Public Consultation
REGDOC-1.6.2, Radiation Protection Programs for Nuclear Substances and Radiation Devices Licences
November 18, 2019 - June 12, 2020
e-Doc 6047666

Comments received from public consultation / Commentaires reçus dans le cadre du processus de consultation

Comments received:
• during first round (November 18, 2019 to January 31, 2020): 112 comments from 14 reviewers
• during feedback period (May 28 to June 12, 2020): 39 comments from 3 reviewers

Commentaires reçus :
• lors de la première période (18 novembre 2019 au 31 janvier 2020) : 112 commentaires reçus de 14 examinateurs
• lors de la période des observations (28 mai au 12 juin 2020) : 39 commentaires reçus de 3 examinateurs

Table A: Comments on the "Request for Information" that was included for comment with the draft document:

No comments were received.

Table B: Comments received on the draft document

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
1.	Radioprotection Inc.	Général	**Introduction** Radioprotection Inc. apprécie l'opportunité de commenter ce sujet primordial à la radioprotection appliquée en milieu de travail tant institutionnel qu'industriel. Nous vous partageons nos commentaires comme titulaire de permis de la Commission canadienne de sûreté nucléaire et comme consultant actif en radioprotection depuis plus de 37 ans au Canada avec une équipe de 5 physiciens en radioprotection et deux ingénieurs-physiciens. Nous avons pris cet exercice de révision et de questionnement à coeur, car nous avons déjà été responsables de la radioprotection (RRP) d'un programme complexe de radioprotection pendant 16 ans, nous sommes aussi toujours RRP pour des programmes de radioprotection variés. Nous avons formé plus de 700 responsables de la radioprotection au cours de nos années d'existence et devrons en former bien d'autres. Nous aidons bon nombre de titulaires de permis à répondre aux exigences règlementaires de la CCSN. Nous sommes également actifs en radioprotection des rayons X. et le fait que la source de photon soit différente ne change pas l'approche	Suite à ce commentaire, le document a été révisé afin de clarifier l'utilisation du terme "efficace".

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			d'un programme de radioprotection efficace. **Appréciation générale du document** Le document REGDOC-1.6.2 aidera certainement les responsables de la radioprotection (RRP) et les titulaires de permis de la CCSN à mieux comprendre le rôle d'un programme de radioprotection (PRP) et surtout de l'appliquer de concert avec leurs autres responsabilités. Ce document est nécessaire, car justement les RRP qui investissent 100% de leur temps aux activités du PRP sont une minorité et l'efficacité du programme est alors un élément essentiel du succès du PRP et du RRP. Nous apprécions ce document qui témoigne d'une bonne volonté de la CCSN, comme organisme règlementaire, d'augmenter le niveau des programmes de ses titulaires de permis. L'approche de consultation et le partage détaillé des attentes doivent être soulignés, car l'investissement dans cette approche rapportera du point de vue conformité, si les attentes sont claires et comprises de toutes et surtout, si chaque partie prenante a l'occasion d'y ajouter son point de vue. Nous ajoutons notre contribution de façon générale et par la suite, nous vous détaillerons certains éléments dans le document spécifiquement. **Caractère efficace du programme de radioprotection** Le caractère « efficace » d'un PRP n'est pas défini dans REGDOC-1.6.2. Même dans la section « 1.1 Objet » on ne mentionne pas le caractère « efficace » d'un PRP comme le titre du document l'annonce et la « section 1 : introduction » n'en parle pas. On doit attendre en section 4. Cette omission ne permet donc pas de qualifier ce qu'est un PRP efficace. À quoi juge-t-on l'efficacité du PRP ? Nous espérons que la réponse n'est pas dans la conformité uniquement. Nous recommandons plutôt de lier l'efficacité du PRP aux atteintes des principes de bases de la radioprotection tels que définis par la CIPR : la justification, l'optimisation et la limitation. Bien que la CCSN a inclus dans sa législation, le concept d'optimisation (ALARA), il serait bon de revenir aux autres	

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			concepts et d'établir une certaine hiérarchie des approches, la justification en premier et la limitation en toute fin. À la section 4, il semble y avoir des pistes de définition. Nous comprenons de façon assez fondamentale, que pour un organisme règlementaire, un PRP efficace répond à sa législation. Mais comme nous le savons, la législation est souvent en retard sur les bonnes pratiques et surtout, la législation au Canada comporte un obstacle de plus : les juridictions fédérales et provinciales. Nous proposons que le PRP efficace soit un PRP en évolution constante, qui utilise les meilleures pratiques existantes, qui est questionné par les travailleurs (au sens de la CCSN), les parties prenantes incluant bien sûr, tous les organismes de réglementation en santé-sécurité (pas seulement la CCSN). Le PRP efficace doit permettre aux travailleurs de réaliser leurs tâches en toute sécurité et aussi en conformité. Il importe aussi de mentionner que le PRP efficace passe par la communication et la transparence (voir le point sur la communication).	
2.	Radioprotection Inc.	Général	**Caractère complexe d'un PRP** Dans le même ordre d'idée que la définition du caractère efficace, dans la section « 1.2 Portée » on parle de PRP complexe. Il n'est pas clair pour le lecteur de ce qu'est un PRP complexe. Est-ce le fait que l'on a besoin d'un comité de radioprotection (annexe B mise en référence) ? Est-ce le fait que l'on a plusieurs emplacements, un permis consolidé ou plusieurs permis pour une même organisation ou emplacement ? Incluons-nous le type de risque, modéré à élevé ? Est-ce le cumul des points exprimés par les puces à la section 1.2 ou un ou plusieurs de ces points ? Nous comprenons qu'un permis consolidé puisse être complexe d'un point de vue gestion ou de par la nature même de l'autorisation règlementaire, comme un permis de catégorie II, mais nous avons constaté qu'un permis de jauges portatives touchant plusieurs sites peut s'avérer tout aussi complexe selon la perspective d'exposition, de contrôle des sources, d'interaction avec le public et de conformité. La procédure de gestion des entrées en espace clos présentant des jauges nucléaires est devenue, depuis l'accident de 2014, très complexe tout comme le maintien d'un périmètre de sécurité de gammagraphie industrielle. À cette complexité s'ajoute le fait que les RRP des permis consolidés ou ceux de catégorie II sont souvent plus expérimentés,	Suite à ce commentaire, le texte de la section 1.2 a été révisé afin de clarifier ce que la CCSN considère pour déterminer si un PRP est complexe ou non.

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			ils sont même testés (catégorie II) et peuvent avoir une formation académique et professionnelle en lien direct avec leurs fonctions, contrairement à bien des RRP dont les applications utilisent les substances nucléaires comme on utilise un autre marteau ou tourne-vis. On se rappelle ici que l'on peut se blesser avec des outils de base dont l'utilisation est banalisée. Nous pensons qu'il faudrait donner des exemples concrets de programmes complexes et inclure le plus de titulaires de permis possible dans la portée de ce document puisque l'efficacité du PRP touche et influence tous les programmes. Les intentions de la CCSN avec ce document ne sont pas claires en ce qui concerne l'inclusion des titulaires de permis.	
3.	Radioprotection Inc.	Général	**Le rôle du responsable de la demande** Une autre omission importante à notre avis touche le responsable de la demande et son rôle dans l'atteinte du PRP efficace. On ne définit pas assez son rôle et son interaction dans la section « 2. Responsabilité », surtout que par la suite, on lui attribue différentes responsabilités (section 3.1, et 5.2.3). Le rôle du responsable de la demande, qui devrait s'appeler, selon d'autres documents récents de la CCSN, « le mandataire du demandeur et du titulaire de permis » devrait clairement être lié à la culture de sécurité explicitée en 5.1. La problématique que nous observons dans certains programmes de radioprotection (corroboré par la récente évaluation de la CCSN sur le rôle du RRP) ne touche pas directement le RRP qui est assez encadré par la CCSN, mais concerne un manque d'appui de la part du responsable de la demande qui parfois, ne connaît pas assez l'étendu et la portée du PRP du titulaire de permis qu'il représente. La CCSN devrait, dans cette section, promouvoir des exemples de comportement souhaitables de la part des responsables de la demande sur qui l'efficacité du PRP complexe repose par les moyens (temps et ressources) qu'il ou elle attribuera au RRP dans ses fonctions quotidiennes.	Suite à ce commentaire, le document a été révisé pour utiliser le titre « mandataire du demandeur». Puisque nous ne répétons pas le contenu des autres REGDOCs, nous avons fait un résumé du rôle et des responsabilités du mandataire du demandeur et indiqué à quel endroit le lecteur peut obtenir davantage d'informations à ce sujet (REGDOC-1.6.1, *Guide de présentation d'une demande de permis : Substances nucléaires et appareils à rayonnement*).
4.	Radioprotection Inc.	Général	**Communication et comparaison à la santé-sécurité** Le point précédent révèle une dernière omission du document REGDOC-1.6.2 : Le volet de la communication. Le PRP est avant tout un programme spécialisé de santé-sécurité au travail. Par conséquent, son efficacité et son succès tiendront du	Suite à ce commentaire, le document a été révisé afin d'ajouter le concept des communications.

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			fait qu'il doit être bien communiqué et compris par toutes les parties intéressées du PRP. La section 2 doit préciser une responsabilité de communication du programme, des utilisateurs (travailleurs au sens de la CCSN) au mandataire du titulaire de permis en passant par le ou les RRP. Il serait intéressant pour la CCSN de reconnaître cet élément, de recommander la tenue de petites réunions de sécurité quotidiennes en radioprotection comme on le fait dans d'autres domaines, de recommander aussi l'intégration de certaines procédures de radioprotection aux procédures générales. Le port de gants est aussi requis pour la protection face à d'autres agents (chimiques, biologiques), la procédure de cadenassage s'applique autant aux jauges nucléaires fixes qu'à un moteur de réservoir de mélange. Nous observons que les industries qui utilisent une approche holistique à la santé-sécurité (radioprotection comme un des nombreux facteurs de risques et application du programme selon la nature et l'importance du risque) semblent parvenir à une meilleure compréhension et application du PRP complexe chez les travailleurs que les industries qui fonctionnent en silo (santé-sécurité générale vs radioprotection). Nous ne pouvons nous prononcer clairement sur les institutions de santé, mais pensons que la même approche pourrait s'appliquer, car nous observons aussi des silos dans ces institutions. Le point de la communication est d'autant plus important que la CCSN dans ce document REGDOC-1.6.2 rappelle le concept de la culture de sûreté qui ne peut exister sans une communication efficace de la direction aux travailleurs et des travailleurs à la direction, sans compter que la CCSN s'attend dans un PRP, à une « …maitrise des méthodes de travail par la direction… » (Règlement sur la radioprotection). Pour ces raisons, une définition plus précise des attentes de la CCSN face à un responsable de la demande et les approches de communications « efficace » sont des éléments à renforcer dans le document REGDOC-1.6.2.	
5.	Radioprotection Inc.	Général	**Conclusion** Nous avons offert nos commentaires basés sur l'expérience de terrain, les observations, la participation à des groupes de travail et au moins 24 ans en gestion de programmes de radioprotection. Le document que la CCSN a demandé de commenter sera une source de renseignements importante pour les titulaires de	Suite à ce commentaire, une référence au document *Trousse de bienvenue : mandataire du demandeur, Permis de substances nucléaires et d'appareils à rayonnement* a été ajoutée. Ce nouveau document offre de l'orientation aux mandataires du pour déterminer les ressources qui sont nécessaires au RRP pour accomplir ses

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			permis, les responsables de la demande et les RRP. Le REGDOC -1.6.2 compréhensif pourrait devenir aussi pratique que le REGDOC-1.6.1 l'est pour les titulaires de permis et les RRP. Nous espérons que les commentaires reçus par la CCSN seront aussi nombreux que diversifiés, car ce sujet est fondamental, le PRP « efficace », soutenu par un RRP compétent sont les pierres angulaires des performances d'un titulaire de permis et un gage de sécurité pour toutes les parties prenantes. Le plus récent *Rapport de surveillance règlementaire* de la CCSN (ébauche, octobre 2019) faisait état d'une baisse marquée des performances de certains programmes institutionnels et industriels. Nous croyons que dans les années 20, le défi sera justement d'adopter un programme efficace en radioprotection pouvant concilier les exigences règlementaires et les exigences opérationnelles des titulaires de permis en tenant compte de la réalité des ressources humaines et financières plus rares. En publiant un document clair et précis, en énumérant des exigences ou des attentes sans ambiguïté basées sur des échanges avec des titulaires de permis, la CCSN aidera sûrement les titulaires de permis et les travailleurs à réaliser l'objectif commun de travailler de façon sécuritaire et optimale avec les substances nucléaires. C'est avec cet objectif en tête que nous vous avons proposé ces commentaires.	tâches.
6.	Radiation Safety Program - Diagnostic Services	General	Thank you for the opportunity to comment on this draft REGDOC. This document seems to be a mix of absolute requirements vs small "g" guidance.	As a result of this comment, the document was revised for clarity and all references to 'must' have been changed to 'shall'.. This document provides guidance only. The use of "shall" refers to requirements expressed in the *Radiation Protection Regulations*, the *Nuclear Substances and Radiation Devices Regulations* and REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices*.
7.	Alberta Health Services	General	Thank you for the opportunity to provide feedback on the draft REGDOC-1.6.2, *Developing and Implementing an Effective Radiation Protection Program for Nuclear Substances and Radiation Devices Licences* published November 2019. Observations, comments, and request for clarification on the document have been	Comment noted. This was an oversight on our behalf.

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			collected in Attachment A. One item I would like to raise immediately is the missing "draft or consultative copy" notice on the documents cover that has appeared on previous REGDOC drafts. Other than the lack of catalogue number on the inside first page of the document, there is no mention that it is a proposed copy for consultation. Clearly communicating the 'draft' nature of the document is important to avoid confusion in both the present and the future as to the official status of the REGDOC. Our organization supports the CNSC's work in producing guidance documents such as REGDOC 1.6.2. I hope that this feedback helps in its continued development. If you require further information or have any questions regarding the submission, please do not hesitate to contact me.	
8.	Cameco	General	Cameco Corporation (Cameco) has reviewed and prepared the following comments on the draft REGDOC-1.6.2, *Developing and Implementing an Effective Radiation Protection Program for Nuclear Substances and Radiation Devices Licences* (the REGDOC) for the Canadian Nuclear Safety Commission (CNSC). Cameco's two major concerns are the introduction of a reporting requirement in section 2 and the improper designation of safety culture as a component of a management system in section 5, both of which are discussed below.	Comment noted. CNSC staff responses can be found below.
9.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick	Preface	**Industry Issue (MAJOR)** Licensees appreciate the effort to reduce verbiage by directing readers to *REGDOC-3.5.3, Regulatory Fundamentals* for information on a graded approach. However, users might benefit from a brief description of how a graded approach could apply to this specific REGDOC since it isn't immediately clear which types of licensees this draft is truly intended for.	As a result of this comment, the scope was revised to clarify who the document applies to.

