



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 30, 1999

Mr. Stephen D. Page, Director
Office of Radiation and Indoor Air (Mail Code 6601J)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

Dear Mr. Page:

I am writing to provide you with the U.S. Nuclear Regulatory Commission's (NRC's) comments on the pre-publication copy of Federal Guidance Report (FGR) No. 13, "Health Risks from Low-Level Environmental Exposure to Radionuclides: Cancer," Environmental Protection Agency (EPA) 402-R-99-001, July 1999. We received this document on July 29, 1999, along with a cover letter from Christopher B. Nelson, dated July 23, 1999.

The cover letter indicated that EPA planned to proceed with publication of the final version of FGR No. 13 by the end of August 1999. Therefore, NRC staff moved to swiftly review the pre-publication copy expeditiously. NRC's purpose was to provide, if appropriate, timely requests and recommendations for modifications of the pre-publication version, before publication and distribution of the final version. Our comments reflect this objective.

The short time available and the continued absence of the user guide to the software (DCAL) used for computations of dose and risk, as well as the absence of the code validation, and of the CD-ROM that contains intermediate quantities and other data, have precluded independent verification of the calculational methodologies, models, parameters, and results by NRC and other organizations represented on the FGR No. 13 Interagency Working Group. NRC received the CD-ROM on August 23, 1999, but we have been advised that the user guide to the DCAL software will not be available until October 1999.

EPA responded to NRC's comments on the 1998 interim version in its web-site posting (<http://www.epa.gov/radiation/federal/docs/nrc5resp.pdf>). We note the following about those NRC comments:

- EPA has not modified the document in response to Comment No. 1, concerning the use of several different methods and recommendations of the International Commission on Radiological Protection. NRC continues to believe that the use of different biokinetic and dosimetric modeling schemes will hamper efforts to harmonize Federal and State regulatory efforts in the U.S.

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- As stated in the cover letter, the document has modified and augmented its treatment of uncertainty. This adjustment responds to Comment No. 2, which expressed concern about the vagueness of the interim version in describing and quantifying the uncertainties associated with the risk coefficients. The new Appendix D, on uncertainties, and the subjective estimates of uncertainty, for selected radionuclides and routes of exposure, that were added to Chapter 2, have significantly improved the document. We intend to review these additions in depth. We also note that the EPA response to this comment stated that relevant results of ongoing studies of uncertainties will be incorporated into the discussion of uncertainty in future editions of FGR No. 13. We would welcome such additions.
- The cover letter indicated that the discussion of the linear, no-threshold dose response model has been expanded in the pre-publication version. This action relates to the subject of Comment No. 3, the use of the model. Nevertheless, NRC, along with many others within the scientific community, continues to be concerned that the uncertainties associated with estimating risks from radiation at low doses and low dose rates are significant, and that scientists still have considerable disagreements among themselves about the magnitude of the actual health effects at these levels. NRC requests expansion of the disclaimer statements, on pages 12 and D-26 of the pre-publication copy, to emphasize this serious technical concern, or modification of the "Preface," to include the following: 'Notwithstanding the disclaimers on pages 12 and D-26, NRC believes that because the FGR has radiogenic risks that are expressed as "mortality or morbidity per Becquerel," there is an implied scientific certainty about these minute levels, when, in reality, substantial uncertainty and lack of reliability still remain.'
- The EPA website reply to Comment No. 4, about the contents of the "Preface," stated that "To ensure that the purpose of the report is not misunderstood, we will further emphasize in the final version that use of this document by other Federal agencies for EISs [environmental impact statements], EAs [environmental assessments], and rulemaking is discretionary." The pre-publication version does not include such a statement in the "Preface." The wording needs to be added.
- The EPA website reply to Comment No. 5, about the inability of FGR No. 13 Interagency Working Group members to independently confirm results, because of lack of the CD-ROM containing intermediate quantities and other data, stated that EPA was willing to work with NRC and others, to provide for independent verification. Although NRC has just received the CD-ROM, the other essential components for independent verification continue to be unavailable. In addition, as noted in the above discussions relating to Comments Nos. 1 and 3, NRC does not necessarily agree with, or endorse, the technical contents of the entire document. Accordingly, the statement in the "Preface," noting that NRC has reviewed the technical contents of the report, needs to be removed or modified to state that: "Due to the limited time available for review, and the unavailability of information essential for independent verification of the calculational methodologies, models, parameters, and results, NRC does not necessarily agree with, or endorse, the technical contents of this report."

Questions about our comments may be directed to me or to Dr. Ronald Zelac (301/415-6316, e-mail: rez@nrc.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'Carl J. Paperiello', written in a cursive style.


Carl J. Paperiello, Director
Office of Nuclear Material Safety
and Safeguards

cc: Christopher B. Nelson, EPA
Michael Boyd, EPA
Michael Schaeffer, DOD
Jill Lipoti, CRCPD
Andy Wallo, DOE
Adam Finkel, OSHA
Alan Roberts, DOT
Art Fraas, OMB
Beverly Hartline, OSTP

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Carl J. Paperiello, Director
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cc: Christopher B. Nelson
Michael Boyd

Distribution: [Ticket #NMSS199900376]

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Sincerely,

Original /s/ by Martin J. Virgilio for

Carl J. Paperiello, Director
Office of Nuclear Material Safety
and Safeguards

cc: Christopher B. Nelson, EPA
Michael Boyd, EPA
Michael Schaeffer, DOD
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