REGDOC-2.5.6, *Design of Rooms Where Unsealed Nuclear Substances are Handled*
REGDOC-2.5.6, *Conception des salles où sont manipulées des substances nucléaires non scellées*

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

• Table A: Comments received during first round (October 30, 2020 to March 17, 2021): 158 comments from 17 reviewers

• Tableau A : Commentaires reçus lors de la première période (30 octobre 2020 au 17 mars 2021) : 158 commentaires reçus de 17 examinateurs

Table A : Comments received during first round / Tableau A : Commentaires reçus lors de la première période

	Organization	Section	Comment
1.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Overall regulatory document	Industry Issue: Major The Design Assessment Form is referenced throughout this draft but is not readily available. The references provided are circular and lead back to GD-52. It is clear from the context of this draft that the form has been revised – each numbered item is discussed in the REGDOC – but a form version was not located. Suggested Change: Industry strongly urges CNSC staff to provide licensees with an opportunity to review the revised Design Assessment Form and provide feedback before this REGDOC is published. Given its importance, licensees also encourage CSNC staff to include the form as an Appendix to this REGDOC (or, alternatively, as a link to a stand-alone document on the CNSC webpage). Impact on Industry: Potential compliance issues/concerns cannot be identified if the revised form is not available for industry review before publication.
2.	Énergie New Brunswick Power	Overall regulatory document	Based on a review of the proposed guidelines and requirements, many of the design provisions for fume hoods appear to be applicable to gloveboxes as well. Clarify if this is the intent.
3.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Overall regulatory document	Industry issue: Clarification Based on a review of the proposed guidelines and requirements, many of the design provisions for fume hoods appear to be applicable to gloveboxes as well. Suggested Change:

	Organization	Section	Comment
			Clarify if this is the intent.
4.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Overall regulatory document	Industry Issue: Clarification The term "nuclear medicine – hot lab" is not a referenced classification in the document, but it is used in several passages. Suggested Change: The term "nuclear medicine – hot lab" should be replaced with "nuclear medicine – radiopharmacy"
5.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Overall regulatory document	Industry Issue: Major There are no differences in requirements or guidance between "high-level" and "containment-level" rooms. Suggested Change: Amend requirements to differentiate containment-level rooms or remove this level. Impact on Industry: There is a distinction without a difference made between two classes of rooms. If there is genuinely no difference between how the rooms are designed, the classification should be removed.
6.	Interior Health	Overall regulatory document	The new design for the DAFs is more targeted and that will be helpful for licensees. However, it appears that the new DAFs may not be as complete as the current DAF and do not make clear that certain items have further guidance items that licensees are advised to follow under REGDOC-2.5.6. For example, in the "DAF for Nuclear Medicine room – other", under Section F, it currently says the following: Section G - Waste No requirements. For guidance see REGDOC-2.5.6, *Design Guide for Rooms Where Unsealed Nuclear Substances are Handled* If one goes to the guidance document, then one finds the list of the guidance items and details on them. If CNSC does not want to include each of the guidance items in the DAFs, it may be good to at least re-word the reference to those items in the DAF to make it clear that they exist. For example, the above section could read as follows (suggestions are in bold): Section G -

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			Waste No specific requirements. For guidance items that licensees are advised to follow see REGDOC-2.5.6, *Design Guide for Rooms Where Unsealed Nuclear Substances are Handled* It may be good to reword all the instances on the DAFs where that wording is currently present. At our institutions, we currently use the DAF as a summary of the best practices when designing Nuclear Medicine rooms. The current DAF is a nice and concise summary of those best practices that we can share with management and project teams. However, if those best practices are not summarized in the new DAFs, then I may personally have to extract them from the REGDOC and have a separate document that I can share with those groups (although it will not look as official as a document with the CNSC logo on it).
7.	Radioprotection Inc.	L'ensemble du document réglementaire	•Formulaire d'évaluation de la conception (FEC) Ce document précise les exigences pour chaque catégorie de laboratoires. Les ingénieurs et chargés de projets peuvent apprécier un formulaire central permettant de résumer la portée du projet par le prisme des attentes règlementaires. Nous apprécions le fait que chaque critère du formulaire d'évaluation de la conception (FEC) soit clairement explicité et que la CCSN précise à quel type de laboratoire il s'applique et les attentes et obligation règlementaires pour chaque critère. Par contre, il aurait été pertinent d'évaluer ce formulaire en même temps que son document de référence REGDOC-2.5.6. Il faut souligner ici que le FEC semble une «recommandation » de la CCSN car on utilise le mot « devrait » en page 5. Ce que nous en comprenons, est qu'un spécialiste de permis ne peut l'exiger. Nous n'avons pas identifié de questionnement majeur pour ce document en ce qui concerne les laboratoires qui ne sont pas associés à la médecine nucléaire. Nous avons par contre souligné quelques points génériques qui sont présentés plus loin dans le détail.
8.	Radioprotection Inc.	L'ensemble du document réglementaire	•Problématique de l'objectif d'évaluation de dose du REGDOC-2.5.6. La problématique de ce document concerne l'objectif précis du REGDOC-2.5.6qui consiste à classifier des laboratoires selon les risques d'incorporation des substances nucléaires (en tenant compte des LAI) et à comptabiliser les doses à des personnes d'intérêts, section 5 et annexe C du document. La première partie est assez directe, mais l'évaluation des doses n'est pas simple. Nous apprécions l'effort de la CCSN de donner des exemples concrets pour l'évaluation des doses. Mais cet effort se heurte à une confusion des besoins de l'organisme règlementaire et ceux des chargés de projet de conception ou de rénovation des salles d'imagerie ou de recherche: •La CCSN demande une évaluation des doses des personnes occupant « significativement » les

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			aires de travail, doses provenant des radionucléides exclusivement. •Les chargés de projet de conception d'un département ou d'une section d'un centre de recherche visent indirectement ce but, mais demandent avant tout de connaitre la composition de chacun des murs à construire ou à déplacer en terme de blindage radiologique pour chaque source de rayonnement, nucléaire et rayons X. Cette exigence peut arriver assez tôt dans la vie du projet, en phase de soumission et d'appel d'offre par exemple. L'exemple se trouvant dans le REGDOC-2.5.6 devrait se conclure, en plus du résumé des doses, par un résumé des barrières radiologiques critiques pour le projet. Une curiosité, dans l'exemple principal, le poste de contrôle des salles de caméra n'est même pas précisé. Le document REGDOC-2.5.6 parle de conception, mais les conclusions de conceptions concernant les doses (le blindage ou le design des pièces principales et avoisinantes) sont évacués dans votre document. Et comme l'objectif de la CCSN est la dose provenant des radionucléides seulement, les rayons X ne sont pas considérés. Nous incluons ici les rayons X comme source de rayonnement car les modalités mixtes existent en médecine nucléaire (rayon-X et radionucléides). Nous comprenons que le mandat de la CCSN exclut les rayons X, mais cette dernière devrait alors le préciser et le mentionner dans la portée du document, car certaines salles de médecine nucléaire utilisant aussi un CT diagnostique peuvent être exploitées potentiellement par l'hôpital en plus de la médecine nucléaire dans le cadre de l'imagerie médicale diagnostic conventionnelle. La charge de travail est alors plus significative et peut avoir un impact sur la contribution dans la dose totale. Par contre précisons ici que dans le cadre de l'utilisation normale de la SPECT-CT, la contribution du CT en dose n'est généralement pas significative. Nous comprenons que la CCSN cherche à aider le titulaire de permis à réaliser une évaluation technique qui peut devenir rapidement complexe et élaborée lorsque les radionucléides occupent plusieurs pièces. Par contre, pour la facilité, l'exemple principal suscite plus de questionnements que de réponses. Bien que l'approche de la CCSN présentée dans ce document pour l'évaluation de la dose à un poste occupé est intuitif, en utilisant un modèle «source-cible», nous ne comprenons pas son formalisme et surtout son utilité, si l'on cherche à simplifier l'évaluation pour le titulaire de permis.
9.	Radioprotection Inc.	L'ensemble du document réglementaire	•Pertinence des exemples présentés dans le REGDOC 2.5.6. Parmi les situations problématiques, en utilisant l'exemple principal du document, avec un

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			laboratoire chaud n'ayant aucun blindage, on calcule alors sa contribution à la dose à un poste de réceptionniste qui ne partage aucun mur mitoyen avec des salles pouvant être une source de rayonnement active. Cette réception est entourée de salles administratives. Pourquoi alors la considérer? On prend soin de calculer une contribution de dose d'un endroit situé à plus de13 m (point A) qui traverse plusieurs barrières physiques dont 2 barrières blindées (1.58 mm de plomb chacune) se trouvant à ceinturer la salle de la caméra 2. Si le blindage de la salle de caméra 2a été évalué correctement, il apparaît alors superflu et fastidieux de présumer que le point A va influencer la réception à travers la salle de caméra 2, en plus sur une distance de 13 m et plusieurs murs de gypse. Est-ce bien ce type d'évaluation que la CCSN recherche? De plus, on peut supposer et même le tester, que si on effectue une mesure de rayonnement dans la réception d'un rayonnement provenant d'une source témoin dans la salle A (autre approche suggérée par la CCSN à l'étape 4, page 31), il serait surprenant de lire quelque chose provenant du point A! Pourquoi alors chercher à le calculer? Nous avons commenté spécifiquement certains autres points de cette analyse plus loin. Nous suggérons alors deux éléments pour faciliter la compréhension de la méthode, par des exemples: •Présenter un seul exemple simple, avec 2 ou 3 salles mitoyennes, administratives et classifiées. •Présenter un exemple générique de la géométrie des salles comme on le voit généralement dans les documents NCRP ou comme l'exemple de la TEP présenté en page 42avec tous les paramètres, facteur d'occupation, distance et point d'intérêt etc.
10.	Radioprotection Inc.	L'ensemble du document réglementaire	Le point sur la distance d'intérêt « d » Un risque important pour cette approche « source-cible », est l'évaluation précise de la distance d'intérêt « d » entre la source et le poste occupé et la possibilité que cette distance puisse varier sur la durée de vie des pièces évaluées. Si ce poste change à l'intérieur d'une même pièce, l'évaluation déjà sévère pour les cibles ALARA de 50µSv/an ou 1000µSv/an peut être invalidée et le blindage qui était suffisant essentiellement à cause de la distance plus importante devient insuffisant si le poste de travail (bureau) se rapproche du mur. Par conséquent, une approche d'évaluation systématique des murs mitoyens (barrières radiologiques principales) aux salles contenant des sources de rayonnement et une distance d'intérêt se trouvant à 30 cm de la barrière de l'autre côté de ces murs est une approche plus systématique. Combiné à une évaluation réaliste des facteurs d'occupation et des charges de travail, il nous appert que cette

