

**TESTIMONY OF
Noelle F. Metting, Sc.D.**

**BEFORE THE
HOUSE COMMITTEE ON SCIENCE, SPACE AND TECHNOLOGY'S
ENERGY SUBCOMMITTEE & OVERSIGHT SUBCOMMITTEE**

**HEARING ON
Examining Misconduct and Intimidation of Scientists by Senior DOE Officials**

September 21, 2016

Good morning Mr. Chairmen, Ranking Members, and other Members of the Subcommittees on Energy and Oversight. Thank you for the opportunity to testify at this hearing.

I am a scientist, a Radiation Biologist, currently working for the Department of Energy Office of Environment, Health, Safety and Security within their Office of Public Radiation Protection (DOE/EHSS/AU-22). I am actually on detail from DOE's Office of Science, Office of Biological and Environmental Research (DOE/SC/BER), where, from the year 2001 until December of 2014, I had, among other duties, been tasked with managing DOE's Low Dose Radiation Research Program. For the previous 20 years, I had been a laboratory research scientist working at Pacific Northwest National Lab. I have a Master of Science from the University of Washington, and a Doctor of Science from Harvard University. In my remarks today I will share my personal experience of being fired by DOE, and suffering long months of unemployment, that occurred as a direct outcome of my participation in a briefing for Congressional Staff.

In a nutshell, the circumstances surrounding this intimidation and retaliation are these: Congressional staffers requested an overview of the Low Dose Program, so my immediate supervisor, Dr. Todd Anderson, asked me to prepare a PowerPoint presentation which was duly reviewed, amended, and finalized. In a pre-briefing meeting attended by myself and Drs. Anderson, Carruthers, and Huerta, it was decided that for the Congressional Staff briefing I would present my slides and handouts, and respond only to scientific questions, while Drs. Anderson and Carruthers would handle the budget and policy issues.

During the Congressional briefing the following day, Oct. 16, I presented the agreed upon material and answered accurately the many scientific questions directed to me by House Energy Subcommittee staff member and Council Mr. Aaron Weston and Senate Fellow, Dr. Ron Faibish. The staffers were very knowledgeable in the science, their questions thorough and comprehensive, showing real interest in the subjects. This deep knowledge was unexpected.

After the briefing ended and the Hill staff had left, Dr. Carruthers accused me of advocating and lobbying for the Program and of being too enthusiastic about the research results. I was shocked. During the briefing, I had answered all the questions based on my knowledge as a scientific subject-matter expert, with no intention of lobbying for the Program itself. My only motivation was to fully and truthfully inform Congress about the state of DOE's Low Dose Program research. Drs. Carruthers and Anderson repeatedly accused me of lobbying. Confronted with this unwarranted and unjustified onslaught, I reminded them that they already knew I disagreed with their plan to end support of this research field. I also mentioned my concerns as to how SC/BER management had handled a specific Congressional directive to designate an extra \$16 million to the FY2012 budget for Fukushima-related low dose research.

Thus began an unjust and painful saga of unrelenting intimidation. In just over one uncomfortable week after the briefing, Dr. Anderson removed me as Manager of the Low Dose Program and detailed me to unclassified duties. My management obviously did not want me answering any more questions about the Low Dose Program. A month later, on Dec. 4, 2014, a Notice of Proposed Removal was issued, charging me with "Insubordinate Defiance of Authority" and "Inappropriate Workplace Communication". I was put immediately on administrative leave and subsequently denied access to the contents of my former office. There followed a very long period of stressful activity at my home, alone during the usual work week, cut off from my peers, trying to build a defense to the charges and guided by my NTEU union representative.

In early January I filed a Disclosure and a Complaint with the Office of Special Council regarding the \$16 million dollar budget directive, also sending information to DOE's Inspector General.

Five months later, a final decision of Removal was issued by the Deciding Official, Dr. Steven Binkley, and effective May 16, 2015. On the next business day, Dr. Sharlene Weatherwax, Associate Director for BER, rolled a dumpster to my old office and thus began, or perhaps continued, the removal of the contents, including irreplaceable hardcopy notes, files and documents, and some of my personal possessions.

The Subcommittee may now appreciate that intimidation and retaliation in this case is self-evident.

It is revealing that after I appealed to the Merit Systems Protection Board, and just before the Appeal Hearing started, DOE reached a settlement with me. I am currently employed, but feel there is continuing intimidation. To this day I have not been granted the right to inspect the remaining materials from my old office or to retrieve missing personal possessions.

I suggest it is unacceptable that scientists are put under pressure to espouse views that are not their own, and that federal scientists are persecuted for presenting accurate information and professional opinion to those charged with providing funds for the research, Congress.

In my Written Testimony I have appended a detailed Time Line and a Statement of Facts and Issues prepared originally for my Appeal to the Merit Systems Protection Board. I also include narrative

from the Office of Special Council (OSC) Whistleblower Disclosure and the OSC Complaint of Possible Prohibited Personnel Practice forms that were filed in January of 2015, the decision letter from the OSC Disclosure Unit, and some background on DOE's Low Dose Radiation Research Program.

Thank you again for inviting me to share my experience.

Time Line -- Congressional Staff Briefing of 16 Oct 2014

2014

01 Oct 2014– Received email from Aaron Weston asking for overview and question period regarding Low Dose Program. Forwarded note immediately to my manager, Dr. Todd Anderson.

15 Oct 2014– Pre-briefing meeting, Germantown Building; Drs. Anderson, Julie Carruthers, and me in Todd's office with Dr. Marcos Huerta on telephone

16 Oct 2014 – Briefing in Forrestal Building with Hill staffers Aaron Weston and Ron Faibish

16 Oct 2014 – Post-briefing meeting with Todd, Julie, Marcos, and me

27 Oct 2014 – Todd's office for scheduled performance appraisal; I signed electronically on 29th

29 Oct 2014 –Detail to Other Duties within BER (memo dated October 29, 2014)

04 Dec 2014 – Notice of Proposed Removal (same day as Christmas party!)

04 Dec 2014 – Notice of Administrative Leave

December 2014 until May 2015 – Represented by NTEU for defense (Barry Clark)

2015

~30 January 2015 – **Sent forms to Office of Special Counsel (OSC)**; Disclosure Unit (form OSC-12, disclosure of possible wrongdoing in handling of designated \$16M) and Complaint Unit (form OSC-11, complaint of possible retaliation for disclosing suspicion of mishandling of \$16M at post-briefing)

13 May 2015 – Letter of Decision from Dr. Steve Binkley (Deciding Official), removal from position effective beginning May 16 (Saturday)

18 May 2015 – Sharlene was seen rolling dumpster down hall to my old office—filling dumpster..!
Email to Barry Clark to ask for help

20-21 May 2015 -- Barry sent strong email protesting the ransacking of office; seemed to have halted the activity

22 May 2015 – OSC Disclosures Unit informed me by letter that information provided on Form OSC-12 **is not sufficient** to determine with “substantial likelihood” that wrongdoing was committed.

May-June 2015 – Unexpectedly received some of my possessions from office; several boxes delivered to my home on different days

9 June 2015 – Retained the firm of Alan Lescht and Associates for appeal to Merit Systems Protection Board (**MSPB**)

12 June 2015 – Appeal filed with MSPB

6 Oct 2015 – Received first draft of settlement offer from DOE

Oct/Nov 2015 – No agreement was reached, my lawyer determined we should proceed to MSPB Hearing

12 Nov 2015– **MSPB Hearing** date. Just before the hearing started, settlement was reached, eventually signed, then approved by MSPB

14 Dec 2015 – **Reported to work** again, DOE Office of Environment, Health, Safety and Security, Forrestal Building

15 Dec 2015 – Called BER to ask about remaining office contents, was invited to come in and look for possessions. When I arrived, I was told that AD Dr. Weatherwax was on vacation and had left word that I could NOT look at office contents until she had spoken to me personally on her return. I passed by old office, and it was completely empty.