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	Power, Ontario Power Generation		**Suggested Change** Draw language from REGDOC-3.5.3, to offer additional context. Amend to read, "Regulatory document REGDOC-1.6.2 … provides guidance to nuclear substances and radiation devices licensees and applicants on the development, implementation, management and assessment of their radiation protection programs. It applies to the full range of licensees, from operators of Class 1 nuclear facilities with well-established radiation protection programs, to new applicants seeking to use nuclear materials for medical, industrial or research purposes. Licensing and compliance activities related to REGDOC-1.6.2 will vary widely depending on the type of licenses already held or those being sought. This aligns with the CNSC's graded approach, which is driven primarily by an assessment of the risk associated with the activities being regulated and the performance history of the licensee. For information on the implementation of regulatory documents and ~~on~~ the graded approach, see REGDOC-3.5.3, Regulatory Fundamentals." **Impact on Industry** Insufficient context on a graded approach can make it difficult for licensees to interpret compliance expectations related specifically to their facility.	
10.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power	Preface	**Industry Issue (MAJOR)** As with other recent draft REGDOCs, this document uses the term "must" to express requirements. This is a departure from other nuclear standards, which traditionally use only "shall." It also uses "should," "may" and "can" to describe various levels of guidance, which inadvertently generates more confusion than clarity. **Suggested Change** Industry encourages the CNSC to only use "shall" statements to express requirements and "may" to discuss guidance in this and all other regulatory	As a result of this comment, the document was revised for clarity and all references to 'must' have been changed to 'shall'. This document provides guidance only. The use of "shall" refers to requirements expressed in the *Radiation Protection Regulations*, the *Nuclear Substances and Radiation Devices Regulations* and REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices*.

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	Generation		documents. **Impact on Industry** On its surface, the use of different words to express requirements or guidance appears inconsequential. It is not. Readers of recent draft REGDOCs have found it increasingly difficult to determine what is truly obligatory and what is optional.	
11.	Radioprotection Inc.	1 Introduction	Dernier paragraphe : « …les responsabilités du responsable de la radioprotection (RRP), qui est chargé de **superviser** le PRP. » 1) Nous proposons : « …qui est chargé de **gérer**… » Le RRP est beaucoup plus qu'un superviseur, il est le gestionnaire principal du PRP. 2) Nous vous proposons aussi de définir ici l'idée d'un PRP efficace dès cette section, en introduction, puisque c'est le titre du document. (voir les commentaires généraux précédents).	Suite à ce commentaire, les changements suivants ont été effectués : 1- Le texte a été changé tel que proposé. 2- Le document a été révisé afin de clarifier l'utilisation du terme "efficace".
12.	Radioprotection Inc.	1.1 Objet	Nous proposons d'ajouter le mot « **efficace** » à la fin de la phrase pour faire écho au titre du document.	Suite à ce commentaire, le document a été révisé afin de clarifier l'utilisation du terme "efficace".
13.	Radioprotection Inc.	1.2 Portée	Il manque un bout de phrase à la première phase, ou une ponctuation. Pas clair. SVP relire la phrase. Il faudrait clarifier ce qu'est un PRP complexe et donner des exemples clairs.	Suite à ce commentaire, le texte a été modifié afin de clarifier ce que la CCSN considère comme étant un PRP complexe. Lors de l'évaluation de la demande de permis, la CCSN déterminera si le RPR est complexe et en avisera le détenteur de permis.
14.	AM Inspection Ltd.	1.2 Scope 2nd paragraph	**Industry Issue (Major)** By including "multiple licensed locations" as criteria to determine when a RPP is "complex", the Regulator is equaling the requirements further established ahead in the REGDOC, for big organizations with many different locations in several	As a result of this comment, the scope was revised to clarify who the document applies to. The CNSC will determine if a program is complex or not during the

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			provinces, or small companies with a temporary or overnight parking location in the same province. **Suggested Change** "Characteristics of a complex program include, among others: • consolidated use of nuclear substances licence (use type 815) • multiple licensed locations depending on the organizational size and geographic disparity of sites • multiple licences issued at the same location • multiple licences issued for the same organization" **Impact on Industry** Small companies with geographically – concentrated operations will be unsustainably burdened with additional requirements mentioned ahead in the document, if their RPP is considered "complex".	licence application assessment and will inform licensees.
15.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power	1.2	**Industry Issue** The Scope could more explicitly say which types of licensees this document is intended to guide. If it is not truly meant for licensees with rigorous, site-wide licences, Certified Health Physicists and well-established Radiation Protection Programs, it should simply exempt them. Otherwise, it should overtly identify Class I licensees as those who may wish to consult the REGDOC for information. As currently written, the 2nd sentence grammatically implies that it is nuclear substances and radiation devises – not licensees – who may wish to consult the document for information. A slight edit is needed to correct the intent.	As a result of this comment, the scope was revised to clarify who the document applies to.

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	Generation		**Suggested Change** Amend the 2nd sentence to exempt Class 1 licensees. Otherwise, edit it to read, "Current operators of Class I facilities or uranium mines and mills with nuclear substances and radioactive devices licensed under other classes of licence meet the requirements for a radiation protection program. Given this, they may wish to consult this document for information."	
16.	Radioprotection Inc.	2 Responsabilités en matière de radioprotection	**1) Seconde phrase :** « Le responsable de la demande occupe… » ne devrait-on pas remplacer ce terme par « mandataire du demandeur ou du titulaire de permis comme la CCSN utilise maintenant dans certaines de ses publications pour référer au terme règlementaire officiel ? Sinon mentionner que pour faciliter le texte on utilise le terme connu « responsable de la demande ». **2) Second paragraphe :** « RRP est la désignation couramment attribuée à un **spécialiste de la radioprotection** qui administre un PRP au quotidien.» Est-ce que la CCSN a défini ce qu'est un « spécialiste de la radioprotection » ? Et quelles formation, certification et habiletés sont requises pour être un « spécialiste de la radioprotection» ? Certaines disciplines comme l'ingénierie encadrent l'emploi du terme « spécialiste ». Il semble que la CCSN avait en tête des PRP complexes bien précis pour parler de spécialiste. Nous observons que bien des RRP sont effectivement très qualifiés, mais bien peu peuvent prétendre au terme « spécialiste ». Nous proposons : « RRP est la désignation couramment attribuée à une personne formée en radioprotection qui administre…ou encore faire une précision « RRP est la désignation attribuée à une personne formée en radioprotection…dans le cas des programmes de catégorie II, ces personnes sont souvent des spécialistes en radioprotection ou des physiciens médicaux. » **3) Troisième paragraphe :** « Le responsable de la demande **devrait** s'assurer que des ressources… » Nous proposons de remplacer « devrait » par « doit », ce qui est	Suite à ces commentaires, les changements suivants ont été effectués : 1- Le terme a été modifié tel que proposé afin d'être conforme avec la terminologie utilisée dans le *Règlement général sur la sûreté et la réglementation nucléaires*. 2- Le texte a été modifié tel que suggéré. 3- Le texte a été modifié. Aucun changement n'a été effectué suite au 4ème commentaire. Bien qu'encouragée, la promotion d'une saine culture de sûreté n'est pas une exigence pour les demandeurs et des titulaires de permis de substances nucléaires et d'appareils à rayonnement.

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			en lien avec la section 3,1 et insiste sur le devoir du responsable de la demande. **4) Dans les puces qui suivent**, nous proposons d'ajouter sur une ligne à part, bien en évidence : « Le responsable de la demande doit établir, promouvoir et maintenir une culture de sûreté dans son organisation. »	
17.	Canadian Radiation Protection Association	2	Second paragraph: "RSO is the designation commonly assigned to a radiation safety specialist who administers an RPP on a day-to-day basis." CRPA designates radiation safety professionals to avoid potential confusion. Suggest rewording or more accurately defining "radiation safety specialist". In practice, low-risk or industrial licencees may not be sufficiently trained as, or even presume to be, radiation safety practitioners outside of the scope of their licence.	As a result of this comment, the term was changed to "radiation safety professional".
18.	Golder Associates Ltd.	2, par. 2	" RSO is the designation commonly assigned to a radiation safety specialist who administers an RPP on a day-to-day basis. " Consider clarification as a radiation safety specialist is not a defined/recognized profession and this may lead to confusion on who is suitable or not. Also, low risk use types, e.g., an XRF may not require specialized expertise in radiation but a competently trained individual for the licence activities.	As a result of this comment, the term was changed to "radiation safety professional". As stated in REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices*, the person designated as an RSO is required to have minimal radiation safety knowledge, as well as knowledge on the licensed activity.
19.	Alberta Health Services	2 Paragraph 3	**Issue raised** "The applicant authority should ensure that sufficient resources are allocated to the RSO…" **Comment** Many non-compliances by licensees can be traced back to insufficient resource	As a result of this comment, the text was changed and a reference to the document *Welcome Package: Applicant Authority, Nuclear Substances and Radiation Devices Licences* was added. This document provides guidance to the applicant authority on directing resources to ensure RSO can fulfill their duties.

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			allocation (money, personnel, time) to the RPP. One of the primary responsibilities of the applicant authority is to ensure there are proper resources allocated to the RPP and cannot be optional. Recommend changing "should" to "must".	
20.	Golder Associates Ltd.	2, par. 3	"The applicant authority *should* ensure that sufficient resources are allocated to the RSO…" Consider changing "should" to "must"	As a result of this comment, the text was changed and a reference to the document *Welcome Package: Applicant Authority, Nuclear Substances and Radiation Devices Licences* was added. This document provides guidance to the applicant authority on directing resources to ensure RSO can fulfill their duties.
21.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation	2	**Industry Issue (MAJOR)** Licensees believe the 1st paragraph should be edited for improved clarity. Specifically: 1) The REGDOC should recognize that some licensees, such as NPPs, are required to have health physicists whose training exceeds the requirements for an RSO and can fill that role. 2) The phrase "not delegating accountability" to the RSO is contrary to "acting as a signing authority" in section 3.2 and does not clearly delineate applicant and RSO responsibilities. **Suggested Change** Amend the 1st paragraph to read, "…The applicant authority should delegate duties for the day-to-day oversight of the RPP~~, but not accountability,~~ to an individual known as the radiation safety officer (RSO). A Health Physicist can be delegated as an RSO without additional training or certification. More details on applicant authority responsibilities can be found in REGDOC-1.6.1, Licence Application	No changes were made as a result of the following comments: 1- The document is meant for NSRD licensees. 2- No change was made as a result of this comment. The AA has the authority and accountability over the RPP. As described in the Applicant Authority Form, the AA is ultimately accountable for the program and licence. The RSO is responsible for implementing and managing the RPP, but is not accountable for it.

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			Guide: Nuclear Substances and Radiation Devices [1]." **Impact on Industry** Without the suggested amendments, this section could create uncertainty regarding the responsibilities and training of RSOs. As written, it does not accommodate all licensees. It should reflect the range, size and complexities across the spectrum of licensees in the industry.	
22.	Cameco	2	This section does not accommodate the roles and responsibilities of individuals across the spectrum of licensees and misconstrues how licensees may allocate responsibilities. For example, the phrase "but not accountability" confuses the role of Radiation Safety Officer (RSO) and should be deleted because it is contrary to "acting as a signing authority" in section 3.2. Some licensees may be also able to have a health physicist delegated as an RSO and the section would be improved if this option was recognized. Section 15 of the *General Nuclear Safety Control Regulations* requires licensees *to notify* the CNSC of a person who has the authority to act as an RSO. The use of the term "request" on the form referred to could be misinterpreted to mean that a CNSC approval is required in the appointment of an RSO. Cameco recommends that the section be revised to state that the form *can* be used to notify the CNSC of an appointed person.	No change was made as a result of this comment. This information is required, since the RSO is the liaison with the CNSC.
23.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick	2 and 3.6.1	**Industry Issue (MAJOR)** It is not a regulatory requirement to use the supplied forms to appoint an RSO (or any person) under section 15 of the General Nuclear Safety and Control Regulations. **Suggested Change** Remove all mention of an RSO except in reference to the Class II Nuclear Facilities	No change was made as a result of this comment. The term 'radiation safety officer' is a common term at the CNSC and is used in oral and written communications with NSRD licensees.

