EHSSENTIALS 2014
Environmental, Health & Safety Symposium for Healthcare

OCTOBER 3, 2014
PALO ALTO, CALIFORNIA
STANFORD UNIVERSITY MEDICAL CENTER

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STANFORD HOSPITAL & CLINICS
Stanford University Medical Center
Implementing a Respiratory Protection Program in a Hospital Environment

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What we are trying to accomplish

The purpose of this Respiratory Protection Program (RPP) is to maximize the protection afforded by respirators when they must be used.

- Personnel must have a **thorough understanding of the equipment**
- Respirators must be **accessible** for use by personnel
- **Procedures must be in place to meet the regulatory requirements**
  - Cal/OSHA regulations include the Respiratory Protection Standard (Title 8 California Code of Regulations Section 5144) and
  - the Aerosol Transmissible Diseases Standard (8 CCR Section 5199).
Key Regulatory Requirements

**Respiratory Protection Program**
- Written respiratory protection program with policies and procedures
- Designation of a Program Administrator
- Procedures for hazard evaluation and respirator selection
- Medical evaluation of respirator wearers
- **Fit testing procedures for tight-fitting respirators**
- Procedures for proper use, storage, maintenance, repair, and disposal of respirators
- Training
- Program evaluation including consultation with employees [8CCR 5144(c)]
- Recordkeeping

**Aerosol Transmissible Diseases (ATD)**
- Written ATD Exposure Control Plan, including biosafety plan for laboratory operations
- Designation of a Plan Administrator
- Hazard evaluation and identification of occupationally exposed employees
- Exposure control procedures including respiratory protection
- **Medical services**
- **Procedures for exposure incidents**
- Surge procedures
- Training
- Plan evaluation and procedures for employee participation in review of plan
- Recordkeeping
Aerosol Transmissible Disease Standard

Subchapter 7. General Industry Safety Orders
Group 16. Control of Hazardous Substances
Article 109. Hazardous Substances and Processes

§ 5199 Appendix A – Aerosol Transmissible Diseases/Pathogens (Mandatory)

2009-2010 Flu Season
- Novel H1N1 Influenza

August 2009
- CA ATD Standard Initiated

2010-2011 Flu Season
- Non-Novel H1N1 Influenza

August/Sept 2011
- ATD focus on all ATDs

Focus on H1N1

CDC changes RP for flu
N95 purifying respirator (APR) - Aerosols

- Filters at least 95% of airborne particles
- Certified by NIOSH
- Requires training
- Must be fit tested
- Not resistant to oil

FACE MASKS - Droplet

- Acts as a barrier only
- Not Certified by NIOSH
- Requires no training/ fit testing
Aerosols Require N95 Protection

- Some infections spread easily from person to person by infectious particles that stay suspended in the air. The nuclei are <5 microns in size. When the droplet evaporates, the nuclei remains suspended in the air. These organisms can stay suspended in the air for up to 2 hours and can travel long distances on air currents.

**Novel or unknown pathogens**
- Tuberculosis
- Chickenpox (Varicella)
- Measles (Rubeola)
- Monkey Pox
- Avian Influenza

- Anthrax
- Disseminated Zoster
- SARS
- Smallpox
Droplet Infections – Mask or N95 for aerosol generating procedures

Unlike aerosol infections, the bacterial must be suspended in droplets to be propelled. The droplets can be propelled up to 3 feet and can be deposited on the conjunctiva, nasal mucosa or mouth. The diseases can be spread by droplets:

- When an infected person talks, sneezes or coughs
- During procedures such as suctioning, cough induction or bronchoscopy
Droplet Infections Covered ATD

