

**Testimony of Associate Director Sharlene Weatherwax
Office of Biological and Environmental Research
Office of Science
U.S. Department of Energy
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Mr. Chairmen, Ranking Members, and Members of the Subcommittees, thank you for the opportunity to appear before you today to discuss the Department of Energy's (DOE) Low Dose Radiation Research Program and the decision to end the program in FY 2016.

My name is Dr. Sharlene Weatherwax, and I am the Associate Director for Science in Biological and Environmental Research (BER), in the Department of Energy's Office of Science. My formal education and PhD are in biochemistry, and I have been with the Department for over 15 years, first in the office of Basic Energy Sciences and then in BER. The Low Dose Radiation Research Program is one portfolio element within BER's Biological Systems Science Division.

The Biological Systems Science Division supports a diverse portfolio of fundamental research and technology development to achieve a predictive systems-level understanding of complex biological systems to advance DOE missions in energy and the environment. By integrating genome science with advanced computational and experimental approaches, the Division seeks to gain a predictive understanding of living systems, from microbes and microbial communities to plants and other whole organisms. This foundational knowledge serves as the basis for the confident redesign of microbes and plants for sustainable biofuel production, improved carbon storage, and controlled biological transformation of materials such as nutrients and contaminants in the environment.

BER strategic science directions are guided by input from the research community, scientific workshops, the National Science and Technology Council, the National Academy of Sciences and the Office of Biological and Environmental Research Advisory Committee (BERAC). There is a very competitive environment for funding within BER, with exciting new scientific opportunities identified in workshop reports, DOE's Quadrennial Technology Report, and other sources. One reason for BER's competitive portfolio is the rapidly changing nature of BER science. BER has been instrumental in accelerating the development of DNA sequencing technology over the past 20+ years, culminating in the completion of the human genome sequence in 2003. This scientific and technological triumph of the human genome project, conducted in partnership with the National Institutes of Health, has sparked a revolution in biotechnology that continues to this day with a modest \$4 billion Federal investment yielding an enormous economic impact estimated (in 2011) at \$796B¹.

¹ http://www.battelle.org/docs/default-document-library/economic_impact_of_the_human_genome_project.pdf

Over the last 15 years, DOE has transformed its genome science toward DOE-mission relevant efforts in energy and the environment. The DOE Joint Genome Institute (JGI) is a direct descendent of sequencing projects initially funded to sequence the human genome. Building upon genome sequencing production at the JGI, providing the genetic “parts lists” for plants and microorganisms, BER’s genomic science program has been at the forefront of developing the fundamental knowledge needed to efficiently convert plant biomass into fuels and chemicals as replacements for those currently derived from petroleum. BER basic research is developing the scientific basis for producing the fuels and chemicals needed for a modern society from more sustainable, renewable biomass resources. For example, BER supports basic research to develop new bioenergy crops and improved biofuel production processes². This research is exemplified in the Bioenergy Research Centers (BRCs)³, started in 2007. The BRCs, now in their ninth year of operation, continue to produce the science needed to foster production of fuels and chemicals from renewable biomass by: 1) developing dedicated bioenergy crops across a range of plant species (ex. grasses, trees); 2) improving methods to breakdown biomass into its component parts (cellulose, hemicellulose, lignin); 3) genetically modifying microorganisms for efficient conversion of cellulosic sugars and/or lignin to fuels and chemicals; 4) developing the integrative knowledge needed to sustainably support a biofuels industry, and; 5) working with industry to translate basic science results to commercial practice. To date (Aug. 2016) the BRCs have produced 2314 peer-reviewed manuscripts that have been cited over 70,000 times and 1098 intellectual property disclosures, applications, or patents.

Additionally, BER science continues to be at the forefront of deciphering the underlying principles of genome expression in order to design new biological functions. With continued understanding of the genomic potential of plants and microbes comes the ability to manipulate and design new pathways into plants and microbes for beneficial purposes. Biosystem design concepts are at the heart of the ongoing biotechnology revolution and key to maintaining international leadership in a very competitive biotechnology field.

