| **#** | **Commentor** | **Section** | **Issue** | **Suggested Change** | **MAJOR** or**Clarification** | **Impact**  | **Disposition**  | **Action**  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL)  | General - Overview | Industry appreciates the opportunity to provide comments on this discussion paper for proposed amendments to the Class II Nuclear Facilities and Prescribed Equipment Regulations. The intent of this feedback is to provide early input for consideration during future revisions to the regulation. Where silent on a proposed change within the discussion paper, we are in agreeance with the general concept of the proposed change, but may have additional comments once the draft revisions are developed and provided for further public consultation.The feedback is broken in to Major and requests for Clarification comments. Of note, we are highlighting below several themes which are of particular importance and supported by the comments identified as Major:1. **Recognition of Class I Licensees existing radiation protection requirements and licensed activities:**
	* Where Class II facilities are located within Class I facilities, Class I facilities may already have equivalent safety systems, radiation programs, and other relevant programs protecting workers. The regulations do not recognize these radiation protection requirements and programs already existing for Class I nuclear facilities.
2. **Implementation of a two-stream approach to licensing:**
	* Recognizing the desire to modernize the regulations to allow for novel and innovative designs, there is concerns the shift to a two-stream approach may inadvertently complicate the process for existing licensees; for example:
		1. Classification as “standard” versus “non-standard” as it relates to equipment and/or facilities may not be as simple as described and will require very careful consideration when developing the criteria for these classifications.
3. **Duplication/redundancy of requirements from other regulations:**
	* An important element of modernizing regulations and introducing more flexibility is to eliminate, where possible, any duplicate requirements amongst regulations as well as ensuring the requirements are included in the appropriate regulation while implementation specifics remain in the supporting regulatory documents and standards referenced in the licence.
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|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | General | Class I facilities may already have equivalent safety systems, radiation programs protecting workers and/or may not need the same safety systems as a medical facility protecting a member of the public. The regulations do not recognize the radiation protection requirements and programs already existing for Class I nuclear facilities.  | Suggest adding clauses to allow Class I facilities to take credit for existing, well established and systematic radiation protection programs where risk of exposure to the Class II equipment is limited to Nuclear Energy Workers (NEWs) and not members of the public. | MAJOR | Opportunity for additional flexibility - many licensees have comprehensive and robust ¬competency and training programs as part of their Class 1 licence that are also used for Class II competency and training of staff.  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | Sec. 1, paragraph 5 | Given the Discussion Paper covers “regulation of all particle accelerators (including high-energy accelerators currently regulated as Class IB facilities) under the Class II regime”, there should be mention here (as an additional bullet) or in a suitable place soon after, that the Class I Nuclear Facilities regulations will also be affected. | Future discussion papers or revisions to this discussion paper should recognize the impacts to other regulations, e.g., add a bullet below the 5th paragraph in Section 1 mentioning Class I Nuclear Facilities Regulations.  | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.1.1.1 | To date, CNSC has proposed a lower limit of 1 MeV on accelerators. This suggests the 1 MeV limit is no longer applicable. However, the text is focused on the need to remove the upper limit. | CNSC should confirm if the 1 MeV limit is also being removed. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | Sec. 4.1.1.1, 3rd full paragraph on Page 5 | The statement, “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 to the public and the environment”, should not be a criterion to decide the move of facilities currently regulated as Class IB facilities. Members of the public who are well enough versed in nuclear energy will have no objection either way; those who are not will object to anything that is nuclear. The next sentence is appropriate as justification. | Future discussion papers or revisions to this discussion paper should remove the inference this is a criterion, e.g., remove - ~~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 to the public and the environment.~~ | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | Sec 4.1.1.1, last full paragraph on Page 5 | The use of “harmonized” in place of “reduced in complexity” and “simplified” would align with the final statement noting “commensurate with risks”. | Considering revising in future discussion papers or revisions to this discussion paper:Given that accelerators operating at any energy do not present these complexities, it is reasonable that the licensing regime for accelerators be harmonized ~~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~~ single 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~~ harmonized, it will still be commensurate with the risks involved in constructing, operating and decommissioning these types of facilities. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.1.1.1, paragraph 3 | The reasons for revising the regulations to include all particle accelerators is equally valid for other facilities currently defined as Class IB nuclear facilities. | The revision should consider including all equipment/facilities where the stated reasoning applies.  | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.1.1.1, paragraph 3 | In describing the risks of accelerators, should consider accelerators that contain large amounts of nuclear substances as targets or products (with activity greater than 1015 Bq per year). These targets or products may present a larger risk to the public than the accelerators themselves. This definitional problem already exists in the current regulations where certain facilities that merely contain a piece of Class II prescribed equipment can never be defined as Class IB nuclear facilities. Regulatory uncertainty - problem with the definition may arise where a nuclear facility may fit under both: the definition of a Class I nuclear facility and a Class II nuclear facility simultaneously. | NSCA and Impact Assessment (and their regulations) should align with 1015 Bq per year with a half-life greater than one year. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.1.1.3  | New regulatory requirements introduced for these new definitions should be clearly set out in the regulations to avoid unnecessary/excessive licence conditions. Conditions only described in a licence may introduce confusion with other sections of the regulation. Inclusion of requirements in licence conditions makes it difficult to identify scope of as well as prepare for inspections, e.g.; testing frequency of safety systems may not be specified in the licence. | Suggest a guideline to perform inspection (similar to one used for the NSRD inspections) should be prepared for the Class II portable/mobile prescribed equipment. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.1.1.3 | The definitions for ‘mobile and portable prescribed equipment’ do not need to be added since it could be assumed that any prescribed equipment could be ‘portable’. | Do not include definitions. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.1.2.1 | Currently, the Class II Nuclear Facilities and Prescribed Equipment Regulations (C2NFPER) state: “*Class II nuclear facility means a facility that includes Class II prescribed equipment.*”The proposed change is to “*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 equipmen*t”.**This proposed definition is too broad. For example, it would include compressed air and electrical power supply systems that should not reasonably be expected to be considered part of a Class II facility.Additionally, some components, systems and equipment are intentionally positioned outside of the Class II facility (e.g. irradiator indication lights and fixed area gamma monitors). This proposed definition would unnecessarily expand the current footprint of Class II facilities to include adjacent areas.As described in Discussion Paper DIS-22-01, the appropriate sub-systems and components are already being implemented by current licensees with the current definition of Class II nuclear facility. So, the proposed change does not provide additional safety benefit and will cause confusion. | Do not incorporate the proposed change to the definition of Class II nuclear facility. | MAJOR | The proposed change will cause significant confusion and unreasonably broaden the scope of Class II nuclear facilities with no additional benefit to safety. |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.1.2.1 | Statement: “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...” | This statement appears incorrect. Using the logic provided, a Class-IA facility does not include the ‘facility walls, ceiling and so on’. Under the current regulations, the definition of ‘nuclear facility’ clearly includes shielding and walls.Adding this ‘clarification’ would just add confusion regarding the definition of a Class I nuclear facility. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.2.1 & 4.3.1 | The distinction between “*standard*” and “*non-standard*” facilities is not clear. Specifically, it is unclear what the CNSC means by mass-produced and established equipment designs. For example:* There are only a few irradiators of a specific model in operation (not mass-produced), but they have been in operation for many years (established), will they now be required to renew their licence with a non-standard licence type following an approach similar to a Class I facility?
* Also, a facility uses a piece of prescribed equipment not used in other locations - this would be a “one-off” type of facility, however; the equipment itself is not unique or significantly different than other facilities. Will it require a non-standard licence?

Additionally, the discussion paper describes “*non-standard*” facilities as *“unique facilities that are only constructed once*”. It is unclear if the distinction between “standard” and “*non-standard*” is based on the equipment or the facility. For example:* Many facilities could use the same irradiator, but each have a unique facility design (i.e. irradiation room) only constructed once. Will it require a non-standard licence?
 | Clearly define “standard” facilities such that only truly non-standard facilities are excluded from the definition. The definition should be based on the equipment instead of the facility. Straightforward equipment designs (e.g. irradiator towers) should be considered standard even if they are not mass-produced.Non-standard should not include certified prescribed equipment; rather it should include unique atypical equipment that requires a non-standard approach to Class II licensing. Furthermore, this non-standard licensing approach could be managed with the issuance of a Licence Conditions Handbook to support the Class II licence.Existing certified prescribed equipment should be considered standard and licensed under the current Class II licensing framework.  | MAJOR | The proposed change will unnecessarily apply a Class I facility licensing approach to Class II licensees. This additional regulatory burden does not provide additional safety for Class II licensees.Moving a facility to a Class 1 style of licence is a significant undertaking for the site and is unwarranted when the equipment, although a one-off, is of a certified design. |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.2.2.1,4.2.2.2,4.2.3,4.2.3.2 | The term ‘radiological workload’ in the discussion paper is ambiguous; if eventually used in the regulations, a clear definition should be included in the regulations. According to the current definition for ‘radiological workload’, it must be measured in grays per week at 1 meter, this should be continued. | The use of the existing definition for ‘radiological workload’ (measured in grays per week at 1 meter) should be made clear in the revised regulations, and/or ‘radiological workload’ should be clearly defined for each potential circumstance.  | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.2.2.2 &4.2.3.2 | The proposed simplification recognizes the weekly workload may change with the time over the year. It will assist with tracking and improving safety performance. | Recommend the workload calculation method and frequency be proposed by the licensee and related specifically to the facility design, e.g.; if a Class I facility operation is only affecting Nuclear Energy Workers, the workload limitation should be removed as they are already covered by the existing radiation protection programs/dosimetry. Class I workers are not public domain – recognize industrial setting. While workload can be calculated for Class I workers as described; 1m is not always a meaningful distance for a Class I facility because physical shielding may already designed into our facilities. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.2.2.5 | The CNSC is proposing incorporation by reference of ANSI N43.10. Incorporation by reference of a third party (paid) source of information into a legal requirement may impede the public’s ability to access and understand the legal requirement.Furthermore, referencing third party standards in regulations is not a best practice as the intent of the referenced standards my change without notice or permission of the regulator. | The CNSC should not incorporate a reference to ANSI N43.10. References to standards should be limited to licence conditions and/or licence conditions handbooks. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.2.2.5 | Incorporation of a single standard (ANSI N43.10) is inconsistent with the fact the same organization (ANSI) published several equally applicable standards for prescribed equipment. | The CNSC should not incorporate an industry standard(s) (e.g., ANSI N43.10), but rather define applicable requirements. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.2.2.6 & 4.2.3.4 | The additional requirement to provide the proposed method of disposing of Class II prescribed equipment is not reasonable for a Licence to Construct (LTC). As described in Section 4.2.2.3, the applicant may not know the make and model of the prescribed equipment when applying for a licence to construct. So, the proposed method to dispose of the prescribed equipment may be unknown. The preliminary decommissioning plan can be updated to provide updated information when the application for Licence to Operate (LTO) is submitted (see Section 4.2.3.4).Furthermore, the requirement should be limited to submission of preliminary decommissioning plans and high level requirements. The timeframe from construction to decommissioning may be decades; technical improvements over this time will offer more effective alternatives to those available at the time of application for licence to construct. | Do not require the proposed method of disposing of Class II Prescribed Equipment in the LTC.Description of decommissioning activities for LTC and LTO applications should be limited to preliminary decommissioning plans. | MAJOR | This requirement is duplicated for LTC and LTO, and could create confusion during the LTC application process, and may be difficult to complete when the required information may not be known during the LTC phase.Inclusion of detailed decommissioning plans with the application for licence to construct is an unnecessary administrative burden given decommissioning techniques will advance over time. |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.2.3.1 | Several bullets listed are duplicate requirements of other regulations:* Warning signage is specified in the *Radiation Protection Regulations,* Section 21, and *Nuclear Substances and Radiation Devices Regulations*, Section 23.
