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LOW-DOSE RADIATION

Interagency Collaboration on Planning Research Could Improve Information on Health Effects

Statement of John Neumann, Director,
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Chairman Weber, Ranking Member Veasey, and Members of the Subcommittee:

I am pleased to be here today to discuss federal agencies' requirements and guidance for protecting workers and the public from the harmful effects of ionizing radiation and agencies' support for research on the health effects of radiation at low doses.[1] Radiation comes from natural sources as well medical, commercial, and industrial activities. It has beneficial uses, such as treating cancer, but a large amount of exposure can cause sickness or even death within days, according to the Environmental Protection Agency (EPA). In contrast, low levels of exposure are not known to cause acute health effects but may increase a person's risk of developing cancer.

To protect against cancer and other harmful effects associated with exposure to radiation, EPA, the Nuclear Regulatory Commission (NRC), and other federal agencies have established requirements and issued guidance that apply to a wide range of settings in which such exposure can occur. For example, these requirements include limits on occupational dose, such as for workers in nuclear power plants, and limits on the dose that a facility, such as an industrial site with radiological contamination, can cause to members of the public.[2]

The Department of Energy (DOE) and other federal agencies have also funded research to determine the health effects of exposure to low levels of radiation. However, uncertainties remain about these effects, as DOE's Biological and Environmental Research Advisory Committee recognized in 2016, when it issued a report stating that further research on the cancer risk from low-dose radiation could decrease uncertainty in cancer risk estimates.

My statement today summarizes our September 2017 report on low-dose radiation,[3] which examined (1) how selected federal agencies have

[1]Ionizing radiation includes X-rays, gamma rays, and various types of atomic particles. Natural sources of ionizing radiation include certain foods, such as bananas and Brazil nuts, and soils rich in naturally occurring uranium. This statement uses the term "radiation" to refer to ionizing radiation.

[2]Radiation dose, as used in this statement, refers to the measured or calculated exposure individuals receive.

[3]GAO, *Low-Dose Radiation: Interagency Collaboration on Planning Research Could Improve Information on Health Effects,* GAO-17-546 (Washington, D.C.: Sept. 26, 2017).

developed and applied radiation protection requirements and guidance for workers and the public and (2) the extent to which federal agencies have funded and collaborated on research on the health effects of low-dose radiation. For our report, we reviewed agency documentation and interviewed agency officials on the development of their radiation protection requirements and guidance. In particular, we identified four federal agencies—EPA, NRC, DOE, and the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS)—that have developed requirements or guidance for four settings in which radiation exposure can occur: operation and decommissioning of nuclear power plants, cleanup of sites with radiological contamination, use of medical equipment that produces radiation, and accidental or terrorism-related exposure to radiation. Findings from our reviews of these four agencies in the four settings we selected cannot be generalized to all agencies and settings in which radiation exposure can occur but provide illustrative examples. We also collected and examined data on support for low-dose radiation research from seven federal agencies that fund this research—the Centers for Disease Control and Prevention (CDC) within HHS, the Department of Defense (DOD), DOE, EPA, the National Aeronautics and Space Administration (NASA), the National Institutes of Health (NIH) within HHS, and NRC. In particular, we requested these seven agencies to provide data on obligations for low-dose radiation research for fiscal years 2012 through 2016 and information on the type of research funded.

More detailed information on the scope and methodology of our work can be found in our September 2017 report. We conducted the work on which this statement is based in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In summary, we found that EPA, NRC, DOE, and FDA have generally used the advice of scientific advisory bodies to develop and apply radiation protection requirements and guidance for workers and the public for the four radiation settings in our review. Specifically, the agencies relied on the advice of three scientific advisory bodies that supported the use of the linear no-threshold model for such requirements and guidance. This model assumes that the risk of cancer increases with every incremental increase in radiation exposure. Accordingly, the agencies have set regulatory dose limits and issued guidance to confine exposure

to levels that reduce the risk of cancer, while recognizing that scientific uncertainties occur in estimating cancer risks from low-dose radiation.

