



September 2017

LOW-DOSE RADIATION

Interagency Collaboration on Planning Research Could Improve Information on Health Effects

Why GAO Did This Study

According to EPA, exposure to low doses of radiation does not cause immediate health effects but may increase a person's cancer risk. Federal agencies fund research on cancer risk, but uncertainties remain about risk assessments that federal agencies use to develop radiation protection regulations and guidance.

GAO was asked to examine federal agencies' radiation protection requirements and guidance and related research. This report (1) describes how selected federal agencies have developed and applied radiation protection requirements and guidance and (2) examines the extent to which federal agencies have funded and collaborated on research on low-dose radiation's health effects for fiscal years 2012 to 2016.

GAO selected four federal agencies, based on their development of requirements or guidance for settings in which radiation exposure to workers and the public can occur. GAO reviewed agency documentation and interviewed agency officials on the development of the requirements and guidance. GAO also collected and examined federal-funding data for low-dose radiation research from seven agencies that fund this research.

What GAO Recommends

GAO recommends DOE lead development of a mechanism for interagency collaboration on research on low-dose radiation's health effects. DOE disagreed, stating that agencies set their own research priorities. GAO continues to believe that DOE is in the best position to lead such an effort, as discussed in the report.

View [GAO-17-546](#). For more information, contact John Neumann at (202) 512-3841 or neumannj@gao.gov.

LOW-DOSE RADIATION

Interagency Collaboration on Planning Research Could Improve Information on Health Effects

What GAO Found

The Department of Energy (DOE), Nuclear Regulatory Commission (NRC), Environmental Protection Agency (EPA), and Food and Drug Administration generally used the advice of scientific advisory bodies to develop and apply radiation protection requirements and guidance for workers and the public in the radiation exposure settings that GAO reviewed. These settings were: (1) the operation and decommissioning of nuclear power plants; (2) the cleanup of sites with radiological contamination; (3) the use of medical equipment that produces radiation; and (4) accidental or terrorism-related exposure to radiation. Specifically, the agencies relied on the advice of three scientific advisory bodies that supported the use of a model that assumes the risk of cancer increases with every incremental 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. For example, NRC requires nuclear power plants to consider measures for limiting workers' exposure below NRC's regulatory dose limit, such as by using robots for maintenance work in radiation areas.

GAO identified seven federal agencies that funded research on low-dose radiation's health effects. In fiscal years 2012 to 2016, DOE, NRC, EPA, and four other federal agencies obligated about \$210 million for such research (see table). Although the agencies have collaborated on individual projects on radiation's health effects, they have not established a collaborative mechanism to set research priorities. GAO's previous work has shown that federal agencies can use such mechanisms to implement interagency collaboration to develop and coordinate sound science policies. In the past, DOE took a leading role in this area because DOE provided stable funding and advocated for greater coordination on research on low-dose radiation's health effects. However, since fiscal year 2012, DOE has phased out funding for one of its main research programs in this area. This has created a void in coordination efforts among federal agencies, and no other agency has stepped forward to fill this void. Because of DOE's prior experience as a leader in this area of research and its research responsibility under the Atomic Energy Act of 1954, it could play an important role in helping federal agencies establish a coordinating mechanism for low-dose radiation research.

Federal Funding for Research on Low-Dose Radiation's Health Effects

Dollars are in millions and have not been adjusted for inflation

Agency	Funding, fiscal years 2012–2016
Department of Energy	116.3
National Institutes of Health	88.6
Nuclear Regulatory Commission	2.6
National Aeronautics and Space Administration	1.0
Department of Defense	0.4
Centers for Disease Control and Prevention	0.4
Environmental Protection Agency	0.3
Total	209.6

Source: GAO analysis of agency data. | GAO-17-546

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Abbreviations

ALARA	as low as reasonably achievable
BBEDCA	Balanced Budget and Emergency Deficit Control Act of 1985
BCA	Budget Control Act of 2011
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensations, and Liability Act
CT	computed tomography
EPA	Environmental Protection Agency
DHS	Department of Homeland Security
DOD	Department of Defense
DOE	Department of Energy
FDA	Food and Drug Administration
FY	fiscal year
HHS	Department of Health and Human Services
ICRP	International Commission on Radiological Protection
Joint Committee	Joint Select Committee on Deficit Reduction
Million Person Study	Epidemiologic Study on One Million U.S. Radiation Workers and Veterans
mSv	millisievert
NASA	National Aeronautics and Space Administration
National Academies	National Academies of Science, Engineering, and Medicine
NCRP	National Council on Radiation Protection and Measurement
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NNSA	National Nuclear Security Administration
NRC	Nuclear Regulatory Commission
OSHA	Occupational Safety and Health Administration
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation

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September 26, 2017

The Honorable Barry Loudermilk
House of Representatives

The Honorable Jim Bridenstine
House of Representatives

Ionizing radiation—which comes from both natural sources as well as medical, commercial, and industrial activities—has a number of beneficial uses, including treating cancer or sterilizing medical equipment, but can also be harmful. Ionizing radiation is considerably more energetic than non-ionizing radiation, such as radio- or microwaves and visible or infrared light, and thus has a greater effect on human health.¹ According to the Environmental Protection Agency (EPA), the severity and type of health effects depend in part on the amount and duration of exposure. A very large amount of exposure, such as from a nuclear explosion, can cause sickness or even death within days. According to EPA, low levels of exposure are not known to cause acute health effects but may increase a person’s risk of developing cancer or other health effects, such as genetic mutations, during the individual’s lifetime.

To prevent 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. These requirements and guidance generally follow radiation protection principles that call for radiation exposure to be justified by producing a net benefit and by keeping within regulatory limits (i.e., limits on the dose or limits on the increased risk to health) or, for emergency situations, limits established by non-binding guidance on exposure levels designed to

¹Ionizing 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. Unless otherwise stated, this report uses the term “radiation” to refer to ionizing radiation.

protect those affected.² These regulatory limits and guidance levels that federal agencies have established include:

- limits on occupational dose, such as for nuclear power-plant workers and medical personnel whose work involves the use of radiation;
- limits on dose or increased health risk for members of the public from a facility, such as a nuclear power plant or industrial site with radiological contamination; and
- guidance levels for protecting workers and members of the public during an emergency response to an accidental or deliberate incident that exposes them to radiation, such as an accident at a nuclear power plant or a radiological dispersal device (also called a “dirty bomb”).³

The Department of Energy (DOE) and other federal agencies have funded research to determine the health effects of exposure to low levels of radiation; however, uncertainties remain in understanding the health effects, including the risk of cancer. These uncertainties raise questions about whether dose limits and guidance levels have been set appropriately. For example, there are concerns that the dose limits and guidance levels may be too low, increasing costs to reduce radiation exposure unnecessarily. In contrast, there are also concerns that the dose limits and guidance levels may be too high, causing greater harm than assumed based on limited understanding of the risks.

Several organizations that provide guidance and recommendations to federal agencies on radiation protection have identified research needs to better understand the health risks from low levels of radiation exposure. For example, in 2006, the National Academies of Sciences, Engineering, and Medicine (National Academies) published the seventh in a series of reports to advise the U.S. government on the relationship between

²Radiation dose, as used in this report, refers to the measured or calculated exposure individuals receive. Dose limits and guidance levels place an upper bound on this amount. Individuals can use calculations or small portable instruments to measure radiation dose and estimate the total accumulated personal dose of radiation, and this information can be used to help ensure that individuals stay within dose limits or guidance levels.

³Federal agencies also set separate, lower dose limits and guidance levels for sensitive members of the population, such as dose limits to an embryo or fetus due to the occupational exposure of a declared pregnant woman.

exposure to radiation and human health.⁴ The report identified research needs in a number of areas, such as occupational radiation exposures among nuclear industry workers, to help estimate the risk of cancer from low-dose radiation, which occurs at levels where the biological effects may not be detected and where current research does not definitively establish the extent of cancer risk. In 2015, DOE directed its Biological and Environmental Research Advisory Committee to provide advice on defining a research program that could lead to conclusive results on whether low-dose radiation causes cancer in humans. In 2016, the committee issued a report stating that further research on the cancer risk from low-dose radiation could decrease uncertainty in cancer risk estimates.⁵ For example, according to the report, new tools for conducting biological research could advance the understanding of connections between radiation exposure, DNA damage, tissue responses, and cancer development.

You requested that we examine federal agencies' radiation protection requirements and guidance and related research.⁶ This report (1) describes how selected federal agencies have developed and applied radiation protection requirements and guidance for workers and the public and (2) examines the extent to which federal agencies have funded and collaborated on research on the health effects of low-dose radiation.

