

**Summary Minutes of the  
U.S. Environmental Protection Agency  
Science Advisory Board Radiation Advisory Committee  
Public Teleconference, November 10, 2015**

Date and Time: Tuesday, November 10, 2015, 12:00 p.m. – 3:15 p.m. ET.

Location: Teleconference Only.

Purpose: The purpose of the November 10, 2015 public teleconference was for the EPA's Science Advisory Board (SAB) Radiation Advisory Committee (RAC) to receive a briefing on the EPA's Advance Notice of Proposed Rulemaking (ANPRM) to consider revising the Environmental Radiation Protection Standards for Nuclear Power Operations (40 CFR part 190).

Participants:

SAB Radiation Advisory Committee (For full roster, see Attachment A):

Dr. David B. Richardson, Chair  
Dr. Sally A. Amundson  
Dr. Harry M. Cullings  
Dr. Lawrence T. Dauer  
Dr. Scott Davis  
Dr. Joseph E. Fitzgerald  
Mr. Earl W. Fordham  
Dr. Barbara L. Hamrick  
Dr. Kenneth G.W. Inn  
Dr. Annie B. Kersting  
Dr. Amy Kronenberg  
Dr. Brian A. Powell  
Dr. F. Lennie Wong  
Dr. R. Craig Yoder

EPA SAB Staff:

Mr. Edward Hanlon, Designated Federal Officer

EPA Staff:

Mr. Jon Edwards, EPA Office of Air and Radiation  
Mr. Brian Littleton, EPA Office of Air and Radiation  
Mr. Michael Boyd, EPA Office of Air and Radiation  
Mr. Thomas Peake, EPA Office of Air and Radiation

Other Attendees:

A list of persons present at the teleconference, who requested information on accessing the teleconference line, who participated on the live audio webcast, or who noted via email that they participated on the teleconference, is provided in Attachment B.

Materials Available: The agenda and other meeting materials are available on the SAB website ([www.epa.gov/sab](http://www.epa.gov/sab)) at the following SAB Radiation Advisory Committee November 10, 2015 public teleconference webpage:  
<http://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/b14d863bfc5e93a385257e98003ef3db!OpenDocument&Date=2015-11-10>

## **Teleconference Summary**

The public teleconference was announced in the Federal Register<sup>1</sup> and was conducted according to the teleconference agenda.<sup>2</sup> A summary of the public teleconference follows.

### **November 10, 2015**

#### **Opening Statements**

Mr. Edward Hanlon, the Designated Federal Officer, opened the public teleconference, and made a brief opening statement noting that the SAB Radiation Advisory Committee operates in accordance with the Federal Advisory Committee Act (FACA). He noted the teleconference was open to the public and that Agency-provided briefing materials were posted on the SAB website. Mr. Hanlon noted that Committee members were appointed as Special Government Employees to provide individual expertise and advice, not to represent any organization. He stated that forty sets of written public comments were received as of November 10, 2015 for the Committee's consideration, and that six members of the public had requested to present oral comments during the teleconference. He stated that the SAB Staff Office had identified no financial conflicts of interest or appearance of a loss of impartiality for any Committee members for this briefing. He also noted that minutes of the teleconference were being taken to summarize discussions and action items in accordance with the requirements of FACA.

Dr. David Richardson, Chair of the Committee, then welcomed everyone. Dr. Richardson noted that the goals and objectives for this teleconference were for the SAB Radiation Advisory Committee to receive a briefing on the EPA's ANPRM to consider revising the Environmental Radiation Protection Standards for Nuclear Power Operations (40 CFR part 190). Dr. Richardson summarized the teleconference agenda, and noted that since this was a briefing of the SAB Committee there were no charge questions to respond to during the teleconference. He noted that if members of the Committee wanted to make observations during the teleconference that were relevant to the opening remarks and slides that EPA was presenting, those observations were welcome. Dr. Richardson stated that during this briefing the Committee was not seeking to identify points of agreement nor develop individual or consensus oral or written advice that would be provided to the EPA at this time.

Dr. Richardson noted that six members of the public requested to present oral comments during the teleconference, and that while the SAB Committee was not obligated to respond to written public comments submitted for the Committee's consideration, the Committee members could ask relevant clarifying questions regarding any of the written public comments that the Committee received for its consideration.

Dr. Richardson then introduced Mr. Jon Edwards and Mr. Brian Littleton of the EPA Office of Air and Radiation.

## **Overview of EPA's Advance Notice of Proposed Rulemaking (ANPRM) and Summary of Public Comments on the ANPRM**

Mr. Jon Edwards, Director of the EPA's Radiation Protection Division, noted that his Division has the lead role for the rulemaking on 40 CFR part 190. He stated that under the Atomic Energy Act, the Nuclear Regulatory Commission (NRC) sets standards and the EPA sets regulations to apply those standards. Mr. Edwards noted that public involvement, input and review and comment on rulemaking efforts associated with 40 CFR part 190 was welcome. He stated that the EPA had not yet made decisions on moving forward with rulemaking activities for 40 CFR part 190. He stated that the EPA was currently in a listening mode, and wanted to consider science issues. Mr. Edwards then thanked the SAB for participating in this briefing.

Mr. Brian Littleton of the EPA's Radiation Protection Division then presented his slides<sup>3</sup> entitled "40 CFR part 190 Advance Notice of Proposed Rulemaking and Summary of Public Comments." On slide 1, Mr. Littleton noted that it was not the EPA's intent to weaken the environmental radiation protection standard. He noted that should the EPA move forward with rulemaking activities for 40 CFR part 190, the EPA would revise these regulations appropriately. On slide 3, Mr. Littleton noted that the 40 CFR Part 190 standards for environmental radiation protection for nuclear power operations provide regulations for the uranium fuel cycle and covered cycle steps from after mining operations to disposal. He noted that mining, transportation and disposal activities were not covered by 40 CFR part 190 and that these activities were covered by other regulations.