We also found that, for fiscal years 2012 through 2016, seven federal agencies—CDC, DOD, DOE, EPA, NASA, NIH, and NRC—obligated about $210 million for research on the health effects of low-dose radiation, but annual funding decreased by 48 percent. During the period we reviewed, the seven federal agencies that funded this research collaborated on particular projects, but they did not use a collaborative mechanism to address overall research priorities, such as research needs that advisory bodies identified regarding health effects of low-dose radiation. In the past, DOE provided leadership in this area and advocated for greater coordination on research on low-dose radiation's health effects. However, since fiscal year 2012, its leadership role and funding have decreased because it has phased out funding for its main research program in this area, and no other agency stepped forward to fill this role. We recommended that DOE lead development of a mechanism for interagency collaboration on research on low-dose radiation's health effects. DOE disagreed with our recommendation, stating that agencies set their own research priorities. We continue to believe that DOE is in the best position to lead such an effort.

Background

According to NRC's website, the higher the radiation dose, the sooner the effects of radiation will appear, and the higher the probability of death. Radiation doses such as those received by survivors of the atomic bombs in Japan can cause cancers such as leukemia and colon cancer and, if levels are high enough, acute radiation syndrome. The symptoms of this syndrome range from nausea, fatigue, and vomiting to death within days or weeks. In contrast, the effects of low-dose radiation are more difficult to detect. In particular, below about 100 millisieverts (mSv) (10 rem)—the level below which the National Academies of Sciences, Engineering, and Medicine's (National Academies) 2006 report on radiation and human health considered radiation to be low dose—data do not definitively establish the dose-response relationship between cancer and radiation exposure.[4]

[4]National Research Council of the National Academies, *Health Risks from Exposure to Low Levels of Ionizing Radiation* (Washington, D.C.: National Academies Press, 2006). The millisievert (mSv) and rem are measures of effective radiation dose. One mSv is equal to 0.1 rem.

Selected Agencies Generally Used Advice from Scientific Advisory Bodies to Develop and Apply Radiation-Protection Requirements and Guidance

In developing and applying radiation protection requirements and guidance for workers and the public—specifically, limits on dose or increased health risk and guidance levels on exposure—EPA, NRC, DOE, and FDA have generally taken the advice of scientific advisory bodies. In particular, they have relied on the advice of the International Commission on Radiological Protection, the National Council on Radiation Protection and Measurements, and the National Academies' Nuclear and Radiation Studies Board.[5] This advice includes the use of the linear no-threshold model, which assumes that the risk of cancer increases with every incremental increase in radiation exposure. For example, the National Academies published a report in 2006 stating that the balance of evidence from various types of studies tends to favor a simple proportionate relationship between radiation at low doses and cancer risk. According to the National Academies, the availability of new and more extensive data since the publication of its previous report in 1990 strengthened confidence in the 2006 report's estimates of cancer risk.

The advisory bodies have recognized challenges in accurately estimating cancer risks from very low doses of radiation exposure when using the linear no-threshold model. For example, much of the data on health effects of radiation exposure come from non-U.S. populations, such as Japanese atomic bomb survivors. These individuals received a large exposure to radiation over a short period of time (an acute exposure), and there is uncertainty about the extent to which the health effects for these populations can be extrapolated to a U.S. population that is regularly (chronically) exposed to low-dose radiation.

Nevertheless, NRC officials told us that, in the absence of convincing evidence that there is a dose threshold below which low levels of radiation are beneficial or not harmful, NRC will continue to follow the recommendations of scientific advisory bodies to use the linear no-threshold model. Similarly, officials from EPA told us that they would consider changing the use of the linear no-threshold model as the basis

[5]The International Commission on Radiological Protection is an independent, international organization with members consisting of scientists and policymakers in the field of radiological protection. The National Council on Radiation Protection and Measurements is a congressionally chartered, nonprofit educational and scientific body. The National Academies' Nuclear and Radiation Studies Board conducts studies on safety and other issues associated with nuclear and radiation-based technologies.

of their requirements and guidance only if there were a strong recommendation from scientific advisory bodies on radiation protection as well as an endorsement of the change by the National Academies.

