HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

Brett J. Burk, Executive Director
1313 Dolley Madison Blvd., Suite 402
McLean, VA 22101
703-981-7708; Fax: 800-883-0698
HPS@BurkInc.com
www.hps.org

Comments on (Clement et al. 2021)
Brant Ulsh, Health Physics Society (USA)
2021-08-05

Dear Professor Magnuson:

As requested in your 30 August message, I am enclosing my comments on the paper, "*Keeping the ICRP Recommendations Fit for Purpose*", by Chris Clement. All of my comments are constructed to reference specific lines in the paper. Please feel free to contact me if you have any questions, require any clarifications, or need any other input from me on this assignment. Thank you for the opportunity to serve on this important IRPA Task Group, and I look forward to future assignments.

Best Regards,

Brant A. Ulsh, PhD, CHP
897 Baccarat Drive
Cincinnati, OH 45245, USA
Tel: +1 513 805 3445
Email: brant_u@icloud.com

Specific comments, with reference to line/lines in ICRP paper

Page 1, lines 44-47: "This is the beginning of a process that will take several years, involving open and transparent engagement with organisations and individuals around the world". Excellent – open and transparent engagement is exactly what has been lacking in the past, and what is needed now to increase confidence and buy-in from stakeholders.

Page 1, lines 51-54, and Pg. 3, lines 41-46: "Increased clarity and consistency are high priorities. The better the System is understood, the more effectively it can be applied, resulting in improved protection and increased harmonization". Yes – exactly right! It is not enough to simply make recommendations, but the rationale behind the recommendations must be clearly and succinctly stated.

Page 2, line 3 and Page 4, line 35, and Section 5.5: "Many areas are identified for potential review including:…heritable effects". Why are heritable effects listed as a focus for the upcoming review? I encourage the ICRP to consider the existing substantial body of evidence which has not observed heritable effects (i.e. radiogenic effects in germline stem cells which are then passed to offspring) in humans (Brent 2015). UNSCEAR has concluded,

> "There have been many studies of possible heritable effects following radiation exposure; such studies were reviewed by the Committee in 2001. It has been generally concluded that no heritable effects in humans due to radiation exposure have been explicitly identified (specifically in studies of offspring of survivors of the atomic bombings). Over the past decade, there have been additional studies that have focused on survivors of childhood and adolescent cancer following radiotherapy, where gonadal doses are often very high. There is essentially no evidence of an increase in chromosomal instability, minisatellite mutations, transgenerational genomic instability, change in sex ratio of offspring, congenital anomalies or increased cancer risk in the offspring of parents exposed to radiation. One reason for this is the large fluctuation in the spontaneous incidence of these effects". (UNSCEAR 2013)

What evidence suggests heritable effects should be considered a focus of continued research, rather than an answered question?

Page 4, line 42: "…risks to young children are greater than risks to adults". This is a common assertion, based on children having a greater expected remaining lifespan in which to express radiogenic cancer. However, another important factor to consider in determining the relative risk of children vs. adults is susceptibility for specific types of cancer. As discussed in (Ulsh 2015),

> "UNSCEAR recently reviewed the epidemiologic evidence on the sensitivity of pediatric subjects relative to adults (UNSCEAR 2013), and concluded:
>
> • For 25% of the cancer types, children appear to be more sensitive than adults;
>
> • Children appear to have the same radiosensitivity as adults for 15% of cancer types;
>
> • For 10% of the cancer types, children appear to be less sensitive than adults;
>
> • For 20% of cancer types, no conclusion can be drawn about the sensitivity of children relative to adults because the evidence is too weak; and
>
> • For about 30% of cancer types there is only a weak relationship or no relationship at all to radiation exposure".

Uncritically relying on the rule of thumb that "children are more radiosensitive" can lead healthcare providers to make incorrect decisions about pediatric imaging, for example. I encourage the ICRP to recommend that the situation be considered on a case-by-case basis (particularly in the pediatric imaging setting), taking into account children's longer expected lifespan, cancer-type specific susceptibility, and the specific tissues which will be exposed in a particular imaging procedure. Comprehensive guidance from an organization like The Joint Commission that takes these factors into account would be especially welcome.

Page 4, lines 56-60: "It is also worth considering how the World Health Organisation's definition of health as, 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' (WHO, 1946) could be reflected in the human health objectives". This is absolutely critical, and should be one of the main points of the paper, not just casually mentioned and not further developed. An important health effect in both the Fukushima and Chernobyl accidents was the mental health effects resulting from exaggerated fear, which was in turn a direct product of the current system's unsupportable application of the linear no-threshold model of radiation effects at very low doses (i.e. close to background).