To describe how selected federal agencies have developed and applied radiation requirements and guidance for workers and the public, we first selected a sample of 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. We selected these four settings because they can result in radiation exposure for both workers and the public and because they involve a variety of federal agencies and sites where exposure can occur. Next, through a review of federal radiation-protection requirements and guidance, we

⁴National Research Council of the National Academies, *Health Risks from Exposure to Low Levels of Ionizing Radiation* (Washington, D.C.: National Academies Press, 2006).

⁵Low Dose Radiation Expert Subcommittee of the Biological and Environmental Research Advisory Committee, *Final Report* (Nov. 7, 2016).

⁶This review was conducted in response to a 2015 request from Representatives Barry Loudermilk and Jim Bridenstine, then Chairmen, respectively, of the Subcommittee on Oversight and Subcommittee on Environment, House Committee on Science, Space, and Technology.

identified four federal agencies that have developed requirements or guidance for these four settings—EPA, NRC, DOE, and the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS). 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 provided illustrative examples.

For each of these four settings and selected federal agencies, we reviewed agency documentation and interviewed agency officials on how they developed radiation protection requirements and guidance and how they apply them in practice. In addition, we interviewed stakeholders involved in the four selected settings to obtain their views (1) on the scientific assumptions federal agencies used in developing requirements and guidance and (2) on the costs and benefits associated with applying the requirements and guidance. We selected stakeholders who had studied, issued policy statements on or raised concerns about federal radiation-protection efforts in the four settings in our review and who represented a range of private-sector, professional, state-government, and environmental and public-health interests. Stakeholders we selected included officials from state agencies responsible for radiation protection and representatives of organizations active in the nuclear power industry or radiology and of nonprofit organizations that study issues related to radiation exposure.⁷

To better understand how federal agencies have applied requirements and guidance, we visited three sites—two DOE sites and one EPA site—with radiological contamination: DOE’s Savannah River Site in South Carolina and Site 300 at Lawrence Livermore National Laboratory in California, and the Nuclear Metals, Inc. site in Massachusetts, overseen by EPA. We selected contaminated sites to include at least one large site and one small site, and at least one site managed by DOE and one overseen by EPA. We also visited a commercial nuclear-power plant to observe measures used by the plant to limit radiation exposure, and we interviewed plant personnel regarding their radiation protection program.

⁷NRC is authorized to enter into agreements to allow states to assume regulatory authority over source, by-product, and special nuclear materials in quantities insufficient to form a critical mass. 42 U.S.C. § 2021(b). NRC must find a state program adequate to protect public health and safety and compatible with NRC’s program for regulating such materials before entering into these agreements. According to NRC staff, NRC also retains authority over federal entities, in areas of exclusive federal jurisdiction and for the protection of common defense and security.

We selected a nuclear power plant that was close to one of the contaminated sites we selected and that was able to provide access to us. We interviewed DOE, EPA, and contractor officials at the contaminated sites regarding the measures used for cleanup of radiological contamination and how agencies apply radiation requirements when making cleanup decisions.

For further information on how agencies have developed and applied radiation requirements and guidance, we reviewed the reports of national and international organizations that agency officials and documentation cited as providing advice and recommendations to agencies involved in radiation protection in the United States or other countries. These organizations included the International Commission on Radiological Protection (ICRP);⁸ the National Council on Radiation Protection and Measurements (NCRP);⁹ and the National Academies. In addition, we reviewed documentation from and interviewed officials at five other agencies we identified that play a role in developing or applying radiation protection guidance and requirements. These agencies were the Occupational Safety and Health Administration (OSHA) within the Department of Labor, the National Aeronautics and Space Administration (NASA), the National Institute of Standards and Technology (NIST) within the Department of Commerce, the Department of Defense (DOD), and the Department of Homeland Security (DHS).

To examine the extent to which federal agencies have funded research on the health effects of low-dose radiation, we interviewed officials at a total of 11 agencies—at each of the nine agencies listed above, and also at the National Institutes of Health (NIH) within HHS because it is a main source of federal funding for medical research, and at HHS's Centers for Disease Control and Prevention (CDC) because it funds research to advance the agency's public health mission. In particular, we interviewed agency officials to determine which agencies fund related research, including either epidemiological research on populations of individuals exposed to radiation or radiobiological research on cellular responses to

⁸ICRP is an independent, international organization with members consisting of scientists and policymakers in the field of radiological protection.

⁹NCRP is a congressionally chartered, nonprofit educational and scientific body. It seeks to formulate and disseminate information, guidance and recommendations on radiation protection and measurements that represent the consensus of leading scientific thinking.

radiation exposure.¹⁰ For the purposes of this review, we also included federal agencies' funding of research on high-dose radiation (radiation exceeding the level considered to be low dose) if agency officials indicated that it had potential implications for low-dose research—for example, by helping to address uncertainties in the risk of health outcomes from low-dose radiation.¹¹ We then requested the seven agencies that had funded such research to provide data on obligations for such funding for fiscal years 2012 through 2016 and information on the type of research funded (epidemiological or radiobiological) and the names of individual studies or projects. In addition, we interviewed agency officials about the research these agencies funded. For one program in particular, DOE's Low Dose Radiation Research Program, we requested funding data for every year since the program's inception in 1998 because we found that it had been a primary source of dedicated funding for radiobiological research on the health effects of such radiation. We assessed the reliability of the data we obtained by checking for obvious errors in accuracy and completeness and by comparing the data with other sources of information, such as agency budget documents. We resolved any data inconsistencies we found through e-mail and telephone communications with agency officials. We determined that the data were sufficiently reliable for reporting on the amount of federal funding for research on low-dose radiation and the type of research funded.

To examine the extent to which federal agencies have collaborated on research concerning the health effects of low-dose radiation, we included questions about agencies' research plans as part of our request for data on obligations. In addition, to gain an understanding of the areas in which federal agencies might benefit from collaboration, we interviewed agency officials about their plans for future research, the potential to use results

¹⁰Epidemiological studies examine the causes of health and disease in human populations using a range of approaches. Persons or groups can be followed over time, or information can be collected at a point in time. Studies can examine outcomes that have already occurred and factors that may have contributed to health or disease, or they can monitor a population of interest before a particular disease-related outcome occurs. In contrast, radiobiological studies use laboratory-based methods to examine the effects of radiation on living cells, tissues, and organs.

¹¹We excluded research on products or medicines (typically referred to as countermeasures) that are used for emergency preparedness or response to a radiation accident, such as potassium iodide, and on products or medicines for treating cancer, where radiation exposure is part of the treatment. We also excluded research on the health effects of radiation in space.

of the research in agency efforts to develop and apply radiation requirements and guidance, and their efforts to foster interagency collaboration in funding and conducting research. We compared agencies' efforts with key considerations we have identified in our prior work for implementing interagency collaborative mechanisms, such as interagency task forces, and key practices for enhancing and sustaining interagency collaboration, such as identifying and addressing needs by leveraging resources.¹² We also attended a conference on radiation and health to learn about the results of research in the field and on potential areas of future research. At the conference, we interviewed individual researchers from universities who also attended. In particular, to gain additional perspectives on agencies' plans for future research and the potential for agencies to collaborate, we asked researchers about their areas of research, the support they had received from federal agencies, and about their views on potential areas for future research and its relevance to the development and application of radiation requirements and guidance.

We conducted this performance audit from January 2016 to September 2017 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.

Background

According to NRC's website, 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. The higher the radiation dose, the sooner the effects of radiation will appear, and the higher the probability of death. For example, according to NRC's website, 134 of the plant workers and firefighters battling the fire at the 1986 Chernobyl nuclear power plant accident received high doses of radiation and suffered from acute radiation syndrome. Of these, 28 died within the first 3 months from their radiation injuries.

¹²For further information on these practices, see GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

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' 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.¹³ It is often not possible to determine the extent to which a health outcome such as cancer is caused by low dose radiation because of the potential confounding effects of other chemical and physical hazards and lifestyle factors, such as smoking and diet. In addition, much of the data on health effects of radiation exposure come from non-U.S. populations, such as Japanese atomic bomb survivors, who 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.

The roles of federal agencies in developing and applying radiation protection requirements and guidance vary depending on the setting in which radiation exposure occurs. For the four settings in our review—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—the key agencies for establishing dose limits and guidance levels are EPA, NRC, DOE, and FDA.

- **EPA** advises federal agencies about radiation matters that affect public health and provides technical information for conducting radiation risk assessments; federal and state agencies use such assessments to develop and implement radiation protection regulations and standards. EPA also develops requirements and guidance for particular settings in which radiation exposure can occur. For example, EPA has developed regulations to limit discharges of radioactive material affecting members of the public from operations associated with use of nuclear energy to produce electrical power for public use, such as nuclear power plants. In addition, EPA has developed guidance on establishing protective cleanup levels for radioactive contamination at sites cleaned up under the Comprehensive Environmental Response, Compensation, and

¹³The millisievert (mSv) and rem are measures of effective radiation dose. One mSv is equal to 0.1 rem. NIH officials commented that a growing body of epidemiological evidence suggests that cancer risk can exist below 100 mSv.