On slide 4, Mr. Littleton noted that the units for the last set of bullets on the slide were for gigawatts produced per year. On slide 5, Mr. Littleton noted that since 1977, the use of the term 'collective dose' had fallen out of favor in the scientific community, and that costs were considered when establishing the initial 1977 standards. On slide 6, Mr. Littleton noted that at the time the 1977 standards were developed, the EPA estimated that there be 300 gigawatts of electricity produced per year by the nuclear industry by the year 2000. Mr. Littleton stated that currently 100 gigawatts of electricity was produced by the nuclear industry per year, and noted that this figure had not changed in a decade. He stated that incidents such as the Fukushima Daiichi nuclear disaster had settled down nuclear energy production. He also stated that while dosimetry values used by the EPA relied upon the International Commission on Radiological Protection (ICRP) Publication Number 2 published in 1959, scientific thought on dosimetry and radiology have evolved.

On slide 7, Mr. Littleton noted that the EPA's ANPRM was issued on February 4, 2014, and that while the ANPRM stated that the public comment period was open through August 3, 2014, the EPA was still accepting public comments on the ANPRM. On slide 9, Mr. Littleton noted that the EPA received 33,000 comments from the public so far on the ANPRM, and that this number was growing. He stated that of these 33,000 public comments, 536 were discrete comments and 98% of the comments were duplicates.

On slide 10, Mr. Littleton noted that the EPA's current regulatory standards for 40 CFR part 190 expressed limits in terms of dose, whereas the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) expressed its limits in terms of radiation risk and releases through the environment. Mr. Littleton stated that the EPA could potentially harmonize these different standards through use of similar dosimetry methodology and numerical limits.

On slide 11, Mr. Littleton noted that public commenters stated there would be less uncertainty if the EPA based its risk standard on cancer mortality rather than on cancer morbidity. On slide 12, Mr. Littleton noted that if the EPA proceeded with a dose-based standard, the EPA has not yet decided how it should take into account updated scientific information and methods related to radiation dose. He stated that the EPA was considering use of a single dose approach for developing an updated standard.

On slide 13, Mr. Littleton noted that in updating the dose standard, the EPA was considering whether methodology within the ICRP's Publication Number 60 which was developed in 1991 should be used, or whether methodology within the ICRP's Publication Number 103 which was developed in 2007 should be used. He noted that some public commenters stated that these methodologies should be updated before EPA proceeded with a rulemaking on 40 CFR part 190. He also noted that the EPA, the NRC, and other federal agencies were working with the U.S. Department of Energy's (DOE) Oak Ridge National Laboratory to update national guidance, including guidance on radiological slope factors. He stated that the ICRP's Publication Number 26 and the ICRP's Publication Number 2 does not provide age or gender specific calculations nor assurances for the protection of children.

On slide 18, Mr. Littleton noted that currently spent nuclear fuel and high level nuclear waste is generated and stored at nuclear power facilities. He also stated that there are no limits on the timeframe for storage in spent fuel pools or on dry pads at nuclear power facilities. He noted there are no current disposal sites for these wastes, and that there have been no nuclear waste reprocessing plants in the U.S. since 1980. He also noted there were few public comments on the topics covered in the bullets on this slide.

On slide 19, Mr. Littleton noted that the newer nuclear technologies referred to on the slide related to how the dose standard could be met. On slide 20, Mr. Littleton noted that there were many public comments regarding the linear no-threshold model that is used as a basis for assessing radiological health effects.

On slide 21, Mr. Littleton noted that EPA's Office of Air and Radiation will continue dialogue with several entities in assessing whether to move forward with rulemaking activities for 40 CFR part 190. He stated that if the EPA decided to move ahead with a rulemaking, the EPA's Office of Air and Radiation would contact the SAB RAC potentially as early as 2016 and potentially request early advice for the EPA to consider on technical issues as the EPA conducts its analyses to support a revision to the 40 CFR part 190 regulations. Mr. Littleton noted that during such a potential consultation, the EPA would provide a more detailed set of slides and/or background document(s) with charge questions that the RAC would respond to.

Dr. Richardson thanked Mr. Edwards and Mr. Littleton, and asked if Committee members had any clarifying questions for Mr. Edwards or Mr. Littleton or had any comments related to their presentations. Regarding dose or risk limits, a Committee member asked whether it was the EPA's intention to have a single limit or multiple limits. Mr. Littleton responded that the EPA was considering options on this. Mr. Edwards noted that policy and science issues were at issue on this topic, and that the EPA was in a listening mode. A Committee member noted that the current regulation limits exposure to the whole body to 25 millirem (mrem)/yr., and asked how the EPA interpreted 'whole body' and whether the standard considered average exposure to the whole body. Mr. Littleton responded that the dose limit was based on effective dose plus internal dose, and on a uniform whole body dose.

Regarding slide 5, a Committee member asked who is responsible for storage safety and potential impacts to the environment. Mr. Edwards responded that the EPA is responsible for setting regulations, and the NRC sets up safety licensing. Mr. Edwards noted that the NRC's applicable regulations on safety licensing were found at 40 CFR part 20 and 40 CFR part 50, Appendix I. Mr. Edwards noted that the NRC must ensure that the NRC's licensees are compliant with the EPA's standards. The Committee member asked who is responsible for safety to the environment and to groundwater. Mr. Littleton and Mr. Edwards responded that the NRC addresses onsite releases of contaminants to the environment, and the EPA and the states address releases that might occur to the public.

A Committee member asked how policy would drive decisions regarding whether the EPA would set dose or risk limits. Mr. Littleton responded that EPA would consider the new science that has developed on these issues since 1977, and that policy was part of that decision-making process. He noted that while the RAC should respond to science issues that were being discussed, some topics involved both science and policy issues. Mr. Edwards noted that the EPA considered a number of topics when developing rules, and that science would be a driving function that the EPA Administrator would focus on should the EPA decide to move forward with a revision to the 40 CFR part 190 regulations. Mr. Edwards noted that if the EPA came back to the RAC for a consultation on rulemaking activities for 40 CFR part 190, the EPA would delineate policy issues within any documents that would be presented to the RAC.