21 Dec 2015 – My new supervisor, Edward Regnier, Director of AU-22 informed me that Dr. Weatherwax said she would not allow me to see remaining office materials; did not want to speak with me or to visit her in Germantown Building – too disruptive.

MSPB Prehearing Statement – Narrative Summary

Taken from APPELLANT’S CORRECTED PREHEARING STATEMENT

Dated: November 4, 2015

UNITED STATES OF AMERICA
MERIT SYSTEMS PROTECTION BOARD
WASHINGTON REGIONAL OFFICE

NOELLE METTING, Appellant,
v.
DEPARTMENT OF ENERGY, Agency

I. STATEMENT OF FACTS AND ISSUES

A. Facts

Appellant was previously employed by the U.S. Department of Energy (the “Agency”) as a Senior Radiation Biologist, EJ-0401-04, with the Office of Science (“SC”). Appellant has been a radiation biologist since 1981, and she worked for the federal government for more than 13 years. Throughout her career, she has had no history of discipline or performance issues. As a federal employee, she always received at least fully successful ratings on her performance evaluations.

During her employment with the Agency, Appellant served as the Program Manager of the Low Dose Radiation Research Program (“LDRRP”). Her first-line supervisor was Dr. Todd Anderson, Director, Biological Systems Science Division, SC. On October 1, 2014, Appellant received an email from Aaron Weston, a Congressional staffer. Mr. Weston asked if Appellant would meet with him and Dr. Ron Faibish, Fellow, Senate Energy and National Resources Committee, to discuss the LDRRP. Pursuant to the Agency’s policies and procedures, Appellant did not reply directly to the email and forwarded it to Dr. Anderson.

Dr. Anderson sent it to his supervisor, Sharlene Weatherwax, and to the Agency’s Congressional Affairs Office. Dr. Anderson asked Appellant to develop a PowerPoint presentation to provide a high-level overview of the LDRRP to Mr. Weston and Dr. Faibish. Appellant sent her draft presentation to Dr. Anderson and Dr. Julie Carruthers for review and implemented all changes they requested.

On October 15, 2014, Appellant met with Dr. Anderson and Dr. Carruthers, and Dr. Marcos Huerta via teleconference, to prepare for the briefing. At that meeting, Dr. Anderson and Dr. Carruthers told Appellant that she would share handouts with the briefing participants, present her slides, and answer scientific questions. It was understood that Dr. Anderson and Dr. Carruthers would handle questions about the budget and policy.

Dr. Anderson, Dr. Carruthers, Dr. Huerta, and Appellant presented the briefing to Mr. Weston and Dr. Faibish the following day, October 16, 2014. Appellant handed out the approved materials and began presenting her slides. Almost immediately, Mr. Weston and Mr. Faibish began asking Appellant complicated questions about the effects of low dose radiation (e.g., adaptive response, radiation-induced

cancer, hormesis, low dose-rate epidemiology). They wanted to know what results were obtained from the research Congress funded.

Before Appellant answered questions, she looked pointedly at Dr. Anderson and Dr. Carruthers to give them an opportunity to interject, but they did not. As Dr. Anderson and Dr. Carruthers had instructed her on October 15, 2014, Appellant answered the questions about scientific and research-related issues, and deferred all questions about the budget to Dr. Anderson. On two occasions, Dr. Carruthers asked Appellant to continue with her slides, and she did.

However, the Congressional staffers continued to ask Appellant questions about the details of the research. When asked to elaborate about the adaptive response research, Appellant mentioned a newly published paper on research conducted in 2014, which she had recently received from Program Investigator Zhi-Min Yuan. One of the staffers asked Appellant to confirm that the research discussed in the paper was conducted in 2014; he sounded surprised that the LDRRP still had ongoing research. Appellant had a copy of the paper in her briefcase because she had been reading it earlier, and she gave the paper to Dr. Faibish. Mr. Weston also asked for a copy of the paper, and it was agreed that Appellant would send a copy to Mr. Weston via Janine Benner.

One of the staffers asked Appellant if she believed 100 mSv was a reasonable level to define as a “low dose.” Appellant truthfully responded that she believed 150 mSv might be more appropriate, but that the LDRRP defined “low dose” as 100 mSv. When questioned about animal research, Appellant answered that new results showed the critical need to study whole biological systems (the “systems biology” approach) in order to see subtle biological effects, such as radio-adaptive responses in normal tissues.

In response to a question about how the Million US Worker Epidemiological Study (the “Million Worker Study”) was relevant to the LDRRP, Appellant confirmed that the Million Worker Study was relevant to the very low radiation doses that had been experienced after the Fukushima nuclear accident in the wake of the recent Japanese earthquake and tsunami. Either Mr. Weston or Dr. Faibish asked Appellant about the progress of the Million Worker Study and when it would be completed. Appellant answered that the completion date was uncertain because the project was not fully funded.

The staffers discussed H.R. 5544 with Drs. Anderson and Carruthers. One of the staffers turned to Appellant and asked whether, in her scientific opinion, a National Academies report on low dose research would be appropriate at that time. Appellant said that, in her opinion, it would be appropriate.

After the briefing ended, Dr. Carruthers confronted Appellant and accused her of advocating for LDRRP and being too positive about the research results. Appellant was shocked and asked why no one had interrupted to redirect the conversation as they saw fit. The discussion became heated. Dr. Carruthers told Appellant had made a big mistake by communicating her enthusiasm for the LDRRP to Congressional staffers, and she and Dr. Anderson accused Appellant of lobbying and refusing to follow their instructions. Appellant felt attacked and cornered. She was clearly upset and said that she disagreed with the Agency’s plan to end the LDRRP, which Dr. Carruthers and Dr. Anderson already

knew. Appellant also questioned them about how SC management handled a specific Congressional directive to designate an extra \$16 million to the LDRRP budget for FY2012.

Appellant did not inappropriately communicate enthusiasm, lobby, or refuse to follow instructions. Rather, she truthfully answered the questions posed by Mr. Weston and Dr. Faibish because she felt obligated to provide honest answers to Congress. Based on Dr. Carruthers' and Dr. Anderson's criticism and accusations, it is clear that they expected Appellant to either misrepresent the LDRRP results or withhold information from Congress.

Appellant never refused to "subordinate herself to the SC management position" or said that she would "take every opportunity to undermine SC management decisions." She never did anything to oppose SC management for the remainder of her employment with the Agency.

On or about October (29) 2014, Dr. Anderson removed Appellant as Program Manager for LDRRP and detailed her to a position with unclassified duties. On December 4, 2014, Dr. Anderson issued a Notice of Proposed Removal (the "Proposal"), proposing to terminate Appellant for one charge of "Insubordinate Defiance of Authority" and one charge of "Inappropriate Workplace Communication."

Appellant, by her National Treasury Employees Union ("NTEU") representative Barry Clark, submitted a written response to Deciding Official Dr. Steven Binkley, Associate Director, Advanced Scientific Computing Research, SC, on or about December 17, 2014. Appellant, via Mr. Clark, provided an oral reply on February 3, 2015. In her written and oral replies, Appellant asserted that the Agency had proposed her removal in retaliation for her whistleblowing activity. Appellant alleged that the charges could not be sustained, that the penalty was unreasonably harsh pursuant to the factors set forth in *Douglas v. Veterans Administration*, 5 M.S.P.B. 313 (1981), and that she was being retaliated against for whistleblowing. Specifically, Appellant made protected disclosures when she refused to misrepresent and withhold information about the LDRRP from Congressional staffers during the briefing on October 16, 2014. Appellant alleged that she also made protected disclosures on October 16, 2014, when she questioned SC management's handling of a Congressional directive to increase funding for the LDRRP in FY2012.

