems.

The argument for requiring frequent testing of security systems closely follows that given above for safety systems. Currently, all licensees who may possess nuclear substances have a condition attached to their licence that states they must follow the requirements of REGDOC-2.12.3, *Security of Nuclear Substances*, which includes requirements for testing installed security systems. Therefore, there will be no additional regulatory burden placed on licensees as a result of making this change.

4.2.3.4 Proposed change: 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.

Reasoning: Technical reasoning for this proposal is identical to that presented in section 4.2.2.6 of this discussion paper and will not be repeated here.

While it may seem like a duplication of requirements to request this information during the construction phase and again for an operating licence application, this is necessary as the information regarding final disposition of the Class II prescribed equipment may have changed since the facility was constructed (and plans may continue to evolve throughout the life of the facility as conditions change). Furthermore, it is proposed that this information be required for mobile/portable Class II prescribed equipment, which does not require a construction licence, meaning the application for an operating licence would be the only opportunity to obtain this information.

4.2.4 Decommissioning licences

A small number of changes are being proposed to section 5 of the current C2NFPER, which deals with the information to be provided in support of an application to decommission a Class II facility. Proposed changes include adding a requirement that decommissioning activities be carried out or supervised by persons holding a licence to service Class II prescribed equipment.

Changes being proposed are mostly a result of lessons learned from operational experience gained in licensing the decommissioning of Class II facilities since the last regulatory review.

[9] The Canadian Partnership for Quality Radiotherapy is a radiotherapy industry group that has developed a set of standards, in partnership with the CNSC, that define recommended safety system tests and the recommended frequency at which they should be performed. This is widely accepted by the industry and used as the *de facto* acceptable standard in the absence of CNSC regulatory requirements.

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

Reasoning: In order to decommission a facility, it is necessary to dismantle the facility in part or in whole. According to the definitions in the current C2NFPER, "servicing" explicitly includes "dismantling" (no change is being proposed to this definition as a result of this regulatory review).

Note that it has not yet been decided if this change would be reflected in the C2NFPER themselves or in an associated regulatory document instead. It is mentioned here for the sake of completeness.

4.2.5 Servicing licences

A small number of changes are being proposed to section 7 of the current C2NFPER, which deals with the information to be provided in support of an application for a licence to service Class II prescribed equipment.

Changes being proposed are mostly a result of lessons learned from operational experience gained in licensing the servicing of Class II facilities and prescribed equipment since the last regulatory review.

4.2.5.1 Proposed change: 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).

Reasoning: The C2NFPER currently have no requirements for applicants to describe how they will ensure radiation safety during servicing operations. Applicants are instead required to submit their servicing procedures, which typically comprise several hundred pages of detailed instructions for such things as removing covers or replacing mechanical/electrical components, with a few pages of safety precautions interspersed throughout the document, some of which may pertain to radiation safety. Making this change will ensure that information that is actually relevant for ensuring radiation safety is submitted in support of an application to service Class II prescribed equipment. Since applicants will be required to explain how they will ensure radiation safety while performing servicing, it not necessary to require applicants to describe the actual steps of servicing the prescribed equipment. However, it is proposed that a table of contents of standard servicing procedures be requested; performance of servicing that is not covered by such standard procedures may require notification to and possibly prior approval from the CNSC.

As this is a replacement of one regulatory requirement with another, it is expected that there will be a net-zero effect on regulatory burden for licensees who perform servicing of Class II prescribed equipment.

4.2.6 Licence exemptions

A small number of changes are being proposed to sections 8 and 9 of the current C2NFPER, which deal with the activities that may be carried out without a CNSC licence in respect of Class II facilities or prescribed equipment. Proposed changes include removing the exemption from

licensing for geophysical well logging accelerators, and adding a licence exemption for the import and export of Class II prescribed equipment that does not contain a nuclear substance.

Changes being proposed are mostly a result of lessons learned from operational experience gained in the licensing of Class II facilities and prescribed equipment since the last regulatory review.