A Committee member asked how cost would factor into decisions regarding development of a new standard. Mr. Littleton responded that the EPA was considering this issue, and noted that the current standard was developed with cost impacts in mind. Another Committee member asked whether 40 CFR part 191 discussed a dose-based standard. Mr. Littleton and Mr. Edwards noted that 40 CFR part 191 provided environmental protection standards for high-level nuclear waste, spent nuclear fuel, and transuranic waste. They noted that 40 CFR part 191 Subpart A limited releases from nuclear power facilities to different levels, including 25 mrem/yr. They also stated that 40 CFR part 191 presented a 15 mrem/yr dose standard for protection of the public from exposure to long term disposal.

Regarding slide 16, a Committee member asked for clarification on the industry's voluntary programs to protect groundwater. Mr. Littleton responded that the nuclear power industry initiated voluntary groundwater programs after identifying that releases were occurring into groundwater from their facilities. He noted that the Nuclear Energy Institute's (NEI) Initiative 07-07 sets an industry-wide voluntary process in place to prevent contamination of groundwater at nuclear power plants, and also sets procedures for how to respond and who to notify if nuclear contamination is detected at nuclear power facilities. Mr. Littleton noted that it was unclear whether these protections were sufficiently protective of human health and the environment, and whether the EPA or the NRC should codify these requirements. Mr. Edwards noted that the EPA is charged with establishing an environmental standard, and that the NEI's Initiative 07-07 sets forth a procedural process that is not linked to a federal standard. He noted that the EPA is asking the public what the EPA should consider, given the EPA's authorities and responsibilities.

Regarding slides 14 through 17, Dr. Richardson asked how radiation limits were related to groundwater protection. Mr. Edwards responded that the radionuclide release standards referred to in Issue 3 within slides 14 and 15 were developed using the 1977 standard which set environmental release caps based on total gigawatts. Mr. Edwards noted these radionuclide release standards were not developed using a groundwater limiting pathway. Mr. Littleton noted that 40 CFR part 190 standards apply to all pathways, and thus the water resource protection

standard within 40 CFR part 190 is a subset of the overall standard.

Regarding slide 17, a Committee member asked for clarification on the bullet that noted that some members of the public believed that Maximum Contaminant Levels (MCLs) should not be used as the basis for establishing a ground water protection standard for radiation since new risk levels have not been adopted. The Committee member also noted that some members of the public believed that that the EPA should update MCLs consistent with 4 mrem/yr for beta-emitters. The Committee member noted that the Safe Drinking Water Act (SDWA) used older science and not the most recent science to set these MCLs. Mr. Edwards responded that in addition to MCLs, the SDWA also sets Maximum Contaminant Levels Goals (MCLGs). Mr. Edwards stated that when the EPA established these goals for radionuclides, they set the MCLGs at zero since they are carcinogens. Mr. Edwards noted that an important policy issue was that if an MCLG is set at zero, even if evolving science supports a higher level, the EPA could not change the MCLG to 'backslide' and make the standard less stringent than zero.

A Committee member asked whether MCLs for radiation were dose-based values. Mr. Edwards noted that MCLs for radiation were annual dose-based limits. He noted that under the SDWA, these MCL's applied at drinking water taps/faucets in households. He also stated that it was the EPA's policy that the EPA would enforce these MCLs at the source of the groundwater, and that under the 40 CFR part 190 regulations a question was whether MCLs would be the allowable limits at the nuclear power facility fence line.

A Committee member asked whether the EPA ever made decisions that were not risk based. Mr. Edwards responded that 40 CFR part 300 codified the risk range. Another Committee member noted that the 4 mrem/yr standard for beta-emitters was based on scenario derivation, and asked if the standard could be changed based on a revised scenario. Mr. Edwards stated that this was a question for the EPA's Office of Water.

## **Public Comments**

Dr. Richardson stated that six members of the public requested to present oral comments during the public teleconference, and that the oral public commenters had three minutes to speak. He noted that it was important for the Committee to consider public comments, and that Committee members have the opportunity to ask clarifying questions of the oral public commenters. He also noted that there were a number of written public comments posted on the SAB's website for the briefing.

Ms. Diane D'Arrigo, representing Nuclear Information and Resource Service, presented her oral statement. Ms. D'Arrigo stated that she had been tracking radiation issues since the 1970s, and that she and several dozen organizations provided written comments to the committee. She noted that according to the National Academies of Science's (NAS) Biological Effects of Ionising Radiation Committee VII (BEIR VII) report on health risks from exposure to low levels of ionizing radiation, and according to the EPA's publication on "EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population" (i.e., the EPA Blue Book), females and especially female children were susceptible to radiation. She noted that gender- and age-averaging was not acceptable since such averaging did not protect the most vulnerable population. She stated that lifecycle phases that depend on reproduction should be protected, and that history has shown that radiation is more harmful than understood. She stated that since radiation at low doses was harmful, any changes in dosimetry values, or any changes in the 40 CFR part 190 regulations that would result in higher than current limits or that would lead to

release of a low dose that would not need to be regulated, would be objected to by members of the public. She noted that the EPA's emphasis should be protection from exposure, and that the ICRP's limits should not be adopted by the EPA. She noted that current regulatory levels under 40 CFR part 190 exceeded the allowable risk range, and that the EPA's changes to the 40 CFR part 190 regulations should correct this error.