Liability Act (CERCLA). It has also developed guidance on levels of radiation exposure that would trigger public safety measures, such as evacuation, to minimize or prevent radiation exposure during an emergency.

- **NRC** is responsible for protecting people and the environment from unnecessary exposure to radiation as a result of civilian uses of nuclear materials. Among other things, NRC has established dose limits for workers and the public exposed to radiation from the operation and decommissioning of nuclear power plants, as well as minimum requirements for emergency plans for protecting members of the public from exposure in the event of a radiological emergency. NRC also has the primary responsibility for licensing, inspecting, and regulating medical uses of nuclear material.
- **DOE** is responsible for ensuring that its facilities are managed to protect workers and the public. As part of this responsibility, DOE has established radiation dose limits for workers at its facilities and public dose limits for DOE radiological activities, including cleanup of radioactive contamination at DOE sites.¹⁴ In addition, under the Atomic Energy Act of 1954, DOE is the federal agency that currently has primary responsibility for research related to nuclear energy. This responsibility includes the protection of health during activities that can result in exposure to radiation. DOE addresses this requirement through research to determine if DOE workers and people living in communities near DOE sites are adversely affected by exposures to hazardous materials from site operations. DOE's National Nuclear Security Administration (NNSA) assists in emergency response to accidental or terrorism-related exposure to radiation by characterizing radiation levels in the area of an accident or terrorist event and providing information to emergency-response decision makers.¹⁵
- **FDA** has issued radiation safety regulations for medical equipment, such as diagnostic X-ray systems. According to FDA officials, FDA's regulations generally do not limit the dose to the patient but instead prescribe mandatory performance standards for most radiology medical devices, such as standards for the display of cumulative time

¹⁴DOE cleans up certain of its sites under CERCLA. EPA's guidance concerning cleanup levels for radioactive contaminants applies to these sites.

¹⁵NNSA was created by title XXXII the National Defense Authorization Act for Fiscal Year 2000, Pub. L. No. 106-65 (1999). It is a separate semiautonomous agency within DOE, with responsibility for the nation's nuclear weapons, nonproliferation, and naval reactors programs.

that an X-ray system is activated.¹⁶ FDA has also developed guidance for state and local agencies to aid in emergency response planning for accidental or terrorism-related radioactive contamination of human food and animal feeds.

Other federal agencies also have roles in radiation protection. For example, ionizing radiation is addressed in specific OSHA standards for general industry, shipyard employment, and construction.¹⁷ According to DOD officials, DOD operates facilities and engages in activities where radiation exposure can occur and implements occupational and public dose limits established by NRC and states in which these facilities and activities are located. NASA sets radiation exposure limits for space flight and supports research on the health effects of cosmic radiation to better manage health risks to astronauts. DHS's Federal Emergency Management Agency provides guidance on responding to incidents involving release of radioactive material and has established procedures for review and approval of state and local emergency plans for the offsite effects of a radiological emergency that may occur at a commercial nuclear power facility.

Two U.S. scientific advisory bodies—the National Academies' Nuclear and Radiation Studies Board and the National Council on Radiation Protection and Measurements (NCRP)—and one international body—the International Commission on Radiological Protection (ICRP)—are involved in analyzing scientific developments regarding the health effects of radiation exposure and advising federal agencies.

- The National Academies' Nuclear and Radiation Studies Board conducts studies on safety and other issues associated with nuclear and radiation-based technologies. The board has published a series of seven reports to advise the U.S. government on the relationship between exposure to radiation and human health, with the most recent report published in 2006.
- NCRP, a congressionally-chartered, nonprofit educational and scientific body, seeks to formulate and disseminate information, guidance, and recommendations on radiation protection and measurements that represent the consensus of leading scientific

¹⁶Under the Mammography Quality Standards Act, FDA has established a maximum dose limit for mammography testing.

¹⁷See 29 C.F.R. § 1910.1096 (general industry); § 1915.57 (shipyard employment); § 1926.53 (construction industry).

thinking. NCRP issues reports on specific issues of concern to federal agencies, such as on the use of medical equipment that produces radiation.

- ICRP, an independent, international organization with members consisting of scientists and policymakers in the field of radiological protection, offers recommendations to regulatory and advisory agencies on protection against radiation. In addition to addressing particular areas within radiological protection, its publications describe an overall system of radiological protection.

Several other organizations are involved in scientific research and standards setting for protection against radiation. For example, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), which includes 27 United Nations states as members of its scientific committee, has a mandate to assess and report on levels and effects of exposure to radiation. Its summaries of basic scientific studies, along with scientific developments reported by the National Academies and other national organizations, serve as a primary source of information for NCRP and ICRP. The International Atomic Energy Agency, in collaboration with other organizations, has issued basic safety standards for protecting people and the environment from harmful effects of radiation. It has also issued safety requirements for preparedness and response for a nuclear or radiological emergency. The World Health Organization, one of the organizations that has collaborated with the International Atomic Energy Agency, also supports research on the health effects of radiation.

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

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. Three scientific advisory bodies—ICRP, NCRP, and the National Academies' Nuclear and Radiation Studies Board—have 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. The requirements and guidance the four agencies have developed and applied vary depending on the settings, in part because the scientific advisory bodies on which the agencies relied have also developed recommendations specific to the settings we reviewed.

Support of Scientific Advisory Bodies for Use of the Linear No-Threshold Model

In developing and applying radiation protection requirements and guidance for workers and the public—specifically, developing 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. 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. The model is used to estimate the risk of cancer when the overall level of exposure is in the range considered to be low dose. At this level of exposure, data from epidemiological studies of individuals exposed to radiation provide evidence of increased risk to cancer, but with uncertainties about the extent of this risk.

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) is 1 mSv (0.1 rem), or a hundredth of the level the National Academies considers low dose.¹⁸

Three key scientific advisory bodies—ICRP, NCRP, and the National Academies’ Nuclear and Radiation Studies Board—have supported use of this model for development of radiation protection requirements and guidance. For example:

- **ICRP**, in its 2007 update to its recommendations on radiological protection, stated that at low doses of radiation, it considers the linear no-threshold model to be the best practical approach to managing risk from radiation exposure. In addition, ICRP stated that this model is consistent with the principle that actions should be taken to avoid or diminish harm to human life or health that is scientifically plausible but uncertain, as is the case at low doses of radiation. ICRP’s update also explained that it periodically re-evaluates its recommended dose limits based on its evaluation of new scientific data and information.

¹⁸According to NRC’s website, natural, or background, sources of radiation include naturally occurring radioactive minerals such as potassium in our own bodies or the ground and cosmic radiation from space. The average natural background level of radiation in the United States, including exposure from radon, is about 3.1 mSv (0.31 rem) per year.

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- **NCRP**, in a 2001 study on the linear no-threshold model that it continues to reference today, noted that the existing epidemiological data on the effects of low-dose radiation are inconclusive and, in some cases, contradictory, prompting some observers to dispute the validity of the linear no-threshold model. Nevertheless, NCRP concluded that while there is uncertainty about the health effects of low-dose radiation, the linear no-threshold model is more plausible than other models, such as the hormesis model, which assumes that low-dose radiation protects against rather than increases the risk of cancer.¹⁹ Further, according to NCRP's president, recent epidemiological studies indicate that the preponderance of evidence continues to support the linear no-threshold model for use in radiation protection.
 - **The National Academies**, in its 2006 report on low-dose radiation, supported the use of the linear no-threshold model, stating that the balance of evidence from epidemiologic, animal, and mechanistic studies tends to favor a simple proportionate relationship at low doses between radiation dose 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. For example, the 2006 report incorporated data from an additional 15 years of follow-up of Japanese atomic bomb survivors and from studies of nuclear workers exposed to low-dose radiation.

