

2012

MCW's Respiratory Protection Program Manual

Describes requirements of the OSHA-compliant respiratory protection program at MCW, and must be made available to any employee upon request.





Medical College of Wisconsin (MCW) – Respiratory Protection Program Manual

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Reference Links

Medical Questionnaires – On-Line Forms:

- [Medical Questionnaire - Initial](#)
- [Medical Questionnaire – Annual Renewal](#)

CDC/NIOSH Guidance Documents:

- [Understanding Respiratory Protection Against SARS](#)
- [NIOSH TB Respiratory Protection Program in Health Care Facilities – Administrator’s Guide](#)



- [Interim Guidance on Infection Control Measures for 2009 H1H1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel](#)

OSHA Standards:

- [Respiratory Protection Standard \(29CFR1910.134\)](#)
- [Appendix D of OSHA's Respiratory Protection Standard](#) – this must be provided to all employees voluntarily wearing disposable N95 respirators

MCW Respiratory Protection Policies:

- [Respirator Fit Test Policy \(CL.OH.290\)](#)
- [Respiratory/Tuberculosis Protection Plan \(CL.OH.300\)](#)



I. Introduction to the Respiratory Protection Program

This program was instituted in response to the pandemic flu virus (novel H1N1), and to address the current Center of Disease Control (CDC) and Occupational Safety and Health Administration (OSHA) recommendations for respiratory protection throughout both MCW's clinical and research settings.

MCW requires respiratory protection for certain jobs and tasks at MCW, which may include:

- Medical staff exposed to patients with confirmed or potentially active tuberculosis,
- Medical staff conducting procedures that may aerosolize infectious particles (e.g. aspirations, intubations),
- Research staff potentially exposed to infectious agents in biocontainment laboratories,
- Morgue staff potentially exposed to formaldehyde vapors or airborne particulates during certain tasks,
- Animal technicians and other staff handling animals in certain situations, to prevent exposure to animal allergens or pathogens,
- Trained emergency response staff potentially exposed to particulates or vapors associated with small chemical spill clean-up,
- Trained Environmental Health & Safety (EHS) staff which may perform certain procedures when handling waste materials, and
- Maintenance personnel working in certain areas or performing certain tasks.

MCW has determined that exposure to patients with confirmed or suspected seasonal influenza will be controlled by wearing surgical masks, which require no fit testing, and provide only droplet protection. Current CDC and OSHA recommendations require the use of a N95 respirator whenever an individual may be exposed to *Mycobacterium tuberculosis* or any other aerosolized biologic hazard. Host health care institution policies regarding respirator use will be followed by as appropriate. Medical procedures which are known to generate such aerosols will require those involved to wear a tight-fitting facemask or Powered Air Purifying Respirator (PAPR), which will require a medical, training, and fit testing (Note: Fit testing required for tight-fitting facemasks only).

- a. **Applicable Regulatory Requirements** – Occupational Safety and Health Administration (OSHA) requirements for a Respiratory Protection Program apply to all occupational exposures to contaminated air where the employee is:
 - Exposed to a hazardous level of an airborne contaminant,
 - Required by the employer to wear respirators, or
 - Permitted to wear respirators on a “voluntary” basis



- i. **OSHA Respiratory Protection Standard – 29 CFR 1910.134**) – OSHA’s regulatory requirements for any company requiring respiratory protection be worn in certain situations.

- ii. **OSHA’s Access to Employee Exposure and Medical Records standard (29 CFR 1910.1020)** – Records of medical evaluations required by the Respiratory Protection Standard must be retained and made available in accordance with 29 CFR 1910.1020.

II. Program Purpose and Scope

Purpose - The Respiratory Protection Program at MCW exists to protect employees from exposure to an identified chemical or biological contaminant.

Scope - This program covers all clinical or research employees of MCW who wear or may be required to wear tight-fitting respirators, or loose-fitting PAPRs.

