Submissions Received during Public Consultation of Discussion Paper DIS-13-01-Proposals to Amend the Radiation Protection Regulations / Mémoires reçus lors de la consultation publique sur le document de travail DIS-13-01, Modifications proposées au Règlement sur la radioprotection

Please note comments submitted are posted in the official language in which they were received. / Veuillez noter que les commentaires soumis sont publiés dans la langue officielle dans laquelle ils ont été soumis.

Associations and Organizations / Associations et organisations :

- Association québécoise des physiciens médicaux cliniques
- Canadian Nuclear Association / Association nucléaire canadienne
- Nuclear Waste Management Organization / Société de gestion des déchets nucléaires
- Radioprotection Inc.

Educational Institutions / Établissements d'enseignement :

- McGill University / Université McGill
- McMaster University / Université McMaster
- University of Toronto / Université de Toronto

Government / Gouvernement :

- Health Canada / Santé Canada
- National Defence / Défense nationale

Health Care Facilities and Hospitals / Soins de santé et hôpitaux :

- BC Cancer Agency / Agence du cancer de la C.-B.
- Cancer Care Manitoba / Action cancer Manitoba (1)
- Cancer Care Manitoba / Action cancer Manitoba (2)
- Cancer Centre of Southeastern Ontario / Centre de cancérologie du Sud-Est de l'Ontario
- Centre hospitalier universitaire de Québec (1)
- Centre hospitalier universitaire de Québec (2)
- Health Sciences Centre Winnipeg / Centre des sciences de la santé de Winnipeg (1)
- Health Sciences Centre Winnipeg / Centre des sciences de la santé de Winnipeg (2)
- Health Sciences Centre Winnipeg / Centre des sciences de la santé de Winnipeg (3)
- Health Sciences Centre Winnipeg / Centre des sciences de la santé de Winnipeg (4)
- Health Sciences Centre Winnipeg / Centre des sciences de la santé de Winnipeg (5)
- Ottawa Hospital / Hôpital d'Ottawa
- St-Boniface General Hospital / Hôpital général de St-Boniface

- Sunnybrook Health Sciences Centre / Centre des sciences de la santé de Sunnybrook
- Victoria General Hospital Winnipeg / Hôpital général de Victoria, à Winnipeg

Individuals/ Personnes :

- Dr. Jerry Cuttler
- Michael Grey
- Steve Staniek

Industrial Radiography / Gammagraphie industrielle :

- Acuren
- AM Inspection Ltd.
- Stasuk Testing and Inspection Ltd.
- Team Industrial Services TISI Canada Inc.

Life Sciences / Sciences de la vie :

- Best Theratronics
- Nordion

Nuclear Power Plants and Research Reactors / Centrales nucléaires et réacteurs de recherche :

- AECL / EACL
- Bruce Power
- Énergie NB Power
- OPG

Uranium Mining and Exploration/ Extraction et prospection de l'uranium :

- Areva
- Cameco
- Rio Tinto

AQPMC
Association québécoise des physiciens médicaux cliniques

Comité d'assurance qualité et de radioprotection

6 décembre 2013

Commission canadienne de sureté nucléaire

Objet : Commentaires sur le document de travail DIS-13-01 *Modifications proposées au Règlement sur la radioprotection*

Nous vous soumettons nos commentaires sur le document de travail DIS-13-01, *Modifications proposées au Règlement sur la radioprotection*. Nous remercions la CCSN de nous offrir l'opportunité de commenter tout projet de publication. En tant que titulaires de permis, nous pouvons poser un regard critique sur les implications que pose une mise en œuvre de nouvelles directives ou exigences réglementaires. Notre souci est d'assurer une utilisation sécuritaire de l'énergie nucléaire dans un environnement hospitalier. Nos commentaires seront donc teintés par la mise en application du DIS-13-01 dans un milieu hospitalier.

- Section 2.2 : Article 3 : Administration de substances nucléaires à des fins thérapeutiques
    - La définition de « personne soignante » devrait référer à une « dispense de soins ». Il ne faudrait pas que cette définition soit interprétée comme étant d'office tout membre de la famille immédiate, incluant les enfants.
    - L'ajout d'une exigence réglementaire de déclaration aux personnes soignantes assurera une pratique uniforme au pays dans les centres hospitaliers.
- Section 2.2 : Article 4 : Programme de radioprotection : Contraintes de dose
    - L'intégration des contraintes de dose au règlement permettrait une application généralisée du principe ALARA. Cette intégration ne garantirait cependant pas une application uniformisée au pays ; les restrictions de la dose individuelle pour un même type de substance radioactive d'un titulaire de permis à l'autre pourraient encore varier.
    - Bien qu'il soit raisonnable d'arriver à des restrictions de la dose différentes dans des industries différentes ayant des activités autorisées différentes, il apparait moins raisonnable d'accepter des restrictions différentes de la dose entre différents titulaires de permis issus de la même industrie et partageant la même activité autorisée.
    - La population canadienne devrait bénéficier du même niveau de protection contre le rayonnement ionisant issu de l'utilisation de l'énergie nucléaire. La CCSN devrait s'assurer d'une mise en application uniformisée du concept des contraintes de dose, s'il est décidé à l'intégrer aux exigences réglementaires ou aux lignes directrices réglementaires.
- Section 2.2 : Article 7 : Renseignements à fournir : Renseignements à fournir à tous les travailleurs
    - Une culture de transparence aidera à sensibiliser tous les travailleurs des risques associés à l'utilisation de l'énergie nucléaire.
    - Il faut cependant être prudent de ne pas générer des craintes et angoisses auprès des travailleurs n'exécutant pas d'activité autorisée. La définition devrait se restreindre aux travailleurs exécutant des activités autorisées et non d'avoir été mentionné dans un permis. Il

advient parfois que des travailleurs, qui n'exécutent aucun travail relié à l'activité autorisée, soient mentionnés dans un permis. Ces travailleurs ne devraient pas être inclus dans la nouvelle définition, car ils ne s'exposent aucunement au rayonnement ionisant direct relié à l'activité autorisée. Dans cette optique, l'emploi du vocabulaire « travailleur » nous semble inapproprié, car trop général et trop inclusif.

- Nous sommes d'avis qu'une déclaration à tous les « travailleurs » (tel que nous le définissons ci-haut) du fait qu'ils soient ou non TSN est l'aspect le plus important d'une culture de transparence.
- Ces déclarations et confirmations des « travailleurs » (tel que nous le définissons ci-haut) d'avoir été informés génèreront une charge de travail additionnel aux responsables de la radioprotection.
- Tous les travailleurs non TSN et tous les TSN considérés comme recevant un niveau de dose efficace annuel entre 1 mSv et 5 mSv ne sont pas tenus de porter des dosimètres individuels d'un service de dosimétrie autorisé (articles 5(2)b) et 8). La proposition de la CCSN d'exiger d'informer les « travailleurs » de leurs niveaux de dose une fois par année vient en contradiction avec l'exigence de dosimétrie individuelle.
- Nous soutenons une proposition d'informer annuellement les travailleurs qui « disposent d'une dosimétrie individuelle ». Cette proposition génèrera cependant une charge de travail additionnelle aux RRP. La tâche serait grandement allégée si le Fichier dosimétrique national du Canada offrait un moyen de produire facilement et rapidement un rapport écrit des niveaux de doses individuelles. La CCSN pourrait adresser une telle demande au FDN.
- Nous suggérons qu'un « seuil de déclaration annuelle des doses » soit instauré ; le bénéfice de déclarer aux travailleurs des doses annuelles nulles est discutable lorsque nous pesons la lourdeur administrative et de gestion d'une telle déclaration sans seuil. En milieu hospitalier, une grande proportion des travailleurs enregistre des doses annuelles nulles ou au seuil de détection de la dosimétrie individuelle.
- Nous ne soutenons pas une proposition de déclaration annuelle de la dosimétrie individuelle du personnel n'exécutant pas des activités autorisées, car nous ne soutenons pas la proposition de définition de « travailleur » pour cette catégorie de personnel.
- L'article 5(2) b) permet une évaluation de la dose, sans mesure directe. Il ne faudrait pas que cet article soit abrogé au profit exclusif des mesures directes. Ceci engendrerait des coûts et une lourdeur administrative considérables peu justifiables.

- Section 2.2 : Article 7 : Renseignements à fournir : Ajout de l'obligation de fournir des renseignements à propos des situations d'urgence
  - La transmission de ces renseignements est déjà partiellement appliquée. Une application complète et réglementaire augmentera la tâche des RRP et soulève quelques questions.
  - À quelle fréquence faudra-t-il informer les travailleurs ? Un rappel des tâches et responsabilités en situation d'urgence devrait être prévu, mais la fréquence pourrait dépendre de la probabilité et gravité de la situation d'urgence.
- Section 2.2 : Article 7 : Renseignements à fournir : Ajout de l'obligation de fournir des renseignements aux travailleurs à propos de l'allaitement

  - Nous soutenons la proposition d'informer les travailleuses à propos des risques potentiels pour les bébés nourris au sein liés à l'incorporation de substances radioactives par la mère.

- Section 2.2 : Article 8 : Obligation d'utiliser un service de dosimétrie autorisé
  - Nous soutenons la proposition d'obliger le titulaire de permis à utiliser un service de dosimétrie autorisé pour mesurer les doses équivalentes supérieures à 50 mSv sur la peau, la peau des mains ou des pieds. Ceci est cohérent avec l'exigence actuelle de mesurer les doses efficaces supérieures à 5 mSv.
- Section 2.2 : Article 11 : Travailleuses enceintes du secteur nucléaire
  - Nous soutenons les propositions de modification.
  - Cependant, il faudrait ajouter une obligation à la travailleuse d'informer le titulaire de permis par écrit qu'elle cesse l'allaitement. Ceci permettra au titulaire de permis de réintégrer la travailleuse dans ses conditions de travail initiales.
  - L'obligation de déclaration devrait être exigée uniquement si les conditions de travail de la travailleuse offrent un risque d'incorporation de substances nucléaires. Plusieurs activités autorisées n'offrent aucun risque d'incorporation. Il serait alors inutile d'imposer à la travailleuse une telle déclaration.
- Section 2.3 : Article 13 : Limites de dose efficace
  - Nous confirmons que les modifications proposées n'auront aucun impact, sinon minime, sur le fardeau administratif.
  - Généralement, la langue mathématique offre moins de place à l'interprétation que la langue française ou anglaise. Néanmoins, nous sommes d'accord avec les modifications proposées.
  - Le remplacement des LAI par des coefficients de dose devra être tel que les coefficients sont facilement connu de tous. S'il faut les exclure dans la réglementation afin d'en faciliter leur mise à jour, il faudra déterminer un mécanisme qui assurera que tous les titulaires de permis utilisent la même version des coefficients.
- Section 2.3 : Article 13 : Limites de dose efficace : Définition de la période de dosimétrie de cinq ans
  - Les périodes fixes de dosimétrie de cinq ans offrent l'avantage d'une uniformisation nationale ainsi que d'une facilité d'administration.
  - Les périodes fixes facilitent les comparaisons entre les divers titulaires de permis.
- Section 2.3 : Article 14 : Limites de dose équivalente : L'expression « mains et pieds »
  - La clarification proposée d'utiliser « peau de chaque main et de chaque pied » élimine effectivement toute ambiguïté. Nous appuyons cette proposition.
- Section 2.3 : Article 14 : Limites de dose équivalente : Limites de dose équivalente pour le cristallin
  - Le personnel en milieu hospitalier, régie par la LSRN, reçoit des doses aux cristallins bien en deçà des nouvelles limites proposées. Aucun impact n'est à prévoir.
  - Cependant, certains membres du personnel, non régis par la LSRN, reçoivent des doses aux cristallins avoisinant les limites proposées. Il serait souhaitable que les réglementations provinciales suivent les recommandations de la CIPR.

- Section 2.3 : Article 15 : Situations d'urgence
    - « … *prise de mesures <u>volontaires</u> visant à …* » Il faudrait être plus clair à savoir si « volontaire » signifie une décision du travailleur ou de son employeur. En situation d'urgence, une personne ayant un rôle prédéterminé d'intervention d'urgence (premiers répondants, personnel médical) peut-elle refuser les tâches 1 et tâche 2 même si ses tâches professionnelles le dictent ?
    - « … *femmes ayant signalé être enceintes ne doivent pas prendre part* ... » qu'en est-il de la femme allaitante introduite à l'article 11 ? Comment la réglementation prévoit-elle gérer ces travailleuses qui ne sont plus enceintes, mais qui allaitent ?
    - « *… agit de son propre chef pour sauver une vie humaine peut dépasser les limites …* » Est-ce dire que le personnel médical pourrait de facto être soustrait aux articles 13, 14 et 15 étant donné que ses tâches visent à sauver les vies ? Il faudra porter un jugement afin de départir les actes médicaux prévenant un risque de dose engagée élevée menaçant la vie du patient, d'un risque de dose engagée ne menaçant pas la vie du patient. Il est question ici de faire la balance entre le risque d'une dose engagée fatale d'un patient et le risque pour le personnel médical d'intervenir pour en diminuer le risque létal.
- Section 2.3 : Article 15 : Situations d'urgence : Dépassement d'une limite de dose applicable au cours d'une situation d'urgence
    - Il faudrait inclure tous les employeurs et travailleurs autonomes impliqués dans la gestion d'une situation d'urgence (premiers répondants, personnel paramédical, personnel médical et médecins) même s'ils ne sont pas titulaires d'un permis. La *Loi sur la sûreté nucléaire* le permet-elle ?
- Section 2.3 : Article 16 : Dépassement des limites de dose
    - La proposition de référer uniquement aux limites de dose du TSN, même pour les non TSN allégera effectivement le fardeau administratif en permettant l'application de procédures en cas de dépassement des doses uniques.
    - Cependant, il ne faudrait pas que cette proposition ait l'effet pervers d'encourager les titulaires de permis à réduire le nombre de déclarations des TSN en conservant une plus grande proportion du personnel non TSN.
- Section 2.3 : Article 17 : Autorisation de retourner au travail
    - L'article 17(1) indique que l'autorisation de retourner au travail est donnée par la CCSN. En retirant les articles 17(2) et 17(3), la méthodologie de calcul utilisée par la CCSN n'est plus divulguée. Il faudra s'assurer d'une uniformité, au sein du personnel de la CCSN, dans l'évaluation du risque.
- Section 2.3 : Article 21 : Affichage aux limites et aux points d'accès
    - Nous aimerions connaitre l'opinion de la CCSN quant à l'utilisation du concept de « Time Averaged Dose-Equivalent Rate » (TADR) utilisé par la NCRP américaine. L'affichage aux limites et points d'accès pourrait bénéficier du concept TADR.
- Section 2.6 : Article 24 : Document à tenir par le titulaire de permis
    - Pourquoi une exigence de conserver les registres sur l'exposition professionnelle une fois que la personne a quitté l'emploi ? Le FDN ne remplit-il pas cette fonction de cumuler et tenir les

registres de l'exposition professionnelle de tous les Canadiens ayant eu un dossier ? Pour une visée d'archive, le FDN est certainement l'endroit centralisé le plus approprié au pays.

- Sachant que le Canada dispose du FDN, nous nous interrogeons sur la plus-value que chacun des titulaires de permis conserve les registres de dose une fois que l'employé n'est plus à son emploi.

- Section 2.8 : Annexes 1 et 2
  - Nous comprenons la lourdeur administrative qu'impose la mise à jour d'un règlement canadien. Afin de permettre une utilisation rapide des dernières données scientifiques dans le calcul des doses, le retrait des facteurs de pondération du règlement est une avenue.
  - Cependant, cette suppression du règlement rend la position officielle de la CCSN quant à l'utilisation de certaines données scientifiques versus d'autres moins transparente, à moins qu'un mécanisme suppléant soit mis en place.
  - L'exclusion des facteurs de pondération du *Règlement sur la radioprotection* est acceptable pour autant qu'une référence « officielle » de la CCSN soit tenue à jour et réfère aux données permettant de calculer d'une façon uniforme les doses à travers le Canada.
  - Il ne faudrait pas se retrouver avec une situation où différentes méthodologies de calculs et différents facteurs de pondération arrivent à des résultats de dose différents.
- Section 3.1 : Article proposé sur les appareils de détection et de mesure du rayonnement
  - En milieu hospitalier, le *Règlement sur les substances nucléaires et les appareils à rayonnement* et le *Règlement sur les installations nucléaires et l'équipement réglementé de catégorie II* ont déjà des exigences quant à l'utilisation des appareils de détection et de mesure du rayonnement. Nous ne prévoyons pas de fardeau administratif additionnel si ces exigences sont reprises dans le *Règlement sur la radioprotection*.
- Section 3.2 : Article proposé sur les responsabilités liées à la radioprotection
  - Nous appuyons l'ajout de cet article. La désignation officielle d'une personne responsable de mettre en œuvre le programme de radioprotection est importante.
  - Similairement à l'article 15 du *Règlement sur les installations nucléaires de catégorie II*, ne voudrait-on pas une accréditation officielle, par le personnel de la CCSN, de la candidature proposée par le titulaire de permis ? Notre proposition impose une lourdeur administrative à la CCSN, mais permet de s'assurer que le candidat possède réellement les qualifications requises pour assumer les responsabilités qui lui incomberont.
  - Une consultation publique a eu lieu sur le document de travail REGDOC-2.2.3 portant sur l'accréditation du personnel responsable de la radioprotection. Nous avons soumis nos commentaires à l'égard de ce projet de document. Ceux-ci doivent être considérés comme faisant partie intégrante de nos commentaires à la présente proposition d'ajout d'article.
- Section 3.2 : Article proposé sur les responsabilités liées à la radioprotection : Transporteurs de substances nucléaires
  - Nous réitérons notre opinion déjà soumise dans le cadre de la consultation publique sur le document GD -338 (REGDOC-2.12.3) que le transporteur devrait être responsable du transport des matières radioactives et non le titulaire de permis ayant recours à son service commercial.

Soyez assuré de notre entière collaboration,

Sincèrement,

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Christophe Furstoss	Hôpital Maisonneuve-Rosemont	Montréal
Lysanne Normandeau	Centre hospitalier universitaire de Montréal	Montréal
Alain Gauvin	Centre universitaire de santé McGill	Montréal

C C : François Deblois, président, Association québécoise des physiciens médicaux cliniques

December 9, 2013

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Canadian Nuclear Association Comments on Discussion Paper DIS-13-01, Proposals to Amend the Radiation Protection Regulations

The Canadian Nuclear Association (CNA) has approximately 100 member companies, representing over 60,000 Canadians [1] employed directly, or indirectly, in exploring and mining uranium, generating electricity, and advancing nuclear medicine.

We have reviewed Discussion Paper DIS-13-01, Proposals to Amend the Radiation Protection Regulations [2] and have the following comments that we wish to provide. There are several examples where the proposed changes could result in a high administrative and cost burden to our members with little demonstrated benefit to safety. Specific items that should be changed are given below.

2.2 Section 7 "Worker"

The CNSC proposal to require all workers performing work that is referred to in a licence to have information and training provided on radiological dose risks, dose limits, and individual dose levels poses an unnecessary burden on the industry. For workers (including contractors) who are not expected to receive doses any greater than those received by the public, the additional requirement would not result in improved safety.

Our members suggest that the CNSC either continue using the term "Nuclear Energy Worker" or replaces it with something like "exposed worker" and can be defined as a person who performs work referred to in a licence where the work has the potential to expose the worker to a recordable dose.

2.2 Section 7 Additional Requirements Related to Emergencies

The CNSC proposes to introduce a requirement to subsection 7(1) for all licencee's to inform all workers of their duties and responsibilities in the event of an emergency.

The application to all workers is too broad and it limits a licensees ability to assign additional duties in case of emergency, where real-time response and job assignment may be required. The proposed requirement to inform "all workers" also could be interpreted as extending to non-licensee staff

responding to a nuclear event. During such an event, members of the off-site workforce may support the response. A note should be added as follows.

"It is understood that in certain emergency situations, staff may be required to perform additional duties which may not have been anticipated in advance. In such cases, it is acceptable for the licensee to provide work assignments and pre-job briefings at the time of the event as appropriate to meet the intent of this provision."

2.2 Section 7 Addition of the Requirement to Provide Information to Female Workers With Respect to Breastfeeding

It is not clear if this requirement applies to non-licensee staff responding to an event. Our members do not support this applying to all emergency workers. It would be a significant administrative burden with no apparent safety benefit, and could result in a delay to a non-radiological emergency. The section should be revised to include the statement *"this does not apply to emergency responders, e.g. ambulance, who would not normally be exposed."*

2.2 Section 11 Pregnant Nuclear Energy Workers

The proposed amendment is to introduce a requirement for a female worker to inform the licensee in writing if she is breast feeding.

If the direction of the Discussion Paper is to move from having most workers established as the equivalent of Nuclear Energy Workers (NEWs), than all female workers in this category will need to inform the licensees in writing. Unless this requirement specifically applies to those females who are potentially receiving a recordable dose, it would be a challenge to implement these requirements due to privacy / anxiety concerns. While it is reasonable to implement this new proposed requirement for female NEWs it is recommended that the term "Nuclear Energy Worker" continues to be used in order to distinguish between those who are potentially exposed to ionizing radiation versus those who are not.

2.3 Section 14 Equivalent Dose Limits for the Lens of the Eye

The CNSC staff proposed to change the equivalent dose limit for the eye for a NEW from the current limit of 150 mSv to 50 mSv in a one-year dosimitry period, and to add a new dose limit of 100 mSv in a five-year dosimitry period.

Our members believe that reducing the dose limit for the eye is not justified, and it also would impose significant administrative burdens and costs without benefit. As well there are technical issues with determining eye dose at this time; therefore there is no way for licensees to consistently demonstrate compliance with the proposed new limits.

Our members propose a change in the dose limit to the eye of *"100 mSv per one-year dosimitry period and 250 mSv per five-year dosimitry period."*

2.5 Section 20 Labeling of Containers and Devices

The wording in the existing Radiation Protection Regulations regarding the requirement for the labeling of waste containers is confusing, and in instances has been interpreted very broadly. Our membership recommends that the hazard information labeled on waste containers should display dose-rate only, rather than the radionuclide, form and activity.

2.6 Section 24 Records to be Kept by Licensees

CNSC staff propose changing the requirements for licensees to retain worker dose records and requested industry input to determine the most appropriate approach.

The National Dose Registry (NDR) is the repository for dose records and as such should be where dose records are retained over a worker's life. If it is desired for licensees to have auditable records, a shorter retention time would be more appropriate and recommends that dose records be retained by the licensee for 5 years and by the NDR permanently.

Section 3.1 Proposed Section on Radiation Detection and Measurement Instrumentation

CNSC staff have proposed that each piece of radiation detection equipment require calibration done in accordance of IAEA Safety Report Series, No. 16, Calibration of Radiation Protection Monitoring Instruments.

It is extremely difficult to demonstrate compliance with IAEA Safety Report Series, No. 16. It would require significant costs and administrative burdens to implement all of the technical requirements, and it is not believed that it would provide additional safety benefits.

Currently instrumentation requirements are defined in multiple regulatory documents and should be consolidated in one place. The CNA recommends that this one place be the Radiation Protection regulations. However specific standards should not be included in a regulation but rather they should be identified by the licensee through the licensing process.

Section 4 Carriers of Nuclear Substances

The Discussion Paper includes a proposal to amend the Radiation Protection Regulations in order to make radiation protection requirements for carriers of nuclear substances consistent with those applicable to licensees and their workers.

Our members recommend that the radiation protection program requirements for carriers stay within the Packing and Transport of Nuclear Substances Regulations to ensure that they remain consistent with the IAEA transport regulations.

We thank you for the opportunity to share our views on the proposed amendments to the radiation protection regulations. If after reviewing this submission you have any questions, please feel free to contact myself at 613-237-4262.

Sincerely,

Dr. Peter Poruks
Manager of Regulatory Affairs
Canadian Nuclear Association

Cc.

Dr. John Bennett, President, Canadian Nuclear Association
Heather Kleb (M.Sc.), Vice President, Canadian Nuclear Association

References

[1] Canadian Manufacturers and Exporters, 2012, *Nuclear, A Canadian Strategy for Energy, Jobs and Innovation*, 2012 September presentation deck.
[2] Canadian Nuclear Safety Commission, *Proposals to Amend the Radiation Protection Regulations*, DIS-13-01, 2013 August.

The purpose of this e-mail is to provide feedback on the Discussion Paper DIS-13-01, *Proposals to Amend the Radiation Protection Regulations*, on behalf of the Nuclear Waste Management Organization. We have one comment regarding the proposal to amend the Regulations, as follows:

> Section 16: When Dose Limit Exceeded
>
> We note that the third paragraph in DIS-13-01, Section 16 (page 17), of the CNSC proposal indicates that an amendment is proposed which "...would only require a person be removed from work that is likely to add to his or her dose if the person may have or has exceeded any of the dose limits that apply to NEWs or pregnant NEWs, as specified in sections 13 and 14". The preceding paragraph indicates the "person" to which this applies is a non-NEW.
>
> This amendment appears to allow the licensee a means of exposing a non-NEW to doses in excess of those applicable to non-NEWs specified in Sections 13 and 14 of the Regulations. The wording of this amendment should be reconsidered to eliminate any potential confusion regarding its applicability.

Should you have any questions, please do not hesitate to contact me.

Thank you,

Mihaela Ion, Ph.D.

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Commission canadienne de sûreté nucléaire

Commentaires sur les modifications proposées au Règlement sur la radioprotection

DIS-13-01

2 décembre 2013

Par :

Stéphane Jean-François, ing., CHP, M. Env.

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Description du contexte

Radioprotection Inc. est une compagnie de consultants en radioprotection qui offre un service intégré à ses clients depuis 1982 dans le domaine des radioisotopes comme dans le domaine des rayons X. Nous étalonnons les radiamètres, vendons des appareils de mesure, faisons les épreuves d'étanchéité et offrons la formation dans tous les domaines en radioprotection. Nous faisons les calculs de blindage des pièces et les inspections requises dans le cadre du programme provincial de radioprotection des appareils à rayons X.

Plusieurs de nos clients sont des détenteurs de permis de la Commission canadienne de sûreté nucléaire, d'autres sont des utilisateurs de radiamètres. Nos commentaires sont livrés comme suite à des discussions informelles avec nos clients lors de formation en radioprotection ou de visites techniques à leur site de travail et de discussions avec les membres de notre équipe de professionnels.

Nous pensons qu'il importe de donner suite à une demande de consultation de la CCSN et espérons que les modifications proposées au Règlement sur la radioprotection en seront enrichies.

COMMENTAIRES ET OBSERVATIONS

Article 1

Aucun commentaire, cet article devra simplement être conséquent avec les modifications apportées dans la réglementation.

Article 2

Aucun commentaire.

Article 3

Nous sommes d'accord avec cette proposition d'ajouter la définition de « personnes soignante », mais la CCSN devrait expliquer la rationnelle de cette définition lorsque l'on parle de « plein gré » et de « bénévolement ». Est-ce que la CCSN veut s'adresser exclusivement aux « membres du public », les non-TSN qui ne sont même pas « travailleurs » au sens de la Loi de la CCSN ?

À notre avis, il existe présentement, au moins une catégorie de professionnels qui ne sont pas nécessairement couverts par la réglementation. Ils font le transport de personnes hospitalisées entre un centre de longue durée par exemple, et un centre de traitement de médecine nucléaire. Ils véhiculent les patients qui retournent à leur point d'origine après avoir reçu un traitement sous la limite entendue de 1110 MBq (30 mCi). Il nous est arrivé de rencontrer ces personnes qui ne sont pas nécessairement prises en charge par le titulaire de permis responsable des traitements. Par conséquent, ces personnes ne portent pas nécessairement de dosimètres, mais une récente étude dosimétrique que nous avons faite sur plus d'un an nous a permis de constater qu'une même personne avait reçu 85% de la dose annuelle pour un membre du public avec une possibilité de dépasser cette limite. Bien que cette situation ne représentait pas un risque pour le travailleur, nous vous demandons d'inclure, dans la définition de « personne soignante » , le concept de salaire et de travailleur pour uniformiser ce qui se fait sûrement chez d'autres titulaires de permis, soit la prise en charge de ces travailleurs qui sont des contractuels externes par rapport au titulaire de permis. Nous pensons que cette approche aiderait à sensibiliser certains titulaires de permis à leurs obligations.

Article 4

Aucun commentaire.

Article 5

Aucun commentaire.

Article 7

Renseignements à fournir à tous les travailleurs

Nous aimerions comprendre cette approche proposée par la CCSN. Pourquoi exiger d'un « non-travailleur du secteur nucléaire » (non-TSN) de signer un document qui confirme qu'un membre du public n'est pas à risque ? Pourquoi ajouter à l'obligation déjà existante de tenir une liste de travailleurs autorisés (donc dûment formés), l'obligation de les faire signer un document qui va simplement créer une certaine confusion ? Car s'il n'y a aucune différence du point de vue du risque radiologique entre eux et quelqu'un qui n'est pas travailleur au sens de la CCSN (membre du public en dehors du cadre réglementaire du permis de la CCSN),

pourquoi alors faire signer un document légal ? Est-ce que la CCSN pourrait alors, dans l'application de cet aspect, considérer le document de formation comme acceptable ou veut-elle avoir un document identique à celui des TSN ? Nous comprenons l'exigence réglementaire et légale de déclarer au TSN qu'il ou elle peut excéder les normes des non-TSN et que ce dépassement n'entraîne aucun risque indu, la logique du dépassement d'un premier seuil règlementaire se tient, mais comment justifier la même approche pour un travailleur qui ne dépassera jamais le premier seuil règlementaire de 1 mSV ? Cette exigence entraînera une charge administrative supplémentaire pour le titulaire de permis sans même ajouter un élément de radioprotection valable.

De la même manière, il fait du sens d'enregistrer les doses aux travailleurs qui peuvent en recevoir, mais il est difficile de comprendre pourquoi l'évaluation de ces quantités, lors de la demande de permis et lors de la rédaction du rapport annuel ne serait plus suffisante pour les non-TSN. Il est difficile de concevoir l'ampleur du fardeau administratif pour certains détenteurs de permis qui trouvent déjà que la CCSN demande beaucoup de documents pour un risque faible d'exposition; or certains détenteurs de permis ont plus de 50 travailleurs autorisés sur leur liste de travailleurs autorisés, sans compter le roulement de personnel dans certain cas. Un compromis que la CCSN accepte une évaluation par catégorie de travailleur ou par tâche que le titulaire de permis pourrait soumettre et conserver dans son programme, car ultimement, il revient au responsable de la radioprotection de faire l'inventaire des personnes touchées par son programme et de catégoriser le risque relatif tout en tenant ses travailleurs formés et informés.

Ajout de l'obligation de fournir des renseignements à propos des situations d'urgence

En ce qui concerne les situations d'urgences, nous sommes surpris de cette addition, puisque le titulaire de permis se doit déjà d'avoir des mesures d'urgence approuvées pour certains types d'urgence. Est-ce que la CCSN suppose que ses titulaires de permis écrivent actuellement des procédures d'urgence sans en faire la formation ou la démonstration sur le terrain ? Il ne fait aucun doute que si telle est la raison, l'approche de la CCSN est adéquate, mais elle va assurément engendrer une charge administrative importante pour certains titulaires de permis qui présentent des procédures par souci de conformité plutôt que par prévention ou besoin réel. Il faut par contre réaliser que les mesures d'urgence pour des substances nucléaires ne diffèrent pas nécessairement des mesures d'urgence pour toute autre source de risque. Par conséquent, un détenteur de permis industriel qui utilise des jauges nucléaires ne devrait pas subir un fardeau administratif nécessairement plus grand car ses procédures et sa formation génériques seraient déjà suffisantes. Dans ce cas, nous pensons qu'un simple document d'attentes administratives sur les mesures d'urgence serait, à cette étape, plus pertinent qu'un article réglementaire. Nous pensons que la progression par petits pas est souhaitable s'il existe encore des détenteurs de permis qui ne valident pas leurs procédures, régulières ou d'urgence, alors que cette étape nous apparaît comme une évidence.

Ajout de l'obligation de fournir des renseignements aux travailleuses à propos de l'allaitement

Cette approche est pertinente et conséquente aux principes ALARA bien qu'il soit surprenant qu'un programme de radioprotection d'un titulaire de permis qui inclut le risque interne pour les travailleuses ne considère pas déjà cette option.

Article 8

Aucun commentaire.

Article 11

Aucun commentaire.

Article 12

Aucun commentaire.

Article 13

Aucun commentaire.

Article 14

Aucun commentaire.

Article 15

Le texte des modifications proposées est bien conçu et présente de façon raisonnable les exceptions touchant un titulaire de permis qui applique ses mesures d'urgence. Est-ce que l'énoncé de la Tâche 1 doit être perçu comme un « et » (conditions simultanées requises) donc « effets déterministes ET prévention de l'occurrence de conditions catastrophiques » ? Nous considérons que puisque la limite de dose efficace pour le travailleur en mesure d'urgence est placée à 500 mSv, nous devrions remplacer le « et » par un « ou » pour la tâche 1, surtout que l'interprétation des effets déterministes graves y est clairement décrite. Par conséquent, la première partie de l'énoncé de la tâche 1 ou la seconde partie de l'énoncé de la tâche 1 devraient être, pris séparément, des motifs suffisants pour pouvoir dépasser le 50 mSv et avoir droit à 10 fois plus, ce qui place le travailleur d'urgence dans une région de doses générant des changements sanguins potentiels. Une clarification des intentions de la CCSN à cet égard serait bénéfique.

Article 16

Cette modification est compréhensible, car dans l'intervalle située entre 1 mSv et 50 mSv, d'autres travailleurs désignés TSN par un même titulaire de permis pourraient toujours travailler, ce qui rend le retrait des non-TSN embêtant pour le titulaire de permis qui est aussi un employeur. Mais nous percevons une certaine contradiction avec le principe énoncé et sous-entendu par les modifications à l'article 7.

On cherche dans l'article 7 à sensibiliser le travailleur désigné « non-TSN » avec un document qu'il doit signer de la même façon que pour les TSN, mais à l'article 16, on isole seulement les TSN. Nous pensons qu'il faut être consistant : si l'on inclut les non-TSN avec les TSN pour des exigences administratives de désignation de catégorie de travailleur, pourquoi exclure ces mêmes travailleurs lorsque l'on parle d'un potentiel dépassement de la limite du 1 mSv ? Nous comprenons le fardeau administratif et financier potentiel et actuel, et pour le réduire, ne suffirait-il pas d'imposer un suivi des doses plus sévère durant la période située entre l'enquête pour dépassement de doses et la conclusion de cette enquête ? Sans retirer le travailleur, ne pourrait-on pas le surveiller plus par une dosimétrie directe ou des périodes de dosimétrie plus courtes, ou du moins, écarter les causes potentielles de la surdose alléguée ? La CCSN ne peut exiger du titulaire de permis de traiter le non-TSN de la même façon qu'un TSN pour les renseignements à fournir et en même temps exempter les non-TSN d'un possible retrait lorsque la dose de 1 mSv est peut-être dépassée. Cette action envoie un message mitigé au travailleur. De plus, nous pensons que justement, l'obligation de devoir, en cas de dépassement de la dose par un non-TSN, pratiquer un retrait potentiel est une raison pour le titulaire de permis de bien évaluer les risques potentiels et de classifier, avant l'occurrence de tout événement, le travailleur comme TSN ou non-TSN.

Article 17

Aucun commentaire.

Article 18

Aucun commentaire.

Article 19

Aucun commentaire.

Article 20

Aucun commentaire.

Article 21

Aucun commentaire.

Article 24

Dans toutes nos formations chez Radioprotection Inc., nous recommandons déjà aux responsables de la radioprotection de conserver les documents liés à la dosimétrie pour la durée de vie des travailleurs, plus précisément, nous suggérons le chiffre arbitraire de 100 ans. De plus en plus, les entreprises ont un programme corporatif d'aliénation des documents (document retention schedule) qui permet de gérer l'obsolescence des documents, en accord avec les exigences réglementaires en vigueur. Par conséquent, nous pensons que la modification à l'article 24 est un pas dans la bonne direction, mais que cette modification doit se faire avec une meilleure sensibilisation des titulaires de permis à l'importance d'une bonne gestion des documents et du fardeau financier potentiel de ne pas conserver des documents qui peuvent aider en cas de litige avec un travailleur par exemple. Donc la CCSN devrait, dans un premier temps, sensibiliser les titulaires de permis sur l'importance de conserver la documentation critique que représente la documentation de dosimétrie et de donner et permettre si nécessaire, des moyens simples de conservation des documents comme la numérisation des données papier. La CCSN devrait aussi encourager les fournisseurs de services de dosimétrie approuvés (SDA) à optimiser la distribution des données électroniques, ce qui aiderait, à un moindre coût, les titulaires de permis à conserver les documents pour une période plus longue.

Article 25

Aucun commentaire.

Annexes 1 et 2

Aucun commentaire.

Nouveaux articles

Appareils de détection et de mesure du rayonnement

L'exigence d'utiliser un appareil adéquat paraît superflue, puisqu'il est implicitement requis d'utiliser un appareil adéquat pour le type d'activité effectuée. Il nous apparaît que cette approche résulte simplement d'une formation insuffisante des utilisateurs d'appareil. Par contre, nous proposons de demander une formation minimale dans l'utilisation des appareils de détection des rayonnements, puisque justement, une utilisation non adéquate ou une lecture erronée peuvent entraîner une exposition injustifiée pour les travailleurs. Par conséquent, nous suggérons que l'utilisateur soit formé à l' utilisation de l'appareil avant d'indiquer quel appareil il doit utiliser, puisque la première exigence entrainera nécessairement une plus grande conformité à la seconde.

L'étalonnage des radiamètres sous les exigences de l'AIEA pourrait entraîner un fardeau administratif supplémentaire, mais il est pertinent que la CCSN adopte une norme internationale.

Article proposé sur les responsabilités liées à la radioprotection

La plupart des demandes de permis de la CCSN exigent la désignation, par écrit, d'un responsable de la radioprotection et demandent à ce dernier de signifier son acceptation des tâches que le titulaire de permis lui attribue. Nous sommes en accord avec cette approche de clarification des attentes de la CCSN bien que cette approche soit un peu redondante.

Transporteur de substance nucléaire

Dans cette catégorie de travailleur et de fournisseurs de service, comme pour les titulaires de permis, il existe des comportements exemplaires et d'autres nécessitant une correction majeure. Nous pensons qu' il est nécessaire et impératif que la CCSN inclue plus précisément ses attentes dans la réglementation et considère même la possibilité de demander un permis aux transporteurs car nous avons observé plusieurs cas démontrant un manque de formation basique en radioprotection de la part des transporteurs et une ignorance de certains concepts fondamentaux en radioprotection.

Discussion

Nous sommes généralement en faveur de toute modification qui entraîne une clarification du règlement actuel. La précision des termes employés et les attentes réglementaires sont des éléments importants d'un programme règlementaire en radioprotection. Ces clarifications rendent notre travail plus efficace.

Par contre, nous somme d'avis que les modifications administratives concernant les renseignements à fournir (article7) sont un fardeau administratif non justifié et que les efforts devraient se faire du côté du transport, car l'écart en conformité , entre un travailleur conforme et un travailleur non conforme y est le plus grand.

Signatures

Nom : Stéphane Jean-François, Ing.,M. Env. , CHP Spécialiste certifié en radioprotection/Certified Health Physicist Président, Radioprotection Inc.		Date :4 déc 2013

To whom it may concern November 13, 2013

Re Proposals to amend the CNSC Radiation Protection Regulations:
Discussion Paper DIS-13-01.

Thank you for the opportunity to comment on this proposed amendment.

These remarks are in my capacity as a radiation safety officer (RSO) for a publicly funded, not-for-profit, Class II medical facility providing treatment to cancer patients.

SECTION 7

1 The proposals in Section 7 to broaden the scope of the radiation safety program from nuclear energy worker to "worker" are worrisome. The current method of identifying a particular subset of workers that require management is well handled in the hospital setting with the NEW designation. The replacement of NEWs by the rather vague and undefined term "worker", even in the context of the current definition of work referred to in a license, may lead to the creation of a large and unmanageable group of employees and co-workers that will require an unnecessary amount of management, especially in the university-hospital setting.

2 The amendment requiring that workers be informed of their dose levels should be modified so that NEWs be informed of their dose in writing only when it surpasses an action level. The current amendment could be interpreted to mean that NEWs having a zero recorded dose must be informed of this fact – this would seem to be an unreasonable demand on a radiation safety program.

3 Requiring all workers to be advised of duties during an emergency occurring in a Class II facility seems unrelated to the potential risk. Typically a subset of implicated employees are identified for a reactive response. Implicating a large group of workers in emergency preparedness – especially in the hospital setting - may have the unintended consequence of producing radiation anxiety. In addition, Class II facility workers have a very high likelihood of public and patient interaction – unnecessary emphasis on very low risk emergency preparedness related to Class II equipment may also inadvertently cause radiation anxiety in the public.

SECTION 21

While there are no proposed changes to this section, I would like the CNSC to consider beginning to apply the concept of the TADR (time averaged dose-equivalent rate). This is a concept employed by the USNRC as well as jurisdictions in Europe. The current definition of 25 micro Sv/hr seems ill defined – especially in the context of medical linacs which run on a duty cycle of about 0.1% with the beam on. In addition the current definition does nor discriminate between continuous dose rate and long term occupancy-

weighted dose rate. Considering the application of TADR, as defined in NCRP 151, might be useful in this context.

Perhaps the CNSC would consider adding in section 21, a paragraph (c) which might read:
(c) or, notwithstanding (b), there is a reasonable probability that a person in the area, room or enclosure will be exposed to a time averaged dose-equivalent rate greater than 20 μSv/h.

This would be especially useful in installations such as medical facilities with conventional or robotic linacs, and would give the CNSC the discretion to apply the most sensible signage policy as required by different operating conditions in different (Class I or Class II) nuclear facilities.

Thank you for the outreach concerning this proposed regulation amendment and for the opportunity to comment on Proposals to amend the CNSC Radiation Protection Regulations: Discussion Paper DIS-13-01.

Yours sincerely,

Michael Evans, M.Sc., FCCPM, FCOMP

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2013 December 9

Via email

Radiation Protection Division
Canadian Nuclear Safety Commission
P. O. Box 1046, Station B
Ottawa, ON K1P 5S9

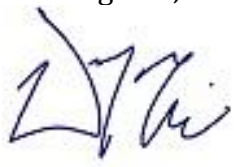
RE: McMaster University Health Physics Department Comments on DIS-13-01 Proposals to Amend the Radiation Protection Regulations

I am writing to provide comments by McMaster University's Health Physics Department on the proposals to amend the Radiation Protection Regulations as described in CNSC Discussion Paper DIS-13-01.

The comments are listed in the attachment.

Please do not hesitate to contact me if you have any questions or concerns regarding this matter, or if you require additional information.

Best regards,



Dave Tucker, CHP MSc RRPT CRPA(R)
Senior Health Physicist

cc. Chris Malcolmson CHP, MSc CRPA(R)
Diana Moscu PhD, CRPA(R)

Section 4: Removal of Reference to radon progeny.

The intention to replace the current dose conversion conventions with dosimetric protocols consistent with other radionuclides is desirable. However, the change appears to be premature as the dosimetric approach for radon progeny has not been determined by the ICRP and dose coefficients are not available.

In addition, the regulations should be amended to clarify the conditions under which exposure to radon progeny is to be considered occupational exposure.

Section 4: Dose Constraints

The intention not to include an amendment to explicitly address dose constraints is supported.

Section 7: Provision of Information

The broadening of the requirements to "provide information" and to inform each individual of their effective and equivalent doses in writing annually is opposed in the strongest possible terms. This will add confusion and excessive administrative burden without adding any safety benefit. The apparent attempt to limit the scope of the obligation through defining a worker as "a person who performs work that is referred to in a licence" is insufficient unless CNSC staff intend to explicitly include a list of occupations or positions to which this obligation extends. The practicality of that is doubtful. Consider, for example, a University with a licence for the consolidated use of nuclear substances. No workers are referred to in the licence. One type of work that may occur is the entry of a tradesperson to a posted laboratory to deliver supplies or perform a minor repair. Are these workers to be tracked and informed annually of their (non) dose?

Consider other alternatives, such as linking the requirement for individual notification to those receiving 1 mSv per annum (rather than related to NEW/Non-NEW status) and the requirement to make dose information available for persons with lower doses (e.g., posting of dose reports or access to a website). At the very least, a *de-minimus* dose criteria should be introduced with any broadening of the requirement. For example, inclusion of workers deemed to have a reasonable probability of exceeding 0.05 mSv (in keeping with the default ALARA criteria in G129). However, the current situation with explicit requirements for NEWs is sufficient and ensures that any person with an effective dose over 1 mSv per year is explicitly informed of their doses. It is recommended that no change be made to this requirement.

Section 8

No objection to the proposed amendments.

Section 11: Pregnant Nuclear Energy Workers

The proposed mechanism to address potential doses to breast-feeding infants of Nuclear Energy Workers seems excessively broad. Perhaps a right to accommodation for breast feeding workers who elect to self-identify would be more appropriate.

Section 13: Effective Dose Limits

In general, the changes are supported. As noted previously, an explicit method of addressing radon progeny should be retained until the new dose coefficients are established. The described

wording for calculating effective dose is correct in principal but the wording is not sufficiently precise. A reference to ICRP guidance, in the way that the Packaging and Transportation of Nuclear Substances Regulations refer to the "IAEA Regulations", might be preferable.
The retention of the current system for 5-year averaging is supported because the potential improvement in safety would be small compared to the potential costs and administrative burden of making a change.

Section 14: Equivalent Dose Limits

As the equivalent dose limit for the skin applies to the most exposed 1 cm^2 and the limits for the skin and the skin of the Hands and Feet have the same value, it is unclear what purpose is served by having a distinct limit. It may be interpreted that a separate limit is specified for the Hands and Feet because they are not subject to the averaging restrictions of Section 14 (3).
While adoption of the ICRP recommended dose limit for the lens of the eye appears inevitable, it is essential that CNSC staff provide clear expectations regarding measuring and monitoring doses at this level. CNSC Guidance documents such as G-91 "Ascertaining and Recording Radiation Doses to Individuals" are silent on this topic.

Section 15 Emergencies

The proposed changes to this Section are opposed. Further industry consultation should occur before any changes to this section are made.

The current main section 15(1) is "permissive" – it specifies that the dose limits may be exceeded during control of an emergency. The proposed language is prohibitive - it would prohibit exceeding dose limits except under specific designated tasks. This change should not be made as the list of conditions ("Tasks") under which it would be appropriate to exceed normal occupational dose limits will never be accurately captured. The proposed tasks do not address, for example, actions to save a major capital investment. These may not be directly linked to averting a large collective dose. For example, would it be appropriate to let an evacuated hospital burn down because it might take 50.1 mSv to the most exposed individual to fight the fire? Would it be appropriate to limit efforts to avoid having to use emergency core cooling that would render a research reactor inoperable in the future because of a similar dose projection? It is recommended that these values and the general nature of this section not be altered. Licensees should propose the process for implementing emergency dose limits, and for managing doses within the limits, that are appropriate to their site emergency plans.
The blanket prohibition on inclusion of declared pregnant persons in the "control of an emergency…" seems to be excessively broad. It seems likely that the intent is to prohibit them from roles in which implementation of emergency dose limits is required. As worded, it seems to imply that no roll in an emergency plan is appropriate for a declared pregnant female.

Section 19: Obligation of Licensees

The language of this section should address the fact that some persons who may be occupationally exposed, such as visiting faculty and international researchers visiting Canadian facilities, do not have a Social Insurance Number.

Section 24: Records to be Kept by Licensees

The proposal under consideration to require licensees to retain records until a former worker reaches a certain age or for 30 years after cessation of the work is opposed. Clarity regarding the current requirements could be provided without substantively changing the requirements. Long

term retention of occupational exposure records is the role of the National Dose Registry and should not be the role of individual licensees. Any prescribed time period for retention of records by the licensee should be tied to retention of the licence and should not exceed 5 years beyond the licence period. A *de-minimus* level of dose (for example, 0.05 mSv in a year in keeping with the default ALARA criteria of G-129), to which the requirements for record retention apply, should be specified.

New Sections: Section on Radiation Detection and Measurement Instrumentation

While the importance of radiation safety instrumentation is acknowledged, this section seems inconsistent with the rest of the regulations in terms of the level of prescriptive detail. For example, proper selection and use of respirators and PPE is important but the programs related to this are not prescribed in the regulations. Publication of a regulatory guideline and proposal of instrument quality assurance programs by licensees would likely be a more appropriate approach.

Comments on the DIS-13-01 Sandu Sonoc, University of Toronto

Name of the reviewer: Date:…… /…../					
Com-ment No	**Chapter/ Section/ Sub-heading**	**Page No**	**Line/s No**	**Comment/Information**	**Proposed Change**
1	7	8		Individual and written information about the dose received to all workers	This change will cause unnecessary burden to the licensees. Currently most of the dosimetry providers provide to all workers the possibility of reading their doses online (if they are interested). I suggest that if the workers can read their doses records, only the doses above the "Action Levels" to be communicated individually and in writing to all workers. If there are no action levels then only the doses above the regulatory levels to be communicated individually and in written.
	13	12		Definition of the 5-year period	I suggest we leave it as it is
3	24	21		Records to be kept	Since all dose records are kept by the National Dose Registry (as I know without time limit) it will be an unnecessary duplication of the records, and a very complicated task to be on the licensees.

4	3.1	24			I like the IAEA book, and I agree all calibration must be done according to a standard.

Comments from Health Canada / Radiation Protection Bureau

CNSC Discussion Paper DIS-13-01
Proposals to Amend the Radiation Protection Regulations

The following contains a compilation of comments from staff of Health Canada's Radiation Protection Bureau.

Section 4: Radiation Protection Program
Dose constraints

P7: The CNSC is seeking feedback on its decision to forego the introduction of dose constraints to the Radiation Protection Regulations. It is anticipated that any future changes to regulatory expectations for demonstrating ALARA could have an impact on licensees. This impact would likely be low for licensees with already-robust ALARA programs, since their programs have internal limits and performance goals for reducing doses to levels that are ALARA. For other licensees, this might be a new concept that would require programmatic changes. Should regulatory expectations change with respect to the use of dose constraints, the CNSC would seek stakeholder feedback at that time.

> Comment: Dose constraints are a key component of the system of radiological protection as described in ICRP 103, 109 and 111, and in the International Basic Safety Standards. Given the desire to review the current Radiation Protection Regulations in light of changes to international benchmarks, the CNSC should consider how best to incorporate the concept of dose constraints at this time.

Section 7: Provision of Information
Addition of requirement for the provision of information related to emergencies

P8: The Radiation Protection Regulations do not specifically require workers to be informed of their duties and responsibilities in the event of an emergency. Since an emergency could certainly affect all workers, the CNSC proposes to introduce a requirement to subsection 7(1) for all licensees to inform all workers of their duties and responsibilities during an emergency.

> Comment: "Emergency" in this context should be defined, and specifically as to whether to it refers only to an emergency impacting licensed activities that could lead to a radiation exposure, or any emergency impacting the facility. The regulations should also clarify if "workers" refer only to those undertaking activities related to the license, or all workers employed by the

licensee. In the latter case, this could be an unnecessary administrative burden on large organizations with only limited licensed activities.

Section 13: Effective Dose Limits
Effective dose limits

P12: Therefore, it is proposed to remove any direct references to radon and radon progeny, as well as the reference to the related terms "working level" and "working level month.

Comment: The impact of this change on the reporting to and handling of data within National Dose Registry would need to be assessed.

Definition of the Five-Year Dosimetry Period

P13: The CNSC has found that licensees have generally accepted the five-year dosimetry period as it is currently defined. Health Canada's National Dose Registry has also accommodated its system to receive and monitor worker dose records in a manner consistent with the dosimetry periods defined in the Regulations.

Comment: The National Dose Registry (NDR) is currently managing the five-year dosimetry period using two approaches in order to accommodate requirements of both the CNSC and provincial regulatory authorities: the fixed five-year dosimetry period used by the CNSC, and a rolling five-year dosimetry period used by the majority of provincial regulatory authorities. From an operational point of view, the NDR would prefer to have a rolling five-year dosimetry period for all regulators.

Section 15: Emergencies

P15: The CNSC is proposing that section 15 deal with all aspects of the emergency including: applicable dose limits, the requirements for and actions to be taken when emergency dose limits are exceeded, and the required process for the transition from emergency-related work to future work activities for persons who have exceeded (a) dose limit(s) during the emergency.

It should be understood that, during both the control of an emergency, and the consequent immediate and urgent remedial work leading up to the transition to recovery, the applicable dose limits for effective and equivalent doses to persons (as proposed below) must be considered discrete and separate from the dose limits defined in sections 13 and 14 of the current Radiation Protection Regulations.

Comment: In order to effectively implement this approach, the Regulations will need to clearly define the emergency phase as well as "consequent

immediate and urgent remedial work" during which the emergency dose limits apply, and when they cease to apply.

Section 19: Obligations of Licensees
Obligation to report measured doses to the National Dose Registry

P19: Section 19 of the Radiation Protection Regulations specifies that licensees who operate a dosimetry service must file specific information with Health Canada's National Dose Registry (NDR). This information is with respect to each nuclear energy worker for whom the licensed dosimetry service has measured and monitored a dose of radiation, and it includes the following: given names, social insurance number, sex, job category, location, and date of birth, and the doses received by and committed to the worker.

> Comment: Clarity is required as to whether this includes the reporting of doses received in an emergency (Section 15). Such requirements will have an impact on reporting of doses to the National Dose Registry, and the management of these doses within the National Dose Registry.

P19: The CNSC is proposing to state explicitly that the licensees whose NEWs are monitored by an LDS must provide the required information to the LDS, for the purpose of reporting doses to the NDR. This would require rewording of section 19, potentially with an addition of a subsection specifying the requirement that every licensee shall provide, to every licensee who operates a dosimetry service, the information currently listed in paragraphs 19(a) through (g).

> Comment: To facilitate management of records submitted to the National Dose Registry, provision of the worker's Social Insurance Number (SIN) should also include the associated name on the SIN card. Enforcing the use of official SIN card information will help data management by all entities (LDS, NDR, employers...). This process has been confirmed by the SIN Management Services of Service Canada.