Under this model, federal regulations set dose limits for radiation exposure that are below the level in the National Academies' 2006 report on radiation and human health for defining low-dose radiation. For example, NRC's annual dose limit for members of the public (excluding natural, or background, sources of radiation) from operation of nuclear power plants is a hundredth of the level the National Academies considers low dose. NRC based the dose limit on an advisory body recommendation that the cancer risk to the general public from exposure to radiation should be comparable to the public's risk from everyday activities, such as taking public transportation.

The low-dose radiation limits and guidance that federal agencies have developed and applied vary depending on the settings in which exposure can occur. For example, NRC has established limits on occupational dose that apply to nuclear power-plant workers; these limits are higher than NRC's annual dose limit for members of the public but are still below the level the National Academies considers low dose. In keeping with advisory body recommendations, NRC also applies the principle that doses should be kept as low as reasonably achievable (ALARA). NRC defines ALARA to mean making every reasonable effort to maintain exposures to radiation as far below dose limits as is practical. At a nuclear power plant we visited as part of our work, representatives told us that under their ALARA plan, the plant set its own dose limit for workers at 40 percent of the NRC's regulatory limit. Moreover, officials at the plant told us that they have been able to keep exposures below the plant's own limit by continuously seeking opportunities to reduce unnecessary worker exposure to radiation, such as using robots to perform maintenance work in radiation areas.

In contrast to radiation exposure received from nuclear power plants, FDA officials stated that the agency regulates the maximum radiation output of medical equipment, instead of setting limits on the total amount of radiation exposure to patients. According to FDA officials, FDA does not generally have the authority to regulate the total amount of radiation exposure a patient receives from medical imaging equipment.[6] However,

[6]Under the Mammography Quality Standards Act, FDA has established a maximum dose limit to patients for mammography testing.

in keeping with the principle that radiation exposure should be kept as low as reasonably achievable, FDA encourages voluntary measures by health care providers, such as to investigate and determine whether it is possible to reduce radiation exposure to patients from the use of medical-imaging equipment.

Seven Agencies Have Funded Research on the Health Effects of Low-Dose Radiation but Have Not Collaborated on Overall Research Priorities

From fiscal year 2012 through fiscal year 2016, seven federal agencies obligated $209.6 million for research on the health effects of low-dose radiation, but they did not use a collaborative mechanism to address overall research priorities in this area. DOE and NIH accounted for most of the funding, with DOE obligating $116.3 million and NIH obligating $88.6 million, or about 56 percent and 42 percent of the total, respectively. The five other agencies—NRC, NASA, DOD, EPA, and CDC—obligated the remaining $4.7 million, or about 2 percent of the total.

DOE has two offices that have funded research on the health effects of low-dose radiation—the Office of Science and the Office of Environment, Health, Safety and Security—according to funding information DOE provided. The Office of Science established the Low Dose Radiation Research Program in 1998 and funded it through fiscal year 2016. A primary focus of this program was radiobiological research, which examines molecular and cellular responses to radiation exposure. According to DOE's website for the program, the program provided data and information about the low-dose range of exposure, producing 737 peer-reviewed publications as of March 2012. The Office of Environment, Health, Safety and Security provided funding for epidemiological studies, including studies involving Japanese atomic bomb survivors.[7]

NIH has funded and conducted both epidemiological and radiobiological studies on low-dose radiation, according to NIH officials. The officials stated that the studies are conducted through the National Cancer Institute's internal research program for radiation epidemiology, as well as through NIH's research programs for external funding of investigator-initiated research. Other institutes of NIH, including the National Institute of Environmental Health Sciences, also fund research related to the

[7]Epidemiological studies examine defined populations of workers and other individuals and the effects on their health after exposure to radiation.

health effects of radiation exposure as part of NIH's overall mission to fund medical research.

Among the other agencies that provided some funding to low-dose radiation studies, several provided funding to the Epidemiological Study of One Million U.S. Radiation Workers and Veterans (Million Person Study)—an ongoing study headed by the National Council on Radiation Protection and Measurements. DOE also provided funding for this study.

