HISTORICAL PERSPECTIVE

• RAMAZZINI WROTE IN *DE MORBIS ARTIFICUM*, 1713:
  • "We must not underestimate the maladies that attack stone-cutters, sculptors, quarrymen, and other such workers……
  • "He was told by a master stonecutter that when he was chiseling stone a dust arose, so fine that it penetrated the ox-bladders hanging in the workshop; in fact in the course of one year he found that a handful of this dust had accumulated inside a bladder...."
UNITED STATES: 2013

OCCUPATIONAL EXPOSURE TO RESPIRABLE CRYSTALLINE SILICA

• OSHA'S PROPOSED RULE:

MEDICAL SURVEILLANCE

(SECTIONS 1910.1053 (H) AND 1926.1053 (H))

MEDICAL SURVEILLANCE

• PURPOSE:
• TO DETECT DISEASE AS EARLY AS POSSIBLE, IN ORDER
• TO FACILITATE SECONDARY PREVENTION.
• IT ALSO
• IMPROVES PRIMARY PREVENTION.
SILICA-RELATED LUNG DISEASE

- SILICOSIS
- BRONCHITIS
- COPD
- PLEURAL FIBROSIS
- SILICOPROTEINOSIS
- LUNG CANCER
- PULMONARY TUBERCULOSIS
- CONNECTIVE TISSUE DISORDERS

THE PROPOSED RULE: MEDICAL SURVEILLANCE

PROVISIONS:
- CONTENT
- PERIODICITY
- MEDICAL MONITORING TRIGGER
- SHARING OF MEDICAL/WORK RESTRICTION INFORMATION BY THE PLHCP

MEDICAL SURVEILLANCE: CONTENT

MEDICAL QUESTIONNAIRE

OSHA:

"A medical and work history, with emphasis on:
Past, present, and anticipated exposure to RCS, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and symptoms of respiratory disease; history of TBC; and smoking status and history."
MEDICAL SURVEILLANCE: CONTENT

MEDICAL QUESTIONNAIRE

• COLLEGIUM RAMAZZINI:
• A STANDARDIZED MEDICAL AND EXPOSURE/WORK HISTORY ATTACHED AS APPENDIX.
• CR RATIONALE:
• TO ENSURE COMPREHENSIVE MEDICAL AND WORK HISTORIES;
• TO STANDARDIZE SURVEILLANCE ACROSS WORK SITES.

PULMONARY FUNCTION TESTING

• OSHA:
  • SPIROMETRY PERFORMED BY A NIOSH-CERTIFIED SPIROMETRY TECHNICIAN

• COLLEGIUM RAMAZZINI:
  • SPECIFY THE USE OF STANDARDIZED EQUIPMENT COMPLIANT WITH ATS/ERS CRITERIA;
  • SPECIFY THE USE OF NHANES III REFERENCE STANDARDS FOR TEST INTERPRETATION;
  • REQUIRE COMPARISON OF CURRENT TEST RESULTS WITH PREVIOUS TEST RESULTS TO ASSESS CHANGE OVER TIME.
PULMONARY FUNCTION TESTING

• COLLEGIUM RAMAZZINI:
• CR RATIONALE:
  • SILICA-RELATED NMRD SIGNIFICANT CAUSE OF DEATH;
  • STANDARDIZATION OF METHODS AND EQUIPMENT ENSURES QUALITY + RELIABILITY OF DATA;
  • RELIABILITY & COMPARABILITY OF PFT INTERPRETATION DEPENDS ON CHOICE AND CONSISTENCY OF REFERENCE STANDARDS.
  • EXCESS LOSS OF LUNG FUNCTION MAY OCCUR IN ABSENCE OF "ABNORMAL" TEST RESULT.

CHEST RADIOGRAPH

• OSHA:
  • CHEST X-RAY CLASSIFIED ACCORDING TO THE ILO SYSTEM OF CLASSIFICATION AND INTERPRETED BY A NIOSH-B READER; OR
  • "AN EQUIVALENT DIAGNOSTIC STUDY."
  • QUERY: EQUIVALENCY OF CHEST CT OR HRCT SCAN?

• COLLEGIUM RAMAZZINI:
• CONSIDERATIONS:
  • PURPOSE
  • RADIATION EXPOSURE
  • ACCESSIBILITY
  • INTERPRETATION
  • UNEXPECTED CONSEQUENCES
  • COST
### MEDICAL SURVEILLANCE: CONTENT

#### CHEST RADIOGRAPH
- **COLLEGIUM RAMAZZINI:**
- Presently Chest CT and HRCT are **not** “equivalent diagnostic studies” for medical surveillance for NMRD pursuant to the standard.
- The digital chest radiograph is an “equivalent diagnostic study.”

#### OTHER TESTS

**OSHA:**
- Provision for “any other tests deemed appropriate by the PLHCP.”
- Silent on medical surveillance for lung cancer.

