

Letter from

Senator Barack Obama and Representative Henry A. Waxman

to

Stephen L. Johnson
Administrator, U.S. Environmental Protection Agency

May 30, 2008.

United States Senate

WASHINGTON, DC 20510

May 30, 2008

The Honorable Stephen L. Johnson
Administrator
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW, Room 3426 ARN
Washington, DC 20460

Dear Administrator Johnson:

We are writing to inquire about the continued use by the Environmental Protection Agency of the so-called "Reference Man standard," a benchmark for radiation exposure in humans. The Reference Man is used to evaluate the risks of developing cancer from a given level of radiation.

According to the *Report of the Task Group on Reference Man (1975)*, issued by the International Commission on Radiological Protection, the "Reference Man standard" refers to the effects of radiation exposure on a male "between 20-30 years of age, weighing 70 kilograms [154 pounds], who is 170 centimeters [5 feet, 7 inches] in height, and lives in a climate with an average temperature of from 10 degrees to 20 degrees Celsius [50 to 68 degrees Fahrenheit]. He is a Caucasian and is a Western European or North American in habitat and custom."

Recently, the National Academies of Sciences issued its updated report on the effects of low-levels of radiation on humans, the Biological Effects of Ionizing Radiation Report (BEIR VII). This report concludes that females have a considerably higher risk of cancer compared to males exposed to the same levels of radiation, and that children have a higher risk of cancer compared to adults exposed to the same levels of radiation.

On January 31, 2008, the Radiation Advisory Committee of the EPA Science Advisory Board reported to you on their review of EPA's response to the National Academies' report. Among other things, the Science Advisory Board recommended that EPA consider the applying the concept of a "Reference Family," described by the International Commission on Radiological Protection, which would be more inclusive than present approaches.

It is our understanding that the "Reference Man standard" continues to form the basis for many EPA regulations and guidance documents governing radiation exposure to humans. These include EPA's Federal Guidance Report No. 11, which addresses occupational exposures to radiation, and Federal Guidance Report No. 12, which addresses exposure to external radiation from contaminated soil. We are interested in receiving information on the EPA standards, guidance, and procedures that explicitly or implicitly use the Reference Man standard.

Specifically, please provide the following information.

1. Identify and briefly describe the existing regulations, guidance documents, and any analytical procedures that were explicitly or implicitly based on the Reference Man standard.

The Honorable Stephen L. Johnson
May 30, 2008
Page Two

2. Identify and briefly describe any ongoing rulemaking actions or work to develop new or updated guidance where EPA is explicitly or implicitly relying on the Reference Man standard.
3. Explain whether EPA believes the continued use of the Reference Man benchmark in existing or ongoing regulations and guidance is scientifically valid in light of the most recent findings of the National Academy of Sciences regarding the higher risks for women and children from radiation exposure.
4. Explain whether EPA agrees with the Science Advisory Board that the "Reference Family" would be a more representative approach. If yes, please explain how and when EPA plans to update its existing guidance and regulations to incorporate this approach. If no, please explain why not.

Please provide this information by June 30, 2008. Thank you for your attention to this request.

Sincerely,



Barack Obama
United States Senator



Henry A. Waxman
Chairman, House Oversight and
Government Reform Committee

This page intentionally blank

Letter from

Robert J. Meyers
Principal Deputy Assistant Administrator
Office of Air and Radiation, U.S. Environmental Protection Agency

to

Senator Barack Obama

July 24, 2008



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 24 2008

OFFICE OF
AIR AND RADIATION

The Honorable Barack Obama
United States Senate
Washington, D.C. 20510

Dear Senator Obama:

Thank you for your letter of May 30, 2008, co-signed by Chairman Henry Waxman, in which you were inquiring about the U.S. Environmental Protection Agency's (EPA) use of the Reference Man standard. I appreciate your interest in this issue.

EPA is at the forefront of incorporating age- and gender-specific differences in our risk-based radiation protection guidance and regulations. Many of the older dose-based worker protection regulations and guidance documents written when Reference Man was the state of the science are now under consideration for updating. As described in our responses below, more recent guidance and regulations already incorporate the age-specific risk differences implied in the term, "Reference Family."

Your letter refers to both the National Academy of Sciences (NAS) 2007 report on the Biological Effects of Ionizing Radiation (BEIR VII) and the International Commission on Radiological Protection's (ICRP) Publication 89 that supplements Reference Man with more detailed age- and gender-specific data. EPA was a major sponsor of BEIR VII and also supported the scientific work at Oak Ridge National Laboratory that provides part of the underpinnings of ICRP Publication 89. As your letter notes, we requested that EPA's Science Advisory Board (SAB) review our proposed approach for incorporating BEIR VII recommendations in the upcoming revision of our radionuclide cancer risk coefficients. Taking into consideration the SAB's interim advice, we are submitting a final draft document, detailing our methodology, later this summer.