Page 6, Lines 36-40: "…optimisation of protection and safety should not consistently seek the lowest exposures or risks possible, but a balance of factors including dose, risk, and other considerations. ICRP Task Group 114 aims to clarify how to take into account these other considerations including societal, environmental, economic, and general wellbeing". This should be the central recommendation, as it is the most significant challenge of the current system of radiation protection. Regulators pay lip-service to this concept, but when an emergency actually happens, they inevitably resort to driving doses as low as possible and ignore other factors.

Page 7, Lines 7-12: "A holistic approach could also consider factors beyond the radiological, including how to promote reasonable caution while avoiding undue conservatism within the System and its implementation. Further guidance may be needed on decision-making where doses are very low (e.g., well within normal variations in natural background), and the inferred risks for people and the environment are very low". This is absolutely critical. As recommended by UNSCEAR,

> "In general, increases in the incidence of health effects in populations cannot be attributed reliably to chronic exposure to radiation at levels that are typical of the global average background levels of radiation. … the Scientific Committee does not recommend multiplying very low doses by large numbers of individuals to estimate numbers of radiation-induced health effects within a population exposed to incremental doses at levels equivalent to or lower than natural background levels" (UNSCEAR 2012)"

IRPA should recommend a suitable stopping point for ALARA (Abelquist 2019), where in general, radiation risks are so small as to be unobservable (or may not exist at all), and are almost always outweighed by nonradiological risks, costs, and other social factors. Radiation doses within the normal variations in natural background are certainly below this point.

Page 10, Lines 11-24: The paper states,

> "Specifically, ICRP considers that 'the involvement of stakeholders is a proven means to ensure incorporation of values in the decision-making process, improvement of the substantive quality of decisions, resolution of conflicts among competing interests, building of shared understanding …, and building of trust in institutions' (ICRP, 2006).

ICRP recently clarified the ethical foundations of the System in ICRP *Publication 138* (ICRP 2018). The procedural values of inclusiveness, accountability, and transparency are directly related to stakeholder engagement which can support and broaden the decision-making processes, such as by highlighting considerations beyond the direct effects of radiation exposure".

I enthusiastically agree with these points. On this basis, the Health Physics Society requests that these comments be transmitted by IRPA to the ICRP. If, through the deliberative process, IRPA rejects or modifies these comments, we request that the rationale be explained in a transparent and publicly available record. Similarly, we encourage IRPA to request the same from the ICRP – a publicly available and transparent record of the disposition of the comments IRPA provides to the ICRP. It is imperative that the ICRP holds itself to the same standards of transparency and accountability it recommends for others involved in advising and setting public policy.

Page 10, Section 3.3: A welcome addition to this section would be a discussion of title protection. Radiation protection duties are increasingly being performed by individuals from allied fields (e.g. industrial hygiene), who may lack specific training, experience, or expertise in radiation protection. IRPA should vigorously advocate for recognition of the unique qualifications of radiation protection professionals.

Page 16, Lines 21-25: The paper states, "Even if there are still large uncertainties at low doses (UNSCEAR, 2012), some recent results demonstrate relationships at doses <0.1 Gy (Lubin et al., 2017; Little et al., 2018; Hauptmann 2020) with little evidence of the existence of a threshold". None of the cited studies demonstrate the absence of a threshold. As discussed in (Ulsh 2018), the cited study by (Lubin et al. 2017) did in fact present data consistent with a threshold of 0.03 Gy in the incidence of childhood thyroid cancer. The (Little et al. 2018) study did not formally test for thresholds, nor did they consider the hormetic dose-response suggested by the data they presented. They reported relative risk values <0 (though not statistically significantly so) for the lowest dose bins they considered for: (1) all myeloid malignant neoplasms, (2) acute myeloid leukaemia and myelodysplastic syndromes, (3) acute myeloid leukaemia, (4) chronic myeloid leukaemia, and (5) acute leukemia. Only acute lymphoblastic leukaemia and leukaemia, excluding chronic lymphocytic leukaemia showed no obvious suggestion of a hormetic response. Nonetheless, the authors did not remark on this pattern and did not report testing hormetic or linear with threshold dose-response models. (Hauptmann et al. 2020) did not report formal tests for thresholds. To be clear – I am not advocating hormetic or threshold models. Rather, I am advocating recognizing these as alternative hypotheses to be tested along with a LNT model. Further, I dispute the conclusion that these studies provide, "little evidence of a threshold", when one of the three did in fact present data consistent with a threshold, and the other two did not report testing for thresholds.