* Weekly or per-shift radiation dose limits are redundant due to the requirement to propose action levels in the General Nuclear Safety and Control Regulations, Paragraph 3(1)(f). Action levels trigger reporting on exceedances of expected levels of radiation.
 | Exclude requirements already included in other regulations.  | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.2.3.1 | Information submitted as part of a licence application becomes part of the licence basis. It is unclear why submission of policy documentation is required? | Consideration should be given to the amount of information required as part of the application. | MAJOR | Including additional policies as part of the application increases regulatory burden, with no added benefit to safety. |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.2.3.3,4.4.2.3 | ‘Safety systems’ are not defined in the regulations and similar requirements are not imposed to Class I nuclear facilities. Testing methods and frequenciers should be based on the defined reliability of components; acknowledging they may differ for different systems and implementations.In addition to requesting clarity on the definition of ‘safety systems’, it is noted a similar requirement to test is not found in the *Class I Nuclear Facilities Regulations*. | Define “safety systems”.Requirements for testing should remain general similar to the *Radiation Protection Regulations*, Section 25. Consideration should be given to other methods and frequencies to improve flexibility, including:- testing safety systems prior to any single use, therefore, no frequency is predefined for equipment not operated daily, -manufacturer’s handbook suggestions should be accepted methodology and frequency. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.2.3.3 | The inclusion of “*installed security system*s” in this proposed change is redundant since Class II licences require compliance with REGDOC 2.12.3, “*Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material, Version 2*”. Licensees have already demonstrated how they comply with REGDOC 2.12.3 and have CNSC acceptance. This may be confused as an additional regulatory requirement.For example, Class II facilities located within Class I facilities may credit the Class I security systems. This has been accepted by the CNSC, but this change to the C2NFPER may be interpreted as a new requirement to have security systems specific to the Class II facility. | Do not include “installed security systems” in the scope of this change as these are covered in RegDoc-2.12.3. | MAJOR | Although this is intended to be a redundant addition, it may be interpreted as a new regulatory requirement. |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.2.4.1CE: Combine 38-40 | The C2NFPER definition of “*servicing*” applies to Class II prescribed equipment. The proposed change refers to “the facility in part or in whole”. This broadens the scope of servicing and creates additional regulatory burden by unnecessarily requiring a servicing licence.Dismantling a facility involves a number of steps. Many of the steps are not related to radiation equipment. Once the Class II equipment (isotopes, accelerators, etc) has been removed, the dangers associated with the equipment are no longer present and the remainder of the Class II facility may be dismantled as with any other, non-licensed facility. The need for dismantling by persons with a valid CNSC servicing licence should only be applicable while the prescribed equipment is present, and only in relation to the Class II facility (while the prescribed equipment is present).  | Do not expand the scope of “servicing” beyond the definition of C2NFPER. Keep the current scope to servicing of Class II Prescribed Equipment rather than other parts of the facility. | MAJOR | Requiring persons who have a CNSC service licence to dismantle the facility does not provide any additional safety benefit once the Class II prescribed equipment and its associated risks have been removed. |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.2.6.2 | The C2NFPER definition of Class II prescribed equipment should be interpreted to mean that it is an irradiator or teletherapy machine specified in C2NFPER that contains a radioactive source. Equipment that does not contain a source should not be considered prescribed equipment. This would be similar to the Nuclear Substances and Radiation Devices Regulations definition of radiation devices, which are also certified by the CNSC. This would eliminate the need to add this exemption in Section 4.2.6.2. | Change “use” to “contain” in the C2NFPER definition of Class II Prescribed Equipment instead of adding this exemption. | MAJOR | Changing “use” to “contain” will greatly simplify the Class II Prescribed Equipment regulation and will eliminate the need to add this exemption in Section 4.2.6.2. |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.3.2 | The discussion paper is silent on the requirements and responsibilities regarding recertification of Class II equipment. | Clarify if recertification is required and if so is it similar to the requirements and responsibilities for the Nuclear Substances and Radiation Devices Regulation. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.3.2.2 | Clarify the details required for the description of the proposed safety interlock system. The devices that activate the interlock system may not be part of the Class II prescribed equipment. For example, the device that stops the Class II prescribed equipment when the facility door is opened may be unique to a facility and not described with detail in the application for Class II prescribed equipment certification. If certificates include specific details about the facilities to describe safety interlock systems, instead of only the Class II prescribed equipment, the certificates will be not be applicable to multiple facilities. This will create additional regulatory burden and expand the scope of the certificates beyond Class II prescribed equipment. | Clarify if the application for Class II prescribed equipment will be required to include a description of the safety interlock system of the Class II prescribed equipment. Devices that satisfy the radiation protection safety systems required under C2NFPER s15 will be connected to this interlock system, but may be unique to each facility and should not be included in the application.  | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.3.2.2 | It is not clear if interlocks are required only for Class II nuclear facilities or for any Class II prescribed equipment, even those operated outside a facility. | Acknowledge in the text that the design of Class II prescribed equipment operated outside of a facility may not be able to incorporate interlocks. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.4.1.1 | “Determining whether radiation is present” does not account for background radiation or low-level radiation present in the facility when the Class II prescribed equipment is shut down. | Clarify that there must be a method for measuring radiation within the controlled area rather than “determining whether radiation is present”. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.4.1.1 | The definition of “controlled area” is not consistent with the definition found in REGDOC-3.6. Terminology amongst regulations should be consistent.  | Consider substituting ‘controlled area’ with a more appropriate term or description. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.4.2.1 | Many of the requirements found in section 15 cannot be applied to Class II prescribed equipment operated outside of a facility. | Specific requirements on prescribed equipment may be the only option regarding prescribed equipment operated outside of a facility, see requirements under *Nuclear Substances and Radiation Devices Regulations*, section 30. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.4.2.2 | Proposing alternative arrangements may not always be possible for existing facilities or may entail updates to a number of licensees’ documents, procedures, and processes to accommodate alternative arrangements. | The document should clarify the applicability of this proposed requirement to existing systems and the process for implementation should this requirement be included. Furthermore, clarification on how this would be implemented, i.e., proposed alternate equal/enhanced safe method would be described in procedures submitted with the licence application and then accepted by CNSC. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.5.1.1 | Currently, Senior Health Physicists who are responsible for the radiological safety at Class I facilities, and Class II facilities within those Class I facilities may be credited as Class II Radiation Safety Officers (RSO) as described in C2NFPER s15.12.The proposed change will remove s15.12 and require Senior Health Physicists to follow the Class II RSO certification process or request an exemption.There is significant redundancy in the certification process for Class II RSOs who have been certified as Senior Health Physicists.It is not clear if the exemption referenced in 4.5.1.1 is an exemption from the C2NFPER or if a new subsection would be added to s15 describing this exemption.There does not appear to a strong rationale for this change as it is not described as being aligned with current practices or based on operational experience. | Keep section 15.12 as currently written in C2NFPER.Or, amend section 15.12 to allow Class I licensees to demonstrate that Senior Health Physicists overseeing the radiological safety at the Class II facility have the equivalent knowledge and competency based on their Class I certification and the licensees training program for the Class II facility. In such a case, the Senior Health Physicist would be exempt from the additional Class II certification process and would be credited as the Class II RSO. | MAJOR | Currently, Class I licensees credit their Senior Health Physicists as Class II RSOs based on the exemption from certification described in C2NFPER s15.12. This is important to maintain defense-in-depth staffing such that the Class I licensees are not left without a Class II RSO if the Class II RSO named on the licence is no longer able to fulfill the role (e.g. leaves the role). The proposed change would require additional individuals to follow the Class II RSO certification process which is largely redundant and creates an additional regulatory burden. |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.5.1.1, | The suggested requirements for certified staff (RSOs) are inconsistent with the requirements for Class IB nuclear facilities. | The requirement for certified staff should remain as it is at present or be removed. | MAJOR | Additional regulatory burden. |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.5.2.1 | Currently, there is no recertification period for Class II RSOs. The proposed change would add a recertification period of an undefined frequency.Licensees should be responsible for ensuring their Class II RSOs continue to have the knowledge and competency required to perform their duties after initial certification. This is a general requirement of the General Nuclear and Safety Control Regulations. The CNSC currently provides oversight of licensee training programs through audits and inspections.There does not appear to a strong rationale for this change as it is not described as being aligned with current practices or based on operational experience. | Do not add the requirement for periodic recertification for Class II RSOs.Instead, credit the licensee’s continuing training program and evaluate effectiveness as part of the inspection process. | MAJOR | The addition of a periodic recertification process adds additional regulatory burden without evidence any benefit to safety. This could be better assessed as part of the inspection process. |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.6.1.1 | The discussion paper is silent on the requirements for retaining records. | The records retention period should not be longer than 5 years after equipment removal. The only exception being worker dose records. | Clarification |  |  |  |
|  | Bruce Power, Ontario Power Generation (OPG), Canadian Nuclear Laboratories (CNL),  | 4.6.2.1 | The discussion paper is silent on the distribution of responsibilities for keeping records.  | Further clarification needed on severance of responsibilities for keeping records. Confirm the compliance responsibility for records retention will be independent and remain with the respective licence holder; e.g., equipment operator responsible for keeping their records and service provider is responsible for their records. | Clarification |  |  |  |
|  | Ontario Tech University | 4.1.1.3 | It is reasonable to add definitions formobile and portable prescribedequipment. However, this may causeconcern for current Class II NuclearFacilities that have prescribed equipmentthat can be considered portable. Facilitieswith portable Class II prescribedequipment but are fixed inside a class IInuclear facility should not have to renewtheir license defined as portable. | Since many Class II prescribed equipmentcan be considered portable, the CNSC mustinclude in their definitions the intent of theClass II prescribed equipment (i.e., whetherits use is to be 1. portable and be movedoutside of a defined facility, or, 2.stationary and not leave a defined facility). |  |  |  |  |
|  | Ontario Tech University | 4.2.1.1 | The two-stream approach is reasonable asit will support novel research andinnovation that incorporate Class IIprescribed equipment. However, thecurrent delineation between "standard"and "non-standard" must be furtherclarified but not prescriptive. Reasonbeing: Non-standard facilities may wantthe ability to use CNSC certified massproduced and established equipmentdesigns but prefer a license conditionshandbook due to not being able to meetprescriptive requirements despite havinghigh-level safety and security that issatisfactory. Alternatively, some standardfacilities may want to use novel noncertified class II prescribed equipment in afacility with the current prescriptiverequirements to ensure safety. | The current the delineation between"standard" and "non-standard" needs toeither be:1. better defined, or2. not defined but left up to the discretionof the CNSC depending on the review ofthe application, or3. not defined but left up to the applicantto choose whether they would like thestandard or non-standard approach, or4. not defined but left up to the applicantto choose and at the discretion of theCNSC.Either #3 or #4 are preferred.In any case, it is imperative that the CNSCprovide applicants with a license guide fornon-standard Class II facilities. |  |  |  |  |
|  | Ontario Tech University | 4.2.2.6 | It is reasonable to add to the constructionlicense "a requirement that the proposedmethod of disposing of Class II prescribedequipment (and any activatedcomponents or materials) be providedwith the preliminary decommissioningplan." | Most applicants already know what class IIequipment will most likely be used at thistime. The alternative would be for theapplicant to find out after constructing thefacility that their license to operate isdenied due to an inadequatedecommission plan. This amendment willdecrease the risk of this happening. |  |  |  |  |
|  | Ontario Tech University | 4.2.3.1 | It is getting convoluted with the standardvs. non-standard, and mobile vs.stationary. | Consider just having standard vs. nonstandard and include mobile in the nonstandard stream path since manyprescribed requirements may not apply.Create a license guide for non-standardClass II facilities and include a section onmobile class II equipment OR create astandalone license guide for mobile class IIequipment. | Clarification |  |  |  |
|  | Ontario Tech University | 4.2.3.3 | The 4.2.3.3 Proposed change: "Requireapplicants to submit the proposedmethods and frequency for testing thesafety systems set out in section 15 of theC2NFPER, as well as any installed securitysystems" is reasonable. However, thesafety and security systems still need to bedefined. Additionally, this will beredundant if the current securityrequirements already are required(Nuclear Security Regulations and REGDOC2.12.3) | The CNSC needs to GENERALLY define thesafety and security systems requirementswithout being too prescriptive for theproposed change. E.g., The requirement isto notify a central response team upon analarm trigger. A facility may notify theresponse team through an alarm triggerthrough security dispatch's console, a textmessage to the responder's cell phone, andan email to security dispatch's centralemail address. The License Holder shouldnot be penalized if upon inspection it isfound that the email notification is notworking, but the other 2 responsemechanisms are working as intended.Last, it should be clear that the applicableNSR or REGDOC 2.12.3 requirements takesprecedence if it already applies to thefacility/equipment. |  |  |  |  |
|  | Ontario Tech University | 4.2.4.1 | It is unreasonable that thedecommissioning person/entity "in whole"requires a CNSC servicing license. Most ofthe class II facility was built bytradespersons, not radiation specialists.Most of a class II facility is not radiationrelated and does not require radiationspecialists. Requiring the decommissionperson/entity have a CNSC servicinglicense only guarantees the pool ofallowable persons/entities are decreasedand the cost burdens are increased. Thiswill not guarantee better quality service oradd any value to radiation protection. | Keep the servicing definition the same.This captures the class II prescribedequipment requiring dismantling as part ofdecommissioning. Alternatively, remove"in whole" and ensure the scope of theservicing license requirement is specific toclass II prescribed equipment only whilenon-radiation aspects of decommissioningcan be performed by non-licensed persons. |  |  |  |  |
|  | Ontario Tech University | 4.2.6.2 | Depleted uranium incorporated in anymaterial or substance and in which theconcentration of source material is greaterthan 0.05 weight % is still under the exportcontrol list. | Clarify whether the ECL still applies and ifso, if there are steps being taken withGlobal Affairs to remove depleted uraniumfrom the ECL. | Clarification |  |  |  |
|  | Ontario Tech University | 4.3.1.1and4.3.1.2 | The CNSC should be applauded for addingthis exemption. | As a research-intensive institution, this willprovide our researchers with moreinnovative and applied researchopportunities using particle acceleratorsand neutron generators. The CNSC shouldimplement this exemption. |  |  |  |  |