Ms. D'Arrigo noted that a risk-based approach was favorable to a dose-based approach since members of the public can more readily understand what it means to be exposed to levels of radiation under a risk-based approach. She also stated that the definitions of millirem were changing to allow more releases of radionuclides. She noted that she strongly objected any delegation of authority to the NRC due to its lack of enforcement. She stated that the EPA does not know whether the NRC was complying with 40 CFR part 190 regulations, since there was no real time monitoring or reporting. She stated that low-level radiation wastes were currently being generated at higher rates than in previous years and that this was not being evaluated by the EPA or the NRC. She stated that the EPA should not facilitate new technologies related to reprocessing of radiation materials and also prevent such reprocessing since the reprocessing process removes the hottest part of radioactivity and releases the radionuclides. She also stated that the EPA should protect all waters to the maximum extent possible, and protect groundwaters and surface waters to levels provided within SDWA drinking water standards.

Dr. Richardson asked whether any Committee members had any questions for the speaker. Upon hearing no questions from the Committee, Dr. Richardson then recognized the next public speaker.

Mr. Dennis Nelson presented his oral statement, reading from a statement<sup>4</sup> that was posted onto the SAB teleconference website. Mr. Nelson noted that dose models that have been developed by health physicists were inappropriately borrowed from the disciplines of pharmacology and toxicology and did not apply to the physical damage caused by ionizing radiation in the human body. He stated that chemical damage caused by toxic materials was targeted to specific biochemical and physiological pathways and was based on toxin concentrations and the activation energy of the toxic reaction. He noted that dose is appropriate for assessing chemical toxicity because chemical energies are low. He stated that ionizing radiation produces very high energies, and can produce massive damage to cells at a microscopic level. He noted that this damage has no threshold and must be repaired by cellular processes, and that there is a need for research on the degree of biological repair that occurs following radiation exposure and damage. He noted that this research is difficult since the effects depend on the location of damaged cells and which sub-cellular organelles (e.g., mitochondria) are affected. He stated that damage to mitochondria is particularly problematic since such damage could release molecules that affect other mitochondria. He stated that radionuclides released into the environment are incorporated into body tissues and act like microscopic time-bombs at a microscopic level. He stated that damage to a stem cell is particularly problematic because such damage greatly affects the repair capacity of the body. He noted that any reference to radiation damage as a "dose" should be viewed with skepticism, and he urged the EPA not to relax the current standard since the current standard is already relaxed.

Dr. Richardson asked whether any Committee members had any questions for the speaker. Upon hearing no questions from the Committee, Dr. Richardson then recognized the next public speaker.

Mr. Jerry Hiatt presented his oral statement. Mr. Hiatt noted that he is a senior project manager and a certified health physicist, and a representative of the NEI. He stated that regarding Issue 4 (Water Resource Protection) in the slides presented by Mr. Littleton, Mr. Hiatt agreed with the EPA's statement that groundwater and surface water were valuable resources. Mr. Hiatt stated that it was appropriate not to include water standards in the EPA's 1977 rulemaking, and that releases from nuclear power facilities to groundwater and surface water resulted in smaller doses than releases by air. He noted that between 1977 and 2009, the nuclear industry has reduced releases by over 98%. He stated that if the rationale for not including water standards in the EPA's 1977 rulemaking was valid at that time, the rationale should be more valid in 2015 since releases from nuclear power facilities to groundwater and surface water are lower in 2015. He stated that the EPA's finding for not including water standards in the EPA's 1977 rulemaking should therefore be followed currently by the EPA. He stated that the NRC's current regulatory framework has adequately protected human health and the environment. He noted that the nuclear industry's underground initiative and underground piping initiative had received unanimous approval from all nuclear operators. He stated that these initiatives provide for self and peer assessments. He also noted that the existing approaches for protection of human health and the environment from releases from nuclear power facilities were consistent with current policies for protection at nuclear power facilities.

Dr. Richardson asked whether any Committee members had any questions for the speaker. Upon hearing no questions from the Committee, Dr. Richardson then recognized the next public speaker.

Ms. Cindy Folkers presented her oral statement as a representative of Beyond Nuclear.Org, reading from a statement<sup>5</sup> that was posted onto the SAB teleconference website. Ms. Folkers noted that the RAC membership should include experts in in-utero development, in reproductive assessment, and in how to assess and examine risks surrounding nuclear power facilities. She stated that in its comments to the NRC in a petition for rulemaking, the EPA recognized there is complex DNA damage from radiation. She stated that certain human life stages are uniquely vulnerable to damage from radioactivity. She noted that members of the public living around nuclear power facilities licensed by the NRC should know how these facilities affect their health. She stated that European studies show effects from cancer risks, and that there was a need for an improved understanding of cancer risks surrounding nuclear power facilities. She noted that biomarker measurements and other methodologies were needed to assess such cancer risks.

Dr. Richardson asked whether any Committee members had any questions for the speaker. Upon hearing no questions from the Committee, Dr. Richardson then recognized the next public speaker.

Dr. Alfred Meyer presented his oral statement as a representative of Physicians for Social Responsibility, reading from a statement<sup>6</sup> that was posted onto the SAB teleconference website. Dr. Meyer stated that the RAC should discuss certain life stages that are vulnerable to radiation exposure, such as reproduction and child development. He stated that standards that are established should protect the most vulnerable life stages, and that the RAC should reconsider any scientific or regulatory information that does not protect such stages. He stated that if standards do not protect the most vulnerable life stages, then unknown intergenerational effects would be bequeathed into future generations. He stated that the NAS has stated that all exposure to radiation increases health risks, and that the RAC membership should include experts on this topic.

Dr. Richardson asked whether any Committee members had any questions for the speaker. Upon hearing no questions from the Committee, Dr. Richardson then recognized the next public speaker.