Page 16, Lines 27-35: This section states, "In a review of all relevant epidemiological studies, NCRP concluded that current epidemiological data support the continued use of the linear no-threshold (LNT) dose-response relationship for radiological protection purposes with no other model representing a more pragmatic interpretation (NCRP 2018)". The NCRP's review has been strongly criticized for, "…setting the LNT as the null hypothesis, and shifting the burden of proof onto LNT skeptics… arbitrary exclusion of alternative hypotheses, ignoring criticisms of the LNT, cherry-picking evidence, and making policy judgements without foundation" (Ulsh 2018). Specifically, (Ulsh 2018) disputed the argument that no other dose-response model is more pragmatic than the LNT model,

> "Alternative dose-response models (e.g. linear with threshold, hormetic, etc.) don't have to be "more pragmatic or prudent" than the LNT. Rather, they have to be tested against the appropriate no effect null hypothesis. If the evidence in favor of any tested alternatives is insufficient to reject the no-effect null, then the null stands. Furthermore, when testing the other, non-LNT alternative hypotheses, the correct null of no-effect has to be excluded in favor of one (or more) alternative hypotheses".

These criticisms were submitted to the NCRP under the auspices of the American Academy of Health Physics as 117 comments on the NCRP's draft report, and in a peer-reviewed publication following NCRP publication of its final report. The NCRP did not respond to the pre-publication comments and did not make any discernable corresponding changes to its draft report, nor has any response been forthcoming to the same criticisms presented in (Ulsh 2018). The NCRP's nonresponsiveness is not consistent with the recommendations on transparency and stakeholder involvement presented in (ICRP 2018), discussed above. Furthermore, this is just the latest example of a longstanding pattern of stakeholder criticisms of the LNT being ignored by expert advisory bodies and regulators. I again refer to comments the HPS has previously provided to IRPA regarding the application of the LNT model, and I request that these comments be conveyed by IRPA to the ICRP (Goldin 2020, Goldin 2021), especially:

- The HPS position statement, Radiation Risk in Perspective (https://hps.org/documents/radiationrisk.pdf) advises against estimating health risks to people from exposure to ionizing radiation that are near or less than natural background levels because of the large statistical uncertainties at these low levels. We state "...below levels of about 100 mSv above background from all sources combined, the observed radiation effects in people are not statistically different from zero." Also "...the LNT hypothesis cannot provide reliable projection of future cancer incidence from low-level radiation exposure." This position is based on known scientific evidence that (1) molecular-level radiation effects are non-linear, (2) radiogenic health effects have not been consistently demonstrated below 100 mSv, (3) dose-rate is a known factor that has demonstrated non-linear responses, and (4) misuse of collective dose in radiation protection planning and risk assessment decisions where "...the multiplication of small risk coefficients by large population numbers leads inevitably to unsupportable claims of cancer risk from ionizing radiation." The last factor is central to much of the regulatory problems encountered in the United States, and noted in the IRPA statement, regarding cleanup of contaminated sites.
- The HPS position statement, Uncertainty in Risk Assessment (https://hps.org/documents/riskassessment_ps008-2.pdf) states "…the expenditure of public and private funds to mitigate these risks should be commensurate with the public health benefits expected to be achieved" Examples of problem areas include (1) 100- to 1,000-fold discrepancies in permissible exposure levels among various

> regulations, all based on much the same scientific risk-assessment data, (2) proposed expenditures of billions of public and private dollars to clean up radioactively contaminated federal and commercial sites without careful consideration of the proportionality of costs to the public health benefits to be achieved, and (3) extensive delays in licensing facilities for the disposal of radioactive wastes and other applications of nuclear technologies. Perhaps most notable is the acknowledgement that cancer and other health effects have not been observed consistently at low doses (< 0.1 Gy), much less at the even lower doses (< 0.01 Gy) typical of most occupational and environmental exposures. We continue to recommend that regulations intended to achieve very low levels of radiation exposure should take full account of the uncertainties in risk estimates; otherwise, they may result in enormous expenditure of limited resources with no demonstrable public health benefits. In fact, some regulatory positions may increase overall public health risk when extreme measures, such as population relocation, to avoid effective doses of 50 mSv are imposed, due to physical injuries, mental health, and somatic illness induced by the stress of relocation, as appears to have occurred at Fukushima".

