

National Institutes of Health

Respiratory Protection Program

2018

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Respiratory Protection Program (RPP) Manager.

Significant Content Changes Since Prior Version:

1. RPPM and DOHS not responsible for PAPR testing.
2. Clarification that each IC is responsible for purchasing PAPRs should their employees require them.
3. RML is the only group to use Qualitative rather than Quantitative fit testing, and only allowed to do so until Dec. 31st 2018.
4. Clarification on scheduling.
5. Removal of citations from OSHA; OSHA does not apply to other federal agencies, so it is not a regulatory compliance driver. However, I noted that the NIH RPP is to be equivalent or more protective than OSHA.
6. Fixed the volunteer-N95-usage section (Appendix A); it is now more clear, includes keeping facial hair out of the respirator's sealing zone, and contains a small tear-off section to function as a reminder for the user. This leaves the user an easy way to contact DOHS and also reminds them of the general rules of thumb to keep in mind.
7. Clarification on End-Of-Service-Life-Indicators and what is acceptable or not.
8. Identified the need to document key decisions throughout various parts of the RPP processes and associated documents or choices.
9. Clarified that DOHS and RPPM are not the appropriate individuals for administering the medical questionnaire; OMS is.
10. Removed medical screening questionnaire from DOHS domain entirely; Appendix C-3 removed. Only OMS should do medical questionnaires.
11. Clarified roles and responsibilities of supervisor a bit; noted "timely manner" because DOHS has had problems with people being over 300 days overdue on their fit tests.
12. Clarified that the individual is responsible for maintaining their PAPR in good working condition and checking on the PAPR components, etc.
13. Clarified that it is the individual's responsibility to notify DOHS that they want a fit test.
14. Clarified what to do if individuals fail RPP training module.
15. Clarified why facial seal is important.
16. Requires that if On-the-Job-Training (OJT) is used, it should be supplemental. Online training and exams are still required.
17. Clarification on storage of respirators and components.
18. Clarification on repair of respirators and re-testing before putting a respirator back into use.
19. Clarification on RPP record keeping. OMS keeps medical records, not TAB.

Editorial/Minor Changes:

1. Grammar/spelling/punctuation as needed.
2. Format changes, including standardized cover page per DOHS requests.
3. Fix spacing between periods, semicolons, colons.
4. Fixed margins.

CONTENTS

1.0	INTRODUCTION.....	1
1.1	Purpose	1
1.2	Scope and Applicability	1
2.0	DEFINITIONS.....	2
3.0	RESPONSIBILITIES.....	4
3.1	Respiratory Protection Program Manager (RPPM).....	4
3.2	Safety Specialist	5
3.3	Supervisor.....	5
3.4	Employee.....	5
3.5	Occupational Health Registered Nurse (OHRN)	5
3.6	Occupational Medical Services Physician/Physician Assistant (OMS-P/PA)	5
3.7	Contractors	5
4.0	RESPIRATORY HAZARD ASSESSMENT, RESPIRATOR SELECTION, and MEDICAL EVALUATION.....	6
4.1	General	6
4.2	Respiratory Hazard Assessment.....	6
4.3	Respirator Selection	6
4.4	Medical Evaluation.....	7
5.0	RESPIRATOR TRAINING AND FIT TESTING.....	8
5.1	Training Objectives	8
5.2	Scheduling.....	8
5.3	Training Syllabus	8
5.4	Respirator Fit Testing.....	9
5.5	Quantitative Fit Testing Procedure.....	9
5.6	Qualitative Fit Testing Procedure (Only applicable to Rocky Mountain Labs [RML] until Dec. 31 st 2018).....	9
6.0	RESPIRATOR USE.....	10
6.1	Face-piece Seal Leakage	10
6.2	Continuing Respirator Effectiveness.....	10
6.3	Issuance of Respirators.....	10
6.4	Identification of Filters and Cartridges	10
6.5	Glasses.....	11
7.0	RESPIRATORY MAINTENANCE AND CARE.....	11
7.1	Respirator Cleaning and Disinfection	11
7.2	Respirator Storage	11

7.3	Respirator Inspection.....	12
7.4	Respirator Repair.....	12
8.0	SUMMARY OF THE ENROLLMENT PROCESS.....	12
8.1	Enrollment for Negative Pressure Respirators.....	12
8.2	Enrollment for Powered Air Purifying Respirators.....	13
9.0	PROGRAM EVALUATION.....	13
10.0	RECORD KEEPING.....	13
10.1	Medical Evaluation.....	13
10.2	Fit Testing.....	13
10.3	Respiratory Protection Program.....	13
	APPENDIX A: INFORMATION FOR EMPLOYEES USING RESPIRATORS WHEN NOT REQUIRED UNDER THE STANDARD.....	14
	APPENDIX A: INFORMATION FOR EMPLOYEES USING RESPIRATORS WHEN NOT REQUIRED UNDER THE STANDARD.....	14
	APPENDIX B: Respirator Decision Logic.....	16
	APPENDIX C-1: ASSIGNED PROTECTION FACTORS ¹	18
	APPENDIX C-2: OSHA Medical Evaluation Questionnaire for Respirator Use - Initial Clearance...	19
	APPENDIX D-1: Half & Full Face Respirator Training Outline.....	24
	APPENDIX D-1A: Half and Full Face Respirators - Test.....	27
	APPENDIX D-2: SINGLE USE RESPIRATOR TRAINING OUTLINE.....	28
	APPENDIX D-2A: SINGLE USE RESPIRATORS - test.....	31
	APPENDIX D-3: POWERED AIR-PURIFYING RESPIRATOR TRAINING OUTLINE.....	32
	appendix d-3A: POWERED AIR-PURIFYING RESPIRATORS (Air Mate) - test.....	37
	APPENDIX D-3B: POWERED AIR-PURIFYING RESPIRATORS (breathe easy) - test.....	39
	APPENDIX D-3C: POWERED AIR-PURIFYING RESPIRATORS (max air) - test.....	41
	APPENDIX E-1 QUANTITATIVE FIT TESTING PROTOCOL.....	44
	APPENDIX E-2: QUALITATIVE FIT TEST (QLFT) PROTOCOLS.....	46
	APPENDIX E-3: USER SEAL CHECK PROCEDURE.....	51
	APPENDIX F-1: RESPIRATOR CLEANING PROCEDURES.....	52
	APPENDIX F-2: RESPIRATOR INSPECTION CHECKLIST.....	53
	APPENDIX F-3: RESPIRATOR FIT-TESTING PROCEDURE FOR N-95 RESPIRATORS.....	54
	Appendix F-4: IRF-FREDERICK POSITIVE PRESSURE, SUPPLIED-AIR PROTECTIVE SUITS RESPIRATORY PROTECTION PROGRAM (RPP).....	56
	Appendix G-1: NIH Respiratory Protection program.....	62

**The National Institutes of Health
Office of Research Services
Division of Occupational Health and Safety**

RESPIRATORY PROTECTION PROGRAM

1.0 INTRODUCTION

1.1 Purpose

The National Institutes of Health (NIH) Respiratory Protection Program (RPP) establishes uniform procedures, in accordance with the [Occupational Safety and Health Administration \(OSHA\) Standards, 29 CFR Part 1910.134, Respiratory Protection](#), for the appropriate selection, use, and care of respiratory protective equipment for NIH employees.

1.2 Scope and Applicability

The Office of Research Services (ORS), [Division of Occupational Health and Safety](#) (DOHS), [Technical Assistance Branch](#) (TAB), provides administrative management for the NIH RPP. The NIH RPP applies to all Federal Employees at the NIH. Several employee groups provide additional, site-specific RPP training and administrative management, including: the NIH [Division of Fire and Rescue Services](#) (DFRS), the NIH [Division of Police](#) (DP), the NIH [Clinical Center](#) (CC), and any NIH Biosafety Level 4 (BSL-4) facilities. Most NIH contractors are not covered under the NIH RPP (the rare exceptions to this will be determined by DOHS TAB and documented). Those contractors not covered by the NIH RPP shall develop appropriate, adequate measures that provide their workers with respiratory protection and document/maintain records accordingly.

DFRS and DP employees are fully covered under the NIH RPP for operations requiring the use of negative pressure, tight fitting respirators. The DOHS, TAB provides support by providing respirator fit testing services to employees of the DFRS and DP. The DFRS and DP provide all other training and administrative management components for their own respective RPP.

CC employees are fully covered under the NIH RPP for operations requiring the use of negative pressure, tight fitting respirators. The CC Safety Office provides administrative management support for the NIH RPP within the CC, including: providing administrative management for patients on acid fast bacilli (AFB) and special respiratory isolation precautions for employees who perform higher risk procedures (e.g. work in the mycobacteriological laboratory) associated with patient care; determining the type and model of respirators to be used in the CC. If an employee is expected to use a Powered Air Purifying Respirator (PAPR), DOHS will provide initial and annual training through the HealthRX Respirator Fit module. The department/institute the employee is from will provide their employees with the corresponding PAPR on the job training and ensure the PAPR is being used correctly. Determination of who should be in the RPP is the responsibility of the employee's direct supervisor and OMS.

The use of Positive Pressure Airline Suits (PPAS) are required in NIH BSL-4 facilities. These facilities establish their own specific requirements, separate from those described in the NIH RPP. Employees



working in BSL-4 facilities receive respiratory support and training through the BSL-4 training program(s). Contact the Biosurity Manager for more details. See Appendix F-4, IRF-Frederick Supplied Air Respirator Program.

Voluntary use of a [National Institute of Occupational Safety and Health](#) (NIOSH) approved negative pressure respirator (e.g. half-face respirator) requires partial participation in the program. If the DOHS, TAB determines that voluntary use will not in itself create a hazard, the supervisor must provide the employee with the written information provided in [29 CFR Part 1910.134, Appendix D, Information for Employees Using Respirators When not Required Under Standard](#). See Appendix A, Information for Employees Using Respirators when Not Required Under the Standard. The employee must be medically cleared by the NIH [Occupational Medical Service](#) (OMS) to wear a respirator, and the employee must receive training on proper respirator maintenance procedures. The DOHS, TAB must determine that voluntary use will not in itself create a hazard and the employee must be provided with the information in Appendix A. The use of a dust mask (not defined as a respirator) does not require participation in the NIH RPP.

1.3 Policy Statement

It is the policy of the NIH to provide, at no cost to the employee, respiratory protection when: the best available engineering controls fail to adequately reduce employee exposure to respiratory hazards; substitution of respiratory hazards with less hazardous elements is not feasible; modifications in hazardous operations fail to reduce exposures to below regulated or acceptable levels; or, national guidelines for minimizing health care associated infections recommend respirator use. Respiratory protection shall be provided during interim periods when engineering controls are being implemented and no other means of worker protection is available. The Respiratory Protection provided by NIH shall be equivalent to or more protective than protection described in OSHA standards 29 CFR 1910.134. Industry best practices should be applied when practical, to reduce employee exposures.

2.0 DEFINITIONS

Air-Purifying Respirator

A respirator with an air-purifying filter, cartridge, or canister capable of removing specific air contaminants by passing ambient air through the air-purifying element.

Aerosol-Removing Respirators

A respirator that provides respiratory protection against airborne particulate matter, including dusts, mists, and fumes, but they do not protect against gases, vapors, or oxygen deficiency. It is a subset of an air-purifying respirator.

Assigned Protection Factor (APF)

The minimum expected workplace level of respiratory protection provided by a properly functioning respirator.

Respirator Cartridge

A container with a filter, sorbent medium, or combination of these items that removes specific contaminants (particulates, gases, and/or vapors) from air passed through the container.



Dust Mask

A mask that is not designed as a filtering face piece and is not certified by NIOSH for use as a respirator. The user is not required to participate in the NIH RPP.

Employee Exposure

Exposure to a concentration of an airborne contaminant that would occur if the employee were not using a respirator.

End-Of-Service-Life Indicator (ESLI)

A system that warns a respirator user of the approach of the end of adequate respiratory protection (i.e., a sorbent media is approaching saturation).

Filter

A respirator component used to remove particulates from inspired air.

Fit Factor

A quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit Test

A qualitative or quantitative evaluation of the air seal between the respirator and an individual's face.

Full-Face Respirator

A face-piece that covers from roughly the hairline to below the chin. On average they provide the greatest protection, usually seal most reliably, and provide some eye protection.

Gas/Vapor-Removing Respirators

Air purifying respirators that protect against certain gases and vapors by using various chemical cartridges (usually activated charcoal) to purify inhaled air. They are a subset of air-purifying respirators.

Half-Face Respirator

A face-piece that fits over the nose and under the chin and does not protect the eyes.

Immediately Dangerous to Life or Health (IDLH)

Any atmosphere that poses an immediate hazard to life or poses immediate irreversible debilitating effects on health.

Negative Pressure Respirator

A respirator in which the air pressure inside the face-piece is negative during inhalation with respect to the ambient air pressure outside the respirator.

NIOSH Approved

A respirator that has been tested by the National Institute for Occupational Health and Safety and assigned a NIOSH approval number.