Mr. Daniel Hirsch presented his oral statement as a representative of the Program on Environmental and Nuclear Policy at the University of California at Santa Cruz, reading from a statement<sup>7</sup> that was posted onto the SAB teleconference website. He stated that he was associated with a non-governmental organization that sent a detailed comment letter regarding the contemplated changes to the EPA's radiation protection standards. He noted he was struck by what was omitted in the EPA's presentation on 40 CFR part 190. He stated that while the EPA noted that its efforts to revise 40 CFR part 190 were driven by science and that the EPA had no plan to relax radiation standards, the standards that the EPA was considering to propose did not include new science and would dramatically increase permissible radiation exposures. He stated that risk estimates from the NAS's National Research Council and from the EPA have increased markedly based on new science. He noted that the accumulated scientific evidence accepted by the EPA has shown radiation to be five times more dangerous than when the current 40 CFR part 190 standards were adopted in 1977. He also noted that a recent publication by David Richardson and his colleagues demonstrated that the cancer risk reduction factor known as DDREF (Dose and Dose Rate Effectiveness Factor) should be abandoned, which would result in radiation to be seven to eight times more dangerous than when the current 40 CFR part 190 standards were adopted in 1977. He noted that the current 40 CFR part 190 whole body dose limit of 25 millirem/year was equivalent to a  $2 \times 10^{-3}$  risk level which is 20 to 2,000 times outside of the EPA's long-standing acceptable risk range for other carcinogens. He stated that there was no technical basis for the EPA to allow radiation to have a higher cancer rate than other contaminants, and that the EPA should reduce permissible exposures to 0.01-1 mrem/year in order to reach a  $1 \times 10^{-6}$  risk level. He stated that the EPA was not currently recommending to address these issues nor considering changes to current radiation dose limits, and that the EPA should consider and address these issues.

Mr. Hirsch also noted that the EPA's suggestion to eliminate the organ dose limits in 40 CFR 190 and move to an "effective dose equivalent" (EDE) would increase permissible exposures to many radionuclides and markedly weaken standards. He stated that, for example, permissible exposures for many plutonium isotopes would increase by a factor of 33 if the EPA eliminated the organ dose limits and moved to an EDE. He noted that David Brenner of Columbia University has stated that the EPA does not appropriately count cancers in its assessment, and discounts cancers based on the degree of pain and suffering and years of life lost from cancer. Mr. Hirsch also noted that the NRC's radiation protection regulations at 10 CFR 20 are based on exposure to 100 millirem per year which results in approximately a  $1 \times 10^{-2}$  risk. He stated that the NRC's tables of permissible concentrations of radionuclides do not comply with 40 CFR 190, would allow the risk equivalent of a chest X-Ray every week, and were not being enforced. Mr. Hirsch stated that since a large portion of the EPA uses a risk range approach towards addressing exposures, the EPA should not allow exposures to radionuclides that would not be allowed for other carcinogens.

Dr. Richardson asked whether any Committee members had any questions for the speaker. Upon hearing no questions from the Committee, Dr. Richardson thanked the oral presenters.

### **Clarifying Questions**

Dr. Richardson continued Committee discussion and reopened opportunity for further questions

for Mr. Edwards or Mr. Littleton. Regarding Issue 3 in the slides, Dr. Richardson asked for the EPA's rationale regarding placing or not placing release limits on tritium and C-14. Mr. Littleton responded that the EPA assessed whether tritium or C-14 could be sufficiently removed from air or water. Mr. Littleton noted that the EPA assessed the scale and levels at which tritium and C-14 would be emitted from nuclear power plants and facilities. Mr. Littleton stated that the EPA concluded that no technology could economically reduce tritium and C-14 levels to acceptable limits. A Committee member asked whether technologies were currently available to economically reduce tritium and C-14 levels to acceptable limits. Mr. Littleton responded that preliminary studies indicate that it would be difficult to economically reduce quantities of tritium and C-14 from nuclear power facilities. Mr. Littleton stated that the EPA had not yet conducted a cost/benefit analysis and thus this conclusion could not be made with certainty.

A Committee member noted that the slides indicated that the nuclear power industry stated that there was no need to reduce krypton levels since krypton has low level energy emissions. The Committee member asked whether the energy emission levels for krypton were similar to energy emission levels for C-14 and tritium. Mr. Edwards and Mr. Littleton responded that they did not have data available to answer this question. A few Committee members noted that krypton was a gas and was difficult to trap, that krypton was a risk in Nevada groundwater, and that the rationale for setting krypton standards was its persistence in the environment. A Committee member noted that krypton was a noble gas and was not a reactive gas.

A Committee member asked whether the EPA planned to adopt the BEIR VII guidance, and another Committee member stated that the EPA was striving to be consistent with the BEIR VII guidance. Mr. Boyd responded that the EPA published risk models in its Blue Book, and that the Blue Book incorporated the BEIR VII guidance. He stated that the EPA was in the process of developing a new dose coefficient, and that the technical support document for this new coefficient would be compatible with the Interstate Technology and Regulatory Council (ITRC) factors and with the BEIR VII guidance. Mr. Boyd noted that this new dose coefficient and supporting documentation was still being developed and would take a few years to be completed. He noted that the ITRC was developing new biokinetic information that be incorporated into the EPA's new dose coefficient. Mr. Edwards noted that the NAS, ITRC, and other radiation protection bodies and organizations all have critical roles in the scientific factors that the EPA would consider if the EPA moved forward with rulemaking efforts associated with 40 CFR part 190.

A Committee member asked whether and how the release limits and radiation protection standards that were referred to in the slides were policed and whether the NRC tracked these limits. Mr. Littleton noted that the NRC provided compliance assurance associated with the 40 CFR part 190 regulations. Mr. Littleton stated that the NRC could provide information on how it polices the regulations. He also stated that the EPA was considering changes to the standards that may affect the NRC's role in policing the 40 CFR part 190 regulations.