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

Reasoning: The CNSC currently issues operating licences for geophysical well logging accelerators that are operated underground within prospective oil wells for the purpose of detecting and characterizing hydrocarbon deposits. While this is the primary use of these types of equipment, they are in fact operated above ground on a regular basis for the purpose of calibrating detectors that are attached to the logging accelerators. Licensees who use the equipment for this purpose undergo compliance verification on a regular basis, and CNSC inspectors confirm that when the logging accelerators are operated above ground, it is done in a safe manner. However, there are no specific regulatory requirements for shielding design, safety interlocks and so on since these facilities are currently exempt from licensing. While operating, if left unshielded, a typical well logging accelerator will generate a nearly isotropic field of neutrons with a dose rate of approximately 150 mSv/hr at 1 m, representing a significant radiation risk. Because of this risk, licensing of these above-ground enclosures is necessary to ensure proper radiation protection measures are put in place.

While operation of geophysical well logging accelerators below ground is already licensed by the CNSC, the addition of requirements for operation in an above-ground facility may represent a small to moderate regulatory burden for a small number of licensees[10] in order to ensure that their existing, unlicensed enclosures meet the same regulatory requirements proposed for all Class II facilities.

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

Reasoning: The C2NFPER currently allow, without requiring a licence, the possession, transfer and production of Class II prescribed equipment that does not contain a nuclear substance. Given this, in conjunction with the fact that there is no radiological risk from this type of equipment when it does not have a supply of electricity to generate radiation, it is not unreasonable to also allow import and export of this type of equipment.

Equipment that is brought into the country without the knowledge of the CNSC represents approximately the same risk as equipment that is manufactured in Canada without the knowledge of the CNSC, an activity that is entirely legal as it is exempt under the current C2NFPER. In both cases, the equipment must be licensed by the CNSC before it can be operated.

Export of Class II prescribed equipment that does not contain a nuclear substance[11] represents no risk to Canada or to the rest of the world as it does not fall within the definitions of controlled

[10] At the time of writing, there were 7 licensees operating geophysical well logging accelerators in Canada.
[11] Note that this will include depleted uranium that is used for shielding, and any activated components that may be present within the prescribed equipment.

nuclear substances or equipment, as defined by the *Nuclear Non-proliferation Import and Export Control Regulations*.

4.3 Certification of Class II prescribed equipment

This section describes the changes being proposed to those parts of the C2NFPER that pertain to the certification of Class II prescribed equipment. Proposed changes to the current exemptions from certification, as well as the information that must be submitted in support of an application for a certificate, will be discussed.

Details of the proposed changes and the reasoning for each are presented below.

4.3.1 Exemptions from certification

Certification of Class II prescribed equipment builds efficiency into the CNSC licensing regime by allowing for a one-time safety assessment of the design of mass-produced equipment so that it does not need to be performed each time an applicant wishes to licence the use of the equipment in Canada. Under section 10 of the current C2NFPER, all Class II prescribed equipment used in Canada must be certified unless it is used for development purposes or for scientific research that is not conducted on humans.

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

Reasoning: The original intent of this clause was to exempt from certification unique research facilities (i.e., those that are only constructed once). However, Class II prescribed equipment that will be used solely for research purposes may still be mass-produced and sold commercially. Given that such equipment presents the same radiological risks as any other Class II prescribed equipment, exempting it solely based on the fact that it is used for research does not meet the intent of the original regulation.

With regard to unique research facilities, it is proposed that these would continue to be exempt from certification, as described in section 4.3.1.2 of this discussion paper.

Note that if this proposed change is accepted, it is further proposed that non-unique, uncertified research equipment currently appearing on a CNSC licence continue to be licensed under a clause added to the C2NFPER to accommodate these licensees for the lifetime of the equipment.

4.3.1.2 Proposed change: Add an exemption 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).

Reasoning: As mentioned above, one of the objectives of Class II prescribed equipment certification is to build efficiency into the licensing system so that safety analysis of the equipment need not be performed each time the equipment is licensed. If the equipment/facility will only be constructed once, there is no value added in certifying the equipment. The safety analysis that would have been done as part of certification will instead be performed as part of the licensing process; therefore, safety will still be assured.

If the proposed change to adopt a two-streamed approach to licensing (see section 4.2.1 of this discussion paper) is accepted, it is expected that most unique equipment/facilities that are only constructed once would be licensed under the non-standard stream, and would therefore not require certification.