More recent integrative science within BER combines efforts across the portfolio to develop a deeper understanding of sustainable practices for bioenergy production. BER’s efforts in plant and microbial systems biology is being combined with environmental process understanding to develop new sustainability research approaches for bioenergy production. Better understanding of complex plant-soil-microbe interactions that drive sustainable bioenergy crop production will

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Lignocellulosic Biomass for Advanced Biofuels and Bioproducts workshop report:

[http://science.energy.gov/~media/ber/pdf/workshop%20reports/Lignocellulosic Biomass for Advanced Biofuels and Bioproducts.pdf](http://science.energy.gov/~media/ber/pdf/workshop%20reports/Lignocellulosic_Biomass_for_Advanced_Biofuels_and_Bioproducts.pdf)

³ 2014 Bioenergy Research Centers report available online:

<http://genomicscience.energy.gov/centers/BRCs2014HR.pdf>

enable reliable predictions of bioenergy crop yield under differing environmental conditions and/or geographic regions, important for sustaining a bioenergy industry.

In addition to these major efforts in bioenergy-related research, BER has also managed a basic research program in Low Dose Radiation Research since 1998. At that time there was ample evidence from atomic bomb survivor studies to clearly indicate a statistically significant linear response between observed human health effects (cancer) and radiation at relatively high doses but no statistically significant data available at the low doses (less than 100mSv) more commonly experienced by most people. The low dose program was developed to specifically address what if any effects low doses of radiation could have on human health below 100mSv⁴.

Over the past 18 years the program has provided new technological advances and fundamental scientific understanding of the mechanisms cells use to sense, repair and adapt to the impacts of low dose radiation. Research investigations have included a number of critical biological phenomena induced by low dose exposure including adaptive responses, bystander effects, genomic instability, and genetic susceptibility. The program has supported the development of systems genetic strategies, including the role of epigenetics in integrated gene function and response of biological systems to environmental conditions, with a goal of translating molecular-scale effects of low dose radiation to whole model organisms. The program outcomes and data are available to the community and other interested agencies through peer-reviewed scientific publications.

The program more recently has also supported epidemiological research such as the “Million Worker Study” being conducted by the National Council on Radiation Protection and Measurements. The health effects of low dose radiation are subtle and very difficult to experimentally discern. Very large sample sizes are needed to lend sufficient statistical power to the analysis of the experimental observations. This large epidemiological study is evaluating data collected and available from over a million radiation workers; funding is provided not only by DOE, but also by the Nuclear Regulatory Commission, Environmental Protection Agency, and National Aeronautics and Space Administration. Analysis of the results could provide the necessary statistical power to draw conclusions and make recommendations on the health effects of low dose radiation. This study focusing on analysis of former radiation workers and veterans complements research from the Division of Cancer Epidemiology and Genetics of the National Cancer Institute (NCI), one of the National Institutes of Health (NIH). The Division’s Radiation Epidemiology Branch specifically focuses on identifying, understanding, and quantifying the risk of cancer in populations exposed to medical, occupational, or environmental radiation, and to advance our understanding of radiation carcinogenesis. The total amount of funding that the

⁴Millisievert. The sievert is the SI unit for dose of ionizing radiation on the human body. The average person receives about 3.1 mSv per year from natural radiation. <http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/bio-effects-radiation.html>

DOE Office of Science has devoted to the Low Dose Research Program from its inception is over a quarter of a billion dollars.

The program was not intended to address regulatory policy but rather to advance the fundamental science of radiation impacts on biological processes. The Environmental Protection Agency and the Nuclear Regulatory Commission (NRC) bear the responsibility for establishing generally applicable and legally enforceable standards for the protection of human health and the environment from radioactive materials. EPA standards set protective limits on the radioactivity in soil, water and air that comes from human use of radioactive elements. The NRC licenses and regulates the Nation's civilian use of radioactive materials to protect public health and safety and promote the common defense and security. The NRC sets dose limits for both members of the public and workers in the nuclear industry.

Current radiation protection standards are based on the presumption that any exposure to radiation presents some risk of cancer to the exposed individual. That is, the relationship between cancer risk and radiation exposure is linear and there is no threshold level of radiation below which there is not some risk of cancer. Any changes to the current protection standards would require strong and compelling evidence that a higher amount of radiation is safe.