- Diphtheria pharyngeal
- Epiglottitis, due to *Haemophilus influenzae* type b
- *Haemophilus influenzae* Serotype b (Hib) disease/*Haemophilus influenzae* serotype b -- Infants and children
- Influenza, human (typical seasonal variations)/influenza viruses
- Meningitis
- *Haemophilus influenzae*, type b known or suspected
- *Neisseria meningitidis* (meningococcal) known or suspected
- Meningococcal disease sepsis, pneumonia (see also meningitis)
- Mumps (infectious parotitis)/Mumps virus
- Parvovirus B19 infection (erythema infectiosum)
- Pertussis (whooping cough)
- Pharyngitis in infants and young children/Adenovirus, Orthomyxoviridae, Epstein-Barr virus, Herpes simplex virus,
- Pneumonia
- Adenovirus
- *Haemophilus influenzae* Serotype b, infants and children
- Meningococcal
- *Mycoplasma, primary atypical*
- *Streptococcus Group A*
- Pneumonic plague/*Yersinia pestis*
- Rubella virus infection (German measles)/Rubella virus
- Severe acute respiratory syndrome (SARS)
- Streptococcal disease (group A streptococcus)
- Skin, wound or burn, Major
- Pharyngitis in infants and young children
- Pneumonia
- Scarlet fever in infants and young children
Surgical Masks

- **Surgical mask are approved** by both NIOSH and the Food and Drug administration (FDA).
- It is important to know that according to the FDA Facemasks [&) respirators are devices that when properly worn may help prevent the spread of germs (viruses and bacteria) from one person to another.
- Facemasks and N95 respirators **do not provide complete protection** from airborne germs and other contaminants. They are one part of an infection-control strategy that should also include frequent hand washing, social distancing, and staying home when sick.
Aerosol-Generating Procedures
High Hazard Procedures

**High Hazard Procedures require one level higher protection**

Procedures performed on a person who is a case or suspected case of an aerosol transmissible disease in which the potential for being exposed to aerosol transmissible pathogens is increased due to the reasonably anticipated generation of aerosolized pathogens. Such procedures include, but are not limited to:

- sputum induction, bronchoscopy, aerosolized administration of pentamidine or other medications,
- pulmonary function testing, autopsy, clinical, surgical and laboratory procedures that may aerosolize pathogens.

**General rule: Use next level up protection for high hazard procedures. All aerosol high hazard procedures require a PAPR/CAPR.**
Essential Program Elements

- An effective respirator program must cover the following factors:
  - All procedures in written form
  - Respiratory Program Administrator
  - Periodic Program evaluation;
  - Selection of an appropriate respirator approved by the National Institute for Occupational Safety and Health (NIOSH);
  - Training
  - Annual Face Seal Fit testing
  - Inspection, cleaning, maintenance, and storage
  - Medical evaluations
  - Work area surveillance
Written Program

Employers must evaluate the effectiveness of a company’s respirator program regularly and modify the written operating procedure as necessary to reflect the evaluation results.

Respiratory Program Administrator

The person you designate to run your program will be called the **respiratory protection program administrator**, and he or she will have specific duties and responsibilities that are detailed in the *California Code of Regulations, Title 8 (T8 CCR), Section 5144, Respiratory Protection*.  

Qualified program administrator required 5144(c)(3)
Respirator Program Administrator (RPA)

- The RPA should be an individual, not a department or group of administrators, and affected employees need to know who that person is.

- The RPA must be appropriately trained and knowledgeable about the requirements of the Cal/OSHA Respiratory Protection Standard and all elements of the Respiratory Protection Program that need to be implemented in order for it to be effective.

- Upper management has ultimate responsibility for all aspects of this program and shall give the RPA full authority to make the necessary decisions to ensure its success.
Respirator Program Administrator (RPA)

- Conduct a **hazard assessment** and select the appropriate level of respiratory protection for each task or job title with exposure.
- Develop and monitor respirator maintenance procedures.
- Coordinate purchase, maintenance, repair, and replacement of respirators.
- Routinely evaluate the effectiveness of the RPP, with **employee input**, and make any necessary changes to the program.
Training

Training must be comprehensive enough for the employee to demonstrate a knowledge of the limitations and capabilities of the respirator, why the respirator is necessary, and how improper fit, usage, or maintenance can compromise the respirator.