Section 4: Radiation Protection Program

Dose constraints

The CNSC is seeking feedback on its decision to forego the introduction of dose constraints to the Radiation Protection Regulations*. It is anticipated that any future changes to regulatory expectations for demonstrating ALARA could have an impact on licensees. This impact would likely be low for licensees with already-robust ALARA programs, since their programs have internal limits and performance goals for reducing doses to levels that are ALARA.*

Director Nuclear Safety (D N Safe) agrees with the decision to forego the introduction of dose constraints. However, we believe that the usefulness of the ALARA concept should also be reconsidered and hopefully abandoned. The use of ALARA was possibly justifiable in the last century when the dose limits were higher. Currently, the dose limits are so very low that the use of ALARA can not be justified on any reasonable grounds, especially in the case of 'public' dose. For all practical purposes 1, or 10, or 100 µSv refers to the same 'non significant' dose. Abandoning the ALARA convoluted reasoning will clear the language and the message: one can not claim on one side that nuclear operations are safe, and add ALARA on the other …'just in case'. It is one or the other. Keeping ALARA keeps the public uneasy with all things 'nuclear'.

Section 13: Effective Dose Limits

Effective dose limits

The CNSC proposes to replace the use of ALI with dose coefficients to directly calculate the effective dose of any one component.

Similarly, the CNSC proposes to eliminate the term "E", as defined in subsection 12(1) of the existing Regulations. Since the term "E" includes doses from external sources, as well as some doses from internal sources, it has not always been properly understood. Moreover, the combining formula includes a term for the dose from internal sources of radiation, in addition to the term "E"– which appears to be a double counting of doses.

Sections 12 and 13 could certainly use some improvement. For the benefit of all concerned, standard definitions should be used (from the new and revised BSS, for example, *IAEA's General Safety Requirements*, GSR Part 3 (Interim), see Schedule III**). There is no particular reason to single out radon exposures, they should be treated as any other committed (internal) dose.**

Section 14: Equivalent Dose Limits

The term "hands and feet"

Item 3 in the table in subsection 14(1) of the current Radiation Protection Regulations *specifies dose limits for the "hands and feet". The actual intent of this requirement is to limit the dose to the skin of any hand or foot; however, the wording is ambiguous and has sometimes been misinterpreted as "the total dose to all hands and feet". The CNSC*

therefore proposes to change the wording "hands and feet" to "the skin of each hand and foot".

[10] ICRP 103 indicates that the operational quantity to be used for measuring dose to the hands and feet is $H_p(0.07)$, which is the personal dose equivalent at a depth that represents sensitive skin cells. (Skin is the most radiosensitive part of the hands and feet).

"Hands and feet" should be deleted from the Table. Line 2 "Skin" is entirely sufficient to describe the situation. Section 14.(3) takes care of all the explaining:

14. (3) ~~When skin is unevenly irradiated,~~ *the equivalent dose received by the skin is the average equivalent dose over the 1 cm^2 area that received the highest equivalent dose*. (Possibly add: "The skin of the hands will most often be the area of interest", or use the IAEA phrasing from the new BSS: "*The equivalent dose limits for the skin apply to the average dose over 1 cm^2 of the most highly irradiated area of the skin. The dose to the skin also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin*").

Section 20: Labelling of Containers and Devices

Since January 2006, under an exemption granted by the Commission to section 8 of the Nuclear Substances and Radiation Devices Regulations, *a person may possess, transfer or use an unlimited number of radium luminous devices without a licence, provided that radium is the only nuclear substance in the device and the device is not disassembled or tampered with. The exemption was granted by the Commission following an assessment of the risk associated with the possession of devices containing radium luminous compounds. This assessment concluded that the risks to persons are low, as long as the devices are intact and handled safely.*

The disposal aspect should also be addressed specifically.

3.1 Proposed Section on Radiation Detection and Measurement Instrumentation

The CNSC is considering establishing requirements in the Radiation Protection Regulations *related to the provision and use of radiation monitoring equipment. These requirements would apply to all licensees. Examples of this type of equipment include electronic personal dosimeters, survey meters, contamination meters and area monitors.*

…Proposed requirements for the Radiation Protection Regulations *related to use of calibrated equipment will be similar to those in the above-mentioned regulations. The CNSC is proposing that each radiation detection instrument require calibrations done in accordance with an established standard. The calibration standard currently under consideration is the IAEA Safety Report Series, No. 16,* Calibration of Radiation Protection Monitoring Instruments.

The 153 pages of the quoted IAEA document are difficult to read and understand. It is a basic guidance document, and not a standard. As the document states in the section 1.2 SCOPE*: "Because of the multitude of applications for radiation monitoring instrumentation, e.g. in medicine, radiography or agriculture, it is impossible to describe the complete calibration of all instruments in one report. However, the considerations described here should serve as a basis for calibrating radiation protection instruments."*

Reference should be made instead to ISO and IEC standards in general terms. As the IAEA document states itself in section 1.1. BACKGROUND:

"Since the publication of Technical Reports Series No. 133 [1] in 1971, considerable progress in standardizing reference radiation fields and calibration procedures has been made by the International Organization for Standardization (ISO). In addition, the International Electrotechnical Commission (IEC) has produced many standards on the performance specifications and type testing of radiation protection monitoring instruments. ...The change to SI units in radiation monitoring as well as the introduction of new operational quantities in ICRU Reports 39, 43, 47 and 51 [2–5] make it additionally important that Ref. [1] be revised to reflect all these changes."

If "*the CNSC is considering establishing requirements in the* Radiation Protection Regulations *related to the provision and use of radiation monitoring equipment",* these requirements should refer to general international and/or national standards without pointing to a particular document, especially if "*these requirements would apply to all licensees*". If any additional details are needed, they should appear in a CNSC 'standard' or 'guidance' document. The need of a CSA standard on the subject should be evaluated.

**Comment submitted on behalf of National Defence – Director Nuclear Safety
by Roger Hugron, Head of the Nuclear Safety Studies and Analysis Section,
D N Safe 3, on 9 December 2013**

BC Cancer Agency

22 August 2013

Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
280 Slater Street
Ottawa, Ontario K1P 5S9

Re: DIS-13-01, Proposals to Amend the *Radiation Protection Regulations*

We are writing to provide commentary on the Proposals to Amend the Radiation Protection Regulations and the impact on the BC Cancer Agency.

General comments not specifically addressed

In the document, you refer or hint at a lifetime dose of 1 Sv (1000 mSv). The idea presented was a person chronically getting 20 mSv/y would in a 50 year career achieve a lifetime dose of 1000 mSv. This however is not the only road to large doses. Emergency situations can potentially give a large dose (up to 500 mSv). There seems to be no limit on the number of Emergencies nor restrictions that Emergencies might pose to an individual. For example, if a person had a 400 mSv dose in an Emergency, would this plus whatever their current history, would this not alter allowable doses for the remainder of their career such that they would reasonably not exceed 1000 mSv?

We have a question regarding the interpretation of the phrase “in writing”. Are the some circumstances where training with a presentation suffices to meet this requirement? Technically the information is presented in writing in the form of a presentation. The worker signs off on the training, which acknowledges this information. Does this suffice?

Section 3A

We could alter some of our radiation safety information given to the patients and this would be relatively a minor impact on our program.

Our chief concern is the Agency has direct contact with the patient and not the caregiver. This complicates the requirement to inform the caregivers of their potential dose.

Section 4

Would it be a good idea to have dose constraints- may make us more like the international community and we might be able to get away from the 50microSv/yr ALARA dose limit.

Section 7

This section will have the biggest impact on us.

The information we give to NEW’s will have to be given to all workers who have to sign that they have read and understood it. From the definition this would seem to imply all badged workers.

It also wants us to inform all workers of their annual dose individually and in writing! We find this pointless because the majority of readings are zero (non-reportable). This would a large administrative burden to send out literally hundreds of letters stating you had no reportable dose. We feel a better approach would be to inform individuals in writing only if their dose exceeds our Action level or perhaps the legal public limits for Effective or Equivalent doses.

We would also have to inform staff of their duties in an emergency – mostly this is done in training sessions we don't explicitly give associated health risks with emergencies. Also could be required to give information to emergency responders such as fire brigade, police, etc. In addition, where would our commitment to train end? We have many different groups of people, not all directly under the Radiation Safety Program, but who may have a role to play in an Emergency. For example, the Emergency Management Team is a multidisciplinary team of people with medical, administrative and radiation oncology experiences. More clarification is required.

All female staff would have to inform us in writing that they are pregnant. We have a form for NEWs and this could easily be rolled out for other workers.

The requirements for staff to tell us in writing that they are breast feeding seem a little nonsensical especially for RT staff. This is a requirement targeted at people working with open sources. The majority of sources in radiotherapy are either sealed or artificially produced through electrical means (X-rays tubes, linacs). There is little chance that they would be exposed to anything that would impact the breast milk.

That aside, there are practical problems with breast feeding women. There are some women who breast feed their children for years. Are we to limit their work for all that time. Would staff be willing to openly comply with such restrictions?

Section 11

This is similar to the comments in Section 7 regarding breast feeding women

Section 13

We believe it is more efficient and accurate to write the actual equations for determining effective doses than to replace them with a written description. Some care with the use of the equations would be required. One possibility is to have supplementary documents that show by example how the equations are to be used or interpreted.

We would also encourage a larger list of isotopes with dose coefficients. Particularly isotopes for PET and positron emitters e.g. Ra223 is not listed but we've recently started working with it.

The definition of the 5 year period would be a fixed period. This adds simplicity and clarity on how to use this period but it presents a problem. If a worker loads the dose at the boundary they could legally have 200 mSv spread over a four consecutive years. In this circumstance a 5 year rolling period would perhaps make more sense.

Section 15

There are now three sets of emergency situations, but the third is more hidden and less explicit.

- *Task 1: when voluntarily undertaking actions to prevent severe deterministic effects[13] and actions to prevent the development of catastrophic conditions that could significantly affect people and the environment*
- *Task 2: when voluntarily undertaking actions to avert a large collective dose*

The third is "*A person who acts voluntarily to save human life may exceed the dose limits prescribed by sections 13, 14, and 15 of these Regulations."* but it is not presented as explicitly as Task 1 or 2.

It may be useful to present examples for each situation.

Section 16

We like the extension to authorization to return to work when a worker exceeds 50 mSv & not 1 mSv. The latter was very restrictive and in convenient.

Could there be additional clarification regarding exposures known to be non-personal in nature. For example, a therapists dropped their badge in linac bunker. The badge received let's say 70 mSv. We know this is a non-personal exposure, so would restricting their duties be truly necessary until the authorization to return to work is completed?

Section 17

Deletions of pro-rated dose formulas seems like a good idea

Section 19

The licensee is given the right to submit the required information (SIN etc) to register NEWs with the NDR. What is not addressed are the rights of licensees if they have workers on a badge program. We classify our workers as members of the public but we still monitor their doses with a badge program. It would be useful if this regulation addressed this group of people i.e. If a licensee chooses to badge their workers, then they must register the worker with the NDR and have the right to submit the required information.

Section 21

Posting of signs at the 25 μSv/h level: Is this the instantaneous dose rate or time averaged dose rate or the dose rate at which staff would get a particular dose in a particular time period? Clarification would help.

How does this affect enclosed spaced in a vault. Is there a criteria for deciding when a closest is not considered a room?

BC Cancer Agency

Section 24

Record retention – dose records kept until staff is 75 or 30 years past cessation of work – is this worker cessation or the cessation of that activity. The second would require a lot more records to be kept.

Schedules 1 and 2 – useful to have tables in regs as one less document to hunt down – could just refer to them

Proposed new section – Survey meters

Class II only requires calibration of survey meters – if we have to calibrate contamination meters and area monitors – do these have to be done by a calibration service or can they be done in house? At frequency of calibration or are you expecting us to follow the IAEA document.

Additionally there are practical problems with Area Monitors. Some are wall mounted and not easily removed to be sent for calibration. Further, if an Area Monitor is removed, is there an expectation to have a replacement Area monitor in place or can we cope with a protocol to use portable monitors?

For some use types, we are not interested in the exposure rate but rather the meter is used to detect a source with a simple YES/NO response to the question "Is there a source present?" Are there any calibration standards that address meters used in this function?

Proposed new section – Responsibility for Radiation Protection

Would this impact the job description? Can the agency assume that the RSO's will take on this role? It sounds like the RSO is the best person for this role but it is not clear this would be the same position.

The Class I regs have a 5 year period for certification at which point the RSO has to renew their certificate.

From: Dave Niven [mailto:Dave.Niven@cancercare.mb.ca]
Sent: Friday, November 22, 2013 10:21 AM
To: Consultation
Subject: Question regarding DIS-13-01

Hi there,

I'm a Health Physicist working at CancerCare Manitoba, a CNSC licensed facility. We're reviewing the proposed changes to the Radiation Protection Regulations in order to provide our comments and I had one point that I wanted to clarify.

In the proposed changes to section 11, *Pregnant Nuclear Energy Workers*, there is a suggestion to introduce requirements for a female worker to inform the licensee in writing if she is breast-feeding and for the licensee to adapt the working conditions in respect of exposure to that worker if necessary. Will these requirements apply only to Nuclear Energy Workers, or are they intended to apply to more broadly to the new definition of "worker?"

Thanks very much,

Dave Niven, M. Sc., P. Eng
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December 9, 2013

Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
280 Slater Street
Ottawa, Ontario, Canada K1P 5S9

Re: Response to Discussion Paper DIS-13-01, Proposals to Amend the Radiation Protection Regulations

CancerCare Manitoba is a health-care facility located in Winnipeg, MB which operates several Class II facilities for radiotherapy purposes. We also possess some sealed source radioisotopes used for research and calibration under our Nuclear Substance and Radiation Device licenses.

Our staff have taken the time to review the proposed changes to the CNSC Radiation Protection Regulations outlined in Discussion Paper DIS-13-01. We have included our comments in the attachment to this letter for your review.

We greatly appreciate the opportunity to discuss and comment on the proposed changes, and in particular were pleased with the four month time period which was set for consultation.

Sincerely,

Dr. Ingvar Fife
Radiation Safety Officer
Department of Radiation Protection
Division of Medical Physics
CancerCare Manitoba

Cc: D. Niven, CCMB
D. Dombrosky, CCMB
E. MacKinlay, CCMB
C. Schroeder, CCMB

Response by CancerCare Manitoba to Discussion Paper DIS-13-01,
Proposals to Amend the Radiation Protection Regulations

Section 3: Administration of Nuclear Substances for Medical Purposes

Proposal: *The CNSC is proposing to add a subsection to section 3 that would require licensees to inform caregivers that they may incur radiation exposure above the dose limit for any person other than a nuclear energy worker, during their comfort and care of patients.*

Comment: CCMB agrees that caregivers should be informed that they may incur additional radiation exposure during the comfort and care of patients. We would, however, like to highlight some potential areas of concern that we hope will be taken into account when this change is made to the regulations.

The CNSC should ensure that the requirements are reasonable and manageable, such as limiting the requirement to the "primary" or "planned" caregiver(s). Otherwise, the additional administrative burden may, in some instances, be higher than anticipated; for example:

- If there are several different caregivers who cannot be given the information at the same time
- If a substitute caregiver must step in with short notice
- If, in the case of a child, there may be custody issues or disputes that make it difficult to share information

The administrative burden will also depend on the compliance criteria for this requirement. If CNSC inspectors will require records confirming that the information was received and understood by specific named caregivers, this requirement could become onerous. As an example, many patients live in outlying communities far from the hospital, and it could be difficult to verify on a person-by-person basis that all caregivers from that community receive the information. Therefore, the CNSC should also ensure that manageable compliance criteria are well defined before implementing this requirement.

Section 7: Provision of Information

Proposal: *The CNSC proposes to replace the term "nuclear energy worker" in section 7 of the Regulations with the term "worker", using the following existing definition: "a person who performs work that is referred to in a licence." If this change is adopted, paragraph 7(1)(a) would also be amended to ensure that every worker is informed whether he or she is a NEW and paragraphs 7(1)(b), (c), and (d) would apply to all workers. Similarly, subsection 7(3) would need an amendment requiring licensees to obtain written acknowledgement from all of their workers having been informed of the matters referred to in subsections 7(1) and 7(2).*

Comment: All staff performing work that is referred to in a licence at CCMB are currently provided with radiation safety training, whether or not they are designated as Nuclear Energy Workers. These procedures are described in the documentation that is currently included as an Appendix in our operating licence. CNSC inspectors review our training records while they are on site in order to verify that we have provided the appropriate information to our staff. While the administrative burden in obtaining a written acknowledgement from "workers" would not be significant in our case, we see no need to include this as a regulatory requirement as it has been proven to be very effective when implemented at the licensing level.

Proposal: *The CNSC proposes that workers be informed of their dose results (both effective and equivalent dose) on an annual basis, although more frequent reporting would be encouraged. This proposed amendment would also clarify that licensees must inform each worker, individually and in writing, of their dose levels.*

Comment: None of the staff members working at CCMB have been declared as Nuclear Energy Workers as they are not expected to receive doses above the public limits. Despite this, all staff members performing work under a license are given personal dosimeters and the vast majority of the results are consistently below the reporting limits. In our licensing documentation, we have committed to informing our staff if they receive an annual dose above a specific threshold. The requirement to inform all workers of their dose levels individually and in writing would result in a large number of notifications being sent to staff indicating that they have received no dose over the year. Considering that our current practice has been shown to work well and has been accepted by the CNSC, the addition of this regulatory requirement would add an administrative burden with no corresponding increase in safety or awareness at our facility.

Addition of the requirement to provide information to female workers with respect to breast-feeding

Proposal: *The CNSC proposes to expand the requirements in subsection 7(1) of the Regulations to include the provision of information, to each female worker, on the potential risks to breast-fed infants from intakes of radioactive substances by the workers, during both routine operations and emergencies.*

Secondly, the CNSC proposes an amendment to subsection 7(2), to ensure that all licensees inform all female workers, in writing, of their rights and obligations as breast-feeding workers under section 11.

Comment: As noted in a previous comment, it would not be a significant administrative burden to provide additional information to staff members during our existing radiation safety training and to obtain a written acknowledgement that they have received the

information. This includes information on the potential risks to breast-fed infants from intakes of radioactive substances and the rights and obligations of breast-feeding workers.

However, at CCMB our staff members work with medical linear accelerators and a few sealed sources. There is almost no possibility that a staff member, breast-feeding or otherwise, would receive an uptake of any radioactive substance. This requirement would result in an additional administrative burden for no real safety gain and thus we would prefer that it be handled on a case-by-case basis in the licensing documentation for each licensee.

Section 11: Pregnant Nuclear Energy Workers

Proposal: *Introduce a requirement for a female worker to inform the licensee in writing if she is breast-feeding.*

Comment: As per the previous comment, there is almost no possibility that a CCMB staff member, breast-feeding or otherwise, would receive an uptake of any radioactive substance and certainly none that would result in a dose to a breast-fed infant in excess of 1 mSv/year. This requirement would therefore result in an increased administrative burden with no real benefit.

It could also be viewed by some staff members as an invasion of privacy. While there is merit in this proposal in some instances, if there is no risk to the child then how a mother feeds her child should be of no business to her employer or any regulating body. Several CCMB staff members have indicated they feel this requirement in unnecessary given their work environment as well as the fact that they are not even designated as Nuclear Energy Workers. We would therefore prefer that it be handled on a case-by-case basis in the licensing documentation for each licensee.

Definition of the Five-Year Dosimetry Period

The CNSC is seeking stakeholder feedback on whether to maintain the current approach of fixed five year dosimetry periods or to introduce rolling five-year dosimetry periods.

Comment: CCMB supports maintaining the current approach of fixed periods. This system has posed no problem for us in the past and we see no benefit to our organization in changing to rolling five-year periods.

Section 15: Emergencies

Proposal: *Replace the existing text in section 15 of the Regulations with the following…*

…Task 1: when voluntarily undertaking actions to prevent severe deterministic effects and actions to prevent the development of catastrophic conditions that could significantly affect people and the environment

Task 2: when voluntarily undertaking actions to avert a large collective dose

Comment: Overall, CCMB agrees that additional clarity with respect to emergency situations will be beneficial. However, the creation of two different dose limits for "Task 1" and "Task 2" could potentially be confusing. The difference between "conditions that could significantly affect people and the environment" (task 1) and "a large collective dose" (task 2) is not well defined, and in the midst of an emergency the distinction may not be clear until the situation is under control. The benefits of creating two emergency dose limits for different tasks rather than the single limit that is currently in place is not clear.

Section 24: Records to be kept by Licensees

Proposal: *In determining an appropriate timeframe* [for the retention of dose records], *the CNSC considered the IAEA revised BSS as a benchmark. The IAEA recommends that occupational exposure records for each worker shall be maintained during and after the workers working life, at least until the former worker attains or would have attained the age of 75 years, and for not less than 30 years after the cessation of the work in which the worker was subject to occupational exposure.*

Comment: In our opinion, a requirement to maintain personal dosimetry records for the periods recommended by the IAEA would be excessive. This is in part due to the fact that the National Dose Registry maintains the dose history of all individuals who have been monitored by a CNSC licensed dosimetry service. We would prefer that section 24 of the *Radiation Protection Regulations* be amended to provide the necessary clarity to the requirement from the *General Nuclear Safety and Control Regulations*, where records for which no retention period is specified be retained until one year after the expiry of the license that authorizes the activity.

Comment: "Ces exigences s’appliqueraient à tous les titulaires de permis. Il peut s’agir de dosimètres individuels électroniques, de radiamètres, de contaminamètres et de systèmes de surveillance de zone."

--> est-ce bien nécessaire si le système de surveillance de zone est testé chaque jour?

Date: 2013-12-09
Fournisseur: Janelle Morrier
Organisation: CHU de Québec
Courriel: Janelle.morrier@mail.chuq.qc.ca

Comment: Dans l'emsemble, les propositions de modifications sont très pertinentes.

2.2, Article 2 :
En ce qui concerne la transmission des doses aux travailleurs, la CCSN propose qu’on informe ces derniers des résultats relatifs à leurs niveaux de dose (dose efficace et dose équivalente) une fois par an, même si on encourage une transmission plus fréquente de ces données. Cette modification confirmerait par ailleurs que les titulaires de permis sont tenus d’informer chaque travailleur, individuellement et par écrit, de leurs niveaux de doses.

Commentaires : Dans un grand centre hospitalier comme le CHU de Québec, près de 500 dosimètres sont émis. L'obligation d'aviser par écrit chaque travailleur individuellement génère un fardeau administratif important. Il faudrait analyser la possibilité d'aviser par écrit seulement seulement ceux qui ont une dose non nulle ou considérer un affichage de groupe...

2.6, Article 24
Pour déterminer une période appropriée, la CCSN s’est appuyée sur les NFI révisées de l’AIEA. L’AIEA recommande que les registres sur l’exposition professionnelle de chaque travailleur soient conservés pendant et après la vie active du travailleur, au moins jusqu’à ce que l’ancien travailleur atteigne l’âge de 75 ans (ou jusqu’à la date où il l’aurait atteint), et pendant au moins 30 ans après qu’il ait quitté le poste pour lequel il subissait une exposition professionnelle.

La durée de conservation est majeur, particulièrement lorsque nous avons près de 500 dosimètres. La déclaration obligatoire (modification proposée à l'article 19) au Fichier dosimétrique national répond à l'objectif visé!!!

Date: 2013-12-09
Fournisseur: Mario Chrétien
Organisation: Centre hospitalier (CHU de Québec
Courriel: mario.chretien@mail.chuq.qc.ca

Winnipeg Regional Health Authority / Office régional de la santé de Winnipeg
Caring for Health / À l'écoute de notre santé

RADIATION SAFETY OFFICE

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Consultations
Canadian Nuclear Safety Commission

Via E-mail

19 NOV 2013

Dear Sir/Madam:

RE: Discussion Paper DIS-13-01, Proposals to Amend the *Radiation Protection Regulations*

I have reviewed the Proposals to Amend the *Radiation Protection Regulations* Discussion Paper several times and each time I become more and more convinced that many of the proposed amendments if adopted will greatly increase administrative burden for RSOs and Managers but do little in terms of increased safety for workers or the public.

Section 2 Application

Non-occupational caregivers should be exempt from the RPR Dose-Limits **regardless of the patient's location**. Many parents of children with life-threatening illness want to be with their child, oftentimes the therapy patient is accommodated in hospital due to young siblings at home – the parents are typically providing psychosocial support while professional nursing staff is providing nursing care.

Section 3 Administration of Nuclear Substance for Medical Purpose

Requirement for licensees to inform caregivers of minimal risk that they are accepting seems that licensees will have to start obtaining "sign-offs" from non-occupational caregivers else how will they prove to CNSC Inspectors that the caregivers are being informed? A whole new set of records to maintain and have available during an Inspection. Is there actual experience that Canadian licensees are not ensuring that caregivers are informed?

Will the CNSC be providing an acceptable statement or instruction to use?

Section 4 Dose Constraints

The decision by CNSC to forgo introduction of Dose Constraints into the RPR is a good decision.

Section 7 Provision of Information

We are accustomed to Nuclear Energy Worker (NEW) Acknowledgments and before that ARW Acknowledgments and cannot understand what would be gained by informing a worker in writing that they **are not** an NEW – but do understand that this would lead to many more pieces of paper to be filed and produced for Inspectors.

We are already informing NEWs of occupational exposure as Dosimetry Reports are received and "badged" non-NEWs at least annually – this proposed amendment is not of concern in that regard. What is of concern is the workers working with low energy emitters such as those doing I-125 RIA or working on the lab bench with H-3 or C-14 – they are not issued dosimeters because of the low energy of the materials they are working with – so there are no "dose results" to inform them of.

Generally we are not opposed to the proposed provision regarding licensees informing workers with regard to duties & responsibilities during an emergency as well as health risks and protective actions/measures. It is not clear however that if the proposed amendment is adopted if licensees will have to explicitly tie this information together in a separate training module or if we can continue to cover this material during relevant portions of separate training modules.

The proposal to expand 7 (1) to include a requirement that each female worker is explicitly informed on potential risks to breast fed infants from intakes of radionuclides during routine operations & emergencies is **much too broad**. A more reasonable approach may be to require licensees to make a determination whether such a risk exists in their operations (routine and emergency) and only be required to inform female workers who may be breast feeding an infant in cases that there is an actual risk. For instance, a licensee with a Consolidated Uses or "815" licence may determine that its workers who may just be doing I-125 RIA with kBq quantities or doing bench-work with small MBq quantities of H-3 & C-14 would not likely be placing their breast-fed infant at any risk, similarly Nuclear Medicine Technologists (NMTs) performing only Diagnostic Nuclear Medicine may not be in situations where a breast-fed infant may be at risk due to an intake by their mother however it may be determined that a risk to breast-fed infants exists with Radiopharmacy Technologists and NMTs working with large amounts of I-131 for Therapeutic Nuclear Medicine. It would be more desirable if licensees whose operations may really place workers infants at risk be required to do a risk assessment and proceed from that rather than subject all licensees to informing many female workers that there is little risk to the worker or breast-fed infant.

So if some rationalization can be done with regard to the above then I would expect that 7 (2) be modified in it **only be aimed at female workers who are truly at risk** instead of all female workers across the board.

The Discussion Paper forecasts only a minor impact if the proposals in 7 (1) and 7 (2) for female workers are adopted – I think that there would be a **huge impact and large administrative burden**.

Section 8: Requirement to Use Licensed Dosimetry Service

Overall we are not overly concerned with the proposed amendment that a licensee must use a Licensed Dosimetry Service to measure and monitor skin dose to NEWs who have a reasonable probability of receiving an equivalent dose to skin or skin of an extremity greater than 50 mSv in a one year dosimetry period but do have a concern with what justification by licensees will be acceptable as to why their workers are not likely to receive an exposure of 50 mSv or greater to skin or skin of extremities in one year.

We have several Diagnostic NM departments in our organization whose NMTs wore extremity dosimeters (supplied by NDS) for some time and then ceased wearing Extremity Dosimeters when experience showed that annual skin extremity exposures were low – in other words, **past extremity dosimetry experience showing that annual exposures did not approach 50 mSv/yr should be sufficient justification** for not implementing extremity dosimetry now if operations are essentially unchanged since extremity dosimetry monitoring was last performed.

Section 11: Pregnant Nuclear Energy Workers

The CNSC proposal to require **all** breast feeding workers to notify the licensee in writing if she is breast-feeding is much too broad and should only be applied in circumstances where a risk of significant radionuclide intake is likely to cause an intake to the breast-feeding infant.

The CNSC proposal for licensees to make accommodations for breast-feeding workers to ensure that the breast-fed infant does not receive a dose in excess of 1 mSv per year may be a reasonable approach, providing that CNSC Inspectors use reason in determining whether an actual risk is present in the licensee's operations.

The proposed amendment regarding breast-feeding workers would be a huge administrative burden, particularly to licensees whose operations would not be of particular intake risk. The second last paragraph on page 10 of DIS-13-01 states "The CNSC surmises that very few breast-feeding women actually work in environments that would require their employers to make this accommodation." Surely there must be a better way to protect the few Canadian workers who might be in the particular environment than creating a huge administrative burden for all licensees.

Section 13: Effective Dose Limits

The current approach with fixed Five Year Dosimetry Periods ought to be maintained. Rolling periods would lead to increased administrative burden.

Section 24: Records to be Kept by Licensees

Increased clarity is generally attractive. Amending S24 RPR to provide increased clarity with respect to expectations for occupational exposure records and including a specific time period for retention of occupational dose records would likely be a positive development. Setting a retention period of fifty (50) years would be much less burdensome than seventy (70) years.

Proposed Section on Radiation Detection and Measurement Instrumentation

There are advantages and disadvantages in adding such a section to RPR and using the IAEA Safety Report Series No. 16 as the "gold" standard. My concern is that many hospitals and some universities do radionuclide-specific calibrations for their Contamination Meters using open source material with kBq quantity calibration sources prepared on-site, verified in a clinical Dose Calibrator. Such sources are not "NIST-traceable" or traceable to a national standard. The alternative of going with "NIST-traceable" sealed sources would be cost-prohibitive to many hospitals and academic institutions and might result in many Contamination Meters no longer having radionuclide-specific correlations.

I urge staff and the Commission to hold off this particular proposed amendment and take it to discussion forums with industry user groups like the Canadian Radiation Protection Association (CRPA) and the Canadian Industrial Radiography Safety Association (CIRSA) over the next couple of years at their annual meetings.

Proposed Section on Responsibility for Radiation Protection

Licensees are already required to identify an Applicant Authority, Signing Authority and RSO (with RSO's qualifications & job description) in licence applications however licensees have not generally been required to document required competencies and qualifications. Requiring licensees to not only document identified competencies and qualifications but documenting that the selected individual maintains the documented competencies and qualifications will likely create a large administrative burden.

It is possible that if the select individual is a Certified Health Physicist (CHP), a Registered Radiation Safety Professional (CRPA (R) credential) or recognized by the Canadian College of Physicists in Medicine (CCPM) that might be sufficient proof if the licensee can demonstrate on-going CHP-certification or CRPA (R) or CCPM-certification status (all three credentials have maintenance requirements to maintain that status) for the selected individual.

Thank You for the opportunity to comment on DIS-13-01.

Sincerely,

J. Dovyak

Jeff Dovyak RTNM, CRPA (R)
Radiation Safety Coordinator

Comments on:

Proposals to Amend the
Radiation Protection Regulations
Discussion Paper DIS-13-01
August 2013

Submitted by:

Dr. Sandor Demeter

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Submission date: November 21,2013

The comments are framed by the ICRP (ICRP 103) system of radiological protection relative to:

The principle of justification: *Any decision that alters the radiation exposure situation should do more good than harm*

The principle of optimization of protection: *All exposure should be kept as low as reasonably achievable, taking into account economic and societal factors with restrictions on individual exposure to limit inequities in the dose distribution*

The principle of application of dose limits: *The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits recommended by the Commission.*

In General

As the draft proposal makes strong reference to ICRP 103 it would be helpful to justify each proposed change back to the broad principles of justification, optimization and the application of dose limits.

Section 1: Interpretation and Applications

- Concur - definition changes are needed to reflect changes between ICRP 60 and 103

Section 2.1 Application

- *The intent is to state in subsection 2(2) that the licensee is exempt from the dose limits described in sections 13 and 14 of the Regulations in respect of all persons described previously in 2(2)(a), (b) and (c).*
- I support the intent of this proposed change especially relative to caregivers of those that have undergone a nuclear medicine diagnostic or therapeutic procedure. There are circumstances, especially in pediatric patient populations, where the presence of a family or other “care-giver” is crucial for both physical and mental health reasons. These circumstances are uncommon and usually would not constitute a significant population collective dose to care-givers as it would only be a short window of exposure.
- However, I feel it is still important to counsel individuals being discharged on how to minimize exposure to others (especially relative to nuclear medicine therapeutic procedures) and to counsel personal care-givers who on practical ways to reduce their exposure but still allow them to provide the needed support (in keeping with proposed changes to 2.2. Section 3).

- I don't think the setting should matter, i.e. Whether the non-occupational care-giver is outside, or inside, a medical facility. Parents who are visiting and providing parental support for their I-131 threated child, in hospital, would be a good example. The exemption should apply for all settings.

2.2: Obligation of Licensees and Nuclear Energy Workers

Section 3: Administration of Nuclear Substance for Medical Purposes

- It is our current practice to do a assess, and document, the suitability for outpatient therapy (i.e. I-131). I don't feel this proposed amendment not would require any change to this particular practice relative to the patient themselves.

- It is easy to inform caregivers, those that we know of, that they may receive more than 1 mSv of dose and compare this to normal background dose. However, the non-occupational care-giver "pool" may be a complex set of family and friends and it may not be administratively feasible to ensure that we have communicated (and documented same) to all potential caregivers. In common practice the most significant potential caregiver usually comes to our I-131 patient therapy consult session and radiation safety counseling, verbally and via a pamphlet, is given to the patient and whoever accompanies him or her. It would be reasonable to assume that information from this session would be shared with any other potential care-givers. In addition, our department can be contacted should any questions or concerns arise for the short period of time of precautions post therapy.

- The issue of informing the caregiver of "minimal risk" is more difficult as there is no agreed or scientifically substantiated "individual" risk assessment message for this level of exposure. The ICRP recommends against using "population" based effective dose risk estimates, such as those published by in BEIR VII, for individual risk assessment.
    - *Effective dose is intended for use as a protection quantity. The main uses of effective dose are the prospective dose assessment for planning and optimisation in radiological protection, and demonstration of compliance with dose limits for regulatory purposes. Effective dose is not recommended for epidemiological evaluations, nor should it be used for detailed specific retrospective investigations of individual exposure and risk. (CIRP 103 Executive Summary (j))*

- We normally counsel I-131 patients about deterministic (e.g. salivary gland inflammation) effects and about the minimal and "theoretical" risk of 2nd malignancies form their therapy dose (one major study by Sawa et al. *Thyroid* 19(5);2009 estimated risks ranging from 0.1 to 1%

increased lifetime risk of cancer, primarily leukemia). Given the magnitudes of lower dose received by caregivers it is uncertain that a valid risk estimate can be given other than to say wherever reasonably possible it is prudent to reduce radiation exposure. My concern is if there is direction to inform caregivers of their "minimal risk" the message has to be valid and consistent across licensees.

Section 4: Radiation Protection Program

- Radon
  - It makes sense to manage Radon exposure/intake in a similar fashion to other sources. Radon is currently an outlier.
  - It may be a good idea to retrospectively assess what recent exposure data would look like with the new dose coefficients as this may drive a need for further radiation mitigation strategies.
- Dose constraints
  - I think dose constraints are already in place for some circumstances, e.g. as guidelines (e.g. public exposure when designing a nuclear medicine facility)
  - If dose constraints are entrenched in the regulations they have to be flexible enough to allow for specific circumstances and, at the same time, be consistent enough to ensure harmonized practice across sites
  - If there is to be a lowering of dose constraints beyond current practice then strong consideration needs to be given to economic ramifications – a cost effectiveness economic model (i.e. incremental cost per reduction in uSv) may be helpful to guide policy
  - The current practice of "soft" dose constrains, versus entrenched in regulations, seems to be appropriate for now.

Section 7: Provision of Information

- Provision of information to all workers ("a person who performs work that is referred to in a license")
  - I understand that, broadly speaking, a licensee should know specifically who has access and handles nuclear substances in their facility/operation and should take steps to ensure that occupational and public radiation safety issues are appropriately managed. I believe this is currently being done under the current licensing process and the degree of radiation protection oversight is titrated to specific access and handling scenarios (e.g. a medical physicist needing a low dose point source as a flood source is categorically different, from a risk perspective, versus administering a liquid I-131 dose)

    - I have concerns the proposed changes would create a considerable amount of paperwork having a significant administrative and economic impact.
    - What is the driving force or justification for this proposed change?

- Addition of requirement for the provision of information related to emergencies
    - I suspect the end result of such a change would be that "all" workers would be required to "inform" a specific person(s) if an accident or emergency occurred (e.g. a spill) and then a relatively small set of workers (most likely NEWs) would be responsible for managing the situation from there on.

- Addition of the requirement to provide information to female workers with respect to breast-feeding
    - It is a very unlikely scenario that a breast fed women of a Nuclear Medicine NEW would receive > 1mSv from breast milk – has it ever been documented?
    - Many workers will take advantage of maternity leave and will not be a work for a good portion of the breast feeding period.
    - Theoretically possible with I-131
    - Perhaps a pragmatic way of managing this is that breast feeding NEWs are required to report that they are breast feeding if they, in a pre-hoc determination, work in a setting for which it would reasonable to assume that work place accommodations would be necessary. For example, in a clinical Nuclear Medicine clinic for which I-131 is <u>not</u> dispensed or handled, it does not make sense to invoke a significant administrative burden. I think a pre-hoc determination and targeted duty to notify the employer based on the current license conditions would make more sense.

Section 8: Requirement to Use Licensed Dosimetry Service

- Support

Section 11: Pregnant Nuclear Energy Workers

- see comments on breast feeding – Section 7

Section 14: Equivalent Dose Limits

- Support more specific terminology for dose to hands and feet
- Lens of eye dose
    - Feasible, economical and reproducible means of measuring dose to the eye are needed given the proposed significant drop in dose limits.

New Sections Proposed for the Radiation Protection Regulations

- **3.2 Proposed Section on Responsibility for Radiation Protection**

- There first needs to be an agreed upon, feasibly attained and maintained, set of competencies that CNSC would champion and use as the benchmark for assessment.

- Perhaps there could be two categories of radiation protection individuals. The first are certified or accredited by a CNSC approved organization or agency for which content specific competency and ongoing continuing education is deemed to be acceptable (e.g. Certified Health Physicist (CHP), a Registered Radiation Safety Professional (CRPA (R) credential) or recognized by the Canadian College of Physicists in Medicine (CCPM) etc.)

- If a radiation protection individual does not have CNSC approved "credentialing" then proof of content specific competency and ongoing applicable continuing education would not be unreasonable. As per my first bullet, such a requirement would have to be standardized, and feasible, across licensees and the administrative burden of documentation and record keeping would need to be kept to a minimal. It should be kept in mind that many "RSOs" perform many functions and their "RSO" duties constitute a small portion of their work-time.

Thank you for the opportunity to comment on this important draft document

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From: Jeremy Phipps [mailto:jphipps@exchange.hsc.mb.ca]
Sent: Monday, November 25, 2013 2:40 PM
To: Consultation
Subject: DIS-13-01 Comments
Hello,

I have a couple of comments to share on the discussion paper DIS-13-01.

Section 3:

The CNSC is also proposing to add a subsection to section 3 that would require licensees to inform caregivers that they may incur radiation exposure above the dose limit for any person other than a nuclear energy worker, during their comfort and care of patients.

This infers that a nuclear medicine department is responsible for informing anyone who may be involved in the patient's care, even if the care would not exceed dose limits to the public. To inform everyone who may be involved in the patient's care over the course of their treatment could be a logistical nightmare. Through informing the patient how to minimize exposure to others essentially accomplishes this goal. The patient will do what they need to do to reduce exposure to others, and this is a procedure that is laid out and effective.

I also think we need to look into what a minimal risk means, as this question will be asked by caregivers. As soon as I tell a family member that because of the care they are going to be providing they will incur a minimal risk, many questions will arise. From experience the only way to relieve radiation related concerns for some is to monitor their exposure directly (EPD or TLD). This would not be an option in this case. I have no problem informing the patient how to reduce exposure to others, but would have a harder time explaining risk to a caregiver. Risk needs to be defined. Are we informing of the increased risk of cancer? radiation sickness? Genetic changes? There are many types of risks that can be associated with radiation exposure, would there be a standardized position on what types of risk should be discussed? Also could this discussion hinder patient care based on the possibility of fear that could be present in a percentage of the population. Even technologists who are educated in the field can have irrational fears surrounding the use and effect of radiation. I would hate for our patient to not receive appropriate care out of irrational fear even with an radiation safety awareness session.

Section 7:

This provision applies specifically to NEWs; there is no regulatory requirement for licensees to provide this information to other persons working at CNSC-licensed facilities or performing CNSC-licensed activities. Furthermore, the Regulations do not specify a time period for reporting dose results to workers. The CNSC believes this information is important and relevant to all persons who work at licensed facilities or perform licensed activities, and should therefore be made available to them in a timely manner.

"licensees must inform each worker, individually and in writing, of their dose levels".
"worker" refers to NEW and non-NEWs alike?

How do you inform a worker of a dose if they are not monitored? Is this a way to monitor more people?

Do we have to inform every position in the hospital that they are not a NEW? This doesn't seem like a good use of resources. The intent is to increase radiation safety and awareness with those

that are working with radiation. If there is no fear of increased exposure that is what should be conveyed.

In a hospital setting where there are hundreds of workers that may or may not enter a licensed area such as a nuclear medicine department, how do you inform them of their dose, if they are not monitored. I'm thinking of maintenance, housekeeping, security etc.

Or in the case of low level labs where C14 is used how do you inform them that their dose is zero quarter after quarter.

Where there is a risk, there should be information provided, where there is not a risk, information should be available but not provided.

Thank you for receiving comments on this proposal. There appears to be some changes that will not increase the safety of workers, or the public , only increase the amount of resource allotment and record keeping. I do hope all comments are taking into consideration.

Jeremy Phipps- *RTNM,CTIC(N), BSc*
Charge Technologist
Clinical Instructor/Radiation Safety Officer
Nuclear Medicine
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204 787 3848

Good Morning,

I would like to add a couple of comments to the proposed amendments.

Section 7 Provision of Information – the Idea that we (as a licencee) shall document that a non-NEW acknowledges that they are not going to be designated as a NEW does not seem to be necessary. We already have a program in place to document NEW designation and acknowledgement, those staff that have not signed this acknowledgment can expect to receive little to no additional occupational exposure as governed by the regulations. The additional paperwork seems to be redundant.

Section 13 Effective Dose Limits – The 5 year fixed dosimetry period is a more desirable system to implement than a rolling 5 year term. It provides a constant across the board when having to perform calculations. Adding a rolling 5 year term adds a variable to the calculation which may lead to incorrect calculations.

Thank you.

Best Regards,

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December 5, 2013

Mr. Marc Dallaire
Director General, Regulatory Policy Directorate
Canadian Nuclear Safety Commission

Re: Proposals to Amend the Radiation Protection Regulations

Dear Mr. Dallaire:

I am writing to you to comment on the Canadian Nuclear Safety Commission's (CNSC's) discussion paper DIS-13-01: "Proposals to Amend the Radiation Protection Regulations". For brevity, I will call this DIS-13-01 in the remainder of this letter.

I was informed of DIS-13-01 by my regulatory licensing officer at the CNSC and by an excellent summary of the proposal in the regular CNSC Feedback column in *InterActions*, the newsletter of the Canadian Organization of Medical Physicists.

To give some context, I am writing to you in my capacity as a Radiation Safety Officer (RSO) working in a cancer center and hospital in Ontario. This is a publicly funded, not-for-profit institution. My portfolio as RSO covers both Class II and NSRD licences as the hospital has activities in both a Class II managed cancer centre and in an NSRD managed nuclear medicine department. One positive aspect of my role as RSO has been the consistent collaborative interaction that I have had with licensing officers and inspectors from both CNSC divisions. I have particularly appreciated that CNSC staff have recognized some of the unique pressures in the health care system that one must work under while maintaining the CNSC regulatory requirements. I appreciate that by putting out DIS-13-01, the CNSC is continuing to solicit comments from our specialized community. My comments are specific to the hospital environment.

I have a number of other small concerns, but I suspect they are the result of a lack of understanding on my part at this time. I trust that there will be some refinement of details as DIS-13-01 continues through its consultation process. Here are some concerns that I wish to address in this first stage of the consultation:

1. I can appreciate the effort in Sections 2 and 3 to make the requirements for persons exposed for therapeutic purposes clearer. Unfortunately, the specific changes proposed are still unclear; perhaps giving the exact wording proposed would improve clarity.
2. With the changes in Section 3, will we be expected to give the information in writing or in person, or either? Specifically, if we have an interview program in our policies for outpatient treatment to determine the suitability of a patient, do we need to extend the interviews to the caregivers? Or can we present the information in our written educational material alone?
3. The proposals in Section 7 to broaden the scope of the radiation safety program to "worker" are also unclear. Specifically who is a worker? In our radiation safety policies (and hence in our licence activities) we mention staff such as security personnel, nurses, secretaries, etc. in our hospital who may be remote from any radiation activities. They are mentioned because we have decided our policy will be to give regular radiation safety in-services to them to assure them that they are not exposed to radiation in the course of their work. Since they are listed in our licence activities, would they be 'workers' as defined in the proposed changes? And must we communicate an annual dose to each of

them in writing? This would only be possible individually if we monitor each of them separately. Therefore, there seems a potential large administrative and perhaps monetary requirement to this change that does not reflect any safety gain. This point needs further clarification.

4. Similarly, the requirement to advise all workers of duties and responsibilities during an emergency seems unrelated to the potential risk. Typically in the hospital setting we identify and train only the expert workers (perhaps not limited to NEWs) if they are expected to respond to a radiation emergency. In part this is to avoid radiation anxiety to people who will never be involved. Unnecessary emphasis on very low risk emergency preparedness may raise anxiety without any improvement of the excellent radiation safety records we already achieve in hospitals. And,
5. Finally, I believe the CNSC has missed an opportunity to alleviate some radiation anxiety for workers and public in the hospital setting that arise because of the signage requirements of Section 21 in the regulations. Specifically, we spend a considerable time ensuring that dose levels in the hospital environment are not dangerous and that a dangerous exposure would never be expected to happen even in the limited controlled areas as defined in Section 21. Yet we are directed in the regulations to post a sign at access points specifically saying "RAYONNEMENT-DANGER-RADIATION". I have been asked by staff in a number of in-services why the signs say "DANGEROUS" if the area is such that their expected exposure even in these areas would be limited to less than the dose levels encountered annually in their day to day lives. It would be beneficial and reassuring if the signage could be moderated somewhat, perhaps using words such as "CAUTION RADIATION AREA - ATTENTION ZONE DE RAYONNEMENT" in the hospital setting. Of course the specific signage could be validated by the CNSC for a particular area during the licensing process, so appropriate wording would still be regulated.

I trust that these comments prove somewhat helpful. I hope that as the CNSC tunes any potential revisions of the Radiation Protection Regulations that it will continue to work together with radiation safety personnel in hospitals to sustainably maintain the safety of Canadians.

Yours truly,

L. John Schreiner, Ph.D., FCCPM

Radiation Safety Officer and Chief, Medical Physics Department

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Radiation Safety & Emergency Preparedness Department
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November 28, 2013

Canadian Nuclear Safety Commission
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Ottawa, Ontario, Canada K1P 5S9
Fax: 613-995-5086

Dear CNSC:

I would like to take this opportunity to acknowledge the initiative of the CNSC on making changes to the Radiation Protection Regulations. These amendments would harmonize the Regulations with updated international standards. In addition, these amendments do clarify requirements and address existing gaps.

The Ottawa Hospital would like to comment on Discussion Paper DIS-13-01, proposals to amend the *Radiation Protection Regulations*.

We have categorized our comments in two categories:

A) Amendment that will have a positive impact on our Radiation Protection Program or

B) Amendment that will either require further clarification and/or will have a significant impact on resources or program.

A) The following amendments reflect a positive impact on the radiation program:

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	TOH Comments	Impact on The Ottawa Hospital
3	Administration of Nuclear Substances for Medical Purposes		Addition of a definition of the term "caregiver" to section 1. Addition of a requirement for licensees to inform caregivers that they may incur radiation exposure that exceeds the dose limit for any person other than a nuclear energy worker.	To clearly state who would qualify as a caregiver. To ensure licensees take reasonable measures to ensure that caregivers are aware that they are acting in such a capacity and accept the minimal risk associated with the potential to exceed the dose limit for any person other than a nuclear energy worker.	This will formalized existing practice within our facility
14	Equivalent Dose Limits	The dose limit in item 1, under column 4 in the table outlined in section 14.	Amendment to the dose limit for the lens of an eye for a nuclear energy worker from the current limit of 150 mSv per one-year dosimetry period to 50 mSv per one-year dosimetry period. Addition of a new dose limit for the lens of an eye for a nuclear energy worker of 100 mSv per five-year dosimetry period.	To align the dose limits for the lens of an eye with the ICRP's latest recommendation, in order to protect workers' health and safety	Lens of eyes for NEW from the current 150 mSV to 50 mSV per one year. We appreciate the new changes to lens dose limit

B) The following amendment will either require further clarification and/or will have a significant impact on resources.

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	TOH Comments	Impact on The Ottawa Hospital
7	Provision of Information	7. (1) Every licensee shall inform each nuclear energy worker, in writing, (*a*) that he or she is a nuclear energy worker;	7. (1) Every licensee shall inform each worker, in writing, (*a*) whether he or she is a nuclear energy worker;	• We require further clarification from the CNSC regarding who is involved in doing "work listed on a licence or work in nuclear facility". In the context of our hospital, are housekeeping, security, or facility staff included? These workers may only be in the area intermittently (example, facility to change a light bulb). If so, this is an extremely high administrative burden. • Confirmation regarding "in writing": email ok? Or signing beside your name on dose report? • Proposed method of dose assessment for non-NEW workers. Individually? Task or job specific estimate? • Clarification re: would we have to have workers who are involved in facility but not NEW's sign their own declaration?	Extremely large administrative burden should we have to notify all hospital workers in writing of their annual dose. Extremely large number of people affected. We estimate that approximately 2000 letters per year to be issued if all staff involved in area are included. Large time investment for little gain, in particular for peripherally involved staff whose contact with radioactive material is minimal.
			Addition of a specific requirement to inform all workers of their duties and responsibilities in the event of an emergency.		
		(*d*) of the worker's radiation dose levels	Amendment to specify that workers be individually informed of their dose results (both effective dose and equivalent dose) on an annual basis.		
			Addition of a requirement to subsection 7(1) to include the provision of information to each female worker on the potential risks for a breast-fed infant from intakes of radioactive substances by the worker Addition of a requirement to subsection 7(2) to ensure that every licensee informs each female worker, in writing, of their rights and obligations as a breast-feeding worker under section 11.	Clarification regarding breast-feeding declaration. Does this apply to all workers? Or just NEWS? Not clear from changes document.	If implemented, this requirement has medium impact, as we need to revise our documentation and training materials in order to provide the additional information to female workers.

11	Pregnant Nuclear Energy Workers		Addition of a requirement for a female worker to inform the licensee in writing if she is breast-feeding. Addition of a requirement for a licensee to adapt the working conditions in respect of exposure to the breast-feeding female worker, during both routine operations and emergencies, to ensure the breast-fed infant is protected as required for a member of the public.	Clarification regarding breast-feeding declaration. Does this apply to all workers? Or just NEWS? Not clear from changes document.	It is assumed that very few breast-feeding women actually work in environments that would require TOH to make this accommodation. Nonetheless, the proposed amendments result in a medium administrative burden.
15	Emergencies		Replace current text with new text that incorporates relevant clauses from the IAEA revised BSS with respect to dose limits for emergencies. Introduce new requirements for when dose limits are exceeded during an emergency and for the associated return-to-work processes for workers. The proposed text for section 15 is described in detail in the discussion paper.	Clarification of emergency definition. Any spill or deviation? Or emergency on the scale of the regulations where someone could get the emergency dose limit?	Medium impact on budget and program.

Appendix B presents the CNSC's proposals for new sections to the *Radiation Protection Regulations*.

Proposed new section	TOH Comments	Impact on The Ottawa Hospital
Radiation Detection and Measurement Instrumentation	Clarification of whether contamination meters, and other area monitors, EPD's, not directly used for regulatory purposes, etc are included? Calibration of contamination meters extremely costly, in time, calibration costs, extra loaners.	This would pose a significant administrative burden.

Should you have any we would be happy to elaborate on the above observations

Yours truly,

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Section 3: Administration of Nuclear Substances for Medical Purposes

The CNSC is proposing to include a definition of the term “caregiver” in the *Radiation Protection Regulations.* This definition would indicate that a caregiver is a person, outside of a medical facility, who willing and voluntarily – and not as an occupation – helps in the care, support and comfort of patients who have been administered a nuclear substance for therapeutic purposes.

The definition of caregiver should not include the statement “outside a facility”. For radionuclide therapy patients that are admitted to hospital, especially in the case of end-of-life or palliative care, caregivers may decide to willing and voluntarily help in the care, support and comfort of patients who have been administered a nuclear substance for therapeutic purposes. It is unlikely the caregiver will see the exposure as a concern when compared to the foreseeable death of the patient. Caregivers of patients who have been administered a nuclear substance for therapeutic purposes should not be subject to RPR regulations and dose limits.

The CNSC is also proposing to add a subsection to section 3 that would require licensees to inform caregivers that they may incur radiation exposure above the dose limit for any person other than a nuclear energy worker, during their comfort and care of patients.

Due to the various configurations of households there may be multiple caregivers who may exceed a dose limit for any person other than a nuclear energy worker. Requiring licensees to consult with all caregivers in a household may incur significant administrative burden and costs to the healthcare system. There will be a significant increase in the amount of time required by physicians, technologists or radiation safety officers to consult all caregivers of a patient. Consider a patient that has a partner, siblings, children, grand-children, parents, or home care staff providing care in one form or another. With home care, sometimes it is a different staff member arriving in the home several times a week. How would a licensee ensure each home care staff has been informed? In order to ensure compliance, there would be less administrative burden to require admission to hospital for patients that do not live alone rather than investigate the number of caregivers and consult each one. However, admission of the patient to hospital would result in significant costs to the health care system.