III. Roles and Responsibilities

a. Program Administration –

- i. The **Director of Environmental Safety & Health (EHS)** in consultation with the Manager of Occupational Health Services, is responsible for
 1. Determining what criteria will govern respirator use at MCW,
 2. Program and policy development and revisions, and
 3. In the event of respirator shortages, the Manager of Occupational Health Services will determine what changes will be instituted at MCW regarding the clinical use of respirators.
- ii. The **Manager of Occupational Health Services** is considered the **Program Administrator**, and is responsible for the day-to-day administration of the program, and must keep current on respiratory protection and maintain an awareness of good practice and changing regulations. This person or his/her designee may:
 1. Conduct fit testing,
 2. Conduct training,
 3. Review medical questionnaires,
 4. Maintain all medical records and fit test results associated with respirator use,
 5. Maintain training records associated with respirator training (Records must be kept and made available to the employee and his/her representative, as prescribed under the OSHA standard 29 CFR 1910.1020), and
 6. Conduct a medical review if any medical problems from respirator use are observed by the respirator wearer.
- iii. The **Environmental Health and Safety (EHS) Department** (Safety Officer or Certified Industrial Hygienist) is responsible for evaluating hazards and performing risk assessments associated with occupational exposure and respirator use, and respirator selection. EHS may conduct training and fit

testing, periodically review documentation required under the OSHA Respiratory Protection standard, and evaluates and updates the written program as necessary.

The EHS department may train others to perform fit testing and conduct annual training. This training will provide information necessary to (i) properly train the staff who will be required to wear respirators, and (ii) conduct fit testing and teach others if necessary, how to conduct a proper fit test.

- b. **MCW Occupational Health Services (MCW-OHS)** is responsible for overseeing the medical aspects of this program, including determining the criteria for medical exams, the frequency of medical exams, and the questions making up the medical questionnaire. The Medical Director has determined questions 1-9 are the only applicable questions for use of disposable N95 respirators, under the conditions of use expected at the facility. If necessary, MCW-OHS will provide additional medical evaluation. If a full-face respirator is being worn, the Portacount quantitative fit test is done in order to achieve a Protection Factor of 50.
- c. **Supervisors** are responsible for ensuring employees under their supervision have received training, fit testing, and have approved medicals to be able to wear respirators. Each supervisor must know when and where respiratory protection is required, and enforce the use of proper respiratory protection when needed.
 - i. For research staff, each supervisor must work with the EHS if any concerns about the respiratory protection program are brought forward, and must notify the EHS if any employee has concerns about wearing a respirator.
 - ii. For clinical staff, each supervisor must work with MCW-OHS if any concerns about the respiratory protection program are brought forward, and must notify the MCW-OHS if any employee has concerns about wearing a respirator.
 - iii. **Employees** who may enter patient isolation rooms where patients are (i) isolated with airborne or airborne/contact precautions, or (ii) involved in procedures that may generate infectious aerosols, are responsible to
 1. **Annually** attend training, submit a medical questionnaire for evaluation, and be properly fit tested for a respirator PRIOR to wearing respiratory protection.



2. Follow proper procedures for wearing a respirator. Employees may **not** wear a respirator unless they are clean-shaven, have been properly trained, fit tested, and are medically qualified.
 3. Notify their supervisor if they have any problems with respirator fit, or experience symptoms (e.g. difficulty breathing, chest pains) associated with respirator use.
 4. Report any health concerns relating to respirator use or changes in health status to the MCW-OHS.
- iv. Employees that may be required to wear a respirator for clinical exposures may include nursing staff, physicians, or those providing therapy or other activities.
 - v. Non-clinical employees may be required to wear a respirator for research or lab-related exposures, which may include research investigators and their staff; animal husbandry workers if required for particulate protection; facility personnel entering biocontainment facilities or doing certain tasks; morgue employees; or EHS employees that may be involved in small spill clean-up, or waste handling activities.

IV. Respiratory Protection Program Elements

- a. **Training** –Training will be conducted initially, and annually thereafter. Training may be conducted in groups (e.g. as part of “Authorized User Training” for those with access to the containment lab), or individually. One-on-one training may be conducted in conjunction with the fit test, however only subsequent to an approved medical clearance.