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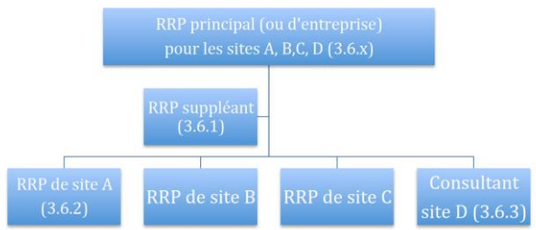
	Power, Ontario Power Generation		and Prescribed Equipment Regulations. Remove all mention to a requirement to fill out specific forms when notifying the Commission. **Impact on Industry** This adds requirements to licensees that have not gone through a regulatory impact analysis.	
24.	Radioprotection Inc.	3 Responsable de la radioprotection	Nous proposons ici ou au début de la section 3.6, un organigramme qui résumerait certaines structures des programmes de radioprotection rencontrés. Cet organigramme illustre bien des points de cette section et le lecteur moins expérimenté peut se retrouver et se reconnaître dans la structure de gestion illustrée.  Vous pourriez alors préciser vos attentes pour chaque type de RRP à partir de ce graphique.	Aucun changement n'a été effectué suite à ce commentaire. Bien que le graphique décrit correctement le contenu de la section, il ne reflète qu'une partie du RRP. Puisque les structures organisationnelles peuvent varier considérablement d'un détenteur de permis à l'autre, ce graphique pourrait ne pas s'appliquer à certains d'entre eux et créer davantage de confusion que d'orientation.
25.	Radioprotection Inc.	3.1 Fonctions	1) Par souci de clarté, il semble manquer un 3.6.x qui exprimerait ce qu'est un RRP principal ou d'entreprise (ce que plusieurs appellent RRP corporatif). Les exigences devraient être assez claires et devraient permettre l'intégration du PRP d'entreprise dans chaque site. Un RRP principal est le RRP qui réunit les points suivants : •Lien officiel du titulaire de permis et de la CCSN •Gestion du PRP d'entreprise adaptée à chaque site concerné	Suite à ces commentaires, les changements suivants ont été effectués : 1- le terme « RRP principal ou d'entreprise » a été remplacé par « le RRP » dans l'ensemble du document, puisque c'est le terme utilisé par la CCSN lors des échanges avec les détenteurs ou demandeurs de permis. 2- La CCSN utilise à une approche de cas par cas lors de

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			•Évaluation des performances de chaque site par rapport à des attentes communes d'entreprise (analyse des variations d'un site à l'autre, promotion des bonnes pratiques, etc.) •Expert, référence d'entreprise et contact pour les RRP de site en ce qui concerne la radioprotection 2) Nous vous suggérons aussi d'expliciter le type de structure de permis que la CCSN recommande pour ce type de programme, car un PRP et un RRP d'entreprise peuvent être institués pour des raisons d'économie d'échelle (un programme unique pour plusieurs sites), mais on peut décider de demander à la CCSN un permis par site pour limiter la responsabilité du permis à un site par exemple. Qu'elle est l'approche envisagée/suggérée/préconisée par la CCSN dans ce cas de programme d'entreprise ? 3) **Le second paragraphe** (pratique exemplaire) n'est pas souvent observé dans la pratique des programmes de radioprotection, tant complexes que simples à moins que le responsable de la demande soit le supérieur hiérarchique du RRP. Nous sommes d'accord avec les principes énoncés dans ce paragraphe, mais nous ne les trouvons pas réalistes. Si cette approche est souhaitée par la CCSN, nous suggérons que le rôle du responsable de la demande soit partagé avec le supérieur hiérarchique du RRP. **4) Le dernier paragraphe** de cette section (avant dernière phrase) : « Pour la supervision d'un PRP complexe, le fardeau de la réglementation devrait être assumé par un RRP à temps plein. » Cette phrase porte à confusion : •Qu'est-ce qu'un PRP complexe (voir nos commentaires précédents) ? •Qu'est-ce que le fardeau de la réglementation ? •Pourquoi la réglementation uniquement comme responsabilité ?	l'évaluation des demandes de permis. Ni le *Règlement général sur la sûreté et la réglementation nucléaires* ou le *Règlement sur les substances nucléaires et les appareils à rayonnement* ne précisent si un permis doit être émis à une organisation plutôt qu'à un site au sein d'une organisation. Ce document s'adressant à des organisations de taille et de type d'activités variées, il est impossible de suggérer une structure universelle. 3- Une référence au document *Trousse de bienvenue : mandataire du demandeur, Permis de substances nucléaires et d'appareils à rayonnement* a été ajoutée. Ce nouveau document offre de l'orientation aux mandataires du demandeur pour déterminer les ressources qui sont nécessaires au RRP pour accomplir ses tâches. 4- Le texte en lien avec le fardeau de la réglementation a été retiré.

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			•Un RRP à temps plein signifie-t-il que 100% du temps de travail du RRP est assigné au PRP ? •Qui d'autre que le RRP assume le fardeau de gestion du PRP si ce n'est pas assumé à temps plein ? Nous trouvons que cette phrase devrait être précisée. Le PRP est plus que de la réglementation, et c'est d'ailleurs une des raisons pour lesquelles les PRP sont complexes ! De plus, comme la CCSN permet des consultants comme RRP, cette section semble un peu contredire cette possibilité, car peu de consultants sont RRP à temps plein dans une institution ou entreprise.	
26.	Golder Associates Ltd.	3.1, par. 1	" The applicant authority *should* ensure that competing duties or priorities are not assigned to the RSO that might detract significantly from their ability or availability to manage the RPP." Consider changing "should" to "must"	As a result of this comment, the text was changed and a reference to the document *Welcome Package: Applicant Authority, Nuclear Substances and Radiation Devices Licences* was added. This document provides guidance to the applicant authority on directing resources to ensure RSO can fulfill their duties.
27.	AM Inspection Ltd.	3.1 Duties 1st and 4th paragraphs	**Industry Issue (Major)** The idea of RSO responsibilities as essential to the industry is laudable, but the language used basically states that organizations with complex RPP not using a full-time RSO are not meeting CNSC expectations. **Suggested Change** 1) "…The responsibilities of an RSO ~~are not an adjunct to another~~ shall be prioritized over other job tasks of the RSO…" 2) "…For overseeing a complex RPP, the regulatory burden is ~~expected~~ recommended to be handled by a full time RSO. For low-risk use types, the RSO	As a result of these comments, the text was revised for clarity.

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			could manage the RPP on a part time basis, while assuming other duties…" **Impact on Industry** CNSC should not get involved in the internal manpower organization of the different Licensees.	
28.	Alberta Health Services	3.1 Paragraphs 1 & 4	**Issue raised** "The **applicant authority should ensure** that competing duties or priorities are not assigned to the RSO that might detract significantly from their ability or availability to manage the RPP." and "The **RSO must be given** sufficient time to properly plan, monitor, manage and conduct the activities required to demonstrate compliance with all regulatory requirements." **Comment** The use of "should" and "must" seen contradictory here. Many licensees have 'part-time' RSOs that struggle with managing the RPP due to time constraints and competing priorities. This has been a continuing issue for some time and can be largely resolved by making it the responsibility of the applicant authority to ensure they have either selected a person that has sufficient time to devote to the RPP or have provided that person with the necessary time. Recommend changing "should" to "must".	As a result of this comment, the text was changed and a reference to the document *Welcome Package: Applicant Authority, Nuclear Substances and Radiation Devices Licences* was added. This document provides guidance to the applicant authority on directing resources to ensure RSO can fulfill their duties.
29.	Radiation Safety Program -	3.1	"As best practice the applicant authority should provide the RSO with a description of the duties, as well as the number of hours the RSO should be dedicating to them."	As a result of this comment, the text was changed and a reference to the document *Welcome Package: Applicant Authority, Nuclear Substances and Radiation Devices Licences* was added.

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	Diagnostic Services		RSO duties are generally outlined by the RSO's direct reporting person and in most cases that is probably not the Applicant Authority (AA). Some organizations have set out RSO duties in a Radiation Safety Policy (RSP) contained in the organization's Radiation Safety Manual (RSM).	This document provides guidance to the applicant authority on directing resources to ensure RSO can fulfill their duties.
30.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation	3.1	**Industry Issue (MAJOR)** Licensees have concerns with the following: 1)The 1st paragraph does not recognize that in some larger organizations, the applicant authority may not always have direct, day-to-day supervisory responsibilities for the RSO in their wider organization. Also, the last sentence of the 1st paragraph says, "… not an adjunct to another job task; …" This may create confusion for smaller licensees since an RSO may have numerous job tasks, as recognized in the 4th paragraph. What is important is that the RSO has sufficient time and resources to complete the applicable job tasks. 2)Many of the duties listed for an RSO in Appendix A – and referenced in the 3rd paragraph of this section -- would to be delegated to other staff. **Suggested Change** Amend the 1st paragraph to read, "The applicant authority, or those who directly supervise the RSO, should ensure that competing duties or priorities are not assigned to the RSO that might detract significantly from their ability or availability to manage the RPP. The responsibilities of an RSO are ~~not an adjunct to another job task; they are an~~ essential ~~element for~~ to ensur~~e~~ing the safe use of nuclear substances and radiation devices." Amend the 2nd paragraph to read, "~~As best practice, the applicant authority should provide~~The RSO should be given ~~with~~ a description of ~~the~~ their duties~~, as well as and guidance regarding the number of hours they the RSO should be dedicating to them~~. The ability of the RSO to manage the RPP should be evaluated by an	1- As a result of this comment, the text was changed and a reference to the document *Welcome Package: Applicant Authority, Nuclear Substances and Radiation Devices Licences* was added. This document provides guidance to the applicant authority on directing resources to ensure RSO can fulfill their duties. 2- The lists of duties are examples only.

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			appropriate level of management and/or the applicant authority at defined intervals~~,~~ ~~in order~~ to identify where additional time or other assistance is needed. Amend the 1st sentence of the 3rd paragraph to read, "The RSO typically ensures the non-exhaustive lists of tasks described in appendix A are performed." **Impact on Industry** For large organizations, no single person or alternate(s) or site specific individual can manage the duties and authorities as described. The industry has Radiation Protection Program Manager(s) for the administration of the RPP and qualified Health Physics staff who help oversee the implementation of the RP Program. As currently written, all these staff would need to be designated as an RSO and some larger licensees with complex, well-established RPP programs may be required to structure themselves in inefficient, ineffective ways to ensure the RSO reports directly to an applicant authority. Without the suggested edits, the implication would be significant cost and administrative effort s with no corresponding improvement to nuclear safety.	
31.	Cameco	3.1	1) As above, section 3.1 is not well suited for all licensees. Larger organizations may have program managers and health physicists who help oversee the radiation protection program in which case it is impractical to require the RSO to report directly to the applicant authority. The first sentence of section 3.1 should be revised to "...authority is accountable, or those who directly supervise the RSO, should ensure..." For smaller licensees, the reference to an RSO having responsibilities that "are not an adjunct to another job task..." is confusing. What is important is that the RSO has sufficient time and resources to complete the applicable job tasks and these requirements are independent of other tasks an individual may perform. The last sentence in the first paragraph should be revised to "...responsibilities of an RSO are essential to ensure the safe use of nuclear substances..."	As a result of the second comment, the text was modified as suggested. No changes were made as a result of these comments: 1- The AA has the authority and accountability over the RPP. As described in the Applicant Authority Form, the AA is ultimately accountable for the program and licence. The RSO is responsible for implementing and managing the RPP, but is not accountable for it. Since this document is meant for licensees with various sizes and organisational structures, the document was kept generic so it could

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			2) The second paragraph should be revised to "[t]he RSO should be given a description of their duties. The ability of the RSO to manage the RPP should be evaluated by management or applicant authority at defined intervals to identify where additional time or other assistance may be needed." 3) For some licensees, many of the tasks in Appendix A would be delegated to other workers. The first sentence of the third paragraph should be amended to read "[t]he RSO typically ensures the non-exhaustive list of tasks described in Appendix A are performed."	apply to all NSRD licensees. 3- The lists of duties are examples only.
32.	Radionuclide Safety Committee (Shared health Manitoba)	3.2	Thank you for the opportunity to comment on draft REGDOC 1.6.2. I would like to submit the following comments related to the document. It is appreciated that there is a separate appendix dealing with complex radiation safety programs that utilize corporate RSO's, however in the body of the document there should be more direction or more concise wording regarding items that may be carried out by a corporate RSO in place of the site RSO as the current wording causes the following concerns; With regard to section 3.2 on the authority of the RSO, I feel that for a complex radiation safety program, such as those encountered in large health care settings, it is not necessarily appropriate for the site RSO to require direct contact with the applicant authority. In these complex programs however I would suggest that the corporate RSO would be the appropriate conduit for communication with the applicant authority, just as they are for all CNSC related communications. This should also apply in the case of signing authority as the corporate RSO is capable of ensuring that the whole program is suitably equipped etc where as a site RSO will not have that information. It is also unfeasible for a site RSO to modify the policies within the program wide radiation safety manual. It is agreed however that they should be able to recommend changes to these policies through their corporate RSO / Radionuclide	No change was made as a result of this comment. The text states that the site RSO should report to the RSO, not to the applicant authority. The site RSO does not have the responsibilities or duties mentioned in the comment. The document states that the RSO remains the person responsible for overseeing the overall RPP and is the main liaison with the CNSC.

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			Safety Committee etc. and they should have the authority to modify local / site policies and procedures as required.	
33.	Radioprotection Inc.	3.2 Pouvoirs du RRP	Cette section au complet est très importante et devrait faire partie du PRP. De plus, cette section devrait aussi être copiée intégralement dans le formulaire de désignation du responsable de la demande.	Le personnel de la CCSN tiendra compte de ce commentaire lors de la révision du formulaire ainsi que du REGDOC-1.6 1, *Présentation d'une demande de permis : Substances nucléaires et appareils à rayonnement.* La CCSN a récemment publié le document *Trousse de bienvenue : mandataire du demandeur, Permis de substances nucléaires et d'appareils à rayonnement*. Ce nouveau document offre de l'orientation aux mandataires du demandeur pour déterminer les ressources qui sont nécessaires au RRP pour accomplir ses tâches.
34.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation	3.2	**Industry Issue (MAJOR)** Licensees, especially those with well-established regulatory frameworks and processes, believe it is not appropriate to require an RSO to be the signing authority for all radiation safety matters. This is more appropriate as guidance. **Suggested Change** Amend the 2nd paragraph to read, "In particular, the RSO may act as signing authority on all matters of radiation safety, the CNSC licence and the obligations of the licensee and ~~must~~ have necessary authority to: 1. communicate directly with the applicant authority ~~2. act as signing authority on all matters of radiation safety, the CNSC licence and the obligations of the licensee~~ 2. immediately stop any work, task or undertaking that the RSO considers unsafe or	No change was made as a result of this comment. This document is meant for NSRD licensees. REGDOC-1.6.1: *Licence Application Guide: Nuclear Substances and Radiation Devices* states that, unless mentioned otherwise, the RSO is considered to have signing authority for all matters related to the CNSC licence.