Section 7: Provision of Information

In this respect, the CNSC proposes to replace the term “nuclear energy worker” in section 7 of the Regulations with the term “worker”, using the following existing definition: “a person who performs work that is referred to in a licence.”

If this change is adopted, paragraph 7(1)(a) would also be amended to ensure that every worker is informed whether he or she is a NEW and paragraphs 7(1)(b), (c) and (d) would apply to all workers. Similarly, subsection 7(3) would need an amendment requiring licensees to obtain written acknowledgement from all of their workers of having been informed of the matters referred to in subsections 7(1) and (2).

It is anticipated that there will be a significant administrative burden to inform all workers under a licence whether or not worker is a NEW. The administrative duties for keeping track of paper work for all workers in a large health care facility would be tremendous when considering the number

of workers who perform work related to the licensee and the movement of employees within a healthcare facility. This occurs because many workers hold casual, float or part-time positions in areas of nursing, lab, housekeeping, maintenance, security and administration.

First, the CNSC proposes to expand the requirements in subsection 7(1) of the Regulations to include the provision of information, to each female worker, on the potential risks to breast-fed infants from intakes of radioactive substances by the worker, during both routine operations and emergencies.

Secondly, the CNSC proposes an amendment to subsection 7(2), to ensure that all licensees inform all female workers, in writing, of their rights and obligations as breast-feeding workers under section 11. The CNSC's further proposed changes to section 11 of the Regulations are presented later in this discussion paper.

From Section 11:

- the first is to introduce a requirement for a female worker to inform the licensee in writing if she is breast-feeding.
- the second is a requirement for a licensee to adapt the working conditions in respect of exposure to that worker, during both routine operations and emergencies, to ensure the breast-fed infant is afforded the protection required for a member of the public. In other words, the licensee would need to make accommodations to ensure a breast-feeding worker would not receive an intake of a radioactive substance that would result in a dose to her breast-fed infant in excess of 1 mSv per year.[5]

It would be difficult to ascertain the risk to a fetus from ingestion of contaminated breast-milk and also to quantify the amount to the fetus to ensure it less than 1 mSv per year. The additional restrictions that will be applied to all breast-feeding workers (not just NEWs) would likely cause administrative burden on the licensee. Similar to a previous example, in a large health care facility there are a significant number of workers who hold casual, float or part-time positions in areas of nursing, lab, housekeeping, maintenance, security and administrative. With the regulations already in place for radioactive iodine, it seems unreasonable to introduce a program to monitor for ingestion of other radionuclides commonly used in healthcare facility such as Tc-99m to all workers in addition to NEWs.

The CNSC is proposing that a licensee must also use a licensed dosimetry service to measure and monitor radiation to NEWs who have a reasonable probability of receiving an equivalent dose to the skin, or to the skin of any hand or foot, that is greater than 50 mSv in a one-year dosimetry period.

The term "reasonable probability" does not indicate explicitly to a licensee of when hand or foot is required therefore it is likely that all NEWs would be required to wear ring dosimeters. It will increase the administrative burden and costs for the additional dosimetry.

Section 14: Equivalent Dose Limits

The term “hands and feet”
Item 3 in the table in subsection 14(1) of the current *Radiation Protection Regulations* specifies dose limits for the “hands and feet”. The actual intent of this requirement is to limit the dose to the skin of any hand or foot; however, the wording is ambiguous and has sometimes been misinterpreted as “the total dose to all hands and feet”. The CNSC therefore proposes to change the wording “hands and feet” to “the skin of each hand and foot”.

Should the licensee be required to use dosimeters on each hand and foot for workers, it will increase administrative burden and costs to the licensee for additional dosimetry.

Section 24: Records to be Kept by Licensees

In determining an appropriate timeframe, the CNSC considered the IAEA revised BSS as a benchmark. The IAEA recommends that occupational exposure records for each worker shall be maintained during and after the worker's working life, at least until the former worker attains or would have attained the age of 75 years, and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure.

Facilities with the substantial number of workers on dosimetry generate a vast quantity of records. It is unlikely that a licensee will track when records will be disposed based on a worker’s 75th birthday or 30 years after cessation of work. In our case, the records are stored off-site and will remain there indefinitely. It is rare to have old dosimetry records retrieved and I would be curious to know what would be the purpose. In today’s technological age, it would be more prudent that the *National Dose Registry* ensure that records are kept indefinitely electronically. Licensees would carry dosimetry records and dispose en bloc after an absolute time period eg. 50 years.

New Sections

Radiation monitoring equipment must be appropriately selected for the types, levels, and energies of the radiation encountered, and it must be capable of performing accurately and reliably in operating field conditions during routine work and emergencies. Instruments must also be tested routinely to verify proper functioning including, where appropriate, for battery power level, high voltage and source response.

Licensees would likely incur significant costs to ensure contamination meters and other radiation detection equipment are calibrated under the same conditions as survey meters.

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2 October 2013

Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
280 Slater Street
Ottawa, Ontario, Canada K1P 5S9

Dear Sir/Madam:

We have read with interest the recent CNSC discussion paper, DIS-13-01, "Proposals to Amend the Radiation Protection Regulations". We have some concerns and some questions regarding a few of the proposed amendments, which are listed below:

(1) Section 3, "addition of a requirement for licensees to inform caregivers that they may incur radiation exposure that exceeds the dose limit for any person other than a nuclear energy worker." At Sunnybrook Health Sciences Centre (SHSC), we run into a couple of situations where this may apply: (a) out-patient treatments with high activity of I-131 for treatment of thyroid cancer or Lu-177 for treatment of neuroendocrine disease where the patient involved is not entirely independent and requires some assistance from a caregiver and (b) out-patient treatments with permanent implants of brachytherapy sources (e.g., I-125 or Pd-109) for prostate or breast cancer where the patient involved is not entirely independent and requires some assistance from a caregiver. We believe it will be difficult for SHSC to ensure that all potential caregivers are informed in this way. We do not think that it is reasonable to believe that all potential caregivers will be identified in advance of all out-patient isolations (which may last for a period of roughly a week) and even contacting people identified as potential caregivers by patients will add considerable time to our clinical departments. It would be more practical for SHSC to provide the out-patients themselves with information to provide to any potential caregiver, but SHSC would have difficulty ensuring that the information was passed on. We therefore seek clarification of the requirement to "take reasonable measures to ensure that caregivers are aware they are acting in such a capacity and accept the minimal risk..."

(2) Section 7, "every licensee shall inform each worker..." We have a distinct problem with the change requiring that all "workers" be provided information that was previously only required for NEWs. As noted, "worker" is defined as "a

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person who performs work that is referred to in a licence". This is not, however, a conventional definition of "worker" as used in common practice at large facilities such as hospitals. At SHSC, "worker" would be conventionally taken as any SHSC employee. The term NEW is useful in that it makes clear that there is a specific sub-group of employees or others who require additional information and monitoring. We would much prefer it if a term other than "worker" were used for this additional "special" subgroup. SHSC employs roughly 10,000 people, all of whom would likely consider themselves "workers". If we are required to do something special for all "workers", but we did that something for a sub-group of "workers" (taking "worker" in the conventional sense), we raise the possibility of issues such as union grievances or issues of distrust arising. We suggest that you retain NEW for one special subgroup and then add RW (for Radiation Worker) for this new sub-group of workers.

(3) Section 7 "workers be individually informed of their dose results": there is a statement that there will be clarification on what this means – it has been our experience that different CNSC inspectors interpret this differently. We can't really comment on this issue unless we actually see the text in clarification. We would hope that posting results in areas accessible to all workers would be sufficient to meet this requirement. If we have to give results to all workers individually and get them to sign off that they received the information, then this would be a major headache, particularly at the cancer centre part of our facility.

(4) Section 26 – removal of schedules 1 and 2 – where would the "official" versions of these schedules then be found for use in calculations?

(5) Appendix B – radiation detection and measurement instrumentation – could you be more specific as to the requirements? What, for example, would be required in terms of testing an area monitor in a hot lab or brachytherapy room?

Thank-you for considering these comments.

Sincerely,

Curtis B. Caldwell, Ph.D., MCCPM
Corporate Radiation Safety Officer

Geordi Pang, PhD, FCCPM
Radiation Safety Officer
Brachytherapy and Teletherapy,

Cindy Matheson
Assistant Radiation Safety Officer

From: Daniel Levin [mailto:DLevin@exchange.hsc.mb.ca]
Sent: Tuesday, October 29, 2013 10:02 AM
To: Consultation
Subject: Discussion Paper DIS-13-01, Proposals to Amend the Radiation Protection Regulations

Dear Sir/Madam:

RE: Discussion Paper DIS-13-01, Proposals to Amend the Radiation Protection Regulations
Pages 5 & 6, Items 2.1 Section 2 and 2.2 Section 3

I am writing concerning the definition of a caregiver for the purposes of caring for a patient who has received "a nuclear substance … for therapeutic purposes". I do not have any issue with the inclusion of those people who are "acting as a caregiver, outside a medical facility and not as an occupation". I think this is entirely appropriate. Unfortunately I think it is limiting and does not recognize current medical and therapeutic practice.

We are proposing a small change to the definition of caregiver in order to have a major positive impact on patients' experiences undergoing radionuclide therapy. We suggest removing the phrase "outside a medical facility" and leaving the definition at those "acting as a caregiver, but not as an occupation". This would allow family, adequately informed about the possibility of radiation exposure, to provide the support that patients need. We must remember that these patients have cancer, and need their loved ones around them.

The problem arises particularly with radionuclide therapy for children. Many of these patients will need in-patient admission for their therapy because of their home situation, especially if there are siblings. Another reason for admission is to reduce the total body radiation dose to the patient by maintaining adequate levels of hydration, which is difficult to achieve as children often do not drink enough. In these situations it is very important for the child to have the support of their parents, and likewise for the parents to be able to be able to have some contact with their child. The family members can be rotated, and limits to contact enforced so as to ensure that the caregiver does not incur radiation exposure above the dose limit for a nuclear energy worker, and in practice exposure can be kept much lower.

Adult patients will also benefit from the support of family even in the absence of a need for direct care. These patients have cancer, and these procedures are stressful times for them. To remove the opportunity for their family members to provide care and have contact with the patient, even in a medical facility, is to deprive patients of support which we would all expect during difficult times.

Daniel P. Levin, MD, FRCPC

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From: Diana Arnal [mailto:DARNAL@vgh.mb.ca]
Sent: Tuesday, November 26, 2013 12:41 PM
To: Info
Subject: comments on DIS-13-01

Thank you for the opportunity to provide comments to the proposed changes to the Radiation Protection Regulations. The hyperlink in the document was not working when tried so please accept this email as my contribution.

Sections 2 & 3:
The term "outside a facility" should not be included. In many cases a caregiver may be a family member or friend to the patient that voluntarily opts to provide care regardless of the location their loved one is, or the possible exposure to themselves, particularly in palliative situations.

There are many different configurations of households and as a result the number or variation of caregivers at any one time could change greatly depending on circumstance e.g. homecare. It would be unreasonable to assume that every person who may provide care to the patient could be accounted for and therefore documented. Would it not be simpler to provide a household with some basic radiation protection information that could be shared with anyone who may find themselves in the role of caregiver?

Section 7:
This change could result in a significant increase in the amount of paperwork for an RSO and cost to a facility for notification to non NEW's of their status. At our facility, workers who are not considered NEW's such as housekeeping, security, and cardiology staff, already have to complete a self learning Radiation Safety package and document that they have read the information. I believe it would be less administrative burden to just include a statement of notification in this package.

Section 11:
There are already regulations in place for iodine so I don't see the point in imposing regulations on facilities that use solely Tc or other non volatile products.

Section 14:
After prolonged use, hand dosimeter use was discontinued at our facility as it was established that the doses received by the workers weren't close to reaching limits. To have to reintroduce their use would create unnecessary cost and paperwork.

Section 24:
Is the National Dose Registry not already required to keep these records indefinitely? Why duplicate this requirement for individual facilities? It is unreasonable for a licensee to have to track multiple variables (age, retirement or termination date, death) in order to dispose of dosimetry records. Could a set amount of time be imposed instead so that licensees could retain these records and dispose of en masse?

Sincerely
Diana Arnal
Charge Technologist/RSO
Nuclear Medicine Department
Victoria General Hospital
Winnipeg, MB

1781 Medallion Court
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December 20, 2013

Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
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Ottawa, Ontario, Canada K1P 5S9

Attention: Aurèle Gervais, Media and Community Relations

CNSC Document, Proposals to Amend the Radiation Protection Regulations, Discussion Paper DIS-13-01, August 2013

Government of Canada, Radiation Protection Regulations, SOR/2000-203, Current to September 16, 2013

CNSC Document, Proposed Amendments to Regulations Made Under the Nuclear Safety and Control Act, Discussion Paper DIS-13-02, November 2013

Government of Canada, Nuclear Safety and Control Act, S.C. 1997, c. 9, Current to November 13, 2013

The CNSC requests for comments on Discussion Papers DIS-13-01 (August 9, 2013)[1] and DIS-13-02 (November 21, 2013)[2] provide an opportunity to challenge the basis for our current radiation protection regulations in light of new revelations: the recent publication in the Archive of Toxicology of an article and two letters.

The article by renowned toxicologist Edward Calabrese (2013a) provides much evidence that, in 1956, the US National Academy of Sciences (NAS) changed the basis for radiation protection from a "tolerance dose" concept employed in the 1934 ICRP standard for radiation protection of radiologists (ICRP 1934) to the linear dose response model for cancer risk assessment without scientific justification. The NAS letter to the editor (Ciceroni and Crowley 2013) states that the Calabrese article is improper and not substantiated. The response by the author (Calabrese 2013b) criticizes the NAS letter and points out its failure to address the extensive evidence that appears in the article.

The linking of low radiation to a risk of cancer in the 1950s was based on the idea that radiation produces genetic damage and that some of these mutated cells *progress* into cancer cells. For more than fifty years, this concept has created enormous fear, uncertainty and doubt about the safety of exposures to small doses of radiation and chemicals, even though positive health effects

[1] http://www.nuclearsafety.gc.ca/eng/acts-and-regulations/consultation/history/dis-13-02.cfm
[2] http://www.nuclearsafety.gc.ca/eng/acts-and-regulations/consultation/history/dis-13-01.cfm

had been identified by medical scientists and practitioners soon after x-rays and radioactivity were discovered.

For more than twenty years, scientists have known that the spontaneous rate of DNA damage far exceeds the DNA damage rate induced by background ionizing radiation (Billen 1990). Recent evidence indicates that the endogenous rate of single-strand breaks (SSBs) is more than a million times the rate induced by average background radiation. The natural rate of double-strand breaks (DSBs), which is the concern regarding cancer risk, is a thousand times greater than the rate of DSBs by background radiation (Feinendegen et al. 2013). Therefore, low radiation levels are not a significant cause of DNA damage and cancer.

How then does ionizing radiation produce health effects? Feinendegen et al. (2013) point out that all living organisms possess very powerful adaptive protection systems that repair or remove cell, tissue and organ damage, and restore organism health. Radiation is one of the stressors that modulate the protection systems; high radiation impairs protection, while low radiation up-regulates many protection systems (> 200 genes) that act to produce very important positive health effects, including a *lower* incidence of cancer. This is the mechanism for the significant net beneficial effects of low doses even below ~ 200 mSv or 20 rem. At higher doses, additional protective mechanisms against cancer development operate.

The continued application of the invalid linear dose response model for cancer risk assessment raises fears about the safety of exposures to small doses of radiation (and chemicals). Linking low radiation to a "risk of health effects" and the emergency measures to mitigate exposure to low radiation levels has caused and continues to cause many premature deaths and enormous psychological suffering of large populations who received small radiation exposures from nearby damaged nuclear reactors. On-going use of this incorrect and unscientific methodology blocks nuclear energy projects and severely constrains vital applications of x-rays and radioisotopes in medicine.

I urge the CNSC to discard this politicized science, examine the scientific evidence and implement the recommendations in the new article by Cuttler (2013b) in the Canadian Nuclear Society Bulletin. These include changes to the Canadian documents that define the requirements for radiation protection and nuclear safety.

Sincerely

Jerry M. Cuttler, DSc, PEng

Attachment: Comments on DIS-13-01, DIS-13-02 and the Radiation Protection Regulations

Enclosures: Cuttler JM. Remedy for Radiation Fear—Discard the Politicized Science. Canadian Nuclear Society Bulletin 34(4): 23-28 (December 2013)

Archive of Toxicology article, NAS Letter to Editor and Calabrese Response

References:

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Attachment: Comments on DIS-13-01, DIS-13-02 and the Radiation Protection Regulations

Comments on the Radiation Protection Regulations, SOR/2000-203—September 16, 2013

General Comment

The current regulations are based on politicized science. They should be revised to be compatible with radiobiological evidence. The following information is very important and should be highlighted.

1. Spontaneous DNA damage, mainly from reactive oxygen species, occurs at very high rate; the rate of these endogenous double-strand breaks (DSBs) is more than 1000 times the rate of DSBs induced by a background radiation level of 1 mGy per year. Low radiation is an insignificant cause of DSBs.
2. Biological organisms have very powerful adaptive protection systems against damage to their cells, tissues and the entire organism, regardless of whether the harm is caused by natural (endogenous) processes or by external agents, including ionizing radiation.
3. Low radiation up-regulates adaptive protection systems resulting in a net health benefit: repair and removal of damage and promotion of healing. High radiation impairs protection systems.

The effect of radiation on an organism's protective systems is what determines whether a health benefit or risk occurs. The dose or dose-rate at which benefit transitions to harm is the threshold. Radiation protection regulations should permit exposures below the threshold for harm and restrict exposures in the harmful range, above the threshold.

Specific Comments:

1. Radiation Protection Program: In light of the evidence that low radiation up-regulates adaptive protection systems, which result in net health benefits , the concept and requirement of “as low as reasonably achievable” (ALARA) is not appropriate for protection of health and the environment. Implementation of ALARA could result in precautionary actions that cause more harm to health and the environment than the assumed benefit of avoiding hypothetical risks. Instead, the requirement should be “as high as reasonably safe” (AHARS), which would include an adequate margin of safety between a maximum permissible level and the known threshold for harmful biological effects.
2. While control of high radon concentration is appropriate in mining activities, radon levels in homes are generally far below the threshold for net harm and should not be regulated. The radon scare creates unwarranted fears, unnecessary precautionary measures and depressed home prices.
3. The scientific evidence on the effect of radiation on the fetus should be considered when setting the permissible radiation level for pregnant workers. Politicized science should be discarded.
4. The dose limits should be revised. They should be based on the known dose threshold for harm from acute radiation exposure and the known dose-rate threshold for chronic radiation exposure.

5. Use of the invalid linear no threshold (LNT) concept for cancer risk assessment, which is politicized science, should be discontinued. Stop linking ionizing radiation to a risk of cancer.
6. Based on biological evidence, the threshold for evacuations from low dose rate radiation could be raised to about 700 mGy (70 rad) per year, which is the threshold for harmful health effects.

Comments on the Proposals to Amend the Radiation Protection Regulations, DIS-13-01

General Comment

The general and specific comments on SOR/2000-203, provided above, are applicable to DIS-13-01. The current radiation protection regulations should be amended to simplify the requirements, in view of the evidence that low radiation up-regulates adaptive protection systems resulting in net health benefits. No regulations should be issued to protect organisms or the environment against (human-caused) ionizing radiation exposures that induce net beneficial health effects. Most worker exposures are well below the radiation dose or level at which net harmful effects occur; however, the current regulations are based on a desire to protect against hypothetical cancer risks that were calculated using the invalid LNT methodology and the principle of ALARA. Complying with overstringent regulations could create non-radiation safety hazards and unnecessarily high maintenance costs.

Comments on Proposed Amendments to Regulations Made Under the Nuclear Safety and Control Act, DIS-13-02

General Comment

The requirements for nuclear energy facilities should not be more stringent than the requirements for the conventional energy facilities that burn hydrocarbon fuels (such as methane and gasoline) or use hydraulic (hydroelectric dams), wind or solar energy. The number of accidents in the facilities related to the use hydrocarbon fuels and the corresponding number of casualties far exceed the number of accidents and casualties of nuclear facilities. Before amending the already overly restrictive regulations for nuclear facilities, actions should be taken to issue and/or amend the regulations for hydrocarbon energy facilities to achieve a comparable level of safety.

To address the lessons from the Fukushima experience, a very important requirement is the communication of accurate information to everyone, as soon as possible, about the extremely low or non-existant “risk of health effects" to the surrounding population of a hypothetical release of radioactive material from a damaged nuclear plant.

Other recommendations:

- Organize scientific and public meetings to discuss the health benefits and risks of radiation.
- Regulatory bodies and health organizations should examine the scientific evidence.

- Radiation protection regulations should be changed. They should be based on science instead of politicized science. Stop linking ionizing radiation to a risk of cancer.
- The basis for radiation protection should be restored to the *tolerance dose* (threshold) concept, in light of more than a century of medical evidence.
- Calculation of cancer risk using unscientific concepts, such as the LNT model, should be stopped.
- Regulation of harmless radiation sources, such as radon in homes, should be stopped.

Remedy for Radiation Fear – Discard the Politicized Science

by JERRY M. CUTTLER[1]

[Ed. Note: The following reviewed paper was submitted to the Bulletin.]

Abstract

While seeking a remedy for the ongoing crisis of radiation fear in Japan and everywhere else, the author reread a recent article on radiation hormesis. It describes the political motivation for creating this fear and mentions the evidence, in the first UNSCEAR report, of a factor of 3 reduction in leukemia incidence of the Hiroshima a-bomb survivors in the low dose zone. Producing a graph of the tabulated data reveals that they fit a hormetic J-curve, not a straight line as reported. UNSCEAR data on the lifespan reduction of mice and Guinea pigs exposed continuously to radium gamma rays indicate a threshold at about 2 gray per year. This information contradicts the conceptual basis for radiation protection and risk determination that was established in 1956-58. In this paper, beneficial effects and thresholds for harmful effects are discussed, and the biological mechanism is explained. The key point is the discovery that the rate of spontaneous DNA damage (double-strand breaks) is more than 1000 times the rate caused by average background radiation. It is the effect of radiation on an organism's very powerful adaptive protection systems that determines the dose-response characteristic. Low radiation up-regulates adaptive protection systems, while high radiation impairs these systems. The remedy for radiation fear is to expose and discard the politicized science.

Introduction

Almost three years have passed since a major earthquake and devastating tsunami damaged the Fukushima-Daiichi nuclear power plant. An evacuation order forced 70,000 people to leave the area, while an additional 90,000 left voluntarily and subsequently returned. Many of those who left under the forced order have not gone back to their homes as removal of radioactivity continues. Approximately 1,600 people died, mainly due to psychological stress, in the evacuation process (Mainichi 2013)–about the same number of deaths in the Fukushima Prefecture from the earthquake and tsunami combined (Japan National Police Agency 2013). The precautions taken to avoid hypothetical health risks have proved to be much more harmful than the asserted risks.

The tragedy is that the radiation dose-response characteristic for leukemia in humans had been determined in 1958, but it was disregarded because of the policy decision to adopt the linear no-threshold (LNT) dose-response model. The threshold model had been the "gold" standard for medicine and physiology since the 1930s; however, in 1956, the US National Academy of Sciences adopted the LNT model for evaluating genomic risks due to ionizing radiation. The Genetics Panel members believed there was no safe exposure for reproductive cells. They thought that the mutation risk increased with even a single ionization. In 1958, the National Committee for Radiation Protection and Measurement generalized the LNT concept to somatic cells and cancer risk assessment. Soon after, the other national and international organizations adopted this model for radiation-induced genetic and cancer risks (Calabrese 2013a, 2013b).

Radiation Hormesis - A remedy for Fear

The enormous social fear and media frenzy surrounding the release of radioactivity from the damaged Fukushima NPP led the author to study again the facts in a remarkable paper by Jaworowski (2010) on radiation hormesis. He described the exaggerated fear of irradiating healthy tissues that arose during the Cold War period with its massive production and incessant testing of nuclear weapons. Radioactive materials from the atmospheric tests spread over the whole planet. People were quite rightly scared of the terrifying prospect of a global nuclear war and large doses of radiation from fallout. However, it was the leading physicists responsible for inventing nuclear weapons who instilled a fear of small doses in the general population. In their highly ethical endeavour to stop preparations for atomic war, they were soon joined by many scientists from other fields. Eventually, this developed politically into opposition against atomic power stations and all things nuclear.

Although the arguments of physicists and their followers were false, they were effective; atmospheric tests were stopped in 1963. However, this was achieved at a price–a terrifying specter had emerged of small, near zero radiation doses endangering all future generations. This became a long-lived and worldwide

1. Cuttler & Associates Inc, Mississauga, Ontario, Canada

UNSCEAR 1958. Table VII. Leukemia incidence for 1950–57 after exposure at Hiroshima[a]

Zone	Distance from hypocentre (metres)	Dose (rem)	Persons exposed	L (Cases of leukemia)	$\sqrt{L}$	N[b] (total cases per 10^4)
A	under 1,000	1,300	1,241	15	3.9	12,087 ± 3,143
B	1,000–1,499	500	8,810	33	5.7	3,746 ± 647
C	1,500–1,999	50[c]	20,113	8	2.8	398 ± 139
D	2,000–2,999	2	32,692	3	1.7	92 ± 52
E	over 3,000	0	32,963	9	3.0	273 ± 91

[a] Based on data in reference 13 (Wald N. Science 127:699-700. 1958). Prior to 1950 the number of cases may be understated rather seriously.

[b] The standard error is taken as: N times ($\sqrt{L}/L$).

[c] It has been noted (reference 15, 16) that almost all cases of leukemia in this zone occurred in patients who had severe radiation complaints, indicating that their doses were greater than 50 rem.

societal affliction nourished by the LNT assumption, according to which any dose, even that close to zero, would contribute to the disastrous effect. Radiation hormesis (Luckey 1991) is an excellent remedy for this affliction, and it is perhaps for this reason that it has been ignored and discredited over the past half century. What happened more than 50 years ago still influences the current thinking of both the decision makers and those who elect them.

The linearity assumption was not confirmed by early or later epidemiological studies of Hiroshima and Nagasaki survivors. No hereditary disorders were found in the children of highly irradiated parents. The United Nations Committee on the Effects of Atomic Radiation (UNSCEAR) was concerned mainly with the effects of nuclear tests, fulfilling a political task to stop weapons testing. The committee had mixed opinions regarding the LNT model, and its first report, UNSCEAR 1958, contains conflicting statements. Jaworowski states: "hormesis is clearly evident . . . in a table showing leukemia incidence in the Hiroshima population, which was lower by 66.3% in survivors exposed to 20 mSv, compared to the unexposed group (p.165). This evidence of radiation hormesis was not commented upon. Since then, the standard policy line of UNSCEAR and of international and national regulatory bodies over many decades has been to ignore any evidence of radiation hormesis and to promote LNT philosophy."

The very important data in UNSCEAR 1958, Table VII were not presented in graphical form. Figure 1, given here, shows these data together with the LNT model from 1300 to 0 rem[2]. A line through 100 rem was added to take into account Footnote c, which states that the doses in Zone C "were greater than 50 rem."

These Hiroshima leukemia data strongly contradict the LNT model, which predicts an increased degree of risk as the radiation dose increases. The data clearly indicate a reduction in incidence, by a factor of 3, in the dose range from about 0.1 to 10 rem (1 to 100 mSv). The threshold for increased risk is about 40 rem (0.4 Sv). The leukemia data fit a hormetic J-curve; they do not fit a straight line.

UNSCEAR 1958, page 165 in paragraph 31, states: "In zones A (1300 rem), B (500 rem), and C (50 rem), the values of P_L were calculated[3] to be . . . This finding was taken to support the suggestion that the extra leukemia incidence is directly proportional to radiation dose, and conversely to argue against the existence of a threshold for leukemia induction."

The discussion in paragraph 33 states "that a threshold for leukemia induction might occur. In fact, according to table VII a dose of 2 rem is associated with a decreased leukemia rate." But this observation was rejected because "the estimates of dose ... are much too uncertain ..." UNSCEAR should not have marginalized, because of dose uncertainty, the observation of this strong reduction in leukemia incidence for the 32,692 survivors in Zone D, which was far below the leukemia incidence of the 32,963 survivors in Zone E (the controls). This data disproved the LNT dose-response model, and UNSCEAR should have rejected the LNT model in its report.

Fliedner et al (2012) pointed out that bone marrow stem cells, which produce the blood cell components, are very sensitive to radiation, yet they are remarkably resistant to chronic low-dose exposure regarding function and maintenance of blood supply. Moreover, no increased cancer deaths occurred at doses below 700 mGy per year despite the fact that the latency time for leukemia is much shorter than for other radiation-induced cancers. This clear evidence of radiation hormesis – an absence of cancer risk at low dose radiation – adds to many other data of this kind and should cause UNSCEAR, the NAS and all radiation protec-

2 The different radiation units are discussed in Appendix 1.

3 P_L is the extra probability of leukemia occurring in an exposed person per rem and per year elapsed after exposure.

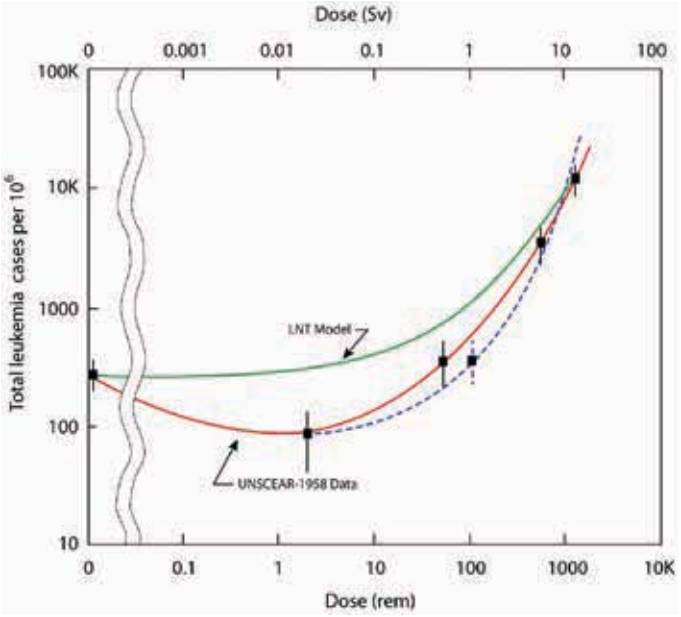

Figure 1. Leukemia incidence in the Hiroshima survivors for 1950-57.

tion organizations to revoke the generalized link they created in 1958 between low radiation and a risk of cancer; this link is the basis for the fear we see today.

Regarding the present concern about radiation-induced "health effects" on the residents around the Fukushima NPP, UNSCEAR states that that none were observed (UNSCEAR 2012, Chapter IIB, Section 9(a)) and discusses in Chapter III, Section 1 the difficulties in attributing health effects to radiation exposure and inferring risks. Section 2 points out that failure to properly address uncertainties can cause anxiety and undermine confidence among the public, decision-makers and professionals. If it wished, UNSCEAR could have attributed beneficial health effects to the low radiation, based on the extensive evidence in Annex B of its UNSCEAR 1994 report. This report contains summaries of 192 studies on *adaptive responses.* There have also been hundreds of additional scientific studies published during the subsequent 20 years. The World Health Organization's health risk assessment report (WHO 2013) contains estimates of lifetime risks of cancer; however, it uses the invalid LNT methodology.

Beneficial Effects

Positive health effects were identified by medical scientists and practitioners soon after x-rays and radioactivity were discovered in 1895-96. High, short-term exposures were harmful, but low acute doses or low dose-rate long-term exposures were beneficial. Often this was found inadvertently, while diagnosing bone fractures or other medical conditions. Recent review papers describe accepted medical applications, such as, accelerated healing of wounds and infections, cancer cures, and treatments of inflammations and arthritis that occurred before the introduction of the cancer scare in the late 1950s (Cuttler 2013). A new review discusses the historical use of low radiation to cure pneumonia (Calabrese 2013c), a very common occurrence in hospitals.

Beneficial effects have been known and studied for well over a century. The mechanism is explained in a medical textbook, in a chapter by Feinendegen et al. (2012). The key point is the discovery more than 25 years ago that spontaneous (endogenous) DNA damage, by the attack of reactive oxygen species (ROS), occurs at a relatively very high rate compared to the damage rate caused by natural background radiation. The natural rate of single-strand breaks from ROS attacks per average cell is many millions of times greater than the rate induced by ~ 1 mGy per year. Single-strand breaks are readily repaired, but double-strand breaks (DSBs) are relevant to induction of cancer and other genetic changes. Non-irradiated cells contain from about 0.1 to numerous DSBs at steady state. This agrees with the calculated probability of 0.1 for a DSB to occur per average cell in the human body per day from endogenous, mainly ROS sources (Pollycove and Feinendegen 2003). The probability of a radiogenic DSB to occur per day in background radiation is on average only about 1 in 10,000 cells. So the ratio of spontaneous to radiogenetic DSBs produced per day is about 1,000; i.e., the natural damage rate is a thousand times greater than the damage rate due to background radiation.

The critical factor is the effect of radiation on an organism's very powerful biological defences and protection systems, which involve the actions of more than 150 genes. They act on all the damage that is occurring (and its consequences) due to both internal causes and the effects of external agents. A low radiation dose or low level radiation causes cell damage, but it up-regulates adaptive protection systems in cells, tissues, animals and humans that produce beneficial effects far exceeding the harm caused by the radiation (Feinendegen et al. 2012). The net beneficial effects are very significant in restoring or improving health. The detailed behaviours of the defences are very complex, but the evidence is extremely clear. They range from prevention/cure of cancers to the very important medical applications of enhanced adaptive protections in the responses to stresses and enhanced healing of wounds, curing of infections, and reduction of inflammation, as mentioned earlier. In contrast, high level irradiation impairs these systems.

Thresholds for Harmful Effects

The evidence of net beneficial effects requires the determination of the threshold for harmful effects. This was known through more than thirty years of

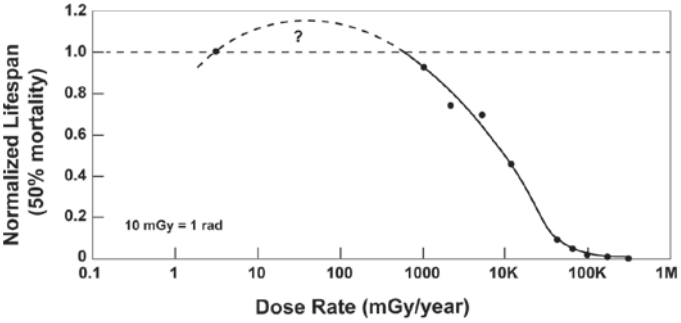

Figure 2. Lifespan versus radiation level (Cuttler 2013)

human experience when the first radiation protection *tolerance dose*, 0.2 roentgen per day or ~ 700 mGy per year, was established for radiologists in the early 1930s. Figure 2 is the result of a recent assessment of lifespan data for dogs exposed to cobalt-60 gamma radiation (Cuttler 2013). The threshold for net harm is also ~ 700 mGy per year. Similar data are found in UNSCEAR 1958, Annex G, page 162. The threshold for lifespan reduction of mice and Guinea pigs exposed to radium gamma rays is 4 roentgen per week or ~ 2000 mGy per year. Their mean survival time is 7% longer than the controls at a dose rate of 0.5 roentgen per week, which is about 240 mGy per year.

The "accepted" threshold for recognizing harmful late effects after a short-term exposure, according to a large set of experimental and epidemiological data, is an absorbed dose of about 100 mGy. However, the UNSCEAR data for leukemia incidence among the Hiroshima survivors, shown in Figure 1, suggests a threshold of about 400 mGy for leukemia.

Invalid basis for the LNT model

Calabrese reviewed the evolution of radiation protection from the tolerance dose (threshold) concept to the LNT concept. It began when early geneticists discovered that large numbers of mutations could be induced in germ cells of fruit flies by ionizing radiation. This would enable eugenicists to modify organisms for utilitarian purposes (Muller 1927). A high dose, at a high rate, produced a mutation rate that was 150 times greater than the spontaneous rate. This and other high-dose studies indicated that the mutation rate was proportional to the dose. A radiation target theory was developed by physicists to model the process of radiation-induced mutation, with mathematical calculations related to quantum mechanics (Calabrese 2013a). They established a conceptual framework for gene structure, target theory for the induction of mutations by ionizing radiation, the single-hit mechanism hypothesis to account for the shape of the LNT dose response and the application of this dose-response

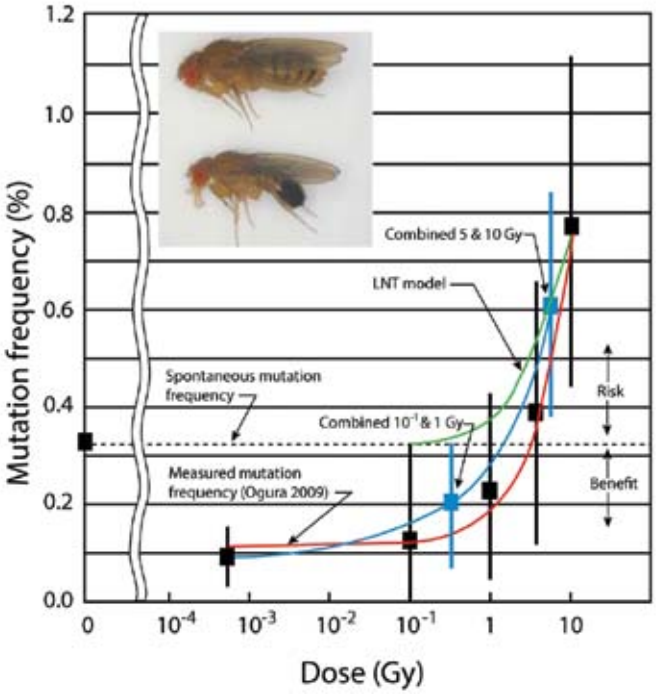

Figure 3. Fruit fly mutation frequency versus radiation dose (Cuttler 2013). A binomial distribution is assumed for the occurrence of the mutations. Each error bar is two standard deviations from the mean frequency. The data points at 0.3 Gy (0.19%) and at 7 Gy (0.61%) are obtained by "pooling" the Ogura et al (2009) data at 10^{-1} and 1 Gy, and at 5 and 10 Gy, respectively. Note that the mean mutation frequency is below the spontaneous level (0.32%) when the dose is below 1 Gy.

model for what was to become modern cancer risk assessment. However, bio-organisms do not behave according to this model. The Caspari and Stern (1948) study that irradiated 50,000 fruit flies to a dose of ~ 50 roentgen at a low rate, revealed a mutation rate that was the same as the 50,000 controls. This study was ignored. Recent studies on fruit flies at very low dose rate indicate a mutation frequency far below the spontaneous rate – genetic benefit instead of risk – below an absorbed dose of about 1 Gray, Figure 3 (Cuttler 2013). This evidence clearly falsifies the LNT model.

Discussion

Many researchers use the LNT model to predict the lifetime risk of cancer from a small dose of radiation. They calculate the expected cancer incidence from a very low dose by connecting a straight line between the zero-dose, zero-incidence point and the high-dose cancer incidence data of the A-bomb survivors. This procedure can only yield a risk of cancer. Most epidemiological studies are designed to measure radiation-induced cancer incidence, so they do not report any

observations of beneficial effects. The data are fitted to the LNT model, presuming it is valid. Scott et al. (2008) list seven approaches that make it difficult to recognize bio-positive effects and thresholds, concluding that there is no credible evidence to support the contention that CT scans will cause future cancers. Scott (2008) points out three epidemiological "tricks" that are commonly employed to obtain a LNT dose-response curve. Relative risk and odds ratio values are often shown instead of cancer incidence data. In view of the extensive evidence of beneficial health effects and reduced health risks from low doses, misrepresentations of data and deceptions are exploited to fit the LNT model.

Conclusions and Recommendations

Social concern about the safety of all nuclear technologies is caused by the ideological linkage of any (human-made) radiation exposure to a risk of health effects, namely cancer and genetic harm, using the LNT model to calculate health risks. This link, created in the 1950s to stop the development and production of nuclear weapons, is maintained in spite of the extensive biological evidence of beneficial effects from low dose or low dose rate exposures. Ignoring biological facts and refusing to revert to the threshold model concept for radiation protection has created an enormous barrier against social acceptance of nuclear energy and the use of radiation-based medical diagnostics. The remedy is to discard this politicized science.

This enormous radiation scare surrounding the Fukushima-Daiichi is a very serious crisis. It should be looked upon as an opportunity to make changes in attitudes and concepts that would not otherwise be possible.

The following three fundamental messages should be communicated to everyone in order to explain the real effect of radiation on health and to eliminate the irrational fear.

1 Spontaneous DNA damage, mainly from reactive oxygen species, occurs at very high rate; the rate of double strand breaks (DSBs) is more than 1000 times the rate of DSBs induced by a background radiation level of 1 mGy per year.

2 Biological organisms have very powerful adaptive protection systems against harm to their cells, tissues and the entire organism, regardless of whether the harm is caused by natural internal processes or by external agents.

3 Low radiation generally up-regulates adaptive protection systems resulting in a net health benefit to the organism in terms of response to stress. High radiation generally impairs protection systems and results in more net harm than benefit. The effect of radiation on the protective systems is what determines the health benefit or risk.

Other recommendations are:

- Scientific societies should organize meetings to discuss the health benefits and risks of radiation.
- Regulatory bodies and health organizations should examine the scientific evidence.
- Radiation protection regulations should be changed. They should be based on science instead of politicized science.
- The basis for radiation protection should be restored to the *tolerance dose* (threshold) concept, in light of more than a century of medical evidence.
- Calculation of cancer risk using unscientific concepts, such as the LNT model, should be stopped.
- Regulation of harmless radiation sources, such as radon in homes, should be stopped.
- Based on biological evidence, the threshold for evacuations from low dose rate radiation should be raised from 20 to no more than 700 mGy per year, i.e., from 2 to ≤ 70 rad per year.

Appendix 1

Radiation dose is the amount of energy deposited in an irradiated object. Many different units have been used during more than 115 years of work with ionizing radiation (Henriksen et al. 2013, Chapter 5).

- Radiation dose is measured in units of gray (Gy), the System International (SI) unit. When one kilogram absorbs a joule of radiation energy, its radiation dose is one gray. So 1 Gy = 1 joule/kg, and 1 milligray (mGy) is a thousandth of a gray
- The roentgen unit R is a measure of radiation exposure, i.e., the ionization of air molecules. If soft tissue is exposed to gamma radiation of 1 R, the radiation dose will be approximately 9.3 mGy.
- The radiation absorbed dose (rad) was developed in 1953. One rad is 100 erg per gram or 10^{-2} joule/kg. Therefore, 1 gray = 100 rad.
- When biological organisms are irradiated with different types of radiation (x-rays, gamma rays, sub-atomic particles) the biological end result for the same dose given in Gy may vary. A relative biological effectiveness (RBE) factor is calculated for humans, and the dose is multiplied by the RBE weight factor to obtain "the effective dose." The unit is called rem in the old system and sievert (Sv) in the SI system. For x-rays and gamma rays, the RBE = 1. For these types of radiation, rem = rad and sievert = gray. One Sv = 100 rem.

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REVIEW ARTICLE

How the US National Academy of Sciences misled the world community on cancer risk assessment: new findings challenge historical foundations of the linear dose response

Edward J. Calabrese

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Abstract This paper extends several recent publications indicating that Hermann J. Muller: (1) Made deceptive statements during his Noble Prize Lecture on December 12, 1946, that were intended to promote the acceptance of the linear dose-response model for risk assessment for ionizing radiation and (2) that such actions of Muller were masked by a series of decisions by Muller's long-time colleague and esteemed radiation geneticist Curt Stern, affecting key publications in the mutation literature. Such actions further enhanced acceptance of the linearity dose-response model while preventing Muller's deceptions from being discovered. This paper provides documentation that Muller reinforced such practices within the scientific literature in the early 1950s, by supporting scientifically questionable actions of Stern. Detailed documentation is provided that demonstrates how these actions affected national and international risk assessment policy for ionizing radiation and chemical carcinogens via the recommendations of the National Academy of Sciences Biological Effects of Atomic Radiation committee in 1956, to adopt the linear dose-response model.

Keywords Mutation · Linearity · Dose response · Risk assessment · History of science · Muller

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Introduction

It was recently discovered that the 1946 Nobel Prize Lecture for Biology and Medicine by Laureate Hermann J. Muller misled the audience on the nature of the dose response in the low-dose zone concerning the effects of ionizing radiation on germ-cell mutagenicity to advance an ideologically motivated risk assessment policy (Calabrese 2011a, b, 2012). Evidence to support this conclusion is found in Muller's own words from letters he sent to Professor Curt Stern of the University of Rochester, an expert in radiation genetics. Stern sent Muller a manuscript by Ernst Caspari and himself on November 6, 1946, for review as Muller was a paid consultant to the project (Calabrese 2011c). This manuscript demonstrated support for a threshold dose response, while challenging the linear dose-response single-hit mutagenicity mechanism model, based on an extensive study of ionizing radiation on mutation in the germ cells of male fruit flies. On November 12, 1946, Muller acknowledged receipt, noting that the findings strongly challenged the linearity dose-response concept and, given their importance, needed to be replicated as soon as possible (Calabrese 2011c). This long-term study used the lowest ionizing radiation dose rate yet reported. Despite this new information, Muller would go on to deliver his Nobel Prize Lecture some 5 weeks later (December 12, 1946), proclaiming that one could no longer consider the possibility of a threshold dose response for germ-cell mutagenicity. The only option, he argued, was to switch to a linearity dose-response model for risk assessment (Muller 1946a).

Muller, of course, made these public claims while knowing that the most extensive and relevant testing supported a threshold interpretation. A letter from Muller to Stern 5 weeks after the Nobel Prize Lecture (January 14, 1947)

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confirmed his support for study replication, that he had no technical criticisms of the Caspari study, and supported publication especially in view of the caveats worked into the discussion, hopefully preventing acceptance of a threshold interpretation (Calabrese 2012; Lilly Library 1947a, January 14 letter). In effect, Muller told the Nobel Prize Lecture audience one story while in private correspondence he revealed a profoundly different view. According to his former student, friend, and colleague, Crow (1995), it was well known that Muller would try to win arguments by exaggeration and overstatement. Crow found this behavior exasperating as Muller would often end up hurting his case by unnecessarily misrepresenting facts and circumstances, incorrectly thinking it would help him win his argument. This same behavioral trait was evident at the Nobel Prize Lecture.

Before his Nobel Prize Lecture, Muller sought to raise concern over the public health implications of ionizing radiation and to change the risk assessment process for ionizing radiation from the use of a threshold dose-response model to the far more conservative linear dose response. This goal was essentially shared by the entire radiation geneticist community. Following his Lecture, Muller would now have two goals: Protecting his reputation by ensuring that his misleading comments would not be discovered while still aggressively pushing acceptance of the linearity agenda. Both goals were entangled; being such an important scientist and leader any fall in Muller's status would have a devastating impact on the acceptance of the linearity dose response, especially if it involved an ideological misrepresentation about the linearity concept. Muller achieved both goals due to decisions of Stern that discredited the findings of his colleague and co-author Ernst Caspari, thus saving Muller from criticisms about his Nobel Prize Lecture while supporting the questionable findings of Delta Uphoff, another co-author. Muller's misleading comments and the Stern's apparent data obfuscations would not be revealed for more than 60 years while the linearity acceptance goal by regulatory agencies worldwide was attained. The present paper extends the recent reports of Calabrese (2011a, b, 2012) with newly discovered findings that demonstrate a carefully focused and timed set of inexplicable scientific judgments by Muller concerning the nature of the dose response. These actions reinforced his Nobel Prize Lecture comments and the actions of Stern that enhanced the goal of achieving a switch from threshold to linearity. This paper also demonstrates the profound impact of the Stern/Muller actions on the radiation genetics community based on the scientific publication record and dose–response recommendations/conclusions supporting a linearity dose–response risk assessment model by the highly influential NAS BEAR I Committee, Genetics Panel.

Part 1—Stern's plan to promote linearity

Curt Stern was a long-time supporter of the idea that ionizing radiation affected germ-cell mutation in a linear dose-response manner. He expected that this would be observed in studies he was directing under the aegis of the Manhattan Project using fruit flies. While a linearity dose-response was reported in acute studies with X-rays (Spencer and Stern 1948), the most significant test would take place with the research of Ernst Caspari when gamma radiation would be administered up to a 13,200-fold lower rate than in the Spencer research. In a troubling development, Caspari reported to Stern that his findings did not support a linear interpretation but rather a threshold dose response. Based on letter correspondence between Stern and Caspari, Stern initially refused to accept this interpretation, arguing that the mutation threshold response was most likely due to unusually high control group values (i.e., spontaneous mutations in sperm stored in the spermatheca of the female for 3 weeks) which masked a radiation-induced treatment effect (Calabrese 2011b). Caspari then researched this issue by exploring the literature and obtaining substantial unpublished data on this specific issue from Muller based on research during his appointment at Amherst College (1940–1945). Caspari argued that his control group mutation data were not aberrant but consistent with the literature and Muller's data for aged sperm whether stored in the spermatheca of the female or in the male. As a result of the Caspari analysis, Stern withdrew his objection and accepted the conclusion that the control group spontaneous mutation values were within the normal range. Since Stern could not dismiss the findings of Caspari due to the controls, he then opted for an alternative but bizarre strategy to marginalize the threshold dose-response conclusion. Stern directed the manuscript discussion to explain why these data should not be accepted and utilized until it was determined why Caspari's findings differed from those of Spencer and Stern's acute study which they claimed supported linearity. It was this manuscript of Caspari that was sent to Muller for review just prior to his Noble Prize Lecture.

It is odd that investigators reporting on striking new findings, using the most advanced methods and the lowest dose rate yet studied, would demand the reader not take the data seriously. Stern placed no such restriction upon the Spencer paper, a study with considerable methodological limitations [e.g., inadequate control groups, inappropriate data combining for statistical analysis, lack of adequate X-ray instrumentation calibration, poor temperature control, and dose rates differing by as much as 10-fold (10 and 100 r/min) between treatments, thereby creating two experimental variables within one experiment] (Calabrese 2011b). Furthermore, there were at least two dozen significant methodological differences between the two studies

making them not directly comparable. Stern published the manuscript (Caspari and Stern 1948) with its misdirected discussion, without apparent independent, peer review in the journal for which he was the editor, that is, *Genetics*.

Comment

Based on this temporal sequence, it would appear that the principal driving force to challenge the Caspari findings that supported a threshold interpretation was his advisor and co-author, Curt Stern. It was Muller who indicated that the findings of Caspari needed to be replicated since they were contrary to a linear single-hit dose-response interpretation. Of particular note, however, was that the only changes made to the Caspari manuscript following the review of Muller was to add the name of Muller to the acknowledgments section and to remove the statement from the conclusion that the findings supported a tolerance or threshold interpretation (Calabrese 2011b).

Part 2—the replication studies

Since Ernst Caspari and Warren Spencer were no longer available to continue experimentation, Stern engaged the services of a Master's student, Delta Uphoff, to assess why the Caspari study did not support a linear interpretation. The results of the initial experiment were deemed by Stern as not usable as her control group spontaneous mutation rate was strikingly low, being outside the expected range for aged sperm (~40 % lower than expected); no conclusions could be drawn from the study (Uphoff and Stern 1947). A similar very low control group spontaneous mutation rate response for aged sperm in her second experiment would also make such data uninterruptable. In her third and final experiment, Uphoff reported control values in the normal range for aged sperm but the radiation treatment response was itself aberrant, far exceeding predicted responses assuming low-dose linearity (Calabrese 2011b).

Stern: What to do next

Finding a way to support linearity was the prevailing theme. For example, when Caspari had shared his data with the Head of Genetics at the Brookhaven National Laboratory and future member of the BEAR I Committee/Genetics Panel, Milislav Demerec, he wrote to Caspari asking what can be done to save the single "hit" linearity dose-response paradigm (Calabrese 2011b; American Philosophical Society 1947f, September 25). The "hit theory" for ionizing radiation-induced mutation was first postulated by Timoféeff-Ressovsky et al. (1935), providing a theoretical mechanistic foundation for the LNT dose-response model. Given his goals and ideology, Stern had little choice. Another experiment was not going to be practical as Uphoff would leave for a position with the NIH. In the absence of new data, Stern decided upon a new strategy to "save" the single-hit linearity dose response. In order to achieve this goal, he would have to do two things: (1) Reverse his position on the Uphoff control group data, declare that they are normal, not aberrant, making the Uphoff experiments now interpretable and (2) challenge further the credibility and acceptance of the Caspari study (i.e., beyond the misdirected discussion of the Caspari/Stern paper). Stern took the bold action of asserting that the Uphoff control group data were part of the normal distribution. He offered no explanation or assessment of the literature to justify this conclusion. This would not be difficult as only very few people would have known about his earlier concerns with the Uphoff control group data, since the manuscript (Uphoff and Stern 1947) detailing such concerns was never submitted for publication but was placed in the Atomic Energy Commission (AEC) archives, initially as a classified manuscript. Thus, the written critique of the Uphoff control group data and letter communications on this topic were generally not known or available.

The Uphoff and Stern (1949) paper also raised a number of doubts about the Caspari paper such as whether its non-treatment effect/threshold finding was the result of "errors in sampling." Given standard professional protocol, the "errors in sampling" hypothesis was a surprising and unexpectedly harsh challenge to the work of Caspari, a University of Rochester team member, especially since this criticism had never been raised previously by Stern, Muller, or others in previous detailed evaluations. In fact, there was never any documentation to support this possibility. Further, Stern also raised the specter of the Caspari control being elevated by unnecessarily stating that his control group was higher than each of the controls of the three Uphoff experiments. Stern neglected to state that two of the Uphoff studies had aberrantly low control group values based on the published literature and Muller's data. This decision by Stern would now make the Uphoff experimental data "interpretable," whereas several months before he judged it as "uninterpretable." Also, the third Uphoff experimental control data were indistinguishable statistically from the Caspari control (0.2489 vs. 0.2352 %). Such actions helped to achieve the above-stated goals of enhancing the credibility of the Uphoff data while marginalizing the Caspari findings.