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			approche est préférable à celle présentée car cette approche est pérenne sur la durée d'utilisation des salles. Si la dose répond à ALARA à30 cm de l'autre côté de la barrière principale, on a plus à considérer les autres pièces, à moins qu'elles soient elles-mêmes des facteurs contributifs à la dose.
11.	Radioprotection Inc.	L'ensemble du document réglementaire	Le nouveau document se distingue par la clarté des attentes pour le FEC mais aussi, son aspect très technique qui dépasse le cadre de la radioprotection conventionnelle. En ce qui concerne l'évaluation des doses, on devrait la rendre pérenne et indépendante du positionnement de certains éléments structuraux mobiles (distance d). L'écart entre les objectifs d'évaluation de doses de la CCSN et les objectifs des chargés de projet doit être adressé car le document est un document de conception, et on évacue dans les exemples, ce qui devrait être sa conclusion principale, les compositions des barrières radiologiques. La CCSN demande des doses, les chargés de projet demandent le blindage à installer. Ces évaluations se font dans le cadre de projets complexes qui demandent beaucoup de temps et de coordination de la part des responsables de la radioprotection qui n'ont pas toujours le temps ou la compétence pour mener ce projet seul, malgré les exemples qui prennent une très grande place dans le document. Il importe, pour la réussite des projets, de bien souligner la collaboration entre les professionnels concernés, autant du côté de l'ingénierie des projets que des professionnels en radioprotection, responsable de la radioprotection, technologues en médecine nucléaires, ingénieurs-physiciens, ingénieurs biomédicaux et physiciens en radioprotection ou physiciens médicaux. L'approche ALARA inclut toujours les facteurs économiques et sociaux, et la définition précise et réaliste des enjeux du projet, charges de travail, occupations actuelles et anticipées font le succès d'un projet de conception et de construction de laboratoires de substances nucléaires, sujet au cœur du document REGDOC-2.5.6.
12.	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	L'ensemble du document réglementaire	« Le document devrait préciser que certaines salles en médecine nucléaire, telles les salles de bain et les salles d'attente de patients injectés, devraient être considérées pour les calculs de blindage, même si elles ne sont pas classifiées comme laboratoire de médecine nucléaire. En fonction de la disposition des locaux, les doses en provenance de ces salles peuvent être significatives et doivent être considérées par le physicien qui procède au calcul de dose pour les employés du département. La Commission devrait penser à encourager sous forme d'orientation l'installation d'un moniteur de rayonnement dans les laboratoires de médecine nucléaire – radiopharmacie. Les moniteurs de

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			rayonnement sont utilisés notamment aux postes de traitement des installations de production d'isotopes. Ils peuvent aviser les utilisateurs d'une augmentation soudaine du débit de dose dans la pièce et réduire ainsi les risques de doses élevées au personnel. La Commission devrait consulter la Fiche des laboratoires de médecine nucléaires dans le Répertoire des guides de planification immobilière – Unités d'imagerie médicale du Gouvernement du Québec (pp. 54-58). Cette fiche a été mise à jour en 2018 pour inclure les exigences pour les enceintes de préparation stériles (EPS) dans les laboratoires de médecine nucléaire - radiopharmacie. La Commission devrait considérer les exigences pour ce type d'enceinte afin d'éviter des incohérences avec les exigences de radioprotection.
13.	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	L'ensemble du document réglementaire	Il est important que les FEC soient cohérents avec le REGDOC-2.5.6.
14.	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	L'ensemble du document réglementaire	Est-ce qu'il y aura une période de révision pour ceux-ci ou est-ce sous-entendu qu'ils doivent être commentés pendant la période de consultation se terminant au 12 février ?
15.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Preface	Industry Issue: Major As with many other REGDOCs, industry is concerned with the potential interpretation of "should" and "may" statements in this draft. Some CNSC staff view "should" and "may" statements not as guidance or options to consider (as indicated in the Preface), but expectations that must be followed except in rare occasions. Suggested Change: Industry urges CNSC staff to consult with stakeholders - perhaps as part of its current review of the Regulatory Framework - to reach a definitive understanding among staff, Inspectors and licensees regarding the interpretation of "should", "shall" and "may" statements in all REGDOCs. Impact on Industry: A definitive, common understanding will reduce confusion and improve compliance. Some "should" statements in regulatory documents require significant resources to either implement – or to explain to CNSC staff why it is not implemented – with no commensurate increase in worker safety.
16.	Radioprotection Inc.	Préface	Précisions sur les termes « devrait » et « doit »

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			Quelle est l'ouverture de la CCSN aux orientations (devrait)? Est-ce que le titulaire de permis peut ne pas respecter les orientations?
17.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Section 1.1	Industry Issue: Major As currently written, the Purpose of this draft REGODC is unclear and incomplete. Similar to comment #5, the use of "shall" for design requirements is unclear for existing laboratories/rooms that were designed before the issue of this proposed REGDOC. This draft says it "provides requirements and guidance for designing" a nuclear medicine room or a nuclear substance laboratory where unsealed substances are to be handled. It should also confirm that it does not apply to established laboratories/rooms and more clearly say that licensees can use alternative, graded approaches to meet the safety goals of the listed design criteria. Suggested Change: CNSC staff is urged to clarify the Purpose to say this REGDOC is not retroactive and does not apply to existing laboratories/rooms.It should be clear to all readers that established, compliant facilities will be "grandfathered" (i.e. for permanent building installations like ductwork or ventilation, for a laboratory or room that is leased, permanent structures that cannot be changed or where construction cannot be completed, etc.) Impact on Industry: An unclear Purpose could generate confusion regarding expectations for long-established, compliant laboratories/rooms. It is industry's understanding that guidance or requirements of REGDOC 2.5.6 would be utilized to design a room and/or when applying for a licence to use unsealed nuclear substances (i.e. new construction, major renovations or significant changes to current licensed activities). Extensive renovations or construction to existing licensed rooms where unsealed nuclear substances are handled would not be required (unless significant changes are made, as outlined in Section 2, such as demolishing walls, etc.)
18.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Section 1.1	Industry Issue: Clarification Section 1.1 implies a focus on laboratories and medicine rooms while section 1.2 defines the much broader scope of "rooms where unsealed nuclear substances are to be handled." It is unclear if the document intends to address the broader scope, which could include rooms within industrial facilities, or if the sole focus is laboratories and medicine rooms. Suggested Change:

	Organization	Section	Comment
			Align text in sections 1.1 and 1.2 to better define the scope of the document.
19.	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC):	Section 1.1	Dans les centres de recherche, les types d'utilisation de sources non scellées peuvent être très variées. Il peut arriver qu'un usage de source se situe dans la zone grise entre « manipulation » et « entreposage ». Tout comme le document définit le type de manipulations qui requièrent une classification « laboratoire de médecine nucléaire », il pourrait définir le type de manipulations qui requièrent une classification élémentaire à confinement. Modification suggérée : Inclure une définition claire et détaillée du terme « manipulé » ou « manipulation» lorsqu'on fait référence aux sources non scellées. La CCSN devrait préciser ce qui est entendu par les « permis de salle de médecine nucléaire ou de laboratoire de substances nucléaires » puisqu'il n'est clair si cette appellation fait référence aux types d'utilisation présentées à l'annexe B du REGDOC-1.6.1 ou si elle englobe également les types d'activités visées par le REGDOC-1.4.1.
20.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Section 1.2	Industry Issue: Major Similar to comment #6, it is unclear to industry whether the scope of the document is meant to include locations where unsealed nuclear substances are generated but not "handled." Suggested Change: Rooms, areas and enclosures used for decontamination of items contaminated with a nuclear substance should either be included or excluded from scope. Impact on Industry: As currently written, it is unclear if decontamination facilities are within scope of this document. Existing decontamination facilities may not meet this REGDOC's requirements.
21.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Section 1.2	Industry Issue: Major The lifecycle scope of this document should be addressed. Suggested Change:

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			Areas undergoing decommissioning may have residual nuclear substances and temporary supporting areas cannot be designed according to this draft REGDOC. Impact on Industry: It is unreasonable to design a room in a facility to accommodate ongoing decommissioning activities. Temporary areas, rooms and enclosures should not have to be designed as per the REGDOC.
22.	Radioprotection Inc.	Section 1.2	La portée du document est incomplète. On devrait ajouter: « Ce document ne concerne pas la portion rayons X des appareils utilisés en imagerie ou en recherche et la CCSN s'attend à ce que le titulaire de permis tiennent compte, au besoin, des contributions significatives des rayons X dans le calcul total des doses et par conséquent des attentes de blindage.
23.	McMaster University	Section 2	This section currently requires that a DAF is completed and submitted for any major renovation or change to licensed activities in a room. This recommendation does not follow a graded approach that is related to risk. Suggested Change: Revise recommendation to require a DAF only if the renovation or change to licensed activities result in an increase in risk. For example, if shielding is being added, this improves safety and decreases risk. Impact on Industry: Administrative requirements that do not improve safety result in unnecessary cost and regulatory burden on licensees. The completion of a DAF, internal reviews and regulatory communication are unnecessary loss in time and money that could be applied in areas that improve safety.
24.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Section 2	Industry Issue: Major This section suggests a "mobile unit" that uses unsealed nuclear substances should have an assessment separate from the rooms in which it is used. Suggested Change: Include a statement in the Scope that confirms this guide does not apply to a mobile unit. Impact on Industry: The room in which a mobile unit that dispenses unsealed substances for in situ tests or tracer studies should not be subject to this design guide. If this is not the case, many separate

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			rooms and even potentially exterior locations may require design as per this REGDOC.
25.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Section 2	Industry Issue: Clarification The last paragraph of section 2 uses the phrase, "nuclear substance laboratory or nuclear medicine room." This was the old terminology from GD-52. Suggested Change: Amend the final paragraph to read, "After a licence for a room where unsealed nuclear substances are handled has been issued …"
26.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Section 2	Industry Issue: Clarification Industry appreciates the CNSC providing examples of when a DAF should be completed, but believes the examples related to "nuclear substances" should not be included. Suggested Change: To avoid confusion, remove the following examples from the bulleted list on page 4 of section 2: - changing the amount of nuclear substances handled- adding nuclear substances- increasing activity of nuclear substance
27.	BC Cancer – Provincial Health Services Authority	Section 2	In this section, examples of when a DAF should be completed are provided. These examples include "adding nuclear substances" and "increasing activity of nuclear substances" for existing licences. We understand the requirement to complete a DAF for a new construction or major renovations, but do not agree this should be a requirement for a room already licensed for work with nuclear substances. Unless adding/increasing activity of nuclear substance results in a change in room classification where the handling of nuclear substances will occur, we believe there should not be a requirement to submit a full DAF.
28.	Canadian Nuclear Laboratories (CNL)	Section 2	It is not practical to provide the CNSC with a tentative schedule of examinations for the 12-month period starting April 1st of the following year. This equates to a 19-month look ahead. The CNSC fiscal year operates April to April and most licensees do not. Suggested change: Provide a calendar year look-ahead rather than one for the CNSC's April-to-April schedule. Amend: • The 4th bullet in section 2.1.1 to read, "by October 1st each year, to provide the CNSC with the tentative schedule of … examinations for the next calendar year and promptly inform the CNSC of any change to this schedule".