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			which may contravene the NSCA, its regulations or the CNSC licence 3. implement and enforce any changes to any work, task or undertaking which are necessary to ensure that the licensee remains compliant or returns to compliance 4. modify any policy and any procedure, and ensure that the changes are properly documented and communicated to workers **Impact on Industry** For large corporations, there may already be a framework for existing regulatory relations and processes.	
35.	Cameco	3.2	Cameco does not agree that the RSO must act as a signing authority on all matters of radiation safety and strongly recommends that the second numbered paragraph be deleted or the introductory phase should be revised to a permissive statement.	No change was made as a result of this comment. This document is meant for NSRD licensees. REGDOC-1.6.1: *Licence Application Guide: Nuclear Substances and Radiation Devices* states that, unless mentioned otherwise, the RSO is considered to have signing authority for all matters related to the CNSC licence.
36.	Radioprotection Inc.	3.3 Qualifications	1) Nous pensons que cette section devrait faire l'objet d'un développement plus approfondi et bien plus éclairant de la part de la CCSN. La CCSN reste encore très vague sur le sujet des qualifications des RRP et met encore le poids des vérifications sur les RRP et les titulaires de permis. La CCSN ne vérifie pas les qualifications des RRP qui ne sont pas RRP de programmes de catégorie II. Par conséquent, la CCSN devrait être claire sur ses attentes de qualification. De plus, nous sommes déçus, mais pas étonnés de voir que parmi les bonnes connaissances des RRP, on ne retrouve que des habiletés règlementaires dans les puces présentées dans cette section alors que le RRP n'est pas seulement un expert en droit. Nous suggérons en première place **dans la section suivant le second paragraphe (puces de connaissances) :** « • principes fondamentaux de radioprotection de la CIPR	Suite à ce commentaire, les changements suivants ont été effectués : 1) La liste a été modifiée. Toutefois, la CCSN ne peut pas promouvoir une organisation en particulier pour la puce en lien avec les principes fondamentaux de radioprotection 2) Un lien vers la liste des fournisseurs de services sur le site de la CCSC a été ajouté. Les détenteurs de permis ont la responsabilité de déterminer les besoins de formation de leur organisation en fonction des activités autorisées par leur permis. La CCSN n'évalue pas les fournisseurs de formation et ne peut pas offrir de recommandation aux détenteurs et demandeurs de permis. La certification des formateurs n'est pas incluse dans les

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			• principes physiques de base en radioprotection et en radiobiologie • principe de dosimétrie, instrumentation adéquate et pertinente • La LSRN et les règlements connexes… etc. » 2) De plus, nous sommes surpris de lire qu'un fournisseur de formation puisse être évalué par les commentaires d'anciens clients. Bien que cette approche est à l'image des médias sociaux et de l'appréciation instantanée des services sur la base d'un échantillon plus ou moins représentatif, nous encourageons ici la CCSN à investir ce secteur et à évaluer elle-même les formations disponibles sur le marché. Le modèle français certifie le RRP et les formateurs. Nous suggérons de commencer par certifier les formateurs et leur programme de formation. 3) Dans l'autre section de **puces des autres connaissances** : Nous suggérons que la dernière puce : « la gestion et l'utilisation sécuritaires des substances nucléaires et des appareils à rayonnement, y compris… » soit remplacée par 2 puces pour bien indiquer l'importance de la connaissance intrinsèque des autres éléments de santé-sécurité qui sont présents dans certains programmes de radioprotection : « •… la gestion et l'utilisation sécuritaires des substances nucléaires et des appareils à rayonnement • la gestion des procédures sécuritaires d'entrée en espace clos, de cadenassage des sources d'énergie, de gestion des utilisations de produits biologiques ou chimiques ainsi que tous les éléments de gestion de la santé-sécurité propre à votre installation comme l'instauration de périmètres de sécurité fonctionnels, les utilisations adéquates d'équipement personnel de protection, etc. » Nous suggérons ces ajouts dans l'optique que ce document s'adresse aussi au type de programme complexe que peut représenter l'industriel.	Règlements de la CCSN. Aucun changement n'a été effectué en lien avec le dernier commentaire, puisque les procédures spécifiques à l'organisation doivent être documentées dans le PRP et communiquées aux travailleurs.

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37.	Radiation Safety Program - Diagnostic Services	3.3	"The RSO is encouraged to make use of accreditation programs for RSOs which provide qualifications for the proposed use of nuclear substances and prescribed equipment." Canadian organizations that accredit RSOs ought to be listed here or in an appendix (that includes the Canadian Radiation Protection Association (CRPA) and the Canadian Organization of Medical Physicists (COMP)). There are a number of Canadian vendors who provide RSO training courses, those ought to be listed as well. While RSO accreditation is valuable, an appropriate RSO training course should be a minimum requirement.	As a result of this comment, the text was modified and a link to the CNSC's service providers page was included. The CNSC does not endorse any specific service providers. It is up to the licensee to determine which provider suits their needs.
38.	Canadian Radiation Protection Association	3.3	"The RSO is encouraged to make use of accreditation programs for RSOs which provide qualifications for the proposed use of nuclear substances and prescribed equipment." Please clarify the difference between accreditation and training. Please recognize that while RSO accreditation is valuable, an appropriate RSO training course should be a minimum requirement. It is suggested that Canadian organizations that accredit RSOs be listed here, or in an appendix. This includes the Canadian Radiation Protection Association (CRPA) and the Canadian Organization of Medical Physicists (COMP). Similarly, a link to the Nuclear Substances and Radiation Devices Service Providers site could be provided to better steer those unfamiliar to training resources.	As a result of this comment, the text was removed and a link to the CNSC's service providers page was included. The CNSC does not endorse any specific service providers. It is up to the licensee to determine which provider suits their needs.
39.	Alberta Health Services	3.3 Paragraph 1	**Issue raised** "…in accordance with the licence conditions of the CNSC licence."	As a result of this comment, the text was modified.

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			Comment To a new licensee or inexperienced RSO, this wording can give the impression that RSO only needs knowledge about the licence conditions, and no other regulatory criteria such as legislation and regulations. Recommend rewording to state "…in accordance with the applicable regulatory criteria" to be more encompassing.	
40.	Alberta Health Services	3.3 Paragraph 2	**Issue raised** "…accreditation programs for RSOs…" **Comment** What does the CNSC consider an accreditation program for an RSO in Canada? The CRPA(R) designation offered by the CRPA is probably the closest thing to RSO designation but it is meant to identify Registered Radiation Safety Professionals and not specifically RSOs. Further expansion on the CNSC perspective on RSO accreditation is encouraged.	As a result of this comment, the text was removed and a link to the service providers page was included. The CNSC does not endorse any specific service providers. It is up to the licensee to determine which provider suits their needs.
41.	Golder Associates Ltd.	3.3, par. 2	**"**The RSO is encouraged to make use of accreditation programs for RSOs which provide qualifications for the …**"** Suggest changing to "where accreditation exists". If this is meant to refer to training where there is no accreditation, consider providing link to providers (with the understanding this may not equate to endorsements).	As a result of this comment, the text was removed and a link to the service providers page was included. The CNSC does not endorse any specific service providers. It is up to the licensee to determine which provider suits their needs.
42.	Radiation Safety Program - Diagnostic	3.4	"The RSO should have relevant and practical work experience in conducting the proposed licensed activities. The CNSC expects the RSO to be familiar with the nature and characteristics of the nuclear substances and radiation devices that are to be authorized under the CNSC	As a result of this comment, the section has been revised. CNSC staff have not included the number of years of experience, since that level of detail could restrict the licensees staffing process. The goal in this section is to ensure that the individual has some relevant

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	Services		licence, any proposed licensed activities that will be conducted and other ancillary hazards that may impact the licensed activities." Perhaps some times could be suggested here, for example at least one to three years.	knowledge and experience.
43.	Radioprotection Inc.	3.5. Formation continue	**3e paragraphe : «** La formation de recyclage **devrait** être offerte au moins tous les 5 ans… » Nous n'avons pas observé de PRP qui peuvent dépasser une fréquence de 5 ans pour le recyclage de RRP. La CCSN demande de façon assez catégorique lors des renouvellements de permis, une fréquence de 5 ans pour les RRP et de 3 ans pour les autres travailleurs. Il serait plus juste alors de remplacer « devrait » par « doit », sinon, par souci d'équité, de préciser ici, les cas ou raisons qui permettent à un PRP de dépasser une fréquence de 5 ans.	Aucun changement n'a été effectué suite à ce commentaire. Du contenu supplémentaire a toutefois été ajouté à cette section afin d'offrir davantage d'information. Puisque le *Règlement sur les substances nucléaires et les appareils à rayonnement* et le *Règlement sur la radioprotection* de la CCSN ne contiennent pas d'exigence en lien avec la fréquence de la formation des employés, REGDOC-1.6.2 ne peut qu'inclure de l'orientation à cet effet. La fréquence suggérée pour la formation de recyclage des RRP est entre 3 à 5 ans. Puisque la plupart des détenteurs de permis doivent renouveler leur formation en lien avec le *Règlement sur le transport des marchandises dangereuses* (RTMD) de Transports Canada à tous les 3 ans, plusieurs d'entre offrent la formation de recyclage pour les RRP et les travailleurs par la même occasion.
44.	AM Inspection Ltd.	3.5 Continuing education 3rd paragraph	**Industry Issue** Lengthy is a relative and non quantitative measure of time which allows several interpretations for different Licensees. **Suggested Change** "…Refresher training should be provided at least every five years and when changes to regulatory requirements or licence conditions occur, or in the case of an	As a result of this comment, the text was modified.

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
			RSO's return after ~~a lengthy~~ more than two (2) years of absence…"	
45.	Golder Associates Ltd.	3.5, par. 2	**"**The frequency and extent of the refresher training should be determined, defined and documented**."** This requirement for refresher level training appears more prescriptive than requirements in in Sections 3.3. and 3.4. Additionally, it is suggested radiation professionals [e.g. CRPA(R)] who have mandated professional development be recognized for general refresher activities. Lastly, opportunity to increase clarity because the "frequency" is asked to be determined and defined in paragraph 2 but paragraph 3 states a minimum of 5 years.	As a result of this comment, the text was modified.
46.	Alberta Health Services	3.5 Paragraph 3	**Issue raised** "RSOs **should be made aware** of any changes…" **Comment** As the administrator of the licence and the responsible party for overseeing compliance, the RSO has to be aware of any changes to regulatory requirements that affect the licences activities. From a regulator's perspective, it is reasonable that the RSO is expected to keep up to date on regulatory changes as much as practical. Using the word "should" weakens this responsibility. If the wording remains as "…should be made aware…" who is responsible for making the RSO aware of the changes? Recommend rewording to "RSOs are expected to be aware of any changes…"	As a result of this comment, the text was removed.
47.	Canadian	3.5	Suggest that active participation or continuing education activities required of	As a result of this comment, the text was modified and a link to the

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	Radiation Protection Association		professional radiation societies, e.g. CRPA(R), CHP are sufficient for periodic training requirements. By default, this would not encompass reviewing legislation for updates and this activity is still suggested.	service providers page was included. The CNSC does not endorse any specific service providers. It is up to the licensee to determine which provider suits their needs.
48.	Radioprotection Inc.	3.6. Dotation des RRP	Le principe est clair, le PRP doit fonctionner en tout temps, même si le RRP principal est absent. Ce qui est moins clair est le principe de suppléance. Il n'est pas indiqué dans le PRP bien souvent et les attentes de la CCSN devraient être clarifiées dans cette section. Une question n'a pas été répondue : est-ce que la CCSN s'attend à avoir un « RRP principal » en tout temps pour les PRP complexes?	Suite à ce commentaire, le texte a été modifié. La CCSN n'exige pas qu'un RRP en particulier soit disponible à tout moment, mais bien que le PRP soit maintenu en tout temps.
49.	Golder Associates Ltd.	3.6, par. 1	"As a result, a designated alternate RSO is necessary during an RSO's **temporary** absence" Please define "temporary". Ideally with respect to absences in 3.6.1.	As a result of this comment, reference to "temporary absence" has been removed.
50.	AM Inspection Ltd.	3.6 RSO staffing 2nd paragraph	**Industry Issue** Even though this paragraph express guidance or advice, the word "available" is not clearly defined, and store an exposure device is also a "licensed activity". Please clarify the term and advise if a RSO or Alternate shall be physically available or "on call" on a 24/7/365 basis. **Suggested Change** "The corporate RSO or any person assigned RSO duties, such as an alternate RSO, a site RSO or a consultant, should be <u>available</u> while licensed activities are being performed."	As a result of this comment, the text was changed. Although the RSO, alternate RSO, site RSOs or consultant does not need to be physically available, he/she must be able to be contacted at all times.
51.	Golder Associates	3.6, par. 2	**"** ….**should** be available while licensed activities are being performed. **"**	As a result of this comment, the text was changed.

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	Ltd.		This "should" appears to contradict paragraph 1 where an "alternate" is required. Practically, from a program control perspective, there always needs to be someone knowledgeable at the RSO level available. Suggest this is changed to "must".	
52.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation	3.6	**Industry Issue (MAJOR)** The draft does not make it clear that an RSO with all the stated qualifications is not subject to rejection by the Commission or its staff. **Suggested Change** Include language that confirms RSOs are appointed by licensees to best meet their individual organizational structures and business needs. While RSOs are selected to satisfy CNSC qualifications, their appointments are not subject to refusal by the Commission or its staff. **Impact on Industry** There is no appeal mechanism for a nominated RSO within the Class II Nuclear Facilities and Prescribed Equipment Regulations. Appeals of an administrative decision-maker may be taken to a provincial court unless other mechanisms are present. In this case, they are not.	No change was made as a result of this comment. Although this document can be useful for Class II licensees, it is meant for NSRD licensees. The CNSC has recently published *Welcome Package: Applicant Authority, Nuclear Substances and Radiation Devices Licences* which provides guidance to applicant authorities on the factors that should be considered when designating the RSO.
53.	Alberta Health Services	3.6.1 Paragraph 2	**Issue raised** "The corporate RSO or any person assigned RSO duties, such as an alternate RSO, a site RSO or a consultant, **should be available while licensed activities are being performed**." **Comment** Does this imply that an RSO (primary or alternate) must be present during all	As a result of this comment, the text was changed. Although the RSO, alternate RSO, site RSOs or consultant does not need to be physically available, he/she must be able to be contacted at all times.

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
			operational hours with which the licensed activity is conducted? How does the CNSC define "available" in this context?	
54.	Alberta Health Services	3.6.1 Paragraph 2	**Issue raised** "The CNSC should be notified in the case of **short-term** absences." **Comment** How does the CNSC define 'short-term' absences? A "short term absence" could be as short as 1 or day medical appointments to a couple of weeks for a vacation. Recommend providing a period or definition for "short-term" in this context. Suggest a period less than 60 days be defined as "short term". This would be in alignment with section 15.11 of the *Class II Nuclear Facilities and Prescribed Equipment Regulations.* GNSR 15 already requires the licensee to notify the CNSC of their RSOs (corporate, site, alternate or otherwise). As long as the alternate RSO is capable of covering for the primary RSO, what is the benefit of prior notification to the CNSC? Although the statement is only a suggestion ("should be notified"), informing the CNSC of short absences seems excessive and not to provide any value.	As a result of this comment, reference to short-term absence was removed.
55.	Golder Associates Ltd.	3.6.1, par. 2	"For **short-term**... and ...**long-term** absences…" Please define terms in number of days	As a result of this comment, reference to short-term absence was removed.
56.	Radioprotection Inc.	3.6.1. RRP suppléant	La CCSN fait une différence entre les absences de courtes durées et de longues durées et suggère même d'être avertie durant les absences de courte durée. Si la qualification de PRP complexe est importante pour la CCSN, nous proposons	Suite à ce commentaire, le texte en lien avec les absences de courtes durées a été retiré.