A Committee member asked why uranium 235 and 238 was not of greater concern than plutonium 239 in the potential changes to rulemaking efforts associated with 40 CFR part 190. The Committee member stated that plutonium 239 was not part of nuclear fuel but was a byproduct of the fuel. The Committee member also stated that both uranium 235 and 238 have a greater half-life and are much more mobile in the environment than plutonium 239. The Committee member also stated that nuclear fuel contained a larger portion of uranium 235 and 238 than plutonium 239, unless the uranium was captured by other alpha emitters. Mr. Littleton stated that uranium was captured by other alpha emitters. Mr. Edwards stated that the EPA's

focus was on plutonium that was captured by fuel cells. Mr. Edwards noted that the EPA would provide more information after the teleconference for the Committee's consideration regarding this topic. The Designated Federal Officer noted that this information would be posted onto the Committee's teleconference website upon receipt.

Dr. Richardson and a Committee member asked whether the EPA would use a risk range approach in addition to a dose standard towards addressing radiation exposures. They noted that there may be benefits to such an approach since a large portion of the EPA used a risk range approach towards addressing exposures for other carcinogens, since it would potentially be helpful to know population effects and the risk of radiation exposure at a given dose. Mr. Littleton noted that the EPA's Superfund office converted chemical and radiological contaminants into a risk number targeted to a  $1 \times 10^{-4}$  to a  $1 \times 10^{-6}$  risk range. Mr. Edwards noted that there were instances where the EPA's Superfund program would not be able to meet the EPA's  $1 \times 10^{-4}$  to  $1 \times 10^{-6}$  risk range, and that balancing criteria and costs would be considered for Superfund remedial decisions. Mr. Edwards stated that as the EPA considers decisions regarding rulemaking efforts associated with this portion of 40 CFR part 190, the EPA would identify key science issues associated with the basis for these decisions. Mr. Littleton stated that it was not certain whether there was a good rationale to develop regulatory levels based on both a risk range and a dose standard. He also stated that the EPA would seek to make these regulatory level decisions as transparently as possible, including decisions regarding revisions to standards, how risks would be assessed, and what doses were important to understand. Mr. Boyd stated that when the EPA was first established, the EPA's Office of Research and Development was designated to be responsible for the development of risk coefficients for most constituents, and the EPA's OAR was designated to be responsible for developing risk coefficients for radionuclides. Mr. Boyd stated that there is not always a 1-1 relationship between a risk range or a dose approach towards addressing radiation exposure.

Another Committee member asked whether the EPA perceived risk differently if the risk to be addressed was preventative such as in cases similar to the Superfund program's cleanup actions. Mr. Boyd responded that if the EPA were assessing a particular exposure such as an accidental radiation release near an elementary school, the EPA would not use an age-averaged risk coefficient to assess the risk. He stated that in such scenarios, the EPA would use age-specific risk coefficients to assess such risks. Mr. Boyd noted that the EPA would likely use age-averaged risk coefficients to assess low-level exposures to the public. Mr. Boyd stated that the EPA updates risk coefficients approximately every ten years when baseline rates for breast or lung cancers change.

A Committee member asked whether and how the Federal Guidance Report (FGR) No. 13, entitled "Cancer Risk Coefficients for Environmental Exposure to Radionuclides: Updates and Supplements" would be considered as part of the EPA's rulemaking efforts regarding 40 CFR part 190. Another Committee member asked whether updated dose coefficients that used the most recent science would be provided to the SAB RAC for consideration. Mr. Peake noted that the EPA raised these questions and issues in the EPA's ANPRM. Mr. Boyd noted that the EPA is currently using the FGR 13 risk coefficients within 40 CFR part 190 regulations. Mr. Boyd noted that peer review and public comment was still ongoing regarding potential changes to 40 CFR part 190 regulations, and that the EPA would continue using the FGR 13 risk coefficients until at least after these efforts are completed. Mr. Boyd stated that the EPA has not yet decided whether to move forward with changes to 40 CFR part 190 regulations and whether a risk or dose-based standard would be taken. Mr. Boyd also noted that the EPA was updating dose coefficients based on new science, and that if the EPA moved forward with changes to 40 CFR part 190 regulations

it would seek to incorporate the new FGR dose coefficients in that effort. Mr. Boyd also noted that the EPA and the NRC were providing funding for the ICRP to work on this topic.

A Committee member noted that it appeared that the EPA expects to receive updated risk coefficient information in a relatively short timeframe from the ITRC and from other entities, and asked whether it would be preferred that the EPA hold off on deciding to update its rulemaking efforts regarding 40 CFR part 190 until the updated risk coefficients were available. Mr. Boyd stated that if the regulatory process followed normal time cycles, the updated risk information would be available for the EPA to consider prior to updating the 40 CFR part 190 regulations. Mr. Edwards stated that the EPA has flexibility regarding the schedule for updating the 40 CFR part 190 regulations, and flexibility in gathering background information that would support such a rulemaking. Mr. Edwards noted that the rulemaking process can be long and arduous, that many issues have been identified associated with and updating the 40 CFR part 190 regulations, and that the EPA sought to incorporate good science into its rulemaking efforts. Mr. Littleton responded that in 2008-2010, the EPA estimated that many new nuclear power plants would potentially be opening within a few years, and the EPA sought to put updated 40 CFR part 190 regulations in place to meet this demand. Mr. Littleton stated that these 2008-2010 estimates for new nuclear power plants have changed. Mr. Boyd also noted that existing, operating nuclear power plants were extending their licenses from 40 to approximately 60 years.

A Committee member asked how the EPA calculated effective dose in assessing risks for individual radionuclides. Mr. Boyd responded that the EPA did not calculate effective dose when assessing risks for individual radionuclides. He stated that the EPA chose to protect to a 50<sup>th</sup> percentile level of protection, and could do special assessments to protect certain age groups using available data. Mr. Littleton noted that the EPA would consider, as a policy matter, whether and how effective dose would be used for a proposed standard if the EPA moved forward with rulemaking efforts regarding 40 CFR part 190.

