NIOSH Radiation Dose Reconstruction Program

Ten-year Program Review: Quality of Science – Phase I Report

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Purpose

- 2010: NIOSH initiates 10 Year Program Review of DR
  - Committed to highest quality of science in its programs
  - Recognizes the importance of program transparency and responsiveness to the needs and concerns of stakeholders
- The quality of science is identified as a critical program element for review
  - Many questions on exposure proxies in dose reconstruction (DR) → Focus on indirect exposure assessment (IEA) methods

Background

- NIOSH is charged with providing "reasonable" estimates of radiation doses to covered employees seeking compensation under EEOICPA
  - Reasonable estimates are well-based in science, timely, and fair
  - NIOSH Dose Reconstruction (DR)
- NIOSH evaluates the completeness and adequacy of individual monitoring data and provides remedies for information gaps (42 CFR 82, §82.15)
  - Indirect exposure assessment (IEA) methods are commonly used to fill data gaps

Review Scope and Conduct

- **Scope: Coworker and surrogate data use**
  - "surrogate data" is exposure information from facilities other than that employing the covered worker
  - "coworker" models use exposure data from similar workers (i.e., comparable exposure risks)
- **Two reviewers, working independently:**
  - One focusing on issues related to coworker models
  - One examining the use of surrogate data
- **Review: Internal, peer, and stakeholder (ongoing)**

Report Structure

- General program area on IEA
  - Scientific basis
  - Documentation quality
  - Peer and stakeholder review
- External radiation coworker analyses
  - Review of scientific method
  - K25 coworker model replication
- Public comment
- Summary of findings and recommendations
- Appendix on surrogate data

General Findings: Accomplishments

- Completed 24,000 dose reconstructions
- Several advancements in retrospective exposure assessment
- Gathered and organized a wealth of information on U.S. Atomic Weapons Workers
- Developed and “published” over 100 technical documents on dose reconstruction

General Findings: Authority

- Epi studies rarely benefit from complete exposure information
  - Like DR, Epi studies have often relied on exposure proxies
- Epi research provides a firm foundation for coworker models and other surrogate information in NIOSH DR
  - The use of information from coworkers is clearly authorized under the rule [42 CFR 82, §82.17(a)]
  - The use of surrogate data is an acceptable scientific approach provided that the data complement, but not supplant, information from preferred sources

General Findings: Documentation

- DR documents are a layered structure of policies, plans, procedures, implementation guides, technical information bulletins, and technical basis documents
- Systems available to standardize nomenclature, format, and uniquely identify documents; however, content varied markedly between documents
- All documents are internally reviewed prior to issuance but periodic or external reviews are not required
- Although touted as “living documents,” revision appears infrequent in most cases

General Findings: Methods

- DR uses a graded-approach that balances precision and accuracy (science) with fairness and efficiency (responsiveness)
  - Claimant-favorable bias is preferred
  - Claimant-favorability is implied but rarely quantified
- Better assessment of bias may greatly improve confidence in the program and reinforce assertions of claimant-favorability
  - Biases (in either dose direction) may play a large role in an individual's compensation decision

Specific Findings and Recommendations

- Emphasis on program improvements in areas of documentation, peer review, and validation of exposure assessment methods
  - Documentation (2)
  - Peer and stakeholder review (2)
  - Validation (7)

Documentation

- **Findings:**
  - Overall, the system provided documents that were clear, concise, and relevant to the points of use
  - Some errors and inconsistencies noted
    - Document quality varies by authorship
    - Control of cross-referenced or layered documents was lacking

Documentation—cont.

- **Findings:**
  - Revisions lacked timeliness and, in some instances, appeared unresponsive to concerns raised in previous reviews
    - Revisions slowed by the deliberate manner in which science issues are resolved between the ABRWH and DCAS
    - Revisions can trigger a re-evaluation of DRs regardless of the effect (if any) on dose estimates
      - Delay of minor revisions until more substantive changes are indicated
    - Many documents have not been evaluated since first issued

Documentation—cont.

- **Recommendations:**
  - Recognize interrelationships between documents and avoid transfers of technical inaccuracies
  - Include periodic reviews by subject matter experts to systematically and expeditiously uncover inconsistent and erroneous text
  - Avoid delays in correcting technical inaccuracies
    - Develop/improve methods to initiate, track, and finalize document revisions in a timely manner

Document Review

- **Findings:**
  - External reviews by scientific peers and stakeholders are not required
  - Documentation has benefitted greatly from ABRWH review, although many documents have not yet been reviewed
  - Information is inconsistently sought from stakeholders and only after initial publication
    - Avoidable inaccuracies are identified after publication
  - Weakly defined process for comment resolution

Document External review

- **Recommendations:**
  - Seek external peer review on science documents that have not been reviewed by the ABRWH
  - Expand reviews to systematically solicit input from peers and stakeholders on important scientific issues prior to publication
  - Conduct and record comment resolution in a manner that promotes continued solicitation and consideration of input from scientists, affected workers, and worker advocates

Methods

- **Finding:**
  - Dose estimates from independent modeling were comparable but, on average, < DCAS results
    - Model is reproducible
    - Supports claimant favorability
  - Some models lacked information on source data, assumptions, statistical methods, and limitations
  - Validation was inconsistent or absent from some models
    - Rigorous validation is especially important for "bounding" estimates that rely on models that may poorly describe outlying regions of dose distributions

Methods Improvement

- **Recommendations:**
  - Systematically assess the validity of estimates obtained from current models
    - Examine and quantify coverage, anomalies, and limitations in data selected for coworker analyses
    - Examine between- and within-worker variance components in current coworker models
    - Consider additional strata (exposure determinants) in current models
    - Use well-defined "gold-standards" for comparisons
    - Quantify the degree in which claimant-favorability is achieved (i.e., estimate the bias)

Stakeholder Issues

- Dose reconstruction is a lengthy and complicated process
  - In the absence of information on true dose, judgments were made that potentially bias decisions in a claimant-adverse manner
- Commenters were wary of differences in facilities and jobs that may be inadequately addressed in current models using coworker or surrogate data