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			qu'aucune différence entre la courte durée et la longue durée ne soit faite, car si le PRP est complexe, un incident ou un accident complexe peut arriver autant pendant une absence de quelques semaines que pendant une absence de quelques mois. Sinon, la CCSN devrait préciser dans son exemple, la durée suggérée qui demandera le même niveau de connaissance du RRP suppléant par rapport au RRP principal. Nous précisons que cette suggestion s'applique ici puisque l'on parle de programmes complexes dans ce REGDOC. L'impact de cette proposition de ne pas faire de différence dans la durée est d'avoir systématiquement un suppléant formé selon les mêmes critères que le RRP principal. Par contre, nous sommes conscients que la problématique des dernières années de la faible disponibilité et de la grande mobilité de la main-d'œuvre dans plusieurs secteurs institutionnels et industriels sera un enjeu important. Nous voyons cependant un avantage immédiat aux RRP suppléants qui deviendraient par définition des RRP adjoints : ils permettent un partage des tâches du PRP s'ils se complètent au jour le jour tel qu'indiqué dans le premier paragraphe (RRP adjoint). Nous observons que plusieurs RRP d'institutions sont présentement surmenés et pourraient bénéficier d'un partage des tâches, d'autant plus que le rôle de RRP n'est souvent pas leur unique fonction. Comme la CCSN permet les consultants (section 3.6.3), la suppléance par un consultant devrait être une approche assez naturelle dans ce cas.	
57.	Radionuclide Safety Committee (Shared health Manitoba)	3.6.1	With regards to section 3.6.1, there should be definitions for what is considered a short or long term absence, in terms of period of time away from work as well as nature of absence. Alternatively, the CNSC should provide direction that it is up to licensee's to determine appropriate definitions for their program. With at least five site RSO's, a corporate RSO and his assistant all having up to six weeks of standard vacation time, I am sure our project officer does not want to be informed of every single vacation that every person takes. It is however acknowledged that RSO coverage in the case of any absences, and training of those alternates is important.	As a result of this comment, reference to short-term absence was removed. The REGDOC provides examples as to what can lead to long-term absence. It is up to the licensee to determine when an employee is on long-term absence and to ensure the oversight of the RPP is maintained.
58.	AM	3.6.1	**Industry Issue (Major)**	As a result of this comment, reference to short-term absence was

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	Inspection Ltd.	Alternate RSO 2nd paragraph	Even though this paragraph express guidance or advice, and some examples of "short-term absence" are provided, by not making it a quantitative concept, this forces companies to notify absences, even for a 1-day illness or a 3-day vacation. Furthermore, it does not define which authority in CNSC must be notified. If the purpose is to ensure the right person receives CNSC communications during the absence, it shall be noted that different CNSC Divisions send communications to RSO. **Suggested Change** "…The CNSC should be notified in the case of short-term absences (of seven days or more)…" ***Please also define which authority in CNSC must be notified.*** **Impact on Industry** This creates an additional and unnecessary burden for both Licensees and CNSC.	removed. The REGDOC provides examples as to what can lead to long-term absence. It is up to the licensee to determine when an employee is on long-term absence and to ensure the oversight of the RPP is maintained.
59.	Radiation Safety Program - Diagnostic Services	3.6.1	Element 3.6.1 Alternate RSO seems to contain at least two absolute requirements. "For short-term absences, such as vacation, illness or injury, the alternate RSO should, at a minimum, have knowledge of the regulatory requirements of the licensed activity and all reporting requirements. The CNSC should be notified in the case of short-term absences. RSO training for alternate RSOs is recommended." CNSC should define what a short-term absence is. For licences with Alternate RSOs already identified do CNSC Licensing Specialists really want to be notified about short-term absences like a holiday day or two or three, or a couple of weeks of vacation? Several RSOs in my organization have sufficient seniority such that they may have four to six week's annual vacation each. Perhaps in complex organizations with corporate RSOs or equivalent, tracking of short-term absences could be delegated to the corporate RSO (I already do that within my	As a result of this comment, reference to short-term absence was removed. The REGDOC provides examples as to what can lead to long-term absence. It is up to the licensee to determine when an employee is on long-term absence and to ensure the oversight of the RPP is maintained.

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
			organization)? "In the case of long-term absences, such as maternity or parental leave, temporary assignment to other duties, severe illness or injury, the alternate RSO must have the same level of knowledge about and training on the licensed activities and the regulatory requirements as the RSO. The Request to Appoint a Radiation Safety Officer or an Alternate Radiation Safety Officer form must be completed and submitted to notify the CNSC of the replacement." CNSC should define what a long-term absence is (I suggest at least 60-90 days). My organization has experienced an RSO being off after emergency surgery, the appropriate Licensing Specialist was notified that the RSO was off, the alternate RSO was covering, etc.	
60.	Alberta Health Services	3.6.1 paragraph 3	**Issue raised** "...long term absences…" **Comment** Recommend providing a period or definition for "long-term" in this context. Suggest a period over 60 days as "long-term".	As a result of this comment, reference to short-term absence was removed. The REGDOC provides examples as to what can lead to long-term absence. It is up to the licensee to determine when an employee is on long-term absence and to ensure the oversight of the RPP is maintained.
61.	Golder Associates Ltd.	3.6.1, par. 3	"...the alternate RSO **must** have the same level of knowledge about and training on the licensed activities and the regulatory requirements as the RSO." Suggest changing "must" to "should". For many low or even medium risk types, a working knowledge of the radiation protection program or radiation safety manual, should suffice to maintain the program until an RSOs return.	As a result of this comment, text was added in the section on RSO staffing to clarify that any person replacing or assisting the RSO should have similar levels of training and knowledge on the licensed activities and the regulatory requirements.

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62.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation	3.6.1	**Industry Issue** Licensees believe the REGDOC should provide an appropriate threshold/frequency for notifying the CNSC regarding alternate RSOs. **Suggested Change** Amend the 2nd sentence of the 2nd paragraph, to read, "The CNSC should be notified in the case of short-term absences of more than 21 days."	As a result of this comment, reference to short-term absence was removed. The REGDOC provides examples as to what can lead to long-term absence. It is up to the licensee to determine when an employee is on long-term absence and to ensure the oversight of the RPP is maintained.
63.	Radioprotection Inc.	3.6.2 RRP de site	« Le RRP de site **devrait** faire rapport au RRP d'entreprise… » L'utilisation du « doit » est conséquente au rôle de RRP de site et de RRP d'entreprise. Si aucune communication ne se fait entre le RRP d'entreprise et le RRP de site, la structure ne fonctionnera pas et des écarts de performance sont à prévoir entre les différents sites. « Il devrait être clair que le RRP d'entreprise demeure la personne responsable de la supervision de l'ensemble du PRP… » Nous suggérons à la CCSN de parler de « gestion » au lieu de supervision. Un PRP complexe et consolidé en programme corporatif demande une gestion (ce qui inclut la supervision). Et ce type de phrase devrait se retrouver dans la section qui n'existe pas, 3.6.x RRP d'entreprise.	Suite à ce commentaire, le texte a été modifié tel que suggéré.
64.	AM Inspection Ltd.	3.6.2 Site RSO 1st and 2nd paragraphs	**Industry Issue (Major)** Even though this paragraph express guidance or advice, since "licensed activities in more than one geographical location" can include overnight parking storage in an employee house or a client's temporary jobsite; this request does not seem realistic and can be achieved the corporate RSO or alternate as it has worked until now.	No changes was made as a result of this comment. This document provides guidance only.

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
			Suggested Change "…~~When a licence application to conduct licensed activities in more than one geographical location is submitted, a site RSO should be appointed at each licensed location to implement and maintain the RPP… The site RSO should have similar levels of experience, training and authority as the corporate RSO~~…" **Impact on Industry** This creates additional financial and time constraints for Licensees especially in small companies with locations geographically close.	
65.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation	3.6.2	**Industry Issue (MAJOR)** It's not appropriate to expect a similar level of experience, training and authority for site RSOs who manage sites with lower hazard profiles or less complex RPPs. **Suggested Change** Rephrase the 2nd sentence of the 2nd paragraph to read, "The site RSO should have ~~similar~~ ~~levels of~~ experience, training and authority commensurate with the complexity of the RPP and hazards at their site ~~as the corporate RSO~~." **Impact on Industry** As currently written, the REGDOC does not allow industry to train or qualify staff to a level that is appropriate to the hazard profile they manage.	As a result of this comment, text was added in the section on RSO staffing to clarify that any person replacing or assisting the RSO should have similar levels of training and knowledge on the licensed activities and the regulatory requirements.
66.	Cameco	3.6.2	The statement that "[t]he site RSO should have similar levels of experience, training and authority as the corporate RSO" does not apply to all licensees. This statement should be revised to "[t]he site RSO should have experience, training and authority commensurate with the complexity of the RPP and the hazards at their site" to be consistent with a risk-based approach.	As a result of this comment, text was added in the section on RSO staffing to clarify that any person replacing or assisting the RSO should have similar levels of training and knowledge on the licensed activities and the regulatory requirements.

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67.	Radioprotection Inc.	3.6.3 Consultant	La CCSN doit expliciter ce qui est attendu d'un RRP consultant, car elle semble demander moins qu'un RRP provenant du titulaire de permis. Par exemple, pour un PRP complexe, la CCSN suggère en 3.1 que le RRP soit à temps plein. Comment justifier l'écart entre un temps plein et un temps partiel très variable dans le cas d'un consultant ? Et comme le RRP consultant doit avoir les mêmes qualifications, est-ce que ce consultant doit être formé aux 5 ans ou avoir une formation équivalente ? La phrase « …le titulaire de permis doit s'assurer que le consultant peut passer suffisamment de temps à l'emplacement… » est assez vague et n'engage pas la CCSN, mais bien le titulaire de permis. Le présent document devrait éclaircir les attentes de la CCSN. En 5.1, on parlera de la culture de sûreté. Est-ce qu'un consultant temporaire est à même de bien saisir la culture de sûreté d'une entreprise ou d'une institution ? Probablement, mais il faut y mettre du temps sur les lieux et tisser les liens de confiance et d'échange nécessaires. Mais la CCSN ne présente pas ici de critères d'évaluation pour aider le titulaire de permis à juger de la pertinence du RRP consultant dans le cadre d'un programme complexe. De plus la CCSN devrait rappeler ici que le titulaire de permis reste toujours responsable ultimement du PRP et la délégation de responsabilité n'est pas possible.	Suite à ce commentaire, le contenu de cette section a été modifié. Des précisions ont été ajoutées quant à la nature temporaire du recours à un consultant ainsi que pour réitérer que le mandataire du demandeur demeure responsable pour le PRP.
68.	Radioprotection Inc.	4 Élaboration et mise en œuvre d'un PRP efficace	Nous suggérons ici que la CCSN rappelle ce qu'est un PRP efficace tel que défini dès l'introduction.	Suite à ce commentaire, le document a été révisé afin de clarifier l'utilisation du terme "efficace".
69.	Bruce Power, Canadian Nuclear Association, Canadian	4	**Industry Issue (MAJOR)** REGDOC 1.6.2 refers to REGDOC 2.7.1, Radiation Protection, which is under development and should not be referenced until it is published.	As a result of the comment, only REGDOCs that are already published will be referenced in REGDOC-1.6.2.

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	Nuclear Laboratories, New Brunswick Power, Ontario Power Generation		**Suggested Change** Remove the reference to REGDOC 2.7.1, Radiation Protection **Impact on Industry** As per industry feedback on other drafts, it's inappropriate to reference non-published REGDOCs. Citing REGDOC-2.7.1 prior to publication could generate confusion since the CNSC has not yet dispositioned licensee comments on that draft document.	
70.	Cameco	4	This section refers to REGDOCs under development. Cameco appreciates the difficulty for CNSC in drafting related REGDOCs sequentially. However, it is not possible to review a REGDOC when it references unpublished documents. This introduces uncertainty and confusion and can lead to unintended consequences. As in previous submissions, Cameco strongly recommends that this practice be discontinued.	As a result of the comment, only REGDOCs that are already published will be referenced in REGDOC-1.6.2.
71.	Radioprotection Inc.	5 Système de gestion	**Dernier paragraphe :** « Les sous-sections qui suivent décrivent quatre composantes importantes du système de gestion qui **devraient** être incluses dans le PRP… » Sans surprise, nous vous suggérons de remplacer « devraient » par « **doivent** » puisque ces éléments sont essentiels pour un PRP efficace (surtout les PRP complexes !)	Suite aux différents commentaires sur cette section, le document a été révisé et ce texte n'apparaît plus.
72.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick	5	**Industry Issue (MAJOR)** The last paragraph inappropriately lists safety culture among the management system components to include in an RPP. Safety culture is ***not*** a component of a management system. It is an outcome of, and promoted by, a management system. **Suggested Change** To be consistent with other REGDOCs and promote a better understanding of	As a result of the various comments on this section, the document was revised and this text is no longer included.

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	Power, Ontario Power Generation		safety culture, the CNSC is strongly urged to: •Delete 'safety culture' from the list of management system components •Move subsection 5.1 to precede section 4 Add subsection 4.1 and provide a linking statement to say activities that promote safety culture should be considered in designing the management system. **Impact on Industry** Section 5 is inconsistent with *REGDOC-2.1.1, Management System* causes confusion and mischaracterizes the relationship between safety culture and the management system.	
73.	Cameco	5 and 5.1	Cameco's main concern with the REGDOC is the designation of safety culture as a component of a management system in the last paragraph of section 5. Safety culture it is an outcome of, and promoted by, a management system and is not a component of a management system. This is characterization confuses the relationship between safety culture and the management system and is inconsistent with REGDOC-2.1.1, *Management System.* Cameco strongly recommends that 'safety culture' be deleted as a component of the management system. We suggest that section 5.1, Safety Culture, could be moved to precede section 5 as its own section or as a subsection of section 4. In this location is could preface section 5 by stating that activities that promote safety culture should be considered in management system design.	As a result of the various comments on this section, the document was revised and this text is no longer included.
74.	Radioprotection Inc.	5.1 Culture de sûreté	Nous apprécions de voir cet élément en première position. IRPA, la CIPR, l'AIEA et bien d'autres organismes internationaux se penchent depuis des années sur ce concept. Par contre nous vous suggérons fortement de remplacer l'élément suivant dans la phrase : **3e paragraphe :«** Une saine culture de sûreté évolue à partir de l'élaboration de	Suite aux différents commentaires sur cette section, le document a été révisé et ce texte n'apparaît plus.