4.3.2 Information to be submitted in support of an application for a Class II prescribed equipment certificate

Several changes are being proposed to section 11 of the current C2NFPER, which deals with the information to be provided in support of an application to certify Class II prescribed equipment. Proposed changes include ensuring that security features are taken into account when designing and developing Class II prescribed equipment, and adding a requirement to provide a description of the proposed safety interlock system that will prevent/halt unintended irradiation.

Changes being proposed are mostly a result of lessons learned from operational experience gained in certification of Class II prescribed equipment since the last regulatory review.

In addition to the specific proposed changes outlined below, it is also proposed that section 11 be re-organized or re-ordered so as to group related items where possible. It is hoped this will make the C2NFPER easier for stakeholders to use and implement.

4.3.2.1 Proposed change: Add a requirement to provide the proposed method for securing Class II prescribed equipment that contains a nuclear substance.

Reasoning: REGDOC-2.12.3, *Security of Nuclear Substances*, requires that Class II prescribed equipment be secured when not under direct supervision of the licensee. End users of the prescribed equipment, especially mobile/portable equipment, sometimes struggle to meet these security expectations due to the fact that the equipment design failed to incorporate strong and secure fixation points to which a chain, for example, could be attached. Operational experience gained during compliance verification activities has shown that although the licensee may have constructed a strongpoint in its facility to which the equipment can be secured, there is often no corresponding strongpoint on the equipment itself, thus largely negating the effect of any such security measure. End users therefore often need to incorporate overly complex solutions in order to properly secure their prescribed equipment. Adopting this proposed change will ensure that the manufacturer considers securing the prescribed equipment at the design stage.

4.3.2.2 Proposed change: Add a requirement to provide a description of the proposed safety interlock system that will prevent/halt unintended irradiation.

Reasoning: The radiation protection safety systems required under section 15 of the current C2NFPER are vital to ensuring the safety of workers and of the public who may be in the vicinity of the Class II facility. All of these facility-based systems are connected to the safety interlocks that are built into the Class II prescribed equipment itself, and it is these interlocks that will actually halt or prevent irradiation when one of the required safety system devices is activated within the facility. Understanding the operation of these interlocks and ensuring that they will always “fail safe” is vital in ensuring that the equipment will in fact shut down in the event one of the required facility safety systems is activated. Therefore, it is proposed that this information be submitted in support of an application to certify Class II prescribed equipment.

4.4 Radiation protection requirements

Several changes are being proposed to section 15 of the current C2NFPER, which prescribes the radiation protection safety systems that must be incorporated into all Class II nuclear facilities. Proposed changes include the addition of requirements for safety precautions to be put in place when operating Class II prescribed equipment outside a shielded facility, the addition of a requirement to periodically test installed safety systems, and the addition of the ability to propose equivalent measures when installed safety systems fail.

Some of the proposed changes are a result of operational experience gained in licensing and inspecting various Class II facilities and prescribed equipment since the last regulatory review. However, the most significant change proposed for section 15 of the C2NFPER is to move towards a less prescriptive model in order to increase flexibility while still ensuring safety.

4.4.1 Shift towards a non-prescriptive approach

Section 15 of the current C2NFPER prescribes in great detail the radiation protection safety systems that must be incorporated into all Class II nuclear facilities. As mentioned earlier in this discussion paper, one of the overall goals of this regulatory review is to seek out ways of modernizing the regulations, and to make them more flexible while still ensuring safety. With this in mind, it is proposed that section 15 retain only high-level, outcome-based radiation protection safety system requirements, with details of how these requirements should be implemented contained in a CNSC regulatory document.

4.4.1.1 Proposed change: Replace the current prescriptive requirements with the following outcome-based requirements:

- An area must be defined wherein no persons (other than the patient in a medical facility) shall be present while the Class II prescribed equipment is operating (the "controlled area").
- Irradiation must be prevented until someone enters the defined area where the Class II prescribed equipment is located and ensures that the controlled area is clear of other people and that the equipment is safe to operate.
- Irradiation must be stopped automatically if someone enters the controlled area while the prescribed equipment is operating.
- 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.
- Radiation warning signage and emergency contact information must be posted at the entrance to the controlled area.