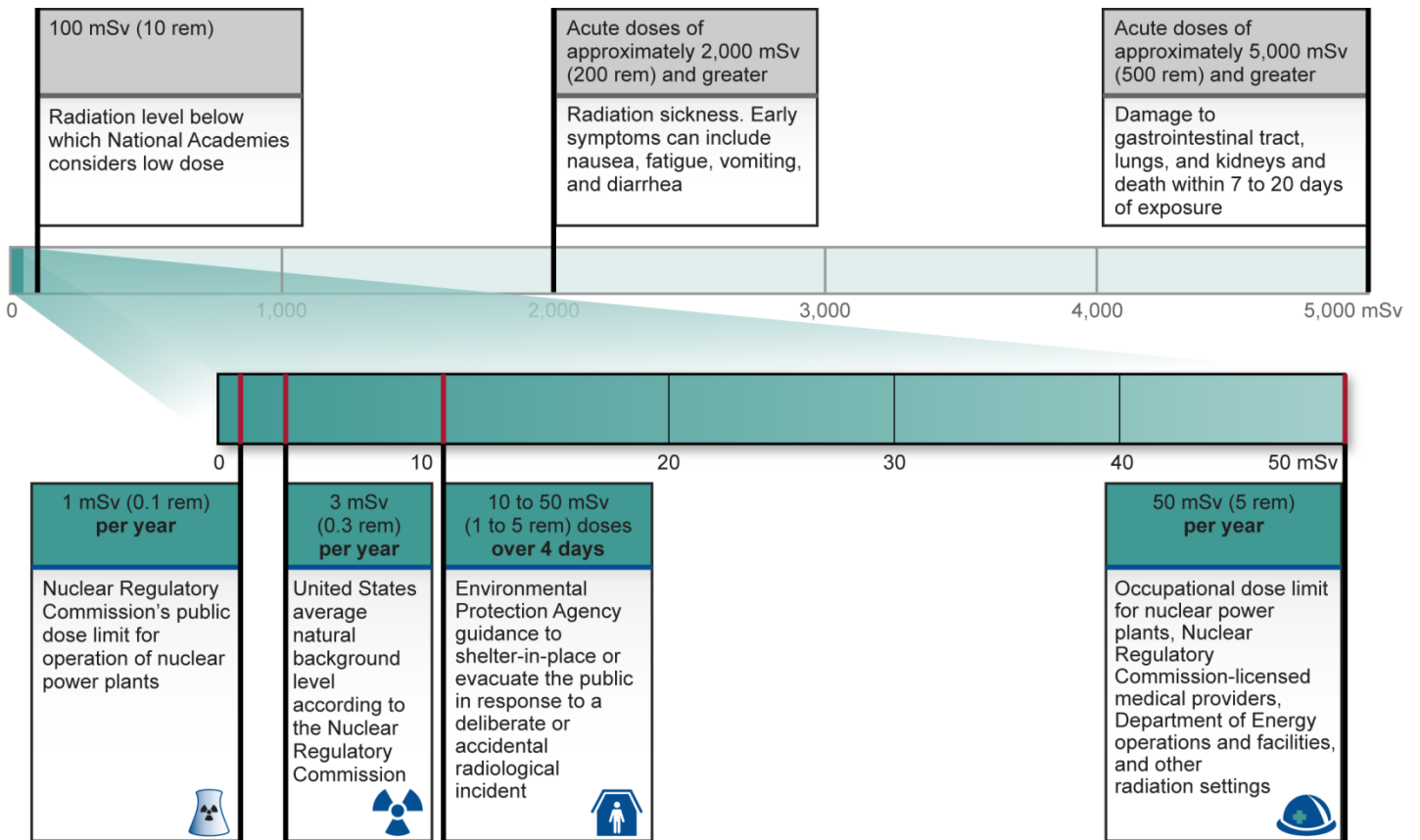
Nevertheless, these advisory bodies have recognized challenges in accurately estimating cancer risks from very low doses of radiation exposure when using the linear no-threshold model. For example, the epidemiological data used to estimate the dose-risk relationship for American workers over a 1-year period are largely from studies of Japanese atomic bomb survivors' exposure to radiation from the atomic bomb. As a result, to account for different doses and dose rates of radiation exposure, advisory bodies have recommended that estimates of the risk of low doses using these data be adjusted accordingly. For example, in radiation protection guidance issued in 2007, ICRP

¹⁹According to the National Academies' 2006 report on low-dose radiation, hormesis is the beneficial effect of a low dose of an otherwise harmful substance. For example, the study stated that some investigators had suggested that radiation exposure may enhance immune response or DNA repair processes. However, the study concluded that at the time of the study's publication, the assumption that the health benefits of low doses of radiation exceed the detrimental effects was unwarranted.

recommended that cancer risk estimates for low doses of radiation be adjusted downward by a factor of one-half.

Figure 1 depicts examples of the dose limits and guidance levels established by EPA, NRC, and DOE. (See app. I for further examples.) As shown in the figure, the public dose limit for nuclear power plants is one-third the U.S. average natural background radiation level.

Figure 1: Examples of Low-Dose Radiation Limits and Guidance in Relation to Background Exposure and High-Dose Levels



Source: GAO analysis of Department of Energy, Nuclear Regulatory Commission, Environmental Protection Agency, International Commission on Radiological Protection, and National Academies of Sciences, Engineering, and Medicine documents. | GAO-17-546

Notes: The millisievert (mSv) and rem are measures of effective radiation dose. One mSv is equal to 0.1 rem.

The approximate doses for acute health effects assume that radiation is in the form of X-rays or gamma rays.

OSHA suggested that radiation sickness could occur at acute doses of approximately 1,000 mSv (100 rem) and greater.

Some stakeholders have questioned whether radiation dose limits based on the linear no-threshold model are too strict, or whether they are strict enough, and have advocated for revising dose limits and guidance levels. For example, in 2015, NRC received three petitions from different individuals proposing that NRC raise its occupational and public dose limits. One petitioner commented that some studies suggest low levels of radiation have protective effects and that the costs of complying with linear no-threshold-based regulations were high.²⁰ Similarly, a joint study by the French National Academies of Science and of Medicine in 2005 concluded that epidemiological studies have been unable to find a significant increase of cancer at low levels of radiation exposure.²¹ Conversely, representatives we interviewed from two nonprofit groups, Physicians for Social Responsibility and Beyond Nuclear, told us that dose limits based on the linear no-threshold model were not strict enough to protect vulnerable groups, such as children and pregnant women and their fetuses.

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 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. In addition, EPA published a paper in 2009 that stated that it believed that the evidence on health effects of radiation exposure does not preclude the possibility of a threshold below which there is no increased risk of cancer, but that the evidence at present does not support the existence of a threshold.²²

²⁰CDC and EPA submitted comments on the petition to NRC in which they disagreed with the petitioners and supported continued use of the linear no-threshold model. For example, EPA noted that, since publication of the National Academies study on low-dose radiation in 2006, evidence has accumulated supporting the use of the linear no-threshold model for regulatory purposes.

²¹French National Academies of Science and Medicine, *Dose-Effect Relationships and Effects of Low Doses of Ionizing Radiation* (Paris, France: March 1995).

²²J.S. Puskin, "Perspectives on the Use of LNT for Radiation Protection and Risk Assessment by the U.S. Environmental Protection Agency," *Dose-Response*, vol. 7, no. 4 (2009).

Agencies' Radiation Protection Requirements and Guidance Vary Depending on the Four Settings Reviewed in Which Exposure Can Occur

Operation and Decommissioning of Nuclear Power Plants

The limits and guidance the four agencies have developed and applied vary depending on the settings in which exposure can occur, as described below. This result is in part because the scientific advisory bodies on which the agencies relied have developed recommendations specific to the four settings we reviewed: (1) operation and decommissioning of nuclear plants; (2) cleanup of sites with radiological contamination; (3) use of medical imaging equipment that produces radiation; and (4) accidental or terrorism-related exposure to radiation.

According to NRC's notice of its final rule for standards for protection against radiation, NRC used ICRP's recommendations issued in 1977 as the basis for NRC's regulations. ICRP stated that it developed its 1977 recommendations on occupational dose limits in part through a comparison between the cancer risk from occupational exposure to radiation and the rates of occupational fatalities in industries recognized as having high standards of safety. Thus, nuclear power plant workers would not face a greater risk of cancer than the fatality risks, whether due to accidents or disease, that workers face in other industries. For the general public, ICRP suggested that the cancer risk—and therefore the dose limit—should be less than that for workers and should be comparable to the public's risk from everyday activities, such as taking public transportation. ICRP further stated that when setting public dose limits, an agency must consider members of the public belonging to critical groups, such as children and pregnant women, who may be more susceptible to the effects of radiation than the population as a whole.

According to one of ICRP's key recommendations for radiation protection, radiation exposure should be limited to keep the likelihood and magnitude of exposure as low as reasonably achievable, taking into account economic and societal factors. In keeping with this recommendation, NRC requires nuclear power plants to have a radiation protection program that includes measures to keep doses 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 consistent with, among other things, the economics of improvements in relation to benefits to the public health and safety.²³ Under the ALARA principle, NRC encourages nuclear plants to demonstrate their use of the principle through cost-benefit analyses or other quantifiable methods.

²³10 C.F.R. § 20.1003.

Cleanup of Sites with
Radiological Contamination

According to NRC officials, nuclear power plants typically set their own occupational dose limits at 40 percent of NRC's regulatory limit of 50 mSv (5 rem) per year, and cost is generally a key criterion that plants use to determine what actions to take to reduce radiation exposures under their ALARA programs. At the nuclear power plant we visited, representatives told us that under their ALARA plan, the plant set its own dose limits for workers at 40 percent of the regulatory limit. 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. According to NRC's 2014 annual report on occupational radiation exposure, none of the 124,831 nuclear power plant workers who were monitored in 2014 received a dose above NRC's regulatory limit,²⁴ and over 99 percent of these workers received a dose below the 40-percent level used by many plants as their own limit.