The Uphoff and Stern (1949) paper changed the way the Caspari data (Caspari and Stern 1948) were perceived and accepted by members of the scientific community. Below are quotes from several papers (Higgins 1951; Singleton 1954a, b) and a dissertation (Jolly 2004) that address very

clearly how the Uphoff and Stern (1949) paper marginalized the research of Caspari. Of particular significance is that the judgments drawn by each of these papers were factually and interpretationally incorrect.

Higgins (1951) stated that "Uphoff and Stern (1949)…concluded that low-level radiation does produce mutations in fruit-fly sperm and that the apparent inconsistencies of previous results were due to different experimental techniques and errors in sampling" (page 10, column 1).

Singleton (1954a) stated that "Caspari and Stern (1948) studying chronic gamma radiation found no increase over controls for doses of 2.5 r/day for 21 days. However, it was later documented by Uphoff and Stern (1949) that the controls used by Caspari and Stern had an abnormally high sex linked lethal frequency and that actually there was an effect of the chronic gamma radiation of 2.5 r/day." (page 599)

Jolly (2004) stated (1) that "Stern and Caspari initially detected no significant difference in the mutation rates on the controls and the irradiated flies, though later they corrected for experimental errors and got a statistically significant difference." (pages 78–79) (2) "The results of Stern's initial experiment failed to support the linear hypothesis for genetic injury. Assuming that something must have been wrong with the experiment, he eventually identified experimental errors, which, when corrected for, supported linearity." (pages 80–81).

Caspari's control group data were therefore once again challenged by Stern; the once aberrantly low controls of Uphoff were now seen as being in the normal range. With these changes, the dose response of the collective grouping of the Stern Drosophila experiments would appear linear. This is the conclusion of what Uphoff and Stern published in their one-page technical note in the 1949 *Science* article summarizing the Spencer and Stern (1948) and Caspari and Stern (1948) papers and the three Uphoff experiments. This 1949 paper, as noted above, did not include mention that the previous conclusions (Uphoff and Stern 1947) about the Caspari and the Uphoff control groups that had been reversed by Stern and the role of the Muller data assessment in the decision-making process. Since the Uphoff and Stern (1949) brief technical paper lacked any information on research methods and other relevant data, the authors promised a detailed follow-up publication to correct this critical limitation, a promise never fulfilled. Given the lack of information provided in the *Science* paper and the prestige of this journal, it raises a question about the circumstances surrounding its publication within this context. It should be noted that Hermann J. Muller's first graduate student (i.e., H. Bentley Glass) became an editor at *Science* in 1948, only months prior to the submission of the Uphoff and Stern manuscript. Glass also had a relationship with Stern with whom he had been awarded a National Research Council post-doctoral fellowship at the Kaiser Wilhelm Institute in Berlin (Erk 2009). Since Glass was an expert on *Drosophila* radiation genetics, it is likely that he oversaw the evaluation of the manuscript. One must also question to what extent Muller/Stern may have exploited their relationship with Glass to facilitate the publication of such a limited paper and used the journal to advance an ideological perspective.

Muller's post Nobel Prize dose–response comments about the Caspari and Stern (1948) study

Muller's statement

In his 1950 article entitled "Some present problems in the genetic effects of radiation" in the *Journal of Cellular and Comparative Physiology* Muller (1950a) provided an explicit characterization of the Caspari and Stern (1948) findings. Muller stated on page 10 "A recent paper by Spencer and Stern…….extends the principle (i.e., one-hit principle) down to total doses of 50 r and 25 r." In the next paragraph, he stated: "It is true, in a parallel paper….Caspari and Stern have reported results somewhat deviating from the above."

Comment

Muller trivialized the significant challenge of the Caspari study to the linearity dose-response paradigm. The key Muller phase concerning the Caspari data is "somewhat deviating". The Spencer and Stern (1948) study involved an acute exposure, that is, all doses of radiation were administered within a few minutes to a few hours. In contrast, the Caspari and Stern (1948) study provided the same total dose as in the Spencer and Stern study but spread over 21 days, at a dose rate up to 13,200-fold lower. The "somewhat deviating" results were such that at the lower dose rate of the Caspari and Stern study, the data supported a threshold interpretation, not the expected linear proportionality response. Muller was quite concerned with the Caspari study as it represented a potentially significant challenge to linearity, repeating this perspective in letters (Lilly Library 1947a, January 14; American Philosophical Society 1946, November 12) to Stern and emphasizing the need to replicate this study, despite the requirement for additional funding and the efforts of multiple scientists and staff for about 1 year. It is also important to note that Muller never mentioned any of the numerous methodological/analysis limitations/flaws of the Spencer and Stern (1948) in any of his publications.

Muller's statement

In footnote 1 on page 10 of the above-cited article, Muller (1950a) stated that "Uphoff and Stern have published a report of further work, with doses as low as 50 r, given an intensity as low as 0.0165 r per minute. The results obtained are entirely in conformity with the one-hit principle. A consideration of these results, together with the early work, leads to the conclusion that the deviation first referred to (the Caspari and Stern 1948 findings) was caused by a value for spontaneous mutation rate that happened to be unusually high."

Comments

Muller claims that the research of Delta Uphoff and Curt Stern is "entirely in conformity with the one-hit principle" (Timoféeff-Ressovsky et al. 1935). What Muller neglected to state was: (1) Uphoff's first experiment displayed an aberrantly low control group response based on Muller's own extensive data involving some 200,000 fruit flies (Muller 1946b). A letter from Curt Stern to Ernst Caspari (undated) (American Philosophical Society Undated, circa July-Aug 1947) addressed the control group issue. It states: "The radiation data continues to be puzzling. Delta's difference between control and exper[imental group] appears to be due mainly to a much lower control group value than yours. However, Muller informs me that his data give an aged control value close to yours. Thus, my first idea that your results could be "explained away" by assuming that your control value happened to be unusually high, seems unlikely. Rather does Delta's control appear too low. Well, we'll have to meet." Muller provided this information to Stern twice in letters dated February 3, 1947, and August 4, 1947 (Lilly Library 1947b, c). It should be noted that the occurrence of increased mutations in aged sperm in the control group as reported by Caspari was not a new concept to Stern. In fact, when Timoféeff-Ressovsky first presented such data in the late 1930s, Stern corresponded with Demerec specifically addressing these findings. These letter exchanges reveal not only Stern's knowledge of the findings, but also of his knowledge that the findings had been subsequently replicated (Lilly Library 1938a, b, c). The report of Rajewski and Timofeeff-Ressovsky (1939) on this topic would most likely have considerable scientific weight as Timoféeff-Ressovsky was on par with Muller for scientific reputation in the area of radiation genetics.

In the Atomic Energy Commission (AEC) manuscript by Uphoff and Stern (1947) concerning her replication of the Caspari study, the low response control group issue was explicitly addressed as follows in their "Discussion" section. "In his extensive studies on the effect of aging on the mutation rate in sperm, H.J. Muller (unpublished) has found a weekly increase of about 0.07 % for sex-linked lethals in various stocks kept at 25 °C. At 18 °C, the temperature used for aging in the laboratory, the weekly increases may be assumed to be slightly less, perhaps 0.05 %. Taking a value of 0.10 %, similar to that of Spencer and Stern's control rate, for sperm before aging, the expected control rate after aging should be approximately 0.25 %. This figure is much closer to the control rate observed by Caspari and Stern than to that found in the present work." In their acknowledgments of this manuscript, Uphoff and Stern stated that "we are very grateful to Dr. H. J. Muller for his permission to quote from his unpublished data." Thus, Muller would have known that his research was used to evaluate the reliability of the Caspari and Uphoff control groups. The control group response of Uphoff and Stern (1947) was sufficiently low such that they stated that the data were uninterpretable (i.e., "a final interpretation of these results cannot be offered."). Uphoff and Stern (1947) explicitly raised the possibility that the low control group values "may reflect a personal bias of the experimenter." The manuscript did not identify whether the bias concern statement was directed to Stern, Uphoff or both, or the type of bias. (2) Uphoff's second experiment also displayed a similarly aberrant low control group response, likewise affecting the possible utility of the data. (3) The third (and final) Uphoff experiment obtained control values in the normal range but an aberrantly high treatment response, even assuming a linearity dose response (see Calabrese 2011a for a detailed evaluation). "Appendix" section provides the temporal letter exchange between Stern and Muller on the key question of control group mutation frequency upon which the acceptance of the Caspari and Uphoff studies are based.

Muller (1950b) discredits the conclusion of Caspari and Stern (1948) by asserting that the control group values were unusually high. (1) Muller failed to state that the "high" control value of Caspari and Stern (1948) was first put forward as a criticism by Stern in the fall of 1946, when Caspari informed Stern that his findings supported a threshold, rather than a linearity interpretation. (2) He also did not report that Caspari successfully rebutted Stern by presenting data on control group responses from published studies in the literature and from unpublished data provided by Muller himself. Muller failed to state that he had published a summary of the mutation rate of sperm stored in the spermatheca for several weeks (Muller 1945). This is the information that he sent to Stern that supported the reliability of the Caspari control group data and marginalized the Uphoff study control group (see "Appendix" section). Later studies by Muller and his student Helen L. Byers at the University of Indiana also supported the Caspari control group mutation frequency (Byers 1954; Byers and Muller 1952). Nonetheless, Muller (1954b) would inexplicably continue his criticism of the Caspari and Stern (1948)

study, repeating the "unusually high control frequency" (page 476) conclusion as a basis to reject its challenge to linearity. The question may be raised as to why Muller would directly contradict himself on such a serious matter and never be exposed to criticism. While any answers to this question must be speculative, Sankaranarayanan and Wassom (2008) unequivocally state that Muller was an "unquestioned authority," suggesting that it would be quite difficult to challenge him or even consider doing so.

It should be noted that in early 1949, Muller became concerned that Robley Evans of MIT was publishing a paper in the journal *Science* on the mutagenic effects of ionizing radiation and the nature of the dose response in the low-dose zone. Muller had reviewed the manuscript prior to publication and was upset that Evans had given credibility to the Caspari and Stern (1948) paper. Muller wrote to Stern (Lilly Library 1949, February 5) requesting that Stern contact Evans and try to convince Evans to withdraw his support for the Caspari and Stern (1948) findings. There is no evidence that Stern did this based on correspondence records. However, it is possible that the subsequent attack of Muller (1950a, b) on the Caspari and Stern (1948) findings was stimulated by this Evans paper (1949) which would need to be "neutralized."

Muller (1954b) also further criticized the Caspari and Stern (1948) paper in a vague manner as being "more doubtful than the others on some other grounds" (page 476), which he never clarified. Such criticism may have referred to the fact that Uphoff and Stern (1947) introduced a modified method of counting sex-linked recessive lethals, one that was different than reported by Caspari and Stern (1948) and also different than Spencer and Stern (1948). Uphoff and Stern (1947) recounted (i.e., adjusted) the Caspari and Stern (1948) data with the new counting method in order for it to be as directly comparable to their study as possible. The results of those adjustments were deemed by Uphoff and Stern to be insignificant in their 1947 paper, resulting in control and treatment responses that were, in fact, even more similar than before the adjustment (i.e., without a treatment effect). The published paper of Caspari and Stern (1948) did not incorporate this adjustment (perhaps resulting in the veiled criticism of Muller 1954a, b), whereas the Uphoff and Stern (1947) manuscript presented the original and adjusted data; only these adjusted data were used for the Caspari and Stern (1948) data as summarized in the 1949 paper in *Science* by Uphoff and Stern. Regardless, the adjustment for differing lethality estimation techniques did not affect the study interpretation. In a letter on February 9, 1949, to Caspari in anticipation of the *Science* publication, Stern (American Philosophical Society 1949, February 9) stated that "It will be shown below (the *Science* manuscript) that the difference in defining a lethal is of no significance in the evaluation of the results."

In his 1950 papers, Muller never addressed any of these critical issues that might affect a decision on the nature of the dose response (Muller 1950a, b). He also failed to state that the Uphoff and Stern (1949) paper was only a one-page summary, has very low control group values, no presentation of research methods and that Uphoff and Stern (1949) promised to publish a detailed paper with all the missing methods and data but had not (and never did). By discrediting the Caspari and Stern (1948) paper and restoring the Uphoff data, Muller was able to protect his scientific reputation, his ethical standing and to give strong support to the linearity single-hit theory dose-response model.

In a second paper in 1950 entitled *Radiation Damage to the Genetic Material* in the *American Scientist*, Muller (1950b) used the findings of Stern and his colleagues to extend "the principle of proportionality of mutation frequency to dose down to doses of 50 r and 25 r and of less than 0.001 r per minute, with a time-intensity relation differing by over 400,000 times from that of our high intensity dose."

Comment

By using the now revitalized data of Uphoff, Muller made the claim of linearity over a 400,000-fold dose range. This was a major conclusion as it gave an assertion of linearity at low dose by a Noble Prize winner who had great authority within the field. Furthermore, Stern (1960) continued to affirm the findings of Uphoff and Stern (1949) in the second edition of his acclaimed genetics textbook, published in English, German, Japanese, Polish, Russian, and Spanish (American Philosophical Society 1973, November) (autobiographical statement), by stating that the dose rate had no impact on the mutation incidence in *Drosophila*, whether administered acutely or given "slowly and continuously, that is, 'chronically,' given over a long period." In order for Stern (1960) to have reached this conclusion, he had to diminish the findings of Caspari and Stern (1948) and accept those of Uphoff and Stern (1949). A further note is that the Muller (1950b) paper contradicted his 1950a paper on the dose rate: The two papers used a different lowest dose rate: 0.001 r/min (Muller 1950b) versus 0.00165 r/min (50 r/30240 min in 21 days) (Muller 1950a)—a 65-fold difference. Muller (1950b) rounded down the 0.00165 r/min rate to 0.001 r/min, increasing the extrapolation range from approximately 250,000- to 400,000-fold. Why Muller rounded the numbers down is not known, nor was it necessary. Secondly, if rounding was to occur it would normally have been rounded up to 0.002 r/min. This action of Muller reveals an effort to exaggerate the linear extrapolation range. Third, Muller (1950b) makes an error in his statement that the linearity was shown with a dose rate "less than 0.001 r per minute" when the actual value was 0.00165 r/min.

Table 1 Hermann J Muller and Curt Stern quotes on low-dose linearity

References	Quote
Muller (1948)	Page 462 "…the frequency of the mutations induced will be proportional to the total dose of radiation received over an unlimited period of time." "There is then absolutely no threshold dose, unlike what is true of many other biological effects of radiation, and even the most minute dose carries a definite chance of producing mutations—a chance exactly proportional to the size of that dose."
Muller (1952)	Page 317 "In making our calculations it is safe, as both the earlier (6–10) and the more recent (11–15) works have agreed, to accept the principle that the frequency of the gene mutations produced is simply (linearly) proportional to the amount of the total accumulated dose received, as expressed in r units. Moreover, as some of these same studies show, this relation holds within wide limits, regardless of how short and concentrated or dilute and protracted the exposure may have been, or whether it was given in one treatment or many." "There are good theoretical grounds for inferring that these principles hold true no matter how small the total dose, or the dose per unit time. Of course, such a sweeping conclusion necessarily involves an extrapolation from actual data. Not until recently has it been possible, because of technical difficulties, to test the mutagenic effectiveness of doses lower than about 13 r per day, totaling 400 r (11–13), and even the most recent work goes down no lower than about 2.5 r per day, totaling 25 r (14, 15)."
Stern (1950)	Page 433 "The proportionality rule has been proven to hold over a wide range. Figure 155 shows that, for Drosophila, the relation is essentially linear over the range from 25 r to several thousand r. It has further been shown that the frequency of induced mutations is independent of the time over which the radiation is applied."
Stern (1960)	Page 491 "It has been established for a variety of experimental organisms that the number of mutations induced by radiation is proportional to the dose. This proportionality has been proven to hold over a wide range of dosages. Figure 202 shows that, for Drosophila, the relation is essentially linear over the range 25–12,500 r (insects, unlike mammals, can survive after exposure to many thousands of roentgens). It would be desirable to extend the data toward dosages lower than 25 r, for instance, to 10 r, 5 r, and still lower. Since, however, the expected differences are small between the rate of mutations in not-artificially irradiated control organisms and that in organisms exposed to low artificial doses, it is difficult to obtain significant results even with large experiments."

Impact of the Stern and Muller deceptions

Effect on the radiation genetics literature/community

In the aftermath of his Nobel Prize Lecture, Muller published his Lecture in the *Journal of Heredity* in 1947 (Muller 1947), assuring its broader distribution. Within 4 months of the Noble Prize Lecture, he gave a lecture to the New York Academy of Medicine during which he affirmed his Nobel Prize Lecture message, stating that there was "absolutely no threshold dose" for mutations and that induced mutational response was proportional to the total dose (Table 1). This presentation was published in the Academy's journal (Muller 1948) soon thereafter. Stern (1950) also cited Spencer and Stern (1948) and Uphoff and Stern (1949) in his acclaimed textbook, emphasizing that the dose response for mutations was linear (Table 1).

These follow-up activities by Stern and Muller had an impact on other leading radiation geneticists influencing them to adopt the linearity dose-response interpretation. Table 2 provides a series of quotations from subsequent publications of leading contemporary radiation geneticists. The quotes are numerous, varied, and a fair representation of what each author stated. These comments strongly support the conclusion that there was a generally consistent view that the nature of the dose response in the low-dose zone for mutations was linear. Most of these quotes directly cite the research of Stern and his colleagues as providing the key evidence supporting linearity, especially that of Spencer and Stern (1948) and Uphoff and Stern (1949). This demonstrates the significance and success of the Stern mediated manipulation of the Caspari and Uphoff studies in affecting mutation dose-response beliefs of key research leaders of the radiation genetics community.

Effect on the BEAR I Committee/Genetics Panel

Crow (1995) noted the following in his historical recounting of the BEAR I Committee Genetics Panel: "the debate over the nature of the dose response for ionizing radiation and mutations had been decided before the convening of the BEAR Committee in November 1955." The accepted view was clear and unified; the answer for the dose response question for mutagenicity was "linearity at low dose."

When reading the transcripts of the BEAR I Committee Genetics Panel, one is struck by the absence of debate and even discussion on the issue of dose response (e.g., linearity vs. threshold). To illustrate the fact that the decision on

Table 2 Radiation genetics quotations about the mutation dose-response following Hermann J Muller's Nobel Prize and Curt Stern's (with Spencer, Caspari and Uphoff) mutagenicity papers

References	Quotes
Catcheside (1950)	Page 592 "The induced mutation is proportional to the total dose over the whole range investigated, down to total doses as small as 25 r. There is good reason to conclude that there is no threshold dose, i.e., no dose so small that it gives no mutational effect. Also, the intensity of the radiation appears to be without effect on the frequency of mutation induced by a given total dose. A dose of 50 r given in a fraction of a minute appears to give no greater effect than the same dose given in the course of a few weeks. There is no threshold, no time factor, and no recovery, the effects being cumulative."
Glucksmann (1950)	Page 42 "The induction of gene mutations is linearly proportional to dose even down to levels of 25 r (Spencer and Stern 1948)."
Lefevre (1950)	Page 341 "It has been amply verified that the number of mutations produced by X-rays is linearly proportional to the total dose applied, even when the total dose received is very small (see Spencer and Stern 1948). Further, the number of mutations produced is independent of the rate of dosage (Uphoff and Stern 1949)."
Sax (1950)	Page 332 "The early work by Muller and by Timoféeff-Ressovsky showed a linear relationship between X-ray dosage and mutation frequency in *Drosophila*. It was also found that the induced mutation rate was independent of radiation intensity. From these observations it was concluded that the X-ray-induced mutations are produced by single 'hits,' and that there is no threshold effect. Spencer and Stern (2) found no increase over the spontaneous mutation rate by irradiating *Drosophila* for 21 days at 2.5 r/day, but later experiments by Uphoff and Stern (3) indicated that low intensities are effective."
Higgins (1951)	Page 9 "As a result of exhaustive experiments on the genetics of the fruit fly, of mice and of many plants, it is held that the number of induced mutations bears a linear relationship to the total amount of radiation absorbed by the sensitive volume of the cell and is independent of either the duration or the intensity of exposure. Consequently, a long exposure to low-level radiation would have the same genetic effect as shorter exposure to a higher level. Experiments of Spencer and Stern (1948) on the fruit fly show that the percentage of sperm containing a sex-linked lethal mutation is increased about .002 per r of radiation exposure and that 50 r exposure is required to double the natural mutation rate." "Spencer and Stern (l.c.) conclude their exhaustive study of the validity of the linear relationship between radiation exposure and mutation frequency with the statement (p. 64): '…for radiation with X-rays, dosages as low as 25 r produce mutations as drastic in their effects and in the same proportion to the dosage as do exposures to high dosages. If an extrapolation is permissible, one may assume that there exists no tolerance dose below which mutations are not induced." "The classical hit theory of induction of mutations, particularly the linear relation between dosage at low levels and mutation rate, has been questioned by Caspari and Stern (1948), who found no significant difference in mutation rates in the sperm of the fruit fly between controls and experimentals exposed to 2.5 r per day for 21 days. Uphoff and Stern (1949), however, after further tests, concluded that low-level radiation does produce mutations in fruit-fly sperm and that the apparent inconsistencies of previous results were due to different experimental techniques and errors in sampling."
Stone (1952)	Page 657 "There is no threshold for genetic mutations…" (cited Muller reference 1950, J Cell Comp Physiol 35(suppl 1):9–70.)
Singleton (1954a)	Page 598 (Discussion) "That a non-linear relationship exists between dose rate of chronic gamma radiation and mutation rate of endosperm characters seems to have been well established by these experiments. This was shown quite conclusively by disproportionately higher mutation rates at the higher dosages, and was definitely indicated by the fact that there seems to be a threshold of dosage required to raise the mutation rate from the spontaneous level to a detectable increase over that level." Page 599 "These data (i.e., data shown in Singleton 1954a study) showing a definite threshold are in contrast to the Drosophila data of Spencer and Stern (1948), where no threshold was indicated even when low doses of radiation were used. In their experiments the effects of acute radiation were studied. Caspari and Stern (1948), studying chronic gamma radiation, found no increase over the controls for doses of 2.5 r/day for 21 days. However, it was later demonstrated by Uphoff and Stern (1949) that the controls used by Caspari and Stern had an abnormally high sex linked lethal frequency and that actually there was an effect of the chronic gamma radiation of 2.5 r/day."
Kelner et al. (1955)	Page 36 "The linear mutation-dose curve indicated for X-ray induced drosophila lethals (Lethals-Dros:X) is perhaps best exemplified by the data of Spencer and Stern (53) for sex linked lethals and may be considered as the classical type of mutation-dose relation. Interpreted within the target theory, the linear relation indicates that a single hit is sufficient to produce a mutation."

Table 2 continued

References	Quotes
Nybom et al. (1956)	Page 81 "In this connection references may be made to the concordant results of Uphoff and Stern (1949) who did not find any threshold in *Drosophila* after low dose rates. A similar result was published by Sax (1950) using chronic irradiation of *Tradescantia* pollen."
Lewis (1957) (This Science article was reprinted in Congressional Testimony)	Page 971 (columns 2 and 3) "Gene mutation has long been known to show a linear relationship with respect to dose of ionizing radiation from studies with *Drosophila*. This linearity has been extended by Spencer and Stern (43) to doses of 50 and 25 roentgens. Gene mutation is also known to be directly proportional to the accumulated dose of radiation, even when the radiation is chronically administered at a relatively low dose rate, as in the studies of Uphoff and Stern (44)."
Norwood (1958)	Page 1929 "Several geneticists[4] have sketched the background which has lead to the concern of this study. Briefly, realization that radiation increases the mutation rate dates back 30 years to Muller's experiments with fruit flies[4e]. Spencer and Stern,[5] using more than 50 million flies, showed that genetic damage was proportional to dosage in the important range of 25 to 50 r. Concern has been heightened by recent findings[4f] that exposure of mice to a given quantity of radiation increases the mutation rate by about 15 times as much as does an equal exposure of Drosophila, which had formerly served as the sole basis for inferring human risks."
Spear (1958)	Page 20 "There is general agreement, however, that mutations can be produced with very low dosage down to a level which approaches natural background (Uphoff and Stern 1949)."
Newcombe (1960)	Page 331 "One basic premise which has not so far been seriously challenged is that the number of gene mutations resulting from irradiation varies in direct proportion to the dose. In other words, there is no threshold level of radiation below which the mutations will not be produced." "In the fruitfly the curve has, by dint of considerable work, been pushed to within 25 roentgens of the origin (Caspari and Stern 1948; Spencer and Stern 1948; Uphoff and Stern 1949) (3, 4, 5)."

LNT had already been settled prior to the creation of the BEAR I Committee, there was no discussion of the scientific foundations of the LNT, including any documenting of its theoretical basis and experimental support, including its strengths and limitations. As noted above, the Genetics Panel placed a high priority on the chronic exposure experiments published under the leadership of Curt Stern. Yet these studies, even ignoring the control group problems of the Uphoff and Stern experiments, had little or no risk assessment relevance. That is, these were sex-linked recessive lethality studies in which the spermatozoa were deposited in the spermatheca of the female. The females were then placed into a type of specialized experimental "hibernation" in which there was a profound alteration of the diet and a lowering of the temperature, changes designed to prevent egg production. The females (with the deposited spermatozoa) were then exposed for 21 days (24 h/day) to gamma irradiation. After the 21 days, the dietary and environmental conditions were changed to permit egg laying so that the testing for sex-linked recessive lethal mutations could take place. In effect, Stern exposed the spermatozoa to ionizing radiation for the equivalent of an entire lifespan, something comparable to a 70–80-year human lifespan. The spermatozoa are known to be highly compromised, having lost much of their normal repair capability. The study represented a worse case exposure scenario, that is, selection of a very susceptible developmental stage linked to a profoundly extended and highly unrealistic exposure period. In effect, the study was a chronic exposure to a cell type that has only a very short developmental stage. The basic concept of the study was not appropriate for a chronic exposure with risk assessment application. The BEAR I Committee incorrectly accepted Stern and Muller's concept of "chronic" for risk assessment purposes as did the entire field and regulatory agencies.

While the BEAR I committee relied upon the findings of the *Drosophila* research directed by Curt Stern, it failed to cite other similarly large-scale *Drosophila* studies (Bonnier and Lüning 1949; Bonnier et al. 1949) in which the lowest total dose was 8 r, below the lowest dose (25 r) of the Spencer and Stern (1948) findings. These papers documented the response of several single genetic loci (e.g., white and forked loci) to which their detailed statistical analysis for mutational studies was applied. The analysis revealed a linear dose response in the dose range of 700–2,800 r, whereas the linearity response was not observed in the low-dose range (8–16 r), where the data were supportive of a threshold response. The authors also suggested that the difference in the shape of the dose response between high and low doses was indicative of differing dose-dependent mechanisms. At the high doses, the linear dose response was consistent with the target theory of Timoféeff-Ressovsky et al. (1935), whereas at lower doses mutational effects could be due to the effects of chemical

mutagens (i.e., hydroxyl radicals from the hydrolysis of water). The dose-dependent mechanism-based hypothesis of Bonnier and colleagues (Bonnier and Lüning 1949; Bonnier et al. 1949) was soon supported with experimental data (Haas et al. 1950; MacKey 1951; Lüning 1954; Barron 1954). According to Barron (1954), "it is dangerous, however, to extrapolate from experimental data with large doses of radiations to what might take place with small doses. In biological systems the effect of ionizing radiations differs qualitatively when the radiation dose is changed. Small doses act by indirect action and produce mainly oxidations. Large doses act by two mechanisms," that is, free radical formation via water hydrolysis and by a direct collision, which is consistent with the target theory.

The Bonnier and Lüning (1949) (Bonnier et al. 1949) papers were also critical of the use of sex-linked recessive lethal experiments for estimating responses in the low-dose zone due to the "impossibility of differentiating between true lethals and semi lethals, and the fact that there are several hundreds of targets per chromosome ready for lethal mutations…" The lack of target specificity would represent an important limitation in the interpretation of dose-response relationships and their potential application to a mechanism-based risk assessment process. Bonnier et al. (1949) also provided a detailed statistical reanalysis of the Spencer and Stern (1948) data challenging the broadly accepted conclusion that the linearity response applied across the entire dose-response range, including the lower dose range. None of these fundamental technical issues were discussed by the BEAR I committee.

Another relevant aspect of the discussion on the nature of the mutation dose response involved the research of Arnold H. Sparrow and W. Ralph Singleton of the Brookhaven National Laboratory. Chairman Warren Weaver introduced their research and its relevance to the BEAR I Committee/Genetics Panel (Weaver W., February 5–6, 1956, see page 110—Transcript) (BEAR I 1956). The discussion of the Sparrow and Singleton data was then led by Committee member Berwind D. Kaufmann, who claimed to have copied several tables from their paper. He stated that Sparrow and Singleton showed that 0.41 r per day yielded a modestly elevated (i.e., less than twice the control values) but statistically significant effect on micronuclei formation. What Kaufmann failed to inform the Committee was that Sparrow and Singleton (1953) specifically stated that a threshold response had been observed at a lower dose. In fact, there was no discussion concerning their threshold dose-response statement by the BEAR I Committee/Genetics Panel. The data in Table 2 (page 35) of the published paper by Sparrow and Singleton (1953) show that 0.084 r per day caused no significant increase in micronuclei. This recounted activity of the BEAR I Committee/Genetics Panel demonstrates that it either ignored or was misled on the published findings of Sparrow and Singleton as the data did not support the pre-determined linear dose-response conclusion. This analysis also suggests that the BEAR I Committee/Genetics Panel was very selective in their choice of what data to consider and that such decisions reveal a prevailing bias supportive of LNT model acceptance.

Since 0.41 r per day of radiation in the Sparrow and Singleton (1953) hypothesis study is more than 1,000 times greater than the naturally occurring intensity, these data do not support the theory that the spontaneously occurring micronuclei are produced by naturally occurring ionizing radiation. The findings of Sparrow and Singleton (1953) were similar to that of Giles (1940) from Harvard who showed that when *Tradescantia* were "subjected to irradiation 1,000 times that due to natural radiation….no increase in aberration was found." Other experiments by Giles indicated that even using ionizing radiation at some 1,800-fold above background no impact on the occurrence of spontaneous mutations occurred.

It is possible to obtain a sense of the personal views of a number of the members of the BEAR I Committee/Genetics Panel on the matter of dose response via two contemporary publication avenues: Testimonies at a 1957 Congressional Hearings (Table 3) and journal publications in the open literature (Table 4) such as a special issue of *Scientific American* on ionizing radiation and several other journals. Based on these collective comments, it follows that the BEAR I Committee/Genetics Panel report and an article in the journal *Science* (Table 5) summarizing the report of the Genetics Panel were replete with statements asserting linearity at low dose.

Placing the new Muller and BEAR I Genetics Panel developments in perspective

The story of Muller's Nobel Prize Lecture is important for its history of science implications, as well as its role in affecting the decision of the US National Academy of Sciences (NAS) to recommend a linearity dose-response policy for assessing risks to the genome from ionizing radiation, replacing the threshold dose-response model. This formal recommendation initiated a series of advisory and regulatory dominoes in essentially all countries to adopt linearity and apply it to somatic effects, that is, cancer risk assessment, for ionizing radiation and later for chemical carcinogens (Calabrese 2009). The linearity decision of the NAS BEAR I Committee/Genetics Panel was strongly championed by Muller, the titular leader of radiation geneticists and with strong ties to all radiation geneticists on the BEAR I Committee/Genetics Panel. In fact, the switch to linearity, which was ushered into the international

Table 3 BEAR I Committee Genetics Panel member quotes at Joint Committee on Atomic Energy—1957

References	Quotes
Muller (1956)	Page 392 "In material of varied kinds, but more especially in *Drosophila*, there is good evidence that over a considerable range of dose (in *Drosophila*, from some 50 r to more than 1,000 r, a more than 20-fold range) the frequency of point mutations (like that of chromosome breaks) is directly proportional to dose."
Crow (1957a)	Page 1013 "4. Evidence from experimental animals, principally Drosophila, indicates that the number of mutations produced is strictly proportional to the amount of radiation received. There are departures from this straight-line relationship at high doses, but these are too high to be likely to be encountered in any ordinary human situation. It is technically impossible to test this relationship for the very lowest doses, but the straight-line relation holds down to the smallest amounts that have been studied." "For these reasons a simple proportionality between the amount of radiation and the number of mutations is fully accepted by geneticists." "The proportionality between dose and mutation production holds irrespective of the intensity or spacing of the dose." Representative Holifield (page 1013) questions Dr. Crow: "This, then, would establish as far as the majority of the geneticists are concerned the principle of linear progression in deleterious effects of radiation regardless of amount?" Dr. Crow answers: "That is correct. A nonthreshold situation, to put this in yesterday's vocabulary." "This means that there is no such thing as a safe dose of radiation to the population. Any amount of radiation, however, small, that reaches the gonads—testes or ovaries—of a person who may later reproduce, involves a risk proportional to that amount."
Glass (1957a)	Page 1030 "The data are most extensive for the fruitfly and the lowest dose that has actually been studied is 25 r." Page 1031 "Because a mutation can be produced by a single ionization in the right place, there is no threshold below which the amount of radiation is too small to produce mutations—that is, every dose produces mutations with a probability equal to its magnitude." "This is to repeat what Dr. Crow said, that there is no safe dose of mutation. This curve continues down without any threshold until it hits the zero point…"
Muller (1957a)	Page 1052 "In respect to the fact that probably there is no threshold, that these effects are proportional to the dose, in this respect these effects of radiation—and also the leukemia—on the exposed individual himself resemble those produced by the radiation in weakening descendants." "You have heard Dr. Glass and Dr. Crow say that geneticists are convinced that there is no threshold for the genetic effects and that others, too, now accept that principle for the genetic effects." "If this is true of these other effects, and it is certainly time we knew whether it was—I think the evidence is convincing that it is—then this important resemblance between the effects on later generations and on the exposed generation is probably not an accidental resemblance. For there is growing reason to infer that this shortening of life and the other long delayed damage done to an exposed individual have their basis in damage done to the genetic material—the chromosomes and their contained genes—of the body's ordinary cells, those of the blood, skin, glands, and so forth, similar to the damage done in his reproductive cells that is passed on to later generations." Page 1056 "Through work on the fruitflies where we have the most exact knowledge to date, unless Dr. Russell has more exact knowledge on mice now, we can get a kind of minimum estimate of the amount of damage to the children by a given amount of irradiation of the parents."
Muller (1957b)	Page 1066 "Since there is much evidence indicating a linear relation between the radiation dose and the frequency of the induced point mutations, even at extremely low doses, and the exactly cumulative nature of these radiation effects, it becomes possible to arrive at probable estimates of the minimum damage done to subsequent generations by any given chronic or acute exposure of parents." Page 1067 "…leukemia and some other malignancies, the induction of which may also be linearly dependent upon radiation dose…"
Joint Committee on Atomic Energy (1957)	Page 12 "…geneticists believe that the direct proportion applied down to zero dose—that is, that there exists no safe "threshold" below which the dose produces no damage, and that damage occurs from any irradiation of the genetic cells, no matter how small the dose."

Table 4 BEAR I Committee Genetics Panel member quotes on low-dose linearity in journals after the BEAR I Committee

References	Quotes
Crow (1957b)	Page 19 (column 2) "2. The number of mutations produced is directly proportional to the dose in roentgens. The linear proportionality over wide dose ranges has been shown in several organisms, especially in *Drosophila*." "Experimental verification in *Drosophila* has been carried to as low as 25 r…" Page 20 (column 1) "The proportionality between dose and mutation production holds irrespective of intensity or spacing,…" Page 20 (column 2) "The conclusions of the previous section imply that there is no such thing as a "safe" dose. Any increase in radiation, however, small, involves a risk proportional to that amount."
Glass (1957b)	Page 956 "Our present evidence indicates that the frequency of these point mutations always increases linearly with the radiation dose (Fig. 1). In Drosophila studies this holds over the range from 25 r to 6,000 r. In some plants, the linear range has been extended down to about 5 r. In mice, the linearity in relation to dose holds over the range from 300 r to 600 r, and there is no sign that it does not hold at lower doses. This linear proportionality to dose, over and above the spontaneous frequency of mutation, implies that (a) as long as dosage is measured in terms of roentgens, that is, in terms of the ionization produced by the radiation, absorbed quanta do not interact to produce effects, but are individually effective; and (b) there is no sign of a threshold dose below which mutations are not produced. Rather, even the lowest doses are proportionally mutagenic, and all doses, however, distributed, are additive or cumulative in effect."
Beadle (1959)	Pages 225 and 226 "…thus there is probably no threshold below which radiation will produce no mutations. Since there is no repair mechanism, once the mutation process is complete, mutations induced at different times will tend to accumulate in a line of descent…"
Hollaender and Stapleton (1959)	"In sum, cell studies have served to elucidate the basic mechanism by which ionizing radiation damages the living organism. They have provided no evidence that there is a true threshold of dosage below which ionizing radiation produces no harmful effects…"

community by the BEAR I Committee Genetics Panel, is the most significant action in regulatory environmental public health history with ever expanding social, political, economic, and public health implications (Hamblin 2007).

The present paper provides the first documentation of how Muller (Muller 1950a, b, 1954a, b) himself used the carefully constructed activities of Stern (described in detail in Calabrese 2011b) to enhance the concept of linearity and to protect his reputation. Muller lent credibility to the technical note of Uphoff and Stern (1949) while further marginalizing the Caspari and Stern study results (Caspari and Stern 1948). The stakes were high on multiple levels and these core individuals knew it. Stern and Muller needed to prevent the acceptance of the Caspari and Stern (1948) study findings in order to sustain the single-hit linearity model. They also needed any criticisms of the Spencer and Stern (1948) and Uphoff and Stern (1949) papers to be muted. They were successful as other leaders of the radiation genetics community simply failed to address the serious limitations of the Spencer and Uphoff findings while incorrectly asserting that the Caspari and Stern (1948) paper suffered from an aberrantly high control value, simply re-stating the demonstrably incorrect, but authoritative conclusion of Muller (1950a).

Despite the fact that Caspari had successfully rebutted the first challenge of Stern concerning the control group spontaneous mutation rate, there is no evidence that he disputed the control group mutation rate reversal decision of Stern barely a year later and of Muller's equally strange affirmation of Stern's position as well (Muller 1950a, b). A January 27, 1949, letter from Caspari to Stern supported the publication of the Uphoff and Stern (1949) paper now adopting part of the mantra of Stern, that is, that there is considerable variability in the mutagenic frequency of sperm prolongedly stored in the spermatheca. This conclusion provided the opportunity to rehabilitate the inexplicitly low control group values of Uphoff. Caspari, however, would not go so far as to also state that his control values were unusually high. At the time of the Uphoff and Stern (1949) article, there were only two papers published in the literature (Rajewski and Timofeeff-Ressovsky 1939; Kaufmann 1947) on aged sperm and mutation and the published abstract of Muller (1946b). Each supported the mutation frequency of Caspari. These findings are consistent with subsequent mutation frequencies in aged sperm stored in the spermatheca of female Drosophila (Byers 1954; Byers and Muller 1952; Rinehart 1969; Graf 1972; Muller et al. 1961). Muller et al. (1961) stated that "The data clearly showed a rise in mutation frequency (averaging some .06 percent of recessive lethals in the X chromosome per week) resulting from storage of the mature spermatozoa in the female" (page 213). Note the striking similarity of how

Table 5 Low-dose linearity quotation in the journal Science from article summarizing the findings of the BEAR I Committee Genetics Panel

References	Quotes
BEAR I (1956)	Page 1159 (column 2) "…the genetic damage done, however, felt and, however, measured, is roughly proportional to the total mutation rate." Page 1160 (column 1) "3) Any radiation dose, however, small, can induce some mutations. There is no minimum amount of radiation dose, that is, which must be exceeded before any harmful mutations occur." Page 1160 (bottom column 1) "The probable number of additional induced mutations occurring in an individual over a period of time is by and large proportional to the total dose of extra radiation received, over that period, by the reproductive organs where the germ cells are formed and stored." Page 1160 (top column 2) "The *total dose* of radiation is what counts, this statement being based on the fact that the genetic damage done by radiation is *cumulative*." Page 1162 (column 2)—how harmful are radiation-induced mutations? "1) Thus the first and unanimous reply to the question posed by the title to this section is simply this: *Any radiation is genetically undesirable*, since any radiation induces harmful mutations. Further, all presently available scientific information leads to the conclusion that *the genetic harm is proportional to the total dose*… This tells us that a radiation dose of 2X must be presumed to be twice as harmful as a radiation dose of X…" Page 1164 (column 1) "…for there is no such figure other than zero." [referring to whether there is an amount of radiation which is genetically harmless (preceding phase)] Page 1164 (column 1) "As geneticists we say: keep the dose as low as you can." Page 1165 (last sentence) "From the point of view of genetics, they are all bad." (referring to the effect of exposures to ionizing radiation)

Uphoff and Stern (1947) characterized Muller's data some 14 years earlier, "a weekly increase of about 0.07 %…" The 0.06 % increase would yield an estimated 0.28 % (i.e., 0.06 % × 3 weeks + 0.10 % background = 0.28 %) mutation incidence after 3 weeks, consistent with the Caspari and Stern (1948) findings, the logic used in Uphoff and Stern (1947) and with the Muller (1946b) statement that "spermatozoa aged several weeks in the female may contain several times as many mutations as they originally had." Furthermore, the reported inter-study variability for mutations of aged sperm and/or stored sperm aged in the spermatheca appears modest with 95 % confidence intervals typically being about ±25–30 % of the mean. The attempt by Stern, therefore to assert that the very low values of Uphoff reflected a highly variable response endpoint was not supported in the contemporary and subsequent literature. Stern never argued his case by a comparative data assessment nor did he address the apparent contradiction with the Muller data and comments which he (i.e., Stern) previously used when he concluded that the Caspari data were credible while those of Uphoff were not. He simply made an authoritative declaration that was accepted without question or comment by the radiation genetics community.

BEAR I Committee/Genetics Panel

The BEAR I Committee/Genetics Panel was comprised of outstanding scientists and national leaders. Despite their significant individual accomplishments in scientific and radiation genetics domains, the committee as a whole lacked extensive experience in conducting low-dose, dose–response studies. Only two of the members had extensive direct experimental dose-response experience (i.e., Demerec and Russell) up to the time of the BEAR I meetings. This experience was essential for evaluating the nature of the dose response in the low-dose zone. Of these two, Demerec had the most extensive and varied experience having dealt with multiple models and agents as well as different types of radiation. His research experience on dose response was spread over a 25-year period starting about 1931. Nonetheless, his dose-response experience with *Drosophila* was limited to only a few high dose studies during the 1930s, a key limitation. Despite his significant and prolonged career at Oak Ridge, Russell was relatively new to the dose-response research area, with about 5–6 years experience at the start of the BEAR I Committee in 1955. In the case of Russell, his developing research findings with mice were still somewhat premature, having little impact on BEAR I Committee/Genetics Panel conclusions. Among the remaining members of the committee, Muller's principal dose-response experience is found in the research of Hanson and Heys (1929), and Oliver (1930, 1931) at the University of Texas and Ray-Chaudhuri (1944) at Edinburgh (completed in 1939), as well as his consultant role with Stern from 1943 to 1946. Limited relevant low dose-response research based on the publication record experience was found for Berwind Kaufmann. Alexander Hollaender, PhD in physical chemistry, had made

important contributions on the effects of UV wavelengths specificity on mutation in bacteria and fungi. He became the director of radiation biology research at Oak Ridge, hiring Russell. Hollaender had no experience with Drosophila research. H. Bently Glass' low-dose experimental research experience was quite limited during BEAR I, becoming far more extensive only after BEAR I. Importantly, very limited to no meaningful dose-response research experience is apparent for the remaining 11 members [George W. Beadle, Charles W. Cotterman, James F. Crow, Gioacchino Failla, Clarence C. Little, James V. Neel, Tracy M. Sonneborn, Alfred H. Sturtevant, Sewall Wright, Warren Weaver (Chair), and Shields Warren] of the BEAR I Committee/Genetics Panel. This situation resulted in the "senior" dose-response experience to reside with Demerec and Muller, two individuals on record to save the "hit" model.

The geneticists on the BEAR I committee were principally basic researchers; their experimental approaches were neither dose response nor risk assessment oriented. Even Muller (1950a, b) claimed that the work of Spencer and Uphoff (with Stern) at low doses would markedly extend his and his students' (e.g., Hanson and Oliver) research conducted at very high doses. Further, in the detailed comments that Muller sent to Stern about the Spencer (Lilly Library 1946, September 13) and Caspari (Lilly Library 1947a, January 14) manuscripts, nearly all dealt with fundamental biological/genetic questions with little direct relevance to risk assessment. Multiple study design issues and other methodological/analysis problems documented in Calabrese (2011b) for the Spencer and Stern (1948) paper were not identified by Muller (Lilly Library 1946, September 13). The members of the BEAR I Committee/Genetics Panel looked to Muller for leadership on matters related to the dose–response. However, Muller displayed critical limitations in assessing such studies based on his written statements. Thus, the methodological and analysis limitations of the Spencer and Stern (1948) paper and the serious flaws of the Uphoff and Stern (1949) paper were missed by the radiation genetics community and the BEAR I Committee/Genetics Panel, a condition that continues (Lipshitz 2005). Of further note is that Muller (1946b) and Kaufmann (1947) published findings on the control group mutation rate of aged *Drosophila* sperm that supported the findings of Caspari and Stern (1948). Kaufmann worked closely with and under the direction of Demerec at Cold Spring Harbor at that time. Furthermore, an October 7, 1947, letter (i.e., 6 weeks before submitting his paper to *Genetics*) from Caspari to Stern (American Philosophical Society 1947g, October 7) stated that "I have discussed the paper (the Caspari/Stern manuscript) with Demerec and Kaufmann. Both did not find very much to suggest……Both Demerec and Kaufmann were impressed by the amount of material which we have. The ageing effect in our experiments is of the same order of magnitude as that found by Timoféeff and Kaufmann." In fact, Caspari and Stern (1948) cited a 1947 paper by Kaufmann as support for control group values of their study. Muller and Kaufmann, both BEAR I committee members, therefore, reported research on mutation incidence of *Drosophila* aged sperm findings consistent with the findings of the Caspari and Stern (1948) paper. Thus, the BEAR I Committee/Genetics Panel should have been informed on the issue of control group validity by Demerec, Kaufmann, and/or Muller as it related to the research of the Caspari and Uphoff studies. However, based on the transcripts of the BEAR I Committee/Genetics Panel, Demerec, Kaufmann and Muller did not provide this information. Knowledge of the mutation rates in aged *Drosophila* sperm should have led to a reconsideration of the Caspari and Stern (1948) paper as well as generated serious questions about the findings and interpretations of the Uphoff and Stern (1949) data. This was a key issue affecting which study would be relied upon by the BEAR I committee. By their actions, the BEAR I committee Genetics Panel came to the erroneous conclusion that the Caspari study was unreliable due to its "unusually high control group value."

The future of ionizing radiation risk assessment was largely determined by the actions of a few, by the failure of the scientific community, especially the radiation genetics community, to probe deeper into the key findings of Stern and his colleagues and journals such as *Science* that published influential but poorly documented findings (Uphoff and Stern 1949). As has been pointed out, the linearity paper of Spencer and Stern (1948) was burdened with numerous methodological limitations that only recently have been documented, as well as statistical analysis limitations that challenged the conclusion of linearity at low dose (Bonnier and Lüning 1949; Bonnier et al. 1949) while the Caspari and Stern (1948) findings supporting a threshold perspective were unfairly marginalized (Calabrese 2011b). Furthermore, the BEAR I Committee/Genetics Panel failed to require Stern to provide the promised detailed accounting for the *Science* article (Uphoff and Stern 1949) upon which they so heavily relied.

According to Muller (1950a, b), by 1950, the radiation genetics community had accepted the linearity risk assessment paradigm (Table 2). Their belief was based largely on the fruit-fly work of Stern and his associates as well as the leadership, prestige, and authority of Muller, as few of the geneticist members of the BEAR I Committee/Genetics Panel had relevant experience with low-dose research. By the time, the National Academy of Sciences BEAR I Committee/Genetics Panel convened, therefore, the decision over the nature of the response in the low-dose zone had been decided by the radiation genetics community as there was no dispute or even debate within the BEAR

I Committee/Genetics Panel over the adoption of linearity to replace the threshold model for germ-cell mutagenicity (Crow 1995). The actions of Stern and Muller had led the way, assuring that the ends (i.e., linearity) justified the means (i.e., unfair/improper scientific evaluation). In fact, it is from this heritage and upon this foundation that regulatory cancer risk assessment theory and practice in the USA and throughout the world was built.

Conclusions

1. This paper provides specific documentation of how Hermann J. Muller supported and extended the like actions of Curt Stern to prevent the scientific community from discovering Muller's Nobel Prize lecture deception and to promote his ideological goal of linearity at low dose for ionizing radiation risk assessment (Table 6).
2. Muller strengthened the questionable actions of Stern in key publications in early 1950s while improperly discrediting the threshold findings of Caspari and supporting the "uninterpretable" data of Uphoff to achieve a linearity interpretation. The bases of these actions are documented in this paper.
3. The paper shows how the actions of Stern and Muller affected numerous publications and the dose–response beliefs of leaders of the radiation genetic community and the NAS BEAR I Committee/Genetics Panel, affecting the adoption of linearity at low dose for ionizing radiation-induced mutation and eventually for carcinogen risk assessment for ionizing radiation and chemical carcinogens.
4. The findings demonstrate that the adoption of the LNT model for risk assessment lacked a proper scientific foundation, yet was accepted by regulatory and public agencies worldwide.

Unresolved issues

1. Why didn't Stern publish the follow-up detailed paper containing the entire methodology for all the relevant data for the Uphoff three experiments?

Table 6 A summary concerning Muller's actions that affected the discrediting of Caspari's findings and acceptance of the Uphoff and Stern conclusions

A five-page detailed letter sent from Muller to Stern dated January 14, 1947, concerning scientific strengths and limitations of the Caspari and Stern manuscript provided no comment on the control group lethality data
Muller was actively researching the area of spontaneous mutations in sex-linked recessive lethality studies using aged sperm stored in the spermatheca of female fruit flies. This was the research method of the Caspari and Stern paper. Muller had been doing extensive research on this topic since the early 1940s. He was a leading authority on the topic
Muller provided his spontaneous control group data to Stern ("Appendix" section) in order to address the concern that Stern expressed about the apparently high control group values of Caspari
Based on the data of Muller, Uphoff and Stern (1947) determined that the average weekly spontaneous mutation rate in *Drosophila* sperm stored in the spermatheca of the female was about 0.07 %, yielding an additional mutation increase in about 0.21 % by 3 weeks, the length of the Caspari sperm storage time. The 0.21 % increase would be added to a background value of about 0.10 %, yielding an estimated control group value of about 0.31 %. The 95 % confidence intervals were about ±0.07 %, with an approximate range of 0.24–0.38 %. The values were obtained when studies were conducted at about 25 °C. At the lower temperature of 18 °C used by Caspari, it was estimated by Stern (and Uphoff) that the rate of increase might be reduced to 0.05 % per week. This would result in an estimated value for the Caspari control of about 0.25 %, nearly identical to his final adjusted value (i.e., 0.2489 %)
Based on these data, Uphoff and Stern (1947) concluded that the Muller data supported the Caspari conclusion that his control data were well within the normal range and not unusual or aberrant. The Muller data lead Uphoff and Stern (1947) to conclude the Uphoff findings were uninterpretable
Continued research in the area of spontaneous mutation in sperm stored in the spermatheca by Muller and his graduate students at the University of Indiana were consistent with this conclusion and quantitative assessment (Byers 1954; Byers and Muller 1952; Graf 1972). These findings were also consistent with that published by other researchers as well (Kaufmann 1947; Rinehart 1969)
Based on this information, the statements of Muller that Caspari's control group data were unusually high are inconsistent with: (1) His own data and that published by other researchers; (2) his previously detailed assessment of the Caspari data; (3) how Uphoff and Stern (1947) evaluated the Muller data, an evaluation that Muller was knowledgeable of, based on an acknowledgment in the Uphoff and Stern (1947) paper, and (4) internal written correspondence between Stern and Caspari
This assessment indicates that Muller's statements that Caspari's control group data were unusually high and adversely affected Caspari's threshold interpretation are contradicted by the body of evidence
While Muller repeatedly challenged the credibility of the Caspari findings by attacking his control group data, he made no statement about the reliability of the extremely low control group data of Uphoff. In fact, he would consistently cite the Uphoff and Stern (1949) paper as being a critical reference to support a linearity perspective
The collective findings on these matters indicate that Muller displayed compromised scientific judgment, having a significant impact on the scientific literature and national and international risk assessment policy that continues to the present

2. Why didn't the radiation geneticist community demand that Stern publish these findings?
3. Why didn't Stern address the scientific basis, if any, of why he reversed his position on the Uphoff control group data?
4. Why didn't Caspari challenge any of the multiple papers that claimed that the Caspari control group data were unusually/abnormally high or that their paper displayed "different techniques" or had "errors in sampling" that accounted for their threshold-like findings?
5. Why did Muller agree to let Uphoff and Stern (1947) acknowledge the use of his aged sperm data that supported the Caspari control groups findings and then repeatedly claim that Caspari's control group values were unusually high, adversely affecting the credibility of this paper?

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Conflict of interest The author declares that there is no conflict of interest.

Appendix

Stern–Muller temporal letter exchange concerning the aged-stored sperm control mutation rate (Source: Lilly Library, Stern–Muller correspondence)

Curt Stern wrote a letter to Hermann J. Muller on January 22, 1947 (American Philosophical Society 1947a), informing him that "At the present time it looks as if our new control data (probably the results of the first 3 months of the first Uphoff experiment; note that her first month's reading was an especially low mutation rate of 0.005 %) for aged sperm are considerably below those of Caspari's." He then asked Muller to "send me your figures on rate of sex-linked lethal in sperm aged several weeks, (most desirably, if you have them, data on 3 weeks), in comparison to control data from non-aged sperm?"

On February 3, 1947 (Lilly Library 1947b, February 3), Muller answered by stating that "…. sperm of males which are about a week old and have been copulating freely (as in Caspari's experiment) during that period have only about .07 or .08 % of lethal. Thus, the latter sperm, after 3 weeks, should contain something like .28 % of lethal."

