Michigan EMS Agency Licensing and Inspection Manual

BETP
Bureau of EMS, Trauma & Preparedness

v. 1.3 August 2019

Record of Changes

Date	Change	Completed by:
8/6/19	Removed Medical Waste Certificate Requirement	Sabrina Kerr
8/13/19	Removed exemption of MFR vehicle inspections.	Derek Flory
8/13/19	Added CLIA Waiver Instructions for EMS Agencies.	Derek Flory

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Introduction

The Michigan Department of Health and Human Services (MDHHS), Bureau of EMS, Trauma & Preparedness (BETP), Division of EMS and Trauma (DET) is responsible for the regulation and coordination of the Emergency Medical Services System (EMSS) in the State[1]. Information provided in this document is intended to supplement the Public Health Code (Part 201 General Provisions and Part 209 Emergency Medical Services), as well as the Administrative Rules (R 325.22101 – 325.22217 Life Support Agencies and Medical Control).

This manual is intended to provide Life Support Agencies (LSAs) and State inspectors with consistent guidance regarding the licensing and inspection processes, and to provide resources that will assist agencies with maintaining licensure.

Agency Requirements

Initial and Renewal LSA licensing requirements are delineated in the following pages. It is the responsibility of the LSA to obtain and maintain licensure through the MDHHS DET. Licenses are renewed annually. Prior to issuing an LSA license, the LSA (with the exception of Medical First Response (MFR) Agencies)[2] must undergo a successful agency inspection. Annual inspections are conducted within the quarter that the license is due for renewal. LSAs that are accredited by the Commission on Accreditation of Ambulance Services (CAAS), are not required to have an annual inspection by the DET; however, the DET reserves the right to conduct validation inspections or inspections in relation to complaints received by the DET.

Generally, LSA inspections are scheduled ahead of time, which allows the agency time to gather all documentation and arrange to have a representative present to meet with the EMS Regional Coordinator. In the case of a complaint, an inspection may or may not be scheduled in advance.

1.0 Initial LSA License

New LSA's wishing to become licensed in the State of Michigan, must complete and submit the forms in Table 1 to be considered for licensure:

Table 1Forms Required for Initial Life Support Agency License Application

Initial Agency License Requirements
Application to Operate (BETP/EMS-352)
Part 1 Life Support Agency License Application (BHS/EMS-180)
Life Support Vehicle Application (**for each vehicle you would like to be licensed**) (BETP/EMS-181)
Certificate of Insurance for Life Support Agencies (BETP/EMS-0092)
EMS Personnel List (BETP/EMS-327)
Ambulance Safety Inspection (**for used vehicles that are greater than 2 years old**) (BETP/EMS-316)
Ambulance Safety Inspection Notarized Statement (**for used vehicles that are greater than 2 years old**) (BETP/EMS-318)
CLIA Waiver (If the Agency is conducting glucometer checks-regardless of level of LSA- or iSTAT tests)
Manufacturers Certificate of Compliance (BETP/EMS-314) (**for all transporting vehicles**)

[1] PA 368 of 1978 as amended §20910. (1)(a)

[2] PA 368 of 1978 as amended §20910. (1)(d)(*iii*)

1.1 Medical Control Approval

Approval from the local Medical Control Authority (MCA) Medical Director is required for each MCA in which the Agency operates. If an agency operates in more than one MCA, a signature is required from each MCA Medical Director.

1.2 Insurance

A current certificate of no-fault insurance coverage with residual liability coverage (property damage and personal injury), or other proof self-insured authority, must be on file with the Department for each type of vehicle and submitted at the time of initial licensing and renewal:

1.2.1 Ground Vehicle*:* not less than one million dollars ($1,000,000);

1.2.2 Air ambulance **(Rotary):** not less than five million dollars ($5,000,000);

1.2.3 Fixed Wing**:** Not less than ten million dollars ($10,000,000)

1.3 Federal Clinical Laboratory Improvement Amendment (CLIA) Waiver

A current waiver certificate must be on file with the Department and submitted at the time of initial licensing and renewal for all BLS, LALS, and ALS agencies. It is required for MFR agencies **If** the agency is doing blood glucose checks as outlined in medical control authority protocols. To obtain the CLIA Waiver, you must apply with the Michigan Department of Licensing and Regulatory Affairs at: https://www.michigan.gov/lara/0,4601,7-154-63294_72971_78688---,00.html. The waiver certificate is good for 2 years.