Employees must have the opportunity to ask questions during training. Employees must demonstrate their understanding of the topics covered in training at the time of fit testing. The trainer will assess the knowledge of the trainee as part of the fit testing procedure. A score of 80% or higher must be achieved if a written test is given, or the training must be repeated. If the fit testing and training is completed together, the trainee must be able to successfully don and doff the mask, and must communicate understanding of use restrictions, proper storage and maintenance, etc.

Training attendance (and quiz scores, if applicable) must be documented and retained by the trainer, as proof of training. Dates of training and fit testing are recorded in a training database, if conducted by EHS. MCW-OHS maintains training and fit testing records for those employees trained and fit tested by that office.

Training must include information on:

- Exposure hazards
- When and why respirators must be used (conforming to CDC Guidance)
- Respirator selection
- Criteria for respirator use
 - Training
 - Medical approval
 - Fit testing
 - How to use a respirator
 - Demonstration of proper donning and removal techniques
 - Inspection
 - User “seal” checks
- Limitations of respirators
- Medical signs and symptoms limiting the use of respirators
- Storing the respirator

- Information on fit testing, and what each employee can expect during the fit test process

b. Respirator Selection

- a. Disposable NIOSH-certified, N95 respirators were chosen for use for both clinical exposures and research-related particulate exposures. The following N95 tight-fitting respirators were chosen on the basis of comfort and fit, and latex-free properties:
 - i. 3M 1870
 - ii. TecnoL N95
 - iii. Other disposable respirators may be chosen at a future date, based on employee preference and availability
- b. North or 3M Half-mask and full-face respirators were chosen for use by Morgue personnel, some facility personnel for overhead dust exposure, and for EHS personnel during minor spill clean-up.
- c. 3M AirMate and EVA Bullard PAPRs are used in the research Biocontainment area (note: EVA Bullard PAPRs are replacing AirMates over time)
- c. Voluntary Respirator Use – Disposable N95 or other disposable respirators are the only “voluntary use” respirator permitted by MCW. MCW does not permit its employees to use personal respirators for work. MCW departments may provide disposable N95 respirators for voluntary use for the following work processes:
 - a. Working in animal areas for comfort or protection of the animals (note: all animal handling staff are fit tested and trained for disposable respirators)
 - b. Maintenance workers (Campus Operations) working in dusty operations
 - c. All employees who voluntarily use disposable respirators will be provided a copy of [Appendix D of the Respiratory Protection Standard](#), which details the requirements for voluntary use.
- d. **Medical Evaluation** – Using a respirator may place a physiological burden on employees that varies with the type of respirator worn, the job and workplace conditions in which the respirator is used, and the medical status of the employee.

Employees need to be medically cleared to wear respirators before using them or being “fit tested.” Negative pressure respirators restrict breathing, some respirators can cause claustrophobia. Each of these conditions may adversely affect the health of some employees who wear respirators. MCS-OHS will medically

evaluate employees to determine under what conditions they can safely wear respirators.

i. Medical Questionnaire –

Any employee required to wear a respirator (this does not include loose-fitting surgical masks) must fill out an [on-line Medical Questionnaire](#), which is reviewed by MCS-OHS. This form is required prior to the first mandatory use of respiratory protection and at least every five years thereafter. This form must also be filled out if the employee's health status has changed, or there have been changes that may affect the fit of the respirator. The employer must provide time at work for the employee to complete the questionnaire, and the employee must be given time and opportunity to discuss any concerns with MCS-OHS.

The Medical Questionnaire is used as a screening tool to judge the ability of someone to wear a respirator. MCW will utilize the mandatory questions 1-9 from OSHA's Respiratory Protection Standard's Appendix C. Anyone answering "yes" to any question 2 through 8 must be further evaluated by MCW-OHS.