On July 23, 1947 (American Philosophical Society 1947b), Stern writes Muller again stating that "I have mislaid your letter of some months ago (February 3, 1947, letter) in which you gave me some details of your own on the mutation rate under various physiological conditions. May I therefore ask you two questions and will you permit me to use your answers in a report which I am just preparing for the Manhattan Project? Obviously, full credit for it would be given. The questions are: (1) What is the spontaneous mutation rate in sperm derived from Canton-special males of from 3- to 6 days old? (2) What is the weekly increase in mutation rate of sperm from such males stored in females?"

On August 4, 1947 (Lilly Library 1947c), Muller responds "When sperm were stored in females, there was a weekly increase in the mutation frequency of about 0.07 %, on the average." On August 7, 1947 (American Philosophical Society 1947c), Stern cabled Muller asking him the temperature used and on August 8, 1947 (American Philosophical Society 1947d), Muller answered via cable indicating "25 °C." A subsequent undated letter, but most likely prior to September 9, 1947 (American Philosophical Society 1947e), Muller noted "A recalculation of my data gives the figure of 0.08 % instead of 0.07 % as the frequency of lethal accumulating in mature sperm per week." Since Uphoff and Stern (1947) did not include this correction in their report to the AEC it suggests that this undated letter was received after submittal of their report to the AEC.

The control value therefore used by Uphoff and Stern (1947) of 0.07 % for the estimated mutation rate of the sperm stored in the spermatheca was based on the earlier letter correspondence-supplied estimates of Muller (Lilly Library 1947b, c, February 3 and August 4) which Muller later clarified as being slightly in error.

The Caspari and Uphoff studies used Drosophila melanogaster fruit flies, breeding Canton-wild-type (S) males with Muller-5 females. Muller claimed (Lilly Library 1947c, August 4) that he never conducted mutation experiments with aged males of the Canton-wild-type stock. Muller stated that he had tested the aged sperm mutation frequency in "a number of different stocks (of Drosophila males) without finding any difference." The rate of increase on a weekly basis was said to be 0.07 % on average. This value of 0.07 % is believed to be prior to the correction to 0.08 %. This suggests that Muller did not observe significant inter-stock variation in mutation rates of the stored sperm.

Stern seems to have completed his Uphoff and Stern (1947) paper for the Manhattan Project during August, 1947. Stern knew that Uphoff's mean mutation frequency was 0.1682 % (0.1365–0.2097 %). This suggests a weekly mean increase in mutation rate of 0.0227 % (0.0122–0.0366 %), far lower than the 0.07 or 0.08 % mean weekly increase in Muller. When Stern wrote to Muller on September 9, 1947, he stated that for the Canton-special stock "…the weekly increase is considerably less than that found by you and others. It seems to be much more of the order of 0.03–0.05." This September 9,

1947, letter was written probably just after the submission of the Uphoff and Stern (1947) paper to the AEC, and definitely before the submission of the Caspari and Stern (1948) paper for publication by Genetics (i.e., November 25, 1947). Thus, the judgments of Uphoff and Stern that found that Uphoff's data were "uninterpretable" and that supported the reliability of the Caspari control data were made with the information provided by Muller during the summer of 1947. The apparent argument that Stern seems to be suggesting in his September 9, 1947, letter to Muller is that the Canton-wild-type stored sperm in the female may yield uniquely lower control mutation values. The argument is tenuous as the far higher weekly rate was consistently shown by multiple investigators, and with multiple Drosophila stocks, only being low in two Uphoff experiments. In fact, significant inter-strain differences on the frequency of dominant lethal mutations as induced by radiation were not reported in various Drosophila strains, including the Canton-special wild-type strain (Demerec and Fano 1944; Strömnaes 1951). This suggestion by Stern was not included in the Uphoff and Stern (1947) report.

This letter exchange between Stern and Muller fails to provide support for the later statements of Muller that Caspari's control group was unusually high. The Muller data and statements also do not provide support for the conclusion that the low Uphoff control data were in a normal range. None of this information was provided by Stern in his *Science* publication to permit the scientific community to better evaluate the Uphoff and Caspari control group data.

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LETTER TO THE EDITOR

Letter from Ralph J Cicerone regarding Edward Calabrese's paper published online first on August 4th: "how the US national academy of sciences misled the world community on cancer risk assessment: new findings challenge historical foundations of the linear dose response." [DOI 10.1007/s00204-013-1105-6, Review Article]

R. J. Cicerone · K. D. Crowley

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Dear Dr. Hengstler

We write to express disappointment with the inappropriate title and unsubstantiated content of Edward Calabrese's paper published online on 4 August: "How the US National Academy of Sciences misled the world community on cancer risk assessment: new findings challenge historical foundations of the linear dose response" (Calabrese 2013).

Professor Calabrese accuses 1946 Nobel Laureate Herman Muller and his colleague Curt Stern of a pattern of deception in their treatment of experiments by another scientist. Calabrese further accuses Muller of inappropriately influencing fellow members of the National Research Council's Committee on Biological Effects of Atomic Radiation (BEAR) (NRC 1956) about the genetic effects of ionizing radiation in humans.

Calabrese uses correspondence between Muller and Stern concerning experiments on germ cell mutations in male fruit flies, along with subsequent scientific publications by both scientists, to make unsubstantiated insinuations about Muller and Stern's motivations: For example, that Muller was "…[p]rotecting his reputation by ensuring that his misleading comments would not be discovered while still aggressively pushing acceptance of the linearity agenda" (p. 2). And "In the absence of new data, Stern decided upon a new strategy to 'save' the single-hit linearity dose response" (p. 3). Calabrese also makes *ad hominem* remarks about Muller to support his accusations: For example, "… it was well known that Muller would try to win arguments by exaggeration and overstatement" (p. 3).

It seems clear from Calabrese's factual descriptions that Muller and Stern were trying to make sense of experiments that yielded unexpected results. It is not surprising that they would question these results and seek to have them replicated. Calabrese clearly disagrees with Stern and Muller's scientific judgments, but he is able to marshal only circumstantial evidence to support his accusations that they sought to suppress the experiments. In the end, the experiments were published (Caspari and Stern 1948) and served to spur-on additional scientific investigations.

Calabrese also asserts that Muller "[m]ade deceptive statements during his Noble (*sic*) Prize Lecture … that were intended to promote the acceptance of the linear dose–response model for risk assessment for ionizing radiation" (p. 1). This assertion is based on statements made by Muller in his lecture in support of the linearity hypothesis even though he had received the manuscript containing the experimental results some 5 weeks earlier. Given Muller and Stern's reluctance to accept the results of these experiments without replication, Muller's decision not to mention them is certainly not surprising. It is unfair to call his behavior deceptive.

Calabrese provides no evidence that Muller inappropriately influenced the BEAR committee or that the NAS or the BEAR committee misled anyone. The BEAR committee considered a large body of scientific work and exercised its own considerable scientific judgment in reaching a consensus conclusion that "the genetic harm [from radiation] is proportional to the total dose" (NRC 1956, p. 23). Moreover, the BEAR committee noted that this conclusion was generally accepted by the genetics community (*ibid*).

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The BEAR committee's conclusion applied specifically to genetic damage resulting from radiation-induced mutations. However, scientific understanding of radiation effects in humans has advanced substantially since the 1956 BEAR report, a fact never acknowledged by Calabrese. Our current understanding of radiation health effects is based on long-term human epidemiological studies on cancer incidence and mortality as well as a large body of radiation biology research. NAS has carried out several reassessments of radiation health effects since the 1956 BEAR report. The latest assessment, Biological Effects of Ionizing Radiation VII, was published in 2006 (NRC 2006). That report concluded that the linear no-threshold model provides "the most reasonable description of the relation between low-dose exposure to ionizing radiation and the incidence of solid cancers that are induced by ionizing radiation" (NRC 2006, p. 6). The report also notes that uncertainties in the linear no-threshold relationship are high at low doses. Future research will likely help to further clarify the relationship between ionizing radiation and disease causation in humans.

It distresses us to see this article's accusations, with no actual supporting evidence, in a serious scientific journal. Drs. Muller and Stern are deceased and cannot defend themselves against these accusations. Both scientists were elected to our academy by their peers (Muller in 1931 and Stern in 1948) in recognition of their considerable scientific achievements, and Muller was honored with the 1946 Nobel Prize in Physiology and Medicine for his lifesaving work on the physiological and genetic effects of X-rays. In the 1950s, he joined his fellow scientists in warning the American people about the dangers of atomic war and fallout. With Linus Pauling, he worked to bring about a worldwide nuclear test ban treaty.

We hope that you will publish this letter so your readers can benefit from a more reasoned treatment of what Drs. Muller, Stern and the NAS have contributed to the field of radiation health effects.

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REPLY

Response to Letter of Ralph J Cicerone and Kevin Crowley regarding "How the US National Academy of Sciences misled the world community on cancer risk assessment: new findings challenge historical foundations of the linear dose response." [DOI 10.1007/s00204-013-1105-6, Review Article]

Edward J. Calabrese

Received: 18 November 2013 / Accepted: 21 November 2013

Dear Editor,

This letter addresses the concerns presented in the letter of President Cicerone concerning my article "How the US National Academy of Sciences Misled the World Community on Cancer Risk Assessment: New Findings Challenge Historical Foundations of the Linear Dose Response" (Calabrese 2013). His summary of my historical conclusion of deliberate scientific misrepresentation by Curt Stern and Hermann J. Muller, which guided the decision of the NAS BEAR I Committee Genetics Panel to support the linear-no threshold model, is strikingly unrepresentative of the information and evidence presented in my article. President Cicerone provided an inaccurate account of my article, particularly when he accused its conclusions of not being justified by "actual supporting evidence." He overlooks and fails to mention the significant amount of the evidence on which the conclusions of my article are based. The substantial amount of the evidence on which my article relied becomes clear when it is read and compared to his letter. Below I highlight some of the most significant elements of this evidence, which President Cicerone, inexplicably ignored. However, prior to my directly addressing the letter of President Cicerone I present a brief summary of my article and the process by which it occurred. This information is necessary to provide the proper context in which to evaluate the position articulated in President Cicerone's letter.

My claim of deliberate scientific deceptions/misrepresentations by two renowned leaders of the radiation genetics community, one a Nobel Prize winner, more than three decades after their deaths was made only after an exhaustive examination of the published literature, previously classified documents, and copious letters and other types of personal documents in the files of Curt Stern, Hermann J. Muller and other key people. The discovery of their scientific deceptions/misrepresentations occurred unexpectedly during research for an earlier paper entitled "Toxicology Rewrites its History and Rethinks the Future: Giving Equal Focus to Both Harmful and Beneficial Effects" (Calabrese 2011a, b, c). Prior to my submittal of this manuscript, I sent it to several people for a final set of informal evaluations. One reviewer's comments, which suggested an extensive study of Muller and his role in the development of the linear-no-threshold (LNT) concept and its acceptance by regulatory agencies, prompted the present Muller–Stern-NAS investigation.

The first inkling of an "honesty" issue occurred after a detailed evaluation of Muller's Nobel Prize Lecture of December 12, 1946 in which he vigorously denied even the possibility of a threshold response for radiation-induced genomic mutation, demanding a switch to a LNT risk assessment model (i.e., note Muller's—"no escape from the conclusion that there is no threshold"—comment during his Nobel Prize Lecture). While his statements were not surprising, I linked them to data that had recently emerged at the University of Rochester. A newly completed chronic study on the effects of ionizing radiation on germ cell mutation in male fruit flies in August 1946 by Dr. Ernst Caspari, working under the direction of Stern, supported a threshold rather than a linearity dose response. The Caspari data were important since they were derived from the strongest low-dose-rate study to date.

The threshold findings were so unexpected and challenging that Stern, a strong proponent of the LNT, refused

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to accept the findings, claiming (without data to support his statement) that the control group was aberrantly high, leading to the false threshold conclusion. However, Caspari found strong literature support for his position, challenged the Stern position and eventually compelled Stern to reverse his stance and to accept or at least acknowledge the threshold conclusion.

Since Muller was a paid consultant to the Stern project, I wondered whether he had seen the Caspari findings prior to his Nobel Prize Lecture. I contacted individuals with expertise on the history of radiation genetics who had knowledge of Muller and Stern. However, no answer to my question was forthcoming. This led me to obtain considerable written correspondence between Stern and Muller and relevant colleagues. A series of letters between Stern and Muller starting in September of 1946 addressed the question. Stern initially told Muller that Caspari had finished his laboratory work, asked Muller if he would review the completed manuscript and Muller agreed. Stern sent Muller the manuscript on November 6 with Muller responding on November 12, indicating that the findings were important since they challenged the LNT in a highly significant manner and as such needed to be replicated as soon as possible. He noted that Caspari was a highly competent investigator, lending more credibility to the findings. He then stated that he would provide a detailed evaluation later. The letter on November 12 from Muller was the answer that I initially sought. Muller indeed had seen the findings of Caspari prior to his Nobel Prize Lecture, understood its importance and challenge to the LNT. Knowing this, Muller went to Stockholm and gave his Nobel Prize Lecture, inexplicably stating that there was no possibility that a threshold dose response could occur for ionizing radiation-induced genomic mutation. Yet, he had just seen copious data supporting this conclusion from the strongest study yet done on the question of chronic low-dose-rate effects, one on which he was a consultant, knew the research team, the facilities and had even supplied his own Muller-5 fruit flies.

I then questioned whether Muller might have changed his mind from the time of the letter on November 12 to Stern to when he gave the Lecture on December 12. However, his January 14, 1947, letter to Stern revealed this was not the case as he not only confirmed the original assessment but emphasized that he had no technical criticisms of the Caspari paper. Following this discovery of the misrepresentations of Muller, it raised two important questions: why would Muller risks his reputation and professional status, and why had this deception not been exposed for nearly seven decades?

Why Muller misled the Nobel Prize Lecture audience can only be speculated upon. It is known that Muller was passionate about his belief that X-rays would induce mutations and that most mutations were harmful. Even though he had an intuitive sense that such mutations could enhance the risk of cancer, he was most concerned with the mutation load of the population. Soon after his discoveries of X-ray induced germ cell mutations, he had been on a mission to convince the medical community to be more responsible in their use of X-rays, especially those involving pregnant women and children. He also strongly advocated for the protection of those working with X-rays. Despite his activism, Muller was strikingly unsuccessful in convincing the medical establishment to adopt his views. He was blocked at each attempt. While Muller had rallied support from other radiation geneticists, it had not yet reached the tipping point to affect government risk assessment procedures or the medical community. Thus, when Caspari obtained data supporting a threshold response, it raised concerns among the radiation genetics community, prompting Milislav Demerec, the highly influential Cold Spring Harbor Chair of Genetics and future member of BEAR I committee, to ask Caspari what could be done to "save" the LNT single-hit theory. On the issue of mutation load, the radiation genetics community believed only they properly understood the problem and only they who could, in essence, save the world (i.e., human genome). It was within this context that Muller took to the podium in Stockholm on December 12, 1946, and made his landmark Nobel Prize Lecture. Muller's speech reflected a classic case of the ends (i.e., more conservative risk assessment procedures) justified his means (i.e., misrepresenting scientific understandings). As pointed out by his colleague and close friend, James Crow, it was not uncommon for Muller to exaggerate in order to win arguments, all to the frustration of his followers. Whatever the real explanation of "why," Muller's behavior at Stockholm revealed a clear case of deception.

Following these developments, more anomalies were uncovered. For example, although Muller could not offer any technical criticisms of the Caspari paper, the Stern directed—and the Muller approved—discussion of the Caspari manuscript was bizarre. The nearly six-page discussion was largely about why the threshold findings should not be accepted until it was determined why they differed from acute exposure which supported linearity as reported in an earlier Spencer study. Of note was that Caspari had incorporated a series of methodological and equipment changes improving upon the Spencer study. Secondly, the Spencer paper had a series of serious methodological flaws that threatened the reliability of its findings in the low-dose zone. Third, there were at least 25 significant experimental differences between the studies, making it impossible to directly compare them. Yet, Stern and Muller failed to see or report the limitations of the Spencer paper while setting up the Caspari manuscript as a type of straw man, preventing any serious consideration of the threshold findings. In fact, in his January 14, 1947, letter to Stern, Muller indicated that the Caspari manuscript could be published given

all the caveats (i.e., road blocks to its acceptance) they placed within the discussion. Caspari, therefore, would get the publication he needed, while the actions of Stern and Muller would blunt any potential impact of the threshold findings and preserve the LNT single-hit theory. I wondered what type of journal would even consider publishing a paper in which the authors demanded the reader not take seriously the data until it was resolved why its results differed from that of another paper when the resolution could not be realistically made. As it turns out, Stern "submitted" both the Spencer and Caspari papers (on which he was co-author) to the journal for which he was the editor (i.e., *Genetics*) on November 25, 1947, with publication occurring about one month later, in January of 1948, with no evidence of an independent peer-review for either paper. These acts of Stern and Muller were consistent with the goal of not only "saving the hit model" but also preventing Muller's Nobel Lecture deception from being discovered.

Stern attempted to replicate the findings of Caspari, recruiting a new graduate student, Delta Uphoff. A significant problem arose in Uphoff's research, obtaining aberrantly low control group values on repeated occasions. Muller's copious control group data (which was consistent with the published literature) supported the validity of Caspari's results while indicating that Uphoff's were aberrant. In fact, in the discussion of their findings in a classified report for the Atomic Energy Commission, the aberrantly low control group values were surprisingly attributed by Stern and Uphoff to investigator bias, which resulted in the uninterpretable characterization of the findings.

When Stern finally did publish these findings as well as the summary results of Spencer and Caspari, it was as a single-page technical note in *Science*. In this note, Stern neglected to report that one year earlier, key findings of Uphoff's research were considered as uninterpretable, due to investigator bias and that Muller's confirmatory data supported Caspari but not Uphoff. Yet, Stern ignored these past assessments, revived the findings of Uphoff calling the control data normal while reversing his position on the acceptability of the Caspari data without justification for either decision…and without any apparent opposition. With the inclusion of the Uphoff and Spencer findings and the marginalization of the Caspari research, the data now would fit a straight line, supporting the LNT. Since no detailed methods and complementary data were provided in the one-page note, Stern promised to provide the missing information in a detailed subsequent paper. However, he failed to do so. A check of the citations and usage of these publications of Stern and colleagues revealed that the Uphoff and Stern paper in *Science* and the Spencer and Stern paper on acute effects in *Genetics* became widely cited and used to derive key understandings of the nature of the dose response in the low dose zone whereas the Caspari paper was not. This observation gives insight and completion to the earlier comment of Demerek of "how can we save the hit model." Stern had found a way to do it, deceptive that it was. Over the next several years, Muller would take the opportunity in his scientific writings to restate support for the Uphoff findings and to marginalize the Caspari work even though his own findings did just the opposite. Muller inexplicably restated the earlier mantra of Stern that Caspari's control group was aberrantly high, falsely suggesting a threshold, knowing all the while that his own data were used to support the opposite conclusion. In later studies at the University of Indiana, his students would go on to support further the Caspari control group findings. Yet, Muller and Stern would fail to correct the record. Likewise, Caspari who once challenged Stern, now remained silent.

According to James Crow, by the early 1950s, the radiation genetics community had settled on the position that the LNT model needed to replace the threshold dose response for mutation. When BEAR I was created in 1955, I thought there would be considerable debate and discussion within the committee over the nature of the dose response in the low-dose zone, yet there was none, based on the transcripts. This issue had been decided before the panel met, and with the BEAR I Committee Genetics Panel stacked with supporters of Muller's perspective, LNT became established. Muller and the radiation geneticist community used the vehicle of the NAS to finally achieve the long sought after goal to use LNT as the default model in risk assessment. In their committee publications and testifying before Congress, the BEAR I Genetics Panel members demonstrated their high reliance upon the Spencer and Uphoff papers, ignoring that of Caspari. Based on the prestige of the NAS and the failure of the NAS administration to properly evaluate the scientific basis of the BEAR I Genetics Panel report, their recommendations were quickly accepted, generalized to somatic cells, and applied to cancer risk for ionizing radiation and later for chemical carcinogens. This is where we are today. This historical summary is fully reported in a series of publications (Calabrese 2011a, b, c). Now consider how the letter of President Cicerone addressed the historical facts.

The letter of President Cicerone:

1. Omitted reference to the experimental replication efforts of Delta Uphoff (under Stern's direction), their written acknowledgment of unacceptably low control group values and their recognition that certain key experimental results were "uninterpretable." These were conclusions that they themselves provided to the Atomic Energy Commission in a formal manuscript that became classified.
2. Omitted the fact that Muller's own findings, which were to be used to challenge the key mutagenicity threshold

data of Caspari, in the end unequivocally supported the reliability of the control values used in Caspari's study.

3. Failed to acknowledge that Muller was aware that his data not only supported both the Caspari control interpretation and the conclusion of a threshold response but also discredited the LNT conclusion of the Uphoff and Stern studies.
4. Failed to acknowledge that the Stern led discussion in the key Caspari threshold paper (Caspari and Stern 1948) had implored the reader not to accept their findings until they were reconciled with an earlier acute study (Spencer and Stern 1948) that seemed to support a LNT dose–response relationship. Stern wrote this knowing that the two studies differed methodologically in more than two-dozen important aspects and that these studies could never be directly compared. Also, the Caspari study was methodologically far superior to the earlier acute study (Spencer and Stern 1948), which had serious concerns regarding its scientific quality.
5. Failed to note that Muller argued in subsequently published material that the Caspari control group was aberrantly high, an argument that had already soundly dismissed using his own data (see #2). In fact, on this point, the entire set of correspondence between Stern and Muller and all subsequent data that further confirmed this conclusion were documented in my paper. Muller's deception on this critical point was as striking as it was easy to prove. The BEAR I Committee Genetics Panel never acknowledged nor challenged Muller on this point. President Cicerone's letter fails to address it as well.
6. Failed to note that Stern published the "uninterpretable" findings of Uphoff in *Science* without acknowledging that one year earlier, they decreed the same data to be "uninterpretable" due to strikingly low values in the control group (see #1), which was attributed to investigator bias in the discussion of their manuscript.
7. Failed to note that Stern reversed his position on the legitimacy of the Caspari study, leading to its rejection on the basis of high control group data, an already discredited conclusion.
8. Failed to acknowledge that Stern published only a one-page technical note on his five experiments, promising to provide a detailed paper at a later date containing all the data and methods. Yet, this promise was never kept.
9. Failed to acknowledge that the BEAR I Committee Genetics Panel never requested the detailed assessment.
10. Failed to acknowledge that the most reasonable and honest position that Muller could have displayed at the Nobel Prize Lecture was that there was uncertainty over the nature of the dose response in the low-dose zone and that more research was required. However, he strongly asserted that there was no longer any basis to support even the possibility of a threshold model and that a switch to LNT was needed. He did this while knowing the results of the Caspari study, acknowledging privately in writing that the study seriously challenged the LNT, claiming he had no technical criticisms of the study, which was performed by a technically competent investigator, and calling for its replication. Thus, Muller behaved like a scientist in private but as an ideologue in public. There was no scientific basis for his statements.
11. President Cicerone claims that my article contained *ad hominem* remarks about Muller. These remarks claimed that Muller would attempt to win arguments via exaggeration and overstatement, frustrating his supporters. However, President Cicerone failed to state that this characterization of Muller's capacity to exaggerate (i.e., misrepresent) in order to win arguments was not mine but one offered by Muller's former student, colleague, close friend and BEAR Committee member, Professor James Crow (1995).

My article revealed that something seriously wrong occurred with the actions of Stern and Muller, leaders of the radiation genetics community. The failure of BEAR I Committee Genetics Panel to achieve its scientific mission of an objective and detailed appraisal of the scientific foundations of the dose response for mutation was also seriously wrong particularly given its societal importance. Yet, national leaders such as President Cicerone would prefer to protect the image of the NAS and the reputations of Stern and Muller rather than assessing objectively the foundations of the risk assessment scheme they created.

While President Cicerone claims that I have unfairly judged Stern and Muller, he is incorrect. The critical judgment emerges from their actions and words, as documented in open publications, now declassified publications and in publicly available private correspondence. The BEAR I Committee Genetics Panel did not study in detail the key papers upon which the decision on LNT was based, but relied upon the judgments of Stern and Muller. The NAS administration failed to properly vet the actions of this committee. The title of my article is appropriate and its content properly substantiated. It is there to be read by all.

Sincerely,

Edward J. Calabrese, Ph.D.
Professor of Toxicology
Department of Public Health
Environmental Health Sciences
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References

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Michael G. Grey
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December 2, 2013

Canadian Nuclear Safety Commission
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(by email to consultation@cnsc-ccsn.gc.ca)

Re: Discussion Paper DIS-13-01 – Proposal to Amend the Radiation Protection Regulations

Dear Sir/Madam:

Thank you for the opportunity to comment on CNSC Discussion Paper DIS-13-01 (Proposal to Amend the Radiation Protection Regulations). I have provided comments on some section of the Discussion Paper below. I must stress that these comments are purely my own and they do not reflect the opinions of my employer or of any other person, company, association or other body.

Section 4 – Radon Progeny

In general, I support the proposal to base radon dosimetry on 'Dose Conversion Factors' rather than 'Working Levels' however I have not had the opportunity to review the technical aspects of this proposal in detail. I assume that there will be an opportunity to review and comment on the technical aspects of this proposal before the Regulations are amended.

I am, however concerned about the administrative burden of revising training and documentation and the disruption resulting from replacing such a well-established concept as working levels in practice but I assume that the mining companies will comment on this in greater detail.

Section 4 – Dose Constraints

I agree with the conclusion stated in the sixth paragraph of the sub-section of DIS-13-01 entitled 'Dose Constraints' (page 7 of the document), specifically "...it decided that introducing a requirement for dose constraints is unnecessary at this time". While I believe that the 'dose constraint' concept has value, I am concerned that the concept is not well understood by either the radiation protection community or the public and that there is the risk that dose constraints could be misinterpreted as de facto limits.

Section 7 – Nuclear Energy Workers

I have long standing concerns about the 'Nuclear Energy Worker' concept. Specifically, I do not believe it is consistent with normal practice in other areas of 'occupational health & safety'. Occupational Health & Safety Regulations generally address issues related to workers, supervisors and employers and all workers have a right to know about the hazards involved in their work whether they are designated as 'Nuclear Energy Workers' or not. Furthermore, I believe that the NEW concept it is increasingly inconsistent with the reality of the nuclear industry.

I agree with the proposal to replace the term 'Nuclear Energy Worker' with the term 'worker' which would be defined as "a person who performs work that is referred to in a licence". I have spent most of my career working for companies that were not licensees but that did supply services to many different nuclear facilities both inside and outside Canada. Canadian nuclear facilities are changing their business model to make greater use of specialist contractors rather than maintaining all of these capabilities 'in-house'. I do however note that the term 'Nuclear Energy Worker' continues to be used throughout DIS-13-01 so consequence of the transition to 'worker' are not entirely clear.

I would suggest that the 'worker' should be interpreted in a manner that is consistent with other Occupational Health & Safety Regulations which would place responsibility for radiation protection on the employer rather than the licensee. However, this may require a fundamental change in the approach to regulation of radiation protection since the employer may not be a licensee but it would be more consistent with the approach in other areas of occupational health & safety.

Section 11— Pregnant & Breast-feeding NEWs

In over 25 years working in the nuclear industry, I have never encountered a situation where a breast-feeding woman was working in a nuclear facility and given current Canadian practice with regard to maternity leave I find it difficult to imagine that this would be a common occurrence. Consequently, I see little need for the Regulations do address this possibility and I believe that the administrative burden created by the need to produce and maintain the required policies and procedures is likely to significantly outweigh the potential benefit.

Section 13 – Effective Dose Limits

I have never used the formula presented in Section 13 of the current Regulations and I believe that the calculation of effective dose following ICRP guidance is preferable (particularly if the dose from radon progeny can be calculated using dose conversion factors). Consequently, I would agree with the revision of this Section to eliminate (i) the term 'E', (ii) the use of Annual Limits on Intake (ALI) and (iii) the formula presented in Section 13.

I do not agree that this change will not create any administrative burden since policies and procedures will have to be revised to incorporate the change but I do believe that this burden can be justified by the benefit of simplifying the Regulations and compliance with those Regulations.

Section 14 – Equivalent Dose Limits

In general, I agree with the proposed changes but I would suggest that the implementation of the equivalent dose limit for the lens of the eye should be delayed until clear guidance on the calculation of this dose is available.

Schedules 1 and 2

I agree with the proposal to delete these Schedules. I believe that any person who is likely to make use of these factors is likely to rely on the most recent ICRP guidance and that technical issues such as these are best addressed through discussion between technical experts at the licensee and the CNSC.

New Section – Radiation Monitoring Instruments

I understand the concern over the selection, calibration and maintenance of radiation monitoring equipment but I do not believe that the Regulations are the proper place to address this concern in detail. It might be appropriate to include a requirement that all monitoring equipment should be suitable for the intended purpose, properly calibrated and maintained in good working order but the Regulations are not the place for detailed requirements. I also note that this type of requirement is not usually included in other occupational health & safety regulations in Canada (e.g.: Canada Occupational Health & Safety Regulations, Ontario Control of Exposure to Biological or Chemical Agents Regulations, etc.). I am concerned that, as the Regulatory requirements become more detailed, it becomes increasing likely that at least some of the requirements will not be applicable or appropriate to all of the equipment that is available on the market.

New Section – Responsibility for Radiation Protection

I share the CNSC's concern about the qualifications of persons who are responsible for radiation protection in various settings and I believe that many other individuals and organizations also share that concern. I note that it is becoming increasingly common for organizations to require some level of professional competence among those performing radiation protection duties but, since there is no appropriate qualification that is recognized in Canada, I find that they are often resorting to requiring inappropriate qualifications (e.g.: requiring that dose assessments be signed and stamped by a licensed Professional Engineer). This problem is not unique to radiation protection and I am not aware of any other occupational health discipline in Canada that has developed a totally satisfactory solution to this problem. However, while I do not object to including a general statement of expectations of the type proposed in DIS-13-01, I am not convinced that is sufficient to address the concern and I believe that a more detailed discussion of this issue with the nuclear industry and radiation protection community is required.

Please feel free to contact me if you have any questions. I can be reached at the address given above or by email at mike@mggrey.ca.

Sincerely;

Michael G. Grey CHP ROH

From: Steve Staniek [mailto:stevestaniek@gmail.com]
Sent: Sunday, December 08, 2013 11:54 PM
To: Consultation
Subject: StaniekResponse

Hello,
Please find my comments to the proposed amendments to CNSC Regulations…

1. Please consider a serious review of the existing requirements for emergency documentation during transport of nuclear gauges. This document places far too much emphasis on international obligations and not enough on domestic obligations that should be kept in place to protect Canadians. Because of our eagerness to join international campaigns operated by the UN, ICRP, IAEA etc…we seem to have lost sight that Canadian radiological needs may be a bit different and should be addressed differently. International agreements appear to have lowered Canadian safety standards. Here are two instances: a) Unsafe Emergency Documents. The case of international shipping documents like the Shippers Declaration for Dangerous Goods, when used within Canada is unsafe because it is meant to provide emergency safety information but it's in encrypted form. The use of TDG language is an obstacle to safety for the general, untrained public who will probably arrive first at a roadside nuclear emergency and find the strange language unhelpful, and taking the place of a document written in immediately understandable language. b) Waving the Most Important Leak Test. The use of international emergency procedures that do not require leak testing a radioactive source after obvious damage, lowers Canada's regulatory requirement to leak test following damage to a radioactive source. I don't understand how the CNSC can encourage violation of Canadian rules in order to harmonize with international rules that may not work here.
2. Please be clear, and as specific as practical about instrumentation. The CNSC has used "survey meter" as the required general instrument for many years, and it has come to mean many things to many licencees because it is ambiguous. You can perform surveys with many types of meters. It would be much clearer if the regulator specified what kind of measurements they are taking about in their requirements. Are they interested soley in dose rates, or cpm, or both. Ambiguity creates confusion, and many regulatory and licensee mistakes have been made over radiation detection instruments because of a lack of clarify. Perhaps using a general term works best, like: "radiation detection instruments."

Thank you for listening,
Steve Staniek.

Acuren Group Inc.
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Phone: (780) 440-2131
Fax: (780) 440-1167

Materials Engineering and Testing
A Rockwood Company

December 2, 2013

Canadian Nuclear Safety Commission
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Fax: 1-613-995-5086

Attention: consultation@cnsc-ccsn.gc.ca

Re: Feedback on DIS-13-01 Proposed Radiation Protection Regulations

Our company is both a stakeholder and have a current CNSC Industrial Radiography license. Below are our comments related to the proposed changes.

1. **Section 21** Amendment to clarify the requirements for posting signs on vehicles used for storage and that are not consigned for transport.

   Concern: The proposed amendment does not supply what the proposed wording will be. There is no clarification if the correct wording is not supplied. Also RPR Section 21 is currently in conflict with NDRD Section 31(1)k regulation that states that radiation warning signs must be posted to prevent entry into an area where the dose rate is greater than 0.10 mSv/h (100 µSv/h). RPR 21 states that radiation warning signs must be posted when there is reasonable probability that a person in the area, room or enclosure will be exposed to an effective dose rate greater than 25 µSv/h.

   Background information: The last time the wording was changed in this section by CNSC, it created conflict within the industry regarding the posting of signs. NDRD Section 31(1)k is still in conflict with section RPR 21. In 2004 Industry requested clarification on the intent of the regulations, and a response was provided. However there continues to be confusion within the industry and the public still crosses the barriers because the first sign is only meant to be a warning. (See attached Appendix A that provides documentation of the request for clarification and the CNSC response from 2004)

   This conflict within the regulations creates an unclear expectation by all stakeholders. Especially for the public where those radiation warning signs are posted to demarcate a zone that is safe. The unreasonable expectation is that two sets of radiation warning signs are required to satisfy each separate regulation. One posting radiation warning signs at 25 µSv/h and radiation warning signs posted at 0.10 mSv/h (100 µSv/h) . Posting two sets of barriers / signs at any job site creates confusion for a member of the public. As described by the CNSC the first sign is to post warning and the second a barrier. There are a very high number of incidents related to barriers being crossed by the public within our industry.

Since 2004 Industry has voiced concerns and commented to the CNSC. This has been brought to the attention of the CNSC Working Group for Industrial Radiography, and suggestions were to submit through this process to have it corrected.

Proposed Solutions:

The RPR amendment must be clear and provide concise information for the protection of the public. The wording must not create confusion for any stakeholders and requirements regarding the proper for posting of radiation warning signs must be consistent between NSRD and RPR regulations.

Proposed wording:

"21. (1) Every licensee shall post and keep posted, a durable and legible sign that bears the radiation warning symbol set out in Schedule 3 and the words "RAYONNEMENT-DANGER-RADIATION" as follows:

(a) Where there is a radioactive nuclear substance in a quantity greater than 100 times its exemption quantity in storage, a radiation warning sign must be posted to prevent entry at which point the dose rate is greater than 25 µSv/h.

(b) Where there is a radioactive nuclear substance used in a permanent fixed situation (such as a portable level gauge) a radiation warning sign must be posted to prevent entry at which point the dose rate is greater than 25 µSv/h.

21. (2) Subsection (1) does not apply in respect of a vehicle that is placarded in accordance with the Packaging and Transport of Nuclear Substances Regulations.

21. (3) Subsection (1) does not apply where an Exposure Device Operator is posting radiation warning signs to prevent entry into an area where the dose rate may be 0.1 mSv /h as a result of possession or use in NSRD.

References:

- Appendix A – Letter requesting clarification on RPR 21 and NSRD 31(1) from 2004. Response from CNSC.
- CNSC Radiation Protection Regulations – SOR/2000-203 31 May, 2000
- NRC Regulations – Part 20 Standards for Protection Against Radiation. Subsection G
- NRC Regulations – Part 20.1601 Control of access to high radiation areas
- NRC Regulations – Part 20.1901 Caution signs
- NRC Regulations – Part 20.1902 Posting requirements.

If you have any questions you can contact us at 780-440-2131 or tlevey@acuren.com

Sincerely,

Thomas A. Levey
Corporate Radiation Safety Director
Acuren Group Inc.

REQUEST FOR CLARIFICATION ON RPR 21

APPENDIX A
1 OF 4.

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Materials Engineering and Testing
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March 1, 2004

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Attention: Linda Keen

Re: Clarity on CNSC Regulations

We are unsure if you are the correct person to be contacted with our concern. We searched the CNSC website to find an organization chart that would lead us in the right direction to deal with our concern.

Our concern relates to the clarity of the following two regulations:

RPR21.(1) that states: *Every licensee shall post and keep posted, at the boundary of and at every point of access to an area, room, enclosure or vehicle, a durable and legible sign that bears the radiation warning symbol set out in Schedule 3 and the words "RAYONNEMENT – DANGER – RADIATION, if:*

(b)There is reasonable probability that a person in the area, room, enclosure or vehicle will be exposed to an effective dose rate greater than 25 µSv/h.

NSRD 31(1) that states: *Every person who operates an exposure device shall:*

(j) place persons or erect barriers to prevent entry into any area within which the radiation dose rate is greater than 0.1 mSv per hour as a result of the possession or use of the exposure device.

We interpret the above regulations as being contradictory to one another.

History

1. Previous Atomic Energy Control Act stated in 18.14(2)(ii) that placing a sufficient number of signs at the perimeter of an area within which the dose rate at the barrier is greater than 0.1 mSv/hour. 18.14(3) stated that when not possible to control the area and meet 18.14(2) that the dose rate be limited to 2.5 µSv/h measured at the perimeter.
2. Canspec procedures did not change as a result of the new regulations were submitted and have been accepted by CNSC during the transition and renewal of licences from the old regulations to the new CNSC regulations in 2001.

3. Canspec has always limited the dose rate at the perimeter to 0.1mSv/hour where we had control, and 2.5 µSv/h where there was no control. An example would be a public restaurant or property line where we were unsure of occupancy.
4. On August 5, 2003 an inspector notified us that radiation warning signs were not posted at an area where dose was above 25 µSv/h contrary to RPR 21. (see attached CNSC index report 215913 and our reply)
5. When we followed up with phone calls and meetings with CNSC inspectors about the requirements we were told that we need two sets of barriers. 1 set at the 0.1 mSv/hour and another posted at 25 µSv/h to warn the public of the dangers at the 0.1 mSv/hour.
6. We also completed a short survey and asked competitors and other CNSC inspectors of the requirements and received majority comments back that the dose rate at the barrier is to be 0.1 mSv/hour.

As a company we are prepared to follow the correct regulatory requirement but request a final ruling of what applies. We totally disagree that there should be signs at two separate locations as this would confuse the public and add to the disrespect of these important barriers. We already have a problem with the public crossing these barriers and not acknowledging the dangers involved.

We hope that CNSC can resolve this regulation controversy and notify other licensees of the decision that is made. If you have any questions or concerns you can contact me at 780-440-2131. Thank-you.

Sincerely,

Tal Pizzey
Corporate Radiation Safety Officer

cc: Thomas Levey
Marty Larabie CNSC
Anthony Hinton CNSC

Response From CNSC - Copy to Tom Levey

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

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Directorate of Nuclear Substance Regulation

Your file Votre référence

Our file Notre référence

March 19, 2004

15-1-9944

Mr. Tal Pizzey
Corporate Radiation Safety Officer
Canspec Group Inc.
7450 – 18th Street
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Subject: Clarity on CNSC Regulations

Dear Mr. Pizzey:

I am responding to your letter of March 1, 2004, which was addressed to Ms. Linda Keen, President of the Canadian Nuclear Safety Commission.

The regulations are not contradictory. RPR 21(1) refers to the posting of warning signs where dose rates exceed 25 µSv/h (or the area contains greater than 100 times the exemption quantity of a nuclear substance). NS&RD 31(1) (j) is specific to the operation of exposure devices and refers to placing persons or erecting barriers to prevent entry where the radiation dose rate is greater than 0.1 millisieverts per hour (100 µSv/h). Posting a sign in compliance with the radiation protection regulation will not prevent entry, but will warn a person that, beyond the sign, are nuclear substances or radiation dose rates which would not be otherwise encountered. Placing persons or erecting barriers in compliance with the NS&RD regulation is intended, as the regulation says, to prevent entry. Logically, the placement of barriers is at a higher dose rate than the placement of warning signs.

At issue is the burden of placing two sets of signs, one set to warn at 25 µSv/h and another set on the barriers which are intended to prevent entry in accordance with NS&RD 31(1) (k). In practice, two sets of signs are not always required as illustrated in the following examples:

Fab Shop Example
Radiation warning signs are posted at an outer gate or in a parking lot. The dose rate at the warning signs never exceeds 25 μSv/hr and satisfies the RPR requirement. The dose rate at the fab shop door (unlocked) may be higher then 25 μSv/hr but it must be below 100 μSv/hr. Inside the fab shop, at 100 μSv/hr, there must be additional signed barriers or a person to prevent entry.

Pipeline Example
A radiographer has posted sufficient signs on the right-of-way ahead of, as well as behind where radiography is being performed. The dose rate at the warning signs never exceeds 25 μSv/hr and satisfies the RPR requirement. The signs are placed in such a manner that they are visible to anybody who is likely to approach the radiation area. The radiographer may place the signs such that a small number of welds can be evaluated without moving the signs every time the source is exposed. In such circumstances, the radiographer or his co-worker must have full visual control of the radiation area ahead and behind at all times when the source is exposed, so that they can prevent entry and also immediately return the source to the shielded position should any individual approach the exposure area.

If the radiographer or co-worker are unable to maintain continuous visual surveillance of the radiation area, additional signed physical barriers to prevent entry are required. This is usually accomplished by placing signed rope, barrier ribbon or a signed wooden saw-horse across the right-of-way.

If you have any further questions, please do not hesitate to contact me at (613) 947-2054.

Yours sincerely,

R.E. Irwin
Director
Operations Inspection Division

c.c.: L.J. Keen
J.K. Pereira
J.W. Blyth
P. Larkin
R. McCabe
M. Larabie

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2008 BEST SAFETY PERFORMER
WORK SAFE ALBERTA

December 5, 2013

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Attention: consultation@cnsc-ccsn.gc.ca

Re: Feedback on DIS-13-01 Proposed Radiation Protection Regulations

I have read the proposal to the amendment on Radiation Protection Regulations. I support the recommendations made by Thomas Levey asking for clarification on Section 21 and agree that the amendment must be clear and concise.

Sincerely,

Michael Korven
President
AM Inspection Ltd.

To Whom It May Concern:
Stasuk Testing & Inspection Ltd. is a stakeholder being an Industrial Radiography Service company operating under a CNSC NSRD Licence Type 812.

I have reviewed the Proposals to Amend the Radiation Protection Regulations DIS-13-01, and have the following comments:

(1) Clarification of the wording for the radiation dose rate at public boundaries for storage vault areas, as well as during field radiography to include wording similar to the following:

Section 21.
(1) Every licensee shall post and keep posted, a durable and legible sign that bears the radiation warning symbol set out in Schedule 3 and the words "RAYONNEMENT-DANGER-RADIATION" as follows:

Radioactive material in storage:
(a) Where there is a radioactive nuclear substance in a quantity greater than 100 times its exemption quantity in storage, a radiation warning sign must be posted to prevent entry at all accessible entrances or demarcated zones where the dose rate is greater than 25 μSv/h.

Radioactive material in permanent fixed usage:
(b) Where there is a radioactive nuclear substance used in a permanent fixed situation (such as a portable level gauge) a radiation warning sign must be posted to prevent entry at all accessible entrances or demarcated zones where the dose rate is greater than 25 μSv/h.

Radioactive material packaged for transport:
(2) Subsection (1) does not apply in respect of a vehicle that is placarded in accordance with the Packaging and Transport of Nuclear Substances Regulations.

Radioactive material in possession or use:
(3) Subsection (1) does not apply where an Exposure Device Operator is posting radiation warning signs to prevent entry into an area where the dose rate may be 0.1 mSv/h as a result of possession or use in accordance with the NSRD regulations.

(2) Proposed Section on Responsibility for Radiation Protection:
I don't have any specific wording at this point except to ask for clarification on two issues:

(i) What would be the legal position of the person appointed to be responsible for implementing the radiation protection program?
Would this person carry all liability for the failure of the program?

(ii) I'm not sure the administrative burden would be low to moderate. This position sounds like it would carry a lot of responsibility and therefore attract higher wages and possibly liability insurance, disclaimers, guarantees for payment for legal advice and counsel etc.

While the Proposed Section can be clearly stated as an administrative position, it's not clear that this person would not be used as a scapegoat when difficult situations arise and blame is to be placed.

This job description needs to be carefully worded to ensure good people can be recruited for this important position.

This ends my comments and thank you for the opportunity of having input on this subject.

Yours sincerely,
David G. Stasuk, P.Eng.
President
Stasuk Testing & Inspection Ltd.
Burnaby, B.C.

413 March Road
Ottawa, Ontario
Canada K2K 0E4
Tel: 613-591-2100

December 6,2013

Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
280 Slater Street
Ottawa, ON, K1P 5S9

Subject: Comments on DIS-13-01

Best Theratronics has had an opportunity to review discussion paper DIS-13-01 regarding the proposal to amend the Radiation Protection Regulations.

Overall, Best Theratronics believes the proposed amendments provide additional clarity to the regulations and are welcomed.

Best Theratronics does have several comments to help further clarify and strengthen the regulations:

1) With regard to section 7, replacing “nuclear energy worker” with the term “worker”, we believe it would be beneficial to further clarify who “a person who performs work that is referred to in a license” is. In a facility such as ours, persons who perform work referred to in the license are provided dosimetry monitoring. However, there are many other personnel who undertake related manufacturing work that are not monitored. Would the intent be that everyone in our facility would become a “worker” as proposed with the new language? Best Theratronics currently provides basic radiation safety training to all personnel. However, radiation dose levels are currently only being monitored for NEWs. Expanding the definition of worker to all employees within our facility would represent a significant financial and administrative burden without improving the health and safety of personnel.

2) There would be no impact on a change to the definition of the five-year dosimetry period. The doses received by Best Theratronics personnel are very low and do approach the limits set out in the regulations.

3) Given Best Theratronics’ current operation procedures, there is no anticipated impact on implementing the proposed changes to section 15.

4) With respect to section 2.6 regarding timeframe for storage of dose records, the proposed timeframe of not less than 30 years after cessation of the work or a worker age of 75 years may be difficult to implement by licensees. 30 years is a long time for record retention. In that time, the company may have been sold several times or no longer exist. There would be a large administrative burden to implement such a policy. We would argue that one of the key reasons for the National Dose Registry is to provide this long-term repository of dose records and that it should remain as such.

5) The addition of a radiation detection and measurement instrumentation section is welcomed. Such a section would help provide guidance to licensees. Currently, Best

Theratronics has an active calibration program for its radiation detection and measurement instruments. As such, we would not anticipate any further administrative or financial burden in having such a section implemented.

6) The addition of a section on Responsibility for Radiation Protection is also welcomed. The CNSC seems to have taken a graded approach with the onus on the Licensee to identify the qualifications and competencies required and to show the selected individual meets those requirements and qualifications. We believe this is the correct approach as each licensee is different and their licensed activities bear various amounts of risk. Further thought and clarification should be provided with regards to the role of alternate radiation safety officers or alternate radiation protection officers. Can these be appointed by the responsible personnel or would they need to be vetted through licensing process?

Sincerely,

Richard Wassenaar, PhD, MCCPM
Director of Compliance, RSO

TEAM® Industrial Services
TISI Canada Inc.

ISO 9001:2008

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Canadian Nuclear Safety Commission
Regulatory Framework Division
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consultation@cnsc-ccsn.gc.ca

December 5, 2013

This letter represents a formal response and comments by TISI Canada Inc to the CNSC's Discussion paper DIS-13-01 Proposals to Amend the Radiation Protection Regulations.

RPR Section 21:

We have no issue with the proposed change and clarification pertaining to vehicle storage and posting of signs. We would however like to see clarification of Section 21 (1).

Proposed clarification of wording if this is in fact the expectation:

"21. (1) Every licensee shall post and keep posted, a durable and legible sign that bears the radiation warning symbol set out in Schedule 3 and the words "RAYONNEMENT-DANGER-RADIATION" as follows:

(a) Where there is a radioactive nuclear substance in a quantity greater than 100 times its exemption quantity in storage, and/or there is a reasonable probability that a person in the area, room or enclosure will be exposed to an effective dose rate greater than 25 µSv/h, a radiation warning sign must be posted to prevent entry at which point the dose rate is greater than .025mSv/hr. **This is a signed warning of entry into a "Restricted Area".**

(b) Subsection (1) applies *in addition* to where an Exposure Device Operator is posting radiation warning **Signs and Barriers** to prevent entry into a **"Controlled Area"** where the dose rate is set at 0.1 mSv /h as a result of possession or use as per the requirements of NSRD section 31 (1)j&k.

(c) Where there is a radioactive nuclear substance used in a permanent fixed situation (such as a fixed gauges,) a radiation warning sign must be posted to prevent entry at which point the dose rate is greater than 25 µSv/h. (We would like to see requirements or expectations here for low risk cat 5 portable gauges as well if any).

Regards

Team Industrial Services
TISI Canada Inc.

Alan Brady
Compliance Director - CHSO,CHSC
Corporate Radiation Safety Officer
TISI Canada Inc

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nordion
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November 19, 2013

Canadian Nuclear Safety Commission
P.O. Box 1046 Station B
280 Slater Street
Ottawa, ON
K1P 5S9

Re: Comments on Discussion Paper DIS-13-01 Proposals to Amend the *Radiation Protection Regulations*

Nordion (Canada) Inc. has reviewed the Discussion Paper DIS-13-01 Proposals to Amend the *Radiation Protection Regulations* and would like to submit the following comments. Please refer to the attached copies of the Appendix tables, as provided in the discussion paper. Nordion's comments are given in the additional column appended to each table.

Sincerely,

Rick Beekmans
Director, QA EHS Compliance
Nordion (Canada) Inc.

cc: J. Kavanagh – Nordion
R. McGregor – Nordion

Encl.: Copy of Appendix A: Table of Proposed Amendments
Copy of Appendix B: Table of Proposed New Sections

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Copy of Appendix A: Table of Proposed Amendments

Appendix A presents the CNSC's proposed amendments to the *Radiation Protection Regulations*, with comparisons between current requirements and proposed changes.

Nordion's comments are provided in the additional column appended to the table.

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
1	Interpretation		Certain definitions in subsection 1(1) would be deleted, added or changed if the amendments proposed in this paper are adopted.		Nordion agrees in principle.

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Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
2	Application	(1) Subject to subsection (2), these Regulations apply generally for the purposes of the Act. (2) Only section 3 of these Regulations applies to a licensee in respect of a dose of radiation received by or committed to a person (*a*) in the course of the person's examination, diagnosis or treatment, as directed by a medical practitioner who is qualified to examine, diagnose or treat the person under the applicable provincial legislation; or (*b*) [Repealed, SOR/2007-208, s. 5] (*c*) as a result of the person's voluntary participation in a biomedical research study supervised by a medical practitioner who is qualified to provide such supervision under the applicable provincial legislation.	Revision to subsection 2(2) in order to clarify that licensees are exempt from the dose limits with respect to those individuals currently described in paragraphs 2(2)(a), (c) and for caregivers. Removal of link between sections 2 and 3.	To clarify and add completeness about which exemptions apply and to whom.	No comment.

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Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
3	Administration of Nuclear Substances for Medical Purposes	When a nuclear substance is administered to a person for therapeutic purposes, the licensee shall, before the person leaves the place where the substance is administered, inform the person of methods for reducing the exposure of others — including anyone providing care and assistance — to radiation from the person.	Addition of a definition of the term "caregiver" to section 1. Addition of a requirement for licensees to inform caregivers that they may incur radiation exposure that exceeds the dose limit for any person other than a nuclear energy worker.	To clearly state who would qualify as a caregiver. To ensure licensees take reasonable measures to ensure that caregivers are aware that they are acting in such a capacity and accept the minimal risk associated with the potential to exceed the dose limit for any person other than a nuclear energy worker.	No comment.

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Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
4	Radiation Protection Program	Every licensee shall implement a radiation protection program and shall, as part of that program, (a) keep the amount of exposure to radon progeny and the effective dose and equivalent dose received by and committed to persons as low as is reasonably achievable, social and economic factors being taken into account…	Every licensee shall implement a radiation protection program and shall, as part of that program, (a) keep the effective dose and equivalent dose received by and committed to persons as low as is reasonably achievable, social and economic factors being taken into account…	The unique treatment of radon progeny, along with the underlying concepts of "working level" and "working level month", is considered to be unnecessary in the context of the Regulations. Furthermore, the models behind the approach to the calculation of radon progeny dose are currently being revised by the ICRP. It is expected these models will soon be replaced by the concept of dose coefficients (similar to the treatment of intakes of other radionuclides). Removal of the specific reference to radon progeny exposure would align with the proposed simplification of the formula used to calculate total effective dose (found in section 8) with the proposed changes to sections 5, 13 and 19.	No comment on working levels or radon progeny. Nordion agrees with the rationale put forth by the CNSC to forego the introduction of dose constraints.

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
5	Ascertainment and Recording of Doses	(1) For the purpose of keeping a record of doses of radiation in accordance with section 27 of the Act, every licensee shall ascertain and record the magnitude of exposure to radon progeny of each person referred to in that section, as well as the effective dose and equivalent dose received by and committed to that person. (2) A licensee shall ascertain the magnitude of exposure to radon progeny and the effective dose and equivalent dose…	(1) For the purpose of keeping a record of doses of radiation in accordance with section 27 of the Act, every licensee shall ascertain and record the effective dose and equivalent dose received by and committed to each person referred to in that section. (2) A licensee shall ascertain the effective dose and equivalent dose…	Removal of the specific reference to radon progeny exposure in subsections 5(1) and (2) would align with the proposed revisions for sections 4, 13 and 19.	Nordion agrees.
6	Action Levels		No proposed change		
7	Provision of Information	(1) Every licensee shall inform each nuclear energy worker, in writing, (a) that he or she is a nuclear energy worker;	7. (1) Every licensee shall inform each worker, in writing, (a) whether he or she is a nuclear energy worker;	The CNSC proposes replacing the term "nuclear energy worker" with the term "worker" using the existing definition found in the Regulations: "a person who performs work that is referred to in a licence". This change would require an amendment to 7(1)(a). As a result, 7(1)(b), (c), and (d) would apply to all workers.	Nordion agrees.