1.3.1 CLIA Waiver Instructions for EMS Agencies.

1.4 Fees

1.4.1 **Agencies** The fee to license a new LSA is $100, with the exception of a new Medical First Responder (MFR) agency, which does not have a fee.

1.4.2 **Vehicles** The fee to license each vehicle is $25, with the exception of MFR vehicles, for which there is no fee (see Vehicle Requirements Section below for more information.

1.5 Application Process

1.5.1 All applications, including **all required forms and fees**, must be submitted to: Bureau of EMS, Trauma and Preparedness, DET Agency Licensing Coordinator at PO Box 30437 Lansing, MI 48909.

1.5.2 The Licensing Coordinator will review the application. If the application is complete, a site visit will be scheduled to occur within 15 calendar days by an EMS Regional Coordinator.

1.5.3 If an application is incomplete, the LSA will be notified within 15 days of receipt requesting additional information.

1.5.4 Licenses will not be issued until all agency and vehicle equipment requirements are met.

2.0 LSA License Renewal

LSA licenses are renewed annually. The Agency License Renewal Application is mailed to each agency approximately 90 days prior to the license expiration date.

2.1 MCA Approval

2.1.1 Approval from the local Medical Control Authority (MCA) Medical Director is required for each MCA in which the Agency operates. If an agency operates in more than one MCA, a signature is required from each MCA.

2.2 Fees

2.2.1 Agencies The renewal fee to license an LSA is $100, with the **exception of a Medical First Responder** (MFR) agency, which does not have a fee.

2.2.2 Vehicles The fee to license each vehicle is $25, with the **exception of MFR vehicles**, for which there is no fee (see Vehicle Requirements Section below for more information.)

2.3 Application Process

2.3.1 All applications, including **all required forms and fees**, must be submitted to: Bureau of EMS, Trauma and Preparedness, DET Agency Licensing Coordinator at PO Box 30437 Lansing, MI 48909.

2.3.1.1 LSAs that are accredited by the Commission on Accreditation of Ambulance Services (CAAS), must supply documentation of such accreditation with the renewal application.

2.3.2 If an application is incomplete, the LSA will be notified within 15 days of receipt requesting additional information.

2.3.3 Before issuing a renewal license, an agency inspection will be conducted within the quarter the licenses are renewed. Licenses will not be issued until all agency and vehicle equipment requirements are met.

2.3.4 LSAs that are accredited by the Commission on Accreditation of Ambulance Services (CAAS), are not required to have an annual inspection by the DET, however the DET reserves the right to conduct validation inspections or inspections in relation to complaints received by the DET. Licensing fees still apply.

2.3.5 If a renewal application is not received within 60 days after the license expiration date, the license will be revoked effective the 61st day.

LATE FEES

Applications received by the det after the expiration date are required to pay a late fee of

- **$300.00 in addition to the $100.00 agency renewal fee. MFR agencies are not exempt from late fees**
- **$100.00 in addition to the $25.00 for each agency vehicle fee. MFR agencies are not exempt from late fees.**

3.0 Ambulance Operation Permanent Upgrade License

Agencies wishing to upgrade a current MFR, BLS, or LALS license to a higher level must apply using the same process as an initial license (See 1.0 above).