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29.	Radioprotection Inc.	Section 2	On devrait présenter un FEC… Pourquoi « devrait » pour le FEC? Quelle alternative efficace existe-t-il? Surtout pour un changement de charge de travail ou la modification des occupations, le FEC « partiel » pourrait être un outil puissant. Nous suggérons que de mentionner que « certaines modifications exigent de remplir les sections pertinentes de la FEC », pas la FEC en entier.
30.	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	Section 2	Le Formulaire d'évaluation de la conception (FEC) devrait apparaître dans la section «Références» du REGDOC-2.5.6 La liste d'activités pour lesquelles un FEC est demandé devrait être restreinte. Les titulaires de permis procèdent régulièrement à des demandes de modification de permis pour des changements mineurs dans leurs activités. La rédaction de nouveaux FEC pour l'ensemble des activités proposées imposera une charge de travail démesurée aux titulaires de permis et à la CCSN.
31.	Health Science Centre	Section s 3 and 3.1	In Section 3.1, paragraph 2, the document states "For the purpose of this document, nuclear medicine rooms are separated into one of two classifications: nuclear medicine – radiopharmacy and nuclear medicine – other." Nuclear medicine - radiopharmacy classification actually isn't used anywhere else in the document except in this statement. Instead, the term "nuclear medicine - hot lab" is used. Nuclear medicine - other essentially includes all rooms for nuclear medicine use with the exception of a hot lab. I suggest using simpler terms for the classifications nuclear medicine room and nuclear medicine hot lab. In the very least, consistent terms should be used throughout the document.
32.	Nova Scotia Health	Section s 3 and 3.1	I prefer the current designation of nuclear medicine rooms where both administering and preparing radiopharmaceuticals are included. I am not sure why the commission is trying to separate out the two. Many rooms in the department tend to be used as dual purpose. Whether prep, injections or imaging. If anything I would prefer a nuclear medicine - storage area to be included. Potentially a therapeutic room area as well.
33.	Shared Health	Section s 3 and 3.1	The second paragraph identifies nuclear medicine – Radiopharmacy and nuclear medicine – other while Table 1 identifies Nuclear medicine – hot lab and Nuclear medicine – other which is it, Hot

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			Lab or Radiopharmacy? Table 1 Nuclear Medicine – hot lab Most Nuclear Medicine departments that I am familiar with have a designated “Hot Lab”. In Winnipeg we have a central Radiopharmacy and radiopharmaceuticals are typically manufactured in our Radiopharmacy, not in the NM department Hot Labs. Requiring all Hot Labs to be designed as high level/containment-level is in my opinion an over-classification. Perhaps what we refer to as Nuclear Medicine Hot Labs in Winnipeg would be better classified as Nuclear Medicine – Dispensing Room. That does not seem to be a classification that is proposed to be available. Nuclear medicine – other Therapeutic in-patient rooms are not currently classified as Nuclear Medicine rooms. Presumably if this definition is carried through to official publication, only new in-patient therapy rooms will require this classification and/or existing in-patient therapy rooms will be grandfathered. Looking at the proposed DAF for Nuclear medicine – other with in-patient therapy rooms in mind, sections “D” and “E” of the DAF are discrepant with in-patient rooms that I am familiar with. Therapeutic in-patient rooms should have their own or a separate classification. Imaging Rooms where nuclear substances are not handled and/or not administered should not be required to have a CNSC room classification.
34.	Insight Medical Imaging	Section s 3 and 3.1	I agree with the last comment by jdovyak that there is a discrepancy with the designations of Nuclear Medicine-Radiopharmacy and Nuclear Medicine-Other. Our imaging group has a centralized radiopharmacy which we call our central hot lab, but it is quite distinct from the hot labs included in each of our various clinics with a nuclear medicine department. I would support the local site hot labs being considered as part of Nuclear Medicine-Other as there is a much lower level of activity being handled and stored there than what is existing in our radiopharmacy where we have generators and produce the daily required products for seven other locations.
35.	McMaster University	Section s 3 and 3.1	Industry Issue: Very focused on nuclear medicine, but a significant number of laboratories at educational

	Organization	Section	Comment
			institutions across the country also use unsealed sources for research, development and educational purposes. How do they fit into this REGDOC? Suggested Change: Clarify that these guidelines apply to more than nuclear medicine.
36.	BC Cancer – Provincial Health Services Authority	Section s 3 and 3.1	Section 3.1 Classification of rooms In this section it states that "nuclear medicine rooms are separated into one of two classifications: nuclear medicine – radiopharmacy and nuclear medicine – other." In Table 1 and through the remainder of the document the classifications are "nuclear medicine – hot lab" and "nuclear medicine –other". For consistency, we suggest that mention of "radiopharmacy" in this section be changed to "hot lab".
37.	The Ottawa Hospital	Section s 3 and 3.1	The Ottawa Hospital agrees with the previous comments regarding the classifications of rooms, particularly hot labs having to meet the same requirements as high level labs and radio-pharmacies. Most of our rooms designated as hot labs only handle unit doses within in a shielded container. Having them meet the requirements of a radio-pharmacy is not consistent with the level of hazard within these rooms. We second the idea that another category, "Hot Lab - Dispensing" would be a practical solution.
38.	Radioprotection Inc.	Sections 3 et 3.1	3.1 Classification des salles Ajout d'une classification: Entreposage de substances nucléaires. L'entreposage peut être une source de dose significative et devrait avoir sa propre classification. Un exemple d'évaluation de la dose d'une salle d'entreposage pourrait être pertinent dans le document REGDOC-2.5.6.
39.	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	Sections 3 et 3.1	Afin de clarifier l'information contenue au paragraphe 4 de l'article 3.1, nous proposons de modifier le paragraphe comme suit : À l'exception des salles classées comme salles de médecine nucléaire – autres et médecine nucléaire - radiopharmacie, toutes les zones, pièces ou enceintes où plus d'une quantité d'exemption d'une substance nucléaire non scellée est manipulée ou utilisée doivent être classées comme laboratoires de niveau élémentaire, intermédiaire, élevé ou de confinement, selon l'activité maximale de toute substance nucléaire devant être manipulée dans la salle en une seule fois (voir le tableau 1). Cela comprend toutes les salles de médecine nucléaire vétérinaire. La conception de la salle de médecine nucléaire - radiopharmacie doit toutefois suivre l'orientation et les exigences décrites pour la classification des salles de niveau élevé/confinement.

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			Les termes « médecine nucléaire – laboratoire chaud » et « médecine nucléaire – radiopharmacie » sont utilisés dans le document pour désigner les mêmes salles. Nous recommandons de n'en utiliser qu'un seul des deux pour des raisons de clarté. Il pourrait être pertinent de clarifier les attentes concernant les salles d'entreposage et de stockage et de faire une distinction entre les requis pour les sources qui pourraient être de forme scellées et non scellées.
40.	Shared Health	Section 4	For NM rooms – other, the requirements specified in the draft DAF do not seem to be noted as requirements in the draft REGDOC. I was not sure where to post this comment.
41.	Radioprotection Inc.	Section 4	Section 4 Exigence et orientation, B à H Code dans le FEC, exigence vs orientation On ne voit pas le nouveau FEC, mais nous suggérons un code qui permet de différencier les exigences par rapport aux orientations.
42.	Health Science Centre	Section 4.1	With changes to design materials and cleaning practices in hospital settings, I am pleased to see the statement flooring should, rather than must, have strippable coating.
43.	Shared Health	Section 4.1	Drop ceiling with tiles is most often used in Winnipeg hospitals, the individual ceiling tiles are easily replaceable. I should not have to justify this on every DAF that I submit, B6 should be varied to accept easily replaceable modular ceilings. I realize that B6 is in guidance but knowing how the CNSC works, the new DAF will require that "The ceiling should be finished with a smooth, washable surface, and all the joints should be sealed" and I will have to keep submitting an 'Exceptions to the DAF' memo.
44.	Sylvia Fedoruk Canadian Centre for Nuclear Innovation	Section 4.1	The requirement for counter tops to include a lip to prevent runoff seems excessive. Standard counter tops stainless and phenolic do not come with a lip. To include a lip requires a custom made counter top. The volume of activity that users handle at one time is small and the majority of users work on top of a bench coat. The bench coat is used to contain any spill or contamination and makes for easy clean up. Requesting a lip seems unnecessary. I do agree with the requirement for a backsplash.
45.	McMaster University	Section 4.1	Industry Issue: B1 requirement for all intermediate and higher level hot lab rooms to have a "chemical-resistant finish in areas where nuclear substances are handled". This is not required for all surfaces in all labs, as it is dependent on the work being performed and chemicals used. Suggested Change:

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			Move requirement for all intermediate and higher level hot lab rooms to have a "chemical-resistant finish in areas where nuclear substances are handled" from Requirements to Guidance, as it is not required in all laboratories. Industry Impact: Reduce administrative requirement to explain why this is not applicable in each laboratory. Removes the burden for requesting or explaining exemptions to the requirements, when they are not required.
46.	McMaster University	Section 4.1	Industry Issue: Drop ceilings are commonly used and easily replaceable. Section B6 does not specify their use and instead requires licensees to defend their use each time. Suggested Change: Section B6 should document the acceptance of replaceable ceilings, so that we do not need to justify their use with each DAF submission. Industry Impact: Administrative requirements that do not improve safety result in unnecessary cost and regulatory burden on licensees. The requirement to defend a currently accepted and long-standing practice results in unnecessary loss in time and money for licensees that could be applied in areas that actually improve safety.
47.	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	Section 4.1	D'après la remarque 2 sous le tableau 1 de la section 3.1, les salles d'entreposage de substances nucléaires sont exclues de la portée du présent document. Le terme stockage devrait donc être retiré du titre de cette section. Orientation B2 : L'utilisation d'un enduit qui peut être retiré facilement en cas de contamination est superflu si le revêtement du sol a déjà un fini lisse, imperméable et lavable et que les joints sont déjà scellés. La dernière phrase du paragraphe devrait être retirée où le terme «devrait» devrait être remplacé par le terme "pourrait". Idem pour la version anglaise où le terme « should » devrait être remplacé par le terme « can ». Orientation C1 : La Commission devrait préciser ses attentes en ce qui concerne l'installation des douches, douches oculaires et éviers pour des raisons d'urgence. En effet, l'orientation C.5 suggère l'installation des trois alors que le FEC révision 2017-05 semble plutôt exiger les 3 et