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
			Addition of a specific requirement to inform all workers of their duties and responsibilities in the event of an emergency.	Introducing this requirement would enhance workers' preparedness and their capacity to respond to emergencies.	Nordion agrees.
		(d) of the worker's radiation dose levels	Amendment to specify that workers be individually informed of their dose results (both effective dose and equivalent dose) on an annual basis.	Currently, section 7 does not specify a time period for reporting dose levels to workers. Moreover, the terminology "in writing" has often been misinterpreted, and it will be clarified via the proposed amendment.	
			Addition of a requirement to subsection 7(1) to include the provision of information to each female worker on the potential risks for a breast-fed infant from intakes of radioactive substances by the worker. Addition of a requirement to subsection 7(2) to ensure that every licensee informs each female worker, in writing, of their rights and obligations as a breast-feeding worker under section 11.	This proposed addition will align the Regulations with the IAEA revised BSS. Refer to section 11 in this table for further proposed changes related to female workers who are breast-feeding.	It could be viewed as an invasion of privacy when the word "obligation" of a breast feeding worker is used. Nordion takes no issue with informing breast feeding workers or with accommodating a requested change in their work duties to avert doses to infants.

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Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
		(3) Every licensee shall obtain from each nuclear energy worker who is informed of the matters referred to in paragraphs (1)(*a*) and (*b*) and subsection (2) a written acknowledgement that the worker has received the information.	Addition of requirement to subsection 7(3) requiring licensees to obtain written acknowledgement from all of their workers of having been informed of the matters referred to in subsections 7(1) and 7(2).		Nordion agrees as long as the requirement to obtain written acknowledgement remains limited to the currently specified subsections 7(1)(a) and 7(1)(b) and would not be extended to 7(1) (d) as this would incur an unreasonable administrative burden.
8	Requirement to Use Licensed Dosimetry Service		Addition of a requirement for licensees to use a licensed dosimetry service to measure and monitor the doses of radiation for nuclear energy workers who have a reasonable probability of receiving an equivalent dose to the skin or the skin of any hand or foot of greater than 50 mSv per year.	The current Regulations have no specific requirements related to the use of a licensed dosimetry service with regard to equivalent dose to the skin, and the skin of any hand or foot. The proposed requirement will clarify the CNSC's expectations.	Nordion agrees. This change is consistent with existing Nordion practice.
9	Collection of Personal Information		No proposed change		
10	Nuclear Energy Worker		No proposed change		

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Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
11	Pregnant Nuclear Energy Worker		Addition of a requirement for a female worker to inform the licensee in writing if she is breast-feeding. Addition of a requirement for a licensee to adapt the working conditions in respect of exposure to the breast-feeding female worker, during both routine operations and emergencies, to ensure the breast-fed infant is protected as required for a member of the public.	To align the Regulations with the IAEA revised BSS and ensure the protection of breast-fed infants.	It could be viewed as an invasion of privacy when the word "obligation" of a breast feeding worker is used. Nordion takes no issue with informing breast feeding workers or with accommodating a requested change in their work duties to avert doses to infants.
12	Interpretation		Certain definitions will be amended or removed as a result of the proposed amendments to section 13.		Nordion agrees in principle.
13	Effective Dose Limits		Amend subsections 13(2),(3) and (4) to describe in written text, as opposed to mathematical formulas, how effective doses are to be calculated. The proposed text would indicate that effective dose would be calculated to include both the sum of relevant doses from external radiation exposures and the sum of relevant committed doses from intakes in the same period.	To simplify and clarify regulatory requirements, while better reflecting how doses are measured and calculated in practice.	Nordion agrees. This does not entail a change in practices at Nordion. Nordion does not have workers near the 20 mSv per year level, and so the 5 year limit has been viewed with little consequence. It presents an unnecessary burden to record and report a five year rolling or five year fixed number to employees. Otherwise Nordion has no comment on a fixed five year or rolling five year limit.

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
		"Hands and feet" are referenced in item 3, under column 1 in the table outlined in section 14.	Removal of direct reference to radon and radon progeny as well as the related terms of "working level" and "working level month".	The unique treatment of radon progeny, along with the underlying concepts of the working level and the working level month, are considered to be unnecessary in the context of the Regulations. Furthermore, the models behind the approach to the calculation of radon progeny dose are currently being revised by the ICRP. It is expected these models will soon be replaced by the concept of dose coefficients (similar to the treatment of intakes of other radionuclides). The removal of specific references to radon and radon progeny, along with the terms "working level" and "working level month", would align with other similar changes proposed for sections 4, 5, and 19.	Nordion agrees.
14	Equivalent Dose Limits	The dose limit in item 1, under column 4 in the table outlined in section 14.	Amendment to the wording "hands and feet" to read "the skin of each hand and foot".	To clarify terminology to more accurately reflect both of the following: the actual measurement of equivalent dose to the hands and feet, and the intent of the dose limit.	Nordion agrees.

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
			Amendment to the dose limit for the lens of an eye for a nuclear energy worker from the current limit of 150 mSv per one-year dosimetry period to 50 mSv per one-year dosimetry period. Addition of a new dose limit for the lens of an eye for a nuclear energy worker of 100 mSv per five-year dosimetry period.	To align the dose limits for the lens of an eye with the ICRP's latest recommendation, in order to protect workers' health and safety.	The Licenced Dosimetry Service Nordion uses measures dose to the lens of the eye, but does not report it on the printed report. Nordion can view this information on the electronic database of the Licenced Dosimetry service provider. Results do not approach existing or proposed limits. Nordion workers are further protected by wearing safety glasses, and dosimeters do not account for this protection. Therefore, assessing doses to the lens of the eye of workers at Nordion would not be overly burdensome.

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
15	Emergencies		Replace current text with new text that incorporates relevant clauses from the IAEA revised BSS with respect to dose limits for emergencies. Introduce new requirements for when dose limits are exceeded during an emergency and for the associated return-to-work processes for workers. The proposed text for section 15 is described in detail in the discussion paper.	To address the CNSC Task Force recommendation that the Radiation Protection Regulations be amended to be more consistent with international guidance and to more fully describe the regulatory requirements needed to address radiological hazards during the phases of an emergency. Section 15 is proposed as a stand-alone section dealing with all aspects of an emergency, including: the applicable dose limits, the requirements for and actions to be taken when emergency dose limits are exceeded, and the required process for the transition from emergency-related work to future work activities for persons who have exceeded a dose limit(s) during the emergency.	Nordion agrees.

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
16	When Dose Limit Exceeded		Amendment that would require a person to be removed from work that is likely to add to his or her dose, if the person may have or has exceeded any of the dose limits that apply to nuclear energy workers or pregnant nuclear energy workers, as specified in sections 13 and 14. Removal of the specific reference to section 15.	To ensure that regulatory requirements are risk-based, while reducing administrative and financial burden associated with removing a person from work when he or she has exceeded a dose limit for any person other than a nuclear energy worker. Section 15 is proposed as a stand-alone section dealing with all aspects of the emergency, including the requirements for and actions to be taken when emergency dose limits are exceeded.	Nordion agrees.
17	Authorization of Return to Work	18(b) the proposed quality assurance program	Removal of subsections 17(2) and (3)	To allow for flexibility in the determination of future dose limits for the purposes of authorizing the return to work of a person who exceeds a dose limit, as specified in section 16.	Nordion agrees.

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
18	Application for License to Operate	18(c) the types of dosimetry services proposed to be provided, including the types of radiation that will be monitored and their respective energy ranges;	18(b) the proposed quality assurance program, including the following elements: management policy; quality assurance program description; review by management; organization and authority; personnel qualifications; procurement; work control; change control; document control; calibration and maintenance; verification; non-conformance; corrective actions; records; and independent audits.	To reflect requirements of S-106, Technical and Quality Assurance Requirements for Dosimetry Services, Revision 1, that are already being implemented by licensees. The amendment would incorporate requirements that apply to all licensed dosimetry services.	No comment.
		18(d) the precision, accuracy and reliability of the dosimetry services to be provided; and	18(c) the types of dosimetry services proposed to be provided;		No comment.
			18(d) the precision, accuracy and reliability of the dosimetry services to be provided, including the provisions for independent testing and a demonstration of successful completion of the independent test;		No comment.
19	Obligations of Licensees		Addition of a requirement that the licensees whose NEWs are monitored by a licensed dosimetry service must provide the required information to the licensed dosimetry service, for the purpose of reporting doses to the National Dose Registry.	To provide licensed dosimetry services with the means to require clients (i.e., CNSC licensees) who need licensed dosimetry services to provide the information specified in the Regulations (see sections 10 and 19 in this table).	No comment.

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
			Addition of a requirement for the licensed dosimetry service to notify the CNSC in writing immediately following the failure of a independent or performance test, and to submit a detailed report, within 30 days of the test failure, outlining the causes of the event and corrective actions.	This requirement already applies to all licensed dosimetry services in Canada and has been stated in S-106, Technical and Quality Assurance Requirements for Dosimetry Services, Revision 1. However, it would be more appropriately captured in regulation.	No comment.
20	Labelling of Containers and Devices		Addition of a requirement to subsection 20(2) that would exempt persons who meet the terms of the exemption for radium luminous devices from the requirements in paragraphs 20(1)(a) and (b).	To align requirements in the Regulations with the licensing exemption listed in section 8 of the Nuclear Substances and Radiation Devices Regulations, in relation to persons possessing, transferring or using radium luminous devices that contain only radium, and that are not disassembled or tampered with.	Nordion agrees.
21	Posting of Signs at Boundaries and Points of Access		Amendment to clarify the requirements for posting signs on vehicles used for storage and that are not consigned for transport.	To clarify the CNSC's expectations for situations in which a vehicle does not require signage in accordance with the Packaging and Transport of Nuclear Substances Regulations.	No comment.
22	Use of Radiation Warning Symbols		No proposed change		

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
23	Frivolous Posting of Signs		No proposed change		
24	Records to be Kept by Licensees		Amendment to clarify the retention period required for dose records, and/or to state the specific time period for the retention of records of doses generated in accordance with subsection 5(1).	To promote consistency among licensees and to clarify CNSC expectations with respect to the required retention period for dose records.	Nordion agrees.
25	Transitional Provisions		Amend section 25 in one of the following ways: 1.Remove section 25 entirely. 2. Revise section 25 to provide transitional provisions for the coming into force of the new Radiation Protection Regulations, with consideration given to possible changes to the definition of a "five year dosimetry period".	1. If there is no change to the current definition of the "five-year dosimetry period", the current section 25 will no longer be required. 2. This is because the dosimetry periods have been defined and applied since the Regulations came into force in the year 2000. 2. If a change is made to the definition of the "five-year dosimetry period", section 25 would require an amendment to identify the transitional provisions.	Nordion agrees.
26	Coming into Force		No proposed change		

Section	Title	Current *Radiation Protection Regulations* (SOR/2000-203)	Proposed amendment	Comments/rationale	Nordion's comments
Schedule 1	Organ or Tissue Weighting Factors		Removal of Schedule 1.	Removing the schedule would avoid the need for further amendments if there are changes to the recommended weighting factors. Furthermore, licensees rarely use the actual weighting factors in dose calculations, so there is no benefit to including the values in the Regulations.	Nordion agrees.
Schedule 2	Radiation Weighting Factors		Removal of Schedule 2.	Removing the schedule would avoid the need for further regulatory amendments if changes are made to the recommended weighting factors. Furthermore, licensees rarely use the actual weighting factors in dose calculations, so there is no benefit to including the values in the Regulations.	Nordion agrees.

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Copy of Appendix B: Table of Proposed New Sections

Appendix B presents the CNSC's proposals for new sections to the *Radiation Protection Regulations.*

Nordion's comments are provided in the additional column appended to the table.

Proposed new section	Comments/rationale	Nordion's comments
Radiation Detection and Measurement Instrumentation	This proposed new section would include requirements related to the provision and use of radiation detection and monitoring equipment. The CNSC is also considering requirements for each radiation detection and monitoring instrument to be calibrated in accordance with an established international standard, such as IAEA Safety Report Series, No. 16, Calibration of Radiation Protection Monitoring Instrument.	Nordion agrees.
Responsibility for Radiation Protection	This proposed new section would introduce a requirement for every licensee to appoint, within its organization, a person or position responsible for the implementation of the radiation protection program. The licensee would be required to identify the qualifications and competencies required for the responsible person, and to demonstrate to the CNSC that the selected individual meets and maintains the minimum competency and qualification requirements. The licensee would also be required to notify the CNSC of the appointment (and any change) of the responsible person.	This wording makes sense for smaller organization, but for larger organizations the regulations require clarity. It would be challenging to appoint one person for this role in a larger organization. This work is done by teams and departments with responsibility being born by a combination of technical experts and management.

AECL EACL

COMPLIANCE
Regulatory Affairs
145-ACNO-13-0024-L
RA-13-030

UNRESTRICTED

2013 December 04

Mr. M. Dallaire
Director General, Regulatory Policy Directorate
Canadian Nuclear Safety Commission
280 Slater Street
P.O. Box 1046, Station B
OTTAWA, Ontario K1P 5S9

Dear Mr. Dallaire:

AECL's Comments on Discussion Paper DIS-13-01: Proposals to Amend the Radiation Protection Regulations

The purpose of this letter is to provide AECL's comments on CNSC Discussion Paper DIS-13-01, *Proposals to Amend the Radiation Protection Regulations*.

AECL has collaborated with Bruce Power, New Brunswick Power Nuclear, and Ontario Power Generation to review the proposed DIS-13-01 in detail and the comments are provided in Attachment A.

There are 13 major comments that must be addressed to make the proposed amendments acceptable to AECL.

AECL appreciates the opportunity to provide a feedback on this regulatory document and is prepared to clarify any comments or concerns.

If you require further information or have any questions regarding this submission, please contact me as below.

Yours sincerely,

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Regulatory Affairs
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TA/mj
Attachment

c C. Carrier (CNSC)

Consultations (CNSC)

A. Bugg	S. K. Cotnam	C. de Vries	J.D. Garrick
R.M. Lesco	S. Mistry	S. Needham	U. Senaratne
K.L. Smith	C.E. Taylor	R. Walker	
>CR CNSC Site Office	>CR Licensing	>SRC	

Attachment A

Industry Comments on Discussion Paper DIS-13-01, Proposals to Amend the Radiation Protection Regulations

#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
1.	2.2 Section 3 Administration of nuclear substance for medical purposes Page 6 "*…require licensees to inform caregivers that they may incur radiation exposure above the dose limit for any person other than a nuclear energy worker, during their comfort and care of patients*."	The proposed definition of "caregiver" does not consider people who are being hired by a member of the public to look after patients who have been administered with nuclear substance(s).	Amend definition to include persons hired by members of the public to look after patients who have been administered with nuclear substance(s).	Clarification	
2.	Dose constraints 2.2 section 4 page 7		Industry agrees with the proposed amendment - not to include the dose constraints due to robust ALARA programs that are already in place in the nuclear industry.		
3.	**2.2 Section 7** **Provision of information to all workers.** **Page 8** **3rd paragraph–** **"*the CNSC proposes to replace the term "nuclear energy worker" in section 7 of the***	**CNSC proposal to require all workers performing work that is referred to in a licence to have information and training provided on radiological dose risks, dose limits, and individual dose levels poses an unnecessary burden on the industry.**	**Industry suggests that the CNSC either continues using the term *"nuclear energy worker"* or replaces it with something like *"exposed worker" and* can be defined as "a person who performs work referred to in a licence where the work has**	**Major**	**The proposed change could result in a high administrative and cost burden with little demonstrated safety benefit. For workers (including contractors) who are not expected to receive doses any greater than those received by the public, the additional requirement would not result in improved safety.**

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	Regulations with the term "worker", using the following existing definition: "a person who performs work that is referred to in a licence*."** **4th paragraph -** **"*If this change is adopted… written acknowledgement from all of their workers…" **pg. 8, 5th paragraph – "*CNSC proposes that workers be informed of their dose limits...on an annual basis..."*** **The wording in the 3rd and 4th paragraphs on page 8 of the discussion paper is confusing. The 3rd paragraph states that the term "nuclear energy worker" will be replaced by the term "worker". The 4th paragraph, states that in paragraph 7(1)(a) every worker would be informed whether he or she is a NEW. The 3rd paragraph on its own implies that the term NEW will no longer be used.** **The definition of "worker" is operationally very vague. For example, a clerk in a nuclear plant might work only in the Administration building and never go into the plant. Another clerk might make daily trips into the radiological areas and wear a TLD badge. Clarity in the terminology to understand the scope is required.**	**potential to expose the worker to a recordable dose" or replaces it with "all workers in security protected areas or radiological zones".**		**In addition, the lack in clarity on the terminology could result in confusion and inconsistency in compliance.** **Dosimetry monitoring of non-NEWs is not necessarily conducted presently. Reporting individual exposures to non-NEWs would require a change to the current risk-informed practices which apply the use of dosimeters when warranted by dose.**
4.	2.2 Section 7 Provision of information to all workers.	Clarity is required to ensure the written notification can also occur by electronic means.	Industry suggests adding the word *"electronic"* to the last sentence in the 4th paragraph. It would read *"Similarly, subsection*	Clarification	

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	Page 8 4th paragraph - *"If this change is adopted… written acknowledgement from all of their workers…"* pg. 8, 5th paragraph – "*CNSC proposes that workers be informed of their dose limits...on an annual basis..."*		*(3) would need an amendment requiring licensees to obtain electronic and/or written acknowledgement from all of their workers of having been informed of the matters referred to in subsections 7(1) and (2)."*		
5.	2.2 Section 7 Provision of information to all workers. Page 8 '*The CNSC proposes to expand the requirements in subsection 7(1) of the Regulations to include the provision of information, to each female worker, on the potential risks to breast-fed infants from intakes of radioactive substances by the worker, during both routine operations and emergencies*"	It is assumed that the provision of information requirement would be in place as long as breast feeding is occurring. In section 11 it is mentioned that the employee will need to inform supervision of the start date; they may also need to do the same for the end date.	Add end date also for the accommodation.	Clarification	
6.	**2.2 section 7 Additional requirement related to emergencies page 8**	**Again, the application to all workers is too broad. Likewise to the previous comment about risk information, a proposed**	**A note should be added as follows: "*It is understood that in certain emergency situations, staff may***	**Major**	**Provision limits licensee ability to assign additional duties in case of emergency, where real-time response and job assignment may be required.**

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	"… the CNSC proposes to introduce a requirement to subsection 7(1) for all licensees to inform all workers of their duties and responsibilities in the event of an emergency."	**requirement to inform "all workers" of their duties and responsibilities during an emergency, and the associated health risks and how they should protect themselves, is likely excessive, e.g. casual part-time employees and contractors who may simply be providing painting or custodial duties to administration buildings outside the radiological zones and outside the protected area. These people are no more at risk than members of the public in the primary zone around the plant.**	***be required to perform additional duties which may not have been anticipated in advance. In such cases, it is acceptable for the licensee to provide work assignments and pre-job briefings at the time of the event as appropriate to meet the intent of this provision."***		
7.	**2.2 section 7** **Additional requirement related to emergencies** **page 8**	**The proposed requirement is to inform "all workers" of their duties in an emergency. Does this requirement extend to non-licensee staff responding to a nuclear event?** **During an event, members of the off-site work force may support the response, and it is not clear if they would be considered as "workers" who would require notification. Planned responses**	**A note should be added as follows:** **"*It is understood that in certain emergency situations, additional staff from off-site organizations may be required to perform additional duties which may not have been anticipated in advance. In such cases, it is acceptable for the licensee to provide work assignments and pre-job briefings at the time of***	**Major**	**Providing this information to off-site authorities would result in a significant burden to licensees, such as training and logistics. This may not be feasible in an emergency situation.**

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		are included in training and development of off-site organization training and development, but licensees cannot track all changes within these organization.	***the event as appropriate to meet the intent of this provision*."**		
8.	**Page 9** **Female workers with respect to breast-feeding.** ***"… to include the provision of information, to each female worker, on the potential risks to breast-fed infants from intakes of radioactive substances by the worker, during both routine operations and emergencies."***	**Currently, radiation protection procedures require female workers to inform their Supervisors in writing of their pregnancy as well as their intention of breast-feeding. According to the procedures, accommodation will be made for those individuals.** **However, implementing this change to all female workers will carry some administrative burden as significant amount of documentation, training materials and communication need to be revised and/or developed.** **In some very special cases, how is this proposed revision applied for transgender individual(s)?**	**Add the qualification: This information to be provided to a female worker who is not normally potentially exposed after she has notified the licensee of her pregnancy.**	**Major**	**Implementing this change to all female workers will carry some administrative burden as a significant amount of documentation, training materials and communication need to be revised and/or developed.**

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9.	**Page 9** ***"…inform all female workers, in writing, of their obligations as breast-feeding workers under section 11."***	**It is not clear whether this applies to non-licensee staff responding to an event. It is not practical to ask this question at the time of the response.**	**Revise to state "this does not apply to emergency responders e.g. ambulance, who would not normally be exposed."**	**Major**	**Industry would not support this applying to all emergency workers. This would be a significant administrative burden with no apparent safety benefit, and could result in a delay to a non-radiological emergency response.**
10.	2.2 Section 8 Requirements to Use Licensed Dosimetry Service (LDS) Pg. 10, paragraphs 2, 3 & 4 – *"The CNSC is proposing that a licensee must also use a LDS … measuring dose to the lens of the eye."*	This proposed amendment is not an issue for industry, as the equivalent dose to the skin of the whole body is measured by Whole Body TLD and reported on. Further, equivalent doses to the skin of hands and feet are measured by extremity TLD, and reported on. Industry expects that the proposed amendment will not result in a significant incremental administrative burden. Industry understands that this amendment is regarding the use of a dosimeter during the routine operations of a licensee. The proposed amendment is not intended to require a licensed dosimetry service to interpret skin contamination events that may have occurred. If not correct, additional clarification is	Revise to state that LDS is not required for dose determination for skin contamination events.	Clarification	

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		needed. Industry supports the CNSC position not to require the use of licensed dosimetry service to measure dose to the lens of the eye as we do not believe this service is available; we note that this points to a problem with prematurely adopting a recent a recent ICRP proposal whose practical implications have not been fully assessed.			
11.	**Section 11** **Page10** **Pregnant NEWs** ***"… a requirement for a female worker to inform the licensee in writing if she is breast-feeding."***	**If the direction is to move from having most or all or more workers established as the equivalent of NEWs or as "workers" then all female workers in this category will need to inform the licensees in writing. Industry is not sure how this will be treated for workers who are not actually doing radiation work or entering the protected areas. It could be viewed as a privacy issue by those who are not anticipating being treated as NEWs. This may cause unnecessary anxiety / concern to those workers.**	**While it is acceptable/reasonable to implement this new proposed requirement for female NEWs, it is recommended that the term "nuclear energy worker" continues to be used in order to distinguish between those who are potentially exposed to ionizing radiation vs. those are not. Similar to comments for section 7 documented earlier, it is also recommended that this requirement is only applied when or after the NEW worker has notified the licensee of her pregnancy.**	**Major**	**Unless this requirement specifically applies to those (females) who are potential receiving a recordable dose, it would be a challenge to implement these requirements due to the privacy/anxiety concern.** **If this requirement only applies to female NEWs instead of all workers, the administrative burden would be reduced significantly and be easier to implement.** **If this proposed requirement applies to all female workers (non-NEWs), it introduces significant cost with no apparent safety benefit.**

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12.	2.3 Section 13 Effective Dose Limits Page 11 *"… the CNSC suggests using written text (as opposed to formulas) to describe how effective doses are to be calculated*	It is unusual that a calculated value is to be replaced with a written text to describe how to perform a calculation. Industry does not support this approach although industry concurs with the wording to describe how the "effective dose" is calculated.	Industry recommends including both written text and mathematical formulas in the document. Alternatively, the CNSC could reference an accepted standard, e.g. ICRP regarding methodology for calculating doses.	Clarification	
13.	Section 13 Effective Dose Limits Page 11 *"The CNSC proposes to replace the use of ALI with dose coefficients to directly calculate the effective dose of any component."*	Industry understands the replacement of ALI would only be for official dose assignment, and is not applicable to any other use of the term.	Modify document to note that licensee may use the terminology in other applications such as work planning.	Clarification	
14.	Section 13 Effective Dose Limits Page 11 *"… the CNSC proposes to eliminate the term "E", as defined in subsection 12(1) of the existing Regulations."*		Industry concurs with the proposed change.		
15.	**Section 14 page 14 Equivalent dose limits for the lens of the eye**	**There has been considerable controversy about the new dose limit. The step change in**	**Since this is a significant change and it does have a significant impact on nuclear industry,**	**Major**	**Reducing the dose limit for the eye is not justified – it imposes significant administrative burden and cost without benefit.**

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	Pg. 14 - "*… the CNSC proposes the following:* • ***to change the equivalent dose limit for the lens of the eye for a NEW from the current limit of 150 mSv to 50 mSv in a one-year dosimetry period*** • ***to add a new dose limit of 100 mSv in a five-year dosimetry period."***	**threshold dose from 5 Sv to 0.5 Sv and lowering the dose limit from 150 mSv to 20 mSv (averaged over 5 years) recommended by the ICRP is drastic and may cause undue concern or anxiety to workers. The question will likely come up: what about all the years our workers were working in these environments. The regulator may have to participate in the response to workers on this issue.** **As noted in the column labelled "Impact on industry if major comment", there are a number of new steps that the industry will have to undertake to demonstrate compliance with the new limits.** **Although these issues can be settled with significant effort and expenditures, there are more serious issues with the bases for the proposed regulations, which are taken directly from a recent publication by the International Committee on Radiological**	**unavailability of approved eye dosimeter (currently) and since cataracts are treatable while cancer is life threatening, industry proposes the dose limit for the lens of the eye for a nuclear energy worker (NEW) as follows:** ***"100 mSv per one-year dosimetry period and 250 mSv per five-year dosimetry period."*** **The proposed change has the following benefits:** • **The dose limits are low enough to make it necessary to provide additional protection for those workers who are exposed to significant eye doses.** • **Eye dose would not be limiting for cases where the eyes were exposed to radiation fields only moderately higher than for the rest of the body.** • **The higher limit would possibly obviate the need for eye dosimetry for most workers, except for the most**		**The costs to implement will be significant, though dependant on impact of CNSC acceptable methodologies to compute non licensed dose. If instrumentation, even if unlicensed, is the only acceptable methodology, those development and implementation costs will be significant. There will also be software development costs. In addition these limits as written will reduce the manpower available to perform the required work thus new workers will have to be trained to perform the same work. If the acceptable methodology is a paper evaluation of the Head and Trunk results to compute lens of eye dose, the costs will be significantly reduced.** **There are technical issues with determining eye dose at this time; therefore there is no way for licensees to consistently demonstrate compliance with the proposed reduced limits.** **This has significant impact for radiological work in non-uniform fields as this affects our whole concept of Head & Trunk Dosimetry. This will be a burden during outages, increasing the number of workers required to complete some work scope.** **This change is significant for an effect that is**

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		Protection (ICRP), ICRP 118 (ICRP Statement on Tissue Reactions and Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context, 2012), along with its statement on tissue reactions. The ICRP began work on the main document in 2005, and issued it for comment as a 315 page document in January 2011. On April 21, 2011, the ICRP issued its statement on tissue reactions, along with its new recommended eye dose limit, with no consultation whatsoever. The final version of ICRP 118 was issued in early 2012. The following are some of the issues that have been identified with the bases for the ICRP's new eye dose limit: • **The eye dose limit is based on a new recommended deterministic threshold of 0. 5 Sv, based on a 1% incidence of clinical opacities in the eye, instead of the more serious**	**highly exposed.** • **The higher dose limit would avoid "nuisance" overexposures where the dose limit was exceeded by a small amount, perhaps because of the uncertainty of measuring the incremental eye dose above the effective dose.** **On the issue of the proposed change to the equivalent dose limits to the lens of the eye, industry recommends that changes to this section of the regulations be delayed until a practical way to measure lens of the eye doses is available that could meet the requirements of a licensed dosimetry service. The fact that the CNSC has proposed that using a licensed dosimetry service is not required for this type of dose measurement is a tacit and realistic assessment that this is not possible at the moment. We believe that this is an area of changing science and that risk from radiation doses to the lens**		**treatable in many cases, especially in countries like Canada. Guidance for licensees in how to ascertain and report dose to the lens of the eye is needed. It should be noted that NRC in the U.S. has not accepted the ICRP recommendation and will not be changing the dose limits to the lens of the eye. This change in the RP Regulations will be a burden to licensees that does not make sense considering the effect that cataracts have on workers. It is difficult to ascertain that radiation exposure was the only causal factor for cataracts in an aging worker, as this condition is very common in an aging population.**

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		detriment of cataracts. The threshold dose is ten times lower than the previous recommended threshold value of 5 Sv. • **The rate of cataracts increases significantly with age, reaching approximately 30% at age 70. Such a high natural incidence rate makes it especially difficult to specify an additional incidence rate of only 1% with reasonable accuracy.** • **Cataracts are readily treatable in developed countries, which are the ones most likely to use significant quantities of ionizing radiation.** • **The effective dose limit is based primarily on a rate of 5% per Sv estimate for detriment, primarily from the risk of <u>fatal</u> cancer. If linearity of cataract formation is assumed, a 1 Sv dose to the eye would result in a cataract incidence rate of 2%. It is not clear why the ICRP considers**	**of the eye is much less serious than other types of radiation exposures. As such, it does not pose an immediate concern and industry recommends that the higher dose limit be retained at this time.**		

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		this lower incidence rate of cataracts, usually readily treatable, to be equivalent to the higher risk of fatal cancer. Cancer is considered to be a stochastic risk while cataract formation is thought to be a deterministic effect. However, there is some doubt about this, and cataracts may be also be a stochastic effect (at least at low doses). Given the significant amount of uncertainty about the incidence rate as well as the etiology of cataract formation, it would have been more appropriate for the ICRP to have recommended a higher dose limit. If one assumes that linearity of cataract formation with dose still holds at doses above 1 Sv, it would take a dose of 2.5 Sv to produce an incidence rate of 5%. One could therefore argue that a suitable dose limit might therefore be 2.5 times the average dose limit			

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		of 20 mSv/y for effective dose, or 50 mSv/y. For operational flexibility, see the dose limits identified in the "Suggested Change" column. • **One other item to note is that typically operational practices evolve to keep the actual doses received for most workers to be well below the dose limits. Even with the higher dose limits it is likely that most workers will receive doses at or below the new dose limits recommended by the ICRP.**			

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16.	Section 14 Equivalent dose limits for the lens of the eye Pg. 14 - "*… the CNSC proposes the following:* • *to change the equivalent dose limit for the lens of the eye for a NEW from the current limit of 150 mSv to 50 mSv in a one-year dosimetry period* • *to add a new dose limit of 100 mSv in a five-year dosimetry period*."	If the dose limit to lens of eye for a non-NEW remains unchanged, does this impact the management of non-licensee staff responding to an event?	Revise to state that this does apply to non-licensee staff responding to an event.	Clarification	
17.	Section 15 Emergencies Page 15 -*"...the applicable dose limits for effective and equivalent doses to persons (as proposed below) must be considered discrete and separate from the dose limits…"*	This proposed change is reasonable and it facilitates facilities to deploy urgent emergency actions. It would definitely eliminate lot of confusion during an emergency situation.	Industry supports this proposed change.		
18.	Section 15 Page 16	The CNSC has used Task 1 and Task 2 with different definitions than the IAEA in GSR 3 (Interim). This may cause confusion.	Consider changing the titles to Task A and Task B to avoid confusion, or adopting the IAEA task numbering convention.	Clarification	

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19.	Section 15 Page 16 "*Females who have declared that they are pregnant shall not be involved in the control of an emergency…"*	Does this provision also apply to women who are breast-feeding?	Should read "…*declared that they are pregnant or breast-feeding…"*	Clarification	
20.	Section 15 Page 17 "*…immediately notify the person and the Commission of the dose:"*	Industry has a concern regarding the proposed requirement to "*immediately*" notify the Commission of the dose to an individual if an emergency dose limit is exceeded. This may not be practicable in certain cases due to safety priorities during the emergency.	Suggest to change bullet 1 to: • *immediately notify the person of the dose, and as soon as practicable, notify Commission staff of the dose;*	Clarification	
21.	Section 16 When Dose Limit Exceeded Page 17	Industry concurs with the proposed amendment.			
22.	Section 17 Authorization of Return to Work Page 18	Industry concurs with the proposed amendment.			
23.	Section 2.4 Dosimetry Services Pg 18-19	There is little value in including this information, since those licensed as dosimetry service providers are required to comply with this Regulatory Standard. Why add requirements from this standard and not others…	Leave the information covered in S-106 out of the RP Regulations.	Clarification	

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24.	Section 19 Obligations of Licensees Pg. 19 – 2nd paragraph *"… that their clients (i.e. CNSC licensees) must submit to them to the necessary information…"*	There is an extra word "to" in the sentence and should be removed.	The paragraph should read. **"***In order for licensed dosimetry services to comply with the requirement to report to the NDR, it is implied – but not explicitly stated – that their clients (i.e., CNSC licensees) must submit to them* ~~***to***~~ *the necessary personal information for each NEW being monitored*."	Clarification	
25.	Section 20 Labelling of containers and devices Pg. 20 – **"***Since January 2006, under an exemption granted by the Commission … a person may possess, transfer or use an unlimited number of radium luminous devices without a licence…"*	Industry cannot locate any documentation that describes this exemption. The phrase "unlimited number" has been quoted incorrectly. Section 8(b) in the existing NSRD Regulations stipulates the possession limit of those devices as follow - "*the person does not possess more than 10 such devices*".	Please provide some guidance on how to find/locate the mentioned exemption documentation. Review wording in the NSRD regulations to ensure alignment.	Clarification	
26.	**Section 20,** **Labelling containers and devices** **2.5 Item 78**	**The requirement of labelling of waste containers.** **The existing wording is confusing, in that it is sometimes interpreted very broadly by inspectors, that waste containers**	**Industry recommends that the hazard information labelled on waste containers should display dose-rate only, rather than radionuclide, form and activity.**	**Major**	**The lack of clarity poses a regulatory risk to licensees for no safety benefit. As long as the hazard in terms of dose-rate is shown, workers are better protected than by providing more technical but less immediately-useful information such as**

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		in use in the field (i.e. in the process of collecting waste in the field, being collected and handled, being processed, BUT NOT YET QUANTIFIED), as requiring the radionuclide, form, activity, to be marked on the container. This is not physically possible for waste that has not yet been quantified by measurement or calculation.			**radionuclide, form, activity.**
27.	**Section 20**	**Issues with application of current requirements. Different regulations make it extremely difficult for licensees to comply, such as requirement to label specific radionuclide content of containers.**	**Further exemptions are required in 20 (2) to remove:** **A) the requirement for labelling of individual radioactive waste packages or items within an access controlled waste container that is already signed and labelled as per 20. (1) (a) and (b), and** **B) the labelling of containers of radioactive substances as per 20. (1) (a) and (b) that are contained within an access controlled room that is already signed and labelled as per the requirements of 21. (a) and (b).** **In case B in lieu of full labelling**	**Major**	**Unnecessary administrative burden to create affix and maintain full information labels and non-ALARA actions to address non-compliances.**

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			the containers, uniquely identifying the containers and a database record of their contents would meet the intent of 20. (1) (a) and (b).		
28.	**Section 24** **Records to be Kept by Licensees: "retention of dose records using the IAEA revised BSS as a benchmark"**	**The National Dose Registry (NDR) is the repository for dose records and as such should be where dose records are retained over a worker's life. If it is desired for licensees to have auditable records, a shorter retention time would be more appropriate**	**Industry recommends that records of doses generated be retained by the licensee for a period of 5 years and by the NDR permanently.** **The NDR becomes the official permanent record repository for dose.** **Industry would welcome further discussion on implementation to reduce the administrative burden on retaining these records.**	**Major**	**The administrative burden related to records retention is excessive, with records of dose recorded in the National Dose Registry.** **As per Health Canada, the purpose of the NDR is as follows:** • **Assist in regulatory control by notifying regulatory authorities of overexposures within their jurisdiction.** • **Evaluate dose trends and statistics to answer requests from regulators and others.** • **Contribute to health research and to the scientific knowledge on risks from occupational exposure to ionizing radiation.** • **Provide dose histories to individual workers and organizations for work planning and for compensation and litigation cases**
29.	Section 24 Page 21 4th paragraph "*records of each worker shall be maintained during and after the*	Industry has concerns with retaining records of dose for all workers.	Refer to previous comments on "worker"	Clarification	

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	worker's working life…"				
30.	**Proposed New Section 3.1 Radiation Detection and Measurement Instrumentation Pg. 24 –"*…The CNSC is proposing that each radiation detection instrument require calibration done in accordance with IAEA Safety Report Series, No. 16, Calibration of Radiation Protection Monitoring Instruments*"**	**Instrumentation requirements are defined in multiple regulatory documents, and need to be in one place.** **Specific standards should not be included in a Regulation.** **For example: Many Nuclear facilities have a number of Fixed Area Gamma Monitors (FAGMs) deployed at various locations on site. The intended use of these devices is to monitor significant change in radiological conditions at the job site and they are not used as survey meters for accurate dose rate measurement or for exposure planning/control or dose assessment purposes.** **Since they are fixed at one specific location and cannot be removed for calibration as per IAEA or ANSI standard. This requirement should not apply to these instruments. In other industries, there are likely other instruments which should not be**	**Consolidate instrumentation requirements in one place. Industry supports this being in the RP Regulations.** **Remove the reference to IAEA Safety Report Series, No. 16. Specific standards and covered instrumentation should not be contained in the Regulation, but identified by the licensee through the licensing process.**	**Major**	**It is extremely difficult to demonstrate compliance with IAEA Safety Report Series, No. 16. It would require significant cost and administrative burden to implement all the technical requirements, with no additional safety benefit.**

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		included.			
31.	**Section 3.2, Pg 24**	**-The General Regulations already require the establishment of a Radiation Protection program, and require a defined organization staffed with qualified, competent people. It is the responsility of the licensee to implement an appropriate organization to ensure regulatory requirements will be met.**	**Do not include this new section as the requirements are addressed elsewhere.**	**Major**	**This adds additional administrative burden to duplicate requirements in already place, with no additional safety burden. It is not clear what problem is being solved.**
32.	**Section 4.0** **Carriers of Nuclear Substances** **Pg. 25, 3rd paragraph – "*The CNSC recently consulted a discussion paper (DIS-12-06) regarding the proposal to amend the Packaging and Transport of Nuclear Substances Regulations (PTNSR).*"**	**Discussion Paper DIS-12-06 has been reviewed extensively by industry. The section that affects RP requirements the most is Section 18 of the PTNSR.** **Below are the issues:** **In Discussion Paper DIS-12-06, the CNSC proposed to** **i) make radiation protection requirements for carriers of nuclear substances consistent with those applicable to licensees and their workers.** **ii) move requirements for a RP program from PTNSR section 18 to the Radiation Protection**	**Industry continues to recommend that the radiation protection program requirements for carriers stay within the PTNSR to ensure that they remain consistent with the IAEA transport regulations.**	**Major**	**Carriers use the PTNSR. Requirements of the RPR are not appropriate for carriers. Refer to industry comments on DIS-12-06.**

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		Regulations.			
33.	Appendix A	Please note the comments to the main text above.	Please note the recommended changes to the main text above should also be applied to the Appendix.	Clarification	
34.	Appendix B	Please note the comments to the main text above.	Please note the recommended changes to the main text above should also be applied to the Appendix.	Clarification	

December 4, 2013

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Dear Mr. Dallaire:

Bruce Power Comments on Discussion Paper DIS-13-01
"Proposals to Amend the Radiation Protection Regulations"

The purpose of this letter is to submit Bruce Power comments on DIS-13-01.

While Bruce Power is generally supportive of the proposed amendments to the *Radiation Protection Regulations,* we do have a number of comments (contained in Enclosure 1).

Bruce Power is particularly concerned with the proposed changes to the dose to the lens of the eye as there are currently no available methods to accurately measure and record dose at the proposed levels. We are also concerned with the proposed change described in 2.2 Section 7 of the Discussion Paper regarding the term "worker". While Bruce Power agrees that there is a need to inform workers of the risks and that the intent is good, the proposed term is too broad and would capture workers that have no need to be informed of the risks due to their work locations (i.e. Bruce Power has worker performing administrative and engineering based CNSC licenced activities outside of the facilities).

The proposal to appoint a person or position within the licensee organization as responsible for the implementing the radiation protection program is also of concern to Bruce Power. As proposed, this results in a regulatory body dictating the licensee's organizational structure. This should not be the practice. Bruce Power is confident that the intent of this proposal is already covered by the requirements in the *General Nuclear Safety and Control Regulations.*

Bruce Power would welcome the opportunity to discuss our comments with CNSC staff and believe that it may be beneficial to have a one day workshop with all interested stakeholders to discuss the proposed changes to the regulations before the revisions are completed.

Bruce Power Frank Saunders Vice President - Nuclear Oversight and Regulatory Affairs
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frank.saunders@brucepower.com

If you require further information or have any questions regarding this submission, please contact Mr. Maury Burton, Department Manager, Regulatory Affairs, at (519) 361-5291.

Yours truly,

for

Frank Saunders
Vice President Nuclear Oversight and Regulatory Affairs
Bruce Power

cc: CNSC Bruce Site Office (Letter only)
R. Lojk – CNSC Ottawa

Enclosure 1

**BRUCE POWER Comments on Discussion Paper DIS-13-01 –
Proposals to Amend the Radiation Protection Regulations
(15 pages)**

NK21-CORR-00531-10965
NK29-CORR-00531-11351
NK37-CORR-00531-02163

BRUCE POWER Comments on Discussion Paper DIS-13-01 – Proposals to Amend the Radiation Protection Regulations

#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
1.	Dose constraints 2.2 section 4 page 7		Agree with the proposed amendment - not to include the dose constraints due to robust ALARA programs that are already in place in the nuclear industry.		
2.	**2.2 Section 7** **Provision of information to all workers.** **Page 8** **3rd paragraph–** ***"the CNSC proposes to replace the term "nuclear energy worker" in section 7 of the Regulations with the term "worker", using the following existing definition: "a person who performs work that is referred to in a licence."*** **4th paragraph -** ***"If this change is adopted... written acknowledgement from all of their workers..."*** **pg. 8, 5th paragraph – *"CNSC proposes that workers be informed of their dose limits...on an annual basis..."*** **This is a critical issue to Bruce Power. The wording in the 3rd and 4th paragraphs on page 8 of the discussion paper is confusing. The 3rd paragraph states that the term "nuclear energy worker" will be replaced by the term "worker". The 4th paragraph, states that in paragraph 7(1)(a) every worker would be informed whether he or she is a NEW. Initially this was very confusing, as the 3rd paragraph on its own implies that the term NEW will no longer be used.** **The definition of "worker" is operationally very vague. For example, a clerk in a nuclear plant might work only in the Administration building and never go into the plant. Another clerk might make daily trips into the radiological areas and wear a TLD badge. Clarity in the terminology to understand the scope is required.**	**Suggest CNSC either continues using the term *"nuclear energy worker"* or replaces it with something like *"exposed worker" and* can be defined as "a person who performs work referred to in a licence where the work has potential to expose the worker to a recordable dose" or replaces it with "all workers in security protected areas or radiological zones".**	**Critical**	**The proposed change could result in a high administrative and cost burden with little demonstrated safety benefit.** **In addition, the lack in clarity on the terminology could result in confusion and inconsistency in compliance.** **Dosimetry monitoring of non-NEWs is not necessarily conducted presently. Reporting individual exposures to non-NEWs would require a change to the current risk-informed practices which apply the use of dosimeters when warranted by dose.**

#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
3.	2.2 Section 7 Provision of information to all workers. Page 8 4th paragraph - *"If this change is adopted... written acknowledgement from all of their workers..."* pg. 8, 5th paragraph – *"CNSC proposes that workers be informed of their dose limits...on an annual basis..."*	Clarity is required to ensure the written notification can also occur by electronic means.	Suggest adding the word *"electronic"* to the last sentence in the 4th paragraph. It would read *"Similarly, subsection (3) would need an amendment requiring licensees to obtain electronic and/or written acknowledgement from all of their workers of having been informed of the matters referred to in subsections 7(1) and (2)."*	Clarification	
4.	2.2 section 7 Additional requirement related to emergencies page 8	The proposed requirement is to inform "all workers" of their duties in an emergency. Does this requirement extend to non-licensee staff responding to a nuclear event and who has the responsibility the licensee or employer? During an event, members of the off-site work force may support the response, and it is not clear if they would be considered as "workers" who would require notification. Planned responses are included in training and development of off-site organization training and development, but licensees cannot track all changes within these organization.		Clarification	

#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
5.	2.2 Section 8 Requirements to Use Licensed Dosimetry Service (LDS) Pg. 10, paragraphs 2, 3 & 4 – *"The CNSC is proposing that a licensee must also use a LDS ... measuring dose to the lens of the eye."*	This proposed amendment is not an issue for industry, as the equivalent dose to the skin of the whole body is measured by Whole Body TLD and reported on. Further, equivalent doses to the skin of hands and feet are measured by extremity TLD, and reported on. Industry expects that the proposed amendment will not result in a significant incremental administrative burden. Industry understands that this amendment is regarding the use of a dosimeter during the routine operations of a licensee. The proposed amendment is not intended to require a licensed dosimetry service to interpret skin contamination events that may have occurred. If not correct, additional clarification is needed. The CNSC position not to require the use of licensed dosimetry service to measure dose to the lens of the eye lis supported as we do not believe this service is available; we note that this points to a problem with prematurely adopting a recent ICRP proposal whose practical implications have not been fully assessed.	Revise to state that LDS is not required for dose determination for skin contamination events.	Clarification	

#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
6.	**Section 11** **Page10** **Pregnant NEWs** ***"... a requirement for a female worker to inform the licensee in writing if she is breast-feeding."***	**If the direction is to move from having most or all or more workers established as the equivalent of NEWs or as "workers" then all female workers in this category will need to inform the licensees in writing. Industry is not sure how this will be treated for workers who are not actually doing radiation work or entering the protected areas. It could be viewed as a privacy issue by those who are not anticipating being treated as NEWs. This may cause unnecessary anxiety / concern to those workers.**	**While it is acceptable/reasonable to implement this new proposed requirement for female NEWs, it is recommended that the term "nuclear energy worker" continues to be used in order to distinguish between those who are potentially exposed to ionizing radiation vs. those are not. Similar to comments for section 7 documented earlier, it is also recommended that this requirement is only applied when or after the NEW worker has notified the licensee of her pregnancy.**	**Major**	**Unless this requirement specifically applies to those (females) who are potential receiving a recordable dose, it would be a challenge to implement these requirements due to the privacy/anxiety concern.** **If this requirement only applies to female NEWs instead of all workers, the administrative burden would be reduced significantly and be easier to implement.** **If this proposed requirement applies to all female workers (non-NEWs), it introduces significant cost with no apparent safety benefit.**
7.	2.3 Section 13 Effective Dose Limits Page 11 *"... the CNSC suggests using written text (as opposed to formulas) to describe how effective doses are to be calculated*	It is unusual that a calculated value is to be replaced with a written text to describe how to perform a calculation. Industry does not support this approach although industry concurs with the wording to describe how the "effective dose" is calculated.	It is recommended to include both written text and mathematical formulas in the document. Alternatively, the CNSC could reference an accepted standard, e.g. ICRP regarding methodology for calculating doses.	Clarification	
8.	Section 13 Effective Dose Limits Page 11 *"The CNSC proposes to replace the use of ALI with dose coefficients to directly calculate the effective dose of any component."*	Industry understands the replacement of ALI would only be for official dose assignment, and is not applicable to any other use of the term.	Modify document to note that licensee may use the terminology in other applications such as work planning.	Clarification	
9.	Section 13 Effective Dose Limits	Industry concurs with the proposed change.			

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	Page 11 *"... the CNSC proposes to eliminate the term "E", as defined in subsection 12(1) of the existing Regulations."*				
10.	**Section 14 page 14** **Equivalent dose limits for the lens of the eye** **Pg. 14 - "*... the CNSC proposes the following:*** • ***to change the equivalent dose limit for the lens of the eye for a NEW from the current limit of 150 mSv to 50 mSv in a one-year dosimetry period*** • ***to add a new dose limit of 100 mSv in a five-year dosimetry period."***	**This is a critical issue to Bruce Power. There has been considerable controversy about the new dose limit. The step change in threshold dose from 5 Sv to 0.5 Sv and lowering the dose limit from 150 mSv to 20 mSv (averaged over 5 years) recommended by the ICRP is drastic and may cause undue concern or anxiety to workers. The question will likely come up: what about all the years our workers were working in these environments. The regulator may have to participate in the response to workers on this issue.** **As noted in the column labelled "Impact on industry if major comment", there are a number of new steps that the industry will have to undertake to demonstrate compliance with the new limits.** **Although these issues can be settled with significant effort and expenditures, there are more serious issues with the bases for the proposed regulations, which are**	**Since this is a significant change and it does have a significant impact on nuclear industry, unavailability of approved eye dosimeter (currently) and since cataracts are treatable while cancer is life threatening, industry proposes the dose limit for the lens of the eye for a nuclear energy worker (NEW) as follows:** ***"100 mSv per one-year dosimetry period and 250 mSv per five-year dosimetry period."*** **The proposed change has the following benefits:** • **The dose limits are low enough to make it necessary to provide additional protection for those workers who are exposed to significant eye doses.** • **Eye dose would not be limiting for cases where the eyes were exposed to radiation fields only moderately higher than for the rest of the body.** • **The higher limit would possibly**	**Critical**	**Reducing the dose limit for the eye is not justified – it imposes significant administrative burden and cost without benefit.** **The costs to implement will be significant, though dependant on impact of CNSC acceptable methodologies to compute non licensed dose. If instrumentation, even if unlicensed, is the only acceptable methodology, those development and implementation costs will be significant. There will also be software development costs. In addition these limits as written will reduce the manpower available to perform the required work thus new workers will have to be trained to perform the same work. If the acceptable methodology is a paper evaluation of the Head and Trunk results to compute lens of eye dose, the costs will be significantly reduced.** **There are technical issues with determining eye dose at this time; therefore there is no way for licensees to consistently demonstrate compliance with the proposed reduced limits.** **This has significant impact for radiological work in non-uniform fields as this affects our whole concept of Head & Trunk Dosimetry. This will be a burden during outages, increasing the number of**

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		taken directly from a recent publication by the International Committee on Radiological Protection (ICRP), ICRP 118 (ICRP Statement on Tissue Reactions and Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context, 2012), along with its statement on tissue reactions. The ICRP began work on the main document in 2005, and issued it for comment as a 315 page document in January 2011. On April 21, 2011, the ICRP issued its statement on tissue reactions, along with its new recommended eye dose limit, with no consultation whatsoever. The final version of ICRP 118 was issued in early 2012. The following are some of the issues that have been identified with the bases for the ICRP's new eye dose limit: • The eye dose limit is based on a new recommended deterministic threshold of 0. 5 Sv, based on a 1% incidence of clinical opacities in the eye, instead of the more serious detriment of cataracts. The threshold dose is ten times lower than the previous recommended threshold value of	obviate the need for eye dosimetry for most workers, except for the most highly exposed. • The higher dose limit would avoid "nuisance" overexposures where the dose limit was exceeded by a small amount, perhaps because of the uncertainty of measuring the incremental eye dose above the effective dose. On the issue of the proposed change to the equivalent dose limits to the lens of the eye, industry recommends that changes to this section of the regulations be delayed until a practical way to measure lens of the eye doses is available that could meet the requirements of a licensed dosimetry service. The fact that the CNSC has proposed that using a licensed dosimetry service is not required for this type of dose measurement is a tacit and realistic assessment that this is not possible at the moment. We believe that this is an area of changing science and that risk from radiation doses to the lens of the eye is much less serious than other types of radiation exposures. As such, it		workers required to complete some work scope. This change is significant for an effect that is treatable in many cases, especially in countries like Canada. Guidance for licensees in how to ascertain and report dose to the lens of the eye is needed. It should be noted that NRC in the U.S. has not accepted the ICRP recommendation and will not be changing the dose limits to the lens of the eye. This change in the RP Regulations will be a burden to licensees that does not make sense considering the effect that cataracts have on workers. It is difficult to ascertain that radiation exposure was the only causal factor for cataracts in an aging worker, as this condition is very common in an aging population.

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		5 Sv. • The rate of cataracts increases significantly with age, reaching approximately 30% at age 70. Such a high natural incidence rate makes it especially difficult to specify an additional incidence rate of only 1% with reasonable accuracy. • Cataracts are readily treatable in developed countries, which are the ones most likely to use significant quantities of ionizing radiation. • The effective dose limit is based primarily on a rate of 5% per Sv estimate for detriment, primarily from the risk of fatal cancer. If linearity of cataract formation is assumed, a 1 Sv dose to the eye would result in a cataract incidence rate of 2%. It is not clear why the ICRP considers this lower incidence rate of cataracts, usually readily treatable, to be equivalent to the higher risk of fatal cancer. Cancer is considered to be a stochastic risk while cataract formation is thought to be a deterministic effect. However, there is some doubt about this, and cataracts	does not pose an immediate concern and industry recommends that the higher dose limit be retained at this time		

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		may be also be a stochastic effect (at least at low doses). Given the significant amount of uncertainty about the incidence rate as well as the etiology of cataract formation, it would have been more appropriate for the ICRP to have recommended a higher dose limit. If one assumes that linearity of cataract formation with dose still holds at doses above 1 Sv, it would take a dose of 2.5 Sv to produce an incidence rate of 5%. One could therefore argue that a suitable dose limit might therefore be 2.5 times the average dose limit of 20 mSv/y for effective dose, or 50 mSv/y. For operational flexibility, OPG proposes the dose limits identified in the "Suggested Change" column. • One other item to note is that typically operational practices evolve to keep the actual doses received for most workers to be well below the dose limits. Even with the higher dose limits it is likely that most workers will receive doses at or below the new dose limits recommended by the ICRP.			

