

# National Personal Protective Technology Laboratory

## NIOSH-NPPTL Respirator Manufacturers Meeting

Site and Product Audits  
Presented by David Book  
April 11, 2007

# Site and Product Audits

## Format of Slides

- Time period in question
- 3 types of slides
  - Point of emphasis
  - Activities seen by Approval Holder
  - Internal process improvements



Workplace  
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**NIOSH**

**NPPTL** *Research to Practice  
through Partnerships*

# Site Audits

## Period 1: 2002-2003

- **Point of Emphasis:** Quality Manuals must be updated by the Approval Holder and reviewed by NIOSH on a timely basis.
- Results: 2002-2003 compliance 48%.  
2005 compliance 82%.

# Site Audits

Activities seen by Approval Holder  
Period 1: 2002-2003

- Introduction of contract auditors.
- ICS as only audit contractor
- Audit frequency:  $\geq 4$  years

# Site Audits

## Internal Process Improvements

### Period 1: 2002-2003

- Standardized audit criteria.  
All Approval Holders evaluated against the same standard.
- Documented audit procedures in SOP 42.
- Annual audit support contracts.

# Site Audits

Period 2: 2004-2005

- **Point of Emphasis:** Testing and Calibration Procedures
- Results: Significant improvement in timeliness of equipment calibration.
- Results: Numerous test procedures revised to reflect actual test performance.
- Results: Test procedures need to be more closely linked to PQP and sampling plans.

# Site Audits

Activities seen by Approval Holder

Period 2: 2004-2005

- Audits of international sites established on a regular basis.
- ICS and Brand Consulting qualified as contractors.
- Audit frequency: ~ 3 years.
- Acceptance of contract auditors by Approval Holder community.

# Site Audits

## Internal Process Improvements

Period 2: 2004-2005

- Standardized contract auditor training program.
- Improved contractor evaluation criteria.
- Learned to write and manage effective federal contracts.

# Site Audits

Period 3: 2006-2007

- **Point of Emphasis:** Product Quality Plans (PQP) and sampling plans.
- **Results:** Significant improvement in awareness of requirements.
- **Results:** Better integration of sampling plans in applications and field verification.

# Site Audits

Activities seen by Approval Holder

Period 3: 2006-2007

- ICS Certification, Brand Consulting and Orion Registrars qualified as contractors.
- Audit frequency: 2 years.
- 2-day audits implemented for some sites.
- New Approval Holders audited within 1 year of first approval.

# Site Audits

## Internal Process Improvements

### Period 3: 2006-2007

- 5-year audit support contract in place.
- Task Order type of procurement increases flexibility for audit performance.
- ~50 site audits performed per year.

# Site Audits

Period 4: 2008-2009

- **Point of Emphasis:** Corporate and support services (design control and purchasing).
- **Point of Emphasis:** Manufacturing sites shared by multiple approval holders.

# Site Audits

Activities to be seen by Approval Holder

Period 4: 2008-2009

- ICS Certification, Brand Consulting and Orion Registrars qualified as contractors
- Audit frequency: 2 years.
- New Approval Holders audited within 6 months of first approval.

# Site Audits

## Internal Process Improvements

Period 4: 2008-2009

- Obtain/train NIOSH resources to improve timeliness of audit follow-up activities.



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# Product Audits

Activities seen by Approval Holders  
2002-2005

- ~ 50 Product Audits performed per year.
- Respirators acquired from a combination of site audit donations and commercial sources.

# Product Audits

## Internal Process Improvements 2002-2005

- Need for a more directed, systematic process for selecting and testing respirators was identified.

# Product Audits

## Activities seen by Approval Holders 2006-2007

- August, 2006 letter requesting information from Approval Holders for data to implement Respirator Selection Logic (RSL) Database.
- October 11, 2006 public meeting announcement that extensions will likely require lab testing.
- Testing requirements clarified in this meeting.

# Product Audits

## Internal Process Improvements 2006-2007

- Respirator Selection Logic developed in 2006.
  - Initial trials of RSL on sample data sets performed in April 2007.
- Respirators to be obtained through commercial channels, not site audits.
- Extension of Approval testing to be included in Product Audit activities.
- # of Product Audits to increase significantly.

# Site and Product Audits

Questions ?