This medical evaluation must be conducted prior to anyone wearing a respirator for work (not including "voluntary use," and prior to "fit testing." Annually, employees will fill out an [on-line Interim Medical Questionnaire for Medical Use](#), which is an update to the medical questionnaire, which is electronically sent to MCW-OHS. OHS will determine if the employee needs follow-up, based on answers to the annual questionnaire. An employee **must** be reevaluated under the following circumstances:

- An employee reports medical signs or symptoms that are related to ability to use a respirator;
 - MCW-OHS informs the employer that an employee needs to be reevaluated;
 - Information from the respiratory protection program, including observations made during fit testing and program evaluation, indicates a need for employee reevaluation; or
 - A change occurs in workplace conditions (e.g., physical work effort, protective clothing, and temperature) that may result in a substantial increase in the physiological burden placed on an employee.
- **Medical determinations** – In determining the employee's ability to use a respirator, MCW-OHS shall issue a written recommendation regarding

the employee's ability to use the respirator from MCW-OHS. The recommendation shall provide only the following information:

- Any limitations on respirator use related to the medical condition of the employee, or relating to the workplace conditions in which the respirator will be used, including whether or not the employee is medically able to use the respirator;
 - The need, if any, for follow-up medical evaluations; and
 - A statement that MCW-OHS has provided the employee with a copy of the MCW-OHS's written recommendation.
- If MCW-OHS finds a medical condition that may place the employee's health at increased risk if a negative respirator is used:
- The employer will accommodate staff unable to use a negative pressure respirator with work assignments that will not involve this as a requirement, or supply the individual with a PAPR.
- Prior to fit testing, and prior to wearing any type of mandatory respiratory protection, each employee must have received medical "clearance" with a written approval from MCW-OHS to wear a respirator. All examinations and questionnaires must remain confidential between the employee and MCS-OHS. MCW-OHS will retain the written recommendations regarding each employee's ability to wear a respirator, and will supply this written recommendation to EHS, in the event EHS will conduct fit testing/training.

- e. **Fit Testing** – Fit testing is an evaluation of a respirator using either a Qualitative Fit Testing (QLFT) or Quantitative Fit Testing (QNFT) method, which evaluates the "fit" of a respirator for each individual user.
- i. Each employee that is required to wear a negative pressure respirator must be fit tested for the exact make, model, and size of respirator that they will be using while working.
 - ii. Each employee must "pass" a fit test before wearing a respirator for work. This fit testing procedure is repeated annually (within 12 months of previous test), and whenever there is a reason to suspect they are no longer getting a proper fit.
 - iii. Some reasons for repeating a fit test include:
 - 1. An employee reports, or MCW-OHS, supervisor, or EHS makes visual observations of changes in the employee's physical condition that could affect respirator fit. Such conditions include,

but are not limited to, facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight.

2. If after passing a QLFT or QNFT, the employee subsequently notifies the employer, EHS, supervisor, or MCW-OHS that the fit of the respirator is unacceptable, the employee shall be given a reasonable opportunity to select a different respirator facepiece and be retested.

Fit testing will be performed by someone who has been trained by a competent person (i.e. Certified Industrial Hygienist), by a Safety Officer in EHS, or by the MCW-OHS staff.

Either the QLFT or QNFT method of fit testing will be used. For QLFT, MCW will use a TSI PortaCount fit tester, and must obtain a “fit factor” of 100 for each N95 respirator. A full-face respirator must obtain a fit factor of 500, using the QNFT method, in order to have a Protection Factor of 50. A QLFT will be conducted using a Bitrex Test or Saccharin kit and method. In the event Powered Air Purifying Respirators (PAPRs) are utilized, there is no requirement for fit testing; however employees must be trained and have received medical clearance to wear a PAPR.