On May 13, 2015, Dr. Binkley issued a Letter of Decision (the "Decision"), in which he stated that he had decided to sustain both charges and remove Appellant from the federal service effective May 16, 2015. Dr. Binkley incorrectly found that the preponderance of the evidence showed that Appellant had engaged in the alleged misconduct. He also failed to properly consider the Douglas factors and imposed an unreasonable penalty of removal. Appellant filed the instant appeal with the Board on June 12, 2015.

B. Issues

1. Whether the Agency proved by preponderant evidence that Appellant engaged in "Insubordinate Defiance of Authority" on October 16, 2014, as specifically stated in the Proposal;

2. Whether the Agency proved by preponderant evidence that Appellant engaged in “Inappropriate Workplace Communication” on October 16, 2014, as specifically stated in the Proposal;
3. Whether removal was a reasonable penalty for the charged misconduct; and
4. Whether Appellant’s removal was a product of retaliation for whistleblowing.

II. AFFIRMATIVE DEFENSE OF RETALIATION FOR WHISTLEBLOWING

...etc...not included here

Dated: November 4, 2015

NARRATIVE FROM THE OFFICE OF SPECIAL COUNCIL FORMS

After the briefing I voiced my doubts concerning a \$16 M funding decision made by SC/BER management in FY2012.

I believed I was fired because after the briefing Drs. Carruthers and Anderson confronted me, accusing me of lobbying. During the ensuing heated discussion, I revealed my discomfort with the handling of some extra funding that had been directed by Congress to be used for low dose research having relevance to the recent Fukushima nuclear disaster. The Notice of Proposed Removal refers to my remarks in rather exaggerated language: “...*You also disparaged BER management of the LDRRP and insulted BER Associate Director Dr. Sharlene Weatherwax....regarding the funding of the million man project....*”

Here I provide the following account of suspicions, taken from the disclosure of possible wrongdoing that I filed with the OSC (form OSC-12) late in January of 2015:

I believe and disclose that The Department of Energy’s Office of Science (SC) management, and particularly the Office of Biological and Environmental Research (BER) failed to follow the express direction of the 112th Congress as regards the use of funds specifically designated to be spent on Fukushima-related radiobiology research. As the long-time Program Manager for DOE’s Low Dose Radiation Research Program, funded within BER’s Radiological Sciences/Radiobiology Subprogram/Activity, I have direct personal knowledge of the events and records involved.

On March 11, 2011, a devastating earthquake and tsunami hit Japan, resulting in huge loss of life from the tsunami flooding, and a subsequent nuclear disaster at the Fukushima Daiichi power plant. In one of many efforts by the United States Government to respond to the public’s concern over the uncertainties of this ongoing health risk, legislation was initiated to fund new research relating to low dose human exposure to radiation. The budget for FY 2012 had been delayed in a continuing resolution, but was resolved in Conference between the House and the Senate. CONFERENCE REPORT 112-331 (Military Construction and Veterans Affairs and Related Agencies Appropriations Act, 2012) was the vehicle for making appropriations for most federal government operations for the remainder of FY2012. It includes the following paragraph on page 854 for DOE/SC/BER:

“Within available funds, \$16,000,000 is provided for radiobiology to help determine health risks from exposures to low levels of ionizing radiation to properly protect radiation workers and the general public, and to conduct studies of health impacts at and around the Fukushima Daiichi nuclear plant.” (Conference Report 112-331)

As Program Manager for the Radiobiology Activity in BER (the Low Dose Radiation Research Program), I was told there would be substantial additional funds available for new DOE research in this activity. In discussions with BER Associate Director Dr. Sharlene Weatherwax, she told me that she would not support actual research in Japan. I then suggested that we use the \$16M to support the major cost of a large US-based epidemiology study that had successfully proven itself as a pilot project: The Million U.S. Worker Study. The Study looks at the health of over a

million radiation workers from the beginning of the nuclear age (including ~365,000 former DOE workers) who had received very low doses in the range of those expected from Fukushima. Dr. Weatherwax approved this idea, the full project proposal was successfully reviewed, and the appropriate paperwork was obtained, including the official signature of Dr. William Brinkman, then our Director (SC-1) for Office of Science. This signature was necessary because the budget for the five-year project was over a \$10 M administrative limit, and thus needed the SC-1 approval. Coordination of the effort for approvals between Dr. Brinkman (SC-1), Dr. Dehmer (SC-2) and BER was handled by Dr. Julie Carruthers (working for SC-2) and Dr. Steven Binkley (then working directly for Dr. Brinkman). Ms. Joanne Corcoran within BER coordinated the research budget under direction of BER AD Dr. Weatherwax. Ms. Corcoran is still in BER and can verify this information. At the last possible moment, Dr. Weatherwax informed me that she had decided against committing to fund the Million US Worker Study for the entire period, due to budget concerns, and that DOE/BER had less than \$1 M to spend on the Study for that year. She implied that we would pick up the funding in the out years, but did not allow me to write the revised Selection Statement to say as much.

I maintained hope that the special funding would be carved out in the next fiscal year, as Dr. Weatherwax had implied. However, the outcome was that the specified \$16 M was never fully allocated for its intended purpose. I now believe it was wrongly redefined to cover the already-funded ongoing research projects of the Low Dose Program for FY2012. I finally realized this when I looked up the [FY 2013 Congressional Budget Request](#) from DOE (February 2012). The detailed budget justification for BER (page 143) stated in part:

“...Funding is completed in FY 2012 for studies of DNA damage and repair in response to low dose radiation of specific gene targets in single cell culture models and for studies informing the exposure risks at the Fukushima Daiichi nuclear plant....”

This statement is simply not the truth -- the critical study that was to better inform the scientific community and the public on the exposure risks at the Fukushima Daiichi nuclear plant had only just barely begun to be funded. The DOE/SC/BER management seems to have brazenly ignored the clear wishes of Congress (laid out in Conference Report 112-331), and then actually lied about completing the work in the FY 2013 Congressional Budget Request. Rather than accept that Congress might want to decide how best to spend our scarce research budget, they purposefully misinterpreted the words in Conference Report 112-331, in order to fund research of their own choosing.

I trust there is a rule against such conduct, and that it can be applied in this egregious instance of wrongdoing. It is very disillusioning to know that at least some of our federal management cannot be trusted to carry out the letter and the spirit of the expressed wishes of Congress.

Please note that it was very hard for me to believe at first that this incident really happened, but my resolve to report it became sufficiently strong when I realized that my knowledge of the incident was perceived to be a possible threat by my managers, such that I am now being unreasonably targeted for removal. I am concurrently submitting a form OSC-11 Complaint of

Possible Prohibited Personnel Activity, based on a previous informal disclosure to my management of the information now contained in this Whistleblower Disclosure.

(NOTE: The full text of Conference Report 112-331 is at <http://www.gpo.gov/fdsys/pkg/CRPT-112hrpt331/pdf/CRPT-112hrpt331.pdf>. The Conference Report pertained to H.R. 2055, the Consolidated Appropriations Act, 2012 (Enrolled Bill [Final as Passed Both House and Senate]); which became Public Law 112-74 on 12/23/2011. The full text of the FY 2013 Congressional Budget Request (Feb 2012) is at <http://energy.gov/cfo/reports/budget-justification-supporting-documents>.

The following is taken from the complaint of retaliation that I also filed with the OSC (form OSC-11) in January of 2015:

“On 12/04/2014 I was served with a Notice of Proposed Removal in connection with an event that warrants no such extreme action. I believe the proposed extreme action is retaliation due to a perceived threat to my management that I would submit a disclosure of wrongdoing, after I had privately told SC management of my suspicions about a possible misuse of funds in FY2012-FY2013.

