

## 8 Things to consider before reprocessing select N95 masks/respirators for the first time

### 1. POLICY & PROCEDURE (P&P)

- Do any current P&Ps need to be updated?
- Does a new P&P need to be developed for N95 Mask Reprocessing During the COVID-19 Public Health Emergency?
- Who will communicate to Health Care Personnel (HCP) that they will now be expected to use a reprocessed N95 Respirator?
- What information will you provide to HCPs to ensure they feel comfortable with the efficacy of a reprocessed N95 Respirator?
- How will you oversee distribution of new/unused N95 respirators to help promote reuse rather than disposal, when applicable?
- How many times do you plan on reprocessing individual used N95 respirators (note limit of two (2))? If more than one (1) time, how will you record/track each time an N95 respirator is reprocessed?
- If throughput capacity does not allow for all departments to reprocess N95 respirators, how will departments receiving new respirators versus reprocessed respirators be decided and who will be responsible for that decision?
- Will any point of N95 collection, storage, transportation or processing be performed under biosafety level (BSL) 2 or BSL-3 conditions? If this will occur under BSL-2 conditions, are there any additional precautions that will be implemented?

### 2. CHAIN OF CUSTODY

- Does a procedure need to be developed between originating department, designated prescreening location, and SPD/CS to ensure chain of custody from the point of collection in the healthcare facility, to the reprocessing facility, through the reprocessing cycle, repackaging, and distribution back to the healthcare facility?
- What information needs to be collected or recorded on the reprocessed N95 Respirator (Employee ID, Department, Date, Model #)?
- How will used N95 respirators be collected and labeled so they can be returned to the appropriate department and individual employee after processing?

### 3. COLLECTION

- Have you identified a designated collection area within each ancillary department that limits cross-contamination or exposure of COVID-19 during transportation?
- How will the used N95 respirators be stored in the collection point prior to pick up and transportation?

- What vessel will you use to collect the used N95 Respirator (brown bag, peel pouch, biohazard container, etc.)?
- Will additional supplies (peel pouches, sterility indicators, labels, bins, etc.) need to be provided to user departments?
- Will the HCPs be instructed to dispose of any visibly soiled N95 Respirator at point of use (to help decrease potential exposure throughout the transportation and pre-screening process)?
- Will training need to be performed with HCPs at the departmental level on the procedure for packaging and sending their used N95 Respirator to the designated prescreening location? If so, who will perform the training?

#### **4. TRANSPORTATION**

- How will used N95 respirators be transported to designated area for prescreening in order to minimize storage of contaminated PPE?
- How will you ensure used N95 respirators are packaged prior to transportation through a clean room to the STERRAD® System?
- How will reprocessed N95 respirators be transported from SPD/CS back to the originating department?
- Who will be responsible from each department to collect reprocessed N95 respirators from SPD/CS?

#### **5. PRE-SCREENING**

- Knowing used N95 respirators will not be decontaminated or cleaned prior to reprocessing, where and how will you designating a prescreening area that will not lead to cross-contamination of a clean area?
- What PPE is required for personnel reprocessing respirators?
- How will your pre-screening process ensure non-approved masks/respirators, such as those that contain cellulose, are not reprocessed?
- How will the receipt of the used N95 respirators delivered from each department be logged/recorded? By Whom? What information will be recorded?
- What hospital personnel will be designated to screen N95 respirators for visible soil?
- Where and how will soiled N95 respirators be disposed?
- If transported in a Tyvek® Pouch, how and who will ensure visibility of the STERRAD™ Chemical Indicator Strip within the Tyvek® Pouch?
- If the STERRAD™ Chemical Indicator Strip is not visible, will this item be repackaged?
- If the HCP information is written on the Tyvek® side, rather than the mylar side of the Tyvek® Pouch (which does not meet AAMI Standards) will this item be repackaged? By who?

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- If there is no HCP information on the transportation vessel, will this N95 Respirator be discarded? Or will the model number be recorded on the Tyvek® Pouch when packaging for reprocessing so this can be stored post reprocessing for potential later use?
- If a used N95 Respirator from a particular HCP has already met the maximum number of reprocessed cycles, will it be disposed? If yes, by who and where?

## 6. PACKAGING & LOADING

- Will additional supplies be needed in order to replicate the process validated by the OEM and in according to FDA recommendations?
- Does your process include instruction for packaging and loading to ensure safe handling and to ensure masks are not crushed or altered?

## 7. STAFF

- Will personnel performing reprocessing be routinely screened for COVID-19 to ensure personnel have not been exposed due to reprocessing and that reprocessed masks are not contaminated by personnel?
- What training is required to ensure safe handling of masks to ensure soiled masks are not mixed with processed, and that processed masks are not contaminated?
- Who will train SPD/CS staff on the new procedures?
- Will a competency be developed for processing of N-95 Respirators (SPD/CS staff)?
- How will you handle an HCP who refuses to use a reprocessed N95 respirator?

## 8. REDISTRIBUTION

- How will reprocessed respirators be handled to ensure they are not contaminated or mixed with contaminated masks?
- Who will pick up reprocessed N95 respirators from SPD/CS for distribution back to the appropriate Department?
- Who, at the Department level, will be responsible for the Chain of Custody of accepting the reprocessed N95 respirators?
- Who will be responsible for distributing the reprocessed N95 Respirator back to the assigned HCP?
- What should happen if a reprocessed N95 Respirator is refused upon redistribution?

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.

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