DOE and EPA both used the recommendations of scientific advisory bodies, including the use of the linear no-threshold model, to develop limits on dose or increased health risk for members of the public from sites with radiological contamination, even though the agencies used different approaches in implementing the recommendations. For example, in an order on radiation protection of the public and environment, DOE set a public dose limit of 1.0 mSv (0.1 rem) per year, which was the dose limit recommended by ICRP in 1990. In developing its recommendations, ICRP used the assumptions of the linear no-threshold model to identify a dose that would not cause more than a small increase in the age-specific mortality rate from cancer. In contrast, according to a 2014 EPA memorandum on cleanup of sites with radiological contamination, EPA uses a risk-based approach to prescribe cleanup levels for carcinogens, including radiation, in a range that will not result in more than 1 in 10,000 to 1 in 1 million additional cancers in a population during their lifetimes. Under this approach, EPA uses the assumption of the linear no-threshold model to set site-specific levels of cleanup that account for various factors, such as the site's expected future land use and the presence of other contaminants, such as chemicals that may also increase the risk of cancer. Under its 2014 memorandum, EPA determined that when using a federal or state standard for radiation protection at sites with radiological

²⁴The number of monitored individuals includes workers who were required to be monitored because they were expected to receive a radiation dose above the monitoring threshold and individuals who volunteered to be monitored, such as visitors and service representatives.

Use of Medical-Imaging Equipment That Produces Radiation

contamination, this standard is generally not sufficiently protective if it is greater than 0.12 mSv (0.012 rem) per year.²⁵

According to FDA officials, FDA does not have the authority to regulate the total amount of radiation exposure a patient receives from medical imaging equipment.²⁶ They also commented that decisions such as the frequency of taking medical images are based on patient need and that those decisions determine the total amount of radiation exposure to the patient. Similarly, ICRP's 2007 guidance on radiation protection states that, while all use of radiation in medicine should be justified and the radiation dose from each examination should be as low as reasonably achievable, radiation dose limits do not apply to medical exposures of patients.

FDA officials stated that, instead of setting limits on total amount of radiation exposure to patients, the agency regulates the maximum limits radiation output of medical equipment. In particular, they stated that the agency based its equipment standards on NCRP guidance from 1968 on medical X-ray and gamma ray protection. They also commented that this NCRP guidance provided a dose rate limit for the equipment and stated that the exposure rate should be as low as reasonably achievable. In a 2005 Federal Register notice on FDA's change to its performance standards for medical-imaging equipment, FDA stated that it used the assumptions of the linear no-threshold model to determine that the health benefits to medical staff and patients (in monetary terms) exceeded the costs incurred by equipment manufacturers and FDA to implement the change.²⁷

In keeping with the principle that radiation exposure should be kept as low as reasonably achievable, FDA encourages voluntary measures by health

²⁵In 2014, EPA lowered the federal or state dose limits or standards for evaluating site-specific cleanup levels from 0.15 mSv (0.015 rem) per year to 0.12 mSv (0.012 rem) per year to account for more recent scientific information showing that the excess lifetime cancer risk from radiation exposure was greater than previously estimated. EPA officials noted that when EPA is using either the risk range or a federal or state dose standard for radiological protection to develop cleanup levels for radiation sites, the 0.12 mSv (0.012 rem) per year dose should not be used as a cleanup level.

²⁶According to FDA and OSHA officials, radiation exposure to physicians and other care providers is regulated by OSHA or NRC, not FDA.

²⁷70 Fed. Reg. 33998, 34014, 34018, 34024-25 (2005). The standards appear in 21 C.F.R. part 1020.

care providers to address radiation exposure to patients from the use of medical-imaging equipment. Under an initiative launched in 2010, FDA identified a number of factors that contribute to levels of exposure that exceed the levels for meeting patients' clinical need, and FDA identified steps to mitigate these factors. For example, its initiative recommended that healthcare professional organizations continue to develop nationally recognized benchmark levels for medical-imaging procedures that use radiation, and FDA stated that it has increased its participation in these efforts both on its own and through collaborative efforts with industry and healthcare professional organizations. Benchmark levels are not mandatory but allow medical facilities to investigate when a medical examination exceeds the benchmark and determine whether it is possible to reduce exposure without adversely affecting image quality.

Accidental or Terrorism-Related Exposure to Radiation

To develop guidance for state and local governments' emergency response to deliberate or accidental radiological incidents,²⁸ EPA and FDA used the recommendations of scientific advisory bodies, including the assumptions of the linear no-threshold model to recommend radiation doses at which protective actions would provide a net benefit when compared with other factors, such as cost of the actions taken. For example, according to its 2016 guidance on emergency response to radiological incidents, EPA compared the cost of evacuation under several scenarios with the number of cancer deaths avoided to recommend a radiation dose to the public at which evacuation should be considered. Using ICRP guidance, EPA assumed a linear relationship between radiation exposure and cancer risk—a principle of the linear no-threshold model—to calculate the number of potential cancer deaths. According to EPA's guidance, the radiation dose the agency identified fell within the risk level it considered acceptable, while also meeting EPA's criteria that the cost of the protective action be justified by the reduction of risk to public health.

According to EPA's guidance, decisions on the radiation doses at which to take protective actions need to consider health risks other than radiation. For example, weather hazards may impede evacuation and favor sheltering-in-place instead. Similarly, EPA's guidance explains that decisions on relocation need to account for a variety of health problems

²⁸EPA's 2016 guidance on emergency response to radiological incidents defines a radiological incident as an event or a series of events, deliberate or accidental, leading to the release or potential release into the environment of radioactive materials in sufficient quantity to warrant consideration of protective actions.

that relocation itself can cause. In its response to frequently asked questions about radiation in Fukushima, Japan, the World Health Organization noted that these problems were evident in the aftermath of the March 11, 2011, earthquake and subsequent tsunami that caused significant damage to the Fukushima Daiichi Nuclear Power Station, releasing radioactive material into the environment. There were no known acute deaths or illnesses from radiation exposure, but the relocation of thousands of people caused an increase in disaster-related deaths, as well as mental health and access to health care issues, according to the World Health Organization.

FDA also relied on ICRP guidance and the linear no-threshold model to recommend radiation doses at which protective actions would provide a net benefit when compared with other factors. In particular, according to a 1998 Federal Register notice about recommendations for accidental radioactive contamination of human food and animal feed, the agency developed protective action guides for state and local agencies responding to these types of accidents. These guides provide a recommended radiation dose range in which countermeasures should be taken for the contaminated food and feed after an accident. This range is based on values set by ICRP on the basis of the linear no-threshold model.

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

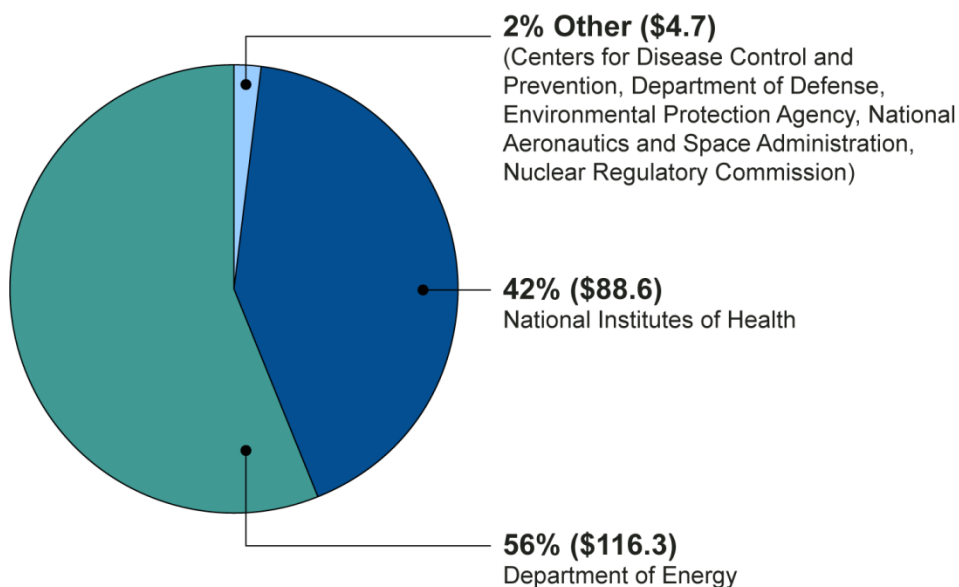
For fiscal years 2012 through 2016, seven federal agencies—CDC, DOD, DOE, EPA, NASA, NIH, and NRC—obligated about \$210 million for research on the health effects of low-dose radiation, but annual funding decreased by 48 percent. During the period we reviewed, the seven federal agencies that funded this 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.