At a post-briefing meeting on 10/16/2014 in the presence of my SC/BER Division Director Todd Anderson, Office of Science (SC), advisor for SC-2 (Patricia Dehmer) Julie Carruthers, and DOE special advisor for SC-1 (P Dehmer, Acting) Marcos Huerta, I voiced my concerns on how BER Associate Director Sharlene Weatherwax had managed funds meant to be spent on new research related to Fukushima in FY2012-13. As Program Manager for the program involved with this research, I knew that less than \$1M of the \$16 M designated by Congress was finally allocated by Dr. Weatherwax for the purpose. I told them that I suspected my management had not represented the matter truthfully in subsequent communications with higher management and with Congress. On 12/04/2014 I received a Notice of Proposed Removal in connection with the briefing itself that I believe is completely unwarranted. I believe the proposed firing is preemptive retaliation for my comments and their perception that I would submit a disclosure of wrongdoing. NOTE: I am submitting OSC-12 Disclosure of Wrongdoing concurrently with this retaliation disclosure.

I believe it is retaliation because the charges made in the Notice of Proposed Removal are gross exaggeration, misstatement, and deliberate misinterpretation of the events of, and surrounding, the briefing of Hill staffers that took place 10/16/2014. I am in the process of rebutting the outrageous allegations with the help of Union (NTEU) representation, but have filed no formal grievances concerning their allegations or acts of retaliation. Witness statements provided to me are not to be trusted, because with the possible exception of Dr. Huerta, the witnesses and their bosses are all implicated in the FY2012-13 wrongdoing. Other persons at the briefing did not provide, or were not asked to provide statements, only those who would naturally have an interest in the FY2012 wrongdoing.

As a final indication and evidence of retaliation, I frankly find it highly suspicious that Dr. Steven Binkley was chosen to be the Deciding Official for my Notice of Proposed Removal, as he is also implicated in my disclosure of wrongdoing, having been (I believe) the closest advisor of our then SC-1 in FY2012-13, Dr. William Brinkman. Dr. Binkley could easily have been a critical party in the funding decisions leading to the wrongdoing.

112TH CONGRESS }
1st Session

HOUSE OF REPRESENTATIVES

{ REPORT
112-331

MILITARY CONSTRUCTION AND VETERANS
AFFAIRS AND RELATED AGENCIES APPRO-
PRIATIONS ACT, 2012

CONFERENCE REPORT

TO ACCOMPANY

H.R. 2055



DECEMBER 15, 2011.—Ordered to be printed

In order to increase transparency and accountability across all Science activities, the Department is directed, not later than September 1, 2012, to create a performance ranking of all ongoing multi-year research projects across the six major Science research programs, including those at universities, national laboratories, Energy Frontier Research Centers, Energy Innovation Hubs and other recipients, by comparing current performance with original project goals. The report shall include an inventory of the number and dollar amount of awards that have been terminated in fiscal years 2011 and 2012 before their multi-year awards have concluded.

The conferees direct the Department to provide to the House and Senate Committees on Appropriations, not later than February 10, 2012, a budget scenario for fiscal years 2013 and 2014 with the Office of Science funded at the fiscal year 2012 level, highlighting funding levels for each major program and project, including activities, such as ITER, with scheduled changes in funding requirements.

Advanced Scientific Computing Research.—The conferees provide \$442,000,000 for Advanced Scientific Computing Research. The conferees support the exascale initiative, but note that future funding for the initiative is contingent upon delivery of the joint exascale plan, as directed. The conferees provide the budget request for the Leadership Computing Facilities and for High Performance Production Computing, in support of continuing petascale upgrades at the three facilities.

Basic Energy Sciences.—The conference agreement provides \$1,694,000,000 for Basic Energy Sciences. The conference agreement includes \$24,300,000 to continue the Fuels from Sunlight Energy Innovation Hub, and \$20,000,000 to establish the Batteries and Energy Storage Energy Innovation Hub. The conference agreement includes up to \$100,000,000 for the existing Energy Frontier Research Centers; \$10,000,000 for predictive modeling of internal combustion engines; \$8,520,000 for the Experimental Program to Stimulate Competitive Research; and no funding for gas hydrates research within the Office of Science.

The conference agreement includes \$97,000,000 to fund each major item of equipment at the level provided in the budget request. Funding provided for the Linac Coherent Light Source II at SLAC is for the exploration and design of the two-tunnel option.

Biological and Environmental Research.—The conference agreement provides \$611,823,000 for Biological and Environmental Research. Within available funds, the conference agreement includes \$12,000,000 to continue nuclear medicine research with human application. The conferees direct the Department to report to the House and Senate Committees on Appropriations, not later than June 1, 2012, on the Administration's strategy to continue funding this research through more appropriate federal agencies with health-focused missions.

Within available funds, \$16,000,000 is provided for radiobiology to help determine health risks from exposures to low levels of ionizing radiation to properly protect radiation workers and the general public, and to conduct studies of health impacts at and around the Fukushima Daiichi nuclear plant.

Department of Energy

FY 2013 Congressional Budget Request



Science

Advanced Research Projects Agency-Energy

**Biological and Environmental Research
Funding Profile by Subprogram and Activity**

(Dollars in Thousands)

	FY 2011 Current	FY 2012 Enacted	FY 2013 Request
Biological Systems Science			
Genomic Science			
Foundational Genomics Research	39,260	63,111	67,292
Genomics Analysis and Validation	10,000	10,000	10,000
Metabolic Synthesis and Conversion	39,912	19,462	19,462
Computational Biosciences	12,683	16,395	16,395
Bioenergy Research Centers	75,000	75,000	75,000
Total, Genomic Science	176,855	183,968	188,149
Radiological Sciences			
Radiochemistry and Imaging Instrumentation	17,540	19,410	17,540
Radiobiology	23,926	15,528	10,620
Total, Radiological Sciences	41,466	34,938	28,160
Ethical, Legal, and Societal Issues	1,000	0	0
Medical Applications	4,000	0	0
Biological Systems Facilities and Infrastructure			
Structural Biology Infrastructure	15,765	14,895	14,895
Joint Genome Institute	68,932	68,500	69,187
Total, Biological Systems Facilities and Infrastructure	84,697	83,395	84,082
SBIR/STTR	0	9,184	9,382
Total, Biological Systems Science	308,018	311,485	309,773
Climate and Environmental Sciences			
Atmospheric System Research	27,822	26,392	26,392
Environmental System Science			
Terrestrial Ecosystem Science	28,727	40,274	51,957
Terrestrial Carbon Sequestration Research	2,966	0	0
Subsurface Biogeochemical Research	48,838	27,380	27,380
Total, Environmental System Science	80,531	67,654	79,337

The approaches employed include genome sequencing, proteomics, metabolomics, structural biology, high-resolution imaging and characterization, and integration of information into predictive computational models of biological systems that can be tested and validated.

The subprogram supports operation of a scientific user facility, the DOE Joint Genome Institute (JGI), and use of

structural biology facilities through the development of instrumentation at DOE's national user facilities. Support is also provided for research at the interface of the biological and physical sciences, and in radiochemistry and instrumentation to develop new methods for real-time, high-resolution imaging of dynamic biological processes.

Explanation of Funding Changes

(Dollars in Thousands)

FY 2012 Enacted	FY 2013 Request	FY 2013 vs. FY 2012
183,968	188,149	+4,181

Genomic Science

Genomic Science research remains a priority activity, with Foundational Genomics Research increasing for the development of synthetic biology tools and biodesign technologies for plant and microbial systems relevant to bioenergy production, carbon and nutrient cycling, and environmental change. Targeted research in Metabolic Synthesis and Conversion on cellulosic ethanol and biohydrogen decreases, as the DOE Bioenergy Research Centers continue to conduct research on advanced renewable biofuels. Computational Biosciences continues to enable the Systems Biology Knowledgebase tools and integrative analysis of plant and microbial functional genomics experimental datasets.

