St. Michael's

Inspired Care. Inspiring Science.

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

The following are comments on the comments relating to Discussion Paper DIS-13-01, Proposals to Amend the Radiation Protection Regulations. The format they follow is a specific comment (*in Italics*) that is identified by the commenter and page number of the comment from the Comments on DIS13-01. Proposal to Amend the Radiation Protection Regulations document. Our Comment follows in relation to our support or not of it in relation to the specific proposal it refers to.

General Comment on the Entire Discussion paper and CNSC Approach to Regulation as applies to the Hospital Sector

We whole heartedly agree with the many commentors such as (Jeff Dovyak RTNM, CRPA (R) Health Sciences Centre Winnipeg), Radiation Safety Coordinator who say that the proposals in this discussion paper (and most recent discussion papers for that matter) will do nothing to increase worker or other person's safety and that the end result will be a greatly increased regulatory burden added to the many other CNSC regulations of already questionable value. The entire hospital sector in Ontario and nationwide is basically under depressionary conditions with huge workloads and too few staff. There are absolutely no new resources that can be devoted to the effort of complying with increased regulatory burden, indeed what exists is in danger of being eroded further due to ever increasing financial pressures. It already takes a huge effort to comply with CNSC regulations just to be issued a satisfactory only rating for a perfect inspection. To add to this already huge regulatory burden with regulations that seem to be made for the sake of regulation is totally unacceptable. Indeed for the field of Nuclear Medicine already facing immense problems we fear this will help hasten the demise of this essential medical field. If anything the CNSC should be re-examining every regulation it has to deem whether it is really necessary or is regulation for the sake of regulation.

Below are our specific comments on the discussion paper DIS-13-01

2.2 Section 3 Administration of nuclear substance for medical purposes Page 6

<u>Comment on the Comment sent in by Jeremy Phipps [mailto:jphipps@exchange.hsc.mb.ca] Sent: Monday, November 25, 2013 2:40 PM (Pg 59 of Comments on DIS13-01. Proposal to Amend the Radiation Protection Regulations)</u>

Jermy Phipps writes:

"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."

Our Comment

We agree 100% with the above comments. Extensive Information is already given to the patient by us at time of administration on how to reduce exposures to others. The patient is the best one to give the information to those who they will be interacting with after leaving the hospital. To try and find every last person be it friend or family member who may or may not end of in a caregiving role is an impossibility. In this new age of AMPs is the CNSC going to charge a technologist or the hospital for not informing the family friend who decides at the last minute they are going to drop by and help out the patient with chores? Is the CNSC going to

insist that the hospital get signed off consents from all possible caregivers for what it itself admits is minimal risk? This has the probability of creating a vast new administrative burden in terms of time and effort for which there is no money and no staff to follow up on and no way to know if you even if you did if you have gotten everyone. We agree also that it could end of hurting patient care if potential caregivers decide to not help a patient if they are actually scared off by the question of risk , however minimal.

Section 4 Dose Constraints

Comment on the comment of Dave Tucker, CHP MSc RRPT CRPA(R) Senior Health Physicist McMaster University Health Physics Department (Pg 26 of Comments on DIS13-01. Proposal to Amend the Radiation Protection Regulations)

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

Our Comment

We agree with the above comment that the decision by CNSC to forgo introduction of Dose Constraints into the RPR is a good decision.

Comment on the 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 (Pg 34 of Comments on DIS13-01. Proposal to Amend the Radiation Protection Regulations)

"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 cannot be justified on any reasonable grounds, especially in the case of 'public' dose. For all practical purposes 1, or 10, or 100 μ Sv refers to the

same 'non significant' dose. Abandoning the ALARA convoluted reasoning will clear the language and the message: one cannot 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'."

Our Comment

We agree with the reasoning outlined above that the ALARA concept cannot be justified anymore on reasonable grounds. Present exposure regulations are set very conservatively. In addition most licensees such as us also have Action levels set a small fraction of the Regulatory limits to alert to anything out of the ordinary that should be investigated. The use of very limited resources, money and time in the hospital environment to try to lower doses or other Radiation safety parameters below already extremely conservative limits is not justified when they achieve no practical purpose and counterproductive.

