

**NIOSH-NPPTL Respirator Manufacturers Meeting**

**April 11, 2007**

# **Present & Proposed Private Label Requirements**

**Jeff Peterson**

# Private Labeling

- Allows an approval holder to enter into an agreement with another company to sell respirators with that specific company's name on the product
- The present approach makes it appear to the user that the company whose name appears on the approval labels and User Instructions is the approval holder
- The approval holder is liable for product quality and publicity which pertains to NIOSH approval

# Present Private Label Request Requirements

- Private labels can presently be issued using one of two methods
  - Private Label Notification Form
    - Used when the part number does not change
  - Extension of Approval
    - Used when the part number does change

# Immediate Revisions to Private Label Request Requirements

- NIOSH will no longer accept the Private Label Notification Form effective May 1, 2007
- All Private Label requests must be submitted as extensions of approval due to labeling issues that NIOSH has discovered in the past year
  - Submission will include assembly matrix, approval labels, user instructions and drawings
  - Drawings should list all relevant Private Labels
  - Submit hardware and fee if base model has not been evaluated in the past year

# Proposed Changes to Private Label Request Requirements

- All requests must be made by filing an extension of approval with all associated documentation as discussed earlier
  - Specific contact information for company receiving private label will need to be provided in the reason for application
  - Statement acknowledging who the approval holder is and under what approval number the respirator has been private labeled must appear as a Special 'S' statement in the user instructions and on the packaging
    - The model ABC filtering facepiece respirator has been manufactured by Approval Holder A for Company B under TC-84A-XXXX

# Proposed Changes to Private Label Request Requirements

- The company whose name will appear on the label will be contacted by NIOSH to insure that they are aware of what a Private Label is and what they can and cannot do
- Submit comments on proposal to Jeff Peterson by June 1, 2007 at [jap3@cdc.gov](mailto:jap3@cdc.gov)

# Questions/Comments