|  | Ontario Tech University | 4.4.2.1 | It is unclear how Class II prescribedequipment operated outside a shieldedfacility can follow the requirements ofsection 15. | Class II prescribed equipment operatedoutside a shielded facility should follow theproposed non-standard facility approach tolicensing instead of applying all of section15. The CNSC should be specific on whatthe requirements are with Class IIprescribed equipment operated outside ashielded facility. |  |  |  |  |
|  | Ontario Tech University | 4.5.1.1 | The change is reasonable. However,expectations for Class Icertified/designated RSOs with Class IIprescribed equipment must be clarified toensure there is no increase inadministrative burden for Class I RSOs ifthere is no added safety value. | Class I certified/designated RSOs shouldincorporate Class II RSO knowledge intothe Class I certification examination, ratherthan requiring the Class IIcertified/designated RSO having toundergo two certification processes (Class Iand Class II). |  |  |  |  |
|  | Ontario Tech University | 4.5.2.1 | The added administrative burden this maycause is worrisome. There must be agraded approach in order to allow theCNSC to evaluate proficiency and it isimplored that the CNSC consider aframework that is efficient and meaningfulin terms of adding safety value. The CNSCshould consider making use of existingframeworks with professionalassociations. | The scope for recertification and reexamination should be limited to thefollowing:\* Class II RSOs in which their Facilities haveadded new Class II equipment to thelicense but was not included in theirprevious certification.\* Class II RSOs in which their Facilities haveshown repeated poor inspection results.\* Class II RSOs that have not attended anyrelevant continuing education within alicense period.Further, Class II RSOs who have takenrelevant continuing education should beaccepted as proof of competency andproficiency. Continuing education can beperformed with professional associationssuch as the Health Physics Society,Canadian Radiation Protection Agency,Canadian Association of Medical RadiationTechnologists, etc.In lieu of continuing education: getting apeer-reviewed article published an in thefield of radiation protection/safety,publishing a book or chapter in radiationprotection/safety, obtaining adegree/diploma in radiation science shouldbe accepted.Last, Class II RSOs with a valid professionaldesignation that is related to radiationprotection and must be maintained(CRPA(R), CHP, RTNM, etc.) should beaccepted as proof of competency andproficiency. |  |  |  |  |
|  | McMaster University | 4.1.1.1  | Revise the definition of Class II prescribedequipment to include all particleaccelerators capable of producing nuclearenergy, with no explicit upper or lowerlimit on beam energy. | McMaster University supports the change to include all particle accelerators capableof producing nuclear energy under the definition of Class II Prescribed Equipment.Accelerators, even those operating at higher energies, do not present the same risksor hazards as other Class I facilities and would be far better categorized with otheraccelerator facilities. The current 50 MeV cutoff for Class II Prescribed Equipment isan arbitrary value not supported by a risk-informed safety case. The proposedchange will make it easier for research and health care facilities to acquire thesetechnologies, which will in turn drive innovation and improve patient outcomeswithout the financial and administrative burdens inherent with Class I licensing. |  |  |  |  |
|  | McMaster University | 4.1.1.2  | The discussion paper does not make it clear how the addition of a definition of“medical accelerator” would impact the regulations. The paper states, for example,that differences with non-medical accelerators include different testing frequenciesfor safety systems. However, section 4.2.3.3 of the discussion paper proposes thatapplicants would submit the proposed methods and frequency for testing the safetysystems, which makes this particular point redundant. Other accelerators besidesmedical accelerators may have non-isocentric designs, and under existingregulations, medical accelerators are not required to have independent radiationmonitors.It is unclear how a “medical accelerator” stream is substantially different from theproposed streams for standard and non-standard facilities. In fact, the word “medicalaccelerator” is only mentioned once outside of this section of the discussion paper,and then only as an example for licencing periods.CNSC should more clearly articulate the reasoning for adding a definition of “medicalaccelerator” and describe how this would affect the regulation of this equipment. | Add a definition for “medical accelerator.”  |  |  |  |  |
|  | McMaster University | 4.1.1.3  | Add definitions for mobile and portableprescribed equipment, which are nottypically operated in shielded, fixedfacilities. | McMaster supports this change. We currently possess a Starfire nGen 400 DueteronDeuteron Generator, which is meant to be mobile. The proposed change shouldsimplify the licencing of this equipment. |  |  |  |  |
|  | McMaster University | 4.1.2.1  | Define a Class II facility as one that includesClass II prescribed equipment fixed in placeinside a shielded room or other enclosure,as well as its related components, systemsand equipment. | In principle, we see no issue with including safety systems as part of the definition ofa Class II facility. Shielding and safety systems such as interlocks and emergencypower-off devices are already covered – at least to some extent – by regulatoryexpectations. However, the expanded definition should be clearly and strictly limitedto safety-related systems only. We are concerned that if the definition is notsufficiently clear, non-safety systems related to the prescribed equipment such asheating/cooling systems, treatment couches for medical accelerators, powersystems, etc. would be drawn into the definition. This would have significantimplications for licensees as it could expand the physical boundaries of the facility,introduce additional requirements for servicing non-safety related equipment, etc. |  |  |  |  |
|  | McMaster University | 4.2.2.1  | Design the C2NFPER in such a way thatstandard facilities would continue to followthe approach used throughout the currentregulations. Non-standard facilities,however, would follow an approach similarto that currently used for Class I facilities,where broad, high-level safety and securityrequirements are in place and a licenceconditions handbook (which describes indetail how the licensee will conduct itsoperations in a safe and secure manner) isdeveloped and incorporated into thelicensing basis. Furthermore, it is proposedthat equipment licensed under the nonstandard stream would be exempt fromcertification (see section 4.3.1.2 fordetails). | McMaster supports this change |  |  |  |  |
|  | McMaster University | 4.2.2.1  | Require radiological workload and beamrelated parameters (where applicable) forall Class II prescribed equipment, not onlyteletherapy machines. | Agreed. This is already required in practice for licence applications. |  |  |  |  |
|  | McMaster University | 4.2.2.2  | Remove the requirement to provide theanticipated number of hours per week thatthe Class II facility will be operated forspecific uses (treatment, dosimetry,servicing or research). | Agreed. A breakdown of use is not required to ensure regulatory requirement (i.e.,annual effective dose limits) are met. |  |  |  |  |
|  | McMaster University | 4.2.2.3  | Remove the current requirement toprovide the proposed responsibilities ofand training program for workers duringthe operation of the facility. | Agreed. The responsibilities and training programs for workers are not required atthe construction phase and in practice are often left out of construction licenceapplications. |  |  |  |  |
|  | McMaster University | 4.2.2.4  | Clarify that a description must be providedof all safety systems that are requiredunder section 15 of the C2NFPER. | Agreed. Including this information at the construction phase will help ensure that nochanges will need to be made to the facility design after construction in complete. |  |  |  |  |
|  | McMaster University | 4.2.2.6  | Add a requirement that the proposedmethod of disposing of Class II prescribedequipment (and any activated componentsor materials) be provided with thepreliminary decommissioning plan. | Agreed, provided it is well understood that the proposed method of disposal of ClassII prescribed equipment would be preliminary and subject to change during theoperating life of the equipment. |  |  |  |  |
|  | McMaster University | 4.2.3.2  | Require radiological workload and beamrelated parameters (where applicable) forall Class II prescribed equipment operatingin a shielded facility, not only teletherapymachines; in addition, remove thestipulation that workload must be trackedon a weekly basis and in units of graysmeasured at a distance of 1 m. | Agreed. Workload and beam-related parameters are already provided for all Class IIprescribed equipment applications. Removing the stipulation to track workload on aweekly basis and in units of grays at 1 m would align with current practice andprovide flexibility for different types of Class II prescribed equipment. |  |  |  |  |
|  | McMaster University | 4.2.3.3  | Require applicants to submit the proposedmethods and frequency for testing thesafety systems set out in section 15 of theC2NFPER, as well as any installed securitysystems. | Agreed. This aligns with current practice. |  |  |  |  |
|  | McMaster University | 4.2.3.4  | Provide details of the disposal method forall Class II prescribed equipment to beremoved from an operating licence,including mobile/portable Class IIprescribed equipment. | Agreed, provided it is well understood that the proposed method of disposal of ClassII prescribed equipment would be preliminary and subject to change during theoperating life of the equipment. |  |  |  |  |
|  | McMaster University | 4.2.4.1  | Ensure decommissioning activities areperformed only by (or under thesupervision of) persons or entities whohold a valid CNSC servicing licence. | McMaster University does not agree with this propose change. Only a decommissioning licence should be required to decommission a Class II facility. Decommissioning a facility and servicing equipment within it are two very differentlicensed activities. Service licences are meant to cover a wide range of work, from standard preventive maintenance to extensive repair work. A decommissioning licensee already needs to demonstrate that they have the capability decommission the facility, including the necessary operational knowledge of the facility and the equipment within it. This issue is already covered in REGDOC-1.4.1, Licence Application Guide: Class II Nuclear Facilities and Prescribed Equipment. Section B.1.4, Decommissioning, states that, “Applicants must either enter the current CNSC licence number that allows servicing of the prescribed equipment or … demonstrate that they meet the requirements for a licence to service.” CNSC must also be careful not to overreach in this area, particularly as there is no proposed change to the definition of servicing in the Class II regulations. While thedefinition of servicing does include “dismantling” of Class II prescribed equipment,and service licences are currently issued for Class II prescribed equipment,decommissioning licences are issued to decommission the entire facility.Decommissioning a facility may include tasks such as decontamination, remediation,or storage/disposal of activated components. These tasks do not fall under thedefinition of “servicing” and can in fact be performed without a licence to serviceClass II Prescribed Equipment. Finally, for licensees without a service licence, requiring them to submit a full application for a servicing licence solely to decommission a facility, on top of submitting a decommissioning licence application, creates a significant regulatoryand administrative burden. |  |  |  |  |
|  | McMaster University | 4.2.5.1  | Add a requirement to provide a descriptionof the methods and/or equipment that willbe used to ensure safety during servicingoperations (e.g., defining circumstances ordose levels that require workers to “backout” of a situation, or steps to take when asituation arises that is not covered bystandard servicing procedures); conversely,remove the requirement for applicants tosubmit their standard procedures and/orequipment for performing servicing (atable of contents of such standardprocedures may be requested instead). | McMaster already has detailed process and procedures in place to ensure radiationsafety during servicing operations. We support the addition of this as a regulatoryrequirement, as well as the change to no longer require applicants to describe theactual steps of servicing prescribed equipment.However, with this change, it is unclear why the CNSC would still require a table ofcontents for standard servicing procedures. If the focus of this regulatory change isto ensure radiation safety during servicing, this information is unnecessary.We are more concerned with the possibility that performance of servicing notcovered by standard procedures may require notification to and possible priorapproval from the CNSC. McMaster operates several unique accelerators for which most servicing may be considered non-standard. If the licensee submits informationto prove that they will ensure radiation safety during servicing, this should be sufficient to cover both standard and non-standard service work, full stop. Given that non-standard servicing may be very technical work performed by experienced and well-trained service engineers, it is unclear what additional value an evaluation by CNSC staff would provide. The requirement for such a review may also delay time sensitive research projects or patient treatments. Contrary to the statement in the discussion paper, such a process would add significant regulatory burden for our accelerator facilities. |  |  |  |  |
|  | McMaster University | 4.2.6.2  | Add an exemption from licensing for theimport and export of Class II prescribedequipment that does not contain a nuclearsubstance. | Agreed. The import/export of Class II prescribed equipment that does not contain anuclear source does not present any risks. |  |  |  |  |
|  | McMaster University | 4.3.1.1 | Remove the exemption for certificationbased solely on the fact that the equipment will be used for scientific research. | The discussion paper states that, “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 valueadded in certifying the equipment.”It is true that equipment used for research may be mass-produced and sold commercially. However, given the often limited funding available for Canadian universities, it is likely that only one of a given model of research accelerator may be sold and operated in Canada, no matter the number sold globally. In this case there are no efficiency gains in certifying that equipment; in fact, in this situation the manufacturer is far less likely to certify the equipment themselves, placing that additional burden on the licensee.McMaster supports the proposed change to exempt “non-standard” equipment from certification. However, the definition of “non-standard” should be based on whether it is likely that the equipment in question would be purchased and installed in Canada more than once, rather than whether it is sold commercially in other jurisdictions. |  |  |  |  |
|  | McMaster University | 4.3.1.2 | Add an exemption for equipment or facilities that are to belicensed under the “non-standard” licensing stream (i.e., unique equipment/facility that is only constructed once). |  |  |  |  |
|  | McMaster University | 4.4.1.1 | Replace the current prescriptive requirements with the following outcomebased requirements. | Agreed. This would provide much more flexibility for licensees. |  |  |  |  |
|  | McMaster University | 4.4.2.2 | Allow licensees to propose and implementalternative or additional safety precautionsin the event of a failure of an installed andapproved safety system. | Agreed. This would allow continued operation of the equipment for time-sensitive work, whether in research or healthcare. |  |  |  |  |
|  | McMaster University | 4.4.2.3 | Add a requirement that licensees must testall installed safety systems on a regularbasis. | Agreed. This is already done in practice. |  |  |  |  |
|  | McMaster University | 4.5.1.1 | Require that every licensee who operatesor services a Class II facility or Class IIprescribed equipment appoint a radiationsafety officer who has been certified by theCNSC. | McMaster University agrees with this change, with the caveat that the CNSC continues to accept individuals that are already certified by the CNSC at a Class I facility as RSOs, without the requirement for additional certification or examination by the CNSC. There are some Class II facilities that are located within a Class I facility.Requiring individuals that have already been certified for the higher risk Class I facility to be certified again for a lesser risk Class II facility at their location is an unnecessary administrative burden that does not improve safety. |  |  |  |  |
|  | McMaster University | 4.5.2.1 | Add a provision under which certificates issued to Class II radiation safety officers will expire after a certain period, to bedefined by the CNSC. Consequently, a clause that will require periodic recertification of a Class II RSO will also be added. | McMaster University does not feel that it is necessary to add expiry dates to Class IIRSO certificates, or to require periodic recertification. The discussion paper statesthat the intent of this change is to “Ensure that individuals who are certified as ClassII RSOs continue to have the required and current knowledge to ensure safety whilecarrying out the licensed activity.” However, CNSC already provides significantoversight of the RSO and the program for which they are responsible, including thoseareas listed in the discussion paper:* procedures and policies related to radiation safety and training are reviewed by CNSC staff to ensure the are acceptable and meet requirements
* the identification and correcting of radiation safety concerns are reviewed byvCNSC staff both during inspections and while reviewing reportable incidents,
* compliance is evaluated through CNSC’s existing compliance verification tools including desktop reviews, annual compliance reports, inspections and enforcement actions.