Reasoning: Given the wide range of equipment and facilities regulated under the C2NFPER (which will be expanded even further if other proposals in this discussion paper are accepted), the use of overly prescriptive regulations in the area of safety systems places inflexible restrictions on current licensees, and restricts the ability of the C2NFPER to adapt to new equipment and facility types that may be licensed in the future. The use of high-level, outcome-based regulations will allow for novel new approaches to ensure safety without placing specific restrictions on the designs.

To support this proposed change, a new regulatory document would be drafted concurrently with the draft regulations. The purpose of the regulatory document would be to provide guidance in the design of safety systems for various types of facilities, and would be amended from time to time as the need arose. In addition, given the non-prescriptive nature of the proposed requirements, they would also be applicable to mobile/portable Class II prescribed equipment and not just facilities, as is the case with the current section 15 of the C2NFPER.

4.4.2 Proposed changes based on operational experience

In addition to the restructuring proposed above, several other changes are proposed as a result of the knowledge gained in licensing and inspecting Class II facilities and prescribed equipment since the last regulatory review.

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

Reasoning: The current C2NFPER only contain provisions for safety systems or precautions to be implemented when Class II prescribed equipment is operated inside a shielded facility, with no such provisions for prescribed equipment operated outside such a facility. This gap is currently being filled through the use of licence conditions that are attached to all CNSC licences currently issued for mobile/portable equipment. Proposed changes to the C2NFPER would follow closely the content of these existing licence conditions (as described previously in section 4.2.3.1 of this discussion paper). As this proposed change is meant to replace existing licence conditions, it is expected that there will be no new regulatory burden on existing licensees.

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

Reasoning: The current C2NFPER state that all Class II facilities must be equipped with the safety systems prescribed by section 15. In the event of a failure of one of the safety systems, there is currently no provision allowing the facility to continue to operate if alternative means are used to temporarily replace the role played by the failed system. If the letter of the law were to be followed, it would result in the licensee shutting down all operations until the safety system could be repaired or replaced, even though reasonable alternatives that still ensure safety may be available. In practice, when such an instance occurs there is usually a conversation between the licensee and the CNSC licensing officer to determine acceptable alternatives. For example, having a radiotherapist actively monitor the entrance to a treatment room when the bulb in a warning light fails is far more logical than shutting down all cancer treatments until the bulb is replaced.

Making this change would align the C2NFPER with existing practices, which allow for flexibility while still ensuring safety, and is not expected to add regulatory burden to existing licensees.

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

Reasoning: This proposed change is aligned with the changes previously proposed in sections 4.2.2.4 and 4.2.3.3 of this discussion paper. In those sections, the proposal is to have applicants submit descriptions of the proposed safety systems and their proposed methods and frequency of testing. This proposed change to section 15 is to add the requirement that licensees must test these safety systems on a regular basis to ensure that they continue to function as expected. As described in section 4.2.3.3, this is something that is already done by licensees and enforced (somewhat indirectly) through the application of section 12(1)(c) of the *General Nuclear Safety and Control Regulations*. As reasoning regarding the importance of periodically testing safety systems is already presented in that section, it will not be repeated here.

Since licensees are already performing this testing, the proposed change would align the C2NFPER with existing practice, and is not expected to increase regulatory burden on existing licensees.

4.4.2.4 Proposed change: 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.

Reasoning: Brachytherapy remote afterloaders that incorporate pure beta emitters as their only nuclear substances are now deprecated; no such equipment has been licensed in Canada since 2007, and there are no indications that this technology will be revived in coming years. Because of this, the proposal is to remove the exemption for this type of equipment. In the unlikely event that an application to licence such equipment is received, the proposal would be to treat it as any other brachytherapy afterloader. While the radiological risk from such equipment is extremely low, it still meets the definition of Class II prescribed equipment, and therefore, appropriate safety systems should be put in place.

With respect to geophysical logging accelerators, the case for ensuring the safety of such equipment was previously made in section 4.2.6.1 of this discussion paper. The same reasoning applies here, and so will not be repeated. Note that this type of equipment would be regulated as mobile/portable Class II prescribed equipment if the proposal to remove its exemption from regulation (see section 4.2.6.1 of this paper) is adopted.

