From: Chambers, Doug <personal information redacted>
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Attention Brian Torrie, Director General Regulatory Policy Directorate

Brian

I have attached a few comments concerning the CNSCs proposed changes to radiation protection for the lens of the eye. Hopefully useful. If you or a member of your staff have questions, I would be pleased to do my best to answer.

Best regards

Doug

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COMMENTS ON PROPOSED REGULATORY CHANGES CONCERNING RADIATION EXPOSURE TO THE LENS OF THE EYE, CNSC'S PROPOSED REVISIONS TO THEIR RADIATION PROTECTION REGULATIONS AS SET OUT IN CANADA GAZETTE PART 1, 153, 1 JUNE 2019

Prepared by Dr Douglas Chambers Arcadis Canada Inc 15 July 2019

1. Background

The word cataract is used to describe any detectable change in the normally transparent lens of the eye. The effect of cataracts may vary from annoyance arising from tiny flecks in the lens to complete opacification and blindness. Most individuals between the age of 65-70 years have some manifestation of lens opacities with some level of vision impairment occuring in 50% of those individuals (e.g., COG 2014).

Exposure to ionizing radiation, either natural or manmade, can lead to the formation of cataracts.

After reviewing recent epidemiology data, ICRP proposed the threshold value for cataracts of an absorbed dose of 0.5 Gy, without any indication that fractionation of dose is less harmful then acute exposure (ICRP 2012). However, ICRP (2012) also reduced the annual equivalent dose limit to the lens from 150 mSv to 20 mSv averaged over 5 years, with maximum of 50 mSv in any single year (ICRP 2012). The ICRP analysis appears to be based on the presumption that given enough time, minor detectable opacities will lead to development of vision impairing cataracts (see for example discussion in COG 2014).

Its beyond the scope of this note to discuss the controversy around the ICRPs recommendation for the lens of the eye, other than to note that there are open questions about whether or not the epidemiological data support a threshold of 0.5 Gy for vision impairing cataract formation (e.g., COG 2014, EPRI 2014).

Thome *et al*. (2018) reviewed all of the published human epidemiological data on the effects of ionizing radiation on the formation of cataracts and conclude that there is no conclusive evidence that radiation exposure down to 0.5 Gy increases the risk of cataract formation. These authors also noted that only very few of the publications that were cited in support of a reduced dose limit have formally calculated a threshold dose, that only a limited number of studies directly relate to occupational exposure scenarios, and that the risk of cataract from occupational exposures is challenged due to differences in the type of exposure, age at exposure, radiation quality and latency.

A separate review by EPRI (2014) arrived at similar conclusions.

The NCRP in Commentary 26 ( )also noted that "*The value of the threshold for detectable opacity or VICs*[visually impairing cataracts] *is less clear, with the epidemiological evidence currently pointing to a threshold for VICs in the region of 1 to 2 Gy. However, NCRP has concluded that it is not possible to make specific quantitative estimates of lens effects thresholds at this time.*" (at page 60).

In response to the ICRPs recommendations, the CNSC has proposed changes to their regulations for radiation protection of the eye. Section 14 of the proposed changes to CNSC's Radiation protection Regulations notes that

"...radiation exposure to the lens of the eye, above a threshold dose, has been linked to its opacification (or clouding of the lens, which, in its advanced stages, is referred to as a cataract".

and goes on to propose

- *to change the equivalent dose[1] limit to the lens of an eye for a NEW from the current limit of 150 mSv to 50 mSv in a one-year dosimetry period; and*
- *to add a new equivalent dose limit to the lens of an eye for a NEW of 100 mSv in a five-year dosimetry period.*

While there are considerable uncertainties over the actual threshold for vision impairing cataracts, it seems prudent (and in my view quite cautious) to lower the annual limit for dose to the lens of the eye to 50 mSv in a year. However, I question the five year cumulative limit. Comments on this aspect follow.

I would be pleased to any questions that may arise from review of my comments below.