As per Appendix C, Candidate Qualifications in REGDOC-2.2.3, *Personnel**Certification: Radiation Safety Officers*, the candidate must demonstrate that theyhave an appropriate level of knowledge covering the items listed in the table below.In our opinion, none of these items require a specific re-evaluation.

|  |  |
| --- | --- |
| **Area to be evaluated for certification** | **Justification for not requiring reevaluation** |
| Relevant provisions of the NSCA andthe relevant sections of regulations | Regulations change infrequently, andwhen they do, CNSC goes to significanteffort to ensure those changes arecommunicated to licensees. In addition,inspectors verify that changes to theregulations have been implemented aspart of their compliance verificationactivities |
| Radiation physics and principles ofradiation safety | Radiation physics and principles ofradiation safety do not changesignificantly over time. |
| Operational activities which arelicensed by the CNSC, and for which thecandidate will be the RSO | Changes to the operational activities or the radiation protection program of the facility must be submitted to the CNSCfor approval – almost always by the RSOthemselves. |
| Any operational requirement from theCNSC, as may be listed in licenceconditions |
| The radiation protection program ofthe facility |

In addition, the RSO certificate is only valid for the specific Class II Prescribed Facilities or Equipment in use at the time of certification. The addition of new facilities or equipment to the certificate already requires additional approval by the CNSC. Should the CNSC proceed with this requirement, they should ensure that continuingprofessional development activities already being undertaken by RSO’s can be used as the basis for recertification. Many RSO’s already maintain at least one, if not more, professional credentials, such as the Radiation Safety Professional registration from the Canadian Radiation Protection Association (CRPA) or the Certified Health Physicist credential from the American Board of Health Physics. Maintenance ofthese qualifications already requires continuing professional development. The additional of further maintenance and tracking for CNSC certification would increase the administrative burden on both the licensee and the individual, with no commensurate gain in safety. |  |  |  |  |
|  | McMaster University | 4.5.2.2 | Add language allowing the amendment ofcertificates issued to Class II radiationsafety officers. | Agreed – this would simplify the process for licensees. |  |  |  |  |
|  | McMaster University | 4.6.1.1 | 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 fromthe licence· Servicing records be retained for a certain period following the day on which the servicing was performed | Agreed. Current document retention periods can be confusing. This will help simplifyrequirements. |  |  |  |  |
|  | McMaster University | 4.6.2.1 | Ensure that records of servicing of Class IIprescribed equipment are:· Kept and retained by the entity whoperformed the servicing· Provided by the entity who performedthe servicing to the operator/owner of theprescribed equipment· Kept and retained by the prescribedequipment operator/owner | Agreed. |  |  |  |  |
|  | University Health Network | 4.1.1.1 | Revise the definition of Class II prescribed equipment to include *all* particleaccelerators capable of producing nuclear energy, with no explicit upper or lower limit on beamenergy. | UHN is in full support of including all particle accelerators capable of producing nuclear energy with noupper limit on beam energy within the Class II definition for the following reasons:* Dose levels generated by particle accelerator use in proton therapy or heavier ion therapy at thetreatment isocenter are similar to those generated by prescribed equipment currently coveredunder C2NFPER.
* Risk of contamination with these higher energy accelerator (proton and carbon therapy) are notat all the same levels with nuclear fission power reactors.

UHN requests clarification on having no lower limit on beam energy. Technically an X‐ray tube is a particle accelerator and currently, an X‐ray emitting devices capable of producing energy below 1 MeV is governed by the provincial regulations. If the proposed definition of Class II prescribed equipment includes all particle accelerator capable of producing nuclear energy with no lower limit on beam energy, this may present confusion on the regulatory governance.UHN requests clarifications on what is meant by “producing nuclear energy”. Definition of “nuclear energy” would be appreciated. |  |  |  |  |
|  | University Health Network | 4.1.1.2 | Add a definition for “medical accelerator”. | UHN does not agree that adding a definition for “medical accelerator” is necessary. The public access to medical accelerator is not much different than for non‐medical accelerator. Testing frequency for medical accelerator performance may be different than for non‐medical accelerator but that for safetysystems is the same for both medical and non‐medical accelerators. Although there are smalldifferences on facility and security design (e.g. higher level of surveillance is required in places where public has access), the differences are not significant to justify an additional definition for “medical accelerators”. |  |  |  |  |
|  | University Health Network | 4.1.1.3 | Proposed change: Add definitions for mobile and portable prescribed equipment, which are not typically operated in shielded, fixed facilities. | This change seems reasonable. No issues or comments. |  |  |  |  |
|  | University Health Network | 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. | UHN does not see the value of this change. The licensing process already covers room shielding,radiation survey and safety systems. The proposal should consider how this change can positively (or not) impact the licensees. The proposed definition requires clarifications on what related components, systems and equipment it includes (e.g. safety systems). |  |  |  |  |
|  | University Health Network | 4.2.1.1 | 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, wouldfollow 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 andincorporated 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) | UHN requests clarifications on how an installation of medical carbon accelerators would be handled under this proposed change |  |  |  |  |
|  | University Health Network | 4.2.2.1 | Require radiological workload and beam‐related parameters (where applicable) for all Class II prescribed equipment, not only teletherapy machines. | UHN agrees with this proposed change. This formalizes current practice. |  |  |  |  |
|  | University Health Network | 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) | UHN agrees with this proposed change. While it is helpful for the applicant to evaluate the specific type of use (treatment, dosimetry, servicing or research) for estimating the annual workload, it does not make a difference in facility design assessment where a total annual workload is used. With that said, UHN thinks it is still good for CNSC to provide guidance and reminder to license applicants to considerthese specific uses so that they are included in the annual workload. UHN would like to suggest a new change where an annual workload does not include one‐time workload (e.g. commissioning). The unit is not used in the same manner during commissioning as it would duringnormal operation. |  |  |  |  |
|  | University Health Network | 4.2.2.3 | Remove the current requirement to provide the proposed responsibilities of and training program for workers during the operation of the facility. | UHN agrees with this proposed change. The information on the responsibilities and training program for workers is usually not available at the construction license application phase. Even if this information is available at this phase, it is likely to be revised later at the routine operating license application phase. |  |  |  |  |
|  | University Health Network | 4.2.2.4 | Clarify that a description must be provided of all safety systems that are required under section 15 of the C2NFPER. | UHN agrees with this proposed change. It aligns with the current practice. It is important to outline the description of all safety systems at the facility construction phase. UHN requests clarifications on the extent of details required in the description of the safety systems (e.g. circuit diagram, functional and technical details). |  |  |  |  |
|  | University Health Network | 4.2.2.6 | Add a requirement that the proposed method of disposing of Class II prescribed equipment (and any activated components or materials) be provided with the preliminarydecommissioning plan. | UHN agrees with this proposed change. It is important for applicant to have a plan for disposal of Class II prescribed equipment and any associated activated components or materials. This will help to plan and allocate appropriate funding required for the disposal cost at the construction phase.UHN requests clarifications on what impact it will have for current licensees. We believe this should not impact current licensees and only apply to new facilities and applicants. Will this change require us to submit the proposed method of disposing of Class II prescribed equipment (and any activatedcomponents or materials) for all the Class II equipment on our license? If there is a commercial equipment that does not have any long‐lived radionuclides or activated components or materials, is there an option to provide a simplified decommissioning plan such as transferring the equipment to another licensee? |  |  |  |  |
|  | University Health Network | 4.2.3.2 | Require radiological workload and beam‐related parameters (where applicable) for all Class II prescribed equipment operating in a shielded facility, not only teletherapymachines; 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. | UHN agrees with this proposed change. This aligns with the current practice where the workload and beam‐related parameters are reported in the Annual Compliance Report for all Class II prescribed equipment and not only teletherapy machines. The workload is not tracked on a weekly basis and in units of grays measured at a distance of 1 m so removing this stipulation will align with current practice. |  |  |  |  |
|  | University Health Network | 4.2.3.3 | 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. | UHN agrees with this proposed change. This aligns with current practice. |  |  |  |  |
|  | University Health Network | 4.2.3.4 | 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. | UHN agrees with this proposed change. Same comment as section 4.2.2.6. |  |  |  |  |
|  | University Health Network | 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. | UHN requests clarifications on what is meant by decommissioning activities to be performed under the supervision of persons or entities who hold a valid CNSC servicing license. Does the supervision require the persons with a CNSC servicing license to be on‐site to provide direct and continuous supervision during decommissioning and disassembly of Class II equipment? Can UHN Radiation Safety haveoversight of the decommissioning activities? If radioactive materials are removed including anyactivated components or materials, we believe that it is safe for decommissioning activities to beperformed by persons who are authorized by the persons who hold a valid CNSC servicing license but not strictly required to be performed only by or under the supervision of persons who hold a CNSC servicing license. |  |  |  |  |
|  | University Health Network | 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 circumstancesor 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) | UHN seeks clarifications on the extent of the description required to be provided of the methods and/or equipment that will be used to ensure safety during servicing operations. UHN already has a standardized procedure in place (e.g. Work Plan) where for any servicing work that is considered “major” or estimated dose levels higher than normal, radiation safety review and approval is required. Radiation Safety will also complete review after the work is completed for these impacted servicing work. UHN agrees with the proposed change in removing the requirement for applicant to submit theirstandard procedures and/or equipment for performing servicing. UHN seeks clarifications on the definition of “standard procedures” and what the table of contents entails. |  |  |  |  |
|  | University Health Network | 4.3.2.1 | Add a requirement to provide the proposed method for securing Class II prescribed equipment that contains a nuclear substance. | UHN seeks clarifications if this proposed change will impact equipment that is already certified. Will the manufacturer be required to provide the proposed security method to the end users? |  |  |  |  |
|  | University Health Network | 4.4.1.1 | 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) shallbe 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 IIprescribed equipment is located and ensures that the controlled area is clear of other peopleand that the equipment is safe to operate.
* Irradiation must be stopped automatically if someone enters the controlled area while theprescribed equipment is operating.
* There must be a method of determining whether radiation is present within the controlledarea and of displaying this fact both within and outside the defined area.
* Radiation warning signage and emergency contact information must be posted at theentrance to the controlled area.