34,938 28,160 -6,778

Radiological Sciences

Radionuclide imaging research for real-time visualization of dynamic biological processes in energy and environmentally-relevant contexts continues, while concluding training activities to transfer synthetic and instrumentation knowledge to the nuclear medicine research community. Research is specifically prioritized to enable mechanism-based models that incorporate both radiobiology and epidemiology, reducing activities in cell-to-cell communication, cell aging and senescence, and cell microenvironment. Funding for research informing the exposure outcomes of the Fukushima Daiichi nuclear reactor is completed in FY 2012.

83,395 84,082 +687

Biological Systems Facilities and Infrastructure

Funding continues to support large-scale, complex genome sequencing and analysis at the Joint Genome Institute, with increasing emphasis on understanding comparative or community-scale plant and microbial genomics. Support continues for the development of instrumentation at SC's synchrotron light sources, neutron sources, and next-generation user facilities for analyzing biological structure-function relationships.

9,184 9,382 +198

SBIR/STTR

SBIR/STTR funding levels are a set percent of overall research funding.

311,485 309,773 -1,712

Total, Biological Systems Science

Radiological Sciences

Overview

Radiological Sciences supports radionuclide synthesis and imaging research for real-time visualization of dynamic biological processes in energy and environmentally relevant contexts. The activity has significantly transitioned from its historical focus on nuclear medicine research and applications for health to focus on real-time, whole organism understanding of metabolic and signaling pathways in plants and nonmedical microbes. Radionuclide imaging continues to be a singular tool for studying living organisms in a manner that is quantitative, three dimensional, temporally dynamic, and non-perturbative of the natural biochemical processes. The

instrumentation research focuses on improved metabolic imaging in the living systems, including plants and microbial-communities, relevant to biofuels production and bioremediation of interest to DOE. The activity also supports fundamental research on integrated gene function and response of biological organisms to low dose radiation exposure, through systems genetics analysis in model systems and epidemiological studies. This activity contributes a scientific foundation for informed decisions regarding remediation of contaminated DOE sites and for determining acceptable levels of human health protection, for both cleanup workers and the public, in the most cost-effective manner.

Funding and Activity Schedule

Fiscal Year	Activity	Funding (\$000)
FY 2011 Current	Research supported the development and use of innovative radiotracer chemistry and complementary radionuclide imaging instrumentation technologies for quantitative <i>in vivo</i> measurement of radiotracer concentration and site-specific chemical reactions. Research was initiated to examine epidemiological models for low dose radiation exposure.	41,466
FY 2012 Enacted	Core research activities in radiotracer synthetic chemistry and complementary imaging instrumentation continues; additional activity includes nuclear medicine research with human application as directed by Congress (in the FY 2012 Energy and Water Development Appropriations conference report [H. Rpt. 112-331]), and a report will be prepared for a strategy to continue this research through more appropriate federal agencies with health-focused missions. Research is completed for integrated training in radiotracer synthetic methodology and <i>in vivo</i> imaging and detection relevant to nuclear medicine applications. Funds support a limited number of systems genetic studies of integrated gene function and response to the environment, drawing on prior studies of specific gene targets and individual cellular response and focusing only at the tissue or whole organism level. H. Rpt. 112-331 directs continuation of research to help determine health risks from exposures to low levels of ionizing radiation, as well as studies of health impacts at and around the Fukushima Daiichi nuclear plant.	34,938
FY 2013 Request	Funding continues for core research activities in radiotracer synthetic chemistry for real-time visualization of dynamic biological processes in the energy and environmentally-relevant contexts. Funding is completed in FY 2012 for studies of DNA damage and repair in response to low dose radiation of specific gene targets in single cell culture models and for studies informing the exposure risks at the Fukushima Daiichi nuclear plant. Research will be completed for the development of a limited number of systems genetic reference mouse populations. Priority research begins to address integration of mechanism-based models that incorporate both radiobiology and epidemiology.	28,160

(Dollars in Thousands)

	FY 2011 Current	FY 2012 Enacted	FY 2013 Request
Radiochemistry and Imaging Instrumentation	17,540	19,410	17,540
Radiobiology	23,926	15,528	10,620
Total, Radiological Sciences	41,466	34,938	28,160

Ethical, Legal, and Societal Issues

Overview

The activity addresses ethical, legal, and societal impacts for application of genomic research results in bioenergy, synthetic biology, and nanotechnology. Beginning in FY 2012, research related to the societal benefits and

implications of DOE mission areas will be addressed within relevant Genomic Science programmatic activities. Beginning in FY 2013, 5% of funding for synthetic biology and biodesign activities in Foundational Genomics Research will be directed toward this research.

Funding and Activity Schedule

Fiscal Year	Activity	Funding (\$000)
FY 2011 Current	Funds supported the completion of individual studies on the societal impacts of synthetic biology and bioenergy.	1,000
FY 2012-2013	Activity is completed.	0

Medical Applications

Overview

This activity supports the design, fabrication, integration, and testing of a 240+ microelectrode visual prosthesis device (the artificial retina). DOE's role in this effort was completed in FY 2011.

Funding and Activity Schedule

Fiscal Year	Activity	Funding (\$000)
FY 2011 Current	BER research on the development of the components of an artificial retina was completed in FY 2010. In FY 2011, research was completed on the 240+ electrode artificial retina device. Integration and final testing and refinement of the assembled device for readiness to transition to pre-clinical testing.	4,000
FY 2012-2013	Activity is completed.	0



U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505
202-254-3600

May 22, 2015

Dr. Noelle F. Metting
13033 Middlebrook Road
Germantown, MD 20874

Re: OSC File No. DI-15-1807

Dear Dr. Metting:

The U.S. Office of Special Counsel (OSC) has completed its review of the information you referred to the Disclosure Unit. You alleged violations of laws, rules, or regulations; gross mismanagement; and an abuse of authority by employees of the U.S. Department of Energy (DOE), Office of Science, Office of Biological Research (BER) in the District of Columbia.

OSC is authorized by law to determine whether a disclosure should be referred to the involved agency for investigation or review, and a report. OSC may refer allegations of violations of law, rule, or regulation; gross mismanagement; a gross waste of funds; an abuse of authority; or a substantial and specific danger to public health or safety. Disclosures referred for investigation and a report by the agency must include information sufficient for OSC to determine whether there is a substantial likelihood of wrongdoing. If a substantial likelihood determination cannot be made, OSC will determine whether there is sufficient information to exercise its discretion to refer the allegations. OSC does not have the authority to investigate disclosures and therefore, does not conduct its own investigations.

In determining whether there is a substantial likelihood that wrongdoing has occurred, OSC considers a number of factors, including the sufficiency and specificity of the information provided and whether the whistleblower has reliable knowledge of the information, such as first-hand knowledge or documentation. Information based on assumptions or speculation does not provide OSC with a sufficient basis to refer allegations to the head of an agency for investigation. Further, we do not have the authority to investigate disclosures, interview subjects or experts, or conduct audits of records through the disclosure process. Rather, our review of a disclosure is based solely on the information the whistleblower provides to OSC.

You alleged that BER improperly used funding appropriated by Congress for "radiobiology to help determine health risks from exposures to low levels of ionizing radiation to properly protect radiation workers and the general public, and to conduct studies of health impacts at and around the Fukushima Daiichi nuclear plant." Specifically, you stated that BER instead used the funds to fund an ongoing study of DNA damage and repair in response to low dose radiation. You also alleged that BER misrepresented their actions by stating that the designated funds would be used for "studies informing exposure risks at the Fukushima Daiichi nuclear plant."