Positive Pressure Airline Suits (PPASs)

A biological/chemical protective suite where the air pressure inside the suit maintains positive at all times. Breathing air is supplied through a supply hose via a compressor or compressed air cylinders.

Powered Air-Purifying Respirator (PAPR)

An air-purifying respirator that uses a blower to force ambient air through an air-purifying cartridge or filter and into the face-piece.

Qualitative Fit Test (QLFT)

A pass/fail evaluation of the seal between the respirator and the individual's face that relies on the individual's ability for sensory response to detect a challenge agent (e.g., sweet taste).

Quantitative Fit Test (QNFT)

A pass/fail evaluation of the seal between the respirator and the individual's face that used an instrument to measure the differential between a level of a challenge agent.

Self-Contained Breathing Apparatus (SCBA)

A respirator that provides breathing gas from a source independent of the surrounding atmosphere instead of purifying the atmosphere. The user carries the gas tank on his/her back.

Service Life

The period of time a cartridge or filter provides adequate protection to the wearer.

Single Use Respirator (SUR)

A NIOSH approved disposable negative pressure respirator with a filter as an integral part of the face-piece or with the entire face-piece composed of the filtering medium (e.g. N-95). SURs require full participation in the NIH RPP when use is required by the employer.

Tight-Fitting Face-piece

A respiratory face-piece that forms a complete seal with the face. It could be a half-face respirator or full-face respirator.

User Seal Check

A self-test conducted by a respirator user to determine if a respirator is properly seated to the face prior to its use in the workplace.

3.0 RESPONSIBILITIES**3.1 Respiratory Protection Program Manager (RPPM)**

The RPPM develops the NIH RPP's written operating procedures; coordinates inventory and acquisitions; remains abreast of changing regulations and recommendations concerning respirator use; and advises supervisors and workers in the selection, use, and maintenance of respirators upon request. The supervisor is responsible for the selection of appropriate respiratory protection. The RPPM shall periodically review and evaluate the effectiveness of the NIH RPP.



3.2 Safety Specialist

Institute or Center (IC) Safety Specialists shall periodically conduct walk-through surveys in their areas of responsibility. Safety Specialists shall notify the RPPM of any potential respiratory hazard noted during a survey and shall assist the RPPM in conducting a comprehensive respiratory hazard assessment for the determination of respirator use requirements.

3.3 Supervisor

The supervisor shall have a comprehensive knowledge of the potential respiratory hazards and respiratory protective requirements for their areas of responsibility. Supervisors shall seek guidance from the RPPM on proper respirator selection. Supervisors shall ensure that employees complete their interval medical clearance, attend annual fit testing, and complete their training in a timely manner.

3.4 Employee

Employees shall remain informed of potential respiratory health hazards and the respiratory protective requirements for their work areas. Employees shall complete a mandatory initial medical clearance, and will complete annual training and fit testing. Employees shall perform a positive/negative fit check with their respirator before each use and follow manufacturer, supervisory, and manufacturer guidelines for use, maintenance, and disposal of their respirator and its components.

3.5 Occupational Health Registered Nurse (OHRN)

Under the direction of the Medical Director, OMS, the OHRN shall provide medical clearance for NIH RPP enrollment through the administration of an initial medical questionnaire. Only employees free of respiratory or cardiac risk factors, as determined by the questionnaire, shall be cleared for respirator use by the OHRN.

3.6 Occupational Medical Services Physician/Physician Assistant (OMS-P/PA)

The OMS-P/PA establishes medical evaluations to determine an individual's health status relative to their ability to tolerate use of a respirator as to avoid an adverse medical event. The assessments are completed on those employees who are not initially cleared by the OHRN.

3.7 Contractors

NIH contractors shall have a fully implemented RPP, in accordance with or better than (RPPM and TAB Director signature concurrence needed for acceptance of alternative program; documentation) the requirements of the OSHA Respiratory Protection Standard, in place before performing work on behalf of the NIH that requires the use of respiratory protection. Contractors are to ensure that they meet *all* applicable RPP requirements (e.g. obtaining a medical clearance, fit testing, training) through their employer. "Applicability" is determined by the DOHS Contractor Safety Program Officer and the TAB Division Director, in cases where there is disagreement or lack of clarity.

TAB only administers these requirements to NIH employees and NIH contractors who meet the specific



conditions and evaluated by the DOHS TAB RRPM; TAB provides the training for N95s and the fit testing.

4.0 RESPIRATORY HAZARD ASSESSMENT, RESPIRATOR SELECTION, AND MEDICAL EVALUATION

4.1 General

Respiratory protection shall not be solely relied upon to provide protection against airborne workplace hazards. Whenever feasible, alternative control methods shall be used to eliminate or reduce hazardous exposures. NIH guidelines for assessing the degree of risk associated with a respiratory hazard, the potential for exposure in the workplace, and the process of selecting an appropriate respirator once a respiratory hazard assessment has been completed is described in the following sections. Supervisors and employees shall notify the RPPM of any significant changes in workplace conditions that may affect respirator use, or if engineering control methods can be used to eliminate the need for a respirator.

4.2 Respiratory Hazard Assessment

A respiratory hazard assessment will be conducted for any potential aerosol or airborne hazards (i.e. chemical, biological, radiological, or physical). Potential respiratory hazards may be reported to the RPPM by Safety Specialists after routine laboratory surveys or experimental protocol reviews, or by concerned investigators or research support personnel. Upon notification, the RPPM, with the assistance of the Safety Specialist, shall conduct a comprehensive respiratory hazard assessment to determine the degree of risk, the exposure potential during the specific operation, and the need for respiratory protection.

The assessment must take into account any hazardous properties of the potential respiratory hazard, as well as the work area characteristics and job description. Oxygen deficient atmospheres, physical and chemical properties of the hazard, adverse physiological interactions and health effects, actual airborne concentrations of the contaminant generated during work activities, and relevant occupational exposure limits (OEL) shall be considered. The location, operation or process characteristics, materials used or produced during the process, the employee's duties and actions, and any abnormal situations or characteristics which may affect respirator selection shall also be considered.

4.3 Respirator Selection

Appendix B, Respirator Decision Logic, shows the NIH Respirator Selection Chart; Appendix C-1, Assigned Protection Factors, and includes the NIOSH Assigned Protection Factors (APFs) for air purifying and powered air purifying respirators. Only NIOSH approved respirators are authorized for mandatory use at the NIH. Several respirators of differing size and type shall be made available to employees to ensure that wearer acceptability plays a role in selection.

If available, gas/vapor-removing respirators shall have cartridges equipped with a NIOSH approved end-of-service life indicator (ESLI). If an ESLI is not available, the supervisor of the affected employee shall implement a cartridge change schedule based on the manufacturer's supplied data, estimated breakthrough periods (provide calculations and reasons for parameters), workplace-specific conditions,



concentrations of contaminants in the workplace air, patterns of respirator use (i.e., whether use is intermittent or continuous throughout the workday), and environmental factors. The method utilized for determining the cartridge change schedule must be scientific in nature, quantifiable, rational, and shall be documented clearly, easily accessible, and available for review by internal and external auditors upon request. Potentially variable (even if only minutely) warning properties, such as odor, absolutely shall not be relied upon as the sole determining factor for cartridge replacement. ESLIs and cartridge change schedules will be reviewed periodically and updated as appropriate.

Aerosol-removing respirators shall be approved by NIOSH as defined under [42 CFR Part 84, Approval of Respiratory Protective Services](#). When particle size and composition are unknown, NIH employees shall only use High Efficiency Particulate Air (HEPA) filters as defined by 42 CFR Part 84.

4.4 Medical Evaluation

The NIH OMS must medically clear NIH employees for respirator use *prior to* adding individuals to the program. OMS adds employees, but only after OMS had medically cleared them for respirator usage. The program to conduct medical evaluations, ensure staff competencies, and abide by applicable regulations for occupational medical information is under the direction of the Medical Director, OMS. Medical clearance evaluations shall be administered confidentially and during normal working hours. Medical records are stored in a secured location with access restricted to authorized personnel only.

The OMS OHRN is responsible for determining fitness for duty for employees who require the use of a respirator. The OHRN shall administer the OSHA Medical Evaluation Questionnaire for Respirator Use, Initial Clearance (See Appendix C-2). Medical evaluation questionnaires shall be administered in a manner that ensures that employees understand the contents and have an opportunity to discuss the questionnaire and results with the OHRN. If an employee successfully meets the medical clearance requirements, the OHRN shall fill out an OMS Medical Evaluation of Functional Activities (MEFA) form. Any limitations for respirator use must be noted by the OHRN on the MEFA form.

If the OHRN fails to clear an employee, he or she shall arrange for the employee to be medically evaluated by an OMS Physician/Physician Assistant (OMS-P/PA). The medical evaluation shall include any medical tests, consultations, or diagnostic procedures that the OMS-P/PA deems necessary to make a final medical clearance determination. If the employee successfully meets the medical clearance requirements, the OMS-P/PA shall fill out the MEFA form. Any limitations for respirator use must be noted by the OMS-P/PA on the MEFA form.

If the OMS-P/PA identifies medical limitations for an employee that restrict the use of a negative pressure respirator, a PAPR shall be provided to that employee by his/her IC. Several PAPR types will be recommended by the RPPM; however, it is the IC's responsibility to purchase, maintain, and train their employees in the appropriate use of the PAPR. If the OMS-P/PA subsequently determines that the employee is fit to wear a negative pressure respirator, the IC is no longer obligated to provide a PAPR to that employee. Certain ICs may have additional protocols and options for use of the PAPR

OMS is responsible for notifying the RPPM when an employee is medically cleared. Upon notification, the RPPM shall schedule the employee for respirator training and fit testing.

OMS shall provide a medical re-evaluation for respirator users whenever:



- A. An employee reports symptoms that are relevant to his/her ability to wear a respirator.
- B. Information from the RPPM, including observations made during fit testing or program evaluation, indicates a need for an employee reevaluation.
- C. A change occurs in workplace conditions (physical work effort, protective clothing, temperature, etc.) that may result in an increase in the physiological burden placed on the employee.

5.0 RESPIRATOR TRAINING AND FIT TESTING

5.1 Training Objectives

Upon completion of training, employees shall be able to demonstrate a working knowledge of the potential respiratory hazards and respirator requirements for their work areas. Employees shall demonstrate proficiency in the proper use, inspection, maintenance, and storage of a respirator. Employees shall understand the respirator's limitations and capabilities, as well as any physical or medical conditions that may limit or prevent the effective use of a respirator.

5.2 Scheduling

It is the employee's responsibility to schedule a fit test with NIH after OMS has medically cleared them and they have completed the Respiratory Fit Test Training. Respirator fit testing (e.g. N-95 respirator) and training (e.g. N-95 respirators, PAPR) shall occur upon initial enrollment in the RPP and every twelve (12) months thereafter. HealthRx will provide a notification to personnel when they are due for the 12-month fit test and/or training. If personnel fail to respond to a notification after one month, they will be removed from the NIH RPP and their supervisor will be notified. This is to keep the database accurate.

More frequent training and/or fit testing will be performed, if needed, through a supervisor's request (for example, observing improper use of respiratory protection, etc.)

If an employee fails to attend a scheduled training and fit testing session, he or she will be removed from the NIH RPP enrollment listing and his or her supervisor shall be notified of the employee's deactivation. The employee will only be reactivated in the NIH RPP when he or she re-schedules and completes training and fit-testing. If an employee does not exhibit sufficient understanding and skill as described above in the use of a respirator, the employee will need to review the training materials and study until they pass the exam. All questions on the exam will be derived from information covered within the provided training materials. If the employee does not understand the questions or the material, they may consult their supervisor, the RPPM, the manufacturer's website (for specific resp. protection equipment), etc. for additional information or clarification, but not during an ongoing exam.

5.3 Training Syllabus

Respirator users will be trained in basic respirator practices using audiovisual materials and by personal instruction as outlined in Appendix D-1, Half & Full Face Respirator Training Outline; Appendix D-2, Single Use Respirator Training Outline; or Appendix D-3, Powered Air-Purifying Respirator Training Outline. Examinations shall be administered at the end each training session online.



5.4 Respirator Fit Testing

If an employee is late by more than 15 minutes, they forfeit their scheduled time slot. This is because fit tests are scheduled only 30 minutes apart and each fit test takes about 15 minutes to conduct and 5-10 minutes to clean up for and set up/log into the database. Tardiness and “fitting-in” of employees more than 15 minutes late tends to cause a chain-reaction of delays that negatively impacts all of the employees scheduled for later that day. Rescheduling the late employee separately reduces negative impacts to other employees. Employees shall be fit tested with the same make, model, style, and size respirators to be used during work. If the employee doesn’t fit the make, model, style, and size of respirator available at their workplace, the RPPM may recommend another respirator if it passes the Respirator Fit Test. If no Respirator can be found, a PAPR may be recommended instead. Respirator fit testing shall be performed for an employee who is using a respirator for the first time and annually thereafter. The fit test shall be administered using the OSHA-accepted [Quantitative Fit Test](#) (QNFT) or [Qualitative Fit Test](#) (QLFT) protocols.