	Organization	Section	Comment
			l'exigence C.1 du REGDOC-2.5.6 demande une approche « adaptée aux activités ». Ce n'est pas clair.
48.	Winnipeg Cyclotron Facility	Section 4.1	*Section 4.1 Finishing and fixtures (for use and storage area)* *Item B6 – The ceiling should be finished with a smooth, washable surface, and all the joints should be sealed. Applicants can suggest suitable alternatives, such as easily replaceable modular ceilings (e.g., drop ceiling with tiles).* Our entire facility is fitted with drop ceilings (as are most other departments in the hospital). The tiles in this type of ceiling are easily replaceable and their hangers are a painted metal which are easy to clean/decontaminate (or remove in a worst case scenario). We should not have to justify the use of a drop ceiling on every DAF that is submitted. Not only is this additional paperwork for the licencee to prepare it is also additional paperwork that the CNSC has to track and reference on their end. B6 should be revised to simply list easily replicable modular ceilings as an acceptable alternative rather than as an example of such. This is especially true if a modular ceiling is a common "exception" that the CNSC already sees and accepts.
49.	Nova Scotia Health	Section 4.2	Item C7 has yielded constant issues with Accreditation Canada. I would like guidance on how we "dedicate" this bathroom for radioactive patients only. Signage only goes so far; are we to physically lock the door and only allow radioactive persons in? This approach has actually been suggested. As one can expect, the patients just go to another washroom down the hall, or in the cafeteria. I understand the need to have a department washroom, however it is unpractical and unlikely that a dedicated nuclear medicine patient washroom is solely used by nuclear medicine patients.
50.	Shared Health	Section 4.2	C5 applies to high-level, containment-level and nuclear medicine – hot lab rooms. I object to the notion that Nuclear Medicine Hot Labs require an adjacent shower. In almost twenty (20) years as a front-line Nuclear Medicine Technologist (NMT) I am only personally aware of our Radiopharmacy's decontamination shower being used twice and that was to get non-radioactive vomitus from a patient off an NMT's hair. In my seventeen (17) years in Radiation Safety, I am not aware of any skin contamination incidents in my healthcare region necessitating a whole-body shower. In these days of tight healthcare dollars the money could be better spent elsewhere, like on ergomics or put towards automated dispensing systems. Requiring showers near NM Hot Labs is not ALARA.
51.	Canadian Nuclear Laboratories (CNL)	Section 4.2	Within the REGDOC Section 4.2, there is a statement "Areas for food and drink preparation, consumption or storage must not be located inside any room in which unsealed nuclear substances are handled". The DAF forms will not demonstrate compliance with this requirement.

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			Suggested change: Clarify within the REGDOC as to whether the location of food and drink preparation, consumption or storage is mandatory. If mandatory, include clause on the DAF.
52.	Radioprotection Inc.	Section 4.2	C7 Toilette pour patient Il serait pertinent d'identifier les toilettes pour patients par un affichage dédié.
53.	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	Section 4.2	Dans le dernier paragraphe, veuillez remplacer l'expression « crochets à manteaux » par « crochets à sarraus ». L'erreur provient d'une mauvaise traduction (« lab coats ») et peut porter à confusion. Veuillez également remplacer l'expression « bac de linge radioactif » par «bac de linge contaminé», qui est plus proche de la terminologie utilisée couramment dans les départements de médecine nucléaire et dans les laboratoires.
54.	Shared Health	Section 4.3	D3 – Each sink should have an overflow outlet. Per Infection Control practitioners in my organization, "Overflows are not to be used due to the related risk as serving as a reservoir for bacteria" and again putting this in an "Exceptions to the DAF' memo is tiresome & frustrating.
55.	Radioprotection Inc.	Section 4.3	L'utilisation des réseaux d'égout… pour l'élimination des substances nucléaires… n'est normalement pas une pratique acceptable. Si la pratique n'est pas acceptable, pourquoi alors existe-il des normes d'évacuation dans le permis? Remplacer le mot « acceptable » par «recommandée ».
56.	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	Section 4.3	Il n'est pas clair si l'expression « hygiène des patients » inclut l'élimination de produits radioactifs par l'urine. Si oui, demander de réaliser des calculs de dose provenant de cette élimination serait un changement radical d'approche de la part de la CCSN et impliquerait une charge de travail importante pour les titulaires de permis. Si la Commission fait ici plutôt référence à des cas spécifiques, par exemple, des doses provenant de bassins de rétention d'eau, elle devrait le préciser au document.
57.	Winnipeg Cyclotron Facility	Section 4.3	*Section 4.3 Plumbing – section D of the Design Assessment Form* *Item D3 – Each sink should have an overflow outlet.* Per Infection Control practitioners in my organization, an acute care hospital, "Overflows are not to be used due to the related risk as serving as a reservoir for bacteria" and again putting this in

	Organization	Section	Comment
			an “Exceptions to the DAF’ memo is tiresome & frustrating.
58.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Section 4.5	Industry Issue: Clarification This section describes Shielding, but includes Radiation Control in the title. Suggested Change: Amend the title of section 4.5 to read, “Shielding – section F of the Design Assessment Form”
59.	Interior Health	Section 4.5	In the “DAF for NM rooms – other”, there is currently no requirement to perform a shielding assessment in Section F. Since that form is meant to include imaging rooms and therapy rooms, I believe that the requirement for a shielding assessment should stay in place for that DAF. Imaging rooms and therapy rooms can require significant amount of shielding, sometimes more than in hot labs (and the DAF for that does require a shielding assessment).
60.	Interior Health	Section 4.5	For Nuclear Medicine therapy rooms, the guidance on item F6 of the REGDOC (page 11) currently reads as follows:F6 – The dose rate outside the room should be less than 2.5 µSv/h. However, on our Nuclear Medicine therapeutic licences, licence condition 2581-0 currently reads as follows: Patient Room Area Control The licensee shall ensure that the dose rate in occupied areas around the patient’s room does not exceed 2.5 microSv per hour or that other patients do not receive a dose in excess of 500 microSv per hospital stay. So on the REGDOC the dose rate requirement is only a guidance, but on the licence it’s a requirement. And on the licence there is an alternate option to ensure that the dose received by other patients is below 500 uSv/hospital stay. If the licence requirement is the one that takes precedence, then it would be good to reconcile the requirement and how it is worded on the REGDOC (and possibly the new DAF).
61.	BC Cancer – Provincial Health Services Authority	Section 4.5	Section 4.5 Classification of rooms In this section it states that section F of the DAF (Shielding and Radiation Control i.e. dose estimates) is only required for high-level, containment-level and nuclear medicine - hot lab rooms. We believe this may be an oversight as it means that CNSC doesn't require dose estimates from nuclear medicine injection rooms or imaging rooms."
62.	Radioprotection Inc.	Section 4.5	Indiquer dans cette section sur les cibles ALARA les mots: « facteurs économiques et sociaux considérés »

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			Si on arrive à 100 µSv au lieu de 50 µSv pour une installation existante, il est assez sûr que la CCSN va accepter la situation à cause du facteur économique impliqué.
63.	Radioprotection Inc.	Section 4.5	F6 Débit de dose à l'extérieur des chambres: «devrait » ou « doit »? selon les conditions de permis. Ajouter aussi la clause de 500 µSv pour une chambre de patient.
64.	Radioprotection Inc.	Section 4.6	La gestion des déchets Prévoir un espace acceptable de stockage des déchets selon les radionucléides et leur gestion prévue. Prévoir (optionnel) un système de détection des rayonnements résiduels pour les déchets contaminés de l'institution (comme on touche dans REGDOC-2.5.6 l'évacuation des liquides et des gaz, on devrait prévoir aussi l'évacuation des déchets.)
65.	Shared Health	Section 4.7	In the draft DAF for NM Rooms – Hot Lab, I am concerned with elements H-1 to H-3 and element K-5, if these elements are to apply to what we call a "Hot Lab" in Winnipeg but perhaps are better described as "Dispensing Rooms". I do not have that concerns if those elements are meant to apply to an actual Radiopharmacy facility.
66.	McMaster University	Section 4.7	Industry Issue: H8 currently requires that nuclear exhaust systems are not connected to the normal room ventilation systems. Although this is a good practice, this has successfully been done in laboratories under the current GD-52 guidelines, with provisions in place to control airflow (e.g. backdraft dampers). Suggested Change: Relocate H8 to the Guidance section, allowing licensees to implement engineered controls to control the flow of air in active ventilation. Industry Impact: Ventilation design, construction and maintenance are one of the most costly systems associated with nuclear laboratories. Unnecessary requirements like H8 can significantly increase or even double the costs associated with implementing these systems, which could lead to hundreds of thousands of dollars in cost to a new construction.
67.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear	Section 4.7	Industry Issue: Major Guidance item H10 does not provide the fume hood user adequate protection upon fan failure

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	Association, Énergie NB Power and Ontario Power Generation.		from exposure from unsealed sources. For example: The fume hood has an operator performing some type of activity that is generating volatile, aerosolized or gaseous nuclear substances and the main electrical power is lost to the exhaust fan. There will be a time delay of up to 2-3 minutes before the diesel generator start and the exhaust fan is up and running. In that time period the operator will be exposed to the hazard. Suggested Change: Amend to read, "Fume hoods, should be supported by automatic backup for emergency power to ensure continuous operation." Impact on Industry: The investment required to implement an uninterruptible operation of exhaust fans for fume hoods would not be commensurate with any potential improvement to nuclear safety.
68.	BC Cancer – Provincial Health Services Authority	Section 4.7	Section 4.7 Room ventilation and air flow – Requirement H9 Grammatical error: Suggest this requirement should read "H9 – Provide detailed information about all…"
69.	Radioprotection Inc.	Section 4.7	4.7 Ventilation des pièces Les exigences et l'orientation de la présente section ne s'appliquent qu'aux salles dans lesquelles sont utilisées des substances nucléaires volatiles, aérosolisées ou gazeuses. » Mettre cette phrase au début de la section 4.7 et la mettre en caractère gras car il existe une confusion avec la protection du produit et la protection des utilisateurs! Au Québec avant 2022, les élutionsTc-99m devront être faites sous flot laminaire. Si la place manque dans le laboratoire chaud, ce système devra aussi être une hotte avec évacuation dédiée pour les besoins de l'Iode-131.
70.	Radioprotection Inc.	Section 4.7	Points H Évaluation et considération de certains éléments de ventilation. S'assurer que les systèmes d'économie d'énergie des hottes automatiques (baisse du débit automatique selon un horaire programmé) puissent être annulés localement en cas de besoin d'utilisation de la hotte en dehors des heures. S'assurer que le fonctionnement des hottes est vérifié à une fréquence raisonnable et qu'une étiquette présente la date de la dernière vérification.