Dr. Noelle F. Metting
Page 2

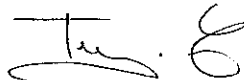
After review and consideration of the information you provided, we have determined that we are unable to refer your allegations to the Secretary of Energy for investigation. Based on the language of the appropriation, Congress granted the agency some amount of discretion with regard to what research to use the funding for. It appears that the ongoing research project on DNA damage in response to low dose radiation falls within the types of work permitted to be funded by the appropriation used because the study involves health impacts from exposure to low levels of radiation. Furthermore, it does not appear that BER misrepresented what the funding would be used for by stating that the research being conducted was "informing the exposure risks at the Fukushima Daiichi nuclear plant" because DNA damage is a potential exposure risk of low levels of ionizing radiation. Accordingly, the information you provided is not sufficient to determine with a substantial likelihood that BER employees engaged in an abuse of authority, gross mismanagement, or violated a law, rule, or regulation. Therefore, we will not take further action regarding these allegations.

Should you wish to pursue these matters further, outside of OSC, you may contact the DOE Office of Inspector General (OIG) as follows: *mail* – 1000 Independence Avenue, SW, Mail Stop 5D-031, Washington, DC 20585; *e-mail* – ighotline@hq.doe.gov; *phone* – (800) 541-1625. More information about DOE OIG can be found on their website at www.energy.gov/ig/office-inspector-general.

Finally, you alleged that BER officials have taken personnel actions against you in retaliation for disclosing the alleged wrongdoing described above. Whistleblower retaliation is an allegation of a prohibited personnel practice and is reviewed by OSC's Complaints Examining Unit (CEU). I understand that you filed a prohibited personnel practices complaint that is currently pending review with CEU examiner James Booker. *See* OSC File No. MA-15-1770. If you have any questions regarding your prohibited personnel practice complaint, please contact Mr. Booker at (202) 254-3675 or jbooker@osc.gov. Because the Disclosure Unit does not review allegations of prohibited personnel practices, we will take no further action regarding those allegations.

Based on the above, we have closed our file on this matter. If you have any questions or comments, please contact me at (202) 254-3678.

Sincerely,



Treyer Mason-Gale
Attorney, Disclosure Unit

KPG:TMG/sss

INFORMATION ON DOE LOW DOSE RADIATION RESEARCH PROGRAM

Briefly, two points should be made about DOE's Low Dose Program:

- **There was, and still is, a critical societal need to study the biological effects of low dose radiation exposure to humans**

What is low dose research? Who needs the research, and why? Here is a concise description of DOE's Low Dose Program that can be found on DOE's current Program webpage:

<http://science.energy.gov/ber/research/bssd/low-dose-radiation/>

Biological Systems Science Division (BSSD)

Radiobiology: Low Dose Radiation Research

The Low Dose Radiation Research Program supports competitive peer-reviewed research aimed at informing the development of future national radiation risk policy for the public and the workplace. The Program supports the Department of Energy's missions in energy and environment and contributes to understanding of radiation-related health impacts at and around the Fukushima Daiichi nuclear plant.

Program Description

The Low Dose Program is unique within the U.S. government in supporting experimental radiation biology research that studies the effects of very low dose exposures. Since its beginning in 1999, the focus of research has been to study cellular and molecular responses to doses of X- or gamma- radiation that are at or near current workplace exposure limits; in general, for total radiation doses that are less than 100 millisievert (10 rem). Currently about 40% of Program funds support research projects at academic institutions and the remaining 60% support program-project research at three DOE National Laboratories, LBNL, ORNL, and PNNL. An Investigators' Workshop is held yearly, and focused topical workshops are held as needed.

Program Funding Opportunity Announcements

Announcements are posted on the [DOE Office of Science Grants and Contracts Website](#) and at [grants.gov](#) Information about preparing and submitting applications, as well as the DOE Office of Science merit review process, is available at the [DOE Office of Science Grants and Contracts Website](#).

For current announcements visit [BER Funding Opportunities](#).

Currently funded research studies focus on radio-adaptive responses, systems genetics of inter-individual variation, low dose and/or low dose-rate effects on: a) proteomic responses, b) the immune system, c) epigenetic regulation, and d) molecular and cellular hallmarks of aging. Several of the experimental projects include important mathematical/risk modeling components. The Low Dose Program is also supporting, through intra- and inter-agency efforts, a mortality study of the early U.S. workers of the nuclear age. The "Million U.S. Worker Study" builds on the investments made and foundations laid by researchers and government agencies over the past

30-40 years. These efforts had established early worker cohorts that can now provide answers to questions on the lifetime human health risks associated with low-level radiation exposures.

Why the Program's Research is Important

The Program supports the Department of Energy's missions in energy and environment. It also contributes to understanding of radiation-related health impacts in and around a facility such as the Fukushima Daiichi nuclear plant. Program research is providing high-value scientific data for input in determining health risks from exposures to low levels of radiation. Performing measurements at low doses is critically relevant because radiation exposures associated with human activity are almost always very low dose and/or low dose-rate exposures. Human exposures are mainly from medical diagnostic tests, but exposures might also occur during waste cleanup, environmental isolation of materials associated with nuclear weapons and nuclear power production, catastrophic natural events, or possibly terrorism incidents. A strong scientific underpinning for our risk regulation is critical to adequately and appropriately protect people while making the most effective use of our national resources.

Data Sharing Policy

Low Dose Program investigators are expected to effectively communicate research results through publication in peer-reviewed journals, and when possible to provide data in a format amenable to deposition in widely held databases. Investigators are also encouraged to communicate with the wider community of concerned persons, so that current thinking and public debate incorporate sound science.

Program Accomplishments

Research from DOE's Low Dose Program re-examines existing paradigms and provides the results that support the development of new, biological paradigms. One example that challenges an old assumption is the finding that exposure to a low vs. high dose of radiation results in both qualitatively as well as quantitatively different cellular and molecular responses, thus demonstrating non-linear response with respect to dose. Another is the finding that in addition to high-dose biological damage that may lead to cancer, very low dose radiation exposure may participate in beneficial biological outcomes by stimulation of our natural tissue surveillance mechanisms. These processes are shaped by physical exposure parameters that include dose, dose-rate and dose-distribution. The research has underscored the importance of the Low Dose Program's effort to study intact-tissue biological response to a stressor such as radiation exposure, rather than studying only the initial events within an individual cell. Low Dose investigators were responsible in 2006 for initiation of a highly valued series of International Systems Radiation Biology workshops. Finally, the Low Dose Program has taken a leading role on the world stage in arguing for the critical need for greater communication and coordination between the fields of radiation biology and epidemiology.

As of March 2012, the Program has produced 737 peer-reviewed publications. Please visit the [Program website](#) for a list of publications and additional discussion of research findings and future directions.

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I note that in checking out the link now provided for the Program website (see above), only the internet archive site “*Wayback Machine*” is accessed.