The DOHS, TAB shall conduct a fit test whenever the employee, supervisor, or the OMS reports a change in the employee’s physical condition that could affect respirator fit.

5.5 Quantitative Fit Testing Procedure

This procedure is considered the gold standard and is the primary method for evaluating the seal between the individual’s face and the respirators at the NIH. The QNFT measures the amount of leakage into the respirator by using an aerosol as a test agent (See Appendix E-1, Quantitative Fit Testing Protocol). The TSI PortaCount™ measures respirator fit by comparing the aerosol concentration outside a respirator to the aerosol concentration inside the respirator. The ratio of the outside aerosol concentration to that of the concentration inside the respirator determines the respirator fit factor. Half-face respirators must achieve a minimum fit factor of 100, and a minimum fit factor of 500 is required for full-face respirators. The fit factor must exceed the assigned protection factor (APF) by at least ten times in order for the fit to be deemed adequate. After completion of training and fit testing requirements, the RPPM shall print the TSI Fit Test Report, sign and date the report, and have the employee sign and date the report.

5.6 Qualitative Fit Testing Procedure (Only applicable to Rocky Mountain Labs [RML] until Dec. 31st 2018)

Qualitative Fit Testing is not acceptable for facilities other than RML, and applies to RML only until the end of the calendar year of 2018. Quantitative Fit Testing more precise and generally better, and is to be used for all other sites/facilities/groups that need Fit Testing.

The Qualitative Fit Test requires the introduction of an aerosol test agent into the area surrounding the head of negative pressure air-purifying respirator users. If the respirator user detects the presence of the test agent (i.e., odor, taste, or irritation), the respirator fit is deemed inadequate. If the user detects no odor, taste, or irritation, the respirator fit is acceptable. Saccharin and irritant smoke QLFT protocols are described in Appendix E-2, Qualitative Fit Test Protocols. Bitex™ may also be used as an aerosol test agent. Qualitative fit tests are only conducted when Quantitative fit tests cannot be and requires DOHS RPPM acceptance and TAB Director approval.



6.0 RESPIRATOR USE

6.1 Face-piece Seal Leakage

It is NIH policy to require that employees wearing mandatory respiratory protection have no hair interfering with the respirator's seal. Hair/Facial hair must not interfere with the seal of a respirator in any way during employee use of the respirator (not merely during the fit test, but also on the job). The entire function of respirators is to protect the worker, and respirators do not function correctly if the seal between the respirator and the employee's skin is broken. The use of respirators with tight-fitting face-pieces by employees with facial hair is prohibited. Facial hair that lies along the sealing area of a respirator, such as beards, sideburns, or mustaches will interfere with respirators that rely on a tight face-piece fit to achieve maximum protection. The areas of the skin, which contact the face or neck seal and nose-cup seal, must be completely free of any hair. Even after the fit test, facial hair in and near sealing areas must continue to be removed to ensure the seal continues to work. Failure to remove facial hair that interferes with the respirator seal will likely result in employee exposure to hazards at their workplace and possibly negative health outcome(s). If corrective glasses, goggles, or other personal protective equipment are required, the employee will receive specific instruction by the RPPM to ensure that interference with the seal of the face-piece does not occur.

Employees shall perform a negative/positive pressure seal check prior to each use following the procedure shown in Appendix E-3, User Seal Check Procedure, Part I, Face-piece Positive and/or Negative Pressure Checks, or as recommended by the respirator manufacturer (Appendix E-3 Part II).

6.2 Continuing Respirator Effectiveness

The supervisor shall periodically monitor the work area conditions, employees, employee behavior, procedural/process changes, and other relevant factors to ensure the continued effectiveness of a selected respirator. Supervisors shall ensure that employees leave the respirator use area whenever:

- A. Employees wash their face and respirator face-piece as necessary to prevent eye or skin irritation associated with respirator use.
- B. Employees detect vapor or gas, changes in breathing resistance, or leakage of the face-piece.
- C. Employees replace a respirator filter or cartridge element that is not functioning properly.
- D. Employee's facial hair seems likely to interfere with the seal of the face-piece.
- E. There is some other factor that seems likely to cause respirator failure/malfunction.

6.3 Issuance of Respirators

Respirators shall be assigned to individual employees for their exclusive use and shall only be issued to NIH employees who have received the appropriate respirator training, fit testing, and respiratory medical clearance. Except for PAPRs, respirators shall not be shared with other employees. Employees shall not be issued respirators without receiving training and/or fit testing. On the job training, on its own, is insufficient; there is online training and an exam for determining proficiency with the information.

6.4 Identification of Filters and Cartridges

NIH shall only provide NIOSH approved filters and cartridges. The RPPM, supervisors, and employees



shall ensure that the labels are not removed, obscured, or defaced. The DOHS maintains a limited supply of respirators and cartridges/filters for initial issuance and emergency use only. It is the responsibility of each IC to supply appropriate replacement cartridges/filters to their employees.

The RPPM will develop a change out schedule for canisters and cartridges (protection from gases and vapors) for employees at locations where wearing respirators is required. No such areas have been identified at the NIH where respirators are required, per OSHA, to be worn for protection from gases and vapors.

6.5 Glasses

Glasses may be worn with half face respirators, only if the glasses do not interfere with the face-to-face-piece seal of the respirator. If an employee must wear a full-face respirator and also requires corrective lenses, the employee may need eyepiece inserts for the full-face respirator. The DOHS will provide guidance on obtaining eyepiece inserts. Corrective glasses with temple bars are not allowed with full face-piece respirators.

Contact lenses are permitted with respirators.

7.0 RESPIRATORY MAINTENANCE AND CARE

7.1 Respirator Cleaning and Disinfection

The NIH provides employees with new respirators. Employees shall clean and disinfect their respirators using procedures described in Appendix F-1, Respirator Cleaning Procedures, or by similar means of equivalent effectiveness. Respirators shall be cleaned and disinfected:

- A. As often as necessary to be maintained in a sanitary condition for respirators that have been issued for the exclusive use of an employee.
- B. After each use for respirators intended for emergency use.
- C. After each use for respirators intended for fit testing and training use.

7.2 Respirator Storage

Respirators must be individually sealed in plastic bags or other suitable airtight containers and placed in locations that protect them from dust, sunlight, extreme temperatures, excessive moisture, or damaging chemicals. They must be stored in such a way that the face-piece and other respirator parts are not distorted. Respirators shall not be stored in areas, such as tool boxes or in lockers, without being placed in a secondary container to prevent face-piece distortion. Store respirators per the manufacturer's directions and email/contact the manufacturer if uncertain. At a minimum, keep a copy of the contact and the manufacturer's response (date, point of contact on both sides, exact question from your group and exact response/quote from the manufacturer). If possible, keep the original response document sent by the manufacturer, especially if the storage method recommended deviates significantly from common practice or is unusual. If the manufacturer has no opinion on the matter or is unwilling to put their comments into writing, ask DOHS for the RPPM recommendation and implement the more protective/conservative option.



7.3 Respirator Inspection

Employees shall inspect respirators prior to each use and during cleaning. If the respirator it is found to be defective during inspection, it shall be returned to the DOHS. Respirator inspection items should include:

- A. Tightness of connections and contact points.
- B. Condition of face-piece, straps, and all other parts and filter and cartridge elements.
- C. Condition of the exhalation and inhalation valves. (If the sides of the exhalation valve do not seal, even slightly, it must be replaced with a new valve).
- D. Pliability and flexibility of rubber parts. Deteriorated rubber parts must be replaced. Unused rubber parts should be worked, stretched and manipulated with a massaging action, according to manufacturer's specifications.
- E. If using a full-face respirator, the condition of lenses should be checked. Lenses must be tight in the face-piece. Scratched or damaged lenses must be replaced.

Random inspections may be conducted by DOHS to assure that respirators are properly selected, fitted, used, cleaned, maintained, and stored. For a detailed respirator check list, refer to Appendix F-2, Respirator Inspection Checklist.

7.4 Respirator Repair

Employees shall promptly remove damaged or defective respirators, and discard them or have them repaired. Defective respirators not yet discarded must be clearly marked as defective immediately after discovery of the defect, and should still be discarded as soon as feasible to prevent accidental use.

Repairs shall only be made according to the manufacturers' recommendations and specifications, and only with NIOSH approved components, by qualified individuals. Repaired respirators must pass testing before being put back into service. Documentation of repaired respirators and also of the testing of such respirators must be maintained by the IC providing the respirator. Also, a copy of the repairs done to a respirator must follow the respirator itself; respirators on loan to another IC, for example, should come with a record of repairs from the IC that purchased and maintains them.

8.0 SUMMARY OF THE ENROLLMENT PROCESS

8.1 Enrollment for Negative Pressure Respirators

Employee clearance for the use of tight-fitting half-face, full-face, and single use respirators requires:

- A. Completion of the Medical Evaluation Questionnaire for Respirator Use: Initial Clearance, which is administered by an OHRN or an OMS-P/PA.
- B. Completion of respirator training.
- C. Completion of respirator fit testing.

NIH RPP employee enrollment and re-enrollment procedures are outlined in Appendix G-1, NIH RPP Enrollment Process. Upon completion of the basic medical evaluation, training, and fit testing, the RPPM



shall issue a copy of the TSI Fit Test Report. Both the employee and the RPPM shall sign the report. This information shall be entered in the RPP database (Microsoft Access program).

8.2 Enrollment for Powered Air Purifying Respirators

Employee use of a PAPR requires participation in the NIH RPP. Employee clearance for the use of PAPRs requires:

- A. Completion of the Medical Evaluation Questionnaire for Respirator Use: Initial Clearance, administered by an OHRN or an OMS-P/PA.
- B. Completion of respiratory protection training. Fit testing is not required for loose fitting PAPRs.
- C. Annual re-fresher training.

NIH RPP employee enrollment and re-enrollment procedures are outlined in Appendix G-1. Upon completion of the basic medical evaluation and training, the RPPM shall record all applicable information in the RPP database.

9.0 PROGRAM EVALUATION

The RPPM shall annually review and evaluate the effectiveness of the NIH RPP. The RPPM shall regularly consult with NIH respirator users to assess employees' views on program effectiveness.

10.0 RECORD KEEPING

10.1 Medical Evaluation

NIH RPP employee medical records shall be retained for a period of thirty (30) years. Currently, this is done electronically by OMS. OMS shall maintain and make available these records in accordance with [29 CFR Part 1910.1020, Access to employee exposure and medical records](#).

10.2 Fit Testing

An electronic copy of the test results for each employee is maintained in the S: drive by DOHS and will be kept for one year after termination of employment.

10.3 Respiratory Protection Program

A written copy of the current NIH RPP shall be maintained by the DOHS, TAB.



APPENDIX A: INFORMATION FOR EMPLOYEES USING RESPIRATORS WHEN NOT REQUIRED UNDER THE STANDARD



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

APPENDIX A: INFORMATION FOR EMPLOYEES USING RESPIRATORS WHEN NOT REQUIRED UNDER THE STANDARD

Respirators are an effective method of protection against designated hazards when properly selected and worn. Respirator use is encouraged, even when exposures are below the exposure limit, to provide an additional level of comfort and protection for workers. However, if a respirator is used improperly or not kept clean, the respirator itself can become a hazard to the worker. If your employer provides respirators for your voluntary use, or if you provide your own respirator, you need to be sure that the respirator itself does not present a hazard by doing the following:

1. **Read, understand, and carry out all relevant instructions provided by the manufacturer** on use, maintenance, cleaning and care, and warnings regarding the respirators limitations. If you are uncertain whether or not an instruction applies, ask the manufacturer for clarification. If any of the instructions are confusing or unclear, ask your Safety Officer or the manufacturer for clarification. Usually, manufacturers will have a helpline for technical support listed on their website, the product manual, or on the item itself. If you have difficulty locating the manufacturer's help line, ask your Safety Officer for assistance.
2. **Carefully select respirators certified for use to protect against the specific contaminant of concern.** The National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services (NIOSH), certifies respirators. A label or statement of certification should appear on the respirator or respirator packaging. The label will tell you what the respirator is designed for and how much it will protect you (the 'protection factor' for a particular respirator). If you are uncertain of which respirator(s) will suit your needs, ask your Safety Officer for assistance.
3. **Do not wear your respirator in atmospheres containing contaminants for which your respirator is not designed to protect against.** For example, a respirator designed to filter dust particles will not protect you against gases, vapors, or very small solid particles of fumes or smoke.
4. **Keep track of your respirator** so that you do not mistakenly use someone else's respirator. Check your respirator before each use to ensure it is in acceptable condition.
5. **Keep hair out of the respirator's seal.**

I have read this document and have had my current questions about this document answered. I understand this document and will uphold its requirements.