Seven Federal Agencies Obligated about \$210 Million for Fiscal Years 2012 to 2016 for Research on Low-Dose Radiation’s Health Effects, but Annual Funding Decreased

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.²⁹ As shown in figure 2, DOE and NIH accounted for most of this 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.

Figure 2: Obligations for Research on Health Effects of Low-Dose Radiation, by Federal Agency, for Fiscal Years 2012–2016

Obligations in millions of dollars.



Source: GAO analysis of agencies' data. | GAO-17-546

Note: Data on obligations for research on low-dose radiation do not include research on products or medicines used for emergency preparedness or response to a radiation accident or for treating cancer, where radiation exposure is part of the treatment. Dollar figures have not been adjusted for inflation.

²⁹Data on obligations for research on low-dose radiation include both epidemiological and radiobiological research. The data also include funding on high-dose radiation research if it had potential implications for low-dose research—for example, by helping to address uncertainties in low-dose risk. We excluded research on products or medicines (typically referred to as countermeasures) that are used for emergency preparedness or response to a radiation accident, such as the use of iodine tablets, and on products or medicines for treating cancer, where radiation exposure is part of the treatment.

The research that the seven federal agencies funded included both epidemiological and radiobiological studies.³⁰ Agency officials told us that both types of research are important to better understand the health effects of low-dose radiation and could inform future efforts to update dose limits and guidance levels for radiation exposure.

Two of the largest epidemiological studies funded by federal agencies were the Epidemiologic Study of One Million U.S. Radiation Workers and Veterans (Million Person Study)—an ongoing study headed by NCRP—and the International Nuclear Workers Study, a multi-year study that includes over 300,000 workers from France and the United Kingdom as well as from the United States. The Million Person Study began in 2009 and includes plans to examine mortality statistics on multiple cohorts (populations) of over 1-million U.S. radiation workers, veterans, and other individuals. The purpose is to provide information about low-dose radiation health risks when the exposures are received gradually over time and not instantaneously, as was the case for the 1945 atomic-bomb exposures in Japan. Officials from two agencies that fund or use the results of research on the health effects of low-dose radiation—DOE and NRC—told us that NCRP’s Million Person Study can help address these research gaps. For example, according to NRC, the study is important research in order for the agency to examine the radiation risks to workers exposed to doses and dose rates in actual exposure settings.

DOE, EPA, NASA, and NRC have provided funding for the Million Person Study. DOE’s Office of Science provided the initial funding of \$500,000 for the pilot study in fiscal year 2009, as well as \$869,000 for a subsequent larger study, as part of its Low-Dose Radiation Research Program, but DOE stopped funding the study in fiscal year 2010 to fund other research priorities. Since DOE’s initial \$500,000 funding for the pilot study, NCRP has received a total of \$4.2 million in additional funding from DOE, EPA, NASA, and NRC, according to DOE officials. In addition, an explanatory statement accompanying the fiscal year 2017 Consolidated Appropriations Act directed DOE to provide not less than \$500,000 from funds for DOE’s Office of Environment, Health, Safety and Security for this study. With the funding it has received, NCRP completed various feasibility studies and follow-up work on several of the different cohorts of individuals included in the overall study. For example, NCRP began work

³⁰Epidemiological studies examine defined populations of workers and other individuals and the effects on their health after exposure to radiation, and radiobiological studies examine molecular and cellular responses to radiation exposure.

on a mortality study of nuclear power plant workers. NCRP has estimated that it would need \$20 million to analyze and report on all of the cohorts included in the overall study. In addition, NCRP's president told us that continuous funding could help to retain the study's original investigators, who might otherwise move onto other work.

DOE also provided about \$2.1 million for the International Nuclear Workers Study for fiscal years 2012 through 2016, and CDC provided \$66,000. According to CDC officials, the workers in the study experienced a similar form of radiation, thereby simplifying the study's analysis, and the results of the study have shown associations between radiation exposure and leukemia and solid cancers.

Additional information on the types of low-dose radiation research funded by federal agencies and the results of this research is described below:

- **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 to fund radiobiological research, and over the course of the program, it provided an average of about \$14 million per year for such research, which included funding for the Million Person Study. 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. According to a 2016 report from DOE's Biological and Environmental Research Advisory Committee, among the important discoveries under the program was a phenomenon known as the bystander effect, where cells may sustain radiation damage even though no radiation passes through them. Other areas of discovery included the role of DNA repair and the immune system, as well as the potential beneficial effects at the cellular level caused by low-dose radiation. The Office of Environment, Health, Safety and Security provided annual funding from fiscal year 2012 through fiscal year 2016 for epidemiological studies in two areas: (1) the Radiation Effects Research Foundation, which conducts studies involving Japanese atomic bomb survivors in Hiroshima and Nagasaki and is a source of data used by national and international standard-setting organizations and scientific advisory bodies to set regulations and (2) assessments of worker and public health risks from radiation exposure resulting from nuclear weapons

production activities in the former Soviet Union, which provided DOE researchers with data from Russian workers who experienced chronic exposure to radiation.

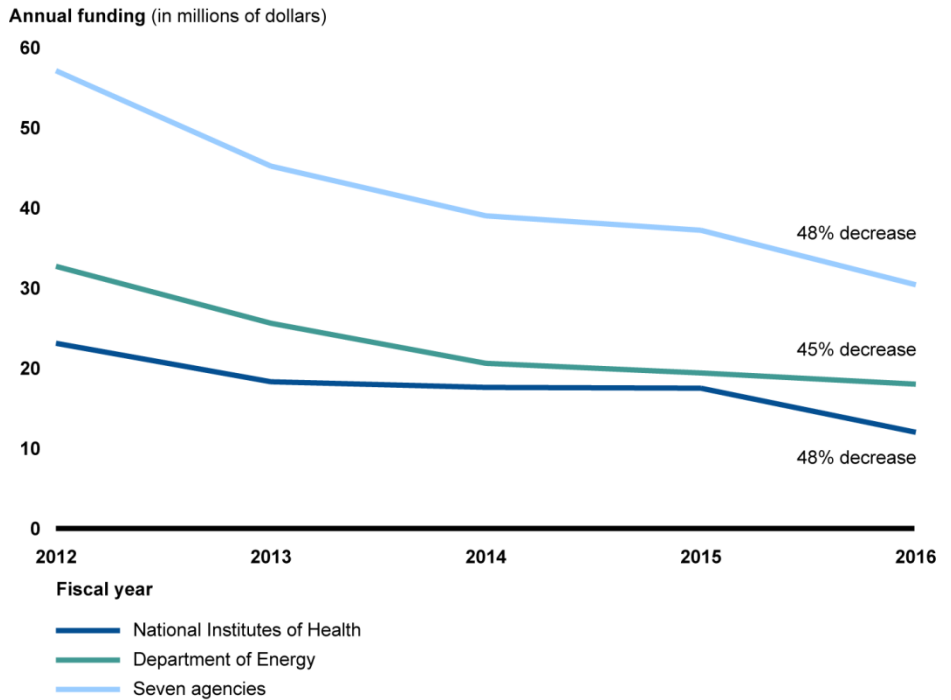
- **NIH** has funded and conducted both epidemiological and radiobiological studies on low-dose radiation, according to NIH officials. The officials stated that the studies are conducted through the National Cancer Institute's internal research program for radiation epidemiology, as well as through NIH's research programs for external funding of investigator-initiated research. The aim of the internal research program for radiation epidemiology is to identify, understand, and quantify the risk of cancer in populations exposed to various types of radiation, and to advance understanding of cancer caused by radiation. Other institutes of NIH, including the National Institute of Environmental Health Sciences, also fund research related to the health effects of radiation exposure as part of NIH's overall mission to fund medical research. Examples of research supported by NIH have included (1) a study conducted in partnership with the U.S. Department of Veterans Affairs on cancer mortality among military participants in U.S. nuclear weapons tests and (2) a tissue bank with samples from Chernobyl survivors. These samples are being used to understand the effects of radioactive exposure from nuclear power plant accidents. NIH has also funded radiobiological research on high-dose radiation, and some of this research also applies to low-dose radiation.
- **EPA** helps fund research through an ongoing interagency agreement with DOE's Oak Ridge National Laboratory, according to EPA officials. The funding supports the development of models that provide information about doses to particular organs from ingestion or inhalation of a specific quantity of a radioactive element, such as cesium or plutonium. According to EPA instructions for calculating radiation dose and risk, EPA uses this information to estimate cancer risks of exposure to over 800 radioactive elements. These estimates, according to EPA, can be used by federal and state agencies to develop and implement radiation protection regulations and standards. EPA also provided funding for the Million Person Study. According to EPA officials, the agency contributed to the study to be able to discuss and review the research in its early stages.
- **NRC** officials we interviewed said that NRC does not generally fund research on radiation's health effects but agreed to provide funding to the Million Person Study with the understanding that NRC would be a minority funding partner in the program. However, after DOE stopped funding the study, NRC became the largest contributor, providing a

total of \$2.1 million in fiscal years 2012 to 2016. NRC also funded an epidemiological study analyzing cancer risks in populations living near U.S. nuclear facilities, but it did not continue the study because of the study's limited usefulness for drawing conclusions about risk and its long duration and high cost, according to NRC officials.