Fit test records must be retained for at least one year, or until the next fit test is performed.

f. Respirator Use (General)

- a. Inspect the respirator prior to use – Each user must inspect the respirator for damage prior to using it. Review and ensure that there are no tears, and if there are, do not use the respirator. PAPR users must verify air flow and check all respirator parts.
- b. Perform a “seal” check prior to each use, to ensure the respirator has a good fit, sealing well around the face.
- c. Wash your face after extended uses of respirators to prevent irritation. Sometimes wearing a respirator for extended periods can cause some skin irritation due to buildup of condensation or oils under the respirator.
- d. Respirators kept for emergency use (i.e. biocontainment emergency PAPRs) are checked on a monthly basis by EHS staff)
- e. Disposable respirators (e.g. filtering facepiece N95 respirators) are meant to be disposed of, and not used over the period of multiple days.

- f. Reusable respirators with chemical or particulate cartridge (negative pressure or positive pressure types) can typically be used multiple times before the cartridge must be replaced. Cartridges should be dated when they are first used. Cartridges used for vapor filtration are dependent upon the chemical exposure:
 - i. HEPA Particulate filters on PAPRs are replaced if air flow decreases (based on flow test conducted before each use.
 - ii. Particulate filters on negative pressure respirators are replaced when they start becoming difficult to breathe through, signifying filter loading.
 - iii. Formaldehyde cartridges – Must be discarded and replaced with a new filter after 3 hours of continual use, or at the end of a shift (whichever is shortest)¹
 - iv. Chemical cartridges used with PAPRs or full-face respirators worn for spill clean-up or chemical bulking will be changed based upon spill event (chemical involved, concentration and duration of the event), and will be determined using the cartridge manufacturer’s Service Life Indicator software (North or EVA Bullard).
 - v. Combination HEPA/chemical cartridges used on PAPRs worn by Facility Maintenance staff working on exhaust fans will be changed annually, due to very low levels of volatile exposures.
- g. **Clinical Use** – Particulate respirators will be used by MCW employees entering rooms under airborne or airborne/contact isolation.
 - a. Mandatory Use - Employees that may be required to wear a respirator include those from nursing, physicians, or other MCW staff. Typically the length of time a respirator will be used at any one time will be less than 30 minutes. Respirator users must:
- h. **Research or Biomedical Research Center (BRC) Use** -
 - a. Mandatory use – Employees may be required to wear particulate respirators during certain animal procedures/animal husbandry procedures to protect against animal allergens or dander associated with various occupational diseases. This is based upon recommendations from MCW-OHS (e.g. working with sheep).
 - i. Any time cage bedding from rodent housing is dumped without the use of a ventilated dump station or biosafety cabinet, a particulate respirator

¹ based upon the [OSHA formaldehyde standard](#)

- (N95 or tight fitting elastomeric HEPA respirator) is mandatory. If cage bedding is dumped into an unventilated dump station that is nearby a ventilated dump station, both technicians must wear respiratory protection.
- ii. HEPA-filtered PAPRs are used by technicians or others entering the containment lab. Alternatively a half-mask negative pressure respirator with a HEPA filter may be used
 - iii. Respirators may be prescribed by EHS, based on a risk assessment of a laboratory safety protocol.
 - iv. Anatomists that are working with cremation remains (full-face HEPA-filtered negative pressure respirator); when using a saw to open the skull of embalmed cadavers, the same respirator is used with a combination HEPA/organic vapor/formaldehyde cartridge. This cartridge life is limited to 3 hours or one shift, whichever is shorter, based on formaldehyde exposure.
- b. Voluntary use – Some employees may choose to wear surgical masks or N95 respirators for protection of the animal, or if someone feels more comfortable wearing a respirator despite engineering controls (e.g. biosafety cabinet, ventilated dump stations, or fume hood).
- i. Facility Maintenance/EHS/Other Uses -**
- a. Mandatory use –
 - i. Disposable N95 particulate respirators or elastomeric negative pressure HEPA-filtered respirators may be worn when:
 - 1. Entering biocontainment laboratories for maintenance work or audits,
 - 2. Working with materials that have visible mold, or
 - 3. Working on rooftop exhaust fans if other exhaust fans in close proximity can not be turned off
 - ii. Full-face negative pressure respirators with multi-gas/HEPA cartridges (Protection Factor of 50) or Full-face hood with EVA Bullard PAPR and multi-gas/HEPA cartridges (Protection Factor of 1000) will be work by EHS staff during spill cleanup which requires respiratory protection. These respirators are also worn when bulking organic solvents in hazardous waste storage areas.
 - b. Voluntary use –