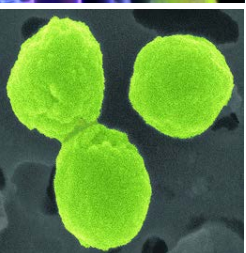
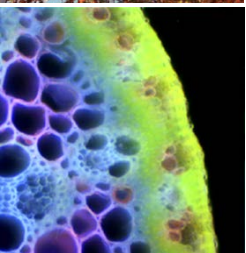
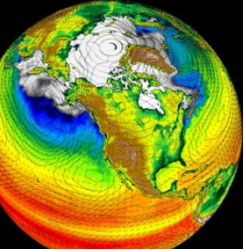
- **DOE’s Low Dose Radiation Research Program is widely recognized for successfully addressing critical research questions related to biological effects of low dose radiation exposure.**
 - a. **Formal reviews of the Low Dose Program:** The DOE/BER Advisory Committee (BERAC) “Committee of Visitors” (COV) reviews (<http://science.energy.gov/ber/berac/ber-cov/>) as well as other BERAC reviews, gave consistently excellent scores and comments to the Low Dose Program. COV reports for 2005, 2008, 2011, and 2014 include this Program. As an example, the 2014 COV report says in part:

*“**Low Dose Radiation.** The Low Dose Program currently focuses on the effects of low dose radiation from the molecular and cellular level to the organismic level with in vivo (murine and porcine) models of low dose radiation effects seen as a significant and unique strength of the program. The research investigates both the targets of transformation (epithelial cells) and the stroma that impact tumor growth. Program productivity has been high with over 700 peer-reviewed publications in its 15-year history. The relative contribution of the SFAs versus University-centered research was not determined by this COV.*

The Low Dose Program is unique in addressing issues central to potential health effects from environmental, occupational, and accidental as well as low-dose medical exposures to ionizing radiation that are a significant and continued concern of the US public. Past research has led to changes in how the risk of radiation and the mechanisms of radiation carcinogenesis are perceived. Most studies of radiation risk have focused on cancer incidence following relatively high doses to the survivors of the A-bombs in Japan in 1945, as well as other populations exposed to acute high doses of radiation. Much less is known about the risks at low doses of <0.1 Gy (10 cGy or 10 mSv), which are frequently encountered as the result of occupational, medical or environmental exposure. Thus, the acquisition of solid scientific evidence regarding the effects of low dose exposure is vital to guiding public policy including exposure limits and radiation remediation standards. Despite the vital importance of the information generated by this program the budget has been reduced from \$21.7M to \$6.2M in the time span covered by this review (2011-2013). The allocation has been evenly divided between National Lab SFAs and the remaining University research groups. Unfortunately, the absence of new low dose SFA solicitations in this review period will compromise the future of this important program.”
 - b. **As the premier low dose radiation research program in the world,** DOE’s Low Dose Program led the field and has become the model on which other countries based their low dose program research portfolios. As Program Manager, I had amassed years of correspondence and meeting notes recording the many interactions that I, the Chief Scientist

for the Program, and the Principle Investigators had undertaken for the purpose of coordinating with colleagues in the European Union, Japan, India, and China. (Unfortunately, as the contents of my office were discarded without my having an opportunity to inspect and save important records such as these, copies were not readily found.)

- c. **Through the years, both formal and informal letters praising** the quality and importance of the Low Dose Program have been sent to the Office of Science from upper management in the DOE Offices of Nuclear Energy (DOE/NE; Dr. Peter Lyons), Environmental Management (DOE/EM; Dr. Ines Triay), and Environment, Health, Safety and Security (DOE/EHSS; Mr. Andrew Wallo). Praise was also received by colleagues in several other federal agencies who managed radiation research portfolios that did not overlap into the low dose region. (Unfortunately, as the contents of my office were discarded without my having an opportunity to inspect and save important records such as these, copies were not readily found.)



DOE's Low Dose Radiation Research Program

Overview and Update

NF Metting, Sc.D., Program Manager

16 October 2014



U.S. DEPARTMENT OF
ENERGY

Office
of Science

Office of Biological
and Environmental Research



The Low Dose Radiation Research Program supports competitive peer-reviewed research aimed at informing the development of future national radiation risk policy for the public and the workplace.



DOE's Low Dose Program:

Is the only program within the U.S. government focusing on low dose biological research

- **DOE** focuses on worker and public safety from very low dose x- and gamma-ray exposures encountered in energy production and environmental cleanup

In contrast:

- **NASA** focuses on astronaut safety from high energy particulate radiation exposures encountered in space flight
- **NIH** (NCI, NIEHS, NIAID) mostly research focused on moderate to higher dose clinically-relevant exposures (200 rads and higher)
- **DOD/AFRRI** focuses research on higher dose exposures, relevant to preserving the health and performance of U.S. military personnel and protecting the public

Who is (or should be) interested in Low Dose Program research?



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- **Department of Energy**
 - Office of Nuclear Energy (**NE**; nuclear power sustainability)
 - Office of Environment, Health, Safety, and Security (**AU-20,10**; setting implementation standards for DOE workers and public)
 - Office of Environmental Management (**EM**; clean up levels; high cost)
 - National Nuclear Security Administration (**NNSA**; emergency response)
 - General Council (**GC-70**; NEPA documentation)
- **Environmental Protection Agency**
 - Setting of general regulatory standards
- **Nuclear Regulatory Commission**
 - Setting of regulatory standards for nuclear power industry
- **Departments of Labor; Transportation; NASA**
 - Worker safety
- **Department of Homeland Security**
 - Emergency response
- **Department of Defense**
 - Military action, emergency response
- **General public** (fear levels: Fukushima, Chernobyl, TMI, ...)



DOE's Low Dose Program:

Supports basic research to decrease the uncertainties and shrink the confidence intervals around the central estimate of risk

- DOE uses risk probability as a basis for radiation protection, but it is not used directly to define radiation protection standards
- Regulatory standards are generally defined as a function of dose, or the directly measurable quantities of exposure, activity, or concentration
- Regulatory levels are consistent with US-NRC and EPA, and with recommendations from NCRP, ICRP
- The risk uncertainty rises drastically in the low dose regime (where we regulate)

Regulation at the upper confidence limit of risk is the current policy decision



Outline

- **History:** *Research to develop a better scientific basis for understanding exposures and risks to humans*
- **Biology:** old assumptions, new paradigms
- **The Low Dose Program today**
- **Million U.S. Worker Study**



The Low Dose Program was initiated in 1999 with a workshop:

Bridging Radiation Policy and Science

An international meeting of experts

Airlie House Conference Center

1 – 5 December 1999

“The lowest dose at which a statistically significant radiation risk has been shown is ~ 100 mSv (10 rem) of x-rays.”

Other Programs are now supported:

- **MELODI** (**M**ultidisciplinary **E**uropean **L**ow **D**ose **I**nitiative)
 - DoReMi, OPERA, RadEpiBio
- **Japan**
- **Other** (China, Korea, India,...)



The Low Dose Program:

- **Provide mechanistic data for the development of a scientific basis for radiation standards in the low dose region**
- **Possible in 1999 because of**
 - **Extensive biological advances associated with**
 - sequencing of the genome
 - the development of gene expression arrays
 - the expansion of information on cell-cell and cell matrix communication
 - **Technologies such as single cell irradiators**
 - (The first research program to emphasize whole tissue responses using these advances)



Historic Animal Studies

- Historic mega-mouse and -dog studies were conducted from 1970s – '90s (49,000 mice, 17,000 beagle dogs)
- Historic (and newer) studies have shown
 - A pronounced dose-rate effect for cancer
 - Strong low dose “sparing” effect
 - Data and tissue archives
- Animal studies help determine if cellular and molecular observations influence disease outcome
- Animal data still provide a link between cell and molecular mechanisms and human epidemiological data for risk assessment.