 | UHN agrees with this proposed change. |  |  |  |  |
|  | University Health Network | 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 | UHN disagrees with this proposed change. While it is appreciated, human factor consideration may make this change problematic. There is a likelihood of “slippage” in notification and declined safety culture because staff may take it for granted they can continue operating the equipment without repairing the malfunction. For safety systems, we would prefer if they are all functional. If there is an extended malfunction, we would like to involve CNSC. |  |  |  |  |
|  | University Health Network | 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 particleaccelerators used for geophysical logging. | UHN agrees with this proposed change.  |  |  |  |  |
|  | University Health Network | 4.4.2.5 | Remove the requirement for a patient viewing system. | UHN disagrees with this proposed change. Having a CCTV that monitors the bunker and not just the patients is a desirable system that should be under the CNSC mandate and to remove it will not be ideal. CCTV has functionality beyond monitoring patients. We agree to remove “patient” from “patient viewing system” but are opposed to removing this requirement. We want to ensure that this does not impact the current practice for non‐medical accelerators (e.g. cyclotron) where a viewing system is notrequired. This requirement will be problematic for these facilities as CCTV is prone to damage byneutrons in the cyclotron vault. |  |  |  |  |
|  | University Health Network | 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 willrequire periodic recertification of a Class II RSO will also be added | UHN disagrees with this proposed change. This change will add regulatory burden on both the licensees and CNSC without any added benefits to safety.Currently it is required for Class II RSO to be re‐certified if returning from an extended absence from RSO duties or returning to RSO duties after certificate invalidation (e.g. resulting from a substantive change to the conditions of the original certification such as a change of duties that are substantially different from that of a RSO). The Class II RSO is expected to perform RSO duties on a regular basis and unlessthere are conditions where the certification will be invalidated as described earlier, the person’squalifications as an RSO will not change over time. The RSO is also likely to hold other professional certifications such as CRPA(R) and CHP, which requires continued education and re‐certification that ensure the person’s up‐to‐date on radiation safety knowledge. The qualification of RSO can also be verified from the compliance state of the Radiation Safety Program, which is regularly audited through CNSC inspections.It is also important to clarify what the re certification process will look like. Will it require re‐examination? If re‐examination is required, it will add much regulatory and administrative burden without added benefit to safety. If it requires RSO to complete refresher training to be re‐certified, then we believe CNSC should provide or support this refresher training. |  |  |  |  |
|  | University Health Network | 4.5.2.2 | Add language allowing the amendment of certificates issued to Class II radiation safety officers. | UHN agrees with this proposed change. This will lessen the administrative burden. |  |  |  |  |
|  | University Health Network | 4.6.1.1 | 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 thatequipment was removed from the licence
* servicing records be retained for a certain period following the day on which the servicing wasperformed
 | UHN agrees with this proposed change. This will help simplify and clarify requirements. In addition to this change, UHN seeks clarifications on what “equipment‐related records” and “servicing records” include. |  |  |  |  |
|  | University Health Network | 4.6.2.1 | 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 prescribedequipment
* kept and retained by the prescribed equipment operator/owner
 | UHN agrees with this proposed change.UHN agrees with this proposed change. |  |  |  |  |
|  | Bryce NelsonUniversity of Alberta | 4.1.1.1 |  | Regarding the subsection "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.": Would it be possible to irradiate target materials such as thorium, uranium, radium, or plutonium on a 24 MeV proton cyclotron (e.g., a TR-24)? There is significant interest in producing short-lived alpha emitters for highly potent targeted alpha particle therapy of advanced cancers, and based on nuclear reaction cross-section data, a TR-24 is well suited for producing useful amounts of Pb-212 (from proton irradiation of thorium) and Ac-225 (from proton irradiation of radium) for research and clinical application. Provided the appropriate cyclotron target technology is employed where the target material is securely encapsulated to prevent any contamination, and any post-irradiation target processing is performed within a separate dedicated alpha lab, would this be possible? Due to the significant global shortage of these desirable therapeutic alpha emitters, we are very interested in pursuing this route to achieve a domestic supply for research and clinical application. Thank you. |  |  |  |  |
|  | Mevex Corporation, a STERIS company | 4.1.2.1 |  | Some sites will consist of a general purpose building that contains a Class II facility. For example, there are some installations in the works that include a compact shield around the Class II equipment, and this shielded system is located within a warehouse and office space to allow the associated activities to operate in the same space as the irradiation activities. Is the intent to license the entire building, or only the components of the shielding, safety system, and equipment inside the building that make up the "Class II facility"?I would like to see the scope of the Class II facility limited to the shielding, equipment, and safety systems associated with the accelerator. If the scope of the Class II facility includes the surrounding building, it will add unnecessary cost and complexity to the licensing process and overall use of the building. |  |  |  |  |
|  | Mevex Corporation, a STERIS company | 4.2.1.1 |  | Our business involves continuous improvement and evolution of the design of accelerators to increase capability and power output available. Does this mean we would be subject to the Class I high level safety and security requirement as well as a license condition handbook? The proposed change does not provide enough clarity about the differentiation between "standard" and "non-standard" to determine if this proposed change would affect our operations. If it does, the impact would be significant, both financially and from the perspective of added regulatory burden. |  |  |  |  |
|  | Mevex Corporation, a STERIS company | 4.2.5.1 |  | Many of the service activities are performed through knowledge gained by on-the-job training, may involve elements of troubleshooting and problem solving, and are not typically fully described in "standard servicing procedures". How will the CNSC handle a licensee the does not have a complete set of service procedures covering all models and variants of accelerator in service? |  |  |  |  |
|  | Mevex Corporation, a STERIS company | 4.3.3.1 |  | It's not clear to me whether or not we would be required to certify each accelerator we produce and test prior to shipping to a customer site. |  |  |  |  |
|  | Mevex Corporation, a STERIS company | 4.3.2 |  | Would this requirement apply to the accelerator, the control system, the shielding system, the power supply, or the entire system once assembled? |  |  |  |  |
|  | Mevex Corporation, a STERIS company | 4.3.2.2 |  | Description of the interlock system may require significant work and will add to the regulatory burden. |  |  |  |  |
|  | Mevex Corporation, a STERIS company | 4.4.1.1 |  | Our systems do not presently have a radiation detector within the controlled area. The operating environment inside the bunker is extremely challenging and sensitive detection equipment will fail in a very short time. We display that the system is in a "beam on" state, but this is based on the ability of the machine to produce radiation rather than based on a radiation measurement directly. |  |  |  |  |
|  | Mevex Corporation, a STERIS company | 4.4.2.3 |  | Will there be a test frequency imposed? We typically install and test 2-4 new accelerators in each of our bunkers each year, and test the safety system at the time of installation of each new accelerator. The frequency is event-based (new accelerator installation) as opposed to time-based. Will this approach be acceptable under this proposed change? We would be open to a maximum interval (eg. 6 months) between safety system tests if there was a machine in continuous operation during that period. |  |  |  |  |
|  | Mevex Corporation, a STERIS company | 4.5.2.1 |  | Suggest that the recertification requirement consider the type of class 2 facility. As an OEM, the RSO roles at our company are continuously involved in the design, analysis, and safety assessment of the machines. While recertification seems generally a reasonable, it may provide little value at an OEM facility such as ours. |  |  |  |  |
|  | Mevex Corporation, a STERIS company | 4.6.1.1 |  | Guidance on the level of detail required for service records would be helpful. Our company has a team of several people continuously involved in servicing equipment around the world and in Canada. Will we need to maintain service records for all sites globally? What information will be required? The shortest reasonable retention period would help reduce the cost and regulatory burden of this change. |  |  |  |  |
|  | Mevex Corporation, a STERIS company | 4.6.2.1 |  | Our company services equipment around the world. Will we need to retain records for service in other countries?Safety operation is largely assured by the safety system, which is generally not touched during service unless the service activities are performed on the safety system itself. Will there be guidance on what level of safety testing is required for service that does not involve the safety system? |  |  |  |  |
|  | Jonathan DoupeAlberta Health Services | 4.1.1.1 |  | The proposed change is to incorporate >50 MeV accelerators (now Class IB) within the Class II regulations. The radiological risks of the two types of accelerators are similar, and some of the challenges faced by Class I facilities in terms of containment, releases to the environment, etc. are not faced to nearly the same degree in Class IB. With this proposed reclassification, it is natural to ask what operations currently conducted at Class IB facilities might also be performed at Class II facilities. There is a great deal of interest in using high-energy cyclotrons to produce therapeutic isotopes for cancer treatment as demand is outpacing supply (e.g., Ac-225 produced at TRIUMF from a 480 MeV proton beam hitting a thorium target). These reactions usually require high energies but not all. For example, Pb-212 could be produced from 24 MeV protons on thorium. Obviously safeguards and Nuclear Material Accountancy would be critical in such work along with proper radioactive waste management. Thorium or radium targets would be much easier to manage in this respect than heavier elements. Reasons as to why Class IB facilities were first in this work on heavy element targets include i) many more nuclear reactions were available at high energies, ii) Class I facilities by their very definition deal with nuclear materials, iii) there was already in-house experience in terms of chemistry and regulatory aspects of alpha-emitters. If the present radiological risks of Class IB and Class II accelerators are judged similar - and that would include the work on heavier element targets in Class IB - then it is worth reassessing what can be done at Class II sites, particularly since there is a need for new supplies of therapeutic isotopes. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.1.1.1 |  | 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. CCMB is in favour of this change. It doesn't affect cancer centres directly, as proton accelerators operate below 150 MeV. We concur that the radiological risk from higher energy accelerators does not warrant classification as a Class I facility. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.1.1.2 |  | Add a definition for “medical accelerator”. CCMB is in favour of this change. The stringent safety system checks needed for a healthcare facility with much more public access are not necessarily applicable to an industrial or research facility with existing access control. We support this change on the condition that facilities with more public or non-NEW access have appropriate safety measures as part of their license condition, including ones that would not normally be required if the facility design warrants it. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 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. CCMB is in favour of this change. Our Class II equipment's supporting infrastructure is treated as part of the installation from an administrative perspective, and the CNSC already approves its use and audits how well it is maintained during inspections. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.2.1.1 |  | 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). CCMB is in favour of this change. It will not change our operating and administrative costs as our Class II equipment is all well-characterized and mass-produced. A separate stream for custom accelerators versus commercial is a great idea; it would allow for project officers to be intimately familiar with the types of sites that they are responsible for.  |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.2.2.1 |  | Require radiological workload and beam-related parameters (where applicable) for all Class II prescribed equipment, not only teletherapy machines. CCMB is in favour of this change. It will not change our operating and administrative costs as we already report estimated workload during construction license applications and Annual Compliance Reports. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 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). CCMB is in favour of this change. It will reduce the burden of applying for licenses. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.2.2.3 |  | Remove the current requirement to provide the proposed responsibilities of and training program for workers during the operation of the facility. CCMB is in favour of this change. This could reduce the waiting time for processing of a construction license.  |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.2.2.4 |  | Clarify that a description must be provided of all safety systems that are required under section 15 of the C2NFPER. CCMB is in favour of this change. This would harmonize the C2NFPER with REGDOC 1.4.1 and removing ambiguity, which is always helpful. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.2.2.6 |  | 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. CCMB is in favour of this change. It will not change our operating and administrative costs as we already plan for this. It would be helpful for newer facilities that are less familiar with disposing of activated accelerator components to avoid the surprise of needing to deal with activated targets, etc. when replacing or upgrading an accelerator. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.2.3.2 |  | 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. CCMB is in favour of this change. It will not change our operating and administrative costs as we already provide this. The removal of the weekly tracking will align with what is currently happening. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.2.3.3 |  |  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. CCMB is in favour of this change on the condition that the requirement is to submit methods and frequency for testing safety systems, as opposed to specifying what that frequency must be. The testing interval should be tailored to the installation. As an example, at our sites testing the emergency stop buttons is part of our accelerators' planned maintenance every five weeks; requiring the testing of the e-stops more frequently would place undue stress on the equipment.  |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 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. This doesn't affect CancerCare Manitoba personally as we hold a servicing licence. This will affect facilities that do not have servicing licences. It is likely better to put this in a REGDOC rather than in the C2NFPER. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 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). CCMB is in favour of this change. It will put a small burden on our facility now, but will GREATLY reduce the burden in the future as we move to newer systems that have different service procedures. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.3.2.1 |  | Add a requirement to provide the proposed method for securing Class II prescribed equipment that contains a nuclear substance. CCMB is in favour of this change on the condition that equipment currently appearing on a CNSC licence will be accommodated for the lifetime of the equipment (similar to 4.3.1.1 for uncertified research equipment that will have a clause added to accommodate the licensees for the lifetime of the equipment). We are concerned about when a device is re-certified: how will existing devices be handled if they do not have an appropriate strongpoint? Will already-sold devices have an exemption, since their end-users have likely already found an appropriate solution? |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.4.1.1 |  | 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. CCMB is mostly in favour of this change as they are satisfied with existing practices. Outcome-based requirements are a good idea, as long as the REGDOC gives appropriate guidance. The Class II application guide REGDOC is a good model to follow in this respect. We are concerned about the "method of determining whether radiation is present," and “display must be within and outside defined area”. For medical linear accelerators the existing solution is "Radiation On" signs at the vault entrance. We do not want to see area monitors being made necessary for linear accelerators, nor signs required within the vault. Language specifying that accelerator radiation sources may use devices that indicate when the accelerator is active should be added to make this explicit. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 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. CCMB is in favour of this change. It is a welcome change that would formalize existing practice. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.4.2.3 |  | Add a requirement that licensees must test all installed safety systems on a regular basis. CCMB is in favour of this change on the condition that the requirement is to submit methods and frequency for testing safety systems, as opposed to specifying what that frequency must be. The testing interval should be tailored to the installation. As an example, at our sites testing the emergency stop buttons is part of our accelerators' planned maintenance every five weeks; requiring the testing of the e-stops more frequently would place undue stress on the equipment.  |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.4.2.5 |  | Remove the requirement for a patient viewing system. CCMB is not in favour of this change. The other application of the viewing system that does fall under CNSC mandate is that it allows staff to see if there is anyone in the room other than the patient (this is in addition to the Last Person Out device). If CNSC is not suggesting that viewing systems be removed, then there are no operating and administrative costs to be saved by this change. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 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. CCMB is not in favour of this change. Requiring certified RSOs to study for and take regular recertification exams would increase operating, administrative and financial costs without any proven benefit. During each CNSC inspection the RSO’s knowledge and competency is evaluated through the evaluation of the Radiation Safety Program. If concern is raised then actions can be required through the Inspection report. We would instead propose requiring a specified number of continuing education credits over a set time period, similar to CRPA(R), to retain certification. The CNSC could provide a listing of topics or courses that would be accepted based on the RSO’s facility type. This would ensure the RSO maintains the required current knowledge. This would also require the licensee to provide time and funds for RSOs to take continuing education, both of which may be difficult to obtain for some RSOs. Required continuing education would be much more helpful for ensuring the RSO has current knowledge than writing exams. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.5.2.2 |  | Add language allowing the amendment of certificates issued to Class II radiation safety officers. CCMB is in favour of this change. RSO certificate amendments are a very good idea, especially with equipment on site changing and upgrading constantly. |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.6.1.1 |  | 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. CCMB is in favour of this change. This will greatly reduce regulatory burden on the licensee. For facilities where the site license doesn't expire, this will allow the disposal of records that aren’t needed.  |  |  |  |  |
|  | Deanne DombroskyCancerCare Manitoba | 4.6.2.1 |  | 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. CCMB is in favour of this change. It will not change our operating and administrative costs as we already retain servicing records. |  |  |  |  |
|  | Trevor BenistonAlberta Health Services- Cancer Care Alberta | Main body |  | We agree with and support the intent to align the regulations with current practices that are otherwise managed through licensing or very generalized regulatory citations. The shift towards outcome-based results, as opposed to prescribed requirements, is the right move in our opinion as well. |  |  |  |  |
|  | Trevor BenistonAlberta Health Services- Cancer Care Alberta | 4.2.3.3 |  | We agree with this change provided the intent is simply to establish in the regulation what is currently done in practice.  |  |  |  |  |
|  | Trevor BenistonAlberta Health Services- Cancer Care Alberta | 4.2.3.4 |  |  We believe decommissioning and disposal information is best provided during the operating application (for commissioning) before the equipment is turned on for the first time or the sources are onsite. Asking for information both at construction and operating licence steps is duplication. If concerned about changes in information, moving the request to the operating licence ensures the most recent information is obtained before activities with radiation can start. |  |  |  |  |
|  | Trevor BenistonAlberta Health Services- Cancer Care Alberta | 4.2.4.1 |  | Clarify: the servicing definition refers to the equipment and not the facility. Is this expected to change with the proposed changes? Having a servicing licence does not automatically confer competency in decommissioning work and vice versa. Decommissioning work is not necessarily servicing work. although there may be an element of decommissioning that require service work (ie: dismantling the prescribed equipment). Dismantling the equipment needs to be performed under a servicing licence, but decommissioning the rest of the facility does not. This could potentially create large costs for a licensee that does not have a servicing licence in order to renovate or remove safety systems from the facility that otherwise could be done by supervision from the licensee. |  |  |  |  |
|  | Trevor BenistonAlberta Health Services- Cancer Care Alberta | 4.2.5.1 |  | We agree with this approach to simplify the servicing licence application and focus on the measures to ensure safe work as opposed to the technical service work itself. |  |  |  |  |
|  | Trevor BenistonAlberta Health Services- Cancer Care Alberta | 4.4.1.1 |  | We support the move to outcome-based requirements as it gives much more flexibility to both the licensee and the regulator than the prescribed approach, but more detail is needed to properly comment on the impact. Determining whether radiation is present within a treatment room and displaying this information both within and outside the defined area is potentially a new requirement for linacs – depending on the final wording. Would the proposed accompanying regdoc become mandatory for some licensees? |  |  |  |  |
|  | Trevor BenistonAlberta Health Services- Cancer Care Alberta | 4.4.2.2 |  | We agree with this change in principle but further detail on the wording is needed. We would prefer the final wording to be fairly non-prescriptive to give a licensee the maximum amount of flexibility to consider/implement alternative measures that meet the outcome and minimize the amount of CNSC approvals necessary. No issue with notifying the CNSC of an alternative measure but would not want to have to wait for approvals unnecessarily. |  |  |  |  |
|  | Trevor BenistonAlberta Health Services- Cancer Care Alberta | 4.4.2.5 |  | We disagree with this change. Viewing systems should remain in place for medical accelerators. Having a viewing system not only protects the patient but also provides a measure of protection to workers. Operators should have the ability to view the facility to ensure no one is present in the room when radiation is produced even when an LPO system is present. The viewing system is an easy system to implement, and it continues the layered approach to safety within these facilities. Removing this requirement reduces the overall safety of the facility even if it may be covered by another regulatory body. |  |  |  |  |
|  | Trevor BenistonAlberta Health Services- Cancer Care Alberta | 4.5.2.1 |  | Are there concerns that current CII RSOs are not demonstrating competency or is there a trend which suggest this is becoming a problem? We generally disagree with the proposed change as RSO proficiency is already evaluated during CNSC inspections and (to a lesser extent) through the ACR. An additional recertification process for RSOs creates more administrative burden (for both licensees and the CNSC) with little gain in our opinion as the RSO is regularly performing the duties of the role for a single licensee/employer. The current certification only applies to the RSO position for a specific licence and is not transferable. The certification is more of a licensing requirement than a professional certification. Perhaps if it became transferrable and used as means of demonstrating the RSOs specific skill set, professional knowledge or ability to fulfil the role of the RSO, periodic recertification would carry more importance. If there is a concern about RSO competency over time, then we suggest using a maintenance process (similar to what the CRPA uses) that considers continuing education, continuous employment as an RSO, and other relevant qualities. We would be opposed to simply writing an exam every so many years. |  |  |  |  |
|  | Elekta | 4.2.3.3 |  | As a manufacturer of Class II equipment (Elekta), we would like to provide input related to the frequency or circumstance for testing power mains as an EPO. Full power down is very hard on treatment units and following this, there is a very good chance that the unit will not then be operable after. Our recommendation is that power mains are only tested during assigned service days, by FSE-giving them time to trouble shoot, if needed. |  |  |  |  |
|  | Elekta | 4.2.5.1 |  | We (Elekta) agree! |  |  |  |  |
|  | Elekta | 4.3.1 |  | We (Elekta) feel that class II equipment that we previously certified for clinical use should be exempt from re-certification once past its end of life. Any facility that then continues to need/use the equipment should then be able use the certificate (change name to theirs) and add an addendum to the existing certificate only stating modifications (ex: remove table, fix gantry angle etc.) |  |  |  |  |
|  | Elekta | 4.3.2.1 |  | We (Elekta) agree-this should be part of the certification process. |  |  |  |  |
|  | Elekta | 4.4.2.3 |  | As a manufacturer of Class II equipment (Elekta), we would like to provide input related to the frequency or circumstance for testing power mains as an EPO. Full power down is very hard on treatment units and following this, there is a very good chance that the unit will not then be operable after. Our recommendation is that power mains are only tested during assigned service days, by FSE-giving them time to trouble shoot, if needed. |  |  |  |  |
|  | Elekta | 4.5.2.1 |  | Regarding re-certification, we (Elekta) do not agree this is necessary for us and our Service only license. We have a National RSO who has produced, and subsequently oversees the Radiation Safety Program. They write, review, and revise our RS procedures; therefore, they are always fully aware of what is current. They also produce all of our applications and submissions to CNSC, so it would be easily apparent to both CNSC and Elekta if they were not qualified, or not performing their job properly. |  |  |  |  |
|  | Elekta | 4.6 |  | We (Elekta) agree |  |  |  |  |
|  | Elekta | Overall Impact |  | I thought the proposed changes were appropriate and mostly tried to harmonize regulations with current practice. In addition, many of the proposed changes will make navigation of the regulations a bit easier for license holders. |  |  |  |  |
|  | Mevex Corporation,A STERIS Company | 4.1.2.1 |  | Some sites will consist of a general purpose building that contains a Class II facility. For example, there are some installations in the works that include a compact shield around the Class II equipment, and this shielded system is located within a warehouse and office space to allow the associated activities to operate in the same space as the irradiation activities. Is the intent to license the entire building, or only the components of the shielding, safety system, and equipment inside the building that make up the "Class II facility"?I would like to see the scope of the Class II facility limited to the shielding, equipment, and safety systems associated with the accelerator. If the scope of the Class II facility includes the surrounding building, it will add unnecessary cost and complexity to the licensing process and overall use of the building. |  |  |  |  |
|  | Mevex Corporation,A STERIS Company | 4.2.1.1 |  | Our business involves continuous improvement and evolution of the design of accelerators to increase capability and power output available. Does this mean we would be subject to the Class I high level safety and security requirement as well as a license condition handbook? The proposed change does not provide enough clarity about the differentiation between "standard" and "non-standard" to determine if this proposed change would affect our operations. If it does, the impact would be significant, both financially and from the perspective of added regulatory burden. |  |  |  |  |
|  | Mevex Corporation,A STERIS Company | 4.2.5.1 |  | Many of the service activities are performed through knowledge gained by on-the-job training, may involve elements of troubleshooting and problem solving, and are not typically fully described in "standard servicing procedures". How will the CNSC handle a licensee the does not have a complete set of service procedures covering all models and variants of accelerator in service? |  |  |  |  |
|  | Mevex Corporation,A STERIS Company | 4.3.3.1 |  | It's not clear to me whether or not we would be required to certify each accelerator we produce and test prior to shipping to a customer site. |  |  |  |  |
|  | Mevex Corporation,A STERIS Company | 4.3.2 |  | Would this requirement apply to the accelerator, the control system, the shielding system, the power supply, or the entire system once assembled? |  |  |  |  |
|  | Mevex Corporation,A STERIS Company | 4.3.2.2 |  | Description of the interlock system may require significant work and will add to the regulatory burden. |  |  |  |  |
|  | Mevex Corporation,A STERIS Company | 4.4.1.1 |  | Our systems do not presently have a radiation detector within the controlled area. The operating environment inside the bunker is extremely challenging and sensitive detection equipment will fail in a very short time. We display that the system is in a "beam on" state, but this is based on the ability of the machine to produce radiation rather than based on a radiation measurement directly. |  |  |  |  |
|  | Mevex Corporation,A STERIS Company | 4.4.2.3 |  | Will there be a test frequency imposed? We typically install and test 2-4 new accelerators in each of our bunkers each year, and test the safety system at the time of installation of each new accelerator. The frequency is event-based (new accelerator installation) as opposed to time-based. Will this approach be acceptable under this proposed change? We would be open to a maximum interval (eg. 6 months) between safety system tests if there was a machine in continuous operation during that period. |  |  |  |  |
|  | Mevex Corporation,A STERIS Company | 4.5.2.1 |  | Suggest that the recertification requirement consider the type of class 2 facility. As an OEM, the RSO roles at our company are continuously involved in the design, analysis, and safety assessment of the machines. While recertification seems generally a reasonable, it may provide little value at an OEM facility such as ours |  |  |  |  |
|  | Mevex Corporation,A STERIS Company | 4.6.1.1 |  | Guidance on the level of detail required for service records would be helpful. Our company has a team of several people continuously involved in servicing equipment around the world and in Canada. Will we need to maintain service records for all sites globally? What information will be required? The shortest reasonable retention period would help reduce the cost and regulatory burden of this change. |  |  |  |  |
|  | Mevex Corporation,A STERIS Company | 4.6.2.1 |  | Our company services equipment around the world. Will we need to retain records for service in other countries?Safety operation is largely assured by the safety system, which is generally not touched during service unless the service activities are performed on the safety system itself. Will there be guidance on what level of safety testing is required for service that does not involve the safety system? |  |  |  |  |
|  | Michael Evans Mcgill | 4.2.3.1 |  | I particularly liked the proposal in 4.2.3.1 which suggests proposed weekly or per-shift radiation dose limits. This begins to nudge CNSC in the direction of considering Time Averaged Dose Rate (as suggested by NCRP 151) in design criteria. For example, the criteria that the 25 microSv/hr Instantaneous Dose Rate (IDR) be a limiting shielding criterion is somewhat problematic especially for medical linacs with robotic devices such as the CyberKnife. The USNRC currently uses discretionary judgement to use TADR, rather than IDR, in assessing design criteria. So, I think the suggestions by CNSC for changes in 4.2.3.1 are a step in the right direction. |  |  |  |  |
|  | Michael Evans Mcgill | 4.4.2.5 |  | One suggestion (4.4.2.5) I disagree with. The proposal to remove the requirement for patient viewing may make some regulatory sense, but it introduces unnecessary risk to the patient. It is needlessly downloading this responsibility to other jurisdictions and will create the possibility for reduced safety. The CNSC currently requires other tests (such as daily output verification) which ensure patient safety, so why relax this simple requirement. In our practice with HDR brachy treatments I would find this especially worrisome and would prefer that the CNSC continue to require this simple safety requirement. It already reflects current practice. |  |  |  |  |
|  | Michael Evans Mcgill | Overall Impact |  | I thought the proposed changes were appropriate and mostly tried to harmonize regulations with current practice. In addition, many of the proposed changes will make navigation of the regulations a bit easier for license holders. |  |  |  |  |
|  | Jeff DovyakShared Health Mannitoba | 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. |  | I am opposed to this proposal. I think that this could be an undue expense to licensees - licensees are qualified to supervise decommissioning of their own facilities. Another consideration is the availability, or lack of availability, of someone with a CNSC servicing licence when a licensee is prepared to begin decommissioning. |  |  |
|  | Jeff DovyakShared Health Mannitoba | 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. |  | I am opposed to this proposal. I think that Class II RSOs who are continuously employed as Class II RSOs should only have to show evidence of relevant continuing education, not undergo recertification (my fear is that to CNSC recertification means another exam). This could be similar to maintenance of registration that the Canadian Radiation Protection Association (CRPA) requires of those with the CRPA (R) credential, or the review of evidence of clinical practice and appropriate continuing education as practiced by the Canadian College of Physicists in Medicine (CCPM). If this proposal is adopted presumably there will be dialog with the regulated community on agreement of what the CNSC considers is relevant or appropriate continuing education. |  |  |