Employee Name (print): _____ Date: _____

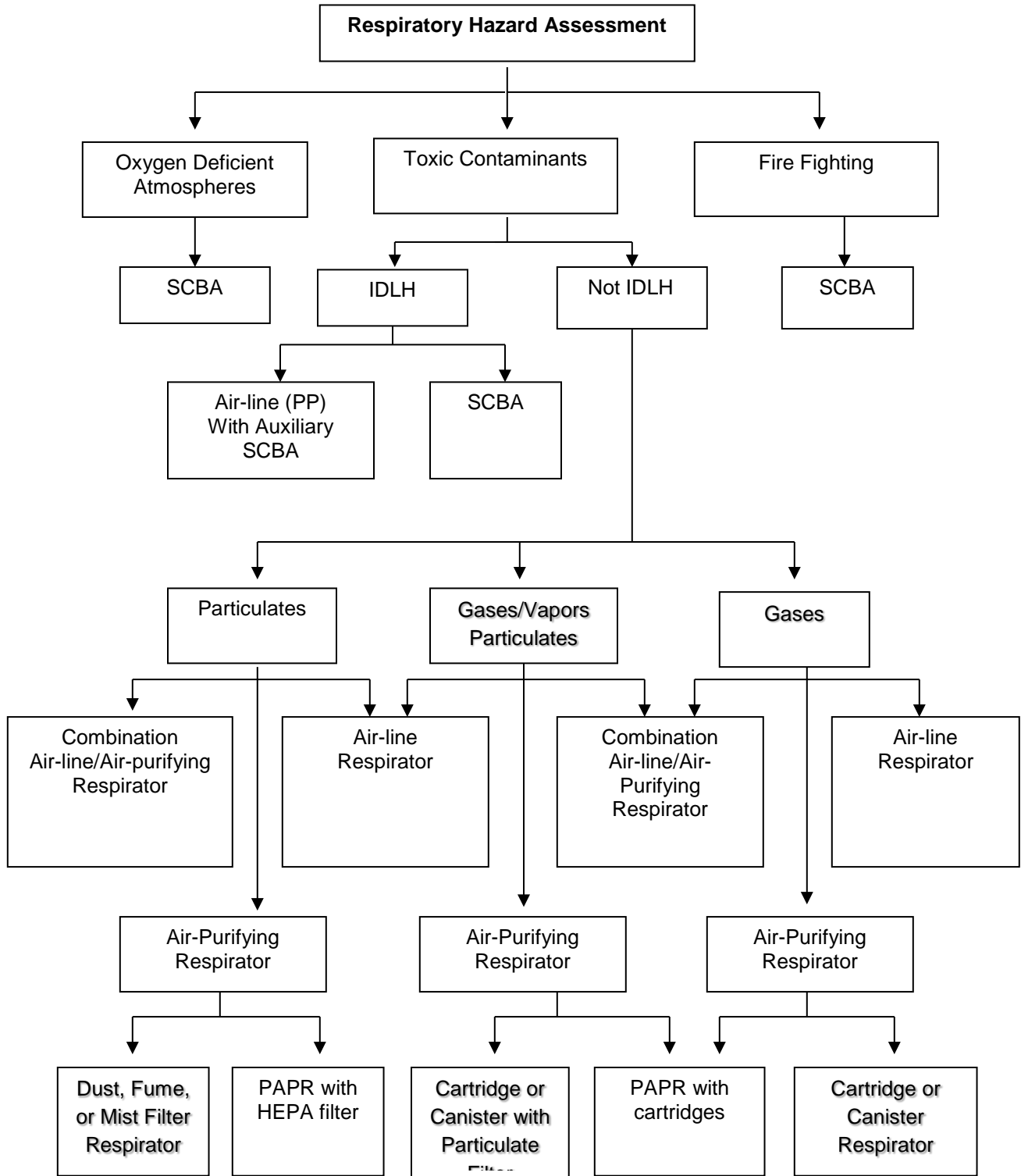
Signature: _____

VOLUNTARY RESP. PROTECTION PROGRAM: 1) Read, understand, and carry out all relevant instructions provided by the manufacturer. 2) Carefully select respirators certified for use against the specific contaminant of concern. 3) Do not wear respirators in atmospheres it wasn't designed to protect against. 4) Keep track of your respirator and ensure it is clean and in working condition; if it's an N95 it may be one-time-use. 5) Keep facial hair and hair in general, away from the seal.

Contact your **Safety Officer** or the Division of Occupational Health and Safety (**DOHS**) if you have any questions: **(301) 496-3457 [DOHS main line]**

[This section to be given to the employee as a quick reference.]

APPENDIX B: RESPIRATOR DECISION LOGIC



APPENDIX C-1: ASSIGNED PROTECTION FACTORS ¹

Table 1. -- Assigned Protection Factors ⁵

Type of respirator ^{1, 2}	Quarter mask	Half mask	Full face-piece	Helmet/hood	Loose-fitting face-piece
1. Air-Purifying Respirator	5	³ 10	50
2. Powered Air-Purifying Respirator (PAPR)	50	1,000	⁴ 25/1,000	25
3. Supplied-Air Respirator (SAR) or Airline Respirator					
• Demand mode	10	50
• Continuous flow mode	50	1,000	⁴ 25/1,000	25
• Pressure-demand or other positive-pressure mode	50	1,000
4. Self-Contained Breathing Apparatus (SCBA)					
• Demand mode	10	50	50
• Pressure-demand or other positive-pressure mode (e.g., open/closed circuit)	10,000	10,000

Notes:

- ¹ Employers may select respirators assigned for use in higher workplace concentrations of a hazardous substance for use at lower concentrations of that substance, or when required respirator use is independent of concentration.
- ² The assigned protection factors in Table 1 are only effective when the employer implements a continuing, effective respirator program as required by [29 CFR Part 1910.134](#), including training, fit testing, maintenance, and use requirements.
- ³ This APF category includes filtering face-pieces, and half masks with elastomeric face-pieces.
- ⁴ The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting face-piece respirators, and receive an APF of 25.
- ⁵ These APFs do not apply to respirators used solely for escape. For escape respirators used in association with specific substances covered by 29 CFR 1910 subpart Z, employers must refer to the appropriate substance-specific standards in that subpart. Escape respirators for other IDLH atmospheres are specified by 29 CFR 1910.134 (d)(2)(ii).

APPENDIX C-2: OSHA MEDICAL EVALUATION QUESTIONNAIRE FOR RESPIRATOR USE - INITIAL CLEARANCE

To the employee:

Please:

1. Complete the attached questionnaire.
2. Complete the attached OMS Clinical Record form. The OMS Clinical Record form will be used to establish or update your existing OMS medical record and to enroll you in the Respiratory Protection Program database.
3. Mail or deliver the completed forms to OMS. The OMS address is: Building 10, Room 6C306, MSC 1584.

Your supervisor:

- Must allow you to complete this questionnaire during normal working hours or at a time and place that is convenient to you.
- Must not review these forms, once you have completed them.

Has your employer explained the medical clearance process to you? Yes No

APPENDIX C-2: MEDICAL EVALUATION QUESTIONNAIRE FOR RESPIRATOR USE - INITIAL USE

Section 1: Please answer each question by printing your response or circling the correct answer.

1. Your name: _____ ID#: _____
2. Today's date: _____
3. Your age (to nearest year): _____
4. Your sex (circle one): Male Female
5. Your height: _____ ft. _____ in.
6. Your weight (lbs.): _____
7. Your job title: _____
8. A daytime phone number where you can be reached by the health care professional who reviews the questionnaire: _____
9. The best time to phone you at this number: _____
10. Check the type of respirator you will use (you can check more than one category):
 - a. _____ N, R, or P disposable respirator (filter-mask, non-cartridge type only).
 - b. _____ Other type (for example, half- or full-face-piece type, powered-air purifying, supplied-air, self-contained breathing apparatus [SCBA]).
11. Will you be expected to use the respirator daily? Yes No
12. Will you be expected to use the respirator more than 5 hours/week? Yes No
13. Will you be expected to exert significant effort while wearing it? Yes No
If "yes", please describe: _____
14. Have you worn a respirator before? Yes No
If "yes", what type(s): _____
15. Do you currently smoke tobacco or have you smoked tobacco in the last month? Yes No

16. Have you ever had any of the following conditions?

- | | | |
|--|-----|----|
| a. Seizures (fits) | Yes | No |
| b. Diabetes (sugar disease) | Yes | No |
| c. Allergic reactions that interfere with your breathing | Yes | No |
| d. Claustrophobia (fear of closed-in places) | Yes | No |
| e. Trouble smelling odors | Yes | No |

17. Have you ever had any of the following pulmonary or lung problems?

- | | | |
|---|-----|----|
| a. Asbestosis | Yes | No |
| b. Asthma | Yes | No |
| c. Chronic bronchitis | Yes | No |
| d. Emphysema | Yes | No |
| e. Pneumonia | Yes | No |
| f. Tuberculosis | Yes | No |
| g. Silicosis | Yes | No |
| h. Pneumothorax (collapsed lung) | Yes | No |
| i. Lung cancer | Yes | No |
| j. Broken ribs | Yes | No |
| k. Any chest injuries or surgeries | Yes | No |
| l. Any other lung problem that you've been told about | Yes | No |

18. Do you currently have any of the following symptoms of pulmonary or lung illness?

- | | | |
|---|-----|----|
| a. Shortness of breath | Yes | No |
| b. Shortness of breath when walking fast on level ground or walking up a slight hill or incline | Yes | No |
| c. Shortness of breath when walking with other people at an ordinary pace on level ground | Yes | No |
| d. Have to stop for breath when walking at your own pace on level ground | Yes | No |
| e. Shortness of breath when washing or dressing yourself | Yes | No |
| f. Shortness of breath that interferes with your job | Yes | No |
| g. Coughing that produces phlegm (thick sputum) | Yes | No |
| h. Coughing that wakes you early in the morning | Yes | No |
| i. Coughing that occurs mostly when you are lying down | Yes | No |
| j. Coughing up blood in the last month | Yes | No |
| k. Wheezing | Yes | No |
| l. Wheezing that interferes with your job | Yes | No |
| m. Chest pain when you breathe deeply | Yes | No |
| n. Any other symptoms that you think may be related to lung problems | Yes | No |

19. Have you ever had any of the following cardiovascular or heart problems?
- | | | |
|--|-----|----|
| a. Heart attack | Yes | No |
| b. Stroke | Yes | No |
| c. Angina | Yes | No |
| d. Heart failure | Yes | No |
| e. Swelling in your legs or feet (not caused by walking) | Yes | No |
| f. Heart arrhythmia (heart beating irregularly) | Yes | No |
| g. High blood pressure | Yes | No |
| h. Any other heart problem that you've been told about | Yes | No |
20. Have you ever had any of the following cardiovascular or heart symptoms?
- | | | |
|--|-----|----|
| a. Frequent pain or tightness in your chest | Yes | No |
| b. Pain or tightness in your chest during physical activity | Yes | No |
| c. Pain or tightness in your chest that interferes with your job | Yes | No |
| d. In the past two years, have you noticed your heart skipping or missing a beat | Yes | No |
| e. Heartburn or indigestion that is not related to eating | Yes | No |
| f. Any other symptoms that you think may be related to heart or circulation problems | Yes | No |
21. Do you currently take medication for any of the following problems?
- | | | |
|-------------------------------|-----|----|
| a. Breathing or lung problems | Yes | No |
| b. Heart trouble | Yes | No |
| c. Blood pressure | Yes | No |
| d. Seizures (fits) | Yes | No |
22. If you've used a respirator, have you ever had any of the following problems?
(If you've never used a respirator, check the following space and go to question 23 _____).
- | | | |
|--|-----|----|
| a. Eye irritation | Yes | No |
| b. Skin allergies or rashes | Yes | No |
| c. Anxiety | Yes | No |
| d. General weakness or fatigue | Yes | No |
| e. Any other problem that interferes with your use of a respirator | Yes | No |
23. Would you like to talk to an OMS medical provider about your answers on this questionnaire?
- | | | |
|--|-----|----|
| | Yes | No |
|--|-----|----|

Section 2: Questions 24 through 29 below must be answered by every employee who has been selected to use either a full-face respirator or a self-contained breathing apparatus (SCBA). For employees who have been selected to use other types of respirators, answering these questions is voluntary.