Section 7 Provision of Information

CNSC Proposal (pg 8 of DIS 13-01) for Reference

Provision of information to all workers

"Paragraphs 7(1)(b), (c) and (d) of the Radiation Protection Regulations require licensees to provide written information to nuclear energy workers (NEWs) about the risks associated with radiation exposure, as well applicable dose limits and individual radiation dose levels, respectively.

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. 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, subsection7(3) would need an amendment requiring

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 acknowledgment from all of their workers of having been informed of the matters referred to in subsections 7(1) and (2).

With respect to the reporting of doses to workers, 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.

Subsection 5(1) of the Regulations requires all licensees to ascertain and record the magnitude of doses received by and committed to each person. However, in practice, licensees do not consistently record and report doses for workers who are not considered NEWs. The proposed amendment to section 7 would likely improve licensee compliance with subsection 5(1); however, certain licensees may incur administrative burden in order to conduct dose assessments for workers whose doses have not been formally assessed in the past. Likewise, certain licensees may incur additional costs to inform workers of their doses individually and in writing."

<u>Comment on the comment of McMaster University Health Physics Department Comments on DIS-13-01 Proposals to Amend the Radiation Protection Regulations (Pg 26 of Comments on DIS13-01. Proposal to Amend the Radiation Protection Regulations)</u>

"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."

Our Comment

We agree in the strongest terms with the above comments by McMaster in opposing the adoption of this provision. The comments on page 8 referred to above especially the following quote are troubling to say the least.

"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."

We seriously hope that the above quote was not written correctly because if it is taken literally it would mean that the hospital is taken to be a CNSC "licensed facility" and therefore all 7,000 employees who work for it are "workers under this new definition and that we must provide this information to all 7,000 inform each one in writing whether or not they are a NEW? Do they seriously think we have the resources to inform everyone of their dose in writing (which is non-existent in almost all cases) on a yearly basis? Even if the definition of a worker is taken as "one who performs work referred to in a licence " this would result in a many fold increase in administrative workload to inform hundreds of laboratory, housekeeping or other staff who may enter a low level use area such as licensed area in the course of a year as Mr. Tucker notes above. This provision alone would result in a many fold increase administrative burden and a huge miss- allocation of resources (both employees and money) that is desperately needed for other things in the healthcare system if we have to send emails to each and everyone informing them individually of their doses

Comment on the following Comment of Jeff Dovyak (Pg 49 of Comments on DIS13-01. Proposal to Amend the Radiation Protection Regulations)

"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. "

Our Comment

We strongly agree with the above comment and that it would have a huge impact and large Administrative burden.

Section 11: Pregnant Nuclear Energy Workers

Comment on the following Comment of Jeff Dovyak (Pg 51 of Comments on DIS13-01. Proposal to Amend the Radiation Protection Regulations)

"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.

Our Comment

We agree with the above comment regarding section 11 and that it would create a huge administrative burden.

Section 13: Effective Dose Limits

Comment on the following Comment of Jeff Dovyak (Pg 51 of Comments on DIS13-01. Proposal to Amend the Radiation Protection Regulations)

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

Our Comment

We agree with this comment that fixed 5 year periods should be kept.

Section 24: Records to be Kept by Licensees

Comment on the comment of Diana Arnal Charge Technologist/RSO Nuclear Medicine Department Victoria General Hospital Winnipeg, MB

"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?"

Our Comment

We agree with the above comment that this is an unnecessary duplication of responsibility already fulfilled by the National Dose Registry. It is also unreasonable to expect an institution to hold on to records for 75 years spanning multiple generations of workers. It would impose yet another administrative burden to keep track of all these records over multiple decades.

Submitted on behalf of St. Michael's by

Jim Fellowes St. Michael's Radiation Safety Officer

St. Michael's

30 Bond Street

Toronto, ON

M5B 1W8