- i. Disposable N95 particulate respirators may be worn during short-term tasks if the person performing the task feels more comfortable. These tasks may include sanding drywall, installing fiberglass wall panels, or removing ceiling panels.
- j. **Contractor Use of Respirators at MCW** – MCW may employ contractors to maintain equipment that is inside the biocontainment facility, which requires a minimum of an N95 respirator for entry.
 - a. Prior to using respirators, a contractor must provide proof of that they have been trained, fit tested and passed a medical within the past year. The contractor is expected to provide their own respiratory protection for entry, and is responsible for the proper use of respiratory protection. In the event they rely on disposable N95's available on-site, the contractor is obligated to provide proof that they have been fit tested for that particular brand and size of disposable N95.
 - b. Prior to conducting a project on-site, where respiratory protection is worn, the contractor (or General Contractor) must submit the written Respiratory Protection Plan (RPP) for each company that may wear respiratory protection. Proof of fit testing, medical clearance, and training must also be available. On large projects, such as asbestos removal projects, this information should be part of the submittal package.
- k. **Respirator Maintenance, Care and Storage** – Parts are not interchangeable between respirators. When repairing respirators or obtaining cartridges, the specific make and model of respirator's equipment must be used!
 - a. Disposable respirators (e.g. N95 particulate filtering facepieces): When used in a biocontainment lab, or for patient contact, these are considered disposable, one-time use respirators. Prior to use, respirators should be stored in such a manner as to maintain their proper shape and not become damaged. Damage can occur to some respirators if heavy items are placed on them, causing the respirator cup to lose its shape and integrity. Respirators can also become damaged and torn, resulting in a respirator that will not provide protection and may not be used.
 - b. 3M AirMate or EVA Bullard Powered Air Purifying Respirators (PAPRs): When used for biocontainment labs, these respirators are stored in the anteroom, directly outside the lab. Emergency use respirators are kept in the cold corridor. Emergency respirators are checked monthly by EHS staff.



- c. North or 3M Half-Mask or Full-Face Negative Pressure Respirators: Respirators are kept in the possession of those who use them. Respirator users are taught to store, clean, and inspect them properly.



V. Program Evaluation

The OHS Nurse Manager will conduct periodic evaluations of the clinical locations to ensure that the provisions of this program are being implemented. The evaluations will include regular consultations with employees who use respirators and their supervisors. Items to be considered will include:

- Comfort
- Ability to breathe without objectionable effort,
- Ability to perform all tasks without undue interference, and
- Confidence in the respirator fit.

EHS will conduct periodic evaluations of respirator use. In 2011, the decision was made to begin purchasing EVA Bullard PAPRs, and begin systematically replacing the older 3M Air-Mate HEPAs in the containment lab. The 3M Air-Mates are still usable, and can be redeployed to other areas, should the need arise.



VI. Documentation and Recordkeeping

- a. A written copy of this program document and the OSHA Respiratory Protection Standard shall be kept in the EHS office and on the MCW Intranet, and made available to all employees.
- b. A copy of this program shall be given to MCW-OHS who will be involved in medical evaluations for respirator use.
- c. Copies of training and fit test records shall be maintained as follows:
 - vi. Copies of training and fit testing records shall be maintained by MCW-OHS. These records will be updated as new employees are trained, as existing employees receive refresher training, and as new fit tests are conducted
 - vii. For employees covered under the Respiratory Protection Program, MCW-OHS shall maintain copies of the medical written recommendation regarding each employee's ability to wear a respirator. The completed medical questionnaires and evaluating physician's documented findings will remain confidential in the employee's medical records (MCW-OHS).