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			S'assurer qu'aucun moyen de ventilation supplémentaire n'interfère avec la performance de la hotte (système portatif de filtration ou ventilateur).
71.	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	Section 4.7	L'emploi de l'expression « dans la mesure du possible » dans l'énoncé de l'exigence H1 n'est pas cohérent avec le fait que ce soit une exigence. L'exigence H1 devrait être reformulée ou déplacée à la section des orientations.
72.	Winnipeg Cyclotron Facility	Section 4.7	*Section 4.7 Room Ventilation and Air Flow – Section H of the DAF* *Item H10 - Fume hoods, including exhaust fans, should be supported by automatic backup or emergency power to ensure continuous operation.* In response to item H10-17. It appears the intent is to revise the previously stated guidance to now be a requirement. This position has raised many questions from our perspective. Should this item be implemented as a requirement and we must action, management has stated its support for funding this initiative. However, we strongly feel this item is based on inaccurate assumptions and against historical precedence. 1. There appears to be no evidence to support this change. Most facilities were originally commissioned without this item and have operated without it since their inception without an incident that this change would have impacted (e.g.WCF has been in operation for more than 10 years). Forcing expensive retrofitting on a facility for no perceived advantage seems wasteful. a. Installation of said backup system would appear to provide no tangible benefit to our facility. Our automatic synthesis units operate using a closed system design and radioactive gases contained using gas collection bags or a gas compression storage system. In a worst-case scenario, should power completely fail at the highest point of activity, all activities would be trapped within the sealed system until power was restored or activity naturally decayed. Based on this, there would be no risk of exposure to those working within the facility, to the general public or the environment. 2. The cost of retrofitting our particular system is extensive. Currently projected impacts are as follows, a. Projected facility downtime and therefore potential patient interruption is estimated at a minimum of two weeks.

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			b. The retrofit is currently estimated to cost between 70k to 80k (this includes the cost of ordering replacement isotopes during the two weeks of downtime). c. Placing the exhaust system alone on backup power in our facility proves to be a more involved task than placing the whole facility on backup power. To that point, moving the whole facility to backup power then places a large amount of administrative burden on our facility in the form operating procedure development and maintenance to deal with the semiannual backup power testing. 3. Production levels and capabilities vary between sites due to the type of cyclotron, its power capabilities and the targets a site has for producing various isotopes. a. Medical isotope production facilities most commonly produce F-18. F-18 is produced in a liquid form and in the event that the liquid is aerosolized it is very reactive and is likely to be found staying to the walls of the hot cell or exhaust system where it will simply decay in place. b. Other isotopes potentially produced by "smaller cyclotrons" include C-11 (produced as a gas with a ~20 minute half-life), N-13 (produced as a liquid with a ~10 minute half-life) and O-15 (produced as a gas with a ~2 minute half-life). Having such short half-lives can only be produced in smaller quantities and the short half-lives lends these isotopes to very quick decay and little to no time to create a hazard to the workers, public or the environment in the event of an exhaust failure. As stated above, the facility is committed to making this change should the CNSC decide to implement the requirement for backup power. However, we believe the above points strongly suggest that such effort is ultimately not required and does nothing to improve the safety of workers, the public or the environment.
73.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Section 4.8	Industry Issue: Major Guidance item I16 discusses laminar flow hoods for the first time in the document. Laminar flow hoods and Biological Safety Cabinet(s) are different than fume hoods and follow their own set of standards which have not been referenced within the document. Suggested Change: Delete I16.Impact on Industry: Sterility does not improve radiological safety. This design feature is out-of-scope.

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74.	BC Cancer – Provincial Health Services Authority	Section 4.8	Section 4.8 Fume hood and hot cell design Guidance I10 As this is guidance we suggest rewording this guidance point to read "I10 – Hot cells should have a means of …"
75.	BC Cancer – Provincial Health Services Authority	Section 4.8	Section 4.8 Fume hood and hot cell design Guidance I13 Not all hot cells have windows. As such we suggest rewording this guidance point to read "I13 – Some hot cells have a window …"
76.	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	Section 4.8	Orientation I.11 : L'utilisation de modules de synthèses devrait être explicitement nommée comme alternative possible à l'utilisation de manipulateur lorsqu'une séquence de réactions chimiques diverses doit être mise en œuvre pour obtenir le produit final désiré. D'autant plus que l'énoncé de l'orientation I.11 est formulé à l'affirmative avec l'utilisation du présent : « sont » et non pas au conditionnel. Ceci autant dans la version française que la version anglaise du document. Orientation I.13 : L'utilisation de modules de synthèses, qui peuvent être programmés à froid, et contrôlées par ordinateur rend moins nécessaire l'intégration d'une fenêtre blindée dans la porte de la cellule chaude. L'énoncé pour être reformulé de la manière suivante : Pour les cellules chaudes qui sont pourvues d'une fenêtre permettant l'observation visuelle des procédés à l'intérieur de la cellule chaude, le niveau de blindage de la fenêtre devrait être équivalent à celui des parois de la cellule chaude.
77.	Winnipeg Cyclotron Facility	Section 4.8	*Section 4.8 Fume hood and hot cell design – section I of the Design Assessment Form* *Item I7 – Have backup power installed for hot cell exhaust fans.* In response to item H10-17. It appears the intent is to revise the previously stated guidance to now be a requirement. This position has raised many questions from our perspective. Should this item be implemented as a requirement and we must action, management has stated its support for funding this initiative. However, we strongly feel this item is based on inaccurate assumptions and against historical precedence. 1. There appears to be no evidence to support this change. Most facilities were originally commissioned without this item and have operated without it since their inception without an incident that this change would have impacted (e.g.WCF has been in operation for more than 10 years). Forcing expensive retrofitting on a facility for no perceived advantage seems wasteful.

	Organization	Section	Comment
			a. Installation of said backup system would appear to provide no tangible benefit to our facility. Our automatic synthesis units operate using a closed system design and radioactive gases contained using gas collection bags or a gas compression storage system. In a worst-case scenario, should power completely fail at the highest point of activity, all activities would be trapped within the sealed system until power was restored or activity naturally decayed. Based on this, there would be no risk of exposure to those working within the facility, to the general public or the environment. 2. The cost of retrofitting our particular system is extensive. Currently projected impacts are as follows, a. Projected facility downtime and therefore potential patient interruption is estimated at a minimum of two weeks. b. The retrofit is currently estimated to cost between 70k to 80k (this includes the cost of ordering replacement isotopes during the two weeks of downtime). c. Placing the exhaust system alone on backup power in our facility proves to be a more involved task than placing the whole facility on backup power. To that point, moving the whole facility to backup power then places a large amount of administrative burden on our facility in the form operating procedure development and maintenance to deal with the semiannual backup power testing. 3. Production levels and capabilities vary between sites due to the type of cyclotron, its power capabilities and the targets a site has for producing various isotopes. a. Medical isotope production facilities most commonly produce F-18. F-18 is produced in a liquid form and in the event that the liquid is aerosolized it is very reactive and is likely to be found staying to the walls of the hot cell or exhaust system where it will simply decay in place. b. Other isotopes potentially produced by “smaller cyclotrons” include C-11 (produced as a gas with a ~20 minute half-life), N-13 (produced as a liquid with a ~10 minute half-life) and O-15 (produced as a gas with a ~2 minute half-life). Having such short half-lives can only be produced in smaller quantities and the short half-lives lends these isotopes to very quick decay and little to no time to create a hazard to the workers,

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			public or the environment in the event of an exhaust failure. As stated above, the facility is committed to making this change should the CNSC decide to implement the requirement for backup power. However, we believe the above points strongly suggest that such effort is ultimately not required and does nothing to improve the safety of workers, the public or the environment.
78.	Winnipeg Cyclotron Facility	Section 4.8	*Section 4.8 Fume hood and hot cell design – section I of the Design Assessment Form* *Item I16 – Laminar flow hoods should be used for procedures that require sterility.* Sterility of a product has nothing to do with radiation safety and should be left in the Health Canada guides and regulations.
79.	McMaster University	Section 4.10	Industry Issue with K4: In some cases, exhaust stacks or vents may not be able to be located downwind from air intakes and the risks do not warrant the costs associated with changing existing building or laboratory designs. Suggested Change: The 'as far as possible from any air intakes' stipulation is already captured by K11 under Guidance. Move K4 to guidance and remove K11. Industry Impact: Ventilation design, construction and maintenance are one of the most costly systems associated with nuclear laboratories. Unnecessary requirements like K4 can significantly increase costs associated with projects. Particularly when adding laboratories to existing building structures, this requirement could lead to hundreds of thousands of dollars in cost to a new construction.
80.	McMaster University	Section 4.10	Industry Issue: K5 currently requires that all licensees "demonstrate via atmospheric dispersion modelling or other calculations that doses to the public arising from both routine releases and foreseeable worst-case scenarios are ALARA and will not exceed the applicable dose limits." This is not currently required in GD-52 and is already addressed in REGDOC-2.9.1. Suggested Change: Remove this requirement, as it is not value added, particularly for nuclear medicine laboratories. This duplicates existing requirements in REGDOC-2.9.1 and leads to confusion. Request removal

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			of this requirement. Industry Impact: The need for atmospheric dispersion modelling and other calculations needs to be commensurate with the risk of the activity being performed. As this is already addressed in a risk-based approach under REGDOC-2.9.1 requirements, it should not be made mandatory here and add unnecessary costs in the ten's of thousands of dollars for consultants.
81.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Section 4.10	Industry Issue: Major Requirement K4, about placing the exhaust stack downwind of the fresh air intake, is unachievable. The wind can shift direction periodically. Suggested Change: Delete K4 Impact on Industry: This requirement would be impossible to implement.
82.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Section 4.10	Industry Issue: Clarification Requirement K6 is unclear. Exhaust fan should be placed close to the discharge point to eliminate as much duct work as possible regardless if it is a fume hood or a hot cell. Suggested Change: Amend to read, "K6 – Locate exhaust fans close to the discharge point."
83.	BC Cancer – Provincial Health Services Authority	Section 4.10	Section 4.10 Ducts, vents and stacks We believe this section is only relevant if volatile, aerosolized or gaseous nuclear substances will be used in the room. As such, we recommend adding similar wording to that found in section 4.7 "The requirements and guidance in this section only apply to rooms where volatile, aerosolized or gaseous nuclear substances will be used."
84.	Radioprotection Inc.	Section 4.10	K3 Un exemple d'identification des conduites devrait être donné. Au lieu du trifolié que l'on demandait dans GD-52, est-ce que « évacuation MD nucléaire » est accepté? Est-ce que l'on pourrait simplement se fier aux principes de santé-sécurité qui demandent d'analyser le contenu des systèmes d'évacuation avant de les ouvrir? Devrait-on identifier les cheminées d'évacuation pertinentes accessibles au niveau du toit?

