

MEDICAL SURVEILLANCE FOR SILICA-RELATED DISEASE: THE COLLEGIUM RAMAZZINI RESPONDS TO OSHA'S PROPOSED RULE

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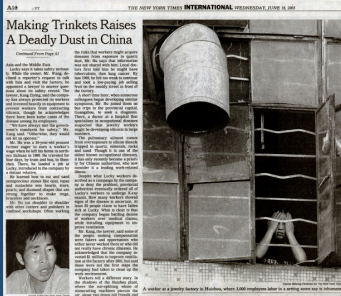
HISTORICAL PERSPECTIVE



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- 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....”

CHINA: 2003



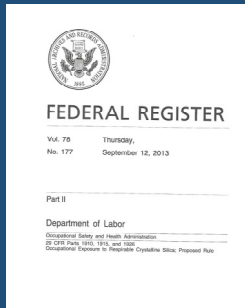
UNITED STATES: 2007



UNITED STATES: 2013



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.

MEDICAL SURVEILLANCE: CONTENT

PULMONARY FUNCTION TESTING

• OSHA:

- SPIROMETRY PERFORMED BY A NIOSH-CERTIFIED SPIROMETRY TECHNICIAN

MEDICAL SURVEILLANCE: CONTENT

PULMONARY FUNCTION TESTING

• 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.

MEDICAL SURVEILLANCE: CONTENT

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.

MEDICAL SURVEILLANCE: CONTENT

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?

MEDICAL SURVEILLANCE: CONTENT

- 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."

MEDICAL SURVEILLANCE: CONTENT

OTHER TESTS

- OSHA:
- PROVISION FOR "ANY OTHER TESTS DEEMED APPROPRIATE BY THE PLHCP."
- **SILENT** ON MEDICAL SURVEILLANCE FOR LUNG CANCER.

MEDICAL SURVEILLANCE: CONTENT

OTHER TESTS

- 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 \leq 3 YEARS PRIOR.
- COLLEGIUM RAMAZZINI:
 - PROVIDES INADEQUATE BASELINE;
 - 3 YEAR WINDOW TOO LONG: MEDICAL HX AND PFTS CAN CHANGE SIGNIFICANTLY.

MEDICAL SURVEILLANCE: PERIODICITY

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 \geq PROPOSED PEL OF 50 $\mu\text{g}/\text{m}^3$
- FOR \geq 30 DAYS/YR.
- COLLEGIUM RAMAZZINI:
- APPROPRIATE TRIGGER:
- OE \geq PROPOSED ACTION LEVEL OF 25 $\mu\text{g}/\text{m}^3$

MEDICAL MONITORING: TRIGGER

- CR RATIONALE:
- OSHA (SECTION XVI) ACKNOWLEDGES SIGNIFICANT RISK REMAINING AT THE PEL - 50 $\mu\text{g}/\text{m}^3$;
- 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 \leq 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."

MEDICAL MONITORING: *SINE QUA NON*

EMPLOYER WRITTEN OPINION

- 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 MONITORING: *SINE QUA NON*

MEDICAL REMOVAL PROTECTION

- OSHA:
- OMITTS 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