

*Insert Facility/Institute Logo Here*

**RESPIRATORY PROTECTION MANUAL *TEMPLATE***

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| Facility: | |
| Manual Title: *Respiratory Protection Manual* | |
| Document Number: *4-02-005* | Version Number: *00* |
| Process Leader: | Effective Date: *MM-DD-YYYY* |
| Other documents cross-referenced in this Manual:   * Biorisk Management Manual (Chapter V, Biorisk Assessment; Chapter VIII, Occupational Health and Medical Surveillance; Chapter X, Entry and Exit Procedures; Chapter XIV, Personal Protective Equipment) (*4-00-001*) * Personal Protective Equipment SOP(*4-02-004*) | |

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INSTRUCTIONS: The Biorisk Management Manual and supporting Standard Operating Procedure (SOP) templates provide a general overview of common considerations and information that should be addressed within a biorisk management system and program. These templates are not exhaustive and facilities must customize each document to ensure it is locally applicable and relevant.

* **Black text** can be considered generic text which may be appropriate for inclusion in a facility’s biorisk management manual and SOPs.
* ***Red text*** should be considered guidance or examples and must be reviewed and replaced with facility-specific information.

1. Purpose

The purpose of this manual is to give standards and guidance for the use of respiratory protection equipment and to assist in the establishment of policies and procedures for the use of respiratory protection at the *[Insert Facility Name]*.

1. Principle

One of the principal routes by which chemicals or pathogens can enter the body is through inhalation. Undesirable health effects can result from an exposure to an excessive airborne concentration of a chemical or biological agent. Respirators and other personal protective equipment may be used where engineering controls and primary containment methods cannot completely mitigate a risk. The need for a respirator is dependent upon the type of operations and the nature and quantity of the materials in use and should be assessed on a case by case basis

This program applies to all personnel and visitors identified by the *Respiratory Protection Program Manager (RPPM)* as requiring respiratory protection equipment (RPE) due to the nature of their work assignment. Appropriate RPE shall be provided by the *RPPM* to these individuals. The use of any RPE by employees other than those identified by the *RPPM* is prohibited. All personnel who must enter an area where the use of RPE is required, even for a short time, will be identified by the area supervisor, and will be provided appropriate RPE by the *RPPM* after all training and medical clearance requirements have been met.

*[Insert Facility Name]* shall only permit the issue of RPE to those personnel who have satisfied the medical and training requirements of this manual.

1. Definitions and Terminology [Adapted from the National Institute of Occupational Safety and Health Respiratory Decision Logic and the Occupational Safety and Health Administration Standard 29 CFR 1910.134]
   1. Air-Purifying Respirator: A half or full-face-piece respirator equipped with air purification cartridges which are designed to remove contaminants from inhaled air.
   2. Cartridge: A small container filled with air-purifying absorbent or adsorbent media.
   3. Challenge Agent: The air contaminant introduced into a test chamber so that the concentration inside and outside the respirator may be compared.
   4. Contaminant: Harmful, irritating, or nuisance material foreign to the normal atmosphere.
   5. Continuous-flow respirators: These respirators send a continuous stream of air into the face-piece at all times. A continuous flow of air prevents infiltration by ambient air into the mask, but exhausts the air supply much more rapidly than positive-pressure or pressure-demand respirators.
   6. Filter: A medium used in a respirator cartridge or canister to remove solid or liquid particles entering the respirator.
   7. HEPA: High Efficiency Particulate Air. Filter media which is rated to capture particles of 0.3 microns in diameter or larger at an efficiency of 99.97 percent.
   8. IDLH: Conditions which pose an immediate hazard to life or may cause irreversible damage to one’s health (Immediately Dangerous to Life and Health).
   9. Negative-pressure-type respirators: Also referred to as “demand” respirators. They draw in air into the face-piece via the negative pressure created by user inhalation. The disadvantage of these respirators is that if any leaks develop in the system, the user draws contaminated air into the face-piece during inhalation.
   10. *NIOSH: National Institute for Occupational Safety and Health. This organization is involved with testing and approval of respirators in the United States.*
   11. Positive-pressure respirators: Also referred to as “pressure-demand” respirators. These respirators maintain a slight positive pressure in the face-piece during both inhalation and exhalation. A pressure regulator and an exhalation valve on the mask maintain the mask’s positive pressure at all times. If a leak develops, the regulator sends a continuous flow of clean air into the face-piece to prevent penetration of contaminated ambient air.
   12. Powered Air Purifying Respirator (PAPR): An air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.
   13. Quantitative Fit-Test: A test which uses instruments to detect leakage while the mask is worn.
   14. Qualitative Fit-Test: A fit-test that requires the respirator wearer’s ability to sense a test agent by taste, smell, or irritation (e.g., isoamyl acetate and saccharin).
   15. Respirator: An approved device designed to provide the wearer with respiratory protection against inhalation of a contaminated atmosphere and/or protection in oxygen-deficient atmospheres.
   16. RPPM: Respiratory Protection Program Manager.
   17. *SCBA: Self Contained Breathing Apparatus: A respirator type in which the clean air source is carried by the wearer.*
   18. Supplied-air respirator: A respirator in which clean air is carried to the wearer or is provided from an external source via an airline.
   19. Test Subject: The person wearing the respirator during fit-testing.
2. Roles and Responsibilities
   1. **Senior and Top Management** ensures that the organization develops a biorisk management program: a set of tools, information and associated actions that are overseen, enforced by senior/top management and continuously improved upon
   2. **Scientific Management** shall establish a comprehensive Respiratory Protection Program (RPP) and appoint a *Respiratory Protection Program Manager* in writing.
   3. The **Biorisk Management Advisor** shall advise upon this and all other facility or organizational biosafety and biosecurity programs.
   4. ***Respiratory Protection Program Manager*** *(RPPM)*:

* Develops, implements and maintains RPP to include an annual review
* Initiates prompt abatement for RPP deficiencies.
* Reviews and approves all RPP Standard Operating Procedures (SOPs) and worksite specific procedures for respiratory protection prior to implementation.
* Coordinates with *Occupational Health and Industrial Hygiene* personnel regarding the type of RPE to be purchased or used.
* Conducts fit-testing and training for the employees after they have been medically cleared to wear a negative pressure respirator or any other RPE with a tight-fitting face-piece.
* Performs fit-testing of personnel annually and identifies appropriate size and type of respirator for each user.
* Trains personnel in the proper use, care, and maintenance of respirators.
* Ensures that all personnel use only approved RPE as designated by the RPPM.
* Repairs respirators using only authorized parts or returns the unit to a factory authorized repair center.
* Issues RPE to employees as required.
* Maintains training, fit-testing and medical clearance records.
* May appoint a *RPE Custodian* to assist with fit-testing, training, ordering/issuing RPE, record-keeping and other duties as assigned.
  1. ***Occupational Healthcare Provider***:
  + Performs medical evaluations of employees assigned to the RPP to determine if workers assigned to tasks requiring the use of RPE are physically, psychologically, and physiologically qualified to use this equipment.
  + Prepares a medical statement for each user, noting whether they are qualified for RPE use, qualified with restrictions (specified), or not qualified.
  + Informs RPPM of employee's ability to use various types of RPE, indicating restrictions, if any, and informs the RPPM of any potential problems.
  1. ***Supervisors*** *and* ***Safety Department***:
  + Ensures risk assessment has been conducted to determine when RPE is necessary.
  + Develops and implements operation specific SOPs for use of RPE. The *RPPM* will approve SOPs prior to their use.
  + Ensures the employees maintain RPE in their work areas in accordance with requirements of this manual.
  + Ensures employees receive initial and annual refresher training in the proper use, care and maintenance of respirators.
  + Ensures that only personnel who have been medically qualified and properly trained are permitted to use RPE.
  1. ***Facility personnel*** *subject to the RPP*:
  + Attend training prior to initial assignment of tasks requiring respiratory protection, and annually thereafter.
  + Obtain and use RPE as instructed by the *RPPM*.
  + Inspect the RPE before and after each use. If a malfunction is noted, report it to your supervisor and the *RPPM*.
  + Perform positive and negative pressure fit-tests prior to each use of RPE with tight fitting face-pieces. See *RPPM* for exchange of cartridges or filters as necessary. Cartridges are to be replaced after approximately *80 hours* of use.
  + Air flow testing for PAPRs will be performed prior to use of the RPE.
  + Perform primary maintenance and cleaning of assigned RPE.
  + Report to Occupational Health Physician for medical examination when requested.
  + Employees issued negative pressure or tight-fitting face-piece respirators (to include filtering face-pieces) must remain clean-shaven. Facial hair will interfere with the seal of the respirator. Employees who do not wish to remain clean-shaven will turn in their respirator to the *RPPM* and will use Powered Air Purifying Respirators with Tyvek hoods when respiratory protection is necessary.
  + Properly implement all applicable biorisk management measures.