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			l'application d'une attitude de questionnement à tous les niveaux de l'organisation, **y compris** la direction. » Remplacer « y compris » par « en commençant par ». Dans une institution ou une entreprise, les leaders montrent l'exemple et initient les changements souhaités. La direction doit représenter le changement, pas seulement en faire partie. Notre commentaire sur la pertinence des responsables de la demande dans un PRP complexe s'inscrit avec ce point sur la culture de sûreté. L'évaluation récente de la CCSN (octobre 2019) sur le rôle des RRP présente que les RRP sont compétents et volontaires, mais que les ressources et l'appui semblent manquer. La CCSN doit soutenir les RRP en promouvant clairement le rôle actif des responsables de la demande dans le succès de la culture de sûreté en radioprotection, comme dans la santé-sécurité en général. La dernière phrase de ce paragraphe doit le montrer : « On s'attend à ce que tous les membres de l'organisation contribuent à favoriser et à soutenir cette culture.» Nous suggérons simplement, pour être compatibles avec ce que nous venons d'écrire : « Tous les membres de l'organisation doivent favoriser et soutenir cette culture. » Comme nous parlons de « culture », les changements doivent venir des parties intéressées, mais la CCSN doit initier le changement au besoin.	
75.	Alberta Health Services	5.1 Paragraph 6	**Issue raised** "From time to time, it is important to reflect on the maturity of the organization's safety culture. At Stage 1, there is an awareness…" **Comment** The paragraphs ends without any further expansion of this idea. Not suggesting that all the stages be defined here but the wording abruptly ends without providing reasons as to why it is important to reflect on the maturity of the safety culture.	As a result of the various comments on this section, the document was revised and this text is no longer included.
76.	Bruce Power, Canadian	5.1	**Industry Issue (MAJOR)**	As a result of the various comments on this section, the document

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	Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation		This section does not align with the content of *REGDOC-1.6.1*, which provides guidance on the application requirements for a nuclear substance and radiation device license. **Suggested Change** Remove this section so requirements align with *REGDOC-1.6.1*. Otherwise, clearly state that it contains ideas a licensee may implement, but the content cannot be used for compliance verification. **Impact on Industry** This section is inconsistent with an existing REGDOC which will generate compliance confusion.	was revised. This document provides guidance only.
77.	Radioprotection Inc.	5.2 Évaluation du PRP	**Premier paragraphe** : « Le PRP **devrait** indiquer des moyens d'évaluer périodiquement le rendement du programme » replacer « devrait » par « doit ». N'est-ce pas une exigence de la CCSN d'avoir dans le PRP une section permettant d'évaluer le rendement ? Nous comprenons que l'on touche dans la section D19 de la demande de permis surtout à la conformité (inspection vs audit), mais la CCSN devrait alors enlever dans les 22 exemples qui suivent, les items qui relèvent plus de l'inspection que de l'audit. Ou simplement exiger une évaluation du rendement minimalement à chaque renouvellement de permis.	Suite à ce commentaire, le texte a été modifié tel que suggéré.
78.	Radionuclide Safety Committee (Shared health Manitoba)	5.2	With regard to section 5.2 and assessment of the RPP, it is suggested that a clear distinction is made regarding guidelines and requirements that relate to internal inspections as opposed to other assessments, and also whether the term self-assessment is referring specifically to internal inspections or includes other types of assessment as well. Section 5.2 appears to be contradicting itself, suggesting in paragraph four that assessments should take place every five years, and then in section 5.2.1 suggesting	As a result of the various comments on this section, the document was revised for clarification.

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			a minimum frequency of annually (with regard to self-assessments).	
79.	Radiation Safety Program - Diagnostic Services	5.2	"The RPP should include means to periodically assess the performance of the program. This may be performed through self-assessments, independent assessments or management reviews. The RPP should define the type(s) of assessment(s) to perform, the frequency and the method(s) to be used. Note: An inspection performed by a CNSC inspector is not considered an assessment activity." I'm confused and wonder how many others are wondering if this section is mixing self-inspection with RPP reviews. "Although the RPP should be assessed at least every five years, the frequency of the assessments will depend on the complexity of the RPP and the risk associated with the licensed activity. The frequency and the chosen method(s) should be defined and documented in the RPP. The basis of the assessments may need to be expanded to account for different use types, associated hazards and mitigating controls." RPP assessment should involve the AA and Radiation Safety Committee (RSC) where one exists. It should not be up to the RSO to set out the RPP assessment.	As a result of the various comments on this section, the document was revised for clarification.
80.	Cameco	5.2.2	Cameco does not agree with the statement that "[independent assessments should be based on the results of self-assessments". We recommend that "based on" should be revised to "informed by" in the last paragraph.	As a result of the various comments on this section, the document was revised for clarification.
81.	Radioprotection Inc.	5.2.1 Auto-évaluation	**Second paragraphe :** même remarque, remplacer « devrait » par « doit » : « Le PRP **devrait** préciser la fréquence… » Nous suggérons aussi d'arrimer les activités d'auto-évaluation avec, minimalement, l'exigence de production du rapport annuel de conformité. Cet élément devrait être apporté ici, car la faible pertinence du RAC est souvent rapportée parmi les	Suite à ce commentaire, le texte a été modifié tel que suggéré.

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			titulaires de permis qui n'y voit qu'une exigence administrative de plus.	
82.	Alberta Health Services	5.2.1 Paragraph 2	**Issue raised** "Based on best practices, self-assessments should be performed at least annually…" **Comment** This seems to conflict (or at least could create some confusion) with section 5.2 which states the RPP should be assessed every five years.	As a result of the various comments on this section, the document was revised for clarification.
83.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation	5.2.1	**Industry Issue** Section 5.2 indicates self-assessments are a 'should.' However, 5.2.1 says self-assessments are 'vital.' These two statements are inconsistent and imply that self-assessments are a 'shall.' **Suggested Change** Align 5.2.1 with 5.2 to ensure it's clear that self-assessments are a 'should' rather than a 'shall.' For clarity, amend the first two sentences to read, "~~Self-assessments, such as internal audits or inspections, are vital in evaluating the implementation and effectiveness of the RPP.~~ If self-assessments are performed, they are generally conducted by …"	As a result of the various comments on this section, the document was revised for clarification.
84.	Radioprotection Inc.	5.2.2. Évaluation indépendante	Dernier paragraphe : Nous ne comprenons pas la phrase : « Les évaluations indépendantes devraient être fondées sur les résultats des auto-évaluations. » Est-ce que l'évaluation est indépendante si on l'appuie sur des résultats des auto-évaluations ? Est-ce que la CCSN ici veut dire que les résultats des auto-évaluations sont un des éléments vérifiés ? Lors du 6e atelier sur la culture de sûreté (IRPA/IOMP/OMS/HPS, février 2019), un élément important apporté était le « peer review » sans faire l'unanimité, car	Suite aux différents commentaires sur cette section, le document a été révisé pour clarifier l'information.

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			personne n'apprécie une évaluation externe ! Cependant, pour changer une culture de sûreté moins performante, nous suggérons que la CCSN encourage l'approche de l'évaluation externe passant par une évaluation volontaire par des pairs ou par un organisme de consultation externe comme la CCSN le précise ici. Cette évaluation doit impliquer le/la RRP et ne doit pas seulement être initiée à partir des auto- évaluations comme le suggère la CCSN. Elle peut aussi faire partie d'un processus d'entreprise/institution comme c'est déjà le cas pour plusieurs entreprises et programmes corporatifs. Les résultats doivent être communiqués ouvertement, à toutes les parties prenantes (voir points 4, 5 ,et 6, page 10) de la culture de sûreté dans le document présent.	
85.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation	5.2.2	**Industry Issue** Clarity is required on the following points: 1)As with 5.2.1, the 1st sentence of the 1st paragraph implies that independent audits are a 'shall.' 2) It's unclear what "should be based on" means in the 1st sentence of the last paragraph. **Suggested Change** Amend: 1)The 1st sentence of the 1st paragraph to read, "Independent assessments are often referred to as external audits and may be ~~are~~ planned and conducted ~~carried out~~ by an external organization at defined frequencies." 2) The 1st sentence of the last paragraph to read, "Independent assessments should	As a result of the various comments on this section, the document was revised for clarification.

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			be informed by ~~based on~~ the results of self-assessments."	
86.	Radioprotection Inc.	5.2.3 Examens de gestion	Cette pratique est une excellente pratique, car le PRP est aussi un programme de gestion, mais nous doutons que tous les responsables de demande soient en mesure d'effectuer ce type de vérification. Nous suggérons un ajout dans la première phrase : **Premier paragraphe :** « Les examens de la gestion sont effectués par le responsable de la demande… » par « Les examens de la gestion sont effectués par le responsable de la demande ou son représentant… » Cet élément confirme encore le point que le responsable de la demande dans un programme complexe doit être bien choisi et que la CCSN doit pouvoir trouver une approche qui permet la désignation d'un responsable de la demande plus près des activités du PRP complexe.	Suite aux différents commentaires sur cette section, le document a été révisé pour clarifier l'information.
87.	AM Inspection Ltd.	5.3 Event investigation 2nd paragraph	**Industry Issue (Major)** There is a substantial difference between regulatory limits and the internal action levels that the CNSC Licensing Division typically demands from Licensees. While regulatory limits are rarely exceeded in Canada and correctly require a report to CNSC, action levels are far more common, normally are the result of accumulated workload and not a single event, and are recurring (the NEW who exceeded an action level for a given period frequently exceeds an action level for the next period since the values accumulate during the year). **Suggested Change** "…When regulatory limits are exceeded or events are determined to be systematic (e.g., recurring action level exceedances), a detailed event report must be provided to CNSC staff…" **Impact on Industry** This additional reporting requirement will impose a bigger burden on RSO and	As a result of the various comments, this section has been removed.

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			Licensees, and it will likely not translate into safer work practices or lower doses received by the employees.	
88.	Alberta Health Services	5.3 Paragraph 2	**Issue raised** "…events are determined to be **systematic** (e.g., recurring action level exceedances), a detailed event report must be provided to CNSC staff." **Comment** The word "systemic" might be the better choice than "systematic" given the message of the sentence.	As a result of the various comments, this section has been removed.
89.	Golder Associates Ltd.	5.3, par. 2	"...events are determined to be systematic (e.g., **recurring** action level exceedances)" Appears to contradict RPR 6 (2)c which implies every action level exceedance is reportable, not just "recurring"	As a result of the various comments, this section has been removed.
90.	Alberta Health Services	5.3 Paragraph 3	**Issue raised** "The corrective actions taken to resolve problems associated with the event need to be accepted by the applicant authority…" **Comment** Acceptance of corrective actions would be subject to the management structure and incident management process in place with the licensee. Not all corrective actions need to be accepted by the applicant authority. However, there definitely needs to be a process with which to inform and involve the applicant authority at some level of incident that is appropriate for the size and complexity of the organization.	As a result of the various comments, this section has been removed.

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
91.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation	5.3	**Industry Issue (MAJOR)** The requirement to submit a detailed report for events determined to be systematic does not align with the reporting requirements of the General Nuclear Safety and Control Regulations. Reporting requirements are already covered by the suite of applicable REGDOCs (3.1.1, 3.1.2 and 3.1.3) and corrective action processes are well established to resolve issues. **Suggested Change** Licensees strongly urge the CNSC to delete the 2nd and 3rd paragraphs and their supporting bullets. Reporting requirements and corrective actions need to align with the GNSCR, applicable REGDOCs and well-established processes. **Impact on Industry** This section confuses event reporting, which is already well covered by existing REGDOCs. Similarly, the corrective action process is well understood and monitored by licensees and there is no need to reference it here.	As a result of the various comments, this section has been removed.
92.	Cameco	5.3	The second paragraph requires a detailed event report for systematic events using "recurring action level exceedances" as an example. There is no legislative authority for a collective report to follow event-specific reports and the reporting regulatory documents, such as REGDOC-3.1.2 do not contemplate this type of reporting. The reference to system event reporting should be deleted from the REGDOC.	As a result of the various comments, this section has been removed.

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93.	Radioprotection Inc.	5.4 Documentation	Nous vous proposons de parler de l'aliénation des documents selon les exigences de la CCSN. Aussi, le terme « manuel de radioprotection », bien que très connu dans certains PRP complexes, n'est pas toujours une réalité pour tous. Par exemple, est-il attendu que le PRP se retrouve entièrement dans un manuel de radioprotection ? Le manuel est parfois dématérialisé et déconstruit en un ensemble de procédures qui répondent à la demande de permis. La documentation devrait aussi contenir les éléments de gestion du programme qui aide à son intégration avec le programme plus général de santé-sécurité.	Suite aux différents commentaires sur cette section, le document a été révisé pour clarifier l'information.
94.	Radionuclide Safety Committee (Shared health Manitoba)	5.4	With regards to section 5.4, I feel that in a complex radiation protection program and organization it is impractical for the RSO and applicant authority to sign and date each policy. Documentation; its review and version control are agreed to be very important however the CNSC should be mindful of the processes that are involved in producing program wide radiation safety manuals for complex programs. In our program policies are reviewed by appropriate stakeholders, edited and approved by the executive members of the Radionuclide Safety Committee including the Corporate Radiation Safety Officer and the original of any approved policy is signed by the CEO according to our corporate policy.	As a result of the various comments on this section, the document was revised for clarification.
95.	Radiation Safety Program - Diagnostic Services	5.4	"The radiation safety manual should be signed and dated by the RSO and applicant authority to confirm that the published version of the manual was reviewed and approved." [4th sentence 1st para] The recommendation that the Radiation Safety Manual (RSM) be signed and dated by the AA & RSO is totally impractical. In my organization our RSM comprises forty-eight (48) RSPs. Each RSP is signed by the corporate President & CEO and they are all dated. As the corporate RSO I send out new and revised RSPs to our stakeholders along with an updated Table of Contents for the RSM. One of my duties to maintain a record of revision of the RSM. I urge that maintaining a record of revision of the RSM be added after the above sentence or replace the above sentence.	As a result of this comment, the text was modified. Having the RSM signed and dated is a good practice, but the licensee is responsible to decide and document how version control is recorded or tracked. There needs to be a mechanism in place to show that the RSM was approved and that it is the version that is being circulated to staff.

