## DEEOIC - Medical Health Science Unit

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### Lesson Objectives

- Describe professional expertise within Medical Health Science Unit
- Provide insights into the work of the DEEOIC Health Physicists and Toxicologists



## DEEOIC Professional Experts

- <u>Health Physicist</u> evaluates occupational radiation exposure and application of the dose reconstruction methodology
- <u>Industrial Hygienist</u> assesses extent, nature and duration of chemical or biological exposure in an occupational setting
- <u>Toxicologist</u> analyzes data and literature relating to the relationship between toxic substance exposure and disease
- <u>Registered Nurse</u> provides medical input on the establishment of medical necessity for requested ancillary medical benefits such as home health care and durable medical equipment

# Role and Function of Medical Health Science Experts

- Evaluation of case-specific referrals to offer expert written advice to claims staff responsible for decision making
  - Provide professional input a case adjudicator can "weigh" in comparison to other available case evidence
  - Help direct the course of development
  - Respond to claimant questions or input
  - MHSU experts <u>DO NOT</u> decide the outcome of claims
- Research and analysis of relevant subject matter to support development of program policies and procedure

### Health Physicists

- Professional experts in evaluating occupational radiation data in application to DEEOIC claim adjudication process
- Evaluate case-specific referrals to provide consultative advice
  - Reworks of dose reconstructions (DR)
  - Final Adjudication Branch (FAB) technical reviews of DR objections
  - Technical evaluations for reopening requests from Policy units
  - Part E health physics evaluations, including dose estimates for non-cancer diagnoses
- Facilitate engagement with National Institute for Occupational Safety and Health (NIOSH)
  - Special Exposure Cohort (SEC) class designation
  - Program Evaluation Report
  - Program Evaluation Plan
  - Case adjudication assistance

### Industrial Hygienists

- Professional experts in assessing the extent and duration of occupational exposure to toxic substances including biological or chemical materials
- Evaluate case-specific situations to characterize exposure to toxic substances in the absence of specific employer-generated monitoring data
  - DEEOIC uses the services of both federal and contractor Industrial Hygienists to profile employee toxic substance exposures
- Industrial hygiene reports are exposure assessments, which describe claimant's exposures at DOE sites in terms of significance. Reports are intended to be as claimant favorable as possible.
  - Significant exposures are described in terms of low, moderate or high and assigned frequencies such as daily, weekly, biweekly, or monthly
  - Incidental exposures refer to exposures that occur in passing only

### **Toxicologists**

- Professional experts in evaluating epidemiological and other scientific data to determine if sufficient scientific basis exists to establish that exposure to a toxin can be found to cause disease
- Conduct research and review published scientific journal articles to determine their applicability to the administration of the DEEOIC
  - Provide analysis and opinion on the establishment of health effects due to occupational exposure
  - Provide analysis and opinion regarding causative thresholds such as latency, routes of exposure, and permissible/acceptable levels of exposure to toxic substances with known health effects
  - Determine if individual claim evidence should be applied broadly as programmatic guidance
- Review case-specific issues when the claimant submits scientific health effect documentation that is not validated by available program resources (e.g., SEM)

### Registered Nurses

- Professional expert in the field of skilled nursing including those functions relating to the provision of medically necessary services and equipment needed to manage disease
- Apply knowledge and experience in evaluating medical records to provide Medical Benefit Adjudicators interpretive advice regarding requested ancillary medical benefits
  - Diagnostic test findings
  - Medical terminology
  - Plan of care/letter of medical necessity
  - In-home health care, assisted living, and hospice

- Auto/home modification
- Ancillary medical services
- Durable medical equipment (DME)
- Medical billing and treatment modalities

## DEEOIC – Health Physics and Toxicology Staffing and Organization

- Medical Health Science Unit (MHSU) employs
  - Two full time health physicists
  - One full time PhD Health Scientist (Toxicologist/Epidemiologist)
  - Available contractor Toxicologists
- Organization
  - Members of the National Office Branch of Policy, Regulations & Procedures
  - Health Physicists and Toxicologist report to the MHSU Supervisor

# Health Physics – Important Information about Assessing Radiation

- Radiation dose reconstructions apply generous estimates of the amount of radiation encountered by an employee
  - Method used to promote positive outcome
  - Speeds the completion of the dose reconstruction process
- Threshold for compensability is a calculation that occupational radiation was probably 50% or greater reason for diagnosed cancer
- Probability of Causation (POC) calculated at the 99<sup>th</sup> percentile confidence limit – considered very reliable
- DEEOIC Health Physicists work to ensure the dose reconstruction and probability calculation occur in a consistent manner based on legal and procedural requirements