4.4.2.5 Proposed change: Remove the requirement for a patient viewing system.

Reasoning: The CNSC's mandate includes protecting the Canadian public from man-made nuclear radiation, as well as the occupational health and safety of those who work with nuclear radiation. However, the health and safety of patients undergoing medical treatments, including those that involve radiation therapy, falls instead within the mandate of other oversight bodies. As a result, the requirement for viewing systems that allow radiation therapy professionals to view the patient during treatment is one that is outside the mandate of the CNSC. Given this fact, such a requirement should not appear in CNSC regulations.

Note that the proposed removal of this requirement from the C2NFPER is not meant to suggest that viewing systems should be removed from existing facilities, and should not be seen as a comment on their value with respect to patient safety.

4.5 Certification of Class II radiation safety officers

This section describes the changes being proposed to those parts of the C2NFPER that pertain to the certification of Class II radiation safety officers (RSOs). Proposed changes include the types of equipment, facilities and activities that will require a certified RSO, as well as the expiration and amendment of RSO certificates.

Details of the proposed changes and the reasoning for each are presented below.

4.5.1 Applicability

Section 15.01 of the C2NFPER currently requires a certified RSO for all Class II facilities and for the servicing of Class II prescribed equipment. RSOs certified by the CNSC are not currently required for licensees who operate Class II prescribed equipment outside a shielding facility (mobile/portable prescribed equipment). Section 15.12 also exempts from certification those who operate a Class II facility and who are certified/designated under subsection 9(2) of the *Class I Nuclear Facility Regulations*. It is proposed to expand the requirement for certified Class II RSOs to these activities.

4.5.1.1 Proposed change: 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. Specifically:

- change the current subsection 15.01(1) of the C2NFPER to include operators of Class II prescribed equipment (not just facilities)
- remove/repeal section 15.12

Reasoning: When the C2NFPER were amended in 2010 to include the requirement for certified Class II RSOs (or more specifically, when the amendment process began some time earlier), all existing Class II equipment was operated inside a shielded facility (with the exception of geophysical well logging accelerators, which are currently exempt from regulation but licensed nonetheless), and therefore the sections of the C2NFPER that dealt with RSO certification were written to pertain to Class II facilities. Now that mobile/portable prescribed equipment has been in use for several years, it is known that the radiological risk from operation of such equipment is at least equivalent to the risk from operating in a shielded facility, and possibly greater given the dynamic nature of the area(s) that may be irradiated during operation. Because of this, safe operation of this type of equipment requires at least the same oversight as that required for a facility.

With respect to repealing section 15.12 (the exemption for a certified Class II RSO when a Class II facility is operated by a person designated/certified under subsection 9(2) of the *Class I Nuclear Facility Regulations*), without explicitly evaluating the qualifications of such individuals it is difficult to ensure that they have the necessary knowledge and competency to oversee the operation of Class II prescribed equipment and facilities. Rather than holding the default position in the C2NFPER that such persons be exempted from RSO certification, it should instead be incumbent on the licensee to explicitly demonstrate that the certification under subsection 9(2) of the *Class I Nuclear Facility Regulations* ensures equivalent knowledge and competency regarding the safety and security requirements for Class II facilities, and that exemption is therefore warranted.

4.5.2 Certificates

Currently, RSO certificates issued by the CNSC are valid for the period during which the person is employed by the licensee as an RSO. Certificates do not expire, and there is no requirement for recertification once a certificate is issued. There is also currently no provision within the C2NFPER that allows for an RSO certificate to be amended, for any reason.

4.5.2.1 Proposed change: 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.

Reasoning: The intent behind this change is to ensure that individuals who are certified as Class II RSOs continue to have the required and current knowledge to ensure safety while carrying out the licensed activity. RSOs must perform many duties in the course of their work, such as developing and updating procedures and policies related to radiation safety and training, identifying and correcting radiation safety concerns, and ensuring compliance with CNSC regulatory requirements. As all of these duties are of a dynamic nature, it is necessary to ensure that RSOs continue to have the knowledge and competency required to carry them out. While this change may result in a small increase in regulatory burden, adding requirements for periodic

recertification will allow the CNSC to evaluate proficiency on an ongoing basis and to ensure that licensees continue to have competent oversight in the field of radiation safety.