A Committee member asked for information on the quantitative uncertainties of the evolving biokinetic information related to radionuclides. Mr. Boyd stated he was not sure what these uncertainties were, but that such uncertainties would be calculated on a radionuclide to radionuclide basis. Mr. Boyd stated that radium, thorium, cesium, and strontium had a large amount of biokinetic information and that therefore the uncertainty bounds for these elements would be tight. He noted that other radionuclides with few animal studies would have higher uncertainty. Mr. Boyd stated that a biokinetic issue was where ingested radionuclide constituents went in the body, and how long such constituents stay in those locations of the body. He noted that metabolism varied between people for these radiation constituents, and that the uncertainties associated with biokinetic modeling were not the largest uncertainties related to potential changes to rulemaking efforts regarding 40 CFR part 190. Mr. Boyd also noted that Monte Carlo analysis would be needed for source modeling that may be conducted to assess potential changes to rulemaking efforts for 40 CFR part 190. He stated that the ICRP's reports provided estimates for uncertainties for individual radionuclides.

Regarding slide 4 of the slides presented by Mr. Littleton, a Committee member asked whether the EPA was considering organ dose in its assessments. Mr. Littleton noted that if the EPA were to update the dose standard, the EPA would potentially use newer dosimetry to assess such an updated dose standard if appropriate data were available. In addition, Mr. Littleton noted the EPA would also consider whether specific assessments for specific organs should be conducted. Mr. Edwards noted that the EPA was considering different options for considering organ doses in order to assess an updated dose standard, and that the EPA received public comments

recommending that the EPA should use an organ-based approach for such an assessment. Mr. Peake stated that the EPA SAB had previously recommended that the EPA should use effective dose in assessing risks for individual radionuclides. Mr. Peake stated that the EPA had not yet decided how to approach such an assessment and would consider various options if the EPA moved forward towards making potential changes to rulemaking efforts for 40 CFR part 190. Mr. Peake noted that if the EPA returned to the SAB RAC in 2016, the EPA may ask the SAB what the EPA should consider in such analyses.

A Committee member asked how the EPA and other agencies would be addressing fundamental source terms, since there have been changes in radiation technology and spent fuel over the past 40 years. The Committee member noted that a Sandia National Laboratories' assessment indicated that dilution occurred from tritium sources and that questions arose regarding the dose standard based on such source terms. Mr. Littleton noted that estimates for the quantities of radiation released incorrectly projected the quantity of gigawatts of nuclear energy that would be produced and the number of nuclear reactors that would be in operation over time. Mr. Boyd stated that biokinetic information related to radiation was evolving, and that improved scientific, peer reviewed data on these topics would be useful to the EPA. Mr. Boyd and Mr. Littleton stated that this information would be made available to the public through federal guidance if the EPA decided to make changes to rulemaking efforts associated with 40 CFR part 190.

A Committee member asked how the EPA's rulemaking efforts regarding 40 CFR part 190 related to the ICRP methodology, and whether these EPA rulemaking efforts and the ICRP's methodologies would be linked. Mr. Boyd responded that the SAB has previously approved the EPA's Blue Book cancer risk calculations to populations, and noted that such calculations used settled science. He stated that new biokinetic information, new source targeting data and new dose information would inform the EPA as the EPA considers established risk per unit dose information.

A Committee member noted that Mr. Littleton stated that the EPA may decide in January 2016 to move forward with its rulemaking efforts regarding 40 CFR part 190. The Committee member stated that the EPA appears to have presented ample evidence to move forward on this path. Mr. Boyd stated that if the EPA decided to move forward with updated rulemaking efforts regarding 40 CFR part 190, the EPA would include such efforts into the EPA's regulatory agenda. Mr. Boyd also stated that a proposed rule may not be available during 2016 if the EPA decided to move forward with such a regulatory effort.

A Committee member asked whether the EPA's comments to the NRC on the reconsideration of the "linear no-threshold" concept could be provided to the RAC for its consideration. Mr. Boyd stated that these comments were in the NRC's public Docket, and that these comments would be forwarded to the Designated Federal Officer for posting onto the RAC's teleconference website.

## Next Steps

Dr. Richardson asked if Committee members had any additional comments to make. Hearing none, he noted that he and the Designated Federal Officer would develop minutes for the public teleconference that would be posted on SAB's website. Dr. Richardson then summarized next steps for the Committee.

Dr. Richardson noted that in early 2016, the EPA planned to make a decision on whether to move ahead with a revision to the 40 CFR part 190 regulations. He stated that if the EPA decided to move ahead with a revision to these regulations, the EPA anticipated coming to the SAB RAC for a consultation as early as spring 2016 in order to request SAB early advice on technical issues for the EPA to consider as it conducted its analyses to support such revisions. Dr. Richardson noted that if a consultation with the RAC would occur on this topic, the EPA would provide a more detailed set of slides and/or background documents, and also provide charge questions that the RAC would respond to.

Dr. Richardson noted that the EPA was currently developing technical documents that would be presented to the RAC during the consultation if the EPA decided to move forward with a revision to the 40 CFR part 190 regulations. He stated that during such a consultation, the EPA may present concepts to the RAC that the EPA was considering related to such revisions. He stated that such a consultation would be conducted either through one or two teleconferences or through a meeting of the RAC, and that the logistics for such a consultation would be posted within the Federal Register.

Dr. Richardson stated that the schedule for follow-up RAC activities was tentative and that in early 2016 the RAC would likely have a better understanding of whether the EPA would seek to have a consultation with the RAC. He stated that the SAB Staff Office would post a Federal Register Notice announcing a consultation meeting onto SAB's website if the meeting or teleconference were scheduled to occur. He stated that the agenda, charge questions to the SAB RAC, review materials, and other meeting materials would be provided on SAB's RAC consultation meeting website before a consultation meeting would occur.

A Committee member asked whether all RAC meetings were required to be public meetings. The Designated Federal Officer responded that under FACA, most Committee meetings were required to be open to the public. The Designated Federal Officer stated that some FACA meetings may be closed to the public under some circumstances, and if so, those circumstances would be described within a Federal Register Notice announcing the closed meeting. He also noted that administrative meetings of the RAC need not be public meetings.

