Reflections of an OSHA Administrator (Official) on the Lab Standard

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Fred’s Lab Background

- College
  - Ruined T Shirt incident of 1971
  - Ruined cut offs incident of 1972
  - Work with University Safety Officer
    - Chemical fume hood rating program
    - Laboratory Safety Training curriculum
History of the Standard
Reasons for Promulgation

- Industry’s concerns
  - 1973 – Promulgation of standards for regulated carcinogens
    - Laboratories use very small amounts of the substances;
    - Laboratory work is done by, or under the direct supervision of, highly qualified personnel.
    - Regulations will disrupt important research
    - Laboratory sections were vacated after SOCMA court challenge
  - Late 1978 - 1981 – Carcinogen Policy Discussion
    - Similar concerns raised
    - Created a forum that prompted the formation of informal groups of laboratory experts to study the problem further.
Laboratories were hazardous

- Hazardous conditions occurred in laboratories
- Highly trained professionals argument was somewhat mythical
  - Experts not aware of hazards
  - Many labs don’t have highly trained professionals
Concerns of Safety Profession

OSHA standards hard to use for lab chemicals

- Health Hazards:
  - Laboratory work does not lend itself to use of PELs
  - OSHA does not have requirements for SOPs, hazard analysis, etc.

- Chemical safety
  - OSHA standards for flammable liquids not easily applied to laboratories
  - No standards about improper storage, chemical mixture, etc.

Laboratory work does not lend itself to specifications

- OSHA standards were very specification oriented
- Novel activities of laboratories made universal specifications difficult
- Transient nature of laboratory work made inspection evaluation unreliable
Concerns of OSHA Field Personnel

- Adopted consensus standards assumed use of a separate laboratory standard

- Health specification standards were not enforceable without exposures above PELs
  - E.g. OSHA’s ventilation standards.

- PPE standards were enforceable and cast a wide net
  - Lacked requirements for program
  - Policy development had not happened
Rulemaking Publication Dates

- April 14, 1981 – Request for Comment and Information
- July 26, 1986 – Notice of Proposed Rulemaking
  - An informal hearing collected 400 pages of comments
  - Ensuing written comments
  - Large Docket
- January 30, 1990 – Final Standard
Design of Standard

- Performance standard
  - Requires an adequate program (Chemical Hygiene Plan)
  - Required an appropriate administrative structure (Chemical Hygiene Officer(s))
- Relies on Industry consensus
  - Outline of Chemical Hygiene Plan is taken from Prudent Practices Manual
  - Appendix A
Concepts in the Standard

- Laboratory Scale – Manipulations by one person
- Laboratory Use of Hazardous Chemicals
  - Chemical manipulations carried out at laboratory scale
  - Multiple chemical procedures or chemicals
  - Procedures are not part of a production process
    - Note Production = Manufacturing
  - Protective laboratory practices and procedures are available
Chemical Hygiene Plan Contents

- Standard Operating Procedures
- Criteria to decide to use hazard control measures
- Maintenance of fume hoods and other control equipment
- Employee information and training
- Criteria for seeking prior approval
- Medical consultation capability
- Designation of Chemical Hygiene Officer
- Procedures for particularly hazardous chemicals
Novel (Unique) Concepts

- Select Carcinogen
  - Designated human carcinogen by NTP
  - Regulated as a human carcinogen by OSHA
  - IARC Group 1
  - IARC Group 2 with special conditions

- Designated Area - For manipulation of
  - Select carcinogen
  - Reproductive Toxin
  - Acute Toxins
Interaction with PELs

- Lab standard preempts all expanded standards unless stated otherwise
  - Formaldehyde standard takes precedence in histology, pathology, human or animal anatomy labs.
- PEL and monitoring schedules for exposures above PEL or Action Level
1910.1450 is not just hazard communication for laboratories!
Hazard Communication in Laboratories

1910.1200
- Keep incoming labels intact
- Maintain safety data sheets received from suppliers
- Train employees on hazards of commercial chemicals

1910.1450
- Train employees on hazards of all chemicals in their work area
- Provide information about
  - Chemical Hygiene Plan
  - PELs
  - Signs and symptoms
  - Location of reference material about chemical hazards
Changes Due to Global Harmonization System

- Replaced specific definitions for types of health and physical hazards with GHS definition of health hazard and physical hazard.
- Added reproductive toxin
- Harmonized the definition of mutagen
- (No change to select carcinogen)
Enforcement Statistics

Two Sets of Data

  - 45 Inspections
  - Private sector and Federal only

  - Public and private sector
  - 658 inspections
  - 1053 citations
Manufacturing Inspections 3/1/11 - 3/1/15

- 332811 Metal Heat Treating
- 332813 Electroplating
- 325412 Pharmaceuticals
- 335999 Electrical Equipment
- 325110 Petrochemical
- 311225 Fats & Oils Refining
- 325520 Adhesive Mfg
- 332111 Metal Forging
- 324110 Petroleum Mfg.
- 333999 Machinery Mfg.
Interpretations
Laboratories not covered by 1910.1450

- Quality control laboratories for production facilities
  - Manufacturing facility QC/QA laboratories
  - “Production” laboratories
    - Dental Laboratories
    - Photographic Laboratories
- Biological laboratories
- Other
  - Laboratories that do not use chemicals (engineering, physics, etc.)
  - Most pilot plants.
Determining coverage

- Facility is covered if its operations meet “laboratory scale” and “laboratory use” only

- Items that don’t determine coverage
  - Repetitiveness of operations
  - Laboratory mock up of manufacturing for R&D purposes
  - Production of test results

- Pharmacy labs are not covered by the lab standard.
Thank You.