Radiation protection regulation in the United States is based on extensive scientific data on radiation-induced cancer in humans, including studies of atomic bomb survivors, and of individuals irradiated medically or occupationally. It is an acknowledgement of the mature state of the science of radiation protection that we now are able to consider age, gender, and organ differences when we recommend limits on human exposure to radiation. Among known and suspected human carcinogens, this degree of refinement in cancer risk assessment is exceptional. Nevertheless, EPA agrees that the best available science needs to be considered when developing regulations and guidance. With this information as background, we are providing the following answers to your specific questions.

1. Identify and briefly describe the existing regulations, guidance documents, and any analytical procedures that were explicitly or implicitly based on the Reference Man standard.

EPA regulations, guidance documents, and procedures issued prior to 1990 (prior to ICRP Publication 60) were based on Reference [Standard] Man, i.e. the healthy young adult male occupationally exposed to radiation. For some regulatory applications, numerical values for radionuclide-specific doses – as distinct from risks – are still taken from the adult worker dose conversion factors provided in Federal Guidance Reports 11 and 12. However, for many years, our calculations of risk and our regulatory actions and guidance for environmental exposures have factored in the varying age-sensitivity of the population.

2. Identify and briefly describe any ongoing rulemaking actions or work to develop new or updated guidance where EPA is explicitly or implicitly relying on the Reference Man standard.

There are no ongoing rulemaking actions or work to develop new guidance relying on the Reference Man standard. Pursuant to the recent (February 2008) release of new general recommendations from ICRP in Publication 103, EPA is having discussions with the Department of Energy (DOE) and the Nuclear Regulatory Commission (NRC) on how best and at what pace to update existing guidance based on Reference Man. The Interagency Steering Committee on Radiation Standards (ISCORS), co-chaired by EPA and NRC, has selected this topic as the main area for discussion at its fall public meeting.

3. Explain whether EPA believes the continued use of the Reference Man benchmark in existing or ongoing regulations and guidance is scientifically valid in light of the most recent findings of the National Academy of Sciences regarding the higher risks for women and children from radiation exposure.

EPA does not believe in continued use of Reference Man, and generally stopped using it in 1990. EPA continues to update and improve its age- and gender- specific models in light of continuing research. EPA's radionuclide-specific cancer risk coefficients are used for calculating the excess cancer risk to the general population from chronic low level exposure to radionuclides in the environment. Our risk coefficients and regulatory actions are "conservative" in that they sum the risks from an entire lifetime exposure, taking into account age-dependent differences in intake, biokinetics, and sensitivity to radiation. Thus, our regulations are fully protective of the entire population, including infants and children. For assessing risk to a specific age group exposed to a relatively large dose of radiation (e.g., in the case of a nuclear accident) an age-specific assessment is justified and EPA has published the tools for performing such an assessment.

At issue now is whether separate male and female risk coefficients should be published for the general population, given the approximate two-fold difference in risk per unit dose estimated in BEIR VII. EPA is now examining how best to account for this difference in future guidance and regulations. Any proposed changes in EPA's radiation risk assessment approach will be subjected to interagency review and public comment through the usual rulemaking and guidance development procedures.

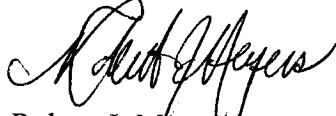
4. Explain whether EPA agrees with the Science Advisory Board that the "Reference Family" would be a more representative approach. If yes, please explain how and when EPA plans to update its existing guidance and regulations to incorporate this approach. If no, please explain why not.

The term "Reference Family" is subject to various interpretations and has not been adopted by ICRP. EPA risk models are already being used for calculating risks to reference individuals, and are organ, gender, and age-specific. Summary risk coefficients are tabulated in Federal Guidance Report 13 for a lifetime exposure to any given radionuclide. Since 1990, EPA has been using this methodology as a basis for developing radiation protection regulations and guidance. These EPA guidance documents use the new ICRP models, particularly ICRP Publication 72, which model dose for six specific age groups. The current EPA dose and risk models calculate dose and risk from birth to age 120 years. These estimates are used in Federal Guidance Report 13 (Cancer Risk Coefficients for Environmental Exposure to Radionuclides; September, 1999), the Radionuclides in Drinking Water Rule (2000), CAP88 version 3.0 (a program for determining compliance with air emission standards under the Clean Air Act), and in the proposed revision to EPA's Protective Action Guides for Nuclear Incidents. Once the proposed changes in EPA's radiation-induced cancer risk models have been reviewed by the SAB and finalized, risks from radionuclide exposures will be recalculated. At that point, EPA will reexamine the need to revise its regulations and guidance for radiation protection.

Finally, we would note that the BEIR VII risk estimates do not differ dramatically from those currently in use by EPA. Therefore, we believe that current standards and guidance are protective.

Again, thank you for your letter. If you have further questions, please contact me or your staff may call Josh Lewis, in EPA's Office of Congressional and Intergovernmental Relations, at 202-564-2095.

Sincerely,



Robert J. Meyers
Principal Deputy Assistant Administrator