|  | Brandon HardyNova Scotia Health Authority | 4.4 |  | A self-shielded Class II device (cyclotron) should be exempt from this proposed regulation as entry into vaults that are self-shielded is deemed safe via annual surveys. |  |  |  |  |
|  | Brandon HardyNova Scotia Health Authority | 4.5 |  | The regulator should provide more information on the frequency of these proposed certification renewal requirements. Our organization does not believe this change to be necessary as all Class II certified RSOs are well informed of regulation and policy. |  |  |  |  |
|  | Dr. Raphael GaleaRES Team Lead / Metrology Research Centre / National Research Council Canada / Government of CanadaChef d’équipe RES / Centre de recherche en métrologie / Conseil national de recherche Canada / Gouvernement du Canada | 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.I would PREFER NO recertification for those licensees which are performing well audit after audit. That is an indication that the RSO is performing their duty. If that is ultimately decided to do so then something at minimum would be a 10 years cycle or LONGER. If certification is to take place then a minimum burden like a short quiz would be preferable for that certification.Perhaps the ideal situation is to have a dynamic recertification policy. No recertification if nothing significant changes or there are no issues during audits. Certification for new RSOs. Certification over a period of 10 years or dynamically to be determined following a justification after an inspection. |  | While I can see the appeal to the proposed change 4.5.2.1, and perhaps my feelings on this are highly dependent on the period which is being considered for recertification (1, 3, 5, 10 years?), I do object to this proposed change. An RSO need not be the individual operating the Class II equipment and hence the burden is placed more on someone giving oversight to safety rather than the safe operation of the equipment by the individuals. The RSO should ensure that proper training in the safe operation of the Class II equipment is performed for certified users and new users but may not need the training themselves. Will the inspection and auditing burden be reduced due to this re-certification? I imagine this will not as the inspections will always need to be performed by the CNSC. Perhaps as the result of failures or non-conformances that result from an audit a particular RSO can be required to recertify, but if inspections indicate that the operation of the Class II equipment is running without incident or issue, then this is simply regulatory burden that adds nothing to the radiation protection program. By admission the change adds regulatory burden but also burden upon the RSO to maintain their certification which may seem insignificant but for the most part RSO duties are often add on responsibilities to the individual accepting this position. |  |  |
|  | Jeff Konieczny | 4.4.2.5 |  | I think the requirement for a patient viewing system should remain in place for medical accelerators. The viewing system is used not just for patients, but to ensure that no one unexpected is in the bunker. Physics testing (especially during commissioning) can deliver massive amounts of radiation making it critical to ensure the room is empty. The bunker is checked before the last person out (LPO) button is pressed but having a full view of the room before actually turning on the beam is very important for radiation safety. |  |  |  |  |
|  | Jeff Konieczny | 4.5.2.1 |  | I agree that recertification is important to ensure competency of RSO's. If recertification is required, it would be a good idea to provide the RSO's with links and references to the study material well in advance. |  |  |  |  |
|  | Tara Hargreaves | 4.2.3.1 |  | With regards to providing a “description of any proposed weekly or per-shift radiation dose limits to be imposed, and the policy for verifying these doses”, it should be understood that some facilities operate in such a way that personnel do not receive a measurable dose. It is hoped that this would not increase the administrative burden on these facilities and that an annual action level would suffice. If personnel already wear dosimeters from a licensed service provider and do not receive any significant dose, it would not make sense to have any additional limits or dose verification. This should only be required as necessary, depending on the facility and the risk. |  |  |  |  |
|  | Tara Hargreaves | 4.5.2.1 |  | The necessity of recertifying Class II RSOs is questionable. While it is agreed that many duties can be of a dynamic nature, many things are slow to change. Equipment is used for decades and regulations are updated infrequently.The Class II RSO also shows continued competence in many ways: during inspections by CNSC inspectors, at the time of licence renewals, when submitting ACRs, by completing refresher training or other maintenance of knowledge and skills. Recertification could be required should a deficiency or non-compliance be found, rather than adding an expiry to the certification.It would be very important to consider the frequency of recertification, the method of recertification, and contingencies should a certified Class II RSO fail recertification. This should not add unnecessary administrative burden on licensees that show a good level of compliance.The rational for adding a recertification requirement for Class II RSOs should be carefully considered. If there is not a solid reason for needing the recertification, then it should not be required. To maintain up-to-date records of certified RSOs, some sort of renewal could be considered, a check-in to verify information and that the RSO is still active. The method and frequency of recertification can only be suggested when the reason for requiring recertification is known. Perhaps other qualifications that must be maintained, such as the professional designation from the CRPA, could stand in for a recertification with the CNSC. Potential stress and burden on individuals and organizations must be carefully considered when implementing any further requirements. Hazard level of the equipment/facility and compliance rating for the licence could also be considered when determining the need for recertification. |  |  |  |  |
|  | Tara Hargreaves | 4.6.1.1 |  | Removing the relationship between record retention and licence expiry is fully supported. This is a confusing way to measure record retention periods. It is hoped that this will be changed in the other regulations as well. |  |  |  |  |
|  | Tara Hargreaves | General Comment |  | The move towards less prescriptive regulations is welcomed. This allows flexibility for situations that may not fit well with overly prescriptive regulations. |  |  |  |  |
|  | Peter McGhee | Main body |  | Overall the initiative and intent of proposed changes is most appropriate and welcomed. Further responses are in support of several points of concern already identified by others. |  |  |  |  |
|  | Peter McGhee | 4.2.2.6 |  | Given the typical expected lifetime of Class II equipment there are very likely details that may not be specifically available when establishing the decommissioning plan. For example, there are different approaches offered by a variety of vendors that may be engaged at the time of actual decommissioning, so provision of that level of detail at the time of installation is unlikely to be possible. As currently presented, level of detail that may be introduced is unclear. |  |  |  |  |
|  | Peter McGhee | 4.4.2.5 |  | Ostensibly, perhaps, patient viewing systems do not fall under the purview of the CNSC but in practice it is a particularly grey area. Operating a treatment unit without a viewing system is fundamentally a bad idea with regard to safety and these systems are often used for other purposes, such as verification of the functionality of in-room warning indicators or simply as a secondary measure to ensure that no one is inadvertently in the treatment suite when radiation is being produced. Having systems in place that ensure or bolster safety for anyone proximal to operation of licensed equipment should be considered a requirement given that safety is an underlying principle that guides the CNSC in the development of regulations; the requirement should remain. |  |  |  |  |
|  | Peter McGhee | 4.5.2.1 |  | A review and assessment of ongoing competency is always a good idea and certified RSOs should not be exempted from such a process. Given that licensed facilities are subjected to routine inspections, would it not be more reasonable to incorporate a specific assessment of the responsible RSO into that process? Ongoing renewal of certification after a set period seems overly cumbersome. Moreover, how is the situation where an RSO loses certification to be handled, i.e., what would be the consequences? In the extreme, would it mean immediate suspension of operations? A more reasonable approach may simply be to, outside of exceptional situations, identify inadequate performance of a certified RSO to fulfil responsibilities during a routine inspection. The consequence would then be a Notice of Noncompliance that would need to be addressed by the licensee. Given the frequency of such inspections, a reasonable measure of maintenance of competency should be realized. |  |  |  |  |
|  | Lesley Buckley | 4.2.2.6 |  | Additional requirement to provide the proposed method of disposing of the the CII PE within the construction license - Any change of this nature needs to recognize that very often the lifetime of the CII equipment is more than a decade, so there should not be an expectation that any great amount of detail could be provided at the time of the construction license. |  |  |  |  |
|  | Lesley Buckley | 4.2.3.4 |  | Same comment as 4.2.2.6 |  |  |  |  |
|  | Lesley Buckley | 4.4.2.2 |  | I agree with this change as it facilitates taking reasonable temporary precautions without delaying operation and without compromising safety |  |  |  |  |
|  | Lesley Buckley | 4.4.2.5 |  | I disagree with the removal of the requirement for a viewing system. While this system is used for patient treatments in some cases, it also plays an important radiation safety role during beam operation and most centres instruct staff that for radiation safety purposes they must always operate with the viewing system on, even during service or commissioning work. Within a radiation therapy setting, no centre would remove these systems for patient treatments. However, having clear regulations requiring these systems as part of the radiation safety system ensures that centres are able to install these system from the first beam on and that they will form an integral part of the safety systems. They also facilitate greater frequency of verifying the functionality of the in-room safety systems and their removal could lead to proposals for a reduced frequency of testing of other safety systems since daily testing would not, in the absence of a viewing system, be reasonable. If they desire is to remove this requirement for some CII facilities, perhaps this could make use of the proposed definition of 'medical accelerator' (4.1.1.2) and keep this requirement for those settings. |  |  |  |  |
|  | Lesley Buckley | 4.5.2.1 |  | I agree in principle with the periodic expiry of RSO certificates which is in line with other professional certifications. Perhaps 'renewal' rather than 'recertification' is a more appropriate approach. For RSOs carrying licenses that have had successful audits, active licensing and that have remained compliant, this may be sufficient for a renewal of the certificate. Performance based renewal would be more effective than an exam based recertification. The exam will confirm the base knowledge required to carry out the RSO role but will not give information about how well the individual performs in the role so repeating this process will not give the CNSC any additional information about the individual. I would encourage the CNSC to add more detail to the type I inspections that focusses specifically on the RSO performance. This would allow for more targeted feedback, or direct suggestions for performance improvement. Although the evaluation of the RSO performance is subjective, the CNSC already takes a similar approach when looking at safety culture of licensees. 4.5.2.2 I agree completely. Equipment changes, new programs are added and the list of licensed activities on the RSO certificate is sometimes overlooked. A simple amendment process would reduce the administrative overhead for both parties. |  |  |  |  |
|  | Lesley Buckley | 4.6.1.1 |  | I agree with this proposal and think that linking the record retention to the removal from service makes far more sense than tying it to a license that may be renewed so frequently that it never actually expires. |  |  |  |  |
|  | Debbie Frattinger Sylvia Fedoruk Canadian Centre for Nuclear Innovation Inc | 4.2.4.1 |  | I am opposed to this proposal. Over the years of cyclotron operation the operator(s) and RSO become well versed in the mechanics of the cyclotron. They gain a wealth of knowledge. Therefore, there is no rational why they cannot decommission a cyclotron. It will not be operational going forward. The same procedure will be followed for decommissioning any other facility (not sure about power plants) which the licensee can complete on their own. Furthermore, if the licensee is responsible to ensure the decommissioning activities are completed correctly I would assume they are capable to complete the task then, if they wish. Requiring a valid CNSC servicing licence company to complete the task is an undue expense to the licensee. I personally decommissioned the Saskatchewan Accelerator Laboratory site before it could become the Canadian Light Source saving the University $2.5M if we had to hire it out. |  |  |  |  |
|  | Debbie Frattinger Sylvia Fedoruk Canadian Centre for Nuclear Innovation Inc | 4.5.2.1 |  | I am opposed to this proposal. Instead of having the RSO write another exam, I would like to recommend the CNSC collaborate with the CRPA (R) program where RSO’s have to show evidence of relevant continuing education. An initial exam is written, then in order to remain a certified RSO the person needs to maintain credits to ensure their status. There is a list of criteria provided under the program. I believe if CNSC wished to add to this list it would definitely be considered. Working together will harmonize the two requirements and increase the value of a CRPA (R). |  |  |  |  |
|  | Kellie FranzShared Health | 4.2.4.1 |  | I am opposed to this proposal. There will be unnecessary expense(s) to licensees. Eachlicensee is qualified to perform or supervise decommissioning of their own facilities.Potentially having to hire someone with a CNSC servicing licence would add the burden of . |  |  |  |  |
|  | Kellie FranzShared Health | 4.5.2.1 |  | I am opposed to this proposal. This could cause undue stress to an RSO, additional costs to a licensee and further administrative burden to the Class II project officers who would now have to enforce and maintain these certificates as they expire.Class II RSOs are already chosen for the position based on their education and experience. Some facilities also invest significantly in additional radiation safety courses to ensure that their RSO has all of the tools necessary to be effective. CNSC assesses these individuals via review of their education as well as administration of an exam prior to certifying them.Provided the certified Class II RSO remains in their current role/department, there should not be a need to re-certify as they have been actively gaining experience through performing their job and undergoing CNSC inspections. The certification is already nontransferable and the individual would have to be certified for each new site or piece of equipment added to their responsibilities. The CNSC inspection process also already acts as a form of reassessment of these individuals and the CNSC maintains the right to revoke a certification if they feel that something is lacking. |  |  |  |  |
|  | Julio Panama | 4.5 |  | I think before any further progress on this proposed changed continues, the change should be clearly defined. Questions such as what will be the recertification period? what would be the recertification process? Need to be defined to avoid confusion. As a general statement such as the one defined in the proposed changes I think recertification of the RSO is unnecessary and only adding regulatory burden. In a short period of time (3 to 5 years) the radiation safety program for which the RSO is responsible to maintain and enforce is audited 2 sometimes even 3 or more times by the CNSC, such inspections should address any deficiencies in the radiation safety program and such in the RSO. I think it would be much better use of time and resources if the CNSC amended section 4.5.2 to include a requirement for minimum education hours in a period of time for the RSO. This would help the RSO to maintain the high level of competency required to manage the radiation safety program. |  |  |  |  |
|  | General Fusion |  |  | Fusion is mentioned in the definition of ***nuclear facility*** in the *Nuclear Safety and Control Act* (NSCA) and covered by the *Class I nuclear facilities regulations*. This leads General fusion to identify three (3) important points:* Fusion machines are defined as Class I Nuclear Facilities Regulations despite of the intrinsic low radiological risk of modern fusion technologies compared to fission Nuclear Power Plants (NPPs). The evidence available at the time the CNSC developed the *Class I Nuclear Facilities Regulations* (2000) was exclusively for ITER-scale or larger devices with specific sets of radiological risk assumptions. Technology has advanced since then, while this literature at the time dealt with situations dominated by the size and choices of a single science-based device being pursued by a non-commercial international organization - ITER. None of the private companies in North America, including General Fusion, are planning to build ITER or machines of this scale.
* The *Class I Nuclear Facilities Regulations* makes fusion machines captive of a regulatory regime dedicated to nuclear “fission” power plants which could lead to considerable efforts for justifying exceptions and supporting engineering judgements.
* The Class II Regulations (equivalent to 10 CFR Part 30 in the USA for which the USNRC is leaning toward for regulating fusion machines as reiterated on the USNRC public meeting on this topic held on November 8th, 2022) is more appropriate for the level of radiological risks involved with fusion machines.