- **NASA** officials told us that the agency mostly conducts research on space-based radiation, which differs from ground-based radiation in terms of its physical characteristics and its effects on health. In the past 5 years, NASA has funded over \$100 million for research on space-based radiation, including research on its health effects, such as on the risk of acute central nervous system effects. The agency also provided funding for low-dose radiation research at DOE, as well as for the Million Person Study.
- **CDC** has provided some funding for epidemiological studies such as those evaluating the long-term effects of occupational radiation exposures or analyzing mortality among nuclear workers, according to funding information provided by CDC. For example, according to this information, CDC partially funded the International Nuclear Workers Study. CDC officials told us that the program has published more than two dozen studies related to occupational exposures and cancer risks among workers across the DOE complex. CDC's National Institute for Occupational Safety and Health also provided funding for institute researchers to conduct studies on flight attendants exposed to cosmic radiation and on uranium miners exposed to radon.
- **DOD** has contributed a small amount of funding for radiation health effects research activities through the Armed Forces Radiobiology Research Institute, according to funding information provided by DOD. Most of the work conducted through the institute is research on radiation countermeasures—treatments that could be used in the aftermath of an attack involving the release of radioactive material. In addition, according to DOD's funding information, the institute provides some funding to researchers in order to better understand, for example, cancer risks due to low-dose radiation exposure.

As shown in figure 3, in fiscal years 2012 through 2016, the seven agencies collectively decreased their annual funding obligations for research on health effects of low-dose radiation by 48 percent, from \$57.9 million in fiscal year 2012 to \$30.4 million in fiscal year 2016, and NIH and DOE decreased their annual funding obligations by 48 and 45 percent, respectively.

Figure 3: Federal Agencies' Obligations for Research on Health Effects of Low-Dose Radiation, Fiscal Years 2012–2016



Source: GAO analysis of agencies' data. | GAO-17-546

Notes: The seven agencies include the Department of Energy, National Institutes of Health, Nuclear Regulatory Commission, National Aeronautics and Space Administration, Department of Defense, Centers for Disease Control and Prevention, and Environmental Protection Agency.

Data on obligations for research on low-dose radiation include both epidemiological and radiobiological research but do not include research on products or medicines used for emergency preparedness or response to a radiation accident or for treating cancer, where radiation exposure is part of the treatment.

Annual funding amounts have not been adjusted for inflation.

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. DOE's Office of Science established this program in 1998 to fund research on the effects of radiation on genomes, cells, and living organisms, with the aim of providing a scientific basis for developing radiation protection standards in

line with the research results that demonstrate the response of complex biological systems to low doses of radiation.³¹ According to DOE officials, decreases in funding for the program reflected a shift toward bioenergy and environmental research within the department's Office of Science. These officials said that the agency provided the final funding for the program in fiscal year 2016. In contrast, funding remained stable for research supported by DOE's Office of Environment, Health, Safety and Security on epidemiological studies in Japan and Russia.

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 commented that sequestration occurred during the time period in which radiation research funding decreased.³² In addition, 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. Table 1 shows agencies' annual obligations for research on health effects of low-dose radiation.

³¹The committee report accompanying the Senate version of DOE's appropriations bill for fiscal year 1999 directed DOE to establish a Low Dose Effects Program to determine the biological effects of exposure to low doses of ionizing radiation by 2008. S. Rep. No. 105-206 at 101 (1998).

³²The Balanced Budget and Emergency Deficit Control Act of 1985 (BBEDCA) established sequestration—an automatic, across-the-board cancellation of budgetary resources—to enforce discretionary spending limits and control the deficit. In August 2011, Congress and the President enacted the Budget Control Act of 2011 (BCA), amending BBEDCA. Among other things, the BCA established the Joint Select Committee on Deficit Reduction (Joint Committee), which was tasked with proposing legislation to reduce the deficit by \$1.2 trillion or more through fiscal year 2021. The absence of such legislation triggered the sequestration process in section 251A of BBEDCA, known as the Joint Committee sequestration

Table 1: Agency Obligations for Research on Health Effects of Low-Dose Radiation, Fiscal Years (FY) 2012–2016

Obligations are in millions of dollars and have not been adjusted for inflation

Agency	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	Total	Percentage of total obligations
Department of Energy	32.6	25.7	20.6	19.4	18.0	116.3	55.5
National Institutes of Health	23.1	18.3	17.6	17.5	12.0	88.6	42.3
Nuclear Regulatory Commission	1.5	0.5	0.5	0	0.1	2.6	1.3
National Aeronautics and Space Administration	0.4	0.4	0	<0.1	0.2	1.0	0.5
Department of Defense	<0.1 ^a	<0.1 ^a	<0.1 ^a	<0.1 ^a	<0.1 ^a	0.4	0.2
Centers for Disease Control and Prevention	0.1	<0.1	0	<0.1	<0.1	0.4	0.2
Environmental Protection Agency	<0.1	0.1	0.1	<0.1	<0.1	0.3	0.2
Total	57.9	45.2	39.0	37.2	30.4	209.6	100

Source: GAO analysis of agency data. | GAO-17-546

Notes: Totals may not reflect summation of obligation dollars because of rounding.

Data on obligations for research on low-dose radiation do not include research on products or medicines used for emergency preparedness or response to a radiation accident or for treating cancer, where radiation exposure is part of the treatment.

Funding for research on high-dose radiation that also applies to low-dose radiation is included in the National Institutes of Health totals.

^aThe Department of Defense did not provide annual funding figures but instead provided a total amount for all 5 fiscal years. The amount shown is an average of the total funding over the 5-year period.

Agencies Collaborated on Individual Projects on Radiation’s Health Effects but Not on Overall Research Priorities

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 the use of several mechanisms,³³ including the following:

- **Joint funding of individual research projects:** For example, as previously mentioned, DOE’s Office of Science, EPA, NASA, and NRC jointly funded the Million Person Study, and CDC and DOE’s

³³In our September 2012 report, we reported that experts have defined an interagency mechanism for collaboration as any arrangement or application that can facilitate collaboration between agencies. See [GAO-12-1022](#).

Office of Environment, Health, Safety and Security helped fund the International Nuclear Workers Study.

- **Participation in interagency committees:** For example, DOD, DOE, EPA, HHS and NRC are members of the Interagency Steering Committee on Radiation Standards, which has a goal of promoting consistency in federal radiation protection programs. Collaborating on research on low-dose radiation is not a committee focus, but the committee provides a forum for sharing information on research developments. Similarly, the head of DOE's Office of Environment, Health, Safety and Security co-chairs a bilateral U.S.-Russian Federation committee for coordinating research on the health effects of exposure to radiation in the Russian Federation from the production of nuclear weapons. CDC, DOD, EPA, NASA, and NRC are also U.S. members of the committee.
- **Participation in meetings and conferences:** For example, in June 2017, DOE's Oak Ridge National Laboratory hosted a workshop on radiation-protection research needs. The workshop agenda included presentations by DOE, EPA, NRC, FDA, and NIH's National Cancer Institute. In addition, DOE officials told us they share research results informally with other agencies through their participation in conferences held by NCRP and other groups, and NIH officials also said that members of the radiation epidemiology scientific community have the opportunity to connect at specialized meetings.

However, the seven agencies that fund research on health effects of low-dose radiation did not use a collaborative mechanism to address overall research priorities, such as research needs that scientific advisory bodies have identified. The 2006 National Academies report to advise the U.S. government on the relationship between exposure to radiation and human health—which was funded in part by DOD, DOE, EPA and NRC—identified 12 areas of research needs. Many of these areas were related to uncertainties from the linear no-threshold model and, by extension, in the agencies' dose limits and guidance levels that are based in part on that model. In addition, as previously noted, the 2016 report of DOE's Biological and Environmental Research Advisory Committee also 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 recommended that, should DOE decide to continue research in this area, workshops be convened to formulate a specific research program. In addition, 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.³⁴

Until recently, DOE's Low Dose Radiation Research Program provided a stable source of funding for such research and according to DOE's website, DOE took a leading role in advocating for greater communication and coordination between the fields of radiation biology and epidemiology. As previously mentioned, 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's decisions to reduce funding the program in fiscal year 2012 and stop funding the program in fiscal year 2016 also reduced the role that DOE previously held as a leading source of federal funding for low-dose radiation research. DOE's reduced role has created a void in federal efforts to maintain a collaborative mechanism for low-dose radiation research, and no other agency has stepped forward to fill this void.