4.0 Ambulance Operation Temporary Upgrade "Bennett Bill" License (Conditional for 2 Years)

An agency upgrade license allows the agency to provide a higher level of service when the agency is able to staff and equip one or more ambulances to provide services at the higher level. In accordance with PA 368 of 1978 as amended, Section 20920(7). Emergency services provided under an upgraded license shall be provided only to an agency that has been owned, operated or under contract to a local unit of government and providing first line emergency medical response to that local unit of government and only in response to a 911 call or other call for emergency transport within the jurisdiction of that local unit of government on or before July 22, 1997.

4.1 Has been a licensed ambulance operation at the transporting Basic Life Support (BLS) or transporting Limited Advanced Life Support on or before July 22, 1997.

4.2 Is able to staff and equip one or more ambulances for the transport of emergency patients at a life support level higher than BLS, or is a transporting limited advanced life support (LALS) service that is able to staff and equip one or more ambulances for the transport of emergency patients at the advanced life support (ALS) level.

4.3 Will provide the services described above in response to a 911 call or other call for emergency transport.

4.4 Licensing Application Process

4.4.1 An agency meeting these requirements is eligible to apply for an agency upgrade license using the department prescribed forms, paying the $100 fee, and including the following supporting documentation:

4.4.2 Verification and description of the staffing and equipment to be used in providing the higher level of life support.

4.4.3 Plan of action to upgrade to the higher level of service over a period of not more than 2 years.

4.4.4 The MCA protocols for the agency upgrade license that address:

4.4.4.1 Quality monitoring procedures.

4.4.4.2 Use and protection of equipment, and patient care.

4.4.4.3 A recommendation from the MCA under which the agency operates, supporting the upgrade and recommending a license be issued by the Department.

4.4.4.4 Any other information required by the department to process the application.

4.4.5 Once all of the required documentation is received at the DET, the proposal will be taken to the Emergency Medical Services Coordination Committee (EMSCC) meeting where it will be reviewed; and a recommendation will be made to the department as to whether or not an ambulance upgrade license should be granted.

4.4.5.1 Upon final review and positive recommendation from the EMSCC, the Department will issue an agency upgrade license.

4.4.6 An agency upgrade license is valid for 2 years from the date of issuance and is renewable for one additional 2-year period.

4.5 Conditional Upgrade Renewal Application Process

4.5.1 An application for renewal of an agency upgrade license shall contain documentation of the progress made on the plan of action.

4.5.2 In addition, an agency that obtains an upgrade license, must annually renew its regular license.

4.5.3 The MCA must provide an annual written report to the EMSCC on the progress made by the agency on the plan of action, including, but not limited to, information on training, equipment, and personnel.

4.6 Revocation of a Conditional Upgrade License

4.6.1 The department may revoke or fail to renew an ambulance operation upgrade license for:

4.6.1.1 A violation of the Public Health Code, Administrative Rules, or for failure to comply with plan of action.

4.6.2 An agency's regular license is not affected by an agency upgrade license, action taken against the agency upgrade license, and the expiration of the agency upgrade license.

5.0 Inspections

There are several forms of agency inspections as indicated below. Agencies are expected to provide the required documentation and access to the state inspectors to demonstrate compliance with the Public Health Code, Administrative Rules and Protocols.

AGENCY REPRESENTATION REQUIRED FOR INSPECTIONS

A service representative shall be available to meet and assist the inspector during the inspection. This individual must be familiar with the agency policies and procedures and practices.

5.1 Routine DET Inspections

5.1.1 EMS Regional Coordinators are assigned to conduct the routine agency and vehicle inspections (see APPENDIX A). They are available for consultation, advice and questions regarding inspections, licensure, and vehicle requirements.

5.1.2 Annual inspections are conducted for all levels of life support agencies with the exception of MFR agencies, which are only subject to vehicle inspections.

5.1.3 The inspections are conducted on-site and consist of a review of documents, and random vehicle inspections.

5.2 Validation Inspections

5.2.1 Validation of compliance following non-compliance Issues may be conducted to ensure that an identified deficiency has been corrected.

