United States Environmental Protection Agency

Radiation Protection Program

Perspective on Radiation Standards and Low Dose Research

Presented to NAS NRSB Committee on Developing a Long-Term Strategy for Low-Dose Radiation Research in the U.S.

Mike Boyd, U.S. Environmental Protection Agency

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A Note on this Presentation

Context

- As described by Dr. Holahan, ISCORS is a forum for information sharing among agencies involved in radiation regulation. As stated on the iscors.org website, its objectives are:
  - Facilitating consensus on acceptable levels of radiation risk;
  - Promoting consistent risk-assessment and risk-management approaches in setting and implementing standards for protection from ionizing radiation;
  - Promoting completeness and coherence of Federal standards for radiation protection;
  - Identifying interagency issues and coordinating their resolution.
- ISCORS has not met since the formation of this NAS committee, so we are not able to present an ISCORS view today.
- My presentation reflects generally available information and, in some cases, my personal views. It is informed by ongoing discussions within the federal government but does not necessarily represent an official position.

Basis for Regulating Radiation in the U.S.

What role does science play?

- Various U.S. laws authorize federal agencies to set standards to protect the public and workers from unnecessary exposure to ionizing radiation.
- Most U.S. regulations are informed by and are broadly consistent with the recommendations of the ICRP, NCRP and IAEA Basic Safety Standards. ICRP and NCRP recommendations are based on scientific consensus publications such as the NAS BEIR reports and UNSCEAR reports.
- Regulations do not automatically get updated when new scientific recommendations occur.
  - Most U.S. radiation protection regulations covering low dose and low dose rate exposures assume a linear dose response relationship, though the assumed risk per unit dose may match the age of the regulation (e.g., BEIR III, V, or VII).
- Nevertheless, state of the art science is the essential ingredient in improving radiation regulations.

What does it take to update a regulation?

Why science alone is not enough.

- Statutory authority – for example, some laws have anti-backsliding provisions against relaxing regulations
- Priority and urgency – an agency's regulatory agenda will reflect its current priorities
- Stakeholder support – the U.S. government's rulemaking process requires strong stakeholder participation and engagement (stakeholders can be anyone with an interest in the rule - the concerned public, industry, local and state government, and others)
- Interagency and public support – OMB will weigh the arguments for and against a proposed rule
- Analysis of a rule's benefits and its costs (metrics will vary but refers to more than just economic costs and benefits)
- A principal goal is to achieve Congress's intention to protect public health.

A Few Examples of High Priority Research

My personal views.

- New research should focus on both cancer and non-cancer endpoints including circulatory disease.
- New research efforts should be well-coordinated with other international research platforms to identify gaps and avoid unnecessary overlap. Examples of ongoing research platforms and coordinating organizations include, but are not limited to:
  - MELODI – Multidisciplinary European Low Dose Initiative
  - OECD/Nuclear Energy Agency High Level Group on Low Dose Research (HLG-LDR)
  - EPRI International Dose Effects Alliance (IDEA)
  - National research efforts such as in Canada, Japan and elsewhere (see presentations from the last Beebe Symposium)
- Refer to recent NCRP Report No. 186 for suggestions to integrate epidemiology with biology. Take note of the recommendations for developing biologically based dose response (BBDR) models informed by the adverse outcome pathway (AOP) approach.
- There should be a public communication component as part of a new U.S. research effort throughout its duration.

Mechanisms for Providing Input to DOE

Possible Role for Individual Agencies

- EPA, and presumably other ISCORS agencies, will welcome the opportunity to have input into the research objectives of the new low dose research initiative, noting that collaboration is called for in the legislation
- Agencies will have different priorities reflecting their individual mandates and challenges. Centralized science and policy leadership would be ideal, but that is not the role of ISCORS.