




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

THE INSPECTOR GENERAL

January 6, 2022

MEMORANDUM

SUBJECT: Hotline: EPA Is Taking Steps to Update Its Federal Radiation Guidance
Report No. 22-E-0016

FROM: Sean W. O'Donnell 

TO: Joseph Goffman, Acting Assistant Administrator
Office of Air and Radiation

The U.S. Environmental Protection Agency's Office of Inspector General [initiated](#) this evaluation to address an OIG Hotline complaint that alleged the EPA is not following the best-available science regarding low-dose radiation because it continues to use the linear no-threshold, or LNT, model to inform its radiation guidance. Our objective was to determine the extent to which the EPA has effectively implemented a process for reviewing and updating its federal radiation policies and guidance, specifically those that rely on the LNT model.

This evaluation supports an EPA mission-related effort:

- Operating efficiently and effectively.

This evaluation addresses a top EPA management challenge:

- Safeguarding scientific integrity.

The EPA's Office of Radiation and Indoor Air, or ORIA, which is under the Office of Air and Radiation, does not have a formal process for updating its radiation policies and guidance, which for the purposes of this report we refer to generally as "guidance." However, the EPA has updated its radiation guidance to incorporate new data. In addition, other federal agencies, such as the U.S. Department of Energy, are leading research efforts on low-dose radiation, which may inform future EPA guidance updates.

We provided the ORIA the opportunity to review a draft of this report. The ORIA responded with minimal technical comments, which we considered and incorporated as appropriate. This report makes no recommendations. As such, you are not required to provide a written response. Should you choose to provide a response, we will post it on the OIG's public website along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal along with corresponding justification.

Background

Radiation is energy given off by matter in the form of rays or high-speed particles. Sources of radiation are both man-made and naturally occurring. There are two types of radiation: nonionizing and ionizing. Examples of nonionizing radiation include radio waves, visible light, and microwaves. Examples of ionizing radiation include x-ray machines; cosmic particles from outer space; and radioactive elements,

such as uranium. Ionizing radiation can damage tissue and genetic material. Although cells in the human body are efficient in repairing radiation damage, if the damage is not repaired correctly, a cell may die or become cancerous. As part of its mission to protect human health and the environment, the EPA implements radiation protection programs and sets regulatory limits for human exposure to ionizing radiation, including to low doses from radioactive elements.

The EPA bases its risk assessments, regulatory limits, and nonregulatory guidelines for human exposure to low-dose ionizing radiation on the LNT model, which assumes that the risk of cancer due to a low-dose exposure is proportional to a dose with no threshold. In other words, the LNT model assumes that ionizing radiation is always harmful and that there is no threshold amount below which radiation exposure is safe.

EPA Provides Guidance for Radiation Protection

The EPA's authority to implement radiation protection programs is derived from Congress and the president through laws and presidential directives, such as executive orders. As the EPA details in its "Radiation Regulations and Laws" [webpage](#), various federal statutes authorize the EPA to establish human health and environmental radiation standards for air, surface water, drinking water, uranium mill tailings sites, and deep geologic repositories.

Pursuant to the Reorganization Plan No. 3 of 1970, when the EPA was created, it was transferred authority under the Atomic Energy Act of 1954 to establish standards for the protection of the general environment from radioactive material. This Act requires the EPA administrator to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States." As such, the EPA provides radiation guidance to all federal agencies through technical federal guidance reports, or FGRs, and policy recommendations.

As of November 2021, the EPA had issued seven FGRs since 1970. The most recent one—FGR 15, *External Exposure to Radionuclides in Air, Water and Soil*—was published in 2019. Prior to 1970, the Federal Radiation Council published eight FGRs. These FGRs cover a variety of technical matters related to radiation protection. Federal and state agencies use these FGRs to develop radiation protection regulations and standards. Regulated entities also use these FGRs to demonstrate regulatory compliance.

Responsible Office

The Office of Air and Radiation develops national programs, policies, and regulations for controlling air pollution and radiation exposure. The ORIA has a mission to protect the public and the environment from the risks of radiation and indoor air pollution. To carry out its mission, the ORIA coordinates across the Agency and with other federal, state, tribal, and nongovernmental organizations, as well as develops criteria, standards, guidance, policies, and programs to limit unnecessary radiation exposure and control exposure to indoor air pollutants.

Scope and Methodology

We conducted this evaluation from June to November 2021. This evaluation was conducted in accordance with the *Quality Standards for Inspection and Evaluation*, published in January 2012 by the Council of the Inspectors General on Integrity and Efficiency. These standards require that we perform the evaluation to obtain sufficient, competent, and relevant evidence to provide a reasonable basis for our findings and

conclusions based on our objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions.

To conduct our work, we met with managers and staff from the ORIA, the Office of Land and Emergency Management, the Office of Research and Development, and the Office of Water. We reviewed the EPA’s requirements for scientific and technical information and data quality, the EPA’s scientific integrity materials, and supporting program documents from the ORIA. We interviewed the hotline complainant and EPA staff and managers to learn about the review of scientific information regarding radiation and to determine whether there is a process for updating radiation policies and guidance documents.

Results

The ORIA does not have a formal process for updating its federal radiation guidance and policies. It does, however, include updating radiation guidance, some of which relies on the LNT model, in its strategic plan, and it updates its guidance as a result of annual priority goals.¹ In addition, the EPA’s use of the LNT model for radiation guidance is based on findings and recommendations by national and international authoritative bodies. The EPA relies on external organizations for radiation research results and data, as well as on the Department of Energy’s Center for Radiation Protection Knowledge and other agencies to monitor the development of new research and updated data.