- | | | |
|---|-----|----|
| 24. Have you ever lost vision in either eye (temporarily or permanently)? | Yes | No |
| 25. Do you currently have any of the following vision problems? | | |
| a. Wear contact lenses | Yes | No |
| b. Wear glasses | Yes | No |
| c. Color blind | Yes | No |
| d. Any other eye or vision problem | Yes | No |
| 26. Have you ever had an injury to your ears, including a broken ear drum? | Yes | No |
| 27. Do you currently have any of the following hearing problems? | | |
| a. Difficulty hearing | Yes | No |
| b. Wear a hearing aid | Yes | No |
| c. Any other hearing or ear problem | Yes | No |
| 28. Have you ever had a back injury? | Yes | No |
| 29. Do you currently have any of the following musculoskeletal problems? | | |
| a. Weakness in any of your arms, hands, legs, or feet | Yes | No |
| b. Back pain | Yes | No |
| c. Difficulty fully moving your arms and legs | Yes | No |
| d. Pain or stiffness when you lean forward/backward at the waist | Yes | No |
| e. Difficulty fully moving your head up or down | Yes | No |
| f. Difficulty fully moving your head side to side | Yes | No |
| g. Difficulty bending at your knees | Yes | No |
| h. Difficulty squatting to the ground | Yes | No |
| I. Climbing a flight of stairs or a ladder carrying more than 25 lbs. | Yes | No |
| j. Any other muscle or skeletal problem that interferes with using a respirator | Yes | No |

APPENDIX D-1: HALF & FULL FACE RESPIRATOR TRAINING OUTLINE

I. Respiratory Protection Requirements

- A. Define
- B. Line of Defense
- C. Purpose

II. Respiratory Hazards In The Workplace

- A. Route of entry:
 - Absorption
 - Ingestion
 - Inhalation
- B. Respiratory hazards
 - Airborne Contaminants:
 - Dust, Mist, Fume, Gases & Vapor
 - Oxygen deficiency & Immediately Dangerous to Life and Health

III. Respirators Types

- A. Two types
 - Supplied Air
 - Air purifying
- B. Air Purifying
 - Half face
 - Advantages
 - Disadvantages
 - Full Face
 - Advantages
 - Disadvantages
- C. Provide protection
 - Air Filters
 - Cartridges
 - Combination
- D. Color-coded Cartridges
 - White-Acid Gases
 - Black-Organic Gas
 - Green-Ammonia Gas
 - Yellow -Acid Gases & Organic Vapor
- E. Warning Properties
- F. Medical Clearance

IV. Respirator Operation, Limitations, and Capabilities

- A. Operation
- B. Limitations

- IDLH atmospheres
- Unknown Hazards
- Poor Warning Properties
- C. Facial hair

V. Inspection

- A. Face-piece
 - Excessive dirt
 - Cracks, tears, holes or distortion from improper storage
 - Cracked or badly scratched lens in full-face-pieces
 - Cracked or broken air purifying element holder(s), badly worn threads, or missing gaskets
- B. Head Straps
 - Examine for breaks
 - Loss of elasticity
 - Broken or malfunctioning buckles and attachments
 - Excessively worn serrations on the head harness that might permit slippage.
- C. Exhalation & Inhalation Values
 - Foreign material, such as detergent residue, dust particles, or human hair under the valve seat
 - Cracks, tears or distortion in the valve material
 - Improper insertion of the valve body in the face-piece
 - Cracks, breaks, or chips in the valve body, particularly in the sealing surface
 - Improper installation of the valve in the valve body
- D. Air-purifying element
 - Incorrect cartridge, or filter for the hazard
 - Incorrect installation, loose connections, missing or worn gaskets, or cross threading in holder, cracks or dents in outside case of the filter or cartridges
- E. Donning instruction, fit checking, and wearing the respirator
- F. Donning
- G. Checking the fit and seals
 - Positive/Negative Test

VI. Respirator Maintenance and Storage

- A. Cleaning
- B. Storage
 - Dust
 - Sunlight
 - Heat
 - Extreme Cold
 - Excessive Moisture
 - Damaging Chemicals

VII. Hands-on

VIII. Quantitatively Fit

APPENDIX D-1A: HALF AND FULL FACE RESPIRATORS - TEST

Name: _____ ID#: _____ Date: _____

1. Which of the following is not a typical means of occupational exposure?

- A. Absorption
- B. Inhalation
- C. Walking
- D. Ingestion

T = True; F = False; Please circle your answer.

- 2. **T F** Air-purifying respirators are designed for use in environments with atmospheric oxygen concentrations below 19.5% oxygen.
- 3. **T F** The purpose of a respirator is to prevent the inhalation of harmful airborne contaminants.
- 4. **T F** Fit-testing is only required once every five years.
- 5. **T F** One should always perform a “negative and positive pressure seal check.”
- 6. **T F** Respirators should be cleaned with a mild acid.
- 7. **T F** Your medical status should be reviewed any time you experience difficulty breathing while using a respirator.
- 8. **T F** Before an air-purifying respirator can be selected, the hazards must be known.
- 9. **T F** Air-purifying respirators can be used when the atmosphere is considered Immediately Dangerous to Life or Health (IDLH).
- 10. **T F** A beard will interfere with the respirator seal.
- 11. **T F** Each time you use a respirator you must be sure it is free of cracks, tears, or punctures.
- 12. **T F** A respirator should be stored away from dust, sunlight, extreme temperature, excessive moisture or damaging chemicals.

(7/14 JP)

APPENDIX D-2: SINGLE USE RESPIRATOR TRAINING OUTLINE

I. Description

The N95 particulate filter respirator provides a tight facial seal for high filtration of submicron particles. This respirator is NIOSH approved as an N95 particulate respirator and has the following basic characteristics:

- A. High efficiency filter media- filter 0.3 micron particles at over 95 % efficiency
- B. Enclosed flexible nose piece
- C. Polyurethane headbands
- D. Available in different sizes and models

II. Intended use

The N95 is intended to minimize exposure of both the healthcare worker and patient to blood and body fluids, airborne microorganisms, and other particulate matter such as animal dander. It provides greater than 95% filtration efficiency of 0.3 micron particles. Some N95s are designed to be resistant to blood and body fluids, where others are not.

III. Donning

- A. Cup the respirator in your hand with the nosepiece at your fingertips while allowing the headbands to hang freely below your hand.
- B. Position the respirator under your chin with the nosepiece up.
- C. Pull the top strap over your head resting it on the crown of your head. Pull the bottom strap over your head and position it around the neck below the ears.
- D. Use both hands and place your pointer and middle fingertips at the top of the metal nosepiece.
- E. Mold the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece.
- F. Pinching the nosepiece using one hand may cause a bad fit and result in less effective respirator performance.
- G. The seal between the respirator and the face should be fit-checked whenever the respirator is to be worn. Place both hands completely over the respirator and exhale. Be careful not to disturb the position of the respirator. If air leaks around the nose, readjust the nosepiece as described in step D, or try a different size or model.

IV. Positive and Negative Pressure Fit Checking

There are two tests that are used in the field/workplace to check the seal of the respirator, known as the positive and negative pressure fit checks. Depending upon the respirator and manufacturer's directions for fit checking, one or both of these tests must be performed every time a respirator is put on and prior to entering a contaminated area.

A. Positive fit Check

- 1. This check only applies to those respirators that do not have an exhalation valve or have an exhalation valve that can be blocked.

2. Cup the hands over the respirator and close or 'block off' the exhalation valve.
3. Exhale gently into the face-piece.
4. If a slightly positive pressure is built up with no apparent outward leakage around the seal, then the face-piece-to-face seal is possibly satisfactory.

B. Negative Fit Check

1. This check applies to those respirators that do not have inhalation valve or have an inhalation valve or hose connections that can be blocked.
2. Cup the hands over the respirator and close or 'block off' the inlet opening
3. Inhale gently so that the face-piece collapses slightly.
4. If the face-piece remains slightly collapsed and no inward leakage occurs, then the face-piece-to-face seal is probably satisfactory.

NOTE: This is very difficult to accomplish with an N95 respirator.

V. Respirator Maintenance

- A. The respirator must be kept in good condition to function properly.
- B. The respirator, when not in use, should be stored in a clean dry location.
- C. Place in a place bag when not in use.
- D. Do not distort the face-piece during storage.

VI. Respirator Limitations

- A. Do not use for protection against gases, vapors, asbestos, for sandblasting, or paint spray operations.
- B. Do not use in atmospheres containing less than 19.5% oxygen.
- C. Do not use when concentrations of contaminants are immediately dangerous to life and health.
- D. Do not abuse or misuse the respirator.
- E. Do not use with beards or other facial hair that prevents direct contact between the face and the edge of the respirator.
- F. Failure to properly use and maintain this product could result in injury or death.
- G. The respirator helps protect against certain particulate contaminants but does not eliminate risk of contracting disease or infection.

VII. Warning Signs During Respirator Use

- A. Difficulty breathing
- B. Dizziness
- C. Respiratory distress
- D. You taste or smell contaminant

VIII. Respirator Disposal

- A. When any part shows evidence of excessive wear.
- B. When there is a tear or rip on the face-piece.

- C. Place in a bag and throw away in a trash can; when soiled with Human blood/body fluids or other infectious materials, place in MPW box.

APPENDIX D-2A: SINGLE USE RESPIRATORS - TEST

Name: _____ ID#: _____ Date: _____

1. Which of the following organization certifies the actual respirator?
 - A. Environmental Protection Agency (EPA)
 - B. Occupational Medical Service (OMS)
 - C. National Institute for Occupational Safety and Health (NIOSH)
 - D. The Government Safety Institute (GSI)
2. **T F** One should always perform a “negative and positive pressure seal check”.
3. **T F** The N-95 respirator filter will capture bacteria and virus sized particles.
4. **T F** A beard will interfere with the respirator seal.
5. **T F** An employer only needs to fit-test an employee every five years.
6. **T F** An N-95 respirator is designed to be a one-time use respirator.
7. **T F** An N-95 respirator provides a maximum 65% filtration efficiency.
8. **T F** Your medical status should be reviewed any time you experience difficulty breathing while using a respirator.
9. **T F** Before an air-purifying respirator can be selected, the hazards must be known.
10. **T F** Air-purifying respirators, such as an N-95 respirator, should not be used in low oxygen environments (below 19.5% oxygen).

(7/14 JP)

APPENDIX D-3: POWERED AIR-PURIFYING RESPIRATOR TRAINING OUTLINE

I. Purpose and Objectives

This training outline will demonstrate the uses, capabilities, limitations, care, and maintenance for both powered air-purifying respirators used at the NIH: 1) Air Hepa Mate, and 2) Breath Easy.

Upon completion of instruction, employees will be able to:

- Define the working principle of a PAPR and its components.
- Describe the operational limitations of PAPRs.
- Use, remove, and replace filters & filter gaskets and battery packs.
- Conduct a pre and post operational inspections.
- Show proficiency with system assembly and PAPR donning.

II. Introduction

Ambient air is drawn thru the belt-mounted filters/cartridges and passes through the breathing tube connected to the hood or helmet. The filtered air passes over the user's face and maintains a positive pressure inside the hood/helmet at all times. The Air Hepa Mate is designed to work with a single internal HEPA filter and only protects the user from dusts, fumes, and mists. The Air Hepa Mate has an internal battery that can be recharged. The Breath Easy uses three cartridges and/or filters to remove contaminants and can be used to protect the user from dusts, fumes, mists, gases, and/or vapors. The Breath Easy has an external battery, which is hooked onto the user's belt and can be removed and charged at a separate location.

III. Operational Limitations

- A. Not for use in atmospheres that are Immediately Dangerous to Life or Health (IDLH).
- B. Not for use where oxygen concentrations are below 19.5% or above 21.5%.
- C. Not for use in working atmospheres that contain toxic gases or vapors when fitted with HEPA filters.
- D. Never open the motor/blower unit of the Breath Easy PAPR.

IV. Air Hepa Mate System

- A. System equipped with:
 - 1. Tyvek hood
 - 2. Breathing Tube
 - 3. HEPA filter
 - 4. Motor/Blower
 - 5. Battery Pack
- B. Replacement parts demonstration
 - 1. Remove and insert the battery.

2. Ensure that a filter gasket is located in the recess above the battery compartment.
3. Replace the HEPA filter (arrow pointing down).
4. Snap the back cover into place.

V. Breathe Easy System

A. System equipped with:

1. Tyvek hood or helmet
2. Breathing Tube
3. Filtering element of choice
4. Motor/Blower
5. Battery Pack

B. Replacement parts demonstration

1. Never open the motor/blower unit of the Breath Easy PAPR.
2. Proper replacement of cartridges/filters.
3. Proper attachment of battery.

VI. Pre-Operational Inspection

A. Prior to the beginning of each work shift, an inspection of the PAPR should include:

1. Inspection of breathing tube, connections, and body.
2. Inspection of filter(s)/cartridge(s) to make sure they are/it is correctly installed and the battery is fully charged.

B. Air flow (Air Hepa Mate)

1. Hold the free end of the tube up by grasping the slotted connector and cover the slots of the connectors with thumb and forefinger.
2. Place the black, bullet-shaped airflow indicator into the tube opening.
3. Switch the unit on and hold the tube so that is vertical and at eye level.
4. The indicator should 'float' on the air coming out; the lower band should be above the connector's rim.
5. If the lower band on the indicator rises above the slotted connected edge, airflow is sufficient.
6. If the indicator fails to rise to this level, check the breathing tube battery and filter.

C. Air flow (Breath Easy)

1. Remove the air tube and insert the air flow indicator into the blower opening.
2. Turn the blower on.
3. The plastic ball should float above the 6 CFM mark.
4. If the indicator fails to rise to this level, check the breathing tube, battery, and make sure the caps are removed from the filters/cartridges.