5.2.2 The state retains the right to conduct random validation inspections of other accrediting bodies for quality assurance to ensure that standards are being maintained or in response to complaints.

5.3 Other State or Federal Organizations

5.3.1 If an agency appears to be non-compliant with other regulations during an inspection, additional entities may be notified and could conceivably conduct further inspections, for example the Michigan Occupational Safety and Health Administration (MIOSHA) or the Federal Drug Enforcement Administration (DEA).

5.4 Commission on Accreditation of Ambulance Services (CAAS)

5.4.1 In accordance with Administrative Rule 325.22127(2), a life support agency that receives accreditation from (CAAS) may not be subject to an agency inspection by the department if the life support agency submits verification of accreditation and maintains accreditation. Accreditation of a life support agency does not prevent the department from conducting a life support agency inspection.

5.5 Complaint Investigation Inspections

5.5.1 Complaints related to non-compliance, multiple, or severe violations of statute or administrative rules may generate an unannounced inspection. In such cases, the inspector(s) may conduct a full inspection or a focused inspection depending on the egregiousness of the complaint.

6.0 Required Documentation

Each agency is required to have documentation as it relates to the disclosure of agency ownership, management, recordkeeping, safety policies and procedures, personnel, protocols, quality assurance and improvement, and equipment and vehicles. Documentation must be available for inspection during the annual inspection or at any other time as deemed necessary by the DET. For a specific list of the required documentation, see APPENDIX B.

Once the Image Trend Agency Licensure module is live, many of the documents can be uploaded to the agency licensing account prior to the agency inspection. If the agency is unable to complete the upload prior to the inspection, the documents must be on site on the date of inspection for review. If a required document is missing at the time of inspection, a violation will be issued. All agencies will receive education about the online licensing module and will be notified when the ImageTrend Agency Licensure module has been implemented.

7.0 LSA Organizational Changes

Any changes that affect an agency license must be reported to the DET Agency Licensing Coordinator as soon as possible either by email, or mail:

7.1 Ownership

7.1.1 Requires a completed and signed Life Support Agency Application.

7.2 Agency name change

7.2.1 Requires a completed and signed Life Support Agency Application.

7.3 Contact person.

7.4 Change in vehicle status.

7.6 Permanent removal of vehicle

7.6.1 A life support agency must notify the department within 30 days when it permanently removes a vehicle from service by completing the Life Support Vehicle application.

7.7 Not capable of meeting minimum staffing or equipment requirements.

7.8 Not able to comply with MEDCOM requirements.

7.9 Change in service area

NOTIFICATION of STAFFING ISSUES

If an LSA cannot operate or staff at least one vehicle for response to an emergency within its service area due to staffing issues, the following should be notified:

- **Dispatch center**
- **Other public safety agencies if appropriate**
- **LSA that will be providing secondary response capabilities**
- **MCA**
- **State**

7.9.1 Requires a completed and signed Life Support Agency Application.

7.10 Downgrade license.

7.11 Cease operation

7.11.1 The license will become null and void and cannot be sold or transferred to another entity.

8.0 Vehicle Requirements

Each agency is required to have at least one vehicle licensed and available to provide service 24 hours a day, 7 days a week at the level of licensure equal to the agency license.

8.1 All new, upgraded, and replacement vehicles must be inspected by the DET and compliance verified before a license is issued to provide service.

8.1.1. An inspection will occur within 15 calendar days from the date of application receipt by the department.

8.2 Once a vehicle is licensed, the Department will conduct random inspections of vehicles during agency inspections.

8.2.1 The department may conduct random renewal inspections of life support vehicles, including medical first response vehicles.

8.2.2 Inspections will be unannounced unless circumstances warrant notifying a life support agency in advance that an inspection of its life support vehicles will be conducted.

8.2.3 A vehicle license may be renewed without an inspection.

8.3 A life support vehicle license is nontransferable.

8.4 A life support agency may temporarily use a state licensed life support vehicle of another licensed life support agency through a loan. Vehicle loans may occur if mechanical problems prevent an agency from deploying its existing vehicles.