**Training must include an explanation of the following:**

- Why respirator use is necessary
- Nature of the respiratory hazard and consequences of not fitting, using, and maintaining the respirator properly
- Capabilities and limitations of the selected respirator
Training

Training must include an explanation of the following:

How to inspect, put on and remove, and check the seals of the respirator;

How to use the respirator effectively in emergency situations, including when the respirator malfunctions; and

How to recognize medical signs and symptoms that may limit or prevent the effective use of the respirator

Users should know that improper respirator use or maintenance may cause overexposure
Voluntary Use

The exception to the full respiratory use program is if an employee selects to use a dust mask for comfort. This is known as **VOLUNTARY USE**.

**Voluntary Respirator Usage** (for comfort purposes)

Stanford Health Care allows the use of filtering-face piece (Dust Mask) respirators for comfort where **NO** respiratory hazard exists.

Appendix D to Section 5144: (Mandatory) Information for Employees Using Respirators When Not Required Under the Standard

Those employees who choose to wear a dust mask voluntarily, are **not** required to participate in the medical clearance and fit testing requirements.
Hazard Assessment

- The RPA will select the types of respirators to be used by hospital staff based on the hazards to which employees may be exposed and in accordance with all Cal/OSHA regulations and CDC and/or CDPH guidelines. [8CCR 5144(d)(1)(B)]

- Need to take into consideration that Maintenance and Housekeeping staff may have the potential to be exposed to hazardous gases, vapors, or dusts in addition to ATDs.

- **Relative to chemical exposures, quantification or objective determination of potential exposure levels where possible.** This will not be done for ATDs. [8CCR 5144(d)(1)(C)]

- The RPA will revise and **update the hazard assessment** any time an employee or supervisor anticipates a new exposure.
Selection of an appropriate respirator - consolidate

If your program *only* utilizes N95s and/or PAPRs for ATD exposures, you may remove mention of other types of respirators.

- The RPA selects respirators to be used by hospital staff based on hazard assessments in accordance with Cal/OSHA, CDC and/or CDPH guidelines.

- **With input from the respirator user, the RPA and supervisor conduct hazard assessments for each work task/work area where there are airborne contaminants.**
  - The most common potential exposure for employees involved in patient care will be ATDs
  - Maintenance and housekeeping staff may have the potential to be exposed to hazardous gases, vapors, or dusts in addition to ATDs.
  - Relative to chemical exposures, quantification or objective determination of potential exposure levels where possible. This will not be done for ATDs.
Chemical Vapor

- **Tight-fitting face piece** means a respiratory inlet covering that forms a complete seal with the face.

- **Perception**—wearing a tight fitting respirator will provide **100% protection factor**.

- The filter or cartridge efficiency, in conjunction with the type of mask help determine the protection factor for a particular respirator, which translates into how effective (how many times over the Permissible Exposure Limit) that mask will be.

- If we could measure the actual concentration of the contamination outside the mask versus the concentration inside the mask, that ratio would be the actual protection factor.
Chemical Vapor

- An **Assigned Protection Factor (APF)** is the level of protection that a particular type of respirator can be expected to provide 95% of the time.

- An APF of 10 means that type of respirator (if used properly) can be safely used in an atmosphere that has a hazardous concentration of up to 10 times the Permissible Exposure Limit (PEL) for that hazard.

- In the United States, the National Institute of Occupational Safety and Health (NIOSH) and the American National Standards Institute (ANSI) both establish APF's for various types of respirators.
Laser Fume

Medical staff may be at risk of infectious diseases transmitted through exposure to a "plume" generated during laser surgical procedures. Currently respirators for laser use are not certified. Many institutions now use N95.

- This plume of mostly **water vapors, organic vapors and carbonized cell fragments** is generated by the irradiation of tissue.

- Suspected concerns associated with this plume are the transmission of **viable human viruses such as HPV, hepatitis or human immunodeficiency (HIV)**, their infectious components, a rancid odor and irritation to the eyes and respiratory tracts.

- Chemicals such as **formaldehyde, benzene and polyaromatic hydrocarbons** can be found in the plumes which can cause flu-like symptoms in people who are exposed to them.
Medical Surveillance

For employees who use respirators solely for compliance with ATD (Section 5199) can complete the questionnaire in Appendix C in lieu of a medical evaluation. Follow-up exam is required for positive responses to questions 1-8 Section 2, Part A of Appendix C.