VII. System Assembly and Donning

- A. Assemble in non-contaminated environment.
- B. To connect the Air Hepa Mate tube to the unit, insert the tube (male end with pin) into the unit and twist clockwise to lock in place. The Breath Easy tube is clamped on with a metal gasket.
- C. To connect the tube to the head piece, insert the free end of the tube into the rear of the head piece unit until it snaps in place. The Breath Easy is clamped on the same way it is connected to the blower.
- D. Properly donning the PAPR:
 1. Place the unit against your lower back and along your spinal column.
 2. Holding it in place, fasten the belt buckle and ensure the unit rests comfortable against your back and turn the unit on.
 3. Pull the hood or helmet over your head and adjust it so the sweatband is on your forehead and the elasticized edge of the face seal fits under your chin. The face seal is pulled as far as possible under your chin and snug around your face.

WARNING:

- A. Protection against airborne contaminants is not provided unless the hood/helmet is correctly positioned over your head and the visor and face seal are correctly positioned in front of your face. An adequate supply of filtered air must be maintained at all times.
- B. If the airflow ceases, decreases, or suddenly increases, leave the work area immediately and check the hood, breathing tube, and motor/blower unit.

VIII. Filter Removal and Replacement for Air Hepa Mate

- A. Change the filter:
 1. When an airflow check of the unit reveals that the airflow indicator does not rise above the specified level.
 2. When the filter is physically damaged.
 3. When water has entered the filter.
- B. Filter & Gasket Removal:
 1. Put the belt through the belt retainers to form a loop that is clear of the unit.
 2. Release the back cover's locking tabs and remove the back cover.
 3. Remove and discard the filter and gasket.
- C. Filter & Gasket Replacement:
 1. Inspect the new filter gasket.
 2. Fit the new filter gasket into the filter support ridge ensuring that the gasket is flush against the side of the unit with no gaps.

3. Fit the new filter into the unit with the arrow pointing into the unit and snap the cover shut.

IX. Filter/Cartridge Replacement for Breath Easy

A. Change the filter:

1. When an airflow check of the unit reveals that the airflow indicator does not rise above the 6 CFM level.
2. When the filter is physically damaged.
3. When water has entered the filter or cartridge.

B. Filter/Cartridge Replacement

1. Make sure you line up the threads properly and screw on slowly.
2. Do not over tighten.
3. Remove caps.

WARNING:

- A. If the equipment is not properly assembled and used in strict conformance with the manufactures specifications, contaminated air may be drawn into the system resulting in exposure that may lead to serious health impairment or death. (MISUSE MAY RESULT IN SICKNESS OR DEATH.)
- B. HEPA filters are only approved for protection against dust, fumes and mists.

X. Air Hepa Mate Battery Pack Use, Removal, and Replacement

- A. Completely exhausted battery should be charged for 14-16 hours.
- B. Repeated charging for more than 16 hours may reduce battery pack life.
- C. When fully charged, the battery should last at least six hours.
- D. Replace battery every three years.
- E. Removal of battery pack:
 1. Remove the back cover and HEPA filter.
 2. Slide the battery clip out of the locking slot.
 3. Lift the battery out.

XI. Breathe Easy Battery Pack Use, Removal, and Replacement

- A. Completely exhausted battery should be charged for 14-16 hours.
- B. Batteries can be left on a multi-charger indefinitely on trickle charge.
- C. When fully charged, the battery should last at least six hours.
- D. Blue batteries are for HEPA filters or cartridges.
- E. Black/Gold batteries are for combination HEPA/gas-vapor cartridges
- F. Replace battery every three years.

XII. Post Operational Maintenance

- A. Wipe the outside of the unit using a soft cloth dampened in a solution of warm water and mild detergent.
- B. ABRASIVE CLEANERS MUST NOT BE USED.
- C. Properly discard cartridges/filter(s).
- D. Disassemble the breathing tube from the headpiece.
- E. Separate the tube from the unit.
- F. Cover both ends of the breathing tube and rinse it under running water.
- G. Hang breathing tube to dry.
- H. After all components have been cleaned, inspect all parts for damage or wear, and replace worn parts.
- I. Dry all parts completely, keeping them away from sunlight and direct heat.
- J. Discard the hood in it's entirety when contaminated.
- K. Remove facial seal from helmet and use warm water and mild detergent to clean the helmet.
- L. Replace old facial seal with new one after helmet has dried.

APPENDIX D-3A: POWERED AIR-PURIFYING RESPIRATORS (AIR MATE) - TEST

Name: _____ ID#: _____ Date: _____

1. The airborne hazards must be known before wearing a PAPR.
 - A) True
 - B) False

2. What does a PAPR fitted with High Efficiency (HE) filters provide protection from?
 - A) Gases and Vapors
 - B) Atmospheres below 19.5% oxygen
 - C) Atmospheres Immediately Dangerous to Life or Health (IDLH)
 - D) Particles

3. Which of the following statements is incorrect?
 - A) PAPRs may only be used in ambient air atmospheres where the oxygen concentration falls between 19.5% and 21%
 - B) PAPRs are not for use in atmospheres which are Immediately Dangerous to Life or Health (IDLH)
 - C) Any manufacturer can be used for replacement parts on any PAPR
 - D) You must know the contaminant you could potentially be exposed to before wearing a PAPR

4. Prior to wearing your PAPR, you should:
 - A) Inspect the breathing tube, body, and unit casing
 - B) Check the airflow by using the airflow indicator (bullet)
 - C) Wash the entire HEPA unit in the sink with mild detergent
 - D) A and B

5. After you finish wearing your PAPR, you should:
 - A) Wipe it down with an abrasive cleaner
 - B) Follow the appropriate decontamination procedures as instructed
 - C) Use dust spray and a cloth to wipe it down
 - D) Use acetone to wipe it down

6. The PAPR airflow is adequate if:
 - A) The plastic bullet floats above the lowest raised line
 - B) The battery has not been placed on the charger for several days
 - C) The plastic ball does not float
 - D) Air is coming out of the tube

7. If the airflow ceases while wearing the PAPR, you should:
- A) Check the power by turning the ON/OFF button on the battery
 - B) Leave the work area immediately
 - C) Wait until you finish your job
 - D) Ask a fellow employee to check the PAPR
8. Change the filter when:
- A) An airflow check of the unit reveals that the airflow indicator does not rise to the specified level, yet the battery is fully charged
 - B) The filter or cartridge is physically damaged
 - C) Water has entered the any of the filters or cartridges
 - D) All of the above
9. A completely exhausted battery pack should be charged for the following time period:
- A) One hour
 - B) 16 - 24 hours, or the period noted in the operating manual
 - C) 48 hours
 - D) Never – battery packs don't get exhausted
10. Care should be taken when handling PAPR components, including the batteries (e.g. do not drop on the ground, etc.).
- A) True
 - B) False

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Correct Answers

1. **A** 6. **A**
2. **D** 7. **B**
3. **C** 8. **D**
4. **D** 9. **B**
5. **B** 10. **A**

(7/14 JP)

APPENDIX D-3B: POWERED AIR-PURIFYING RESPIRATORS (BREATHE EASY) - TEST

Name: _____ ID#: _____ Date: _____

1. The specific airborne hazard must be known before wearing a PAPR.
 - A) True
 - B) False

2. A PAPR fitted with HEPA filters provide protection from?
 - A) Gases and Vapors
 - B) Atmospheres below 19.5% oxygen
 - C) Atmospheres Immediately Dangerous to Life or Health (IDLH)
 - D) Dusts, Fumes, Mists

3. Which of the following statements is incorrect?
 - A) PAPRs may only be used in ambient air atmospheres where the oxygen concentration falls between 19.5% and 21%
 - B) PAPRs are not for use in atmospheres which are Immediately Dangerous to Life or Health (IDLH)
 - C) Any manufacturer can be used for replacement parts
 - D) You must know the contaminant you could potentially be exposed to before wearing a PAPR in the environment

4. Prior to wearing your PAPR, you should:
 - A) Inspect the breathing tube, body, and HEPA unit
 - B) Check the air flow by using the airflow indicator
 - C) Wash the entire HEPA unit in the sink with mild detergent
 - D) A and B

5. After you finish using your PAPR, you should:
 - A) Wipe it down with an abrasive cleaner
 - B) Wipe it down with a damp cloth or an alcohol swab
 - C) Use dust spray and a cloth to wipe it down
 - D) Use acetone to wipe it down

6. The PAPR airflow is adequate if:
 - A) The plastic ball floats between the 4 cfm level and the 6 cfm level
 - B) The plastic ball floats below the 4 cfm level
 - C) The battery has not been placed on the charger for several days
 - D) The plastic ball floats above the 6 cfm level

7. If the airflow ceases while wearing the PAPR, you should:
- A) Check the PAPR's power by turning the ON/OFF button on the battery
 - B) Leave the work area immediately
 - C) Wait until you finish your job
 - D) Ask a fellow employee to check the PAPR
8. Change the filter when:
- A) An airflow check of the unit reveals that the airflow indicator does not rise to the specified level
 - B) The filter or cartridge is physically damaged
 - C) Water has entered the any of the filters or cartridges
 - D) All of the above
9. A completely exhausted battery pack should be charged for the following time period:
- A) One hour
 - B) 16 - 24 hours, or the period noted in the operating manual
 - C) One week
 - D) Never - battery packs don't get completely exhausted
10. Before wearing the PAPR, you should always check to make sure the filters or cartridges are screwed on tightly.
- A) True
 - B) False

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(7/14 JP)

APPENDIX D-3C: POWERED AIR-PURIFYING RESPIRATORS (MAX AIR) - TEST

Name: _____ ID#: _____ Date: _____

1. The airborne hazards must be known before wearing a Powered Air-Purifying Respirator (PAPR).
 - A) True
 - B) False

2. A PAPR fitted with a 99.97% high efficiency (HE) filter provide protection from?
 - A) Gases and vapors
 - B) Atmospheres that are below 19.5% oxygen
 - C) Atmospheres considered Immediately Dangerous to Life or Health (IDLH)
 - D) Dusts and particulates

3. Airflow is good if:
 - A) The yellow Status Indicator LED is lit
 - B) The green Status Indicator LED(s) is/are lit
 - C) The red Status Indicator LED is lit
 - D) I think I feel air blowing across my face

4. Prior to wearing your PAPR, you should:
 - A) Inspect the helmet, filter, and battery
 - B) Check the air flow
 - C) Ensure that all five (5) Status Indicator LEDs briefly light up upon initial start-up and then proceed to good airflow (green)—an LED test
 - D) All of the above

5. After you finish using your PAPR, you should:
 - A) Wipe it down with an abrasive cleaner
 - B) Follow appropriate decontamination procedures as instructed
 - C) Use dust spray and a cloth to wipe it down
 - D) Use acetone to wipe it down

6. Which of the following statements is incorrect?
 - A) PAPRs may only be used in ambient air atmospheres where the oxygen concentration falls between 19.5% and 21%
 - B) PAPRs are not for use in atmospheres which are Immediately Dangerous to Life or Health (IDLH)
 - C) PAPR replacement parts can be used from any manufacturer
 - D) You must know the contaminant you could potentially be exposed to before wearing a PAPR

7. If the airflow ceases while wearing the PAPR in the work area, you should:
- A) Check the PAPR's power by taking off your helmet
 - B) Leave the work area immediately
 - C) Wait until you finish your job
 - D) Ask a fellow employee to check the PAPR when he or she has a moment
8. Dispose of the filter when:
- A) An LED check of the unit reveals that the airflow is low, yet the battery is fully charged
 - B) The filter is physically damaged
 - C) It is part of the decontamination procedure
 - D) All of the above
9. A completely exhausted battery pack should be charged for the following time period:
- A) One hour
 - B) 4 - 6 hours, or the period noted in the operating manual
 - C) One week
 - D) Never – battery packs don't get completely exhausted
10. When using a filter/helmet configuration that requires the use of separate pre-filter, the pre-filter must be in place for the PAPR to be considered an approved respirator.
- A) True
 - B) False
11. Care should be taken when handling PAPR components, including the batteries (e.g. do not drop on the ground, etc.).
- A) True
 - B) False

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Reference: Instruction Manual (P/N 025212215 Rev A2)

Correct Answers

1. **A** 6. **C** 11. **A**
2. **D** 7. **B**
3. **B** 8. **D**
4. **D** 9. **B**
5. **B** 10. **A**

(7/14 JP)

APPENDIX E-1 QUANTITATIVE FIT TESTING PROTOCOL

AMBIENT AEROSOL CONDENSATION NUCLEI COUNTER (CNC):

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing (Portacount™) protocol quantitatively fit tests respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. A probed respirator has a special sampling device, installed on the respirator, which allows the probe to sample the air from inside the mask. A minimum fit factor pass level of at least 100 is necessary for a half-mask respirator, and a minimum fit factor pass level of at least 500 is required for a full Face-piece negative pressure respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

1. Portacount Fit Test Requirements:

- (A) Check the respirator to make sure the respirator is fitted with a high-efficiency filter and that the sampling probe and line are properly attached to the Face-piece.
- (B) Instruct the person to be tested to don the respirator for five minutes before the fit test starts. This purges the ambient particles trapped inside the respirator and permits the wearer to make certain the respirator is comfortable. This individual shall already have been trained on how to wear the respirator properly.
- (C) Check the following conditions for the adequacy of the respirator fit: Chin properly placed; Adequate strap tension, not overly tightened; Fit across nose bridge; Respirator of proper size to span distance from nose to chin; Tendency of the respirator to slip; Self-observation in a mirror to evaluate fit and respirator position.
- (D) Have the person wearing the respirator do a user seal check. If leakage is detected, determine the cause. If leakage is from a poorly fitting Face-piece, try another size of the same model respirator, or another model of respirator.
- (E) Follow the manufacturer's instructions for operating the Portacount and proceed with the test.
- (F) The test subject shall be instructed to perform the exercises that are presented.
- (G) After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

2. Portacount Test Instrument:

- (A) The Portacount will automatically stop and calculate the overall fit factor for the entire set of exercises. The overall fit factor is what counts. The 'Pass' or 'Fail' message will indicate whether or not the test was successful. If the test is a 'Pass,' the fit test is over.
- (B) A record of the test needs to be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model, style, and size of

respirator used; and date tested.