2. **Comments on CNSCs Proposed Radiation Protection Regulation**

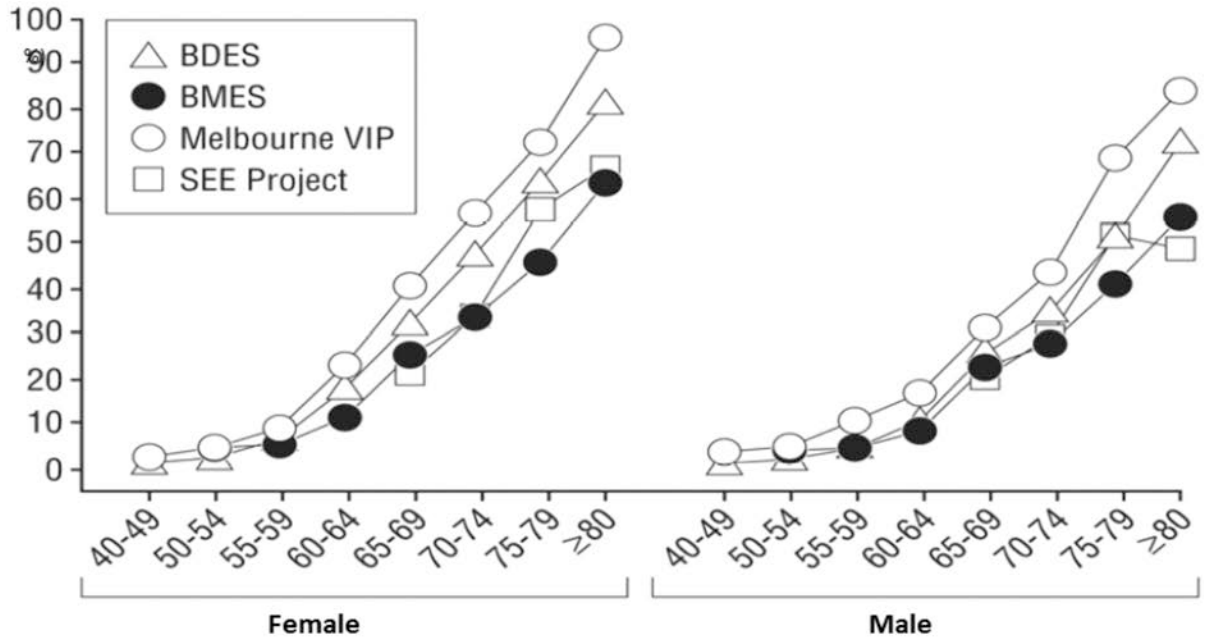
Risk

The CNSC (Canada Gazette) states that *It should be noted that new studies have shown that lens opacity (opacity is a "clouding" of the lens that obstructs the passage of light) can occur at significantly lower doses than originally thought. Given sufficient latency, chronic prolonged exposures and acute exposures can result in similar cataract outcomes.*

[1] The CNSC should consider whether the intended dose is effective dose or absorbed dose. For example, Para 2 of the ICRPs 2011 Statement indicates "For the lens of the eye, the threshold in absorbed dose is now considered to be 0.5 Gy."

The CNSC also notes that cataracts are common in the general population, citing a number of risk factors - such as aging, smoking, diabetes, exposure to sunlight, certain medication and other sources of ionizing radiation – all of which contribute to the development of the various types of cataracts.

We agree that many factors contribute to the occurrence of cataracts and add that age is a key factor- most people will develop cataracts if they live long enough. See for example the following figure (taken from COG 2014). The development of cataracts is multi-factorial, aging is the biggest factor - at the age of 55, few individuals have cataracts; however, after this age the incidence rises sharply, and by age 65 – 69, some level of vision impairment occurs in 20 - 40% of individuals. (SSK[2] 2009 as cited in COG 2014). US data, likely similar to Canadian data, suggests that by age 80, about 70% of people will experience cataracts (Thome et. al., 2018).



The CNSC in their proposed Rule acknowledge that "*This* [high natural incidence] *makes a quantitative assessment of health benefits from the reduction in the equivalent dose limit to the lens of the eye for NEWs challenging.*"

We agree and suggest that the epidemiology on which the ICRPs recommendations are based has substantial limitations as the result of high natural incidence and to date, poor/limited dosimetry.

[2] German Commission on Radiological Protection

Moreover, it is useful to note that as discussed in Thome *et al* (2018), most cataracts are easily treated through surgical replacement of the lens. Thome *et al*. (ibid) note that cataract surgeries are generally performed as outpatient procedures relying only on local anaesthesia and can be completed in less than 30 minutes, that in Ontario alone over 140,000 cataract surgeries are performed annually (approximately 1 for every 100 people), and that cataract surgery has a high success rate of greater than 90% based on improvements in visual acuity[3].