	Organization	Section	Comment
85.	Radioprotection Inc.	Section 4.10	K7 Sections horizontales On devrait préciser « d'identifier clairement (signe trifolié, risque de contamination) les points de collecte des condensats. » Rappeler aussi les changements de directions (coudes) qui peuvent être des points d'accumulation.
86.	Shared Health	Section 5	In Appendix C: Estimating Doses this draft REGDOC does not appear to acknowledge that once a radionuclide is administered to a patient, the patient's body often provides significant shielding of that dose. This would likely result in less shielding being required in the facility design, significantly reducing project cost. CNSC should provide the shielding information required to perform that calculation (it does not seem to appear in Appendix C) instead of describing the patient as an unshielded point source. This approach is consistent with ALARA since the practice of ALARA allows for financial considerations to be taken into account.
87.	BC Cancer	Section 5	Jeff raises an excellent point. The REGDOC points PET facilities towards an AAPM TG document whose methodology does account for patient attenuation of PET emissions. It would make sense if the CNSC suggested methodology also accounted for this.
88.	Canadian Nuclear Laboratories (CNL)	Section 5	Section 5.2 Incorrect references are cited in the final sentence of this section. Suggested change: Amend the final sentence to read, "Complete the development of the examination following the instructions given in paragraphs 5.1.2 and 5.1.3".
89.	McMaster University	Appendix A	Industry Issue: Some common radionuclides have been omitted from Table A1, including H-3 and C-14. Information for these radionuclides is available and should be included here. It would also be great if other radionuclides that are starting to be used more often were included, like In-111 and Ac-225. Suggested Change: Include release limits for H-3, C-14, In-111 and Ac-225. Industry Impact: Not having these radionuclides (particularly H3 and C-14) in the table causes misalignment between the regulator and licensees, leading to confusion and unnecessary administrative burden

	Organization	Section	Comment
			in justification of release limits used.
90.	McMaster University	Appendix A	Industry Issue: Some common radionuclides have been omitted from Table A2, including H-3, C-14 and I-125. Information for these radionuclides is available and should be included here. Suggested Change: Include release limits for H-3, C-14 and I-125. Industry Impact: Not having these common radionuclides in the table causes misalignment between the regulator and licensees, leading to confusion and unnecessary administrative burden in justification of release limits used.
91.	McMaster University	Appendix A	Minor comment: Table A2 has a superscript for I-131, with no reference (175^1). Additionally EU-154 should be revised to Eu-154.
92.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Appendix A	Industry Issue: Major The values presented as conditional clearance levels do not match those present in TECDOC-1000 Suggested Change: Either the REGDOC should match the values in TECDOC-1000 or the method for generating alternate values must be presented. Impact on Industry: Licensees would not be able to adequately justify any variances to the CNSC without adequate discussion of derivation of these values.
93.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Appendix A	Industry Issue: Major TECDOC-1000 includes conditional clearance levels for solid waste. This REGDOC does not include them. Suggested Change: Include conditional clearance levels for solid waste generated using the same method as found in Appendix A. An alternative suggestion would be to include those levels found in IAEA Safety Series No. 115 as per TECDOC-1000.

	Organization	Section	Comment
			Impact on Industry: If conditional clearance levels are presented at all, they must contain solid waste criteria or they will be incomplete. Solid waste represents a far larger impact on the nuclear industry than air or water effluent.
94.	BC Cancer – Provincial Health Services Authority	Appendix A	Table A2: Conditional clearance levels for atmospheric releases We suggest adding the values for N-13 (nitrogen-13) to this table as it is a common gaseous product produced by PET isotope cyclotrons.
95.	McMaster University	Appendix B	Industry Issue: ALIs in Table B1 are not aligned in ICRP guidelines that state that they should be rounded to the 1st significant figure. Suggested Change: Round ALIs in Table B1 to 1 significant figure, as per ICRP recommendations. Industry Impact: No reason to not follow ICRP guidance regarding how ALIs are calculated and utilized. Only leads to confusion between licensees and the regulator when applying these factors.
96.	Bruce Power, Canadian Nuclear Laboratories, Canadian Nuclear Association, Énergie NB Power and Ontario Power Generation.	Appendix B	Industry Issue: Major With recent changes to the Radiation Protection Regulations, it would be inappropriate to include dose conversion factors that are based on ICRP-68. Suggested Change: Use updated dose conversion factors from ICRP reports 130, 134, 137 and 141. Impact on Industry: The dose conversion factors using the new weighting factors and ICRP models are more restrictive than the previous values. For example inhalation values for Co-60, Sr-90, and Cs-137 are 6.45E5 Bq, 1.00E5 Bq, and 2.15E6 Bq respectively. These values are all lower than the values presented in Appendix B. Using the older conversion factors could be seen as a violation of the updated Radiation Protection Regulations.
97.	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	Annexe B	La Commission devrait bonifier le tableau B1 de manière à ce que la grande majorité des isotopes apparaissant sur les permis octroyés y soient présents, dont minimalement les isotopes suivants : - Lutécium 177; - Actinium 225;

	Organization	Section	Comment
			- Titane 45.
98.	McMaster University	Appendix C	Minor Comment: The example table reference should be C2. Additionally, Step 3 of the five-step method is mislabeled (Step 3 should be "Estimating occupancy factor").
99.	Radioprotection Inc.	Annexe C	Cadre général d'estimation des doses Il faudrait aussi mentionner que la distance est l'élément le plus avantageux financièrement dans la conception. Ajouter ce point lorsque l'on parle du temps, la distance et le blindage.
100	Radioprotection Inc.	Annexe C	Tableau C3 « Les contributions des sources A, B et C sont évaluées, car il n'y a pas de blindage entre ces sources et la zone de réception.» Cette affirmation est fausse, il y a un blindage, celle des caméras 1 et 2. Et la salle E2 n'est pas adjacente à la réception. De plus, plusieurs murs de gypse (au moins 2 x 5/8 po. chacun) est un blindage pour le Tc-99m. On comprendrait mieux cette affirmation point pour le F-18 qui a une portée spectaculaire.
101	Radioprotection Inc.	Annexe C	P.33-calcul Erreur de notation Correction: $(5m)^2$ Après ce point, nous n'avons pas eu le temps de vérifier l'ensemble des calculs et affirmations pour le reste du document.
102	Radioprotection Inc.	Annexe C	Référence pour calcul de TEP Une bonne présentation disponible se trouve avec l'AAPM: https://www.aapm.org/meetings/08ss/documents/Wendt.pdf
103	Radioprotection Inc.	Annexe C	Diagramme Très bon diagramme, il faudrait s'en servir pour illustre les données de blindage attendues (facteur d'occupation, distance d'intérêt, etc.).
104	Radioprotection Inc.	Annexe C	Conclusion sur la dose C'est ici que pour un projet générique, la conclusion rencontre les attentes de la CCSN, mais pas

	Organization	Section	Comment
			celle du projet. Nous recommandons de présenter des indications pour le blindage des murs, car ultimement, c'est à cause du blindage que les doses sont atteintes et rencontrent les cibles initiales!
105	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	Annexe C	Le texte de l'annexe C comporte plusieurs coquilles (c. Tableau C2, p.33, p. 37, tableau C6, etc.). La CCSN devrait réviser ses calculs et les résultats obtenus avant de publier officiellement le document.
106	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	All Design Assessment Forms	Section A-5 to indicate "classification of rooms covered by this form" is redundant if there is a separate DAF for each room classification type and that classification is checked/defined at start of form. Suggested Change: Remove Section A-5.
107	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	All Design Assessment Forms	Section A-8 asks for "signature of person responsible". Who is this intended to be? It is unclear as currently written. Should the reviewer/signature be the signing/applicant authority? Should it be the owner of lab? Clarify required reviewer for A-8.
108	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Intermediate level rooms	In the preface of REGDOC-2.5.6 it states that the words "shall" and "must" are used to express requirements to be satisfied by the licensee or licence applicant. It seems unsound that the draft DAF permits applicants to check "shall" clauses as "No" or not being met on the DAF during the application process. For Intermediate Level Rooms this applies to clauses B-1, D-1, E-1, E-2, E-3, and E-4. Suggested change: Clarify in the preface the intent of "shall" and "must" if there is the option to have justified exceptions in Intermediate Level rooms, High Level rooms, Containment rooms, and Nuclear Medicine – hot labs. OR Update the DAF forms to remove the option for "No" for a "shall" or "must" clause for the applicable room type, and provide the option to select "alternate means provided" to align with Section 4 of the REGDOC which states that 'The DAF also provides opportunities to propose alternate means of achieving the intent of the requirements outlined in this section.' MAJOR Impact on industry: A definitive, common understanding of the word "shall" will reduce confusion and improve

	Organization	Section	Comment
			compliance.
109	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Intermediate level rooms	In the DAF form for all room types, clause D-1 is incorrectly identified as “Yes” meeting the requirement. In this instance, applicants should answer “No”. Routinely disposing of nuclear substances via the sewer system (as per “Yes”) does not fulfil the requirement in the REGDOC. Suggested change: Correction of the DAF form to meet the REGDOC clause. MAJOR Impact on industry: As currently written, discharge via the sewer system would be the appropriate design selection, which is not consistent with the REGDOC.
110	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for Intermediate level rooms	The DAF form has many requirements for fume hood and hot cell design that should be expanded to glove boxes (e.g. I-1, I-2, I-3, etc.). Suggested change: Expand clauses for fume hoods and hot cells to glove boxes where appropriate.
111	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for Intermediate level rooms	The DAF form has many requirements for fume hood and hot cell design that should be expanded to glove boxes (e.g. I-1, I-2, I-3, etc.). Suggested change: Expand clauses for fume hoods and hot cells to glove boxes where appropriate.
112	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for Intermediate level rooms	Clause K-3 in all room types of the DAF could be worded more clearly. Suggested change: Propose changing clause K-3 to “Nuclear exhaust ducts are clearly identified both on the ducts themselves and on any plans provided to maintenance personnel or contractors”.
113	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for Intermediate level rooms	In the DAF form, it would be helpful to clarify the clauses where they differ from the REGDOC. Clauses, where reworded on the DAF, should accurately reflect the context in the REGDOC. Suggested change: The following clauses are missing context. The proposed addition of the correct context is provided by the suggested underlined text. These are examples and not an exhaustive list.