In fiscal years 2012 through 2016, the seven agencies who provided funding for research on health effects of low-dose radiation collectively decreased their annual funding obligations in this area by 48 percent, from $57.9 million in fiscal year 2012 to $30.4 million in fiscal year 2016. DOE accounted for a large portion of this overall decrease in annual funding. Specifically, over this 5-year period, DOE reduced its annual funding obligations for this area of research by 45 percent—from $32.6 million in fiscal year 2012 to $18.0 million in fiscal year 2016. According to DOE, the decrease was primarily due to DOE's reduction in funding for its Low Dose Radiation Research Program. According to DOE officials, decreases in funding for the program reflected a shift toward bioenergy and environmental research. Similarly, over the 5-year period, NIH's funding for low-dose radiation research decreased by 48 percent—from $23.1 million in fiscal year 2012 to $12.0 million in fiscal year 2016. NIH officials explained that funding levels for a particular disease or research area can fluctuate depending on several factors, including the number and quality of research proposals submitted and the outcome of NIH's peer reviews of the proposals, as well as the overall research budget.

The seven agencies that funded research on health effects of low-dose radiation for fiscal years 2012 through 2016 collaborated on particular research projects through various mechanisms, including joint funding of individual projects, but they did not use a collaborative mechanism to address overall research priorities. As previously noted, the 2016 report of DOE's Biological and Environmental Research Advisory Committee provided information about research needs in low-dose radiation and found that further research could decrease uncertainty in predicting cancer risk from low-dose radiation. The report stated that other agencies—including NRC, NIH, EPA, DOD, and NASA—could benefit from the reduction in uncertainty that could be obtained by this research.

In our September 2017 report, we recommended that the Secretary of Energy lead the development of a mechanism for interagency collaboration to determine roles and responsibilities for addressing

priorities related to research on the health effects of low-dose radiation. We made this recommendation because our previous work has shown that collaborative mechanisms can serve multiple purposes, such as leading interagency efforts to develop and coordinate sound science and technology policies across the federal government. Although collaborative mechanisms differ in complexity and scope, they all benefit from certain key features, such as leadership.

We directed this recommendation to DOE for several reasons. In the past, DOE took a leading role in advocating for greater communication and coordination between the fields of radiation biology and epidemiology. In addition, DOE is the federal agency that currently has primary responsibility under the Atomic Energy Act of 1954 for research related to the protection of health during activities that can result in exposure to radiation. DOE is well positioned to lead an effort to ensure that federal agencies have a mechanism for interagency collaboration to address overall research priorities related to low-dose radiation health effects because of the agency's past experience as a leader in this area of research. Such an effort could help DOE and the collaborating agencies determine roles and responsibilities, including leadership when addressing shared research priorities.

DOE did not agree with our recommendation. In particular, DOE stated that EPA and NRC also have legal mandates to research low-dose radiation exposure and that these agencies establish their research priorities in accordance with their respective budget authorities and recommendations from independent advisory bodies. DOE stated that as a result, it would not be appropriate for DOE to lead the development of a mechanism for interagency collaboration.

We believe that DOE's concerns stem from a misinterpretation of our recommendation, and we made several changes to our report and our recommendation to clarify DOE's role. We noted that we did not recommend that a mechanism for interagency collaboration serve as a replacement for agencies' legal mandates, budget authorities, and recommendations from independent advisory bodies. Instead, this mechanism would help agencies address shared research priorities. In making our recommendation, we did not specify the coordinating mechanism that agencies should use and instead left it to DOE to lead the development of an appropriate mechanism. We continue to believe that an interagency coordination mechanism for low-dose research is needed and that DOE is in the best position to lead agencies in developing the most appropriate mechanism.

Chairman Weber, Ranking Member Veasey, and Members of the Subcommittee, this concludes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this statement, please contact John Neumann at (202) 512-3841 or neumannj@gao.gov. In addition, contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Individuals who made key contributions to the report on which this testimony is based include Allen Chan, Kendall Childers, Joseph Cook, Richard Johnson, Cynthia Norris, Josie Ostrander, Amber Sinclair, and Jack Wang.