The ICRP 2012 recommendations are based on an underlying assumption of a nominal threshold of 0.5 Gy for acute or protracted exposure but acknowledge that

"*the evidence pertaining to the latter exposures mainly refers to opacities rather than cataracts impairing vision because the follow-up times are shorter in those studies.* ***For chronic exposure over several to many years, much of the evidence refers to minor lens opacities.*** [emphasis added] *Nonetheless, there is no indication that threshold accumulated doses are higher in this scenario. There are no established mitigators of lens radiation injury leading to opacities or cataracts,* ***but lens replacement is a well-established surgical procedure.***" [emphasis added] (at Executive Summary (i)).

Epidemiology

As previously indicated, Thome *et al*. (2018) reviewed and summarized all of the published human epidemiological data on ionizing radiation exposure to the lens of the eye in order to evaluate the proposed threshold. Data from a variety of exposure cohorts are reviewed including atomic bomb survivors, Chernobyl liquidators, medical workers and radiotherapy patients. These authors concluded, that overall, there is no conclusive evidence that the threshold dose for cataract formation should be reduced to 0.5 Gy. These authors note that "*although a number of publications have examined the impacts of radiation exposure on lens opacities, relatively few have provided sufficient data to accurately quantify the level of risk or to calculate a threshold dose. Only a limited number of publications have investigated occupational exposures. The cataract risk from occupational exposures may be much different from the calculated risk in many of the data sets reviewed here, due to differences in the type of exposure (acute vs chronic), age at the time of exposure, radiation quality and latency period*."

NCRP Commentary 26 (at page 60) notes that because of the incoherence of the mechanistic and epidemiologic evidence, it is not yet " *known if radiation cataractogenesis is a stochastic effect or is a tissue reaction in nature. The epidemiological evidence to date indicates a threshold model,*

[3] It should be emphasized that the induction of cataracts is not equivalent to the induction of a cancer and that cataracts, while annoying, at the stage that they become visually impairing are treatable. I am but one example of this.

and NCRP has determined that this model should continue to be used for radiation protection purposes at this time. NCRP also comment that

"*The value of the threshold for detectable opacity or VICs* [visually impairing cataracts] *is less clear, with* ***the epidemiological evidence currently pointing to a threshold for VICs in the region of 1 to 2 Gy.*** *However, NCRP has concluded that it is not possible to make specific quantitative estimates of lens effects thresholds at this time."*

Cumulative Dose

NCRP Report N0 180 at Section 5.2.2.2, NCRP recommends that the annual absorbed dose in the lens of the eye for occupational exposure should not exceed 50 mGy.

The NCRP does not specifically address lifetime cumulative dose for the lens of the eye but elsewhere (Section 5.2.1) notes (in context of stochastic risk)

NCRP recommends that the cumulative lifetime effective dose for an individual from occupational exposure should not exceed 10 mSv multiplied by the individual's current age in years.

In my opinion, if dose to lens to the eye is considered a stochastic effect, then the NCRP approach might be reasonable, if considered as a deterministic (threshold) effect then it should be regulated as such. In either case, the basis for a year cumulative dose limit of 100 a 5-year limit does not follow.

3. Main Observations

- Cataracts are naturally occurring and most people will develop cataracts as they age.

- The epidemiology is not adequate at the moment to be able to define a threshold reliably or even to determine whether lens opacity is a deterministic or stochastic effect.

- ICRP (2012) suggests that the main objective of radiation protection is to "*prevent acute radiation effects, and to limit the risks of late effects to <u>an acceptable level</u>*". [emphasis added]

- As noted above, we are unaware of any basis to set a 5-year cumulative dose of 100 mSv – irrespective of whether the effect of radiation dose to the lens of the eye is a deterministic (threshold/tissue effect) or a stochastic effect.

If stochastic, then a tissue weighting factor proportional to the hazards from cataracts is needed. Given the low hazard, such a tissue weighting factor would be small as the risks from formation of cataracts are small and in any event, cataract surgery for visually impairing cataracts has a high success rate.

If considered deterministic (i.e., with threshold), then a cumulative dose of 0.5 Gy (absorbed dose?), combined with the application of ALARA would seem reasonable.

- The CNSC should consider whether the intended dose unit is absorbed dose or effective dose.

Respectfully submitted by Douglas Chambers 16 July 2019.

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