	Organization	Section	Comment
			• Clause B-1 suggest changing to: “Where nuclear materials are handled flooring, work surfaces, chairs, cupboards and shelving have a smooth, impervious washable and chemical resistant finish”. • Clause E-2 suggest changing to: “Lockable doors installed on restricted rooms”. • Clause E-4 suggest changing to “Clearly delineated designated area where unsealed nuclear substances are handled in rooms not exclusively used for only this practice”.
114	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for Intermediate level rooms	The following wording is repeated: “For further guidance see REGDOC-2.5.6, Design Guide for Rooms Where Unsealed Nuclear Substances are Handled”. Suggested change: Place a single statement at the beginning of the form “For further guidance see REGDOC-2.5.6, Design Guide for Rooms Where Unsealed Nuclear Substances are Handled”. Recommendation is to delete all other statements as it creates a form that is much longer than it needs to be and may take away from the importance of the form.
115	Canadian Nuclear Laboratories (CNL) , New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for High level rooms	In the preface of REGDOC-2.5.6 it states that the words “shall” and “must” are used to express requirements to be satisfied by the licensee or licence applicant. It seems unsound that the draft DAF permits applicants to check “shall” clauses as “No” or not being met on the DAF during the application process. This applies to clauses: B-1, C-1, C-2, D-1, E-1, E-2, E-3, E-4, E-5, K-1, K-2, K-3, K-4, K-5, and K-6 for High Level Rooms, Containment Rooms and Nuclear Medicine Rooms – hot labs. Suggested change: Clarify in the preface the intent of “shall” and “must” if there is the option to have justified exceptions in Intermediate Level rooms, High Level rooms, Containment rooms, and Nuclear Medicine – hot labs. OR Update the DAF forms to remove the option for “No” for a “shall” or “must” clause for the applicable room type, and provide the option to select “alternate means provided” to align with Section 4 of the REGDOC which states that ‘The DAF also provides opportunities to propose alternate means of achieving the intent of the requirements outlined in this section." MAJOR Impact on industry: A definitive, common understanding of the word “shall” will reduce confusion and improve compliance.
116	Canadian Nuclear Laboratories (CNL	Design Assessment Form	There is no difference between sections 4.7 to 4.10 for the two forms. If there is no difference in requirements/form, the two classifications may be redundant.

	Organization	Section	Comment
		for High level rooms	Suggested change: Relax the requirements for High Level rooms to provide a better graded approach, clarify the difference between high level and containment level rooms and/or eliminate one of the classifications. MAJOR Impact on industry: The graded approach has not been achieved, which will cause confusion.
117	Canadian Nuclear Laboratories (CNL	Design Assessment Form for High level rooms	Section J does not have requirements. Suggested change: Suggest adding wording to confirm that section is “for guidance only”.
118	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for High level rooms	In the DAF form for all room types, clause D-1 is incorrectly identified as “Yes” meeting the requirement. In this instance, applicants should answer “No”. Routinely disposing of nuclear substances via the sewer system (as per “Yes”) does not fulfil the requirement in the REGDOC. Suggested change: Correction of the DAF form to meet the REGDOC clause. MAJOR Impact on industry: As currently written, discharge via the sewer system would be the appropriate design selection, which is not consistent with the REGDOC.
119	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for High level rooms	The DAF form has many requirements for fume hood and hot cell design that should be expanded to glove boxes (e.g. I-1, I-2, I-3, etc.). Suggested change: Expand clauses for fume hoods and hot cells to glove boxes where appropriate.
120	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for High level rooms	The DAF form has many requirements for fume hood and hot cell design that should be expanded to glove boxes (e.g. I-1, I-2, I-3, etc.). Suggested change: Expand clauses for fume hoods and hot cells to glove boxes where appropriate.
121	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power	Design Assessment Form for High level	Clause K-3 in all room types of the DAF could be worded more clearly. Suggested change:

	Organization	Section	Comment
	Generation (OPG):	rooms	Propose changing clause K-3 to “Nuclear exhaust ducts are clearly identified both on the ducts themselves and on any plans provided to maintenance personnel or contractors”.
122	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for High level rooms	In the DAF form, it would be helpful to clarify the clauses where they differ from the REGDOC. Clauses, where reworded on the DAF, should accurately reflect the context in the REGDOC. Suggested change: The following clauses are missing context. The proposed addition of the correct context is provided by the suggested underlined text. These are examples and not an exhaustive list. • Clause B-1 suggest changing to: “Where nuclear materials are handled flooring, work surfaces, chairs, cupboards and shelving have a smooth, impervious washable and chemical resistant finish”. • Clause E-2 suggest changing to: “Lockable doors installed on restricted rooms”. • Clause E-4 suggest changing to “Clearly delineated designated area where unsealed nuclear substances are handled in rooms not exclusively used for only this practice”.
123	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for High level rooms	The following wording is repeated: “For further guidance see REGDOC-2.5.6, Design Guide for Rooms Where Unsealed Nuclear Substances are Handled”. Suggested change: Place a single statement at the beginning of the form “For further guidance see REGDOC-2.5.6, Design Guide for Rooms Where Unsealed Nuclear Substances are Handled”. Recommendation is to delete all other statements as it creates a form that is much longer than it needs to be and may take away from the importance of the form.
124	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	Formulaire d'évaluation de la conception pour des salles de niveau élevé	Dans le FEC, à l’exigence H-1, des sections de phrase ont été inversés. Section H - Exigences en matière de ventilation des pièces et de débit d’air H-1 Mesure visant à empêcher que les rejets l’environnement.atmosphériques de substances nucléaires se retrouvent dans Il faudrait plutôt utiliser : Mesure visant à empêcher que les rejets atmosphériques de substances nucléaires se retrouvent dans l’environnement.
125	Canadian Nuclear Laboratories (CNL) , New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Containment level rooms	In the preface of REGDOC-2.5.6 it states that the words “shall” and “must” are used to express requirements to be satisfied by the licensee or licence applicant. It seems unsound that the draft DAF permits applicants to check “shall” clauses as “No” or not being met on the DAF during the application process.

	Organization	Section	Comment
			This applies to clauses: B-1, C-1, C-2, D-1, E-1, E-2, E-3, E-4, E-5, K-1, K-2, K-3, K-4, K-5, and K-6 for High Level Rooms, Containment Rooms and Nuclear Medicine Rooms – hot labs. Suggested change: Clarify in the preface the intent of "shall" and "must" if there is the option to have justified exceptions in Intermediate Level rooms, High Level rooms, Containment rooms, and Nuclear Medicine – hot labs. OR Update the DAF forms to remove the option for "No" for a "shall" or "must" clause for the applicable room type, and provide the option to select "alternate means provided" to align with Section 4 of the REGDOC which states that 'The DAF also provides opportunities to propose alternate means of achieving the intent of the requirements outlined in this section." MAJOR Impact on industry: A definitive, common understanding of the word "shall" will reduce confusion and improve compliance.
126	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for Containment level rooms	There is no difference between sections 4.7 to 4.10 for the two forms. If there is no difference in requirements/form, the two classifications may be redundant. Suggested change: Relax the requirements for High Level rooms to provide a better graded approach, clarify the difference between high level and containment level rooms and/or eliminate one of the classifications. MAJOR Impact on industry: The graded approach has not been achieved, which will cause confusion.
127	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for Containment level rooms	Section J does not have requirements. Suggested change: Suggest adding wording to confirm that section is "for guidance only".
128	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for Containment level rooms	In the DAF form for all room types, clause D-1 is incorrectly identified as "Yes" meeting the requirement. In this instance, applicants should answer "No". Routinely disposing of nuclear substances via the sewer system (as per "Yes") does not fulfil the requirement in the REGDOC. Suggested change: Correction of the DAF form to meet the REGDOC clause.

	Organization	Section	Comment
			MAJOR Impact on industry: As currently written, discharge via the sewer system would be the appropriate design selection, which is not consistent with the REGDOC.
129	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for Containment level rooms	The DAF form has many requirements for fume hood and hot cell design that should be expanded to glove boxes (e.g. I-1, I-2, I-3, etc.). Suggested change: Expand clauses for fume hoods and hot cells to glove boxes where appropriate.
130	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for Containment level rooms	Clause K-3 in all room types of the DAF could be worded more clearly. Suggested change: Propose changing clause K-3 to “Nuclear exhaust ducts are clearly identified both on the ducts themselves and on any plans provided to maintenance personnel or contractors”.
131	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for Containment level rooms	In the DAF form, it would be helpful to clarify the clauses where they differ from the REGDOC. Clauses, where reworded on the DAF, should accurately reflect the context in the REGDOC. Suggested change: The following clauses are missing context. The proposed addition of the correct context is provided by the suggested underlined text. These are examples and not an exhaustive list. • Clause B-1 suggest changing to: “Where nuclear materials are handled flooring, work surfaces, chairs, cupboards and shelving have a smooth, impervious washable and chemical resistant finish”. • Clause E-2 suggest changing to: “Lockable doors installed on restricted rooms”. • Clause E-4 suggest changing to “Clearly delineated designated area where unsealed nuclear substances are handled in rooms not exclusively used for only this practice”.
132	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG):	Design Assessment Form for Containment level rooms	The following wording is repeated: “For further guidance see REGDOC-2.5.6, Design Guide for Rooms Where Unsealed Nuclear Substances are Handled”. Suggested change: Place a single statement at the beginning of the form “For further guidance see REGDOC-2.5.6, Design Guide for Rooms Where Unsealed Nuclear Substances are Handled”. Recommendation is to delete all other statements as it creates a form that is much longer than it needs to be and may take away from the importance of the form.