1. Risk Assessment and RPE Determination

A risk assessment for a given project or procedure must be conducted to determine when RPE is necessary (refer to Biorisk Management Manual (Chapter V, Risk Assessment; Chapter VII, Occupational Health and Medical Surveillance; Chapter X, Entry and Exit Procedures; Chapter XIV, Personal Protective Equipment). Once it has been determined that RPE is necessary, the subsequent selection, procurement, training, use and disposal-related activities can be conducted (refer to PPE SOP).

1. Selection and Procurement of Respiratory Protection Equipment

Respirators shall be selected on the basis of risks to which the worker is exposed. When air purifying respirators are recommended, the appropriate type of filter or chemical cartridge is selected. A respirator and related supplies should be certified or approved by some regulatory body.

* *What level of protection is required?*
* *What type of respirator is needed (e.g., half-face or full-face air purifying respirator, powered air purifying respirator)?*
* *What types of filters are needed (mechanical, gases, volatile organic compounds (VOCs), vapors, chemicals, gas, what particulate size)?*
* *Who is an appropriate vendor for respirators and associated supplies?*
* *Is this manufacturer’s respirator design the least likely to create additional unnecessary risk (e.g. does it provide good peripheral and clear vision, the least physical stress on the individual, etc.)?*

Only the *RPPM* is able to submit orders for RPE. Purchasing will accept requests for purchase of RPE only from the *RPPM*.

1. Medical Clearance

A basic medical evaluation should be undertaken for employees required to wear respirators as part of their work. It should cover contraindicated conditions for respirator usage. Different levels of medical evaluation exist, from simple employee completed questionnaires (refer to Respirator Medical Evaluation Questionnaire, Attachment A), to extensive health status questionnaires to complete physical evaluation by trained medical professionals. A facility should determine which level is most appropriate to their staffing capabilities knowing that failure to evaluate staff may create a risk.

Prior to medical evaluation by the *Occupational Healthcare Provider*, employees will complete a Respirator Medical Evaluation Questionnaire (Attachment A). Present this completed form to the *Occupational Healthcare Provider* who will provide any required medical examinations and sign the Medical Clearance Form (Attachment B) if no contraindications to use of RPE are determined. A copy of the form will be maintained by the employee, the *RPPM* and a copy will be placed in the employee's medical record.

* *What type of medical review is necessary (e.g., questionnaire review, pulmonary function test, chest x-ray, echocardiogram, urinalysis, complete blood count)? Does your Occupational Healthcare Provider have general guidelines for these assessments?*
* *How often will medical clearance be evaluated? Annually?*

1. Fit-Testing

Individuals required to wear negative-pressure respirators should be fitted properly and tested for an adequate seal prior to use in a contaminated atmosphere (refer to Respirator Fit-Testing Guidelines, Attachment C). In addition, instructions on performing positive and negative pressure checks are provided to respirator users so that they may check their respirator’s fit in the field.

* *How is fit-testing conducted (qualitative and/or quantitative)?*
* *How often will fit-testing be evaluated? Annually?*

Negative pressure or tight-fitting face-piece respirators shall not be worn with a beard, sideburns, or a head covering which protrudes under the face-piece. Conditions which prevent a good face-piece-to-face seal, for example, frames of prescription glasses, goggles, absence of dentures, etc., will be cause for denial of RPE use by the employee. Respirators equipped with a face-piece will not be worn if facial hair comes between the sealing periphery of the face-piece and the face, or if the facial hair interferes with valve functions

