National Personal Protective Technology Laboratory

Quality Assurance for Respirators Notice for Proposed Rulemaking (NPRM) Public Meeting

Policy And Standards Development Branch

Marriott Los Angeles Airport

March 30, 2009
### Meeting Format - Agenda

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Administrative Details

Information Docket (Reference Docket # NIOSH 109)
- Mail: NIOSH Docket Office
  Robert A. Taft Laboratories, M/S C 34
  4676 Columbia Parkway
  Cincinnati, OH 45226

- Email: nicindocket@cdc.gov

- Fax: (513) 533-8285

- Phone: (513) 533-8303

- NPPTL Web Site: http://www.cdc.gov/niosh/npttl

- Comments due by Friday, April 10, 2009
Presentations and Questions

- Presentations
- Moderator
  - Max Kiefer
- NIOSH Panel
  - Bill Newcomb
  - Tim Rehak
  - Ted Katz
Overview of Quality Assurance NPRM

- Adds quality management per ISO 9001
- Clarifies auditing procedures and the use of contract auditors
- Allows the use of various sampling plans
- Codifies the use of the standard application procedure
- Calls for linking quality controls to specific sections of 42 CFR part 84
- Adds quality assurance requirements to the existing quality control requirements
- Mandates NIOSH notification of changes in approval holder ownership
- Mandates NIOSH notification of certain customer complaints
- Clarifies the causes for quality related revocation of approvals
Final Details

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