In 1999, five research needs were identified:

- **Understanding biological responses to low dose radiation exposures**
- **Low dose radiation versus endogenous oxidative damage**
- **Thresholds for low dose radiation**
- **Genetic factors affecting individual susceptibility**
- **Communication of research results**

**The real challenge: to do research
at 10 rads or less**

Fourteen years later – 2014



U.S. DEPARTMENT OF
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Radiation physics (*energy deposition*) dictates a linear induction of initial events as a function of dose

Radiation biology shows us that the subsequent biological response is much more complex

DNA repair

Cell apoptotic death

Cell/tissue growth and replacement

Immune system surveillance

★ *Metabolic shift after low (but not high) dose exposure is protective — **very new...***



Fourteen years later – 2014

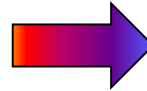
Program Research Results

- Biological systems detect and respond to very low doses of radiation
- Cells not directly exposed can show a biological response to the low dose radiation exposure of neighboring cells
- Cell-cell and cell-matrix communication are critical in the total response to radiation, resulting in whole tissue or organism responses as compared to individual cell responses
- Qualitatively different molecular-level responses result after low doses of radiation vs. high doses of radiation
- Many cellular and tissue-level responses demonstrate non-linear responses with respect to radiation dose
- In addition to radiation-induced DNA damage, other processes are induced by low dose radiation that participate in either increasing or deterring carcinogenesis

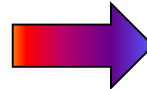
Fourteen years later – 2014

Old Assumptions

Qualitatively similar radiation effects occur at high and low dose exposures



All radiation effects contribute to the process of carcinogenesis



DNA damage is the only mechanism responsible for increasing cancer risk



These assumptions have been prevalent since World War II

New Paradigms

Qualitatively different processes are induced by high vs. low doses/dose-rates

Many radiation effects do not contribute to the process of carcinogenesis

In addition to DNA damage, cancer risk is highly dependent on the cell microenvironment

We now know much more about biology and radiobiology

The Low Dose Program in 2012 (1)



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- **12th year of Program**
- **Joint funding of research with NASA's Space Radiation Research Program**
 - Cellular and molecular responses in normal tissues
 - After high LET radiation exposures
 - At fluences approximating the space environment (high single-cell doses but low tissue doses)
- **Re-analysis of Radiobiology Tissue Archive data at Northwestern University**
 - The Woloschak laboratory hosts several radiobiology archives containing data and tissues from radiobiology very large (mouse, dog) studies conducted in the second half of the 20th century
- **Research to enable mechanism-based models that incorporate both radiobiology and epidemiology**

The Low Dose Program in 2012 (2)



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- **Currently funded projects:**
 - **University-based**
 - Three 5-yr Program Projects in 5th year
 - 21 radiobiology projects in 3rd (last) year or no-cost extensions—
 - 7 of these are joint NASA-DOE projects
 - **Million U.S. Worker Study**
 - **National Lab SFAs: LBNL, PNNL**
- **Communication links with the public; science to inform public debate**
 - Website
 - Workshops
 - Dose ranges charts
- **>700 peer-reviewed publications (www.lowdose.doe.gov)**
- **New public awareness:**
 - **Medical diagnostic doses (CT scans)**
 - **Fukushima – evacuation/relocation**

The Low Dose Program in 2014



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- **Currently funded projects:**
 - **University-based**
 - Two 5-yr Program Projects in no-cost extension
 - 9 radiobiology projects in last-year or no-cost extensions—
 - 3 of these are joint NASA-DOE projects
 - **Million U.S. Worker Study (DOE support ending; supplemented by NASA, NRC, and EPA interagency transfers; needs ~\$5 M/y, 4 yrs)**
 - **National Lab SFAs: LBNL, PNNL (less than \$ 1M/yr)**
- **Communication links with the public; science to inform public debate**
 - Website (no longer fully funded, but still accessed by public)
 - Workshops (last one in 2010) <http://lowdose.energy.gov/workshops.aspx>
 - Dose ranges charts (still requested; ~28,000 given out to date)

Program Coordination: Intra- and Inter-agency



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- **Coordination with DOE/HS:** DOE's Office of Health, Safety and Security—regular meetings with colleagues in HS-13 (Office of Domestic and International Health Studies) [now is AU-10, AU-20]
- **Coordination with NASA:** Joint support of research grants with NASA Space Radiation Health Program; regular meetings, reviews
- **Coordination with AFRRRI:** meetings, reviews
- **RABRAT** —quarterly meetings with agency colleagues interested in radiobiology and emergency response to radiological events (NCI, NIAID, AFRRRI, EPA, DOD, DHS, FDA, CDC, DOE)
- **ISCORS:** Interagency Steering Committee on Radiation Standards, regularly attend meetings as BER observer
- **Coordination with Europe:** MELODI and DoReMi; representatives attend each other's meetings; peer reviewers
- **Coordination with Japan:** representatives attend our Workshops, visit, peer review



Program Evolution /Planning

1999

- Endogenous oxidative damage
- DNA damage and repair
- Adaptive responses
- Bystander effects
- Genetic susceptibility
- Genomic instability
- Risk Communication

Current

- Endogenous oxidative damage
- DNA damage and repair
- Adaptive responses
- Bystander effects
- Genetic susceptibility
- Genomic instability
- **Epigenetics (2006)**
- **Aging endpoints/ homeostasis (2008)**
- **Tissue-emergent carcinogenesis**
- **Low dose epidemiology**
- Risk Communication (website, Dose Ranges chart)

2010+

- Adaptive responses
- Genetic susceptibility
- Epigenetics
- Tissue-emergent carcinogenesis*
- **U.S. workers epidemiology**
- Risk Communication (website, Dose Ranges chart)

* Includes endogenous oxidative damage, genomic instability, aging, homeostasis, and metabolic studies



Low Dose Epidemiology: The Million U.S. Worker Study

- **Discussed informally at the Workshop: Low Dose Epidemiology—What Can it Tell Us? *December 10-11, 2008***
- ***Considered in Office of Science call for ARRA (Recovery Act)***
- **Application via the 2010 Office of Science open call -- “Pilot Study of One Million American Workers and Veterans Exposed to Radiation” *funded in FY2010***
- **“Epidemiologic Study of One Million U.S. Radiation Workers and Veterans”; *funded in FY2012 along with interagency support from NRC, NASA, and EPA***
- **The Study populations** include early DOE and Manhattan Project workers, atomic veterans who participated in nuclear weapons testing in the 1940s and 1950s, nuclear utility workers, medical workers and others involved in the development of radiation technologies, as well as nuclear navy personnel.



The Million U.S. Worker Study - attributes

- **STUDY IS LARGE:** The study is 10 times larger than the study of Japanese Atomic Bomb Survivors. There are no other studies in the world which are as large, with good estimates of dose, with long term follow-up.
- **MANY HIGH-DOSE EXPOSED WORKERS:** There are more high-dose workers in this study than among the Japanese A-bomb survivors, but the workers received their dose gradually over time and not all at once.
- **UNCERTAINTIES WILL BE CONSIDERED:** The research is designed to address the issues of uncertainties in dose estimates during the study.
- **BUILDS ON HUGE PAST EXPENDITURE BY US GOVERNMENT:** The study builds upon a tremendous amount of research, over 50 years, and few components are *de novo*. The total cost paid so far is in the hundreds of millions of dollars.
- **INTER-AGENCY SUPPORT:** The Study is a national effort, with DOD, US-NRC, NCI, and DOE already contributing to the overall vision and funding support. NRC, NASA, and EPA are providing inter-agency funding to the DOE grant.
- **WILL CONSIDER BIOLOGICAL AND EPIDEMIOLOGICAL DATA:** Finally and importantly, the grantees intend to consider the latest radiation biology in applying biologically-sound models to help estimate risks in the low dose region.

BIOGRAPHY

Dr. Noelle F Metting is a Radiation Biologist, currently working for the Department of Energy Office of Environment, Health, Safety and Security within the Office of Public Radiation Protection (DOE/EHSS/AU-22). Formerly, she worked in DOE's Office of Science, Office of Biological and Environmental Research (DOE/SC/BER), where, from the year 2001 until December of 2014, she managed DOE's Low Dose Radiation Research Program. For the previous 20 years, she worked at Pacific Northwest National Laboratory as a laboratory research scientist. Dr. Metting earned a Master of Science in Radiological Sciences from the University of Washington, and a Doctor of Science in Cancer Biology from Harvard University, with a doctoral dissertation entitled *Studies of Radiation-Induced Mutagenesis and Cell Cycle Perturbation*.