EPA Updates Its Radiation Guidance and Has Requested Independent Peer Review

In its *Working Together: FY 2018–2022 U.S. EPA Strategic Plan*, issued February 2018 and updated September 2019, the EPA states that “new science on radiation health effects” would affect its approach to protecting the public from radiation exposure. The ORIA’s strategic plan and annual priority goals also indicate that the EPA’s radiation guidance, which includes FGRs and standard operating procedures, will be reviewed and updated to reflect the current science and policies from external organizations in order to address gaps in or improve the guidance. We found no requirement for the EPA to have a process—formal or otherwise—for updating its radiation guidance, however.

The EPA has updated its radiation guidance in accordance with its strategic plans and annual priority goals. For example, the ORIA issued FGR 15, *External Exposure to Radionuclides in Air, Water and Soil*, in 2019 to update and expand upon FGR 12, *External Exposure to Radionuclides in Air, Water, and Soil*, which was issued in 1993. As of October 2021, the ORIA was developing FGR 16 to update its federal guidance on cancer risk coefficients for environmental exposure to radionuclides based on updated data and models from 2006, 2008, 2011, and 2020.

Furthermore, in July 2021, the Office of Air and Radiation requested that the EPA’s Science Advisory Board review the draft FGR 16 to identify, among other things, any uncertainties associated with the models and data used. According to its charter, the Science Advisory Board is a committee whose objective is to “provide independent advice and peer review to the EPA’s Administrator on the scientific and technical aspects of environmental issues.” The use of such independent peer review is critical to obtain the best-available technical and scientific expertise. The Office of Air and Radiation projects that the Science Advisory Board will complete its peer review of FGR 16 in fiscal year 2023.

¹ *Office of Radiation and Indoor Air: Strategic Plan Fiscal Years 2018–2022; Priority Goals for Fiscal Years 2018–2020.*

Nuclear Regulatory Commission Validated Use of LNT Model

According to the Nuclear Regulatory Commission, the LNT model is a conservative basis for radiation-dose standards and may overestimate risks. In August 2021, however, the Nuclear Regulatory Commission stated that “the LNT model continues to provide a sound regulatory basis for minimizing the risk of unnecessary radiation exposure” to both members of the public and radiation workers.² In addition, the Nuclear Regulatory Commission and the EPA’s use of the LNT model is based on findings and recommendations by national and international authoritative bodies, such as the International Commission on Radiological Protection and the National Council on Radiation Protection and Measurements. According to the EPA, the Agency will continue to use the LNT model as long as those organizations use it.

Low-Dose Radiation Research and Federal Coordination Are Underway

As of November 2021, the Department of Energy leads federal research efforts in low-dose radiation. The results of these research efforts inform the EPA’s use of the LNT model in and updates to its radiation guidance. The 2021 Consolidated Appropriations Act amended section 306(c) of the Department of Energy Research and Innovation Act to call for the Department of Energy to carry out a research program on low-dose and low dose-rate radiation—in other words, both the amount and the frequency of exposure—to:³

- (A) enhance the scientific understanding of, and reduce uncertainties associated with, the effects of exposure to low-dose and low dose-rate radiation; and
- (B) inform improved risk-assessment and risk management methods with respect to such radiation.

In addition, at the request of Congress, the National Academies formed a committee of experts to study the status of low-dose radiation research in the United States. Objectives of the study, which is sponsored by the Department of Energy and is expected to be published in April 2022, include:

- Defining the health and safety issues that must be guided by an improved understanding of low-dose and low dose-rate radiation health effects.
- Recommending a long-term strategic and prioritized research agenda to address scientific research goals.
- Addressing coordination between federal agencies and other national and international low-dose radiation research projects and programs.

The EPA relies on these external research efforts to inform changes to its radiation guidance and to take into account international standards. In addition, the Department of Energy’s Center for Radiation Protection Knowledge and its predecessor, the Dosimetry Research Group, have provided technical support for the EPA’s FGRs, such as supporting and monitoring the development of new models and updated data. A memorandum of understanding that took effect in September 2021 between the Department of Energy, the EPA, the Nuclear Regulatory Commission, and several other federal agencies outlines how the Center for Radiation Protection Knowledge will continue to assist participating agencies

² Linear No-Threshold Model and Standards for Protection Against Radiation, 86 Fed. Reg. Vol. 45,923, August 17, 2021.

³ The Consolidated Appropriations Act, 2021, Pub. L. 116-260, December 27, 2020.

in the development and application of radiation dosimetry and risk assessment methodologies that are based on the best-available scientific information.⁴

Conclusions

The ORIA does not have a formal process for updating its federal radiation guidance, some of which relies on the LNT model, but instead updates the guidance pursuant to its strategic plan and annual priority goals. The EPA relies on the ORIA's strategic plan, as well as on new models and updated data identified by the Center for Radiation Protection Knowledge, to keep its radiation guidance current. By issuing FGR 15, developing FGR 16, and requesting that the Scientific Advisory Board review the draft FGR 16, the EPA has taken steps to ensure that its radiation guidance, including that regarding low-dose radiation exposure, is updated and informed by the best-available and peer-reviewed science.

cc: Michael S. Regan, Administrator
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⁴ Radiation dosimetry is the monitoring of individuals to accurately determine their radiation dose equivalent.