	Organization	Section	Comment
133	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	Formulaire d'évaluation de la conception pour des salles de niveau de confinement	Dans le FEC, à l'exigence H-1, des sections de phrase ont été inversés. Section H - Exigences en matière de ventilation des pièces et de débit d'air H-1 Mesure visant à empêcher que les rejets l'environnement.atmosphériques de substances nucléaires se retrouvent dans Il faudrait plutôt utiliser : Mesure visant à empêcher que les rejets atmosphériques de substances nucléaires se retrouvent dans l'environnement.
134	BC Cancer – Provincial Health Services Authority	Design Assessment Form for Nuclear Medicine room - hot lab	Design Assessment Form - Section H Suggest adding a checkbox at the start of this section stating: • Will volatile, aerosolized or gaseous nuclear substances be used in this room? If answer is No then section is not required.
135	BC Cancer – Provincial Health Services Authority	Design Assessment Form for Nuclear Medicine room - hot lab	Design Assessment Form – Section D D-1 Routinely disposing nuclear substances via sewer system, if yes provide justification below □ Yes, this requirement has been met □ No (justification required) Suggest this is reworded as it seems to require justification for both Yes and No. This is for all room types.
136	BC Cancer – Provincial Health Services Authority	Design Assessment Form for Nuclear Medicine room - hot lab	Design Assessment Form - Section I Suggest adding a checkbox at the start of this section stating: • Does this room contain any fume hoods or hot cells? If answer is No then section is not required.
137	BC Cancer – Provincial Health Services Authority	Design Assessment Form for Nuclear Medicine room - hot lab	Design Assessment Form - Section J Suggest removing this section from the DAF as there are no requirements for any types of rooms. Perhaps Section 4.9 in the document can be consolidated with Section 4.8.
138	BC Cancer – Provincial Health Services Authority	Design Assessment Form for Nuclear Medicine room -	Design Assessment Form - Section K Suggest adding a checkbox at the start of this section stating: • Will volatile, aerosolized or gaseous nuclear substances be used in this room? If answer is No then section is not required.

	Organization	Section	Comment
		hot lab	
139	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Nuclear Medicine room - hot lab	In the preface of REGDOC-2.5.6 it states that the words “shall” and “must” are used to express requirements to be satisfied by the licensee or licence applicant. It seems unsound that the draft DAF permits applicants to check “shall” clauses as “No” or not being met on the DAF during the application process. Suggested change: Clarify in the preface the intent of “shall” and “must” if there is the option to have justified exceptions in Intermediate Level rooms, High Level rooms, Containment rooms, and Nuclear Medicine – hot labs. OR Update the DAF forms to remove the option for “No” for a “shall” or “must” clause for the applicable room type, and provide the option to select “alternate means provided” to align with Section 4 of the REGDOC which states that ‘The DAF also provides opportunities to propose alternate means of achieving the intent of the requirements outlined in this section." MAJOR Impact on industry: A definitive, common understanding of the word “shall” will reduce confusion and improve compliance.
140	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Nuclear Medicine room - hot lab	In the DAF form for all room types, clause D-1 is incorrectly identified as “Yes” meeting the requirement. In this instance, applicants should answer “No”. Routinely disposing of nuclear substances via the sewer system (as per “Yes”) does not fulfil the requirement in the REGDOC. Suggested change: Correction of the DAF form to meet the REGDOC clause. MAJOR Impact on industry: As currently written, discharge via the sewer system would be the appropriate design selection, which is not consistent with the REGDOC.
141	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Nuclear Medicine room - hot lab	The DAF form has many requirements for fume hood and hot cell design that should be expanded to glove boxes (e.g. I-1, I-2, I-3, etc.). Suggested change: Expand clauses for fume hoods and hot cells to glove boxes where appropriate.

	Organization	Section	Comment
142	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Nuclear Medicine room - hot lab	Clause K-3 in all room types of the DAF could be worded more clearly. Suggested change: Propose changing clause K-3 to "Nuclear exhaust ducts are clearly identified both on the ducts themselves and on any plans provided to maintenance personnel or contractors".
143	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Nuclear Medicine room - hot lab	In the DAF form, it would be helpful to clarify the clauses where they differ from the REGDOC. Clauses, where reworded on the DAF, should accurately reflect the context in the REGDOC. Suggested change: The following clauses are missing context. The proposed addition of the correct context is provided by the suggested underlined text. These are examples and not an exhaustive list. • Clause B-1 suggest changing to: "Where nuclear materials are handled flooring, work surfaces, chairs, cupboards and shelving have a smooth, impervious washable and chemical resistant finish". • Clause E-2 suggest changing to: "Lockable doors installed on restricted rooms". • Clause E-4 suggest changing to "Clearly delineated designated area where unsealed nuclear substances are handled in rooms not exclusively used for only this practice".
144	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Nuclear Medicine room - hot lab	The following wording is repeated: "For further guidance see REGDOC-2.5.6, Design Guide for Rooms Where Unsealed Nuclear Substances are Handled". Suggested change: Place a single statement at the beginning of the form "For further guidance see REGDOC-2.5.6, Design Guide for Rooms Where Unsealed Nuclear Substances are Handled". Recommendation is to delete all other statements as it creates a form that is much longer than it needs to be and may take away from the importance of the form.
145	Association québécoise des physicien(ne)s médicaux cliniques (AQPMC)	Formulaire d'évaluation de la conception pour des salles de médecine nucléaire - laboratoire chaud	Dans le FEC, à l'exigence H-1, des sections de phrase ont été inversés. Section H - Exigences en matière de ventilation des pièces et de débit d'air H-1 Mesure visant à empêcher que les rejets l'environnement.atmosphériques de substances nucléaires se retrouvent dans Il faudrait plutôt utiliser : Mesure visant à empêcher que les rejets atmosphériques de substances nucléaires se retrouvent dans l'environnement.
146	BC Cancer – Provincial Health Services Authority	Design Assessment Form	Design Assessment Form - Section H Suggest adding a checkbox at the start of this section stating:

	Organization	Section	Comment
		for Nuclear Medicine rooms - other	• Will volatile, aerosolized or gaseous nuclear substances be used in this room? If answer is No then section is not required.
147	BC Cancer – Provincial Health Services Authority	Design Assessment Form for Nuclear Medicine rooms - other	Design Assessment Form – Section D D-1 Routinely disposing nuclear substances via sewer system, if yes provide justification below □ Yes, this requirement has been met □ No (justification required) Suggest this is reworded as it seems to require justification for both Yes and No. This is for all room types.
148	BC Cancer – Provincial Health Services Authority	Design Assessment Form for Nuclear Medicine rooms - other	Design Assessment Form - Section I Suggest adding a checkbox at the start of this section stating: • Does this room contain any fume hoods or hot cells? If answer is No then section is not required.
149	BC Cancer – Provincial Health Services Authority	Design Assessment Form for Nuclear Medicine rooms - other	Design Assessment Form - Section J Suggest removing this section from the DAF as there are no requirements for any types of rooms. Perhaps Section 4.9 in the document can be consolidated with Section 4.8.
150	BC Cancer – Provincial Health Services Authority	Design Assessment Form for Nuclear Medicine rooms - other	Design Assessment Form - Section K Suggest adding a checkbox at the start of this section stating: • Will volatile, aerosolized or gaseous nuclear substances be used in this room? If answer is No then section is not required.
151	Canadian Nuclear Laboratories (CNL)	Design Assessment Form for Nuclear Medicine rooms - other	In the preface of REGDOC-2.5.6 it states that the words “shall” and “must” are used to express requirements to be satisfied by the licensee or licence applicant. It seems unsound that the draft DAF permits applicants to check “shall” clauses as “No” or not being met on the DAF during the application process. Suggested change: Clarify in the preface the intent of “shall” and “must” if there is the option to have justified exceptions in Intermediate Level rooms, High Level rooms, Containment rooms, and Nuclear Medicine – hot labs. OR Update the DAF forms to remove the option for “No” for a “shall” or “must” clause for the

	Organization	Section	Comment
			applicable room type, and provide the option to select “alternate means provided” to align with Section 4 of the REGDOC which states that ‘The DAF also provides opportunities to propose alternate means of achieving the intent of the requirements outlined in this section." MAJOR Impact on industry: A definitive, common understanding of the word “shall” will reduce confusion and improve compliance.
152	Canadian Nuclear Laboratories (CNL)	Design Assessment Form for Nuclear Medicine rooms - other	In the DAF for Nuclear Medicine rooms – hot, it would be helpful to mark H-9 as being mandatory only for rooms where volatile, aerosolized or gaseous nuclear substances are used. Suggested change: Update H-9 on the DAF for Nuclear Medicine rooms – hot, to indicate that this clause is mandatory only for rooms where volatile, aerosolized or gaseous nuclear substances are used.
153	Canadian Nuclear Laboratories (CNL)	Design Assessment Form for Nuclear Medicine rooms - other	The REGDOC does not have requirements identified for Nuclear Medicine rooms – other, however the DAF includes several requirements that only appear applicable to Nuclear Medicine rooms – hot labs. Suggested change: Align the Nuclear Medicine rooms – other DAF to the mandatory requirements in the REGDOC. MAJOR Impact on industry: As currently written the, DAF for Nuclear Medicine rooms – other, is more burdensome than the requirements of the REGDOC.
154	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Nuclear Medicine rooms - other	In the DAF form for all room types, clause D-1 is incorrectly identified as “Yes” meeting the requirement. In this instance, applicants should answer “No”. Routinely disposing of nuclear substances via the sewer system (as per “Yes”) does not fulfil the requirement in the REGDOC. Suggested change: Correction of the DAF form to meet the REGDOC clause. MAJOR Impact on industry: As currently written, discharge via the sewer system would be the appropriate design selection, which is not consistent with the REGDOC.
155	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB	Design Assessment Form	The DAF form has many requirements for fume hood and hot cell design that should be expanded to glove boxes (e.g. I-1, I-2, I-3, etc.).

	Organization	Section	Comment
	Power), and Ontario Power Generation (OPG)	for Nuclear Medicine rooms - other	Suggested change: Expand clauses for fume hoods and hot cells to glove boxes where appropriate.
156	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Nuclear Medicine rooms - other	Clause K-3 in all room types of the DAF could be worded more clearly. Suggested change: Propose changing clause K-3 to "Nuclear exhaust ducts are clearly identified both on the ducts themselves and on any plans provided to maintenance personnel or contractors".
157	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Nuclear Medicine rooms - other	In the DAF form, it would be helpful to clarify the clauses where they differ from the REGDOC. Clauses, where reworded on the DAF, should accurately reflect the context in the REGDOC. Suggested change: The following clauses are missing context. The proposed addition of the correct context is provided by the suggested underlined text. These are examples and not an exhaustive list. • Clause B-1 suggest changing to: "Where nuclear materials are handled flooring, work surfaces, chairs, cupboards and shelving have a smooth, impervious washable and chemical resistant finish". • Clause E-2 suggest changing to: "Lockable doors installed on restricted rooms". • Clause E-4 suggest changing to "Clearly delineated designated area where unsealed nuclear substances are handled in rooms not exclusively used for only this practice".
158	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), and Ontario Power Generation (OPG)	Design Assessment Form for Nuclear Medicine rooms - other	The following wording is repeated: "For further guidance see REGDOC-2.5.6, Design Guide for Rooms Where Unsealed Nuclear Substances are Handled". Suggested change: Place a single statement at the beginning of the form "For further guidance see REGDOC-2.5.6, Design Guide for Rooms Where Unsealed Nuclear Substances are Handled". Recommendation is to delete all other statements as it creates a form that is much longer than it needs to be and may take away from the importance of the form.