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
96.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation	5.4	**Industry Issue (MAJOR)** Licensees should have the flexibility to document their RPP in a way that best suits their organizational need. This may not necessarily be a safety manual. **Suggested Change** Amend the 3rd sentence to read, "The specific details of the RPP are ~~usually~~ documented, ~~in a radiation safety manual, which is submitted as part of the licence application. The radiation safety manual should be signed and dated by the RSO and applicant authority~~ to confirm its contents were ~~that the published version of the manual was~~ reviewed and approved." **Impact on Industry** For many licensees, there may already be an existing framework for regulatory relations and processes.	As a result of this comment, the text was modified. Having the RSM signed and dated is a good practice, but the licensee is responsible to decide and document how version control is recorded or tracked. There needs to be a mechanism in place to show that the RSM was approved and that it is the version that is being circulated to staff.
97.	Cameco	5.4	The third sentence states that the details of the RPP are usually in a radiation safety manual. This sentence should be revised to "[t]he specific details of the RPP are documented to confirm its contents were reviewed and approved". This would ensure that licensees do not require a safety manual and can document their RPP as appropriate for that licensee.	As a result of the various comments on this section, the document was revised for clarification.
98.	Radioprotection Inc.	ANNEXE A : Fonctions du RRP	Nous suggérons qu'une phrase en début de l'annexe mentionne le rôle collaboratif entre le RRP, le responsable de la demande et les autres membres de l'équipe de gestion d'un titulaire de permis, car le/la RRP ne dispose pas du temps et des connaissances pour gérer seul(e), tous les DSR mentionnés	Suite à ce commentaire, le texte a été modifié tel que suggéré.
99.	Radioprotection Inc.	ANNEXE A : Fonctions du RRP	**Santé et sécurité classique** Nous sommes satisfaits de voir que cet élément est rapporté en premier. Le programme de radioprotection est une partie spécialisée de la santé-sécurité. Nous	Suite à ce commentaire, le texte a été modifié.

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
			suggérons une phrase qui suggère l'homogénéisation et l'intégration du PRP dans le programme de santé-sécurité classique lorsqu'applicables. Cette approche permet une meilleure compréhension pour le travailleur ou la travailleuse qui doit concilier tous les éléments d'un programme de santé-sécurité, pas seulement la radioprotection. Nous suggérons : « Le RRP veillera, lorsqu'applicable, à faire le lien entre les exigences de la radioprotection et les exigences de la santé-sécurité classique. Par exemple : • Le cadenassage d'une source d'énergie touche autant un moteur qu'une jauge nucléaire • L'évaluation des rayonnements en franchissant le seuil d'un espace clos suit la même logique que la détermination d'un gaz toxique, asphyxiant ou explosif • le port de gants lors de la manutention de radionucléides ou d'autres produits dangereux en limite l'incorporation • La ventilation ou la filtration d'une substance volatile radioactive suit le même concept que celui d'une substance volatile non radioactive, etc.	
100.	Radioprotection Inc.	ANNEXE A : Fonctions du RRP	**Gestion de la performance humaine** Nous ne savons pas s'il y a une importance dans l'ordre, mais ce DSR devrait arriver en second et la Radioprotection en troisième, car la radioprotection est ce qui distingue un PRP d'un autre programme de santé-sécurité.	Suite à ce changement, la liste a été révisée afin de présenter les DSR en ordre alphabétique.
101.	Radiation Safety Program - Diagnostic Services	Appendix A: Duties of the RSO	"*Management system* This SCA covers the framework that establishes the processes and programs required to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture.	No change was made as a result of this comment. This list provides examples only. This specific duty could be appropriate in certain organizations.

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
			• conduct assessments of the RPP" [4th bullet] Assessing the RPP is not likely an appropriate RSO duty.	
102.	Radiation Safety Program - Diagnostic Services	Appendix A: Duties of the RSO	*"Radiation protection* This SCA covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations*. The program must ensure that contamination levels and radiation doses received by individuals are monitored, controlled and maintained ALARA. • establish internal administrative and action levels" [7th bullet] RSOs and Licensees should not be lead to believe that the establishment of administrative and action levels is a requirement. Licensees might choose to go with regulatory requirements alone.	No change was made as a result of this comment. This list provides examples only. This specific duty could be appropriate in certain organizations.
103.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation	Appendix A	**Industry Issue** The phrase "lowest level of contamination" in the fitness for service section is unhelpful since the potential dose consequences will vary from site to site due to different radionuclides and measurement capabilities. **Suggested Change** For clarity, amend the final bullet under fitness for service to read, "maintain a sufficient supply of radiation monitoring instruments that are capable of detecting the nuclear substances in use ~~at the lowest level of contamination~~"	As a result of this comment, the text was changed as suggested.
104.	AM Inspection Ltd.	Appendix B.1 3.	**Industry Issue** The term "radiation exposures" in the NDT industry is typically understood as each exposure of the nuclear source out of the exposure device to produce a radiography,	As a result of this comment, the text was changed as suggested.

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
			so it can be misunderstood. **Suggested Change** "…ensure that radiation exposures for all Nuclear Energy Workers and general public are maintained ALARA…"	
105.	Radioprotection Inc.	ANNEXE B : Comité de radioprotection	1) Nous suggérons d'inscrire que le comité de radioprotection soit, dans sa structure, autant que possible, partie prenante ou sous-comité du comité de santé-sécurité d'une institution ou d'une entreprise. Le CRP ne devrait pas travailler en silo, mais évoluer au sein du programme général de santé-sécurité. Ainsi le CRP pour un PRP complexe devrait être représenté au sein du comité de santé-sécurité, car certaines réalités de santé-sécurité sont communes à la biosécurité, à la sécurité des produits chimiques ou des procédés à risques. La CCSN indique déjà que la santé-sécurité devrait faire partie du CRP à la section B2. Pareille structure est souhaitable et permet une synergie des acteurs en santé-sécurité et une meilleure allocation des ressources pour des problématiques communes. Nous précision ici que la santé-sécurité et la radioprotection pourraient avantageusement inclure la gestion environnementale, surtout pour les PRP de sources non scellées qui peuvent être volatiles ou évacuées dans les systèmes de déchets domestiques ou sanitaires. 2) Encore une fois, un autre item de communication doit être bien souligné : les procès-verbaux du CPR devraient être distribués à toutes les parties prenantes et être accessible à tous si applicable. La transparence est un facteur de succès en radioprotection.	1- Suite à ce commentaire, le texte a été modifié. 2- Aucun changement n'a été effectué suite à ce commentaire. Le texte précise que les procès-verbaux devraient être distribués aux membres du comité.

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
106.	Radiation Safety Program - Diagnostic Services	Appendix B.2 Membership	"The RSC should comprise members from multiple disciplines. An RSC should include at least corporate and site RSOs, an authorized user from each type of licensed activity, a representative of the auxiliary personnel (e.g., clerical, janitorial, security), a representative of the nursing service where applicable (therapeutic nuclear medicine licence) and a representative of management. The RSC may also include physicians, physicists and representatives of corporate interest groups, such as managers (senior staff members), workers or specific user units. It should also include a representative of the health and safety committee. Every department that receives occupational dose or has an impact on radiation exposure or safety should also be represented." Existing complex RPPs for long-established organizations may well have evolved historically in a variety of ways and may well not include representation from ancillary services such as housekeeping, maintenance and security. If the concern is to ensure that workers in those areas receive the appropriate training this section isn't the place to cover that in an indirect way.	No change was made following this comment. This document is for guidance only and this text might be helpful for licensees that have never had a RSC.
107.	Radiation Safety Program - Diagnostic Services	Appendix B.2 Membership	"The chairperson should work closely with the applicant authority to ensure effective decisions are made and carried out." That is very vague and should be expanded.	As a result of this comment, the text was removed and the following paragraph was revised to provide more clarity.
108.	Radiation Safety Program - Diagnostic Services	Appendix B.3 Terms of Reference	"The RSC's terms of reference depend on individual circumstances, such as management decisions, corporate procedures, available resources, licence requirements and the magnitude, diversity or complexity of the licensed activities. The terms of reference should contain the following: 6. required meeting agenda items" A concern with including required meeting agenda items in a Terms of Reference (ToR) document is that if an item is not included during a RSC meeting (for a good reason) CNSC may well come back during a Type I Inspection or audit and take the	As a result of this comment, the text was changed.

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
			RSC to task for not following its ToR.	
109.	Radiation Safety Program - Diagnostic Services	Appendix B.4 Meetings	"The circumstances that can trigger a non-routine meeting should also be described in the terms of reference." [2nd sentence, 3rd para] Again a potential concern is that if a non-routine RSC meeting is called for a reason other than what is defined in the ToR the CNSC may take the RSC to task during a Type I Inspection or audit. Some RSCs and licensees might be more comfortable just by stating in the RSC ToR that non-routine meetings can be called by the RSC Chair.	As a result of this comment, the text on non-routine meetings has been moved to the terms of reference section.
110.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick Power, Ontario Power Generation	Appendix B	**Industry Issue** Some licensees have ALARA Committees instead of Radiation Safety Committees, which serve the same purpose. **Suggested Change** Clarify that an ALARA Committee is considered equivalent to a Radiation Safety Committee.	No change was made as a result of this comment. Not all NSRD licensees have an ALARA committee. In addition, the Radiation Safety Committee is the common terminology used for referring to such committee and was the term found in G-121, *Radiation Safety in Educational, Medical and Research Institutions*.
111.	Bruce Power, Canadian Nuclear Association, Canadian Nuclear Laboratories, New Brunswick	5.2.3	**Industry Issue (MAJOR)** As currently written, this section implies that management reviews are a 'shall' and reviews need to be conducted ***by*** the Applicant Authority, not on their behalf. **Suggested Change** Amend the 1st sentence to read, "Management reviews may be ~~are~~ conducted ~~by the applicant authority~~ at a set frequency and their results provided to the applicant	As a result of the various comments on this section, the document was revised for clarification.

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	Power, Ontario Power Generation		authority ~~as an oversight activity~~ to assess the effectiveness of the RPP and ~~to~~ proactively make improvements as required." **Impact on Industry** Without these slight edits, the REGDOC inappropriately suggests the applicant authority must conduct the actual review rather than analyze its results.	
112.	Radioprotection Inc.	5.3 Enquête sur un événement	Nous proposons d'y ajouter un élément de communication des résultats de l'enquête aux parties intéressées, dans la mesure du possible, pour convertir le travail d'enquête en opportunité de communication, d'information et d'apprentissage. L'enquête sur un événement permet de façon concrète de témoigner de la nécessité de certaines mesures dans le PRP et aussi de favoriser la transparence dans le programme.	Suite aux différents commentaires cette section a été retirée du document.

Table C: "Feedback on comments" (opportunity to provide feedback on the comments received):

	Reviewer	Reviewer's Comment and Proposed Change	Response
113.	Shared Health Manitoba	Thank you for the opportunity to comment on comments submitted for this draft REGDOC. The majority of submitted comments seem to have many similarities. Cancer Control Alberta has as usual submitted a well-thought out document and I heartily endorse Mr Beniston's comments #s 5 & 6. However, I do not agree with comment # 7 which suggests a short-term absence be considered less than 60 days.	As a result of this comment, reference to short-term absence was removed.
114.	Shared Health Manitoba	Although it was not what I thought of in terms of notifications for short-term absences, I do not disagree with comment # 9 submitted by CNA, CNL, OPG, Bruce Power and NB Power and could accept that suggestion.	As a result of this comment, reference to short-term absence was removed.

115.	Shared Health Manitoba	Unfortunately, I must disagree with Mr Baldomar of AM Inspection Ltd comment # 5, seven days is **too short** since most RSOs in my organization take two if not three weeks of vacation (i.e. fourteen or twenty-one days) at one time.	As a result of this comment, reference to short-term absence was removed.
116.	Provincial Health Services Authority	**Section 3.1** 1. The following statements are contradictory: First paragraph: … "The responsibilities of an RSO are not an adjunct to another job task;"… Fourth paragraph: …"For low-risk use types, the RSO could manage the RPP on a part-time basis, while assuming other duties."… In our opinion the statement in red in the first paragraph should be removed since the complexities of the program are already discussed in the fourth paragraph.	As a result of this comment, the text was revised.
117.	Provincial Health Services Authority	**Section 3.1** 2. The phrase "complex RPP" is unclear. Fourth paragraph: …"For overseeing a complex RPP, the regulatory burden is expected to be handled by a full-time RSO." In our opinion, the word complex should be described using details such as the number of sites and scope of licensed activities carried out.	As a result of this comment, the scope was revised to clarify the definition of a complex program. The CNSC will determine if a program is complex or not during the licence application assessment and will inform licensees.
118.	Provincial Health Services Authority	**Section 3.3** 1. Please outline what accredited programs are available to fulfill the regulatory requirements and CNSC's expectation stated in this section.	As a result of this comment, the text was modified and a link to the CNSC's service providers page was included. The CNSC does not endorse any specific service providers. It is up to the licensee to determine which provider suits their needs.
119.	Provincial Health Services Authority	**Section 3.5** 1. We suggest the following sentence include the text in red. Second paragraph: The frequency and extent of the refresher training should be determined, defined and documented by the licensee.	As a result of this comment, the section was revised.

120.	Provincial Health Services Authority	**Section 3.5** 2. The phrase “lengthy absence” is unclear.	As a result of this comment, the text was changed and a reference to section 3.4.1, where long-term absence is described, was added.
121.	Provincial Health Services Authority	**Section 3.5** Third Paragraph: ”Refresher training should be provided at least every five years and when changes to regulatory requirements or licence conditions occur, or in the case of an RSO’s return after a lengthy absence.” Will CNSC define lengthy absence or will the licensee determine for their own program?	As a result of this comment, the text was changed and a reference to section 3.4.1, where long-term absence is described, was added.
122.	Provincial Health Services Authority	**Section 3.6.1** 1. The phrases “short-term absence” and “long-term absence” are unclear. Please provide guidelines for the length of time for each situation.	As a result of this comment, reference to short-term absence was removed.
123.	Provincial Health Services Authority	**Section 3.6.1** 2. We don’t believe it is necessary to directly notify the CNSC in all cases of short-term absences of the corporate RSO. We believe email or telephone re-direction is sufficient enough to notify others of the short term absence and would include the contact information to reach the alternate RSO. Second paragraph: … “The CNSC should be notified in the case of short-term absences.”	As a result of this comment, reference to short-term absence was removed.
124.	Provincial Health Services Authority	**Section 3.6.1** 3. We suggest that the second and third paragraphs of section 3.6.1 should be moved to be in Section 3.6 as they describe absences of the corporate RSO.	As a result of this comment, reference to short-term absence was removed.