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.³⁵ Although collaborative mechanisms differ in complexity and scope, they all benefit from certain key features, such as leadership, which raise issues to consider when implementing these mechanisms. Such issues include:

- whether a lead agency or individual has been identified;
- if leadership is shared, whether the agencies have clearly defined roles and responsibilities; and
- how leadership will be sustained over the long-term.

For example, the Interagency Steering Committee on Radiation Standards includes a process for rotating the leadership role among member agencies.

DOE is well positioned to lead an effort to ensure that federal agencies have a mechanism for interagency collaboration to address overall

³⁴In technical comments on a draft of this report, OSHA stated that it could also benefit from the reduction in uncertainty that could be obtained by this research.

³⁵[GAO-12-1022](#).

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 a role is also consistent with DOE's research responsibility under the Atomic Energy Act of 1954. Such an effort could help DOE and the collaborating agencies determine roles and responsibilities, including leadership, when addressing shared research priorities.

Conclusions

DOE and other federal agencies have invested millions of dollars in low-dose radiation research, and this research has led to a better understanding of the health effects of radiation exposure, thereby helping federal agencies develop and implement radiation protection requirements and guidance for workers and the public. DOE has provided more than half of all federal funding for this research over the past several years. Given the reduction in funding for low-dose radiation research, federal agencies can benefit from greater collaboration on addressing their research priorities in this area. Our previous work has shown that collaborative mechanisms can be used for coordinating federal science efforts and that agencies can enhance their collaborative efforts through key practices, such as agreeing on leadership roles and responsibilities. In the past, DOE took a leading role in both funding and evaluating low-dose radiation research, and the agency continues to fund a substantial portion of the research. However, more recently DOE's funding has significantly decreased, resulting in a lack of leadership in this area. DOE, consistent with its past experience as a leader in this area of research and its research responsibility under the Atomic Energy Act of 1954, could assist agencies in developing an interagency collaborative mechanism for the future.

Recommendation for Executive Action

We recommend 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.

Agency Comments and Our Evaluation

We provided a draft of this report to the Department of Commerce; DHS; DOD; DOE; Department of Labor; EPA; HHS's CDC, FDA, and NIH; NASA; and NRC for review and comment. DOE, the Department of Labor, EPA, HHS, and NRC provided technical comments, which we incorporated as appropriate. DOE also provided written comments, which are reproduced in appendix II. The other agencies did not provide any comments.

DOE commented that in general, the draft report reflects how federal agencies, including DOE, developed and applied radiation protection requirements and guidance for workers and the public. DOE did not concur with our recommendation that it lead the development of a mechanism for interagency collaboration on research on the health effects of low-dose radiation. 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. Instead, according to DOE, from its experience, the leadership of an organization with government-wide responsibilities would result in the most effective 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. In particular, 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, such as research needs that the National Academies, in advising the U.S. government, identified regarding health effects of low-dose radiation. According to officials we spoke with from DOE's Office of Environment, Health, Safety and Security, more collaboration among agencies on low-dose radiation research would be very helpful.

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. If the leadership of an organization with government-wide responsibilities would result in more effective interagency collaboration, as DOE suggested in its written comments, then DOE could implement our recommendation by working

with such an organization to obtain its involvement in a coordination 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.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretary of Commerce, the Secretary of Defense, the Secretary of Energy, the Secretary of Health and Human Services, the Secretary of Homeland Security, the Secretary of Labor, the Administrator of EPA, the Administrator of NASA, the Chairman of NRC, and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact John Neumann at (202) 512-3841 or neumannj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

A handwritten signature in black ink, appearing to read "John Neumann", with a long horizontal line extending to the right.

John Neumann
Director, Natural Resources and Environment

Appendix I: Federal Agencies' Radiation Protection Measures for Workers and the Public

To prevent cancer and other harmful effects associated with exposure to radiation, federal agencies have established radiation protection measures that apply to a wide range of settings in which exposure can occur. These measures call for radiation exposure, for workers and for the public, to be kept within regulatory limits (either on dose or increased health risk) or, for emergency situations, non-binding guidance on exposure levels established for protecting individuals. Table 2 shows examples of federal agencies' dose limits, guidance levels, and other radiation protection measures.

Table 2: Examples of Federal Agencies' Radiation Protection Measures in Selected Ionizing-Radiation Exposure Settings

Radiation exposure setting	Radiation protection measure	Agency
Nuclear power plants	Public and occupational dose limits for operation	Nuclear Regulatory Commission (NRC)
	Limit on dose from a site's residual radioactivity to be acceptable for license termination and unrestricted use	NRC
	Public dose limit for planned discharges of radioactive materials	Environmental Protection Agency (EPA)
Cleanup of sites with radiological contamination	Risk limit for public exposure from Comprehensive Environmental Response, Compensation, and Liability Act sites	EPA
	Public and occupational dose limits for DOE sites	Department of Energy (DOE)
	Maximum contaminant levels for drinking water	EPA
Deliberate or accidental radiological incidents	Guidance level for sheltering-in-place or evacuation of the public during the early phase of an incident response ^a	EPA
	Guidance level for relocation (removal or continued exclusion) of the public during the intermediate phase of an incident response	EPA
	Guidance level for restricting use of contaminated drinking water during the intermediate phase of an incident response ^b	EPA
	Guidance levels of occupational exposure during an incident response, including separate limits for protection of critical infrastructure necessary for public welfare and for lifesaving or protection of large populations	EPA
	Guidance level for food interdiction to avoid or limit contamination in human food during the intermediate phase of an incident response	Food and Drug Administration (FDA)

Appendix I: Federal Agencies' Radiation Protection Measures for Workers and the Public

Radiation exposure setting	Radiation protection measure	Agency
Use of medical equipment that produces radiation	Requirement for certain equipment design and other features to reduce radiation exposure from diagnostic X-ray systems	FDA
	Recommended use of diagnostic reference levels to help avoid use of a radiation dose above what is necessary to meet the clinical need in medical-imaging procedures, such as computed tomography (CT) and fluoroscopy exams	FDA

Source: GAO analysis of agency requirements and guidance. | GAO-17-546

^aAccording to EPA guidance, both sheltering-in-place and evacuation may be implemented during the same response to a radiological incident.

^bEPA released and requested public comment on its draft drinking-water protective action guide in June 2016.

Appendix II: Comments from the Department of Energy



Department of Energy
Office of Science
Washington, DC 20585

September 12, 2017

Mr. John Neumann
Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street N.W.
Washington, DC 20548

Dear Mr. Neumann:

We appreciate the opportunity to comment on the draft Government Accountability Office (GAO) report: *LOW-DOSE RADIATION: Interagency Collaboration on Research Planning Could Improve Information on Health Effects*, GAO-17-546. In general, the draft report reflects how United States Federal Agencies, including the Department of Energy (DOE), developed and applied radiation protection requirements and guidance for workers and the public.

Recommendation 1.1: The Secretary of Energy lead the development of a mechanism for interagency collaboration to determine roles and responsibilities, leadership, and funding priorities related to research on the health effects of low-dose radiation.

DOE Response: DOE does not concur with the GAO recommendation.

DOE, the Environmental Protection Agency (EPA), and the Nuclear Regulatory Commission (NRC) all have legal mandates to research low-dose radiation exposure that include establishing generally applicable standards to protect human health and the environment from radioactive materials. DOE, EPA, and NRC establish their research priorities in accordance with their respective budget authorities and recommendations from their independent advisory boards. As a result, it would not be appropriate for DOE to lead the proposed effort. It has been DOE's experience that the most effective interagency collaborations resulted when agencies identified convergent priorities as a result of their individual activities or through a crosscutting effort led by an organization with governmentwide responsibilities.

Additional comments on the report are enclosed. If you have any questions, regarding this response, please contact Dr. Sharlene Weatherwax, Director, Office of Biological and Environmental Research, at (301) 903-3251.

Sincerely,

A handwritten signature in blue ink that reads "John S. Binkley".

John S. Binkley
Acting Director of Science

Enclosure



Printed with soy ink on recycled paper

Appendix III: GAO Contacts and Staff Acknowledgments

GAO Contact

John Neumann, (202) 512-3841 or neumannj@gao.gov.

Staff Acknowledgments

In addition to the individual above, Joseph Cook (Assistant Director), Allen Chan, Kendall Childers, Richard Frankel, Richard Johnson, David Messman, Cynthia Norris, Josie Ostrander, Todd Paulsen, Amber Sinclair, Sara Sullivan, and Jack Wang made key contributions to this report.

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