I also note that there are thousands of biological studies suggesting nonlinear dose-responses that have never, to the best of my knowledge, been systematically evaluated by ICRP or other expert advisory bodies [e.g. the 1269 references listed in (Luckey 1980), 1018 references listed in (Luckey 1991), and another 1092 more contemporary peer-reviewed references in the my personal library, several of which are discussed in (Cardarelli and Ulsh 2018)]. These references span from the late 1800s to today. I encourage the ICRP to evaluate this substantial body of evidence as part of their upcoming review.

REFERENCES

Abelquist EW. To mitigate the LNT model's unintended consequences—A proposed stopping point for As Low As Reasonably Achievable. Health Physics 117: 592-597; 2019.

Brent RL. Protection of the gametes embryo/fetus from prenatal radiation exposure. Health Physics 108: 242-274; 2015.

Cardarelli JJ, Ulsh BA. It is time to move beyond the linear no-threshold theory for low dose radiation protection. Dose-Response 16: 1-24; 2018.

Clement C, Ruehm W, Harrison JD, Applegate KE, Cool D, Larsson CM, Cousins C, Lochard J, Bouffler SD, Cho K, Kai M, Laurier D, Liu S, Romanov SA. Keeping the ICRP recommendations fit for purpose. Journal of Radiological Protection; 2021.

Goldin E. Comments "IPRA Statement on 'Reasonableness' in Optimisation of Protection'. 2020.

Goldin E. Comments "IPRA Statement on 'Reasonableness' in Optimisation of Protection'. 2021.

Hauptmann M, Daniels RD, Cardis E, Cullings HM, Kendall G, Laurier D, Linet MS, Little MP, Lubin JH, Preston DL, Richardson DB, Stram DO, Thierry-Chef I, Schubauer-Berigan MK, Gilbert ES, Berrington de Gonzalez A. Epidemiological studies of low-dose ionizing radiation and cancer: Summary bias assessment and meta-analysis. Journal of the National Cancer Institute Monographs 2020: 188-200; 2020.

ICRP. Ethical foundations of the system of radiological protection: ICRP Publication 138. Ann ICRP 47: 1-65; 2018.

Little MP, Wakeford R, Borrego D, French B, Zablotska LB, Adams MJ, Allodji R, de Vathaire F, Lee C, Brenner AV, Miller JS, Campbell D, Pearce MS, Doody MM, Holmberg E, Lundell M, Sadetzki S, Linet MS, Berrington de González A. Leukaemia and myeloid malignancy among people exposed to low doses (<100 mSv) of ionising radiation during childhood: A pooled analysis of nine historical cohort studies. The Lancet Haematology 5: e346-e358; 2018.

Lubin JH, Adams MJ, Shore R, Holmberg E, Schneider AB, Hawkins MM, Robison LL, Inskip PD, Lundell M, Johansson R, Kleinerman RA, de Vathaire F, Damber L, Sadetzki S, Tucker M, Sakata R, Veiga LHS. Thyroid cancer following childhood low-dose radiation exposure: A pooled analysis of nine cohorts. The Journal of Clinical Endocrinology and Metabolism 102: 2575-2583; 2017.

Luckey TD. Hormesis with Ionizing Radiation. Boca Raton, FL: CRC Press; 1980.

Luckey TD. Radiation Hormesis. Boca Raton, FL: CRC Press; 1991.

NCRP. Implications of recent epidemiologic studies for the linear-nonthreshold model and radiation protection. Bethesda, MD; NCRP Commentary No. 27; 2018.

Ulsh BA. Are risks from medical imaging still too small to be observed or nonexistent? Dose-response : a publication of International Hormesis Society 13: 1-27; 2015.

Ulsh BA. A critical evaluation of the NCRP Commentary 27 endorsement of the linear no-threshold model of radiation effects. Environmental research 167: 1672018; 2018.

UNSCEAR. Report of the United Nations Scientific Committee on the Effects of Atomic Radiation Fifty-ninth Session (21-25 May 2012). New York, NY: United Nations; Report No. A/67/46; 2012.

UNSCEAR. Report to the General Assembly with Scientific Annexes: Volume II. New York, NY; 2013.