8.4.1 The life support agency acquiring the vehicle shall notify the department of the loan within 3 business days using the Loaner Vehicle Application.

8.4.2 The loaned vehicle shall not increase the total number of vehicles the agency is licensed to use.

IMPORTANT TO KNOW

- **Life support vehicle licenses are not transferable**
- **The DET must inspect each vehicle that is added or replaced**

8.5 Add/Upgrade/Remove a vehicle from service

8.5.1 Adding an additional vehicle to the fleet

8.5.1.1 Complete the Life Support Vehicle Application and submit it to the department.

8.5.1.2 A completed Manufacturers Certificate of Compliance is required f the vehicle is for transporting patients.

8.5.1.3 If the transporting vehicle is two years from the date of manufacture, a completed form # BHS/EMS-316 and BHS/EMS-318 must be submitted.

8.5.1.4 Newly added vehicles cannot be utilized until an inspection has been conducted.

8.5.2. Upgrading a current vehicle

8.5.2.1 Complete the Life Support Vehicle Application and submit it to the department.

8.5.2.2 If upgrading a non-transport vehicle to a transport vehicle, it is also necessary to complete the Manufacturers Certificate of Compliance; **and**

8.5.2.3 If the vehicle is two years or older from the date of manufacture, complete form # BHS/EMS-316 and BHS/EMS-318.

8.5.2.4 Newly added upgraded vehicles cannot be utilized until an inspection has been conducted.

8.5.3 Replacing a current vehicle (removing a current vehicle and replacing it with a new vehicle)

8.5.3.1 Complete the Life Support Vehicle Application for the vehicle being removed AND for the new replacement vehicle and submit it to the department.

8.5.3.2 If the newly added vehicle is for transporting patients, complete the Manufacturers Certificate of Compliance.

8.5.3.3 If the newly added transporting vehicle is two years or older from the date of manufacture, complete form # BHS/EMS-316 and BHS/EMS-318.

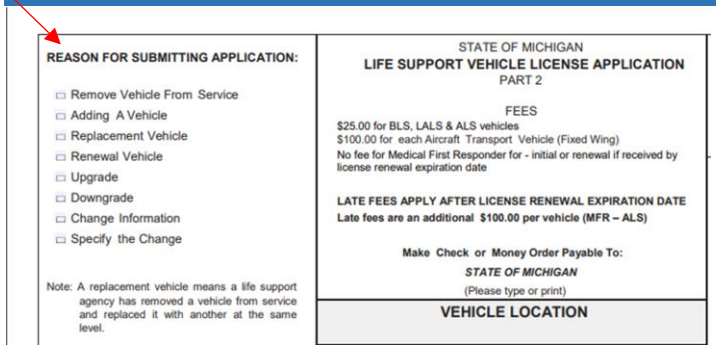
8.5.3.4 Replacement vehicles can be used for 15 days prior to inspection, once correct application and documents are submitted to the Department.

8.6 Vehicle Out of Service

8.6.1 If a vehicle will be out of service due to mechanical, damage, or other issues for more than 30 days or it will be permanently removed from service, the DET Agency Licensing Coordinator must be notified and the vehicle removed from service.

8.6.1.1 To remove a vehicle from service complete form #BHS/EMS-181. Check remove from service and send form to MDHHS via email or fax. No fee is required for removing a vehicle from service.

Form BHS/EMS-181



REASON FOR SUBMITTING APPLICATION:

- Remove Vehicle From Service
- Adding A Vehicle
- Replacement Vehicle
- Renewal Vehicle
- Upgrade
- Downgrade
- Change Information
- Specify the Change

Note: A replacement vehicle means a life support agency has removed a vehicle from service and replaced it with another at the same level.

STATE OF MICHIGAN
LIFE SUPPORT VEHICLE LICENSE APPLICATION
PART 2

FEES
$