- The regulation on respirator protection, T8CCR, Section 5144, does not require an annual review of the medical status of employees who wear respirators; however, additional medical evaluations are required, at a minimum, when:
  - An employee reports medical signs or symptoms related to his or her ability to use a respirator.
  - The PLHCP, program administrator, or supervisor recommends re-evaluation.
  - Information from the respirator program, including observations made during fit testing and program evaluation, indicates a need.
  - Change occurs in workplace conditions that may substantially increase the physiological burden on an employee.
Fit Testing

- All employees who must wear respiratory protection shall receive medical clearance before fit testing is performed.

- Fit tests will be provided at the time of initial assignment and annually thereafter. The ATD Standard as of January 1, 2014 require all employees must be fit tested annually.

- There is no requirement for any type of certification of fit testers.

- Additional fit tests will be provided whenever the employee experiences or the supervisor or RPA observes physical changes that could affect respirator fit. These changes include, but are not limited to, facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight.
Fit Testing Not Permitted

Employer shall not permit respirators with tight fitting face-pieces to be worn by employees who have facial hair that comes between the sealing surface of the face piece and the face.

Please do your part to stamp out Adam Lavine
Fit Testing – opportunity to get feedback

- A qualitative fit test is typically used for all wearers of half-face APRs, including N95 and/or P100 filtering face-piece respirators as well as half-face, reusable APRs.

- You must use one of the approved fit test protocols from the Cal/OSHA standard.

- The qualitative test will follow the protocol for saccharine or Bitrex® solutions found in Appendix A of the Cal/OSHA Respiratory Protection Standard.

- The employee will also receive additional training during the fit testing procedure that will provide him/her an opportunity to handle the respirator, have it fitted properly, test its face piece-to-face seal, wear it in normal air for a long familiarity period, and finally to wear it in a test atmosphere.
Qualitative Fit Testing

**Objective** – pass/fail test that relies on the employee's response to a test agent and the fit test operator’s observations, the fit test operator determines a pass/fail judgment by which the respirator make, model and size may be assigned to the wearer.

- Isoamyl acetate (commonly referred to as banana oil because of its fruit-like aroma),
- saccharin (a sweet-tasting agent),
- irritant smoke (stannic chloride) and
- Denatonium Benzoate (also known as Bitrex).

Prior to conducting the test, the administrator must determine if the subject can detect the test agent.
Quantitative Fit Testing

**Quantifiable**—Provides a numerical measuring of the amount of leakage into the respirator.

Portacount which is based on the CNC (condensation nuclei counter) method.

The other method is the Controlled Negative Pressure (CNP) method.

The OSHA-accepted fit test protocols can be found at 29 CFR 1910.134 appendix A. The American National Standards Institute’s ANSI Z88.10, Respirator Fit Testing Methods provides the step-by-step explanations for conducting the ANSI-accepted fit tests.
Fit Testing

- Fit testing is one of the most important parts of the respirator program because it is the only recognized tool to assess the fit of a specific respirator model and size to the face of the user.

- The Cal/OSHA Respiratory Protection Standard Appendix A has specific protocols which must be followed exactly in fit testing employees for respirators, and it is acceptable to copy and paste one or more of these into your RPP.

- Every respirator wearer must receive fitting instructions, including demonstrations and practice on donning the respirator, how to adjust it, how to perform a user seal check, and descriptions of the specific exercises that are to be performed during the fit test to verify an adequate seal.
Training

- Training shall be provided at the time of initial assignment to respirator use, but before actual use, and annually thereafter. [8CCR 3203(b)(2); 8CCR 5144(m)]

- Additional training will be provided when there is a change in the type of respiratory protection used, or when inadequacies in the employee's knowledge or use of the respirator indicate that he/she has not retained the requisite understanding or skill.