Dr. Richardson asked if Committee members had any additional comments to make. Hearing none, he noted that since all agenda items for the November 10, 2015 teleconference were completed, the Panel's teleconference scheduled for November 13, 2015 from noon to 5pm Eastern was cancelled. The Designated Federal Officer noted that he would place a cancellation notice on SAB's November 13<sup>th</sup> teleconference website.

Dr. Richardson thanked the Committee members, the EPA staff, members of the public and SAB Staff Office. With the meeting business concluded, the Designated Federal Officer adjourned the meeting at 3:15 pm ET.

Respectfully Submitted:

*/Signed/*  
Mr. Edward Hanlon  
Designated Federal Officer

Certified as Accurate:

*/Signed/*  
Dr. David B. Richardson, Chair  
SAB Radiation Advisory Committee

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by Panel members during the course of deliberations within the meeting. Such ideas, suggestions and deliberations do not necessarily reflect consensus advice from the Panel members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters or reports prepared and transmitted to the EPA Administrator following the public meetings or teleconferences.

### **Materials Cited**

The following meeting materials are available on the SAB website ([www.epa.gov/sab](http://www.epa.gov/sab)) or through the following SAB Radiation Advisory Committee November 10, 2015 public teleconference webpage:

<http://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/b14d863bfc5e93a385257e98003ef3db!OpenDocument&Date=2015-11-10>

<sup>1</sup> August 19, 2015 Federal Register Notice announcing the public meeting (80 FR 50275 – 50276)

<sup>2</sup> Agenda for November 10, 2015 public teleconference

<sup>3</sup> EPA Presentation – 40 CFR part 190 Advance Notice of Proposed Rulemaking and Summary of Public Comments

<sup>4</sup> Oral Statement submitted by Dennis Nelson

<sup>5</sup> Oral Statement submitted by Cindy Folkers

<sup>6</sup> Oral Statement submitted by Alfred Meyer

<sup>7</sup> Oral Statement submitted by Daniel Hirsch

## ATTACHMENT A – ROSTER

### U.S. Environmental Protection Agency Science Advisory Board 2016 Radiation Advisory Committee

#### CHAIR

**Dr. David B. Richardson**, Associate Professor, Department of Epidemiology, School of Public Health, University of North Carolina, Chapel Hill, NC

#### MEMBERS

**Dr. Sally A. Amundson**, Center for Radiological Research, Columbia University, New York, NY 10032

**Dr. Jonine Bernstein**, Attending Epidemiologist, Department of Epidemiology and Biostatistics, and co-Leader, Survivor, Outcomes and Risk Program, Memorial Sloan-Kettering Cancer Center, New York, NY

**Dr. Harry M. Cullings**, Chief, Statistics Department, Radiation Effects Research Foundation, Hiroshima and Nagasaki, Japan

**Dr. Lawrence T. Dauer**, Associate Attending Physicist, Radiation Safety Manager, Department of Medical Physics and Department of Radiology, Memorial Sloan Kettering Cancer Center, New York, NY

**Dr. Scott Davis**, Professor and Chairman of the Department of Epidemiology, School of Public Health and Community Medicine, Fred Hutchinson Cancer Research Center, University of Washington, Seattle, WA

**Dr. Joseph E. Fitzgerald**, President, Saliant Inc., Jefferson, MD

**Mr. Earl W. Fordham**, Deputy Director, Office of Radiation Protection, Washington Department of Health, Richland, WA

**Dr. Barbara L. Hamrick**, Radiation Safety Officer, University of California, Irvine Medical Center, Orange, CA

**Dr. Kenneth G.W. Inn**, Radionuclide Metrology Independent Consultant, Ewa Beach, HI

**Dr. Annie B. Kersting**, Director, Glenn T. Seaborg Institute, Physical & Life Sciences (PLS) Directorate, Lawrence Livermore National Laboratory, Livermore, CA

**Dr. Amy Kronenberg**, Staff Scientist, Lawrence Berkeley National Laboratory, Berkeley, CA

**Dr. Brian A. Powell**, Associate Professor, Department of Environmental Engineering and Earth Sciences, Clemson University, Clemson, SC

**Dr. Jacqueline Williams**, Professor of Radiation Oncology, University of Rochester Medical Center, Rochester, NY

**Dr. F. Lennie Wong**, Associate Professor, Department of Population Sciences, City of Hope National Medical Center, Duarte, CA

**Dr. R. Craig Yoder**, Independent Consultant, Crown Point, IN

**SCIENCE ADVISORY BOARD STAFF**

**Mr. Edward Hanlon**, Designated Federal Officer, U.S. Environmental Protection Agency, Science Advisory Board Staff, Washington, DC

## ATTACHMENT B – Other Attendees

### List of Members of the Public Who Requested Information on Accessing the Teleconference Line or Live Audio Webcast, or Who Participated On the Live Audio Webcast:

November 10, 2015

<b>Name</b>	<b>Affiliation</b>
Ashkeboussi, Nima	Nuclear Energy Institute
D'Arrigo, Diane	Nuclear Information and Resource Service
Folkers, Cindy	Beyond Nuclear
Garry, Steven	Nuclear Regulatory Commission
Giardina, Paul	Region 2 EPA
Gray, Erica	No Affiliation Given
Hiatt, Jerry	No Affiliation Given
Hirsch, Daniel	No Affiliation Given
Johnston, Gretel	No Affiliation Given
Kim, Karen	Electric Power Research Institute
Lee, Michel	Indian Point Safe Energy Coalition
Meyer, Alfred	No Affiliation Given
Nawar, Madeleine	EPA
Nelson, Dennis	Support and Education for Radiation Victims
Nichalus, Nick	No Affiliation Given
Reynolds, David	Inside EPA Newsletter
Sheeley, Harriet	No Affiliation Given
Walker, Stuart	EPA