APPENDIX E-2: QUALITATIVE FIT TEST (QLFT) PROTOCOLS

I. SACCHARIN SOLUTION AEROSOL PROTOCOL

A. Taste Threshold Screening:

The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

- (1) During threshold screening as well as during fit testing, the test subject shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.
- (2) The test enclosure shall have a 3/4-inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.
- (3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his or her slightly opened mouth with tongue extended. The subject is instructed to report when he or she detects a sweet taste.
- (4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the threshold check solution into the enclosure. The nozzle is directed away from the nose and mouth of the person. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.
- (5) The threshold check solution is prepared by dissolving 0.83 gram of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution [see (B)(5) below] in 100 ml of distilled water.
- (6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.
- (7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted. If the test subject reports tasting the sweet taste during the ten squeezes, the screening test is completed. The taste threshold is noted as ten regardless of the number of squeezes actually completed.
- (8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the second ten squeezes, the screening test is completed. The taste threshold is noted as twenty regardless of the number of squeezes actually completed.
- (9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the third set of ten squeezes, the screening test is completed. The taste

- threshold is noted as thirty regardless of the number of squeezes actually completed.
- (10) The test conductor will take note of the number of squeezes required to solicit a taste response.
 - (11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject is unable to taste saccharin and may not perform the saccharin fit test.

Note: If the test subject eats or drinks something sweet before the screening test, he or she may be unable to taste the weak saccharin solution.

- (12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.
- (13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.
- (14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

B. SACCHARIN SOLUTION AEROSOL FIT TEST PROCEDURE:

- (1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.
- (2) The fit test uses the same enclosure described above.
- (3) The test subject shall don the enclosure while wearing the respirator. The respirator shall be properly adjusted and equipped with a particulate filter(s).
- (4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.
- (5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.
- (6) As before, the test subject shall breathe through the slightly open mouth with tongue extended, and report if he or she tastes the sweet taste of saccharin.
- (7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of saccharin fit test solution is sprayed into the enclosure using the same number of squeezes (either 10, 20 or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test. A minimum of 10 squeezes is required.
- (8) After generating the aerosol, the test subject shall be instructed to perform the exercises.
- (9) Every 30 seconds the aerosol concentration shall be replenished using one half the original

number of squeezes used initially (e.g., 5, 10 or 15).

- (10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected. If the test subject does not report tasting the saccharin, the test is passed.
- (11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and the test is failed. A different respirator shall be tried and the entire test procedure is repeated (taste threshold screening and fit testing).
- (12) Since the nebulizer has a tendency to clog during use, the test operator must make periodic checks of the nebulizer to ensure that it is not clogged. If clogging is found at the end of the test session, the test is invalid.

II. IRRITANT SMOKE (STANNIC CHLORIDE) PROTOCOL

This qualitative fit test uses a person's response to the irritating chemicals released in the 'smoke' produced by a stannic chloride ventilation smoke tube to detect leakage into the respirator. This procedure is not routinely used at the NIH due to the irritant properties.

A. General Requirements and Precautions:

- (1) The respirator to be tested shall be equipped with high efficiency particulate air (HEPA) or P100 series filter(s).
- (2) Only stannic chloride smoke tubes shall be used for this protocol.
- (3) No form of test enclosure or hood for the test subject shall be used.
- (4) The smoke can be irritating to the eyes, lungs, and nasal passages. The test conductor shall take precautions to minimize the test subject's exposure to irritant smoke. Sensitivity varies, and certain individuals may respond to a greater degree to irritant smoke. Care shall be taken when performing the sensitivity screening checks that determine whether the test subject can detect irritant smoke to use only the minimum amount of smoke necessary to elicit a response from the test subject.
- (5) The fit test shall be performed in an area with adequate ventilation to prevent exposure of the person conducting the fit test or the buildup of irritant smoke in the general atmosphere.

B. Sensitivity Screening Check:

The person to be tested must demonstrate his or her ability to detect a weak concentration of the irritant smoke.

- (1) The test operator shall break both ends of a ventilation smoke tube containing stannic chloride, and attach one end of the smoke tube to a low flow air pump set to deliver 200

milliliters per minute, or an aspirator squeeze bulb. The test operator shall cover the other end of the smoke tube with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.

- (2) The test operator shall advise the test subject that the smoke can be irritating to the eyes, lungs, and nasal passages and instruct the subject to keep his or her eyes closed while the test is performed.
- (3) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties and to determine if he or she can detect the irritating properties of the smoke. The test operator shall carefully direct a small amount of the irritant smoke in the test subject's direction to determine that he or she can detect it.

C. IRRITANT SMOKE FIT TEST PROCEDURE:

- (1) The person being fit tested shall don the respirator without assistance, and perform the required user seal check(s).
- (2) The test subject shall be instructed to keep his or her eyes closed.
- (3) The test operator shall direct the stream of irritant smoke from the smoke tube toward the face seal area of the test subject, using the low flow pump or the squeeze bulb. The test operator shall begin at least 12 inches from the Face-piece and move the smoke stream around the whole perimeter of the mask. The operator shall gradually make two more passes around the perimeter of the mask, moving to within six inches of the respirator.
- (4) If the person being tested has not had an involuntary response and/or detected the irritant smoke, proceed with the test exercises.
- (5) The test subject shall perform the exercises, explained in the following paragraph, while the respirator seal is being continually challenged by the smoke directed around the perimeter of the respirator at a distance of six inches.

The test will be performed in the following manner:

- (a) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.
- (b) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as not to hyperventilate.
- (c) Turning head side to side. Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.
- (d) Moving head up and down. Standing in place, the subject shall slowly move his or

her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

- (e) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.
- (f) If the person being fit tested reports detecting the irritant smoke at any time, the test is failed. The person being retested must repeat the entire sensitivity check and fit test procedure.
- (g) Each test subject passing the irritant smoke test without evidence of a response (involuntary cough, irritation) shall be given a second sensitivity screening check, with the smoke from the same smoke tube used during the fit test, once the respirator has been removed, to determine whether he or she still reacts to the smoke. Failure to evoke a response shall void the fit test.
- (h) If a response is produced during this second sensitivity check, then the fit test is passed.

Note: Bitrex™ may also be used, as per the applicable protocol.

APPENDIX E-3: USER SEAL CHECK PROCEDURE

PART I: FACE-PIECE POSITIVE AND/OR NEGATIVE PRESSURE CHECKS

All employees using a tight-fitting respirator shall perform a user seal check to ensure that an adequate seal is achieved each time the respirator is put on. User seal checks are not substitutes for qualitative or quantitative fit test.

A. Positive Pressure Seal Check

- (1) Close off the exhalation valve.
- (2) Exhale gently into the Face-piece.
- (3) If a slight positive pressure is built up with no apparent outward leakage around the seal, the face-piece-to-face seal is satisfactory.

B. Negative Pressure Seal Check

- (1) Close off the inlet opening of the cartridge by covering with the palm of the hand(s) replacing the filter seal(s).
- (2) Inhale gently so that the face-piece collapses slightly and hold breath for 10 seconds.
- (3) If the face-piece remains slightly collapsed and no inward leakage occurs, the face-piece-to-face seal is satisfactory.

PART II: MANUFACTURER'S RECOMMENDED USER SEAL CHECK PROCEDURES

The manufacturer's recommended procedures for performing a user seal check may be used instead of the positive and/or negative pressure check procedures if the manufacturer's procedures are equally effective.

APPENDIX F-1: RESPIRATOR CLEANING PROCEDURES

- A. Remove filters, or cartridges. Discard or repair any defective parts.
- B. Wash components in warm (43 deg. C [110 deg. F] maximum) water with a mild detergent or with a cleaner recommended by the manufacturer. A stiff bristle (not wire) brush may be used to facilitate the removal of dirt.
- C. Rinse components thoroughly in clean, warm (43 deg. C [110 deg. F] maximum), preferably running water. Drain.
- D. When the cleaner used does not contain a disinfecting agent, respirator components should be immersed for two minutes in one of the following:
 - 1. Hypochlorite solution (50 ppm of chlorine) made by adding approximately one milliliter of laundry bleach to one liter of water at 43 deg. C (110 deg. F); or,
 - 2. Aqueous solution of iodine (50 ppm iodine) made by adding approximately 0.8 milliliters of tincture of iodine (6-8 grams ammonium and/or potassium iodide/100 cc of 45% alcohol) to one liter of water at 43 deg. C (110 deg. F); or,
 - 3. Other commercially available cleansers of equivalent disinfectant quality when used as directed, if their use is recommended or approved by the respirator manufacturer.
- E. Rinse components thoroughly in clean, warm (43 deg. C [110 deg. F] maximum), preferably running water. Drain. The importance of thorough rinsing cannot be overemphasized. Detergents or disinfectants that dry on face-pieces may result in dermatitis. In addition, some disinfectants may cause deterioration of rubber or corrosion of metal parts if not completely removed.
- F. Components should be hand-dried with a clean lint-free cloth or air-dried.
- G. Reassemble face-piece, replacing filters and cartridges where necessary.
- H. Test the respirator to ensure that all components work properly.

APPENDIX F-2: RESPIRATOR INSPECTION CHECKLIST

All respirators must be inspected before and after each use, and during cleaning.

Air-purifying Respirators (Half and Full face-piece)

A. Rubber face-piece - check for:

- (1) excessive dirt (clean all dirt from face-piece)
- (2) cracks, tears, or holes
- (3) distortion (allow face-piece to "sit" - free from any constraints and see if distortion disappears, if not, obtain another face-piece)
- (4) cracked, scratched or loose fitting lenses

B. Head straps - check for:

- (1) breaks or tears (replace head straps)
- (2) loss of elasticity (replace head straps)
- (3) broken or malfunctioning buckles or attachments (obtain new buckles)
- (4) excessively worn serration on the head harness which might allow the face-piece to slip (replace head straps)

C. Inhalation valve exhalation valve - check for:

- (1) detergent residue, dust particles or dirt on valve or valve seat (clean residue with soap and water)
- (2) cracks, tears or distortion in the valve material or valve seat (contact RPPM for instructions)
- (3) missing or defective valve cover (obtain valve cover from RPPM)

D. Filter element(s) - check for:

- (1) proper filter for the hazard
- (2) NIOSH approval designation
- (3) missing or worn gaskets (contact RPPM for replacement)
- (4) worn threads - both filter threads and face-piece threads (replace filter or face-piece, whichever is applicable)
- (5) cracks or dents in filter or cartridge (replace filter)
- (6) end of service life indicator, or end of service date for expiration (Contact RPPM to find out if your filter element has one; if not, ask what will indicate the "end of service")

APPENDIX F-3: RESPIRATOR FIT-TESTING PROCEDURE FOR N-95 RESPIRATORS

(Current as of February 2010)

1. Set up the humidifier (or particle generator) 30 minutes prior to the fit-test.
2. Turn on the computer.
3. Perform the following when the person arrives:
 - a. Ask for their OMS Medical Clearance Form (if initial fit-test); have them fill out the 'Interval Clearance Form' if this is their annual fit-test. Review as appropriate.
 - b. Go through the applicable Power Point presentation
 - c. Issue the written test and review the correct answers.
4. Turn on the TSI PortaCount Pro+ and wait until it completes the warm-up cycle.
5. Open FitPlus v3.4.2 on the computer.
 - a. Ensure that the following database is used: S:\Database\TAS-data\Respiratory Protection Program\TSI database(active)\Fit-test Database.mdb
 - b. Run the daily checks
 - c. Click on the fit-test button and enter the required information—find their name in the database or enter the person's information into the correct places:
 - i. Last name
 - ii. First name
 - iii. Badge ID number
 - iv. Company = NIH
 - v. Location = Institute
 - vi. Custom 1 = Phone number
 - vii. Custom 2 = Bldg/Room
 - viii. Custom 3 = Supervisor
 - ix. Custom 4 = Exposure
6. Prepare the correct N-95 respirator with adaptor probe (first be sure to sanitize your hands or wear non-latex gloves).
7. Place the lanyard around the person's neck—clip the tube into place. Ensure there is enough slack in the tube to allow for up and down head movements.
8. Instruct the person to attach the clear tube to the adaptor probe and have them don the respirator.
9. Click the 'Start' button and instruct the person to follow the prompts on the screen and give them the Rainbow Passage. They should be standing.
10. Ensure that the person is passing each test with a score of at least 100; if not the test may fail, which could be an indication of a bad fit. If the fit-test fails, stop the test and have them re-adjust the respirator and try again. Try a different respirator if it continues to fail. Note that 200+ is the highest score for both the individual and overall scores for an N-95 fit-test. If higher than this, the N-95 box may not have been checked.
11. Once the person passes the fit-test, print the completed report by exiting the testing screen, clicking on the 'Fit Test Report' button on the top of the screen, and printing the individual report.
12. Sign the Fit Test Report.

