NIOSH Conformity Assessment Letter to Manufacturers

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Subject: Requirements and Responsibilities of Approval Holders and Assignees in NIOSH Approved Respirator Private Labeling and Private Packaging Arrangements

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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PRIVATE LABELING

NIOSH Approval Holders and those they designate as Private Label (PL) entities have obligations when an extension of approval request for a private label is granted. All of the requirements listed below are well documented in NIOSH Standard Application Procedures.

To achieve approval for a private label, the Approval Holder has the following responsibilities: 1) serve as the point of contact with the NIOSH staff, 2) submit an extension of approval application providing all relevant PL information to NIOSH, 3) clearly identify the name, location, and contact information for each PL Company designated, 4) manufacture the PL respirator under the approval holder's quality system, 5) enter into an agreement to allow a company to be a PL entity permitted to sell the Approval Holder's respirator.

In addition, the Approval Holder is responsible for the respirator design, quality production and all packaging, labeling, markings, and literature pertaining to the NIOSH approval. This includes correct translation of the public facing documentation to languages other than English, when needed.

All packaging, labeling, markings, User Instructions, and literature are marked to identify the PL Company. The PL respirator name, model number, and part number may or may not be the same as what is used by the Approval Holder. The Approval Holder and NIOSH approval number (TC number) are included in the Special Instructions "S" section of the PL User Instructions. According to the SAP the PL User Instruction "S" section states: *Model/part number "respirator type" has been manufactured by Company (NIOSH Approval Holder) for (Private Label Company) under TC-XXY-nnnn.* Additionally, Special Caution and Limitation "S" is included on all PL Company labels.

The Approval Holder must ensure that the PL Company does not misrepresent the NIOSH approval or make any modifications to the approved design or documentation. The Approval Holder must notify NIOSH of any concerns regarding fraudulent or misuse of approvals granted.

PRIVATE PACKAGING

Private Packaging (PP) differs from Private Labeling. The NIOSH Approval Holder enters into an agreement to have its respirators sold by another Company. The PP Company puts the assembled respirator in a different or additional package. The respirator name, model number, part number, respirator labeling, markings, User Instructions, and literature remain unchanged and identify the Approval Holder. The additional packaging may represent the PP Company and an additional catalog or other reference number.

The packaging must clearly indicate that the PP Company is not the approval holder. Clarifiers, such as "Sold by (PP Company) and Manufactured by (NIOSH Approval Holder) or "Made by (NIOSH Approval Holder) for sale by (PP Company)" must be included on the packaging.

The NIOSH approval label will not be changed. The Approval Holder is responsible for the respirator design, quality production and all packaging, labeling, markings, and literature pertaining to the NIOSH approval. The Approval Holder must ensure that the PP does not misrepresent the NIOSH approval. Approval labels and User Instructions provided on or within the packaging, as part of the NIOSH documentation, must not be changed.

NIOSH does not need to be notified of private packaging arrangements (no application needs to be submitted since PP does not result in any changes to NIOSH documentation on file for the approved respirator configuration).

The NIOSH Approval Holder is responsible for notifying designated PL and PP companies of any changes in approval status, such as stop sale, rescission, or revocation. Under both arrangements, the Approval Holder is responsible for ensuring that PL and PP companies in no way misrepresent the NIOSH approval.