The "EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population" book describes EPA's methodology for estimating cancer risks from radiation exposure based on the National Research Council's 2006 report "Biological Effects of Ionizing Radiation (BEIR VII)," as well as on other updated science. The book calculates cancer risk estimates separately by age at exposure, sex and potentially affected organ. Its risk estimate methodology reflects the scientific consensus of the BEIR VII committee and presents the scientific basis for the estimates. The book takes into account recommendations made by EPA's Science Advisory Board (SAB), which completed its review in January 2010.

The SAB relied on advice from its Radiation Advisory Committee panel of non-EPA scientists chosen for their objectivity, integrity and expertise in radiation science and protection; additionally, the book has undergone an extensive peer review process, which included opportunities for the public and stakeholders to provide comment (<https://www.epa.gov/radiation/blue-book-epa-radiogenic-cancer-risk-models-and-projections-us-population#tab-1>). EPA risk assessment regarding other cancer-causing exposures also follows the linear no-threshold (LNT) methodology in the absence of mode-of-action and/or biological data to the contrary as a public-health-protective measure⁵.

⁵ https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

To date, there are no studies that have been able to establish with sufficient certainty a threshold level of radiation below which a risk of cancer is zero, despite decades of research in this area. In the absence of sufficient data to the contrary, the LNT model continues to be the accepted, albeit conservative, standard on which current radiation worker protection standards are based. Current National and International bodies (National Council on Radiation Protection and Measurements, NCRP; International Commission on Radiological Protection, (ICRP)) continue to recommend the use of the LNT.

The DOE Low Dose Radiation Research program is ending in FY 2016 with a substantial record of fundamental research that has been disseminated in the primary research literature. Despite the program's many research accomplishments, there are no definitive research results sufficient to revise the linear no-threshold model for cancer caused by low dose radiation exposure, and BER's Biological System science portfolio continues to shift more towards bioenergy, biodesign, and environmental microbiology missions. Funding levels for the Low Dose Radiation Research program have been steadily decreasing since 2012, with \$1M appropriated to complete the program in FY 2016.

In June 2015, the Secretary of Energy's Advisory Board (SEAB) was asked by the Secretary to provide a perspective on whether DOE should continue low dose radiation research. SEAB provided a response letter to the Secretary indicating that a small focused program should be maintained and asked that the Office of Science be charged with commissioning a small group of experts to propose a modest multi-year research program in low level radiation exposure. SEAB also acknowledged that "[DOE] should not assume that the results of such a research program would be conclusive⁶."

The Biological and Environmental Research Advisory Committee, our standing advisory committee in BER, was charged⁷ in October 2015 to follow-up on SEAB's response. The subcommittee of discipline experts will address the SEAB recommendations and issue a letter report in October 2016.

The Office of the Associate Under Secretary for Environment, Health, Safety and Security continues to conduct and support health studies and other research activities to determine if DOE workers and people living in communities near DOE sites are adversely affected by exposures to hazardous materials from DOE operations; by enabling appropriate responses to disease outbreaks and radiation accidents; and to address critical research needs for important occupational exposures. These efforts also include international health studies and activities providing new knowledge and information about the human response to ionizing radiation and other industrial exposures encountered in the workplace or within nearby communities; and as a result of nuclear weapons testing, use and accidents. These activities are mandated by Congress or required by international agreement and include studies of human health, environmental

⁶ <http://energy.gov/seab/downloads/letter-low-level-radiation-research>

⁷ http://science.energy.gov/~media/ber/berac/pdf/Reports/LD_Program_Charge_Letter.pdf

impacts, and provision of medical services in several countries including a long term study (since 1947) of Japanese atomic bomb survivors, believed to have the longest history of any ongoing international research program.

BER basic research programs continue to lead exciting and revolutionary changes in biological research for DOE and the Nation. Biology, as a science, is rapidly transforming to a more quantitative and predictive science thanks in large part to BER's pioneering efforts within the human genome project. BER continues to extend its genome science efforts to plants and microorganisms to develop the fundamental scientific understanding needed for solutions to energy challenges of the future.

Thank you for this opportunity to testify, and I look forward to answering any questions you may have.