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Richard Bramhall
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Dear Mr Bramhall.

RE: Justification of radiation exposures of members of the public and workers: review of existing practices; New and Important Information

I am writing in response to your letter of 22 May 2017 (which is an update of your letter of 24 April 2017). That letter responds to my letter of 30 March 2017, in which I advise that your request of 12 November 2016 for a review of the EPR class of practice does not satisfy the necessary criteria under the Justification Regulations.

The Secretary of State has considered your letter of 22 May 2017 and concluded that it does not provide new and important evidence about the efficacy or consequences of the EPR class of practice. The Secretary of State does not consider the information you have provided to be "important" because it still does not significantly change his view of the balance of the economic, social and other benefits of the EPR class of practice relative to is potential health detriments.

In particular, the Secretary of State remains satisfied that the potential health detriment from the EPR class of practice is very low and well understood. The Secretary of State also remains satisfied that you have not presented any sufficiently compelling evidence to demonstrate that the ICRP approach to radiological protection is flawed or is not the appropriate basis for assessing the potential health detriments of radiation.

In considering the information contained in your letter of 22 May 2017, the Secretary of State has been assisted by technical scientific advice from Public Health England (PHE). PHE advises the UK Government and other bodies with responsibility for protection against radiation

on risks connected with radiation exposure. The radiation protection functions set out in the Health and Social Care Act 2012 are delegated to PHE by the Secretary of State for Health.

A number of the points made in your letter of 24 April 2017 are re-statements of points made in your letter of 12 November 2016, and were dealt with in my response of 30 March 2017. There is no benefit in repeating large parts of that here, so this response addresses only on the main *additional* pieces of information provided in your letter of 24 April 2017:

- *ICRP heritable risk factors:* The examples used to demonstrate the claimed error in the ICRP heritable risk rely on data extracted from studies that are not credible or appropriate for this purpose due to their design (population correlation studies). The first example cites a 49% rise in congenital malformations in a 'medium' level contaminated area of Belarus. However, the same study reports a 43% increase in an uncontaminated area. Thus attributing the 49% change to radiation exposure is not justifiable. In the same study higher risk was reported in a 'high' exposure area but the opposite was reported in a further study by the same authors in the same country (Lazjuk et al, 2003, https://doi.org/10.1016/S0890-6238(03)00072-8), casting doubt on the reliability of the values.

- *"Further evidence":* The paper cited in the further evidence section (Fucic *et al*., 2016) does not provide any new evidence, credible or otherwise, that was not already available at the time the justification was published. Many of the studies employed either ecological or population correlation methodology that do not provide a reliable estimate of risk at the individual level.

- *Infant mortality:* The claim that there was a rise in infant mortality in the UK "at the time of the global nuclear fallout" is contradicted by the publicly available data from the Office for National Statistics which shows a clear sustained decreasing trend in rates over the whole 20th Century.

- *Comparison of risks:* The comparison of risks to members of the public as a result of the operation of nuclear facilities based on the risk values proposed in ICRP103 with the '1 in 1 million acceptable risk value as original proposed in the HSE document 'The Tolerability of risk from Nuclear power stations' (ref 35 and 36 in your letter) is in error. The former is measuring risk per unit exposure over a lifetime and the latter is measuring annual risk. The two are not comparable.

- *Ratios of male to female births:* The criticism by De Bellefeuille of the early work of Neel and Schull purporting to show a sex ratio effect in the LSS was addressed in a follow-up study with additional data (Schull et al, 1966, Am J Hum Genet 18:328-38) and concluded based on 73,994 births among exposed parents that: "[t]he suggestion of an effect of exposure on sex ratio in the earlier data is not borne out by the present findings. One can argue either that a small early effect has disappeared or that the original observation had no biological significance". This work did include consideration of children born of parents with only the father or mother exposed and those born of parents who were both exposed.

Your letter of 22 May 2017 also suggests misdirection on the part of PHE with regard to its advice to the Secretary of State on the information provided in your letter of 12 November 2016. In response to those specific suggestions of misdirection:

- *The LSS, internal contamination and uranium:* The analyses of the LSS cohort do not say anything about internal exposures as these have been assessed to be small and impossible to measure at an individual level which would be required for meaningful analysis. Evidence for the biological effects of Uranium as an internal emitter was recently reviewed by the respected United Nations Committee, UNSCEAR (UNSCEAR 2016 report Annex D). This review did not reveal any new or compelling evidence that would alter the current assumptions about risk from internal uranium exposure. The Sawada paper is based on a conference presentation by Dr Sawada and presents his views. It is not a publication of new primary scientific data. The Watanabe paper reports on a population correlation study comparing Hiroshima survivors with a separate control group. Although, the number of cancers seen was higher in the exposed group the methodology in the paper employed does not allow the reason for this difference to be identified. For example, increased surveillance of the survivors could be one reason. The conclusions of the paper are specifically refuted by Grant *et al.* (Environ Health Prev Med. 2009 Jul; 14(4): 247–249).

- *Uranium binding to DNA:* There are a number of studies of the biological effects of uranium exposure, many covered in the UNSCEAR report noted above. Of specific note is a study (Ellender et al, 2001, Int J Radiat Biol 77:41-52) that considered the induction of osteosarcoma and myeloid leukaemia in mice following internal exposure to uranium, plutonium or americium (all three are alpha-particle emitting radionuclides). The effects of all three radionuclides were proportional to the radiation dose delivered, and uranium was the least effective at inducing these effects. This study provides support to the findings of Tanner *et al*. 2012 that indicate the photoelectric effect is small.

- *Dropping the controls:* The comparison of the exposed LSS survivors to a separate control group with the aim of quantifying a dose response relationship is not appropriate. Such population correlation studies, do not produce reliable risk estimates, as a difference in health between the groups could be due to an increased disease rate among the exposed group or a lower than expected disease rate in the control group. Either reason could produce the same result. There was, therefore, a rational and coherent basis for the dropping of the control group in the LSS.

The Secretary of State's conclusion is that as your letters of 22 May 2017 and 12 November 2016 do not contain new and important evidence about the efficacy or consequences of the EPR class of practice, your request does not satisfy the criteria for an application under regulation 10 of the Justification Regulations, and the Secretary of State will not (and cannot) consider carrying out a review of the EPR class of practice.

We note your letter of 17 July 2017 to the Secretaries of State and a response will issue separately.

Yours sincerely,

Matt Clarke
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Department of Business, Energy and Industrial Strategy