13. Make copies of the Medical Clearance, the written test, and the Fit Test Report.
14. Give the person the originals and file the copies in the Fit-Test binder.
15. Update the respirator calendar (Microsoft Excel: S:\Database\TAS-data\Respiratory Protection Program\TSI Database (active)\Fit-Test Calender.xls) by copying the individual result (from the Microsoft Access database: S:\Database\TAS-data\Respiratory Protection Program\TSI database(active)\Fit-test Database.mdb) into the Excel calendar.

APPENDIX F-4: IRF-FREDERICK POSITIVE PRESSURE, SUPPLIED-AIR PROTECTIVE SUITS RESPIRATORY PROTECTION PROGRAM (RPP)

I. Introduction

The primary personal protective equipment (PPE) for personnel entering a BSL-4/ABSL-4 laboratory is the positive pressure encapsulating suit. Currently, labs in North America are using two versions of this suit for operation of their Biosafety Level 4 containment laboratories. The two encapsulating suits available are the Dover CHEMTURION encapsulating space suit (manufactured by ILC Dover, Inc., Frederica, Delaware) and the Sperian Protection Suit (manufactured by Sperian/Bacou Technologies, Lyon, France). At this time the IRF – Frederick BSL-4/ABSL-4 personnel only plan to utilize the Sperian Protection Suits within the containment setting.

Positive air pressure is maintained by umbilical-fed air, supplied to the suit through the air-inlet manifold assembly, for the internal ventilation system, located on the right front torso. Attached to this manifold assembly is an external hose and a regulator, which will control the airflow to the suit. This airflow provides clean air for breathing and prevents intake of potentially contaminated air from the laboratory.

The Sperian Protection Suit has an internal air control and distribution system, which is built into the suit and covered by the suit material. This system is protected by an internal HEPA filter immediately adjacent to the air inlet and inside the suit. The exhaust from this suit is through two magnetic valves.

A. Purpose

This instruction sets forth the minimal acceptable program requirements governing the use of the positive pressure totally encapsulating protective suits (airline suits) used at the IRF-Frederick Biological Safety Level 4 (BSL-4) facility.

B. Scope

This instruction applies to all NIH employees working in the IRF BSL-4 laboratory while the lab is considered “hot”, which requires the use of airline suits.

II. Responsibilities

Assistant Director, Safety Operations (ADSO)

The IRF BSL-4 shall be the direct responsibility of the ADSO, IRF-Frederick, who shall ensure that the procedures in this document are followed at all times. The ADSO may delegate authority for conducting specific programs in the BSL-4 to other appropriate personnel as necessary.

Biosafety Manager (BSM)

- Ensures that all tools and equipment required to perform the suit acceptance tests and suit integrity tests are readily accessible.
- Periodically reviews the Protection Suit Integrity Test Log to ensure all suits are inspected

- every seven (7) calendar days.
- Ensures that the breathing air is checked annually and meets Class D air requirements as specified in Compressed Gas Association Commodity Specification CGA-7.1-1966.
 - Ensures that all employees required to wear a positive pressure totally encapsulating protective suit has completed all of the required training and medical clearance prior to donning the suit.

High Containment Supervisor (HCS)

- Periodically reviews the Protection Suit Integrity Test Log to ensure that all suits are inspected every seven (7) calendar days.
- Removes the exterior suit gloves on any suit that has not undergone an integrity test within the previous seven (7) calendar days. This shall serve as a reminder to the user to perform the test before the suit goes back into service.
- Ensures that all employees required to wear a positive pressure totally encapsulating protective suit has been through all of the required training and medical clearance prior to donning the protective suit.
- The HCS oversees all operations and performance of scientific studies within the IRF BSL-4 and works closely with DOHS and ORF personnel to ensure a safe and efficient working environment within the BSL-4 facility.
- Notifies the Director/Chief Scientist (CS) and the BSM of any incident or problem which compromises staff safety or the integrity of the containment of the BSL-4 laboratory.
- Ensures that appropriate orientation, training and mentoring programs are implemented to achieve the utmost safety in the BSL-4 laboratory. Provides support, as necessary, to the Assistant Director, Safety Operations (ADSO) to ensure that IRF staff completes required safety training techniques required for the safe conduct of the research program and the operation of the BSL-4 laboratory prior to commencing work.
- Suspends access privileges of any BSL-4 employee for failure to follow procedures and comply with safety standards.

All BSL-4 laboratory and support staff are responsible for:

- Ensuring that a Protection Suit Integrity Test has been performed on their assigned suit within the previous seven (7) calendar days, or when the exterior suit gloves are replaced, or when repairs are completed.
- Recording results of the testing in the *Sperian Protection Suit Integrity Test Log, which is located in each Suit Room.*
- Reporting any significant issues or necessary repairs to the IRF HCS or BSM.

Director/Chief Scientist (CS)

- The CS shall assume direct responsibility for conducting the research in the BSL-4 lab in a manner which minimizes risks.
- The Director/CS shall have ultimate responsibility for the safe operations of the scientific studies conducted within the IRF- Frederick.
- Ensures that research and support personnel are aware of general and specific procedures and precautions relevant to the conduct of the selected research programs.

- Instructs personnel on the nature and assessment of both real and potential chemical, radiological, biological, and physical hazards involved in the selected research programs.
- Supervises staff to ensure that performance requirements are met.

Occupational Medical Services (OMS) Physician

The Director, OMS, establishes the medical clearance evaluation for use of the airline suits, surveillance procedures, and reviews the health status of all personnel.

Respiratory Protection Program Manager (RPPM)

The RPPM reviews and evaluates the effectiveness of the IRF-Frederick Respiratory Protection Program, and stays abreast of changing regulations and government alerts concerning its use.

III. Codes, Regulations, & Standards

General Applicability of Codes and Regulations

Except to the extent that more explicit, or more stringent requirements are written directly into this program, all applicable codes and regulations have the same force and effect as if directly copied into this program.

Those standards governing the development of this program include, but are not limited to, the following:

Access to Employee Exposure and Medical Records	29 CFR 1910.1020
Respiratory Protection	29 CFR 1910.134
Respiratory Protection Devices	42 CFR Part 84
Compressed Gases	29 CFR 1910.101
American National Standards Institute (ANSI)	
Practices for Respiratory Protection, Standard	Z88.2-1992
Commodity Specification for Air	CGA G-7.1-1996

IV. Approved Equipment

Any respiratory protection equipment submitted for use in the BSL-4 laboratory, including airline suits, supply hoses, and inlet couplings must first be approved by the Division of Occupational Health and Safety (DOHS) and the HCS.

V. Medical Evaluation

Persons should not be assigned to the use of an airline suit unless it has been determined that they are physically able to perform their assigned duties while wearing the suit.

The Director, OMS, determines medical clearance criteria for use of the airline suit, and prescribes surveillance procedures for workers at the IRF-Frederick. The airline suit user's medical status shall be reviewed periodically by the OMS.

VI. Training Management

Training for scientists and staff to gain access to the BSL-4 laboratory at the IRF is the collective responsibility of the High Containment Supervisor, DOHS Safety Staff and the IRF Office of Research Facilities Development and Operations (ORF) Facility Manager. Personnel with supervisory or auxiliary roles include the High Containment Coordinator, Functional Area Leads, Training Coordinator, and individual laboratory workers.

Training is a regimented program and includes a formalized program through DOHS that includes multi-week didactic and theoretical preparation training. A significant amount of training covers proper donning and doffing procedures, proper techniques for inspecting the suits, proper techniques for inspecting the critical breathing system components prior to entering the laboratory, and proper storage. This course will be followed by mentored training within the BSL-4 containment area, which is a critical aspect of the program for all trainees. Formal and facility specific training will include procedural and safety aspects that are required understanding for all personnel entering the BSL-4 Laboratory. Additional specialized training will be individually based on previous biocontainment experience and his/her role within the BSL-4 facility. In addition, employees must certify in writing: A full understanding of this *BSL-4 Laboratory and Operations Safety Manual*, Complete IRF specific facility training, complete AT LEAST 40 entries/exits with a mentor. (Workers who are able to produce “documented prior BSL- 4 experience” must complete AT LEAST 10 entries/exits.), and complete AT LEAST 100 hours of work within the BSL-4 facility. (This may be reduced to AT LEAST 25 hours based upon documentation of prior experience.)

Annual Refreshers are required if three (3) months has passed since the last BSL-4 entry. The staff member will receive an abbreviated BSL 4 Re-Orientation Training. If twelve (12) months have passed since the last BSL-4 entry, the staff member will repeat the BSL-4 and ABSL-4 Training sessions as appropriate.

VII. Inspection, Cleaning & Disinfecting, Storage

Frequent random inspections shall be conducted by the HCS and BSM to assure that airline suits are properly inspected, cleaned, disinfected, and stored.

Donning & Inspection

In order to ensure the proper functioning of the Sperian Protection Suits and adequate protection of the workers, every user must inspect their suit prior to each donning to look for leaks or signs of wear. Workers must report any significant repairs to the HCS and BSM.

Cleaning and Disinfecting

The facility has a chemical decontamination shower which also serves as an airlock between the BSL-4 laboratory and the “clean” area. Personnel must enter and exit the laboratory through the Suit Room and the associated chemical decontamination shower/airlock. The Micro-Chem Plus Solution disinfectant is applied via high pressure spray nozzles for a period of 4 minutes. The cycle is followed with a 3 minute water rinse cycle for a total of a 7 minute decontamination shower.

Storage

After inspection, cleaning, and necessary repair, airline suits shall be stored in a safe location to protect against dust, sunlight, heat, extreme cold, excessive moisture, or damaging chemicals. Airline suits will be hung up to dry in the suit room, which has been designated as a convenient, clean, and sanitary location.

VIII. Communications

Communications (voice or signal line) are maintained between all individuals in the BSL-4 laboratory. Communication between staff inside the laboratory and staff outside of the laboratory may be accomplished in three ways: intercom, telephone, and an approved 2-way headphone system worn inside of the airline suit. The headphones are primarily used for communication between personnel inside the BSL-4 lab.

IX. Air Quality

- A. Breathing air for the BSL-4 areas is supplied by redundant duplex medical oil-less air compressors and receiver tank system. This system is designed to serve a maximum of 36 people wearing positive pressure suits at any given time.
- B. The breathing air is processed through a quality control tower. Breathing Air Purification Units adjust the humidity, remove impurities via a sorbent bed, and monitor carbon monoxide levels prior to the distribution into the breathing air system. The absence of alarms indicates that the system is safe and ready for occupancy of the lab. Any alarm must be immediately reported to the BSM or HCS.
- B. A separate emergency backup system will provide breathing air for the suits upon compressor failure. Three storage tanks are present, each sized to contain 340,000 liters of standard air compressed to 2,500 psig of pressure. Two tanks will provide the 30-minute storage requirement, while the third tank provides redundancy for maintenance. A high pressure air compressor designed to supply 27 L/s of air at 5,000 psig will slowly fill the storage tanks through manual operation. Once pressurized, the tanks can be isolated with dual isolation valves and maintain their storage capacity.
- C. An automatic switchover valve allows the air to flow from the backup storage system into the main breathing air distribution pipe in the event that the main distribution system loses pressure.
- D. The pressure of air stored in both Breathing Air Storage Tanks and in all three Backup Breathing Air Storage Tanks is verified each day.
- E. There are two air quality control towers, one associated with each compressor. These are inspected daily to ensure proper operational status.
- F. Breathing air is sampled at least annually to ensure it meets at least the requirements of the specification for Grade D breathing air as described in Compressed Gas Association Commodity Specification CGA-7.1-1966.

X. Recordkeeping

A record shall be kept of inspection dates and findings for airline suits. Annual record keeping air quality will be performed by DOHS, IRF staff. Medical records are kept at OMS.

APPENDIX G-1: NIH RESPIRATORY PROTECTION PROGRAM