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11.	Section 14 Equivalent dose limits for the lens of the eye Pg. 14 - *"... the CNSC proposes the following:* • *to change the equivalent dose limit for the lens of the eye for a NEW from the current limit of 150 mSv to 50 mSv in a one-year dosimetry period* • *to add a new dose limit of 100 mSv in a five-year dosimetry period."*	If the dose limit to lens of eye for a non-NEW remains unchanged, does this impact the management of non-licensee staff responding to an event?	Revise to state that this does apply to non-licensee staff responding to an event.	Clarification	
12.	Section 15 Emergencies Page 15 *-"...the applicable dose limits for effective and equivalent doses to persons (as proposed below) must be considered discrete and separate from the dose limits..."*	This proposed change is reasonable and it facilitates facilities to deploy urgent emergency actions. It would definitely eliminate lot of confusion during an emergency situation.	Request clarification in the definition of an emergency for the application and subsequent disapplication of these limits BSS 28406564defin 28406564es a radiation emergency as an event that will cause a member of the public to receive a dose of 5mSv or greater in one year.	Clarification	
13.	Section 15 Page 16	The CNSC has used Task 1 and Task 2 with different definitions than the IAEA in GSR 3 (Interim). This may cause confusion.	Consider changing the titles to Task A and Task B to avoid confusion, or adopting the IAEA task numbering convention.	Clarification	
14.	Section 15 Page 16 *"Females who have declared that they are pregnant shall not be involved in the control of an emergency..."*	Does this provision also apply to women who are breast-feeding?	Should read *"...declared that they are pregnant or breast-feeding..."*	Clarification	

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15.	Section 15 Page 17 *"...immediately notify the person and the Commission of the dose:"*	Industry has a concern regarding the proposed requirement to "*immediately*" notify the Commission of the dose to an individual if an emergency dose limit is exceeded. This may not be practicable in certain cases due to safety priorities during the emergency.	Suggest to change bullet 1 to: • *immediately notify the person of the dose, and as soon as practicable, notify Commission staff of the dose;*	Clarification	
44 a	Section 16 When Dose Limit Exceeded Page 17	Industry concurs with the proposed amendment.			
16.	Section 17 Authorization of Return to Work Page 18	Industry concurs with the proposed amendment.			
17.	Section 2.4 Dosimetry Services Pg 18-19	There is little value in including this information, since those licensed as dosimetry service providers are required to comply with this Regulatory Standard. Why add requirements from this standard and not others...	Leave the information covered in S-106 out of the RP Regulations.	Clarification	
18.	Section 19 Obligations of Licensees Pg. 19 – 2nd paragraph *"... that their clients (i.e. CNSC licensees) must submit to them to the necessary information..."*	There is an extra word "to" in the sentence and should be removed.	The paragraph should read. *"In order for licensed dosimetry services to comply with the requirement to report to the NDR, it is implied – but not explicitly stated – that their clients (i.e., CNSC licensees) must submit to them ~~to~~ the necessary personal information for each NEW being monitored."*	Clarification	

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19.	Section 20 Labeling of containers and devices Pg. 20 – *"Since January 2006, under an exemption granted by the Commission ... a person may possess, transfer or use an unlimited number of radium luminous devices without a licence..."*	Industry cannot locate any documentation that describes this exemption. The phrase "unlimited number" has been quoted incorrectly. Section 8(b) in the existing NSRD Regulations stipulates the possession limit of those devices as follow - *"the person does not possess more than 10 such devices"*.	Please provide some guidance on how to find/locate the mentioned exemption documentation. Review wording in the NSRD regulations to ensure alignment.	Clarification	
	Section 20, Labelling containers and devices 2.5 Item 78	**The requirement of labelling of waste containers. The existing wording is confusing, in that it is sometimes interpreted very broadly by inspectors, that waste containers in use in the field (i.e. in the process of collecting waste in the field, being collected and handled, being processed, BUT NOT YET QUANTIFIED), as requiring the radionuclide, form, activity, to be marked on the container. This is not physically possible for waste that has not yet been quantified by measurement or calculation.**	**Industry recommends that the hazard information labelled on waste containers should display dose-rate only, rather than radionuclide, form and activity.**	**Major**	**The lack of clarity poses a regulatory risk to licensees for no safety benefit. As long as the hazard in terms of dose-rate is shown, workers are better protected than by providing more technical but less immediately-useful information such as radionuclide, form, activity.**
51a	**Section 20**	**Issues with application of current requirements. Different regulations make it extremely difficult for licensees to comply, such as requirement to label specific radionuclide content of containers.**	**Further exemptions are required in 20 (2) to remove: A) the requirement for labelling of individual radioactive waste packages or items within an access controlled waste container that is already signed and labelled as per**	**Major**	**Unnecessary administrative burden to create affix and maintain full information labels and non-ALARA actions to address non-compliances.**

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			20. (1) (a) and (b), and **B) the labelling of containers of radioactive substances that are contained within an access controlled room that is already signed and labelled as per the requirements of 21. (a) and (b).** **In case B in lieu of full labelling the containers, uniquely identifying the containers and a database record of their contents would meet the intent of 20. (1) (a) and (b).**		
20.	Section 2.6 Records to be Kept by Licensees Pg 21	The 30 year time period for record retention is a long time. This could be a burden to a licensee who was closing the business / decommissioning. Consider a mandatory time period in which the CNSC must be notified prior to the licensee destroying/disposing of records.	This approach is not an issue for long-time licensees; however, it could be a burden for smaller licensees others who are getting out of their business. Consider a mandatory time period in which the CNSC must be notified prior to the licensee destroying/disposing of records.	Clarification	
21.	**Section 24** **Records to be Kept by Licensees: "retention of dose records using the IAEA revised BSS as a benchmark"**	**The National Dose Registry (NDR) is the repository for dose records and as such should be where dose records are retained over a worker's life. If it is desired for licensees to have auditable records, a shorter retention time would be more appropriate**	**Industry recommends that records of doses generated be retained by the licensee for a period of 5 years and by the NDR permanently.** **The NDR becomes the official permanent record repository for dose.** **Industry would welcome further discussion on implementation to**	**Major**	**The administrative burden related to records retention is excessive, with records of dose recorded in the National Dose Registry.** **As per Health Canada, the purpose of the NDR is as follows:** • **Assist in regulatory control by notifying regulatory authorities of overexposures within their jurisdiction.** • **Evaluate dose trends and statistics to answer requests from regulators and others.**

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			reduce the administrative burden on retaining these records.		• **Contribute to health research and to the scientific knowledge on risks from occupational exposure to ionizing radiation.** • **Provide dose histories to individual workers and organizations for work planning and for compensation and litigation cases**
22.	Section 24 Page 21 4th paragraph *"records of each worker shall be maintained during and after the worker's working life..."*	Industry has concerns with retaining records of dose for all workers.	Refer to previous comments on "worker"	Clarification	
23.	**Proposed New Section 3.1 Radiation Detection and Measurement Instrumentation** **Pg. 24 –"*...The CNSC is proposing that each radiation detection instrument require calibration done in accordance with IAEA Safety Report Series, No. 16, Calibration of Radiation Protection Monitoring Instruments*"**	**Instrumentation requirements are defined in multiple regulatory documents, and need to be in one place.** **Specific standards should not be included in a Regulation.** **For example: Many Nuclear facilities have a number of Fixed Area Gamma Monitors (FAGMs) deployed at various locations on site. The intended use of these devices is to monitor significant change in radiological conditions at the job site and they are not used as survey meters for accurate dose rate measurement or for exposure**	**Consolidate instrumentation requirements in one place. Industry supports this being in the RP Regulations.** **Remove the reference to IAEA Safety Report Series, No. 16. Specific standards and covered instrumentation should not be contained in the Regulation, but identified by the licensee through the licensing process.**	**Clarification**	

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		planning/control or dose assessment purposes. Since they are fixed at one specific location and cannot be removed for calibration as per IAEA or ANSI standard. This requirement should not apply to these instruments. In other industries, there are likely other instruments which should not be included.			
24.	*Section* 3.2, Pg 24	Bruce Power sees this proposal as the regulatory body dictating how the licensee organization should be set up. This is unnecessary as the General Regulations already require the establishment of a Radiation Protection program, and require a defined organization staffed with qualified, competent people. It is the responsibility of the licensee to implement an appropriate organization to ensure regulatory requirements will be met.	Do not include this new section as the requirements are addressed elsewhere.	Critical	This adds additional administrative burden to duplicate requirements in already place, with no additional safety burden.
25.	Section 4.0 Carriers of Nuclear Substances Pg. 25, 3rd paragraph – *"The CNSC recently consulted a discussion paper (DIS-12-06) regarding the proposal to amend the Packaging and Transport of Nuclear Substances Regulations (PTNSR)."*	Discussion Paper DIS-12-06 has been reviewed extensively by industry. The section that affects RP requirements the most is Section 18 of the PTNSR. Below are the issues: In Discussion Paper DIS-12-06, the CNSC proposed to	Industry continues to recommend that the radiation protection program requirements for carriers stay within the PTNSR to ensure that they remain consistent with the IAEA transport regulations.	Major	Carriers use the PTNSR. Requirements of the RPR are not appropriate for carriers. Refer to industry comments on DIS-12-06.

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		i) make radiation protection requirements for carriers of nuclear substances consistent with those applicable to licensees and their workers. **ii) move requirements for a RP program from PTNSR section 18 to the Radiation Protection Regulations.**			
26.	*Appendix A*	Please note the comments to the main text above.	Please note the recommended changes to the main text above should also be applied to the Appendix.	Clarification	
27.	Appendix B	Please note the comments to the main text above.	Please note the recommended changes to the main text above should also be applied to the Appendix.	Clarification	

Énergie NB Power

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December 6, 2013

Mr. M. Dallaire, Director General
Regulatory Policy Directorate
Canadian Nuclear Safety Commission
280 Slater Street
P.O. Box 1046, Station B
Ottawa, Ontario
K1P 5S9

Dear Mr. Dallaire:

Subject: NB Power Comments on Discussion Paper DIS-13-01, Proposals to Amend the Radiation Protection Regulations

The purpose of this letter is to provide NB Power (NBP) comments on CNSC Discussion Paper DIS-13-01, *Proposals to Amend the Radiation Protection Regulations*. NBP has collaborated with AECL, Bruce Power and Ontario Power Generation to review the proposed DIS-13-01 in detail and these comments are provided in Attachment 1.

NB Power appreciates the opportunity to provide comments on this regulatory document and is prepared to clarify our comments and concerns. If you require additional information, please contact Jennifer Allen, Senior Health Physicist, at 506-659-6579 or JAllen@nbpower.com.

Sincerely,

Keith Mills
DCNO
for Sean Granville

Sean Granville
Site Vice President and Chief Nuclear Officer

SG/JA/sd

cc. Ben Poulet, Pierre Bélanger, Lisa Love-Tedjoutomo, Rachel Lane (CNSC - Ottawa), consultation@cnsc-ccsn.gc.ca
CNSC Site Office
Al MacDonald, Tony Munn, Joe McCulley, Cris Nicolau (NBP)

Attachments:

1. NB Power Comments on CNSC Discussion Paper DIS-13-01, Proposals to Amend the Radiation Protection Regulations.

NBP Comments on Discussion Paper DIS-13-01 –Proposals to Amend the Radiation Protection Regulations

#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
1.	2.2 Section 3 Administration of nuclear substance for medical purposes Page 6 *"...require licensees to inform caregivers that they may incur radiation exposure above the dose limit for any person other than a nuclear energy worker, during their comfort and care of patients."*	The proposed definition of "caregiver" does not consider people who are being hired by a member of the public to look after patients who have been administered with nuclear substance(s).	Amend definition to include persons hired by members of the public to look after patients who have been administered with nuclear substance(s).	Clarification	
2.	Dose constraints 2.2 section 4 page 7		Industry agrees with the proposed amendment - not to include the dose constraints due to robust ALARA programs that are already in place in the nuclear industry.		
3.	2.2 Section 7 Provision of information to all workers. Page 8 3rd paragraph– *"the CNSC proposes to replace the term "nuclear energy worker" in section 7 of the Regulations with the term "worker", using the following existing definition: "a person who performs work that is referred to in a licence."* 4th paragraph - *"If this change is adopted... written acknowledgement from all of their workers..."* pg. 8, 5th paragraph – *"CNSC proposes that workers be informed*	CNSC proposal to require all workers performing work that is referred to in a licence to have information and training provided on radiological dose risks, dose limits, and individual dose levels poses an unnecessary burden on the industry. The wording in the 3rd and 4th paragraphs on page 8 of the discussion paper is confusing. The 3rd paragraph states that the term "nuclear energy worker" will be replaced by the term "worker". The 4th paragraph, states that in paragraph 7(1)(a) every worker would be informed whether he or she is a NEW. The 3rd paragraph on its own implies that the term NEW will no longer be used.	Industry suggests that the CNSC either continues using the term *"nuclear energy worker"* or replaces it with something like *"exposed worker" and* can be defined as "a person who performs work referred to in a licence where the work has potential to expose the worker to a recordable dose" or replaces it with "all workers in security protected areas or radiological zones".	Major	The proposed change could result in a high administrative and cost burden with little demonstrated safety benefit. For workers (including contractors) who are not expected to receive doses any greater than those received by the public, the additional requirement would not result in improved safety. In addition, the lack in clarity on the terminology could result in confusion and inconsistency in compliance. Dosimetry monitoring of non-NEWs is not necessarily conducted presently. Reporting individual exposures to non-NEWs would require a change to the current risk-informed practices which apply the use of dosimeters when warranted by dose.

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	of their dose limits...on an annual basis..."	The definition of "worker" is operationally very vague. For example, a clerk in a nuclear plant might work only in the Administration building and never go into the plant. Another clerk might make daily trips into the radiological areas and wear a TLD badge. Clarity in the terminology to understand the scope is required.			
4.	2.2 Section 7 Provision of information to all workers. Page 8 4th paragraph - *"If this change is adopted... written acknowledgement from all of their workers..."* pg. 8, 5th paragraph – *"CNSC proposes that workers be informed of their dose limits...on an annual basis..."*	Clarity is required to ensure the written notification can also occur by electronic means.	Industry suggests adding the word *"electronic"* to the last sentence in the 4th paragraph. It would read *"Similarly, subsection (3) would need an amendment requiring licensees to obtain electronic and/or written acknowledgement from all of their workers of having been informed of the matters referred to in subsections 7(1) and (2)."*	Clarification	
5.	2.2 Section 7 Provision of information to all workers. Page 8 *'The CNSC proposes to expand the requirements in subsection 7(1) of the Regulations to include the provision of information, to each female worker, on the potential risks to breast-fed infants from intakes of*	It is assumed that the provision of information requirement would be in place as long as breast feeding is occurring. In section 11 it is mentioned that the employee will need to inform supervision of the start date; they may also need to do the same for the end date.	Add end date also for the accommodation.	Clarification	

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	radioactive substances by the worker, during both routine operations and emergencies"				
6.	2.2 section 7 Additional requirement related to emergencies page 8 *"... the CNSC proposes to introduce a requirement to subsection 7(1) for all licensees to inform all workers of their duties and responsibilities in the event of an emergency."*	Again, the application to all workers is too broad. Likewise to the previous comment about risk information, a proposed requirement to inform "all workers" of their duties and responsibilities during an emergency, and the associated health risks and how they should protect themselves, is likely excessive, e.g. casual part-time employees and contractors who may simply be providing painting or custodial duties to administration buildings outside the radiological zones and outside the protected area. These people are no more at risk than members of the public in the primary zone around the plant.	A note should be added as follows: *"It is understood that in certain emergency situations, staff may be required to perform additional duties which may not have been anticipated in advance. In such cases, it is acceptable for the licensee to provide work assignments and pre-job briefings at the time of the event as appropriate to meet the intent of this provision."*	Major	Provision limits licensee ability to assign additional duties in case of emergency, where real-time response and job assignment may be required.
7.	2.2 section 7 Additional requirement related to emergencies page 8	The proposed requirement is to inform "all workers" of their duties in an emergency. Does this requirement extend to non-licensee staff responding to a nuclear event? During an event, members of the off-site work force may support the response, and it is not clear if they would be considered as "workers" who would require notification. Planned responses are included in training and development of off-site organization training and development, but licensees cannot	A note should be added as follows: *"It is understood that in certain emergency situations, additional staff from off-site organizations may be required to perform additional duties which may not have been anticipated in advance. In such cases, it is acceptable for the licensee to provide work assignments and pre-job briefings at the time of the event as appropriate to meet the intent of this provision."* See also previous comments.	Major	Providing this information to off-site authorities would result in a significant burden to licensees, such as training and logistics. This may not be feasible in an emergency situation.

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		track all changes within these organization.			
8.	Page 9 Female workers with respect to breast-feeding. *"... to include the provision of information, to each female worker, on the potential risks to breast-fed infants from intakes of radioactive substances by the worker, during both routine operations and emergencies."*	Currently, radiation protection procedures require female workers to inform their Supervisors in writing of their pregnancy as well as their intention of breast-feeding. According to the procedures, accommodation will be made for those individuals. However, implementing this change to all female workers will carry some administrative burden as significant amount of documentation, training materials and communication need to be revised and/or developed. In some very special cases, how is this proposed revision applied for transgender individual(s)?	Add the qualification: This information to be provided to a female worker who is not normally potentially exposed after she has notified the licensee of her pregnancy. See also earlier comment	Major	Implementing this change to all female workers will carry some administrative burden as a significant amount of documentation, training materials and communication need to be revised and/or developed.
9.	Page 9 *"...inform all female workers, in writing, of their obligations as breast-feeding workers under section 11."*	It is not clear whether this applies to non-licensee staff responding to an event. It is not practical to ask this question at the time of the response.	Revise to state "this does not apply to emergency responders e.g. ambulance, who would not normally be exposed."	Major	Industry would not support this applying to all emergency workers. This would be a significant administrative burden with no apparent safety benefit, and could result in a delay to a non-radiological emergency response.

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#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
10.	2.2 Section 8 Requirements to Use Licensed Dosimetry Service (LDS) Pg. 10, paragraphs 2, 3 & 4 – *"The CNSC is proposing that a licensee must also use a LDS ... measuring dose to the lens of the eye."*	This proposed amendment is not an issue for industry, as the equivalent dose to the skin of the whole body is measured by Whole Body TLD and reported on. Further, equivalent doses to the skin of hands and feet are measured by extremity TLD, and reported on. Industry expects that the proposed amendment will not result in a significant incremental administrative burden. Industry understands that this amendment is regarding the use of a dosimeter during the routine operations of a licensee. The proposed amendment is not intended to require a licensed dosimetry service to interpret skin contamination events that may have occurred. If not correct, additional clarification is needed. Industry supports the CNSC position not to require the use of licensed dosimetry service to measure dose to the lens of the eye as we do not believe this service is available; we note that this points to a problem with prematurely adopting a recent ICRP proposal whose practical implications have not been fully assessed.	Revise to state that LDS is not required for dose determination for skin contamination events.	Clarification	

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#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
11.	Section 11 Page10 Pregnant NEWs *"... a requirement for a female worker to inform the licensee in writing if she is breast-feeding."*	If the direction is to move from having most or all or more workers established as the equivalent of NEWs or as "workers" then all female workers in this category will need to inform the licensees in writing. Industry is not sure how this will be treated for workers who are not actually doing radiation work or entering the protected areas. It could be viewed as a privacy issue by those who are not anticipating being treated as NEWs. This may cause unnecessary anxiety / concern to those workers.	While it is acceptable/reasonable to implement this new proposed requirement for female NEWs, it is recommended that the term "nuclear energy worker" continues to be used in order to distinguish between those who are potentially exposed to ionizing radiation vs. those are not. Similar to comments for section 7 documented earlier, it is also recommended that this requirement is only applied when or after the NEW worker has notified the licensee of her pregnancy.	Major	Unless this requirement specifically applies to those (females) who are potentially receiving a recordable dose, it would be a challenge to implement these requirements due to the privacy/anxiety concern. If this requirement only applies to female NEWs instead of all workers, the administrative burden would be reduced significantly and be easier to implement. If this proposed requirement applies to all female workers (non-NEWs), it introduces significant cost with no apparent safety benefit.
12.	2.3 Section 13 Effective Dose Limits Page 11 *"... the CNSC suggests using written text (as opposed to formulas) to describe how effective doses are to be calculated*	It is unusual that a calculated value is to be replaced with a written text to describe how to perform a calculation. Industry does not support this approach although industry concurs with the wording to describe how the "effective dose" is calculated.	Industry recommends including both written text and mathematical formulas in the document. Alternatively, the CNSC could reference an accepted standard, e.g. ICRP regarding methodology for calculating doses.	Clarification	
13.	Section 13 Effective Dose Limits Page 11 *"The CNSC proposes to replace the use of ALI with dose coefficients to directly calculate the effective dose of any component."*	Industry understands the replacement of ALI would only be for official dose assignment, and is not applicable to any other use of the term.	.Modify document to note that licensee may use the terminology in other applications such as work planning.	Clarification	

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14.	Section 13 Effective Dose Limits Page 11 *"... the CNSC proposes to eliminate the term "E", as defined in subsection 12(1) of the existing Regulations."*		Industry concurs with the proposed change.		
15.	Section 14 page 14 Equivalent dose limits for the lens of the eye Pg. 14 - *"... the CNSC proposes the following:* • *to change the equivalent dose limit for the lens of the eye for a NEW from the current limit of 150 mSv to 50 mSv in a one-year dosimetry period* • *to add a new dose limit of 100 mSv in a five-year dosimetry period."*	There has been considerable controversy about the new dose limit. The step change in threshold dose from 5 Sv to 0.5 Sv and lowering the dose limit from 150 mSv to 20 mSv (averaged over 5 years) recommended by the ICRP is drastic and may cause undue concern or anxiety to workers. The question will likely come up: what about all the years our workers were working in these environments. The regulator may have to participate in the response to workers on this issue. As noted in the column labelled "Impact on industry if major comment", there are a number of new steps that the industry will have to undertake to demonstrate compliance with the new limits. Although these issues can be settled with significant effort and expenditures, there are more serious issues with the bases for the proposed regulations, which are taken directly from a recent publication by the International	Since this is a significant change and it does have a significant impact on nuclear industry, unavailability of approved eye dosimeter (currently) and since cataracts are treatable while cancer is life threatening, industry proposes the dose limit for the lens of the eye for a nuclear energy worker (NEW) as follows: *"100 mSv per one-year dosimetry period and 250 mSv per five-year dosimetry period."* The proposed change has the following benefits: • The dose limits are low enough to make it necessary to provide additional protection for those workers who are exposed to significant eye doses. • Eye dose would not be limiting for cases where the eyes were exposed to radiation fields only moderately higher than for the rest of the body. • The higher limit would possibly	Major	Reducing the dose limit for the eye is not justified – it imposes significant administrative burden and cost without benefit. The costs to implement will be significant, though dependant on impact of CNSC acceptable methodologies to compute non licensed dose. If instrumentation, even if unlicensed, is the only acceptable methodology, those development and implementation costs will be significant. There will also be software development costs. In addition these limits as written will reduce the manpower available to perform the required work thus new workers will have to be trained to perform the same work. If the acceptable methodology is a paper evaluation of the Head and Trunk results to compute lens of eye dose, the costs will be significantly reduced. There are technical issues with determining eye dose at this time; therefore there is no way for licensees to consistently demonstrate compliance with the proposed reduced limits. This has significant impact for radiological work in non-uniform fields as this affects our whole concept of Head & Trunk Dosimetry. This will be a burden during outages, increasing the number of workers required to complete some work scope.

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		Committee on Radiological Protection (ICRP), ICRP 118 (ICRP Statement on Tissue Reactions and Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context, 2012), along with its statement on tissue reactions. The ICRP began work on the main document in 2005, and issued it for comment as a 315 page document in January 2011. On April 21, 2011, the ICRP issued its statement on tissue reactions, along with its new recommended eye dose limit, with no consultation whatsoever. The final version of ICRP 118 was issued in early 2012. The following are some of the issues that have been identified with the bases for the ICRP's new eye dose limit: • The eye dose limit is based on a new recommended deterministic threshold of 0. 5 Sv, based on a 1% incidence of clinical opacities in the eye, instead of the more serious detriment of cataracts. The threshold dose is ten times lower than the previous recommended threshold value of 5 Sv. • The rate of cataracts increases significantly with age, reaching approximately 30% at age 70.	obviate the need for eye dosimetry for most workers, except for the most highly exposed. • The higher dose limit would avoid "nuisance" overexposures where the dose limit was exceeded by a small amount, perhaps because of the uncertainty of measuring the incremental eye dose above the effective dose. On the issue of the proposed change to the equivalent dose limits to the lens of the eye, industry recommends that changes to this section of the regulations be delayed until a practical way to measure lens of the eye doses is available that could meet the requirements of a licensed dosimetry service. The fact that the CNSC has proposed that using a licensed dosimetry service is not required for this type of dose measurement is a tacit and realistic assessment that this is not possible at the moment. We believe that this is an area of changing science and that risk from radiation doses to the lens of the eye is much less serious than other types of radiation exposures. As such, it does not pose an immediate concern and industry recommends that the higher dose limit be retained at this time		This change is significant for an effect that is treatable in many cases, especially in countries like Canada. Guidance for licensees in how to ascertain and report dose to the lens of the eye is needed. It should be noted that NRC in the U.S. has not accepted the ICRP recommendation and will not be changing the dose limits to the lens of the eye. This change in the RP Regulations will be a burden to licensees that does not make sense considering the effect that cataracts have on workers. It is difficult to ascertain that radiation exposure was the only causal factor for cataracts in an aging worker, as this condition is very common in an aging population.

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		Such a high natural incidence rate makes it especially difficult to specify an additional incidence rate of only 1% with reasonable accuracy. • Cataracts are readily treatable in developed countries, which are the ones most likely to use significant quantities of ionizing radiation. • The effective dose limit is based primarily on a rate of 5% per Sv estimate for detriment, primarily from the risk of fatal cancer. If linearity of cataract formation is assumed, a 1 Sv dose to the eye would result in a cataract incidence rate of 2%. It is not clear why the ICRP considers this lower incidence rate of cataracts, usually readily treatable, to be equivalent to the higher risk of fatal cancer. Cancer is considered to be a stochastic risk while cataract formation is thought to be a deterministic effect. However, there is some doubt about this, and cataracts may also be a stochastic effect (at least at low doses). Given the significant amount of uncertainty about the incidence rate as well as the etiology of cataract formation, it would have been more appropriate for the ICRP to have			

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		recommended a higher dose limit. If one assumes that linearity of cataract formation with dose still holds at doses above 1 Sv, it would take a dose of 2.5 Sv to produce an incidence rate of 5%. One could therefore argue that a suitable dose limit might therefore be 2.5 times the average dose limit of 20 mSv/y for effective dose, or 50 mSv/y. For operational flexibility, see the dose limits identified in the "Suggested Change" column. • One other item to note is that typically operational practices evolve to keep the actual doses received for most workers to be well below the dose limits. Even with the higher dose limits it is likely that most workers will receive doses at or below the new dose limits recommended by the ICRP.			

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16.	Section 14 Equivalent dose limits for the lens of the eye Pg. 14 - *"... the CNSC proposes the following:* • *to change the equivalent dose limit for the lens of the eye for a NEW from the current limit of 150 mSv to 50 mSv in a one-year dosimetry period* • *to add a new dose limit of 100 mSv in a five-year dosimetry period."*	If the dose limit to lens of eye for a non-NEW remains unchanged, does this impact the management of non-licensee staff responding to an event?	Revise to state that this does apply to non-licensee staff responding to an event.	Clarification	
17.	Section 15 Emergencies Page 15 *-"...the applicable dose limits for effective and equivalent doses to persons (as proposed below) must be considered discrete and separate from the dose limits..."*	This proposed change is reasonable and it facilitates facilities to deploy urgent emergency actions. It would definitely eliminate lot of confusion during an emergency situation.	Industry supports this proposed change.		
18.	Section 15 Page 16	The CNSC has used Task 1 and Task 2 with different definitions than the IAEA in GSR 3 (Interim). This may cause confusion.	Consider changing the titles to Task A and Task B to avoid confusion, or adopting the IAEA task numbering convention.	Clarification	
19.	Section 15 Page 16 *"Females who have declared that they are pregnant shall not be involved in the control of an emergency..."*	Does this provision also apply to women who are breast-feeding?	Should read *"...declared that they are pregnant or breast-feeding..."*	Clarification	
20.	Section 15 Page 17	Industry has a concern regarding the proposed requirement to	Suggest to change bullet 1 to: • *immediately notify the person*	Clarification	

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	"...immediately notify the person and the Commission of the dose:"	*"immediately"* notify the Commission of the dose to an individual if an emergency dose limit is exceeded. This may not be practicable in certain cases due to safety priorities during the emergency.	*of the dose, and as soon as practicable, notify Commission staff of the dose;*		
21.	Section 16 When Dose Limit Exceeded Page 17	Industry concurs with the proposed amendment.			
22.	Section 17 Authorization of Return to Work Page 18	Industry concurs with the proposed amendment.			
23.	Section 2.4 Dosimetry Services Pg 18-19	There is little value in including this information, since those licensed as dosimetry service providers are required to comply with this Regulatory Standard. Why add requirements from this standard and not others...	Leave the information covered in S-106 out of the RP Regulations.	Clarification	
24.	Section 19 Obligations of Licensees Pg. 19 – 2nd paragraph *"... that their clients (i.e. CNSC licensees) must submit to them to the necessary information..."*	There is an extra word "to" in the sentence and should be removed.	The paragraph should read. *"In order for licensed dosimetry services to comply with the requirement to report to the NDR, it is implied – but not explicitly stated – that their clients (i.e., CNSC licensees) must submit to them ~~to~~ the necessary personal information for each NEW being monitored."*	Clarification	
25.	Section 20 Labeling of containers and devices Pg. 20 – *"Since January 2006, under*	Industry cannot locate any documentation that describes this exemption. The phrase "unlimited number" has	Please provide some guidance on how to find/locate the mentioned exemption documentation. Review wording in the NSRD	Clarification	

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	an exemption granted by the Commission ... a person may possess, transfer or use an unlimited number of radium luminous devices without a licence..."	been quoted incorrectly. Section 8(b) in the existing NSRD Regulations stipulates the possession limit of those devices as follow - *"the person does not possess more than 10 such devices"*.	regulations to ensure alignment.		
26.	Section 20, Labelling containers and devices 2.5 Item 78	The requirement of labelling of waste containers. The existing wording is confusing, in that it is sometimes interpreted very broadly by inspectors, that waste containers in use in the field (i.e. in the process of collecting waste in the field, being collected and handled, being processed, BUT NOT YET QUANTIFIED), as requiring the radionuclide, form, activity, to be marked on the container. This is not physically possible for waste that has not yet been quantified by measurement or calculation.	Industry recommends that the hazard information labelled on waste containers should display dose-rate only, rather than radionuclide, form and activity.	Major	The lack of clarity poses a regulatory risk to licensees for no safety benefit. As long as the hazard in terms of dose-rate is shown, workers are better protected than by providing more technical but less immediately-useful information such as radionuclide, form, activity.
27.	Section 20	Issues with application of current requirements. Different regulations make it extremely difficult for licensees to comply, such as requirement to label specific radionuclide content of containers.	Further exemptions are required in 20 (2) to remove: A) the requirement for labelling of individual radioactive waste packages or items within an access controlled waste container that is already signed and labelled as per 20. (1) (a) and (b), and B) the labelling of containers of radioactive substances that are contained within an access controlled room that is already signed and labelled as per the	Major comment	Unnecessary administrative burden to create affix and maintain full information labels and non-ALARA actions to address non-compliances.

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			requirements of 21. (a) and (b). In case B in lieu of full labelling the containers, uniquely identifying the containers and a database record of their contents would meet the intent of 20. (1) (a) and (b).		
28.	Section 24 Records to be Kept by Licensees: "retention of dose records using the IAEA revised BSS as a benchmark"	The National Dose Registry (NDR) is the repository for dose records and as such should be where dose records are retained over a worker's life. If it is desired for licensees to have auditable records, a shorter retention time would be more appropriate	Industry recommends that records of doses generated be retained by the licensee for a period of 5 years and by the NDR permanently. The NDR becomes the official permanent record repository for dose. Industry would welcome further discussion on implementation to reduce the administrative burden on retaining these records.	Major Comment	The administrative burden related to records retention is excessive, with records of dose recorded in the National Dose Registry. As per Health Canada, the purpose of the NDR is as follows: • Assist in regulatory control by notifying regulatory authorities of overexposures within their jurisdiction. • Evaluate dose trends and statistics to answer requests from regulators and others. • Contribute to health research and to the scientific knowledge on risks from occupational exposure to ionizing radiation. • Provide dose histories to individual workers and organizations for work planning and for compensation and litigation cases
29.	Section 24 Page 21 4th paragraph *"records of each worker shall be maintained during and after the worker's working life..."*	Industry has concerns with retaining records of dose for all workers.	Refer to previous comments on "worker"	Clarification	
30.	Proposed New Section 3.1 Radiation Detection and Measurement Instrumentation Pg. 24 –*"...The CNSC is proposing that each radiation detection instrument require calibration done*	Instrumentation requirements are defined in multiple regulatory documents, and need to be in one place. Specific standards should not be	Consolidate instrumentation requirements in one place. Industry supports this being in the RP Regulations. Remove the reference to IAEA Safety	Major	It is extremely difficult to demonstrate compliance with IAEA Safety Report Series, No. 16. It would require significant cost and administrative burden to implement all the technical requirements, with no additional safety benefit.

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	in accordance with IAEA Safety Report Series, No. 16, Calibration of Radiation Protection Monitoring Instruments"	included in a Regulation. For example: Many Nuclear facilities have a number of Fixed Area Gamma Monitors (FAGMs) deployed at various locations on site. The intended use of these devices is to monitor significant change in radiological conditions at the job site and they are not used as survey meters for accurate dose rate measurement or for exposure planning/control or dose assessment purposes. Since they are fixed at one specific location and cannot be removed for calibration as per IAEA or ANSI standard. This requirement should not apply to these instruments. In other industries, there are likely other instruments which should not be included.	Report Series, No. 16. Specific standards and covered instrumentation should not be contained in the Regulation, but identified by the licensee through the licensing process. .		
31.	Section 3.2, Pg 24	-The General Regulations already require the establishment of a Radiation Protection program, and require a defined organization staffed with qualified, competent people. It is the responsility of the licensee to implement an appropriate organization to ensure regulatory requirements will be met.	Do not include this new section as the requirements are addressed elsewhere.	Major	This adds additional administrative burden to duplicate requirements in already place, with no additional safety burden. It is not clear what problem is being solved.
32.	Section 4.0 Carriers of Nuclear Substances Pg. 25, 3rd paragraph – *"The CNSC*	Discussion Paper DIS-12-06 has been reviewed extensively by industry. The section that affects RP requirements the most is Section 18	Industry continues to recommend that the radiation protection program requirements for carriers stay within the PTNSR to ensure that	Major	Carriers use the PTNSR. Requirements of the RPR are not appropriate for carriers. Refer to industry comments on DIS-12-06.

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	recently consulted a discussion paper (DIS-12-06) regarding the proposal to amend the Packaging and Transport of Nuclear Substances Regulations (PTNSR)."	of the PTNSR. Below are the issues: In Discussion Paper DIS-12-06, the CNSC proposed to i) make radiation protection requirements for carriers of nuclear substances consistent with those applicable to licensees and their workers. ii) move requirements for a RP program from PTNSR section 18 to the Radiation Protection Regulations.	they remain consistent with the IAEA transport regulations.		
33.	*Appendix A*	Please note the comments to the main text above.	Please note the recommended changes to the main text above should also be applied to the Appendix.	Clarification	
34.	Appendix B	Please note the comments to the main text above.	Please note the recommended changes to the main text above should also be applied to the Appendix.	Clarification	

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1.	2.2 Section 3 Administration of nuclear substance for medical purposes Page 6 "*…require licensees to inform caregivers that they may incur radiation exposure above the dose limit for any person other than a nuclear energy worker, during their comfort and care of patients*."	The proposed definition of "caregiver" does not consider people who are being hired by a member of the public to look after patients who have been administered with nuclear substance(s).	Amend definition to include persons hired by members of the public to look after patients who have been administered with nuclear substance(s).	Clarification	
2.	Dose constraints 2.2 section 4 page 7		Industry agrees with the proposed amendment - not to include the dose constraints due to robust ALARA programs that are already in place in the nuclear industry.		
3.	**2.2 Section 7** **Provision of information to all workers.** **Page 8** **3rd paragraph–** **"*the CNSC proposes to replace the term "nuclear energy worker" in section 7 of the Regulations with the term "worker", using the following existing definition: "a person who performs work that is referred to in a licence*."** **4th paragraph -** **"*If this change is adopted… written***	**CNSC proposal to require all workers performing work that is referred to in a licence to have information and training provided on radiological dose risks, dose limits, and individual dose levels poses an unnecessary burden on the industry.** **The wording in the 3rd and 4th paragraphs on page 8 of the discussion paper is confusing. The 3rd paragraph states that the term "nuclear energy worker" will be replaced by the term "worker". The 4th paragraph, states that in paragraph 7(1)(a) every worker**	**Industry suggests that the CNSC either continues using the term *"nuclear energy worker"* or replaces it with something like *"exposed worker"* which can be defined as "a person who performs work referred to in a licence where the work has potential to expose the worker to a recordable dose," or replaces it with "*all workers in security protected areas or radiological zones*".**	**Major**	**The proposed change could result in a high administrative and cost burden with little demonstrated safety benefit. For workers (including contractors) who are not expected to receive doses any greater than those received by the public, the additional requirement would not result in improved safety.** **In addition, the lack in clarity on the terminology could result in confusion and inconsistency in compliance.** **Dosimetry monitoring of non-NEWs is not necessarily conducted presently. Reporting individual exposures to non-NEWs would require a change to the current risk-informed practices**

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	acknowledgement from all of their workers…" **pg. 8, 5th paragraph – "*CNSC proposes that workers be informed of their dose limits...on an annual basis...*"**	**would be informed whether he or she is a NEW. The 3rd paragraph on its own implies that the term NEW will no longer be used.** **The definition of "worker" is operationally very vague. For example, a clerk in a nuclear plant might work only in the Administration building and never go into the plant. Another clerk might make daily trips into the radiological areas and wear a TLD badge. Clarity in the terminology to understand the scope is required.**			**which apply the use of dosimeters when warranted by dose.**
4.	2.2 Section 7 Provision of information to all workers. Page 8 4th paragraph - *"If this change is adopted… written acknowledgement from all of their workers…"* pg. 8, 5th paragraph – "*CNSC proposes that workers be informed of their dose limits...on an annual basis..."*	Clarity is required to ensure the written notification can also occur by electronic means.	Industry suggests adding the word *"electronic"* to the last sentence in the 4th paragraph. It would read *"Similarly, subsection (3) would need an amendment requiring licensees to obtain electronic and/or written acknowledgement from all of their workers of having been informed of the matters referred to in subsections 7(1) and (2)."*	Clarification	

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#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
5.	2.2 Section 7 Provision of information to all workers. Page 8 '*The CNSC proposes to expand the requirements in subsection 7(1) of the Regulations to include the provision of information, to each female worker, on the potential risks to breast-fed infants from intakes of radioactive substances by the worker, during both routine operations and emergencies*"	It is assumed that the provision of information requirement would be in place as long as breast feeding is occurring. In Section 11 it is mentioned that the employee will need to inform supervision of the start date; they may also need to do the same for the end date.	Add end date also for the accommodation.	Clarification	
6.	**2.2 section 7 Additional requirement related to emergencies** **page 8** ***"… the CNSC proposes to introduce a requirement to subsection 7(1) for all licensees to inform all workers of their duties and responsibilities in the event of an emergency."***	**Again, the application to all workers is too broad. Likewise to the previous comment about risk information, a proposed requirement to inform "all workers" of their duties and responsibilities during an emergency, and the associated health risks and how they should protect themselves, is likely excessive, e.g. casual part-time employees and contractors who may simply be providing painting or custodial duties to administration buildings outside the radiological zones and outside the protected area. These people are no more at risk than members of the public in the primary zone**	**A note should be added as follows:** ***"It is understood that in certain emergency situations, staff may be required to perform additional duties which may not have been anticipated in advance. In such cases, it is acceptable for the licensee to provide work assignments and pre-job briefings at the time of the event as appropriate to meet the intent of this provision."***	**Major**	**Provision limits licensee ability to assign additional duties in case of emergency, where real-time response and job assignment may be required.**

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#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
		around the plant.			
7.	**2.2 section 7** **Additional requirement related to emergencies** **page 8**	**The proposed requirement is to inform "all workers" of their duties in an emergency. Does this requirement extend to non-licensee staff responding to a nuclear event?** **During an event, members of the off-site work force may support the response, and it is not clear if they would be considered as "workers" who would require notification. Planned responses are included in training and development of off-site organization training and development, but licensees cannot track all changes within these organization.**	**A note should be added as follows:** **"*It is understood that in certain emergency situations, additional staff from off-site organizations may be required to perform additional duties which may not have been anticipated in advance. In such cases, it is acceptable for the licensee to provide work assignments and pre-job briefings at the time of the event as appropriate to meet the intent of this provision*."** **See also previous comments.**	**Major**	**Providing this information to off-site authorities would result in a significant burden to licensees, such as training and logistics. This may not be feasible in an emergency situation.**

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#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
8.	**Page 9** **Female workers with respect to breast-feeding.** ***"… to include the provision of information, to each female worker, on the potential risks to breast-fed infants from intakes of radioactive substances by the worker, during both routine operations and emergencies."***	**Currently, radiation protection procedures require female workers to inform their Supervisors in writing of their pregnancy as well as their intention of breast-feeding. According to the procedures, accommodation will be made for those individuals.** **However, implementing this change to all female workers will carry some administrative burden as significant amount of documentation, training materials and communication need to be revised and/or developed.** **In some very special cases, how is this proposed revision applied for transgender individual(s)?**	**Add the qualification: This information to be provided to a female worker who is not normally potentially exposed after she has notified the licensee of her pregnancy.** **See also earlier comment**	**Major**	**Implementing this change to all female workers will carry some administrative burden as a significant amount of documentation, training materials and communication need to be revised and/or developed.**
9.	**Page 9** ***"…inform all female workers, in writing, of their obligations as breast-feeding workers under section 11."***	**It is not clear whether this applies to non-licensee staff responding to an event. It is not practical to ask this question at the time of the response.**	**Revise to state "this does not apply to emergency responders e.g. ambulance, who would not normally be exposed."**	**Major**	**Industry would not support this applying to all emergency workers. This would be a significant administrative burden with no apparent safety benefit, and could result in a delay to a non-radiological emergency response.**

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10.	2.2 Section 8 Requirements to Use Licensed Dosimetry Service (LDS) Pg. 10, paragraphs 2, 3 & 4 – *"The CNSC is proposing that a licensee must also use a LDS … measuring dose to the lens of the eye."*	This proposed amendment is not an issue for industry, as the equivalent dose to the skin of the whole body is measured by Whole Body TLD and reported on. Further, equivalent doses to the skin of hands and feet are measured by extremity TLD, and reported on. Industry expects that the proposed amendment will not result in a significant incremental administrative burden. Industry understands that this amendment is regarding the use of a dosimeter during the routine operations of a licensee. The proposed amendment is not intended to require a licensed dosimetry service to interpret skin contamination events that may have occurred. If not correct, additional clarification is needed. Industry supports the CNSC position not to require the use of licensed dosimetry service to measure dose to the lens of the eye as we do not believe this service is available; we note that this points to a problem with prematurely adopting a recent ICRP proposal whose practical implications have not been fully assessed.	Revise to state that LDS is not required for dose determination for skin contamination events.	Clarification	

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#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
11.	**Section 11** **Page10** **Pregnant NEWs** ***"… a requirement for a female worker to inform the licensee in writing if she is breast-feeding."***	**If the direction is to move from having most or all or more workers established as the equivalent of NEWs or as "workers" then all female workers in this category will need to inform the licensees in writing. Industry is not sure how this will be treated for workers who are not actually doing radiation work or entering the protected areas. It could be viewed as a privacy issue by those who are not anticipating being treated as NEWs. This may cause unnecessary anxiety / concern to those workers.**	**While it is acceptable / reasonable to implement this new proposed requirement for female NEWs, it is recommended that the term "nuclear energy worker" continues to be used in order to distinguish between those who are potentially exposed to ionizing radiation vs. those who are not. Similar to comments for section 7 documented earlier, it is also recommended that this requirement is only applied when or after the NEW worker has notified the licensee of her pregnancy.**	**Major**	**Unless this requirement specifically applies to those (females) who are potential receiving a recordable dose, it would be a challenge to implement these requirements due to the privacy/anxiety concern.** **If this requirement only applies to female NEWs instead of all workers, the administrative burden would be reduced significantly and be easier to implement.** **If this proposed requirement applies to all female workers (non-NEWs), it introduces significant cost with no apparent safety benefit.**
12.	2.3 Section 13 Effective Dose Limits Page 11 *"… the CNSC suggests using written text (as opposed to formulas) to describe how effective doses are to be calculated*	It is unusual that a calculated value is to be replaced with a written text to describe how to perform a calculation. Industry does not support this approach although industry concurs with the wording to describe how the "effective dose" is calculated.	Industry recommends including both written text and mathematical formulas in the document. Alternatively, the CNSC could reference an accepted standard, e.g. ICRP regarding methodology for calculating doses.	Clarification	

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#	Document /Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, (if major comment)
13.	Section 13 Effective Dose Limits Page 11 *"The CNSC proposes to replace the use of ALI with dose coefficients to directly calculate the effective dose of any component."*	Industry understands the replacement of ALI would only be for official dose assignment, and is not applicable to any other use of the term.	Modify document to note that licensee may use the terminology in other applications such as work planning.	Clarification	
14.	Section 13 Effective Dose Limits Page 11 *"… the CNSC proposes to eliminate the term "E", as defined in subsection 12(1) of the existing Regulations."*		Industry concurs with the proposed change.		
15.	**Section 14 page 14** **Equivalent dose limits for the lens of the eye** **Pg. 14 - "… *the CNSC proposes the following:*** • ***to change the equivalent dose limit for the lens of the eye for a NEW from the current limit of 150 mSv to 50 mSv in a one-year dosimetry period*** • ***to add a new dose limit of 100 mSv in a five-year dosimetry***	**There has been considerable controversy about the new dose limit. The step change in threshold dose from 5 Sv to 0.5 Sv and lowering the dose limit from 150 mSv to 20 mSv (averaged over 5 years) recommended by the ICRP is drastic and may cause undue concern or anxiety to workers. The question will likely come up: what about all the years our workers were working in these environments. The regulator may have to participate in the response to workers on this issue.**	**Since this is a significant change and it does have a significant impact on nuclear industry, unavailability of approved eye dosimeter (currently) and since cataracts are treatable while cancer is life threatening, industry proposes the dose limit for the lens of the eye for a nuclear energy worker (NEW) as follows:** ***"100 mSv per one-year dosimetry period and 250 mSv per five-year dosimetry period."***	**Major**	**Reducing the dose limit for the eye is not justified – it imposes significant administrative burden and cost without benefit.** **The costs to implement will be significant, though dependant on impact of CNSC acceptable methodologies to compute non-licensed dose. If instrumentation, even if unlicensed, is the only acceptable methodology, those development and implementation costs will be significant. There will also be software development costs. In addition these limits as written will reduce the manpower available to perform the required work thus new workers will have to be trained to perform the same work. If the acceptable**

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	period."	As noted in the column labelled "Impact on industry if major comment", there are a number of new steps that the industry will have to undertake to demonstrate compliance with the new limits. Although these issues can be settled with significant effort and expenditures, there are more serious issues with the bases for the proposed regulations, which are taken directly from a recent publication by the International Committee on Radiological Protection (ICRP), ICRP 118 (ICRP Statement on Tissue Reactions and Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context, 2012), along with its statement on tissue reactions. The ICRP began work on the main document in 2005, and issued it for comment as a 315 page document in January 2011. On April 21, 2011, the ICRP issued its statement on tissue reactions, along with its new recommended eye dose limit, with no consultation whatsoever. The final version of ICRP 118 was issued in early 2012. The following are some of the issues that have been	The proposed change has the following benefits: • The dose limits are low enough to make it necessary to provide additional protection for those workers who are exposed to significant eye doses. • Eye dose would not be limiting for cases where the eyes were exposed to radiation fields only moderately higher than for the rest of the body. • The higher limit would possibly obviate the need for eye dosimetry for most workers, except for the most highly exposed. • The higher dose limit would avoid "nuisance" overexposures where the dose limit was exceeded by a small amount, perhaps because of the uncertainty of measuring the incremental eye dose above the effective dose. On the issue of the proposed change to the equivalent dose limits to the lens of the eye, industry recommends that changes to this section of the regulations be delayed until a practical way to measure lens of the eye doses is		methodology is a paper evaluation of the Head and Trunk results to compute lens of eye dose, the costs will be significantly reduced. There are technical issues with determining eye dose at this time; therefore there is no way for licensees to consistently demonstrate compliance with the proposed reduced limits. This has significant impact for radiological work in non-uniform fields as this affects our whole concept of Head & Trunk Dosimetry. This will be a burden during outages, increasing the number of workers required to complete some work scope. This change is significant for an effect that is treatable in many cases, especially in countries like Canada. Guidance for licensees in how to ascertain and report dose to the lens of the eye is needed. It should be noted that the NRC in the U.S. has not accepted the ICRP recommendation and will not be changing the dose limits to the lens of the eye. This change in the RP Regulations will be a burden to licensees that does not make sense considering the effect that cataracts have on workers. It is difficult to ascertain that radiation exposure was the only causal factor for cataracts in an aging worker, as this condition is very common in an aging population.

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		identified with the bases for the ICRP's new eye dose limit: • The eye dose limit is based on a new recommended deterministic threshold of 0. 5 Sv, based on a 1% incidence of clinical opacities in the eye, instead of the more serious detriment of cataracts. The threshold dose is ten times lower than the previous recommended threshold value of 5 Sv. • The rate of cataracts increases significantly with age, reaching approximately 30% at age 70. Such a high natural incidence rate makes it especially difficult to specify an additional incidence rate of only 1% with reasonable accuracy. • Cataracts are readily treatable in developed countries, which are the ones most likely to use significant quantities of ionizing radiation. • The effective dose limit is based primarily on a rate of 5% per Sv estimate for detriment, primarily from the risk of fatal cancer. If linearity of cataract formation is assumed, a 1 Sv dose to the eye would result in a cataract	available that could meet the requirements of a licensed dosimetry service. The fact that the CNSC has proposed that using a licensed dosimetry service is not required for this type of dose measurement is a tacit and realistic assessment that this is not possible at the moment. We believe that this is an area of changing science and that risk from radiation doses to the lens of the eye is much less serious than other types of radiation exposures. As such, it does not pose an immediate concern and industry recommends that the higher dose limit be retained at this time		

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		incidence rate of 2%. It is not clear why the ICRP considers this lower incidence rate of cataracts, usually readily treatable, to be equivalent to the higher risk of fatal cancer. Cancer is considered to be a stochastic risk while cataract formation is thought to be a deterministic effect. However, there is some doubt about this, and cataracts may be also be a stochastic effect (at least at low doses). Given the significant amount of uncertainty about the incidence rate as well as the etiology of cataract formation, it would have been more appropriate for the ICRP to have recommended a higher dose limit. If one assumes that linearity of cataract formation with dose still holds at doses above 1 Sv, it would take a dose of 2.5 Sv to produce an incidence rate of 5%. One could therefore argue that a suitable dose limit might therefore be 2.5 times the average dose limit of 20 mSv/y for effective dose, or 50 mSv/y. For operational flexibility, see the dose limits identified in the "Suggested Change" column. • **One other item to note is that**			

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		typically operational practices evolve to keep the actual doses received for most workers to be well below the dose limits. Even with the higher dose limits it is likely that most workers will receive doses at or below the new dose limits recommended by the ICRP.			
16.	Section 14 Equivalent dose limits for the lens of the eye Pg. 14 - "*… the CNSC proposes the following:* • *to change the equivalent dose limit for the lens of the eye for a NEW from the current limit of 150 mSv to 50 mSv in a one-year dosimetry period* • *to add a new dose limit of 100 mSv in a five-year dosimetry period*."	If the dose limit to lens of eye for a non-NEW remains unchanged, does this impact the management of non-licensee staff responding to an event?	Revise to state that this does apply to non-licensee staff responding to an event.	Clarification	
17.	Section 15 Emergencies Page 15 *-"...the applicable dose limits for effective and equivalent doses to persons (as proposed below) must be*	This proposed change is reasonable and it facilitates facilities to deploy urgent emergency actions. It would definitely eliminate lot of confusion during an emergency situation.	Industry supports this proposed change.		