**COLLEGIUM RAMAZZINI:**
- Low dose chest CT scan (LDCT) to screen for lung cancer
- **Appropriate for the following employees:**
  - > 20 years occupational exposure;
  - Exposure-related NMRD (silicosis, COPD);
  - H/O cigarette smoking.
MEDICAL SURVEILLANCE: CONTENT

• OTHER TESTS: LDCT
• CR RATIONALE:
  • SILICA IS A RECOGNIZED LUNG CARCINOGEN;
  • DURATION OF OE TO SILICA DIRECTLY RELATED TO LUNG CANCER RISK;
  • SILICOSIS/COPD ARE INDEPENDENT RISK FACTORS;
  • INTERACTIVE EFFECT: SILICA + CIGARETTES > ADDITIVE.

MEDICAL SURVEILLANCE: PERIODICITY

INITIAL MEDICAL EXAMINATION

• OSHA:
  • SHALL BE MADE AVAILABLE WITHIN 30 DAYS OF ASSIGNMENT TO SILICA-EXPOSURE AREA UNLESS COMPARABLE EXAM PERFORMED ≤ 3 YEARS PRIOR.
• COLLEGIUM RAMAZZINI:
  • PROVIDES INADEQUATE BASELINE;
  • 3 YEAR WINDOW TOO LONG: MEDICAL HX AND PFTS CAN CHANGE SIGNIFICANTLY.

FOLLOW-UP MEDICAL EXAMINATIONS

• OSHA:
  • HISTORY, PE, CXR, PFTS, PPD Q 3 YRS
  • UNLESS RECOMMENDED OTHERWISE BY PLHCP.
• COLLEGIUM RAMAZZINI:
  • MEDICAL/EXPOSURE HX AND PFTS: ANNUALLY
  • CXR/PE: Q 3 YRS UNLESS NEW ONSET RESPIRATORY SX AND/OR SIGNIFICANT CHANGE IN FEV1.
MEDICAL SURVEILLANCE: PERIODICITY

FOLLOW-UP MEDICAL EXAMINATIONS
• CR RATIONALE FOR ANNUAL EXAMS:
  • RESPIRATORY SX MAY BE EARLY SIGNS OF SILICA-RELATED LUNG DISEASE, AS IS
  • DECLINING FEV1.
  • JOB-AND TASK-SPECIFIC CHANGES IN SILICA EXPOSURE MAY BE FORGOTTEN AFTER 3 YRS.

MEDICAL MONITORING: TRIGGER

• OSHA:
  • MEDICAL SURVEILLANCE TRIGGERED BY OE TO SILICA > PROPOSED PEL OF 50 µgm/m3
  • FOR > 30 DAYS/YR.
• COLLEGIUM RAMAZZINI:
  • APPROPRIATE TRIGGER:
  • OE > PROPOSED ACTION LEVEL OF 25 µgm/m3

MEDICAL MONITORING: TRIGGER

• CR RATIONALE:
  • OSHA (SECTION XVI) ACKNOWLEDGES SIGNIFICANT RISK REMAINING AT THE PEL - 50 µgm/m3;
  • FEASIBLE (TRIGGERS EXPOSURE MONITORING IN PROPOSED STD);
  • CONSISTENT W EARLIER OSHA STDS: CR VI, METHYLENE CHLORIDE, CD, LEAD, MDA, INORGANIC AS, VINYL CHLORIDE, LAB WORKERS EXPOSED HAZARDOUS CHEMICALS.
MEDICAL MONITORING: 
**SINE QUA NON**

**EMPLOYER WRITTEN OPINION**

- **OSHA:**
  - PLHCP MUST PROVIDE TO EMPLOYER ≤ 30 DAYS A WRITTEN OPINION THAT INCLUDES: "A DESCRIPTION OF THE EMPLOYEE’S HEALTH CONDITION AS IT RELATES TO EXPOSURE TO RCS… AND"
  - "ANY RECOMMENDED LIMITATIONS ON THE EMPLOYEE’S EXPOSURE TO RCS OR ON USE OF PPE SUCH AS RESPIRATORS."

**COLLEGIUM RAMAZZINI:**

- NOTWITHSTANDING THAT "DESCRIPTION" IS VAGUE, INFORMATION ABOUT MEDICAL FINDINGS SHOULD BE PROVIDED ONLY TO THE EMPLOYEE;
- "THE EMPLOYER IS ENTITLED TO KNOW WHETHER OR NOT THE EMPLOYEE IS ABLE TO USE RESPIRATORY PROTECTION – NOTHING MORE.

(IN KEEPING WITH 29 CFR 1910.134(E))

**MEDICAL REMOVAL PROTECTION**

- **OSHA:**
  - OOMITS PROVISION FOR MRP FROM PROPOSED STANDARD.
- **RATIONALE:**
  - "SILICA-RELATED DISEASES ARE CHRONIC AND NOT LIKELY TO REGRESS W TEMPORARY REMOVAL FROM EXPOSURE."
MEDICAL MONITORING: SINE QUA NON

MEDICAL REMOVAL PROTECTION

• COLLEGIUM RAMAZZINI:
• STRONGLY URGED OSHA TO INCLUDE PROVISION FOR MRP IN THE PROPOSED RULE.
• RATIONALE:
• NECESSARY TO WORKER’S FULL PARTICIPATION IN MEDICAL SURVEILLANCE, AND FOR
• EARLY DETECTION OF SILICA-RELATED DISEASE.

MEDICAL SURVEILLANCE: THE COLLEGIUM RESPONDS TO OSHA