General Fusion would like the CNSC to consider taking advantage of this infrequent but timely opportunity to clarify that fusion technologies are included in the scope of the C2NFPER, given the need for a regulatory approach commensurate with the low radiological risks of new and emerging fusion technologies in North America.By doing so, the CNSC would demonstrate that its actions respond to the new Cabinet Directive on Regulations that came into effect in September 2018 to foster an agile regulatory system that is predictable, efficient, and consistent and builds on the government's commitment to modernize our regulatory framework with a focus on supporting innovation. Such an approach is urgently needed to address the rapid pace of evolution of fusion technologies and commercial goals that are now accompanied by robust funding, clear programs, and well-supported timelines.This approach would be consistent with the goals of harmonizing CNSC and USNRC regulatory regimes and would foster the emergence of innovative fusion energy technologies to meet the targets associated with the emergence of a promising and innovative "net-zero" clean energy technologies.The low radiological risks presented by General Fusion’s technology—tritium management, radiation produced during operations, and low-level waste—are well understood and have been regulated under CNSC’s regulatory framework in relation to other technologies for decades (e.g., particle accelerators).The *C2NFPER* approach would more closely align fusion to similar technologies regulated by the CNSC, including particle accelerators, industrial radiography devices, and irradiators. The CNSC’s experience safely regulating these technologies and their related hazards shows that C2NFPER is fully capable of ensuring adequate protection of public health and safety.The *C2NFPER* is also the best approach to support the emerging fusion industry. Its specific licensing process is well understood and would thus provide near-term regulatory certainty needed by General Fusion and its investors. General Fusion plans to complete the conceptual design of its first commercial pilot plant within the next few years, and the *C2NFPER* would allow General Fusion to design this pilot plant to an established regulatory framework, avoiding unnecessary delays created by new regulations.Some key consideration in this regard:* Fusion energy machines do not easily fall under the *Class I Nuclear Facilities Regulations* given the definitions and conceptual approaches are inherently focused on fission reactors. Fusion uses a fundamentally different atomic process from fission, and as such, fusion machines present a completely different risk profile. Fusion does not use special nuclear material or source material and does not create risk for criticality accidents, decay heat removal or high-level radioactive wastes.
* The *C2NFPER* should be used as is and as a basis of safety analyses fort the first fusion machines to enter the commercial market in Canada and should be reviewed when adequate operational experience (OPEX) allows for an informed review and optimal adjustments, if necessary.
* All the fundamental, technologically neutral conceptual and methodological approaches (e.g., hierarchical structure of safety goals, defense in depth, the fundamental principles of justification and optimization for radiation protection) are provided in the current CNSC framework allowing it to properly assess the safety case for fusion technologies without making any changes to the framework. Developing new fusion-specific regulations would be a perilous and unsustainable journey in the absence of the OPEX that is necessary to determine how such regulations could best facilitate fusion facility licensing and regulation.
* This approach has already been used by the US NRC with Part 36 for irradiators, which was developed after decades of irradiator operation around the world to gain the operational experience necessary for a robust regulatory framework, and it took two years after that time to finalize this part of 10 CFR.
* While keeping the focus on the *C2NFPER* and avoiding the development of new regulatory content or expansion of existing content (which would be counterproductive, costly, and time consuming given the lack of sufficient OPEX with fusion technologies), General Fusion believes it is to the advantage of the industry and the CNSC to open the lines of communication earlier than usual for pre-licensing initiatives for fusion technologies ready to engage in safety case discussions. This creates an early exchange between industry and regulators on conceptual designs, allows this relationship to evolve and mature over time, and allows for the inclusion of safety feature considerations early in the process. This early engagement will be supportive of paving the way for a more formal licensing process as the design matures.
* As the design of our commercial fusion pilot plant is still in development and the operating procedures will follow, the safety approach must include appropriate methods, usable despite the lack of operational experience on components, systems, and procedures. Such approaches exist and can be used in early (pre-licensing) discussion with the CNSC to confirm that fundamental safety principles are integrated in the finalization of the design.
* General Fusion strongly believes that the approach that will be the most efficient to optimize rapid emergence of commercial fusion plants in Canada is early industry-regulator interface for performing safety case analysis on conceptual design elements. This approach can influence the direction of the concept and ultimately the design development from its earliest stages by giving useful feedback and guidance to the designer to achieve a safety that is “built in” rather than “added on”.
* A topic of discussion on this front (early industry – regulator interface for pre-licensing efforts) is the optimal Tritium Breeding Ratio (TBR) which greatly depends on the performance of many structures, systems and components of the fusion machine and the tritium extraction/removal systems.
* To optimize waste reduction for the decommissioning phase, General Fusion will be prepared to discuss optimal alloy choices so that all activated materials meet the standards for low-level waste. We anticipate that the activated materials will be all classified as low-level waste. No waste will be classified as high-level waste since no special nuclear materials or source materials are used.
 |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.1 | Commentaires sur les suggestions de modifications relatives à l’interprétation et aux définitions | Nous sommes favorables à l’ajout d’une définition spécifique pour les accélérateurs médicaux et nous croyons que celle-ci permettra de tenir compte des particularités des milieux cliniques. Nous nous demandons toutefois si les milieux d’enseignement clinique comme le cégep de Ste-Foy seront inclus dans cette définition. Bien qu’ils ne s’agissent pas d’un milieu clinique, le type d’équipement est le même et les caractéristiques d’ouverture du milieu y sont semblables. Nous sommes d’accord avec la nouvelle définition d’installation de catégorie II, mais nous sommes d’avis que la notion d’ancrage devrait être plus élaborée dans le règlement. Quelle est l’intention du règlement : assurer la présence d’une barrière physique ou distinguer les équipements qui sont utilisés exclusivement à l’intérieur d’une salle blindée? Il faut éviter que la définition n’induise de la confusion.Nous sommes également favorables aux modifications permettant d’assujettir les appareils de protonthérapie aux mêmes exigences de réglementation pour que les autres équipements de catégorie II afin d’avoir une uniformité des exigences pour les appareils à visée médicale. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.2.2.1 |  | Nous sommes favorables à la modificationproposée puisqu’il s’agit selon nous d’une bonnepratique et que celle-ci est déjà d’usage pour lacuriethérapie. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.2.2.2 |  | Nous sommes favorables à cette propositionet nous partageons l’avis de la CCSN selonlequel cette information n’est pas utile auxfins d’évaluation des blindages proposés. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.2.2.3 |  | 3 Nous partageons l’avis de la CCSN quantau fait que cette exigence est prématurée au moment de la demande de permis de construction et nous sommes donc en faveur de la modification proposée. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.2.2.4 |  | Nous sommes en faveur de cet ajustement pour lever l’ambiguïté et aligner le règlement sur les pratiques actuelles. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.2.2.6 |  | Nous sommes favorables à la logiqued’encadrement « du berceau au tombeau », maisnous jugeons peu utile d’exiger le dépôt d’unplan concret d’évacuation définitive puisquecelui-ci risque peu de se mettre en place tel quelau moment du démantèlement effectif. Nousnous demandons s’il ne serait pas plus efficacede demander un engagement de responsabilitéface aux besoins d’évacuation similaire à ce quise trouve dans le règlement sur les garantiesfinancières. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.2.3.1 |  | Nous sommes favorables à cette proposition. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.2.3.2 |  | Bien que favorables à la proposition, nous suggérons de retirer l’obligation d’un suivi hebdomadaire au profit d’un suivi annuel. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.2.3.3 |  | Nous sommes favorables à la modification durèglement pour inclure l'exigence pour lestitulaires de permis de se doter d’une procédurede test pour les éléments de sûreté.Nous sommes cependant inquiets de la référence directe aux fréquences et méthodes proposées par le TQC du PCQR et de la note en bas de page qui établiraient ces documents comme normes de facto puisque cette formulation n’inclut pas la souplesse que la CCSN semble vouloir promouvoir. Les documents du PCQR reconnaissent d’ailleurs eux-mêmes la possibilité pour un centre de se doter de méthodes et de fréquences autres que celles recommandées dans certaines circonstances. L'approche laissant chaque responsable de permis libre de soumettre ce qu’il juge le plus adéquat compte tenu de son environnement et de ses équipements nous semble à privilégier.Dans le même ordre d’idées, nous partageons les préoccupations formulées par la compagnie Elekta dans le cadre du présent processus de révision et nous souhaiterions que la CCSN s’y montre sensible. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.2.3.4 |  | Nous sommes favorables à la logiqued’encadrement « du berceau au tombeau »,mais nous jugeons peu utile d’exiger le dépôtd’un plan concret d’évacuation définitivepuisque celui-ci risque peu de se mettre enplace tel quel au moment du démantèlementeffectif. Nous nous demandons s’il ne seraitpas plus efficace de demander un engagementde responsabilité face aux besoinsd’évacuation similaire à ce qui se trouve dansle règlement sur les garanties financières. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.2.4.1 |  | Nous sommes en accord avec la logique de la modification proposée, mais nous jugeons qu’il serait souhaitable que le niveau de permis d’entretien requis soit précisé. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.2.5.1 |  | La proposition nous semble pertinente et plus appropriée que les exigences actuelles. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.2.6.2 |  | Nous partageons l’avis de la CCSN quand à la pertinence de prévoir une exemption pour ces activités. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.3.2 |  | Le présent document (DIS-22-01) propose, au paragraphe 4.4.2.3, l’ajout d’une exigence obligeant les titulaires de permis à mettre régulièrement à l’essai tous les systèmes de sûreté installés. Or, pour le circuit d’arrêt d’urgence et les boutons d’arrêts d’urgence, plusieurs manufacturiers indiquent que la méthode recommandée par la CCSN peut causer des dommages aux appareils de traitement. Ainsi, si la CCSN entend mettre de l’avant sa proposition au paragraphe 4.4.2.3, elle devrait préalablement revoir son processus d’homologation afin d’exiger que les manufacturiers déposent, pour chaque éléments de sécurité, une procédure permettant de le tester sans endommager l’équipement. L’ajout d’un alinéa sous l’article 11 (1) pourrait être opportun à cette fin. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.3.2.2 |  | 2 Nous sommes favorables à la mise en place de cette exigence et même surpris de savoir qu’elle ne faisait pas déjà parti de la réglementation. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.4.1 |  | Nous sommes en faveur de l’approche proposée. Nous croyons qu’elle permettra une plus grande flexibilité pour planifier les éléments de sûreté les plus appropriés à chaque installation. Nous voyons également d’un bon œil l’ajout d’un REGDOC pour suggérer des manières de répondre aux exigences en matière de radioprotection. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.4.1.1 |  | Nous nous demandons si la liste d’exigencesprésentées est complète et exhaustive. Si c’est lecas, nous pensons important de souligner qu’uneexigence relative à la présence d’un circuitd’arrêt d’urgence devrait être ajoutée de mêmequ’une autre relative à la détectionindépendante du rayonnement dans les salles decuriethérapie.Nous soulignons également que l’exigence suivante :* une méthode doit être en place pour déterminer si la zone contrôlée est sous rayonnement, et pour afficher cet état tant à l’intérieur qu’à l’extérieur de la zone définie

entrainera des coûts de mise aux normes pour certains établissements si elle s’applique à toutes les installations nucléaires de catégorie II. En effet, il n’existe actuellement aucune exigence d’afficher l’état à l’intérieur de la zone contrôlée d’un accélérateur linéaire médical. Nous sommes néanmoins favorables à cet ajout pour la sécurité du personnel. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.4.2.1 |  | Nous sommes favorables à cette proposition. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.4.2.2 |  | Nous sommes favorables à la mise en place de cette exigence. Nous croyons que cela règlera certains problèmes d’exploitation et permettra d’éviter que la réflexion sur les solutions de rechange raisonnables soit faite dans l’urgence au moment de la défaillance d’un système de sûreté. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.4.2.3 |  | Nous sommes d’accord avec l’ajout d’uneexigence obligeant une mise à l’essai deséléments de sûreté. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.4.2.5 |  | Nous sommes d’accord avec la logique quisous-tend le retrait de cette exigence. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.5.1.1 |  | Nous sommes en faveur de ces deuxpropositions car il s’agissait de lacunes de laréglementation à notre avis. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.5.2.1 |  | Considérant que les inspections fréquentesdonnent déjà la possibilité à la CCSNd’évaluer que les compétences et lesconnaissances du RRP restent pertinentes et àjour et que le règlement actuel donne déjà lapossibilité de retirer l’accréditation si ce n’estpas le cas, le renouvellement d’accréditationsemble superflu. Nous serions plutôtfavorables à l’ajout d’exigences relatives à laformation continue et à l’élargissement del’exigence d’accréditation aux permis desubstances nucléaires et appareils àrayonnement tel que les départements de médecine nucléaire. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.5..2.2 |  | Nous sommes d’accord avec cette propositionqui permettra d’alléger le processusadministratif. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.6.1.1 |  | Nous sommes d’accord avec la proposition delier la conservation à la fin de vie del’équipement plutôt qu’à la durée du permis. |  |  |  |  |
|  | Association québécoise des physicien(ne)s médicaux cliniques (AQPMC) | 4.6.2.1 |  | Nous sommes favorables avec cette proposition qui vient consolider ce qui est déjà fait sur le terrain. |  |  |  |  |
|  | Jeff DovyakShared HealthManitoba | 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.It is gratifying to see that I am not the only Radiation Safety professional who opposes this proposed amendment. The points raised by Ms Franz, Ms Frattinger and Mr Beniston as well as McMaster University and Mr Arnaldo with Ontario Tech University (OUT) particularly resonate with me. |  |  |  |  |
|  | Jeff DovyakShared HealthManitoba | 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.Again I’m glad to see that I’m not the only one who opposes this proposed amendment. Comments from Dr Galea, Mr Hardy, Ms Franz, Ms Hargraves, Ms Frattinger, Ms Dombrosky and Mr Beniston as well as McMaster University, University Health Network and Mr Arnaldo with OTU again resonate with me. I should also say Dr Buckley’s comments here regarding ‘renewal’ vs ‘re-certification’ are well thought out. |  |  |  |  |