125.	Provincial Health Services Authority	**Section 3.6.2** 1. We propose the first paragraph to read as follows (changes shown in red): When a licence application to conduct licensed activities in more than one geographical location is submitted, a site RSO should be appointed for each licensed location. The site RSO should maintain a presence in the workplace by periodically observing work practices to implement and maintain the RPP. The purpose of designating a site RSO is to ensure direct RPP oversight for all locations. The site RSO can be designated by the corporate RSO. We believe there is no need for a site RSO to be present at the site location at all times, but, periodically observing work practices may be sufficient based on the licensed activity that takes place at each site.	As a result of this comment, the text was changed as suggested.
126.	Provincial Health Services Authority	**Section 3.6.2** 2. We propose the second paragraph to read as follows (changes shown in red): The site RSO should report to the corporate RSO on all radiation protection matters. The site RSO should have appropriate levels of experience, training and authority based on the activities of the licensee. At a minimum, they should have knowledge of the regulatory requirements of the licensed activity and all reporting requirements. The roles and responsibilities and the lines of authority for the site RSO must be clearly defined. It should be clear that the corporate RSO remains the person responsible for overseeing the overall RPP and is the main liaison with the CNSC.	As a result of this comment, text was added in the section on RSO staffing to clarify that any person replacing or assisting the RSO should have similar levels of training and knowledge on the licensed activities and the regulatory requirements.
127.	Provincial Health Services Authority	**Section 3.6.2** 3. This section does not mention the need for an alternate Site RSO. To maintain the effectiveness of the RPP, we believe a designated alternate Site RSO may be necessary during a Site RSO's temporary absence based on the licensed activity that takes place at each site.	No change was made as a result of this comment. Licensees can decide to designate an alternate site RSO on its own initiative, but only the RSO and alternate RSO are reported to CNSC.

128.	Provincial Health Services Authority	**Section 5.2** 1. What type of assessment should licensees perform every five years? Fourth paragraph: "Although the RPP should be assessed at least every five years, the frequency of the assessments will depend on the complexity of the RPP and the risk associated with the licensed activity." We believe the type of assessment recommended every five years should be described in more detail. Section 5.2.1 recommends self-assessment to be performed at least annually. The two statements seem contradictory.	As a result of the various comments on this section, the document was revised for clarification.
129.	Provincial Health Services Authority	**Section 5.2** 2. We suggest that an example/template of a Management Review appropriate for an RPP be provided. An example of a self-assessment (Type II Inspection Worksheets) was provided in Section 5.2.1.	As a result of this comment, a reference to CAN/CSA- ISO 9001: 16, *Quality management systems requirements* was added.
130.	Provincial Health Services Authority	**Section 5.2.3** 1. We propose the first paragraph to read as follows (changes shown in red): Management reviews are conducted by the applicant authority or applicant authority representative at a set frequency as an oversight activity to assess the effectiveness of the RPP and to proactively make improvements as required.	As a result of the various comments on this section, the document was revised for clarification.

131.	Provincial Health Services Authority	**Section 5.3** 1. We believe this section should contain only the information in the first paragraph minus the last sentence: "In accordance with the regulatory requirements established in the General Nuclear Safety and Control Regulations, Radiation Protection Regulations, and Packaging and Transport of Nuclear Substances Regulations, 2015, an investigation must be conducted to determine the probable cause of an event. Event investigation is a formal process to identify the probable cause or causes of an event, including the technical issues and organizational factors underlying the event. This determination is also used to help develop corrective actions to restore the effectiveness of the RPP and to prevent the occurrence of a similar event." The remainder of text in this section is confusing and it seems to be incomplete and not consistent with the existing regulations. For example, the remaining paragraphs in this section do not include all reportable incidents, and include examples of incidents that are not currently reportable e.g. events are determined to be systematic. In addition, the last paragraph is unclear if it refers to CNSC corrective actions or internal corrective actions.	As a result of this comment, the section has been removed.
132.	Provincial Health Services Authority	**Section 5.4** 1. We feel that electronic evidence of approval of the Radiation Safety Manual by the RSO and AA is acceptable. We suggest the first sentence of the second paragraph to include this option.	No change was made as a result of this comment. The CNSC does not prescribed how the RSM has to be signed, as long as proof that it has been approved can be provided. Electronic signatures are acceptable, if they are mentioned in the licensee's procedures.
133.	The Ottawa Hospital	**Section 2, Para 1:** '*The applicant authority should delegate duties for the day-to-day oversight of the RPP, but not accountability, to an individual known as the radiation safety officer (RSO)'* The AA typically does not know the details duties that must be carry on. Perhaps a better way would be to delegate th*e responsibility and authority* (just like in para 2 and section 3) to manage and oversee the RPP. Since the RSO is the signing authority, the institution often sees the RSO as the person accountable for the RPP program. The accountability is already delegated by nature of the leadership role but to imply the RSO should not be 'accountable' may risk taking away much of authority and ability to enforce compliance.	No change was made as a result of this comment. The AA has the authority and accountability over the RPP. As described in the Applicant Authority Form, the AA is ultimately accountable for the program and licence. The RSO is responsible for implementing and managing the RPP, but is not accountable for it.

134.	The Ottawa Hospital	**Page 3: AA should ensure the RSO has sufficient resources:** Thank you for including this important point and giving concrete examples of what this entails	Thank you for the comment. The CNSC has recently published *Welcome Package: Applicant Authority, Nuclear Substances and Radiation Devices Licences*, which provides guidance to the applicant authority on directing resources to ensure RSO can fulfill their duties.
135.	The Ottawa Hospital	**Page 4, section 3, para 2: Site RSOs** Site RSO may not be the best or only title option for staff supporting the Corporate RSO. For example, to better align job classification with expertise and responsibilities other titles may be used and job functions categorized by license oversight vs site. Examples of titles uses at The Ottawa Hospital are: Medical Health Physicist and Radiation Safety Specialists.	No change was made as a result of this comment. Since this document is meant for licensees with various sizes and organisational structures, the document uses the term "site-RSO" which is more generic. Text was also added to clarify that the RSO is a term commonly used to designate a radiation safety professional who administers the RPP. The goal is to have someone overseeing the RPP on site.
136.	The Ottawa Hospital	**Page 4, section 3.1, para 1** *'The applicant authority should ensure that competing duties or priorities are not assigned to the RSO that might detract significantly from their ability or availability to manage the RPP.'* Although this is true, it should also be stated to '*not add duties that could create a conflict of interest for the RSO'.* In addition, not to prevent potential career growth for the RSO, one could add to this sentence: *without ensuring additional/adequate resources are added.* *'The ability of the RSO to manage the RPP should be evaluated by the applicant authority at defined intervals, in order to identify where additional time or other assistance is needed.* Most AA want to support the RSO but are often in a conflict of interest position when discussing buget and resources since they oversee other operational programs. For the AA to be able to evaluate the adequacy of resources, a guide or formula taking into account the complexity of the program and other areas under the scope of the RSO would be needed. The AA must also inherently trust and rely on their RSO and support them in meeting their need to effectively oversee the program. Many RSOs are struggling to make their needs for resources understood and met because of that lack of knowledge from the AA.	As a result of this comment, the text was changed. The CNSC has recently published *Welcome Package: Applicant Authority, Nuclear Substances and Radiation Devices Licences*, which provides guidance to the applicant authority on directing resources to ensure RSO can fulfill their duties.

137.	The Ottawa Hospital	**Page 4: last para: Communicate directly with the AA** As recommended in the last paragraph of second paragraph of page 4, and to align with 3.6.2, a Corporate RSO is '*designated to oversee RPP management at the corporate level (corporate RSO) and assisted by other individuals to oversee the program at the site (site RSOs) to ensure the RPP is effectively implemented and applied at the local level'.* Since the Corporate RSO reports directly to the AA and the site or class 2 RSOs also often report to the Corporate RSO within the institution management structure, the requirement stated in the last paragraph on page 4 (section 3.2, 1) that RSO must have the authority to '*communicate directly with the AA'* could get in the way of effective team management and communications. In organizational structure where there is a Corporate RSO, the statement should be revised to state: *communicate with the applicant authority through the Corporate RSO* or *communicate directly with the applicant authority and the Corporate RSO.* The goal is to ensure that the Corporate RSO, by being included in all communications with the AA, can discharge his/her duties to ensure effective and consistent implementation of the corporate program in all areas of the institution.	As a result of this comment, the text was changed.
138.	The Ottawa Hospital	Section 3.3 and 3.4: Mention of applicable university degrees relevant to the role such as Medical Physics, Health Physics, nuclear physics, radiation biology, and for smaller sites, medical radiation technology etc. should be included as favorable knowledge for the role.	No change was made as a result of this comment. Since this document is meant for licensees with various sizes and organisational structures, the document was kept generic so it could apply to all NSRD licensees. The licensee is responsible for identifying the required qualifications according to the responsibilities assigned to the RSO and the complexity of the licensee's use of nuclear substances.
139.	The Ottawa Hospital	Section 3.5: It would be helpful to define the duration of what is considered a lengthy absence.	As a result of this comment, reference to short-term absence was removed. Section 3.4.1 provides examples of long-term absences.
140.	The Ottawa Hospital	Section 3.6.1: It would be helpful to define the duration of short-term absences where an alternate RSO designation is required.	As a result of this comment, reference to short-term absence was removed.
141.	The Ottawa Hospital	Section 3.6.2: This requirement for site RSO to report to Corporate RSO should explicitly extend to class 2 RSO to ensure alignment of corporate program implementation and unified communication.	No change was made as a result of this comment. This document is meant for guidance only, and although this document can be useful for Class II licensees, it is meant for NSRD licensees.

142.	The Ottawa Hospital	Section 4, para 3: In reference to the RPP meeting the requirements of the license application and having sufficient resources and authority...: Including such requirements in the guide so that it becomes an integral condition of obtaining a license would be beneficial in ensuring the resources are in place to support implementation.	As a result of this comment, the text was changed and a reference to the document *Welcome Package: Applicant Authority, Nuclear Substances and Radiation Devices Licences* was added. This document provides guidance to the applicant authority on directing resources to ensure RSO can fulfill their duties.
143.	The Ottawa Hospital	Section 5: Safety Culture: I support the inclusion of foster a safety culture however it is not clear in this guide whether this will be mandatory to implement and/or to document	As a result of this comment, the text was changed. This document is meant for guidance only. Although fostering a healthy safety culture is recommended for any organization, REGDOC-2.1.2, *Safety Culture* does not include requirements for NSRD licensees.
144.	The Ottawa Hospital	Section 6: It would be helpful to define what a 'management review' should include and who, from Management, should be leading. For example, for complex program where there is a Corporate RSO, can that person lead the management review reporting the results to the RSC and AA?	As a result of the various comments on this section, the document was revised for clarification.
145.	The Ottawa Hospital	Section 5.2.2: '*Independent assessment should be conducted after substantives changes to work practices …'* A self-assessment should be done but an independent one may be too onerous or costly and not necessarily required.	As a result of the various comments on this section, the document was revised for clarification.
146.	The Ottawa Hospital	Section 5.3.3: Please clarify what Management Review would entail. If self-assessment and compliance reports are shared with the AA and the Radiation Safety Committee, does this constitute a management review? Can the AA delegate the review to the Corporate RSO who may also be part of the management team?	As a result of the various comments on this section, the document was revised for clarification.
147.	The Ottawa Hospital	Section 5.3.4: Events that should be reported need to be very specific and well defined. RP regs, Transport and Security regulations include more specific event reporting definitions. These should be aligned with this guide.	As a result of this comment, the section has been removed.

148.	The Ottawa Hospital	Section 5.4: Documentation and Policy Approval: the guide should specify that a procedure/policy review and approval system is in place with proper version control, but the way this is done may vary by institutions and requiring the RSO and AA to 'sign' may not work with defined document controls systems. What is important to consider is the process for review and approval such as: frequency of review, what may trigger a review, stakeholders involved in the review, approval and tracking of revisions, published versions, communication and training. The guide should state a minimum revision frequency to the radiation safety manual or individual procedures since the revision process could be staggered.	As a result of the various comments on this section, the document was revised for clarification.
149.	The Ottawa Hospital	Appendix A, Physical design: A form is submitted for each area, room....is this in line with the current design guide?	No change was made as a result of this comment. The list of duties presented in Appendix A are examples only and are aligned with the revised design guide (currently under review).

150.	The Ottawa Hospital	Appendix B, Radiation Safety Committee: 1) Requirement to review all proposed usage of nuclear substances: this should be left to the RSO and only escalated to the RSC when needed. 2) '*Membership should include a representative of the auxiliary personnel (e.g., clerical, janitorial, security)':* these representatives should be included as stakeholders for procedure reviews but not necessarily as members and be invited when relevant discussions occur or as resource members. The comment: *'In general, the RSO should not be appointed chairperson of the RSC, since the RSO is responsible for the 'day-to-day oversight of the RPP and may be too closely involved in the licensed activities to be objective.' This conflict c*ould apply to other role as well, for example if the Chair is held by a Nuclear Medicine Physician. Instead, this could read: the person appointed as Chair should have the ability to be objective. 3) The requirement that*: 'The chairperson shall work closely with the applicant authority to ensure effective decisions are made and carried out'. The* RSC acts as an objective advisory group to support the RSO. There is not a need for the Chair to work closely with the AA but instead the committee works as an independent advisory board and reports presented to the RSC or requested by the RSC can be shared with the AA. The RSC can also help mobilize the members, institution and the AA for the implementation of key actions relating to the RPP. 4) In addition to the minutes, a clear system demonstrating the tracking and closures of action items should be maintained.	No change was made as a result of the first comment. The list provides examples of roles the RSC could be assigned. The roles are established by the RSC, the licensee and the applicant authority and must be documented in the terms of reference. As a result of these comments, the following changes were made: 2) Text was modified. 3) Text has been removed as suggested. 4) Text has been added.
151.	The Ottawa Hospital	References: The Design application guide should be added as a reference.	No change was made as a result of this comment. The information on the design guide is included in REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices*.