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	considered discrete and separate from the dose limits…"				
18.	Section 15 Page 16	The CNSC has used Task 1 and Task 2 with different definitions than the IAEA in GSR 3 (Interim). This may cause confusion.	Consider changing the titles to Task A and Task B to avoid confusion, or adopting the IAEA task numbering convention.	Clarification	
19.	Section 15 Page 16 "*Females who have declared that they are pregnant shall not be involved in the control of an emergency…"*	Does this provision also apply to women who are breast-feeding?	Should read "*…declared that they are pregnant or breast-feeding…"*	Clarification	
20.	Section 15 Page 17 "*…immediately notify the person and the Commission of the dose:"*	Industry has a concern regarding the proposed requirement to "*immediately*" notify the Commission of the dose to an individual if an emergency dose limit is exceeded. This may not be practicable in certain cases due to safety priorities during the emergency.	Suggest to change bullet 1 to: • *immediately notify the person of the dose, and as soon as practicable, notify Commission staff of the dose;*	Clarification	
21.	Section 16 When Dose Limit Exceeded Page 17	Industry concurs with the proposed amendment.			
22.	Section 17 Authorization of Return to Work Page 18	Industry concurs with the proposed amendment.			
23.	Section 2.4 Dosimetry Services	There is little value in including this information, since those licensed as	Leave the information covered in S-106 out of the RP Regulations.	Clarification	

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	Pg 18-19	dosimetry service providers are required to comply with this Regulatory Standard.			
24.	Section 19 Obligations of Licensees Pg. 19 – 2nd paragraph *"… that their clients (i.e. CNSC licensees) must submit to them to the necessary information…"*	There is an extra word "to" in the sentence and should be removed.	The paragraph should read. "*In order for licensed dosimetry services to comply with the requirement to report to the NDR, it is implied – but not explicitly stated – that their clients (i.e., CNSC licensees) must submit to them ~~to~~ the necessary personal information for each NEW being monitored*."	Clarification	
25.	Section 20 Labeling of containers and devices Pg. 20 – "*Since January 2006, under an exemption granted by the Commission … a person may possess, transfer or use an unlimited number of radium luminous devices without a licence…"*	Industry cannot locate any documentation that describes this exemption. The phrase "unlimited number" has been quoted incorrectly. Section 8(b) in the existing NSRD Regulations stipulates the possession limit of those devices as follow - "*the person does not possess more than 10 such devices*".	Please provide some guidance on how to find/locate the mentioned exemption documentation. Review wording in the NSRD regulations to ensure alignment.	Clarification	
26.	**Section 20,** **Labelling containers and devices** **2.5 Item 78**	**The requirement of labelling of waste containers.** **The existing wording is confusing, in that it is sometimes interpreted very broadly by inspectors as waste containers in use in the field (i.e. in the process of collecting waste in the field, being collected and**	**Industry recommends that the hazard information labelled on waste containers should display dose-rate only, rather than radionuclide, form and activity.**	**Major**	**The lack of clarity poses a regulatory risk to licensees for no safety benefit. As long as the hazard in terms of dose-rate is shown, workers are better protected than by providing more technical but less immediately-useful information such as radionuclide, form, activity.**

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		handled, being processed, BUT NOT YET QUANTIFIED) requiring the radionuclide, form, activity, to be marked on the container. This is not physically possible for waste that has not yet been quantified by measurement or calculation.			
27.	**Section 20**	**Issues with application of current requirements. Different regulations make it extremely difficult for licensees to comply, such as requirement to label specific radionuclide content of containers.**	**Further exemptions are required in 20 (2) to remove:** **A) the requirement for labelling of individual radioactive waste packages or items within an access controlled waste container that is already signed and labelled as per 20. (1) (a) and (b), and** **B) the labelling of containers of radioactive substances that are contained within an access controlled room that is already signed and labelled as per the requirements of 21. (a) and (b).** **In case B in lieu of full labelling the containers, uniquely identifying the containers and a database record of their contents would meet the intent of 20. (1) (a) and (b).**	**Major**	**Unnecessary administrative burden to create affix and maintain full information labels and non-ALARA actions to address non-compliances.**
28.	**Section 24** **Records to be Kept by Licensees:** **"retention of dose records using the IAEA revised BSS as a benchmark"**	**The National Dose Registry (NDR) is the repository for dose records and as such should be where dose records are retained over a worker's life. If it is desired for licensees to have auditable records,**	**Industry recommends that records of doses generated be retained by the licensee for a period of 5 years and by the NDR permanently.**	**Major**	**The administrative burden related to records retention is excessive, with records of dose recorded in the National Dose Registry.** **As per Health Canada, the purpose of the NDR is as follows:**

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		a shorter retention time would be more appropriate	**The NDR becomes the official permanent record repository for dose.** **Industry would welcome further discussion on implementation to reduce the administrative burden on retaining these records.**		• **Assist in regulatory control by notifying regulatory authorities of overexposures within their jurisdiction.** • **Evaluate dose trends and statistics to answer requests from regulators and others.** • **Contribute to health research and to the scientific knowledge on risks from occupational exposure to ionizing radiation.** • **Provide dose histories to individual workers and organizations for work planning and for compensation and litigation cases**
29.	Section 24 Page 21 4th paragraph "*records of each worker shall be maintained during and after the worker's working life…*"	Industry has concerns with retaining records of dose for all workers.	Refer to previous comments on "worker"	Clarification	
30.	**Proposed New Section 3.1** **Radiation Detection and Measurement Instrumentation** **Pg. 24 –"*…The CNSC is proposing that each radiation detection instrument require calibration done in accordance with IAEA Safety Report Series, No. 16, Calibration of Radiation Protection Monitoring Instruments*"**	**Instrumentation requirements are defined in multiple regulatory documents, and need to be in one place.** **Specific standards should not be included in a Regulation.** **For example: Many Nuclear facilities have a number of Fixed Area Gamma Monitors (FAGMs) deployed at various locations on**	**Consolidate instrumentation requirements in one place. Industry supports this being in the RP Regulations.** **Remove the reference to IAEA Safety Report Series, No. 16. Specific standards and covered instrumentation should not be contained in the Regulation, but identified by the licensee through**	**Major**	**It is extremely difficult to demonstrate compliance with IAEA Safety Report Series, No. 16. It would require significant cost and administrative burden to implement all the technical requirements, with no additional safety benefit.**

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		site. The intended use of these devices is to monitor significant change in radiological conditions at the job site and they are not used as survey meters for accurate dose rate measurement or for exposure planning/control or dose assessment purposes. **Since they are fixed at one specific location and cannot be removed for calibration as per IAEA or ANSI standard, this requirement should not apply to these instruments. In other industries, there are likely other instruments which should not be included.**	**the licensing process.** **.**		
31.	**Section 3.2, Pg 24**	**The General Regulations already require the establishment of a Radiation Protection program, and require a defined organization staffed with qualified, competent people. It is the responsility of the licensee to implement an appropriate organization to ensure regulatory requirements will be met.**	**Do not include this new section as the requirements are addressed elsewhere.**	**Major**	**This adds additional administrative burden to duplicate requirements in already place, with no additional safety burden. It is not clear what problem is beinbg solved.**
32.	**Section 4.0** **Carriers of Nuclear Substances** **Pg. 25, 3rd paragraph – "*The CNSC recently consulted a discussion***	**Discussion Paper DIS-12-06 has been reviewed extensively by industry. The section that affects RP requirements the most is Section 18 of the PTNSR.** **Below are the issues:**	**Industry continues to recommend that the radiation protection program requirements for carriers stay within the PTNSR to ensure that they remain consistent with the IAEA transport regulations.**	**Major**	**Carriers use the PTNSR. Requirements of the RPR are not appropriate for carriers. Refer to industry comments on DIS-12-06.**

OPG Comments on Discussion Paper DIS-13-01 –Proposals to Amend the Radiation Protection Regulations

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	paper (DIS-12-06) regarding the proposal to amend the Packaging and Transport of Nuclear Substances Regulations (PTNSR).”	**In Discussion Paper DIS-12-06, the CNSC proposed to** **i) make radiation protection requirements for carriers of nuclear substances consistent with those applicable to licensees and their workers.** **ii) move requirements for a RP program from PTNSR section 18 to the Radiation Protection Regulations.**			
33.	Appendix A	Please note the comments to the main text above.	Please note the recommended changes to the main text above should also be applied to the Appendix.	Clarification	
34.	Appendix B	Please note the comments to the main text above.	Please note the recommended changes to the main text above should also be applied to the Appendix.	Clarification	

VIA EMAIL

December 9, 2013

Mr. Mark Dallaire
Director General
Regulation Policy Directorate
Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
280 Slater Street
Ottawa, ON K1P 5S9

Dear Mr. Dallaire:

Re: Comments on Discussion Paper DIS-13-01 *Proposal to Amend the Radiation Protection Regulations*

AREVA Resources Canada Inc. (ARC) appreciates the opportunity to comment on CNSC Discussion Paper DIS-13-01 *Proposal to Amend the Radiation Protection Regulations.* ARC participated as a member of an industry review group on the discussion paper and is generally supportive of the comments provided by the Canadian Nuclear Association. ARC's specific comments on proposed changes to sections of the regulations are provided in the attached table.

ARC would like to specifically address the proposed treatment of radon progeny by the Radiation Protection Regulations. The CNSC is seeking to simplify regulations governing dose by removing all aspects of the unique treatment of radon progeny. To achieve the simplification, a switch is required from the current system which records radon progeny exposure, to a system which records dose. The methodology of converting radon progeny exposure to dose has been the subject of international debate for several years. The uranium industry has presented its concerns to the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA) through an international working group of the World Nuclear Association (WNA). A discussion paper developed by the WNA working group on key issues is attached. ARC observes that a commitment by the CNSC to consult with stakeholders on the adoption of dose coefficients for radon progeny has been made and requests that the consultation be extended to address the methodology used to ascertain dose before the revisions to the Radiation Protection Regulations are completed. Adoption of the proposed ICRP methodology is premature; it should not be adopted without further validation of the models and practical aspects of implementation have been considered.

AREVA Resources Canada Inc.
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If you require any additional information or clarification regarding this submission, please feel free to contact the undersigned at dale.huffman@areva.ca or (306) 343-4569.

Sincerely,

Dale Huffman
Vice President
Safety, Health, Environmental & Quality

Attachments

Industry comments on Discussion Paper DIS-13-01 – Proposals to Amend the Radiation Protection Regulations

Document section/ excerpt of section	Industry issue	Suggested change(if applicable)	Major Comment/ request for clarification [1]	Impact on industry if major comment
Section 4: Radiation Protection Program	Radon Progeny: AREVA agrees that Section 4 can be simplified by removing the reference to radon progeny while preserving the intent of the section.	N/A	Comment	Simplification of Section 4 can be achieved independent of proposed changes in Sections 5 and 13.
Section 4: Radiation Protection Program- Dose Constraints	*Dose Constraints: AREVA agrees with the CNSC conclusion that a requirement for dose constraints is unnecessary at this time.*	N/A	Comment	AREVA looks forward to participating in future discussions about the need for dose constraints within the regulatory framework. AREVA is of the opinion that industry experience shows that radiation doses to workers are currently maintained ALARA in the absence of defined dose constraints.
Section 5: Ascertainment and Recording od Doses	AREVA disagrees that removing the reference to radon progeny exposure is only a simplification of wording. It is a change from recording exposure to radon progeny to a recording dose.	Preserve recording radon progeny exposure.		The National Dose Registry currently records radon exposure rather than dose. Recording of dose due to radon progeny requires the adoption of a convention or methodology. Switching to recording radon progeny dose risk convoluting the radon progeny exposure history of uranium miners in future epidemiological studies.
Section 7: Provision of information to all workers	Reporting individual dose levels to all worker involves an approach that will be a technical and administrative burden of limited value.	Preserve the existing concept of Nuclear Energy Workers.	Comment	At uranium mine sites, there are a significant number of workers involved in the construction of new facilities who have very low exposure to radioactive materials. Requirements to extend monitoring, reporting and training requirements to very low dose workers is not consistent with a risk-informed approach to regulation. The CNSC proposal will result in the consumption of resources with no clear improvement to worker doses. Removing the NEW concept will dilute average radiation dose statistics.
Section 13: Effective Dose Limits	AREVA disagrees that removing the reference to radon progeny exposure is a simplification to the regulatory language; the changes proposed by the CNSC represent the adoption of ICRP's proposed	A technical review and consultation on the treatment of radon progeny is required before changes to Section 13 are completed.	Comment	The international uranium mining community working collaboratively through the World Nuclear Association has developed a discussion paper on the key issues of the international debate on the changes to radon risk and related methodology for ascertaining dose (attached). AREVA looks forward to participating with other stakeholders in consultation

	dosimetric model.			involving the adoption of new dose coefficients.
Section 24: Records to be Kept by Licensees	The National Dose Registry (NDR) is the repository for dose records and as such should be where dose records are retained over a worker's life. If it is desired for licensees to have auditable records, a shorter retention time would be more appropriate.	AREVA recommends that records of doses generated be retained by the licensee for a period of 5 years, given the role of the NDR in Canada.	Comment	The administrative burden related to records retention is redundant and unnecessary with records of dose recorded in the National Dose Registry. The IAEA recommendations to oblige the licensee are perhaps suitable in the absence of a national system.

[1] **Please identify whether the comment is a major comment or a request for clarification**

International Debate on the Changes to Radon Risk: Key Issues for Implementers

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Prepared on behalf of the WNA[‡] Working Group on Uranium Mining Standardization

Abstract

For the uranium industry, the protection of its workforce and the public from radon and its decay products is of critical importance. Emerging issues of importance include the review of the relative risk of radon, the importance of smoking and smoking incidence on radon dosimetry, and the move from an epidemiological approach to a dosimetric approach for assessing the dose conversion. The uranium mining industry acknowledges that risk from radon has changed based upon the latest epidemiology studies. It is also apparent from these studies that smoking plays a dominate role in the determination of the risk and this needs to be carefully considered in the derivation of the conversion between risk and dose. A careful review of the data, including trends in smoking supports a dose conversion value of 6 to 7 mSv/WLM. With regard to the dosimetric approach, the uranium industry believes that more work is needed to validate the dosimetric model and to improve knowledge of radon progeny aerosols conditions in current workplaces. While the dosimetric approach appears to overestimate the dose from radon progeny to non-smokers, this does offer some reassurance that the dosimetry approach is conservative for the estimation of internal doses from other radionuclides. Industry recommends deferring the adoption of the dosimetric approach (for radon progeny) for application in specific workplaces until the needed work is satisfactorily completed. Industry, organized through WNA, plans to test the measurement of radon progeny aerosols conditions in uranium mines. In support of this, it has initiated work on the development of a standardized measurement protocol. The goal is to have publishable quality results within a few years. The industry is also willing to cooperate with research efforts to further validate the dosimetric model.

Background

Since the issuance of the ICRP's[1] 'Statement on Radon' in November 2009, several new developments and considerable discussion have taken place within the international community of radiological protection.

To ensure the uranium industry remains at the forefront of scientific developments on radon, industry experts have participated in a series of discussions on the ICRP developments which took place in 2012. Some of the key events included the IRPA13 international congress which was held in May, a meeting of an OECD/NEA[2] Expert Group on the ICRP Recommendations (EGIR) held in June which has served to conduct a review of an ICRP draft report on radiological protection against radon exposure, as well as a special session on radon at the IAEA[3] RASSC[4] meeting which was also held in June.

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‡WNA: World Nuclear Association

[1]ICRP: International Commission of Radiological Protection
[2] OECD/NEA: Organisation for Economic Co-operation and Development, Nuclear Energy Agency
[3] IAEA: International Atomic Energy Agency, which is part of the United Nations.
[4] RASSC: Radiation Safety Standards Committee

The OECD/NEA EGIR meeting involved about 25 radiation protection experts familiar with radon risk issues who have reviewed and discussed in detail (line-by-line) the ICRP draft report on radiological protection (RP) against radon exposure during two consecutive days. The special session (half day) on radon at the IAEA RASSC meeting involved a wider group of experts (50+) familiar with radon risk developments and related RP issues.

One main finding from these discussions is that the debate on radon risk, which entails a number of complex dimensions, involves input from a wide range of experts from epidemiology and dosimetry and with a range of perspectives on radon issues at work and at home. It also involves perspectives of regulators, miners and others. Such a diversity of expertise and perspectives enriches discussions on radon but also pose extra challenges for informed decision-making. In practice, very few experts have a full understanding of radon issues, from cradle to grave, over the entire scope of expertise and practical implementation.

Hence, there is merit in a consolidated overview of several key issues for implementers (e.g. experts from governments, regulators and industry) that were identified through participation in recent international discussions on radon, and in sharing such information within the community of experts. An overview of these key issues is presented on the next pages. Complementary information that further supports this overview is presented in the Annex.

Overview of Key Issues

Epidemiological approach to estimate the risk of lung cancer from radon exposure:

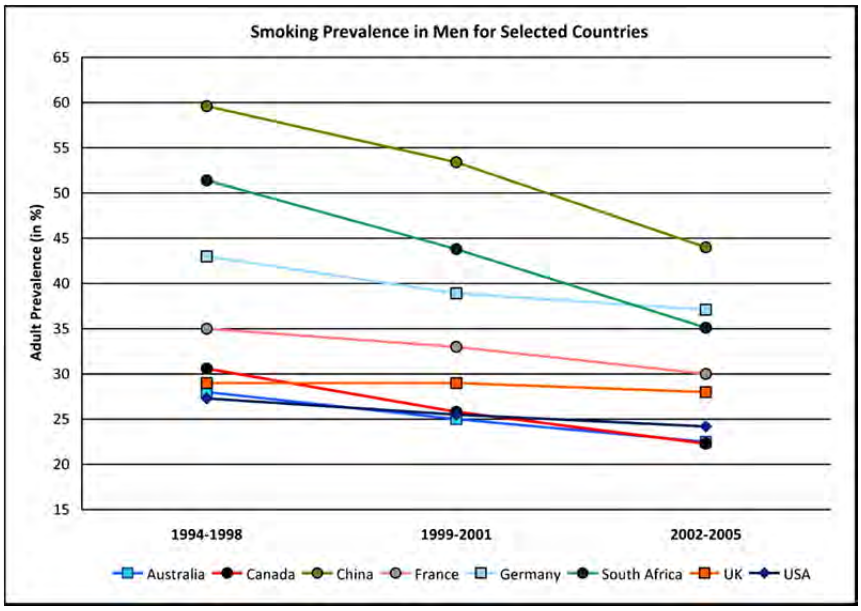
The fact that results from the most recent scientific analyses for uranium miners and for people in homes are coherently pointing at a comparable level of risk (i.e. a value of detriment per unit of radon progeny exposure of about 5×10^{-4} per WLM[5]) is comforting. This new risk estimate is about twice as high as previously thought.

How this new risk estimate translates into a practical quantity - like a dose conversion convention (DCC) or a dose coefficient – that can be more easily used by implementers needs to carefully account for the smoking prevalence of the reference populations that underpin this risk. This is particularly important because lung cancer risk from radon exposure is a relative risk to the baseline risk of lung cancer, and smoking is the predominant cause of lung cancer.

A reasonable “nominal” level of current smoking prevalence in the general mixed population of males and females ranges from about 20 to 30%. This level leads to a “nominal” DCC of about 6 to 7 mSv/WLM. However, a generally declining trend in smoking prevalence has been observed over the most recent decade (see Fig. 1) – thus suggesting a corresponding future declining trend in lung cancer risk from smoking and in turn from radon exposure.

[5] WLM: Work Level Month, a unit of exposure to radon progeny.

Fig 1 – Evolution of Smoking Prevalence in Men for Selected Countries



Due to the predominance of smoking in lung cancer risk, accounting for smoking prevalence and for trend in smoking prevalence is very important for the estimation of a relevant DCC to be used in the evaluation of prospective situations. For situations involving radon and smoking, the benefit from a reduction of smoking prevalence has a much greater impact than any reduction in radon levels in terms of both occupational and public health.

How much more important is smoking (than radon levels) in the reduction of lung cancer risk from exposure to radon exposure? Based on ICRP's value, the lifetime cumulative risk of lung cancer by age 75 is estimated for lifelong non-smokers as 0.5% and 0.7% for radon levels of 100 and 400 Bq/m^3, respectively. The corresponding risks for lifelong smokers are 12 and 16%. This means that for a radon level of 100 Bq/m^3, the estimated number of radon related lung cancers is of the order of 12,000 cases per 100,000 people for smokers, while it is of the order of 500 cases for non-smokers. For exposure to 400 Bq/m^3, the numbers of lung cancers increase to about 16,000 cases for smokers and 700 cases for non-smokers. In other words, a reduction (by factor of 4) in radon levels from 400 to 100 Bq/m^3 would result in a life-saving of about 4,000 persons among smokers whereas it would lead to a life-saving of about 200 persons among non-smokers. Over 95% of the total life-savings in a mixed population of smokers and non-smokers would be for smokers.

Another important consideration is that the lifetime risk of lung cancer from all causes in the general population is typically less than 10% and smoking represents most of this risk. Although radon is thought to be the second cause of lung cancer after smoking, it is clear that reducing radon levels can at best reduce the lifetime risk of lung cancer from all causes by no more than a few percentages. This observation is important to bear in mind as part of both occupational health and public health.

The ICRP has previously recommended that the current DCC of 5 mSv/WLM can continue to be used until new values are published. The current DCC is thought to be very protective of non-smokers. Doubling the current DCC value (to 10 mSv/WLM) without sufficiently accounting for smoking prevalence, seems to be overly protective of current smoking conditions. As viewed earlier, this is because a reasonable "nominal" level of current

smoking prevalence in the general population ranges from about 20 to 30% and that this level leads to a "nominal" DCC of about 6 to 7 mSv/WLM. Consider that a DCC of 10 mSv/WLM would correspond to a population with a smoking prevalence of about 50% which is substantially higher than current nominal smoking prevalence. Moreover, this higher DCC would not account for the generally decreasing trend in smoking that has been observed over the recent decade which will overtime lead to a lower baseline risk of lung cancer and in turn, to a lower (absolute) risk of lung cancer from radon in relation to prospective evaluations. Overall, a DCC of 10 mSv/WLM is likely to be increasingly conservative in the future and out of line with the anticipated future overall population risk. Ultimately, the dose conversion convention value (or the dose coefficient value) to be recommended by ICRP needs to be well supported and to adequately account for a reasonable "nominal" level of current smoking prevalence and trend.

Dosimetric approach to calculate the risk of lung cancer from radon exposure:

The dosimetric approach for radon progeny offers insights into the overall dosimetric approach for other radionuclides. This is important because while there is little or no epidemiological evidence for most other radionuclides, epidemiological evidence data does provide a basis to benchmark the actual risks from radon progeny. In this respect, the results from radon progeny using the dosimetric approach are quite encouraging as they indicate that the dosimetric model overestimates the actual (epidemiological) risk.

As supporting information on the likely overestimation of the dosimetric approach, calculations have shown that the dose coefficient for radon progeny for a non-smoker is 7 mSv/WLM while the epidemiological approach yields a value of about 1 to 2 mSv/WLM. For a non-smoker, this suggests that the dosimetric approach overestimates the risk from radon progeny by a factor of about 3 or more. This gives reassurance that a conservative approach has been taken with the overall dosimetric approach and calculated doses from other radionuclides are unlikely to be underestimated.

Caution in how the dosimetric approach is used for radon progeny is needed because a comparison of outputs between the epidemiological approach and the dosimetric approach suggests that some significant discrepancies remain. In addition to the factor 3 or more overestimation of the dose coefficient for non-smokers, the dosimetric approach's dose coefficients vary by about a factor of 2 between smokers and non-smokers whereas epidemiology shows that the actual variation is significantly higher (similar to the relative cancer risk due solely to smoking). This suggests that the adequacy of the current dosimetric approach to account for smoking and for the multiplicative interactions between smoking and radon exposure should be further examined.

A key outstanding issue of the dosimetric approach for radon progeny is that there is insufficient knowledge on the model and its input parameters at present in order to be sufficiently confident in the calculated dose coefficients. The dosimetric model for radon progeny has not been sufficiently tested against the epidemiological results for specific mines. While the dosimetric model for radon progeny appears to overestimate the dose coefficients for non-smokers by a factor of 3 or more, a validation or "benchmarking" exercise could help to ascertain how well the model accounts for variations in the risk from different radon progeny aerosol conditions. Until this validation work in done, it would be premature to attempt to apply the model to specific work environments.

Moreover, the existing knowledge on the model's required input parameters for mines is outdated and is not representative of modern mines. It can be expected to take several years to gather updated information and during this time it is hoped that improvements in the underlying model can be made. The uranium mining industry supports the concept of using a default value of dose coefficient to generally represent a generic mining environment, in as much as the result agrees with epidemiological studies, but believes that results from the dosimetric model need to be used very cautiously.

Industry is committed to test the characterization for radon progeny aerosols of active areas in modern mines with a view to examine if reliable input parameters can be obtained for the dosimetric approach. Industry understands a need to advance work on this front over the next few years. Some related challenges include: the current lack of relevant data and of a standardized measurement protocol for radon progeny aerosols given that little work has been done in this field over the last two decades; and the very limited capabilities to collect the needed data in the short term.

The combination of very variable mine environments where for example the unattached fraction of radon progeny aerosols in a mine environment can change rapidly from one location to another (metres) and the strong dependence of dose per unit of radon progeny exposure on particle size, suggests that considerable thought is needed to develop an operationally effective approach to implementation of the dosimetric approach in mines with doses relevant to miners actual exposures.

Summary of Uranium Mining Views of the Dosimetric Approach for Radon Progeny

As the risk from radon progeny can be estimated from both the epidemiological approach and the dosimetric approach (benchmarking to epidemiology), the further development of this relation through the examination of the use of the dosimetric approach for radon progeny should be encouraged. Because radon progeny, unlike virtually all other radionculides, has solid epidemiological data to benchmark theoretical internal dosimetry calculations, it offers a unique basis to further improve and give greater confidence in internal dosimetry models. Results to date indicate that the dosimetric approach for radon progeny is quite conservative. In addition, the dosimetric approach for radon progeny may also serve to investigate opportunities for optimal dose reduction in uranium mines.

The epidemiological approach leads to an estimation of radon risk that involves a wide range of macroscopic parameters. However, everything being equal, it allows for an accounting of smoking prevalence in the reference populations which is the predominant cause of lung cancer. As viewed earlier, this is important as the risk from exposure to radon progeny is a relative risk. Putting aside the current limitations of the dosimetric approach (e.g. limited validation, overestimation of risk for non-smokers, inability to adequately account for smoking and for the multiplicative effects of smoking and radon exposure), because of its more detailed input parameters, the dosimetric approach can give the impression of being able to better quantify the risk than the epidemiological approach. However, in practice, it will be very difficult to accurately measure the necessary parameters, thus limiting actual utility of the dosimetric model. In this regard, the two approaches have strengths and weaknesses with arguably comparable, but different, limitations.

All factors considered, industry proposes that the dosimetric approach for radon progeny aerosols in uranium mining should be validated against historic epidemiological studies and further developed to better account for smoking including its trends. Industry believes that there is still research required on the factors influencing dosimetric modeling for modern workplaces prior to implantation of a dosimetric approach. Industry is willing to cooperate with relevant parties in these activities. In addition, industry plans to better characterize radon progeny aerosols in mine workplaces with the goal of producing publishable results over the next few years. During this period of further development of the dosimetric model, industry believes that the most robust basis for calculating doses from radon progeny remains the dose conversion convention (DCC) from epidemiological studies, ideally adjusted for a nominal smoking prevalence or as a minimum, acknowledging the importance of smoking.

Conclusions

The uranium industry is critically aware of the importance of recent changes in radon epidemiology and dosimetry. The industry is fully supportive of adopting the best epidemiological data to calculate the risk and to apply these factors in the day-to-day protection of workers and the public. However, the industry wants to stress the importance of smoking on the amalgamated risk and how the trends in smoking occurrence will change this risk over time. The advances in dosimetry are acknowledged, but there is concern about the limited parameter data which exists on modern workplaces, such as uranium mines. The industry is focused on obtaining this data and believes that until the data is available the epidemiologic approach remains the best mechanism for ensuring radiation protection. However, the use of dosimetric approach could be used for optimization of radiation protection in the interim.

ANNEX

INTERNATIONAL DEBATE ON THE CHANGES TO RADON RISK: KEY ISSUES FOR IMPLEMENTERS (COMPLEMENTARY INFORMATION):

1. Main Outcomes from the Most Recent Epidemiological Analyses (ICRP 115, 2011a): These analyses point at a risk of lung cancer of miners and people at home from exposure to radon progeny (in terms of detriment per unit of radon progeny exposure) of 5×10^{-4} per WLM[6] that is about two times higher than previously thought (ICRP 2011b, para. 33);

    - How this translates into a practical quantity - like a dose conversion factor or a dose coefficient (e.g. expressed in mSv[7] per WLM for general situations; or in mSv per Bq/m^3[8] for homes) – that can be more easily used by implementers is not sufficiently well understood at present. This "translation" needs to carefully account for the smoking prevalence of the reference populations that underpin this risk. This is particularly important because smoking is the predominant cause of lung cancer risk and that lung cancer risk from radon exposure is a relative risk.

2. Smoking: The predominance of smoking in lung cancer risk is increasingly recognized and so are the effects of multiplicative interactions between smoking and radon exposure in relation to this risk. For perspective, it is evident that smoking is by far, the most important cause of lung cancer. ICRP 115 (para. 23) for example, notes that for the same radon exposure, the lung cancer risk from radon exposure is of the order of 25 times greater for smokers than for non-smokers. In absolute terms, the lifetime risk of lung cancer from all causes in the general population is typically less than 10% and smoking represents most of this risk. Radon is thought to be the second cause of lung cancer after smoking. Some important considerations to be noted include:

    a. Current epidemiological studies of miners and people at home, report the risk of lung cancer from exposure to radon as a relative risk. This means that the higher the smoking prevalence in a reference population, the higher is the baseline risk of lung cancer in a reference population and hence, so also, the higher is the risk of lung cancer from radon exposure.

    b. Adequately accounting for the "nominal" smoking prevalence of reference populations that underpin this risk is important.

    c. The significant general decreasing trend in smoking that is observed in populations around the world (see Fig. 1) suggests that the baseline risk of lung cancer will also decrease over time - as for example illustrated by Canadian experience (see Fig. A.1) - and hence the risk from radon exposure will also decrease in time. This decreasing trend in smoking is an important factor that should be accounted for in the estimation of lung cancer risk from radon exposure associated with prospective situations.

3. ICRP's Draft Report on RP against Radon Exposure (TG81, ICRP 2011b): This report puts forward a new policy that aims at improving the control of radon in existing exposure situations (e.g. exposures associated with homes and with past contaminated sites) which

[6] WLM: Work Level Month, a unit of exposure to radon progeny.
[7] mSv: milliSivert, a unit of ionizing radiation dose which accounts for biological effects on humans.
[8] Bq/m^3: Becquerel per cubic metre

have been defined by the ICRP. The ICRP received numerous comments on its draft report that capture both broad and more detailed aspects. For perspective, some of the main points that arose from the earlier mentioned OECD/NEA expert group meeting which reviewed the draft ICRP report included:

- "*Document Overview: It was felt that further editing is necessary for the Commission's message to be completely coherent throughout the document. The document is also in need of some language editing to enhance clarity.*"

- A second main point *("Consistency with the BSS"*) is that this report makes recommendations that have significant differences from the recently developed new IAEA BSS[9] and new EU BSS[10], and as such there is some concern with the implications of the lack of consistency among these reports.

- A third main point ("*Protection in Existing and Planned Situations*") is that the ICRPs discussions of the protection against radon exposure at work – which is a centrally important part of this document – was not presented clearly and that improvements made in the coverage of existing exposure situations have contributed to introducing some confusion in the coverage of radon exposure at work, including (unintentionally) for planned exposure situations, which notably include exposures associated with uranium mines.

Even if these difficulties are overcome by clarifying and improving the logic and nuances of the coverage of radon exposure situations in the draft report, one persisting challenge is the apparent significant variability in the dose conversion convention (or dose coefficient) to be used for radon exposure. For example, an exposure over a full year to a radon level of 300 Bq/m^3 in homes - which currently corresponds to a dose of about 10 mSv/y - was reported by ICRP members to correspond (using a new dose conversion convention or a dose coefficient) to 18 mSv/y and may be even as high as 40 mSv/y[11]. Understandably, this raises concerns in the international community of implementers. In due course, it should be openly addressed as part of an adequate process. ICRP's plans in this regard are not presently known.

Note: The issue of "*Dose Coefficient*" was another main point that arose from discussions during the OECD/NEA expert group meeting: *"The Group noted that final dose coefficient to convert from concentration of Radon-222, in Bq/m^3, to dose, in mSv/a, is currently under discussion. This issue is extremely important for developing protection approaches and criteria, particularly for mixed exposure situation (e.g. exposure to radon-222 and external gammas). The current understanding of the relationship between radon concentration and annual exposure, including a clear expression of how smoking is accounted for in determining the dose coefficient, should be clearly expressed in the document.*"

4. Epidemiological Approach to Estimate Radon Risk and Dose: *Epidemiological Based Dose Conversion Convention (DCC)* - The epidemiological approach notably serves as the current basis for the DCC. The DCC corresponds to the quotient of the risk (LEAR[12]) per unit of radon progeny exposure (WLM) by the risk coefficient per unit of exposure to

[9] IAEA BSS: IAEA Basic Safety Standards: Radiation Protection and Safety of Radiation Sources
[10] EU BSS: European Union Basic Safety Standards Directive
[11] The basis of this variation is not known at present but could involve effects of smoking prevalence in reference populations, and insufficient validation of the dosimetric approach or other factors.
[12] LEAR: Lifetime excess absolute risk

external radiation (mSv). For populations as a whole, the "nominal" DCC for exposure to radon progeny is currently equivalent (based on ICRP65) to 5 mSv/WLM.

- *Smoking and DCC* - Data on the smoking prevalence in selected countries which reveals evidence of a generally declining trend in smoking prevalence is shown on Fig 1. At present, overall smoking prevalence for males and females combined is generally in the order of 20 to 30%. A sensitivity analysis of the DCC to smoking prevalence by SENES (2011) using different published risk models resulted in a median DCC of about 6 to 7 mSv/WLM for a smoking prevalence of 20 to 30% (see Table A.1). Considering the above mentioned generally declining trend in smoking prevalence, this suggests a corresponding future declining trend in DCC for the estimation of lung cancer risk from radon exposure associated with prospective situations.

- Based on ICRP (2011a,b), the lifetime cumulative risk of lung cancer by age 75 is estimated for lifelong non-smokers as 0.4%, 0.5% and 0.7% for radon levels of 0, 100 and 400 Bq/m^3. The corresponding risks for lifelong smokers are 10, 12 and 16%. This means that for a radon level of 100 Bq/m^3, the estimated number of radon related lung cancers is of the order of 12,000 cases per 100,000 people for smokers, while it is of the order of 500 cases for non-smokers. For exposure to 400 Bq/m^3, the numbers of lung cancers increase to about 16,000 cases for smokers and 700 cases for non-smokers. In other words, a reduction (by factor of 4) in radon levels from 400 to 100 Bq/m^3 would result in a life-saving of about 4,000 persons among smokers whereas it would lead to a life-saving of about 200 persons among non-smokers. Over 95% of the total life-savings in a mixed population of smokers and non-smokers would be for smokers.

- Further insight as to the relative contribution of smoking and radon to lung cancer is provided in Table A.2 which is based on information from ICRPs draft report on protection against radon (2011a,b). To illustrate, the ICRP suggests that the underlying (baseline) risk of lung cancer is about 0.4% in non-smokers. Exposure of non-smokers to radon at 100 Bq/m^3 shows a lifetime relative risk of 0.5 % or an incremental (absolute) risk of 0.1%. For smokers exposed to radon at 100 Bq/m^3, the relative risk is about 30 fold. Depending on how the interaction between smoking and radon is assigned (to smoking or to radon), the risk assigned to smoking ranges from about 83% to 99% with the remainder assigned to radon.

- The ICRP has previously recommended that the current DCC of 5 mSv/WLM can continue to be used until new values are published. The current DCC is thought to be very protective of non-smokers. Doubling it (for example, by directly using the new risk factor per unit of radon progeny exposure given in ICRP115) without sufficiently accounting for the smoking prevalence in the reference populations that underpin this risk, seems to be overly protective of current smoking conditions. Evidence suggests that a "nominal" DCC of about 6 to 7 mSv/WLM would be consistent both with the most recent epidemiological analyses and with reasonably accounting for current "nominal" smoking prevalence in reference populations.

5. Dosimetric Approach to Estimate Radon Dose: *ICRP's Position* (2009, 2011a) – proposes to replace the current epidemiologically based DCC (ICRP65) by dose coefficients for the inhalation and ingestion of radon progeny which would be obtained using the dosimetric

approach currently applied to derive dose coefficients for the inhalation and ingestion of all other radionuclides (Marsh et al. 2010). ICRP also said that dose coefficients for radon progeny will be given for different reference conditions of domestic and occupational exposure, taking into account factors including inhaled aerosols characteristics and disequilibrium between radon and its progeny. In the interim, ICRP stated that the current dose conversion values may continue to be used.

A Likely Risk Overestimation by the Dosimetric Approach – The dosimetric approach for radon progeny offers insights into the overall dosimetric approach for other radionuclides. This is important because while there is little or no epidemiological results for most other radionuclides, epidemiological evidence does provide a basis to benchmark the actual risks from radon progeny. In this respect, based on Baias (2010) the results from radon progeny using the dosimetric approach are quite encouraging as they indicate that the dosimetric model overestimates the actual (epidemiological) risk..

As supporting information on the likely overestimation of the dosimetric approach, calculations have shown that the dose coefficient for radon progeny for a non-smoker is 7 mSv/WLM while the epidemiological approach yields a value of about 1 to 2 mSv/WLM (see Fig. A.2). For a non-smoker, this shows that the dosimetric approach overestimates the risk from radon progeny by a factor of about 3 or more. This gives reassurance that a conservative approach has been taken with the overall dosimetric approach model and calculated doses from other radionuclides are unlikely to be underestimated.

Discrepancies in Results Between the Epidemiological Approach and the Dosimetric Approach - The ICRP (2011b) draft report (para. 32) indicates that these discrepancies in the outputs (by a factor of approximately 2 in the past) have been reduced. Although this is encouraging, caution in the early results using the dosimetric approach for radon progeny is needed as a comparison (published by Baias 2010) of outputs between the epidemiological approach and the dosimetric approach suggests that some discrepancies remain (see Fig. A.2). In addition to the factor 3 or more overestimation of the dose for non-smokers, the dosimetric approach's dose coefficients vary by about a factor of 2 between smokers and non-smokers whereas epidemiology shows that the actual variation is about a factor of 25. Another discrepancy in the results is that Baias' dosimetric model outputs (dose coefficients) for non-smokers (NS) fall approximately mid-range between the outputs for heavy long term (HLT) smokers and for heavy short term (HST) smokers. This suggests that the adequacy of the dosimetric approach to account for smoking and for the multiplicative interactions between smoking and radon exposure should be further examined.

References

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SENES Consultants Limited, 2011. "*Report on Scientific Basis of Radon Risk in Uranium Mining and ICRP*."

Fig.A.1 – Evolution of Annual Mortality Rate and Smoking Prevalence (Canadian data)

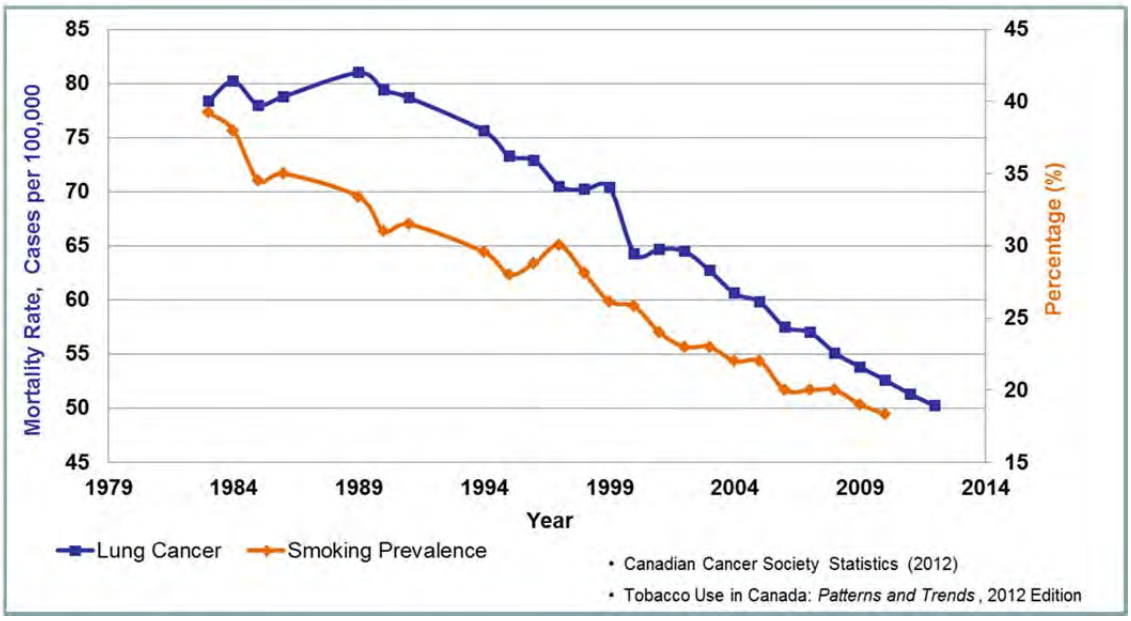

Table A.1 – DCC (mSv per WLM) as Function of Prevalence of Non-Smokers

% non smokers	**100**	**90**	**80**	**70**	**60**	**50**
GSF (ICRP 65)	2	3	4	6	7	8
BEIR VI	3	6	8	11	14	16
FrenchCzech	3	5	8	10	12	15
Ontario	1	3	4	5	6	7
Eldorado	3	7	10	14	17	21
Wismut	2	3	5	6	8	9
Darby	1	3	4	5	6	8

Fig. A.2 – Ranges of Radon Progeny's Dose Conversion and Dose Coefficients

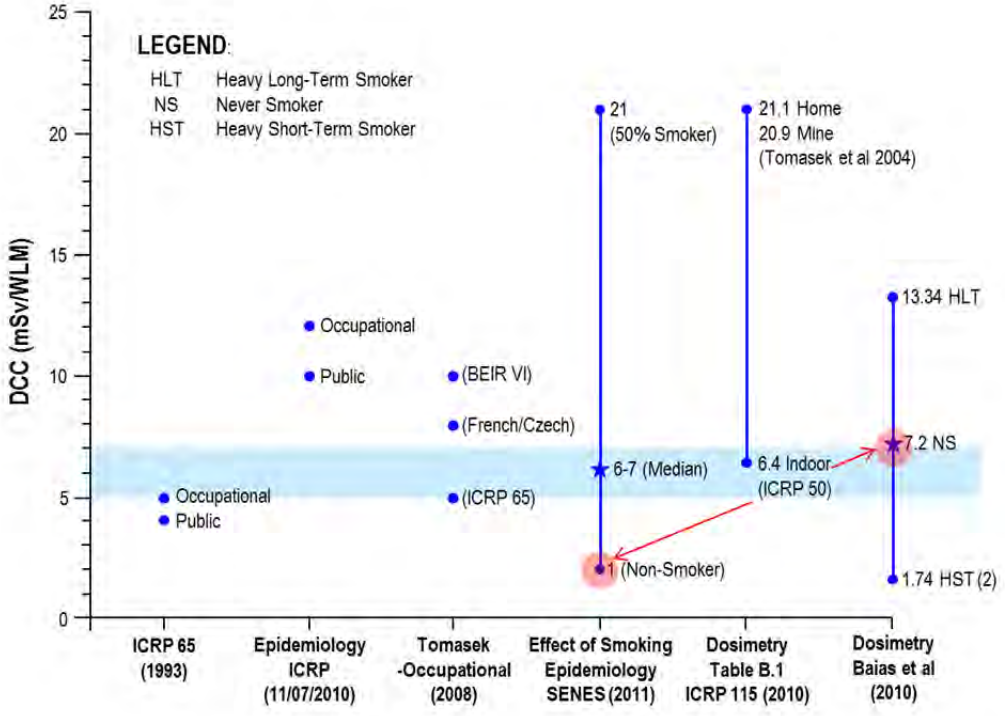

Table A.2 – Example of Contribution from Smoking and Radon*

Exposure Scenario		Lifetime Risk (%)	RR	EAR	Radon	Smoke	Interaction
Base		0.4	1	0			
Radon	100 Bq/m^3	0.5	1.25	0.1	0.1		
Smoke	Lifetime	10	25	9.6	0.1	9.6	
Radon and Smoke		12	30	11.6	0.1	9.6	1.9
					1%	83%	16%

- Partitioning indicates smoking responsible for the vast majority of combined risk
  - 83% if interaction term assigned to radon
  - 99% if interaction assigned to smoking

* Data from lines 852 to 858 of draft ICRP Report on Radiological Protection against radon for lifelong smoking and 100 Bq/m^3 radon.

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December 9, 2013

VIA EMAIL

Mr. Mark Dallaire
Director General
Canadian Nuclear Safety Commission
Regulatory Policy Directorate
PO Box 1046, Station B
280 Slater Street
Ottawa, ON K1P 5S9

Dear Mr. Dallaire:

Cameco Response to DIS-13-01: Proposals to Amend the *Radiation Protection Regulations*

Cameco's comments with respect to Discussion Paper DIS-13-01: Proposals to Amend the *Radiation Protection Regulations* (the Discussion Paper) are set out below.

Introduction

Cameco places a high priority on minimizing health and safety risks associated with our business activities. Cameco's, and our commitment to ensuring the safety of our operations is defined in our Safety, Health, Environment and Quality Policy.

While Cameco supports several of the proposed changes to the *Radiation Protection Regulations* (the Regulations) outlined in the Discussion Paper, some of the proposed amendments are of concern. Our concerns and accompanying recommendations in regards to the proposed amendments are discussed below.

Removal of Reference to Radon Progeny

Cameco supports removal of the terms "radon progeny", "effective dose and "equivalent dose" from paragraph 4(a), and suggests that paragraph 4(a) should simply require radiation exposures be kept ALARA. However, as will be discussed in further detail below, Cameco has reservations about dropping the use of the terms "working level" and "working level month" elsewhere in the proposed amendments.

Dose Constraints

Cameco agrees with and supports the decision of the Canadian Nuclear Safety Commission (CNSC) to forego the introduction of dose constraints into the regulations. The concept of dose constraints would add an unnecessary layer to an already robust system of limits and controls already required and present within the regulatory framework and licensees' program documents. Moreover, Cameco questions whether the dose constraint concept would be a useful tool to demonstrate ALARA, which has been accomplished to date without this concept. Cameco notes the CNSC's willingness to engage in further stakeholder feedback in this regard.

Ascertainment and Recording of Doses

Cameco does not support removing the specific reference to radon progeny exposure in subsections 5(1) and (2). Long-term continuous tracking of radon progeny exposures has been critical to advancing the understanding of the risks from radon progeny through epidemiological studies. While the International Commission on Radiological Protection (ICRP) has indicated it intends to move to a dosimetric model, continuing to track radon progeny exposures in the traditional units is not necessarily incompatible with this approach.

Provision of Information

The CNSC proposes to replace the term "nuclear energy worker" (NEW) with the term "worker", which would be defined as "a person who performs work that is referred to in a licence". In addition, it is proposed that "workers" be informed of their dose results in writing on an annual basis, meaning that individual doses must be determined and assigned to each "worker" (both NEW and non-NEW as currently defined in the Regulations).

These proposed amendments related to collection and reporting of doses to workers who are non-NEWs are not justified from a risk perspective. Currently, for each worker an assessment is conducted on their potential for exposure, which determines whether they should be made an NEW or not. Personnel expected to be well below the public dose limit, by definition, face negligible risk and typically are not individually monitored. The concerns related to this proposed would be somewhat mitigated with a reasonably narrow interpretation of the new proposed definition of a "worker".

The majority of non-NEW workers at our facilities are short-term contractors and many of these can be classified as providing ancillary support services, which are important to the operation of a modern facility (e.g. computer technicians, office equipment repair, specialized engineers, etc.). It is unclear if workers who provide support for work activities mentioned in a licence, but are not directly exposed to any radioactive material, would be considered workers under the proposed amendments. To the extent that this proposal expands the monitoring and administrative burden to very low risk job groups, this proposed change is unwarranted. This proposed change would put licensees in the position of allocating resources to attempt to measure and assign doses, often well below detection capabilities of the dosimetry equipment and methodologies. This is not a reasonable use of resources and, at such low doses, does not add benefit or reduce the risk to those being monitored. For sites with a large number of short-term contractors, there could be significant training and equipment to meet this requirement.

Addition of Requirement for the Provision of Information Related to Emergencies

Cameco is concerned with the proposed amendment to expressly require all workers to be informed of their duties and responsibilities in the event of an emergency, given that the definition of worker may be extended to non-licensed staff responding to an incident at a facility. In addition, licensed staff may need to be assigned new duties in an emergency, and it is not possible to pre-determine all contingencies.

Pregnant Nuclear Energy Workers

With regard to the proposed changes to section 11 to expand the requirements for breast-feeding NEWs, Cameco reiterates its view that this should be clarified to only be applicable to NEWs, and not to all workers.

Effective Dose Limits

Cameco's view is that the use of both a formula and written text would help to clarify how effective doses are to be calculated.

Cameco has concerns with dropping the use of traditional units of measure of radon progeny, i.e., the working level and working level months (WLM). At this time, the practical application of the ICRP's proposed dosimetric model is uncertain and a simple change in the conversion convention between units of WLM and mSv could address the ICRP's stated change in the risk from radon progeny. Cameco believes that the CNSC should not prematurely adopt the ICRP's proposed recommendation of moving to a dosimetric model that has not been adequately validated, nor demonstrated to be practical or possible to measure, in field conditions. The ICRP's dosimetric model for radon potentially may be useful for further scientific research, but not as a basis for regulatory control. Given the broad convergence of epidemiological and dosimetric risk estimates Cameco believes that workers remain well protected by keeping the basis of the limits in epidemiology. Cameco supports the CNSC's stated intention to carefully consider the latest scientific evidence and engage in further consultation before changing the risk estimate for radon progeny.

Five-Year Dosimetry Period

Cameco supports the current approach of fixed five-year dosimetry periods. The current approach provides adequate protection and a change to a moving five-year window will cause an unnecessary change to existing programs without a commensurate benefit to safety.

Equivalent Dose Limits for the Lens of the Eye

Cameco recommends that any amendments to the dose limits for the lens of eye be delayed until a practical way to measure this quantity is available that could meet the requirements of a licensed dosimetry service. The science on this issue is evolving, and risk from radiation doses to the lens of the eye is much less serious than other types of radiation exposures. As such, it does not pose an immediate concern and Cameco recommends that the CNSC use other more flexible

regulatory tools (e.g. licence conditions) to adapt as this issue evolves. Regardless of the regulatory tool used to control doses to the lens of the eye, Cameco believes that the limits proposed by the CNSC are too low when considering the risks from this type of radiation exposure and recommends further consultation be undertaken on this matter.

Records to be Kept by Licensees

Cameco believes that obligation of the reporting the doses from a licensed dosimetry service to the National Dose Registry (NDR) should rest with the licensee of the operation, as opposed to the licensed dosimetry service (LDS). The requirements for managing dose records of workers should be a licensee's responsibility, not the licensed dosimetry service. Under the current system, if mistakes are made in reporting to the NDR by the LDS, the licensee is not aware of them and has no role in being able to correct them. Since the licensee is expected to report doses to the workers and controls all other aspects of the radiation protection program, the licensee should also have the responsibility of submitting the data to NDR. This would improve the accuracy of the records and be a more efficient process.

Overall, Cameco is cautiously supportive of better defining a record retention schedule for radiation dose record, in order to have the same standards applied across the industry. The International Atomic Energy Agency (IAEA) approach is a useful reference; however, Cameco does not support a complete adoption of the IAEA approach, given the existence of the NDR. The NDR can supply dose records for individual workers for future activities, such as epidemiology studies and health-related queries, and thus Cameco questions the utility of requiring licensees to retain dose records for extended periods of time. Furthermore, the IAEA time frames will in some cases extend beyond the life of a licenced organization. Cameco suggests that further consultation be done on this area, as recommended time frames are likely to vary based upon differing opinions as to the underlying purpose of the activity.

Schedules 1 and 2

Cameco supports removing the technical details of the dose calculations (e.g. tissue weighting factors, radiation weighting factors), which can change with new scientific models. This will make it easier to align dose calculations with the latest international recommendations.

Proposed Section on Radiation Detection and Measurement Instrumentation

With regard to the proposal to add a section to the Regulations on radiation detection and measurement instrumentation, Cameco has several concerns. First, the CNSC notes that requirements already exist in other CNSC regulations and we do not support the addition of new requirements in the Regulations. However, Cameco would support a consolidation of requirements.

Conceptually, Cameco supports that calibrations be completed to an accepted standard, but does not believe that the referenced IAEA document should be directly referred to in the Regulations. There are several reasons for this. The IAEA document was published in 2000 and most of the references in the document are more than 20 years old and thus Cameco questions the applicability of the document for modern instrumentation. There are also explicit references to

technical details, such as air kerma to dose conversion factors, which are likely out of date. Cameco believes that a consolidated set of high-level requirements in the Regulations is appropriate and that specific detailed technical issues should be addressed in site-specific licensing documentation.

Proposed Section on Responsibility for Radiation Protection

This is adequately covered in the CNSC General Regulations, which already require the proposed measures to comply with the Regulations and a defined management structure.

Consistency Within the Radiation Protection Regime

Although not covered in the Discussion Paper, we wanted to comment that this would be an opportune time to remove the restrictions in section 13 of the *Uranium Mines and Mills Regulations* about the use of respirators. We note that no similar restriction exists for Class 1 nuclear facilities and the use of respiratory protection is a standard practice for certain tasks in nuclear power plants. Removing this restriction would provide licensees additional flexibility in the controls available to address potential radiations risks.

Carriers of Nuclear Substances

Cameco has already provided comments on the proposed changes to the *Packaging and Transport of Nuclear Substances Regulations* (PTNSR). Briefly, Cameco continues to hold the view that the requirements for the radiation protection program for carriers remain in the PTNSR.

Conclusion

Cameco would be pleased to respond to any further questions. Please contact the undersigned at (306) 956-6685 or liam_mooney@cameco.com.

Sincerely,

R. Liam Mooney
Vice-President
Safety, Health, Environment, Quality & Regulatory Relations
Cameco Corporation

cc: Regulatory Records - Cameco

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9 December 2013

Dear Sir/Madam

Review of the CNSC Draft Discussion Paper DIS-13-01: Proposal to Amend the Radiation Protection Regulations

Rio Tinto is a multinational company with extensive experience in uranium mining. Rio Tinto acquired Hathor Exploration Ltd., which had significant uranium prospects in Canada. Rio Tinto welcomes the opportunity to comment on the Discussion Paper DIS-13-01 Proposal to Amend the Radiation Protection Regulations.

Rio Tinto currently operates two major uranium mines (Rossing in Namibia and Ranger in Australia) and has over 30 years of experience in mining and processing uranium in sensitive environments. Rio Tinto also has a wide range of exploration interests worldwide and in particular interests in Canada such as the Roughrider deposit.

Rio Tinto is substantially supportive of the discussion paper and in particular the move to update the regulations to be compatible with current International Commission on Radiological Protection (ICRP) recommendations and International Atomic Energy Agency guidelines.

The only issue of potential concern is if the Canadian Nuclear Safety Commission wish to incorporate some of the emerging aspects of the ICRP and specifically new approaches to radon and radon decay product dosimetrety and the changes in non-cancer effects (including the lens of the eye). In Rio Tinto's view these two aspects are still very much subject to intense scientific debate and early adoption may be contrary to best practice. Provision could be made for adoption once the science is more fully understood and hence maintain confidence and certainty in these areas.

Rio Tinto thanks the Canadian Nuclear Safety Commission for the opportunity to comment on the discussion paper and once again states our support of the overall approach.
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Yours sincerely

Frank Harris
Chief Advisor Radiation Governance and Product Stewardship