- The standard requires that you get feedback from employees when evaluating your program and it makes sense to gather the feedback at the annual training. However, you may choose some other mechanism for obtaining feedback.
Usual Suspects
MAXAIR Controlled Air Purifying Respirator (CAPR) provides protection against aerosolized and airborne droplet particulates under the Cal/OSHA 5144, Respirator Protection, and are approved under NIOSH 42 CFR Part 84, certification requirements for respiratory protective devices.

The CAPR is preassembled and the flow rate is checked prior to issue for your convenience. The purpose of this section is to familiarize you with the design function of the air purifying system.
The CAPR System configurations are available to provide these benefits in situations where the presence of aerosolized, mist, and droplet pathogens and other particulates could otherwise cause the spread of infections and disease by inhalation and contact.

Ambient air drawn into the helmet liner, passes through a fixed high-efficiency particulate air filter to provide filtered air to the user while maintaining positive pressure inside the Disposable Lens Cuff (DLC) at all times.
The unit is comprised of eight parts.

1. Helmet Liner
2. Helmet
3. Helmet Power Cord
4. Filter Cartridge
5. Filter Cover Cap
6. Disposable Lens Cuff—DLC
7. Li-Ion Battery
8. Battery Belt
The CAPR Helmet has five Status Indicator LEDs located at its underside front that are always visible in the user’s peripheral vision.

They will provide an early warning alert to the user when the CAPR helmet is no longer able to maintain adequate airflow or the battery charge is low.
Check out from Supply Distribution.

**Step 1**

Supply Distribution

To pick up your CAPR go to the Supply Distribution desk. The desk attendant will retrieve a CAPR unit and fill out the initial paperwork.

You will be required to show proof of training and sign for the CAPR.
Use of CAPR

You are allowed to use the CAPR for one shift and no longer than 24 hours.

During periods of non-use it is recommended that you place it back in the plastic “clean” bag.
End of Use

Prior to returning the device, check that all the components are intact and complete the Process Control Form.

Return the CAPR to the Sterilization Process Room H0509.
Check out from Supply Distribution.

Use not to exceed 24 hours / single shift.

Complete Checklist. Return to SPD window.

SPD Disinfects device.

Step 4

Disinfect

SPD will document the condition and time of return. If there are no repairs needed, SPD will disinfect the CAPR.

Once complete the device will be placed in a clean bag and delivered to Supply Distribution.
Supply Distribution will check the condition of the overall device, finalize the checklist, and archive the paperwork and change out the filter based on the condition or total time of use.
Preparation

The battery packs will be placed on chargers. The CAPR will be placed back into the clean bag, along with 3 DLCs and a new Process Control Form.
Step 7

Restock CAPR Ready for Use.

Check out from Supply Distribution.

Use not to exceed 24 hours / single shift.

Complete Checklist. Return to SPD window

SPD Disinfects device.

Returned to Supply Distribution for equipment check.

SD replenishes (DLCs), charges batteries, flow check, etc.

Ready

The assembled CAPR is placed back in its designated bin and is now ready for issue.
Tracking – Maintaining Accountability

Carbonless (3 page) request form
- Track components through Material Mgmt. / User / SPD.
- Able to track how many days out on floor.
- Prepackage for direct distribution to single user.
- Can be easily be added in medical (endoscope) kit.
- Badge Identifier.
PDCA Maintaining Accountability

- Able to track discrepancies
- Offer repairs / replacement
- Benchmark
Equipment Accountability

Keeping track of CAPR equipment is crucial to assuring SHC and SCH maintain compliance and readiness of the protective equipment.
**Publications and Reports**

Respiratory Protection Programs in Hospitals a guide for respirator program administrators May 2012 Compiled by CDPH


**Related Webpages and Resources**

- Respiratory protection resources – general—CDPH
- Respiratory protection resources – health care—CDPH
- Cal/OSHA Respiratory Protection Standard –CDPH webpage with links to the standard and its appendices
- Cal/OSHA Aerosol Transmissible Diseases Standard – CDPH
- Respiratory protection in the workplace – CDPH

**Related Health Information**

- CDPH disease information page