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

Reasoning: The information contained in an RSO certificate includes the RSO's name, the address or location where the licensed activity is carried out, and the type(s) of equipment that the RSO has been certified to oversee. If any of this information changes (for example, the RSO changes their name, or the licensee removes a particular type of equipment), the certificate will contain inaccurate information. In such a case, the only current option is to obtain a new certificate, which represents a regulatory burden since the original certificate may, for example, be referenced by the licensee in other documents or submitted to another authority/group as proof of qualifications. Adopting the ability to amend existing certificates would greatly simplify the process for stakeholders and for the CNSC.

4.6 Records

This section describes the changes being proposed to section 21 of the current C2NFPER, which pertains to records that must be kept and retained in relation to the licensed activity. Proposed changes include removing the relationship between licence expiry and record retention periods, and reviewing the retention periods themselves for various types of records. Changes are also proposed in regard to records created as a result of servicing Class II prescribed equipment.

Details of the proposed changes and the reasoning for each are presented below.

4.6.1 Retention

Most records currently required by the C2NFPER must be retained for a certain period following the expiration of the licence. This represents a significant regulatory burden since some licences have long validity periods, and many others are renewed before expiry.

4.6.1.1 Proposed change: Remove the relationship between record retention period and licence expiry. Instead, it is proposed that:

- equipment-related records be retained for a certain period following the day on which that equipment was removed from the licence
- servicing records be retained for a certain period following the day on which the servicing was performed

Reasoning: Most holders of Class II licences tend to renew their licences before they expire, and so the original licence is revoked when the renewed licence is issued, rather than left to expire. In addition, for certain types of prescribed equipment (such as medical accelerators), the default licensing period is 10 years until expiry. Requiring that records be retained until some time after licence expiry is not reasonable if most licences never actually expire, or expire after such a long time that the records from the beginning of the licence period hold no value by its end.

This requirement also leads to confusion among licenses since there is no reasonable or easily identifiable licence expiry date in such situations, and in most cases, licensees simply seek permission from CNSC licensing officers on a case-by-case basis when seeking to dispose of old records. Using the date on which the equipment was removed from the licence, or the date on which servicing was performed, will result in less ambiguity for the licensee regarding retention

periods and will also remove the necessity to retain records for an unreasonably long time, thus reducing regulatory burden on the licensee.

4.6.2 Proposed changes in relation to records of servicing Class II prescribed equipment

Operational experience gained in performing compliance verification activities over the past several years has shown that records of servicing activities are sometimes not complete or not retained at all. This issue seems further exacerbated when Class II prescribed equipment operators contract external parties to perform servicing on the operator's behalf.

4.6.2.1 Proposed change: Ensure that records of servicing of Class II prescribed equipment are:

- kept and retained by the entity who performed the servicing
- provided by the entity who performed the servicing to the operator/owner of the prescribed equipment
- kept and retained by the prescribed equipment operator/owner

Reasoning: It is important for those who undertake servicing of Class II prescribed equipment to keep and retain records of the issue that caused the servicing to be performed, the steps taken to repair the issue, as well as the tests performed to ensure that the equipment is safe to use following servicing operations.

This information is necessary to ensure that equipment operators and service providers are practising due diligence and following regulatory requirements in the course of servicing work. Servicing records provide a history of the prescribed equipment and the associated systems for assuring the safety of users, and must be easily accessible by both the servicing provider and the equipment operator.

5. Conclusions

With the considerations for potential changes outlined in this document, the CNSC hopes to position the C2NFPER as a set of comprehensive regulations that will address multiple situations relating to Class II facilities and prescribed equipment. The regulations will also be modern and flexible, taking into account the fact that not all Class II prescribed equipment should be regulated using a single approach. Lastly, by streamlining where possible and addressing existing ambiguities, the CNSC hopes to simplify the licensing and certification process for stakeholders while still providing effective oversight.