1. Training

All employees enrolled in the Respiratory Protection Program will receive proper training and education. The training programs will be designed to meet the needs of affected employees, the job tasks, and the type(s) of respiratory protection to be worn. Initial Training will provide individuals with the opportunity to handle the respirator, have it fitted properly, test the face-piece-to-face seal, if applicable, wear it in normal air for acclimation, and finally to wear it in a test atmosphere. The *RPPM* shall ensure that each employee can demonstrate knowledge of all the below information pertaining to training. Training records will be maintained. Training shall include, at a minimum:

* Why the respirator is necessary and how improper fit, usage, or maintenance can compromise the protective effect of the respirator;
* Respirator selection and identification of cartridges, filters, and canisters based on the hazard and respirator capabilities and limitations;
* How to use the respirator effectively in emergency situations, including situations in which the respirator malfunctions;
* How to inspect, put on and remove, use, and check the seals of the respirator;
* How to perform positive and negative pressure tests prior to each use of RPE to ensure satisfactory face seal and valve function;
* Handling, use and care of the respirator, e.g., need for cleaning, maintenance, storage and/or replacement;
* How to recognize medical signs and symptoms that may limit or prevent the effective use of respirators;
* Wearing of contact lenses in contaminated atmospheres with respiratory protection equipment;
* Medical and safety aspects of the program;
* An explanation of why engineering or process-oriented controls are not feasible.

Refresher training will be conducted when the following situations occur:

* Annually.
* When there are changes in the workplace.
* When there are changes in the type of respirator.
* When the employee's knowledge or use of the respirator indicates that the employee has not retained the requisite understanding or skill.
* Any other situation arising in which retraining appears necessary to ensure safe respirator use.

1. Respiratory Protection Equipment Use and Care

Respirators shall be issued for the exclusive use of one worker by the RPPM. Respirators shall be inspected, cleaned and disinfected/decontaminated by the user on a routine basis. Use of respiratory protection equipment is authorized when:

* The *RPPM*, in coordination with the supervisor, has determined that there are no feasible engineering or work practice controls that can be used to adequately control an identified respiratory risk.
* After the *Occupational Healthcare Provider* has determined the user is medically qualified to wear a respirator.
* Training and fit-testing requirements have been met.

Respirator users are responsible for regular cleaning and inspection of their respirators, including looking for defects and missing parts. Respirators should be stored properly in order to protect them from dust, sunlight, excessive heat or cold, moisture and chemicals. No replacement of parts or adjustments to RPE is authorized beyond those specified by the manufacturer's recommendations. Replacement of worn parts, except cartridges or canisters, will be performed by the *RPPM* only. The user is responsible for basic maintenance to include inspection and cleaning of the respirator.

1. Recordkeeping

Written SOP's shall be prepared and maintained for use of RPE in each work area where it is required. Local records of RPE training and fit testing will be maintained by the *RPPM and/or Safety Department*. Additional records will include:

* Date of issue and return of RPE.
* Dates of initial and annual refresher training provided.
* A current inventory of RPE and parts.
* The dates of inspection of RPE.
* The type and manufacturer of the RPE chosen by the employee after training by the RPPM.
* The frequency and method of fit-testing, test results, date, and name of person conducting the test (refer to Respiratory Fit-Test Form, Attachment D).
* Incidents occurring with respirator use, responses to those incidents, the findings of a root cause analysis of the incident and corrective actions taken *(see the Incident Response Program Plan).*

1. Performance Evaluation

Regular monitoring, measuring and evaluation of the appropriateness and effectiveness of the Respiratory Protection Program shall be conducted by the *RPPM* and improvements made where indicated.

1. References
   1. National Institute of Occupational Safety and Health Respiratory Decision Logic- NIOSH Publication 87-108.
   2. Occupational Safety and Health Administration Standard 29 CFR 1910.134- Respiratory Protection (General Industry).
   3. ISO 35001 : 2019, Biorisk management for laboratories and other related organisations, <https://www.iso.org/standard/71293.html>
   4. World Health Organization (WHO), Laboratory Biosafety Manual, 4th Edition, <https://www.who.int/publications/i/item/9789240011311>
   5. Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition, <https://www.cdc.gov/labs/BMBL.html>
2. Attachments
   1. Respirator Medical Evaluation Questionnaire Template
      1. (<http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9783>)
      2. (<http://hhcorporatewellness.org/forms/> )
   2. Medical Clearance Form Template
   3. Respirator Fit-Testing Guidelines
   4. Respiratory Fit-Test Record Form