## Health Physics Dose Reconstruction Reworks

- Reworks evaluate the significance of new or changing factual information that may alter the outcome of a prior dose reconstruction or probability of causation calculation
  - Cancer diagnosis
  - ICD-10 coding
  - Diagnosis date
  - Employment issues facility/work duration
- A validated need for change to a prior dose reconstruction requires a rework
  - Returned to NIOSH to redo the dose reconstruction based on new or corrected information – may not result in a higher probability of cancer being work related

### Health Physics <u>Technical Reviews</u>

- Health Physicist Technical Reviews
  - Evaluation of objections and technical arguments involving science of dose reconstruction and estimating the probability that radiation caused a cancer
  - Originate during case adjudication
    - Objections filed in response to decision making
    - Evaluation of data to justify a reopening of previously denied claims
  - Factors or scientific data that a claimant argues changes an estimate of assigned radiation dose or involves an improper calculation of Probability of Causation
- DEEOIC including its Health Physicists cannot legally address arguments about the methodology applied during dose reconstruction process or the standard for calculating Probability of Causation

#### Suggestions from the Health Physics Team

- Respond to development about the extent and duration of occupational radiation exposure including participation in a computer assisted telephone interview (CATI) conducted by NIOSH
- See staff Procedure Manual Chapter 17: Development for Radiogenic Cancer Claims
- Verify the accuracy of factual information communicated in a DEEOIC decision involving occupational radiation assessment
- Report any new information or needed corrections:
  - All primary diagnosed cancers identified
  - Proper cancer diagnosis

- Accurate cancer date of diagnosis
- Verified period of employment is complete

#### Toxicology – Basic Concepts

- Study of the adverse effects of chemical agents on biologic systems
- Toxicologists are concerned with exposure to chemical agents as a cause of both acute and chronic illness
- Occupational Toxicology:
  - Application of the principles and methodology of toxicology toward chemical and biological hazards encountered at work
  - Draws information from the disciplines of occupational medicine, industrial hygiene, regulatory toxicology, and epidemiology
- Epidemiology:
  - Study of the distribution (person, place and time) and determinants of disease/dysfunction in human populations
  - Epidemiologists study the occurrence of disease or other health-related condition in human populations
  - Designs and conducts studies of human populations to determine whether an increased risk of disease can be attributed to an identified exposure.

#### **DEEOIC - Toxicology Reviews**

- Performs evaluation of medical health science literature to determine existence of humanistic "health effects"
  - Health effect is the relationship between exposure to a toxic substance and disease
  - Exposure is a cause if by modification of the exposure the rate of disease is altered
  - Establishment of a health effect is a determination of the "weight of scientific evidence"
- Written opinion represents an "interpretation" of the weight of scientific evidence based on the Toxicologist's professional training and judgement
  - Alternative viewpoints may exist and can be submitted for consideration
  - DEEOIC Advisory Board has made recommendations for new health effects

#### Toxicology – Weighing Scientific Evidence

- Weighing scientific evidence to establish a humanistic health effect requires considering many variables. Epidemiological principles that determine scientific weight:
  - Strength of the Association statistical calculation (point estimate) between two groups. The higher the calculation the relationship between exposure and disease may be real
  - Consistency of Results different studies and in different populations produce same outcomes
  - Temporal Sequence exposure comes before disease
  - Dose Response Relationship relationship showing a change in exposure has a corresponding increase or decrease in disease.
  - Biological Plausibility causal association fits previously existing biological or medical knowledge
  - Epidemiologic Results Supported by Experimental Evidence deliberate application or withholding of supposed cause to observe effect. This is uncommon in humans because of ethics

#### **Toxicology Guidance**

• The Site Exposure Matrix reports humanistic health effect data accepted by DEEOIC Show DOE sites Show uranium mines Show uranium miles Show Ore-buying stations Show uranium transfer to the site of the site of



- Establishing human health effects requires many studies, consistent results and reliable data to assign scientific weight
- Correlation studies report statistically interesting data but do not weigh the significance of identified associative findings. An increase in disease in a specific worker population does not mean a shared exposure to a specific toxin is a definitive causal factor

## Submitting Health Effect Data for Consideration

Use the SEM Portal for submitting disease-related information

#### www.sem.dol.gov

- For case specific submissions provide the complete copy of the medical health science literature that supports a contention that exposure to a toxin causes a claimed, diagnosed disease
- Ensure the medical health science literature speaks to the disease in question and relates to toxins for which exposure at an atomic weapon site potentially occurred
- Medical opinions of aggravation or contribution are dependent solely on the interpretation of the available medical health science evidence by the physician making such an opinion.
- Review Chapter 15 of the DEEOIC Procedure Manual for more information on the Toxicology review process.

#### Questions



Questions can also be submitted to <a href="mailto:DEEOIC-Outreach@dol.gov">DEEOIC-Outreach@dol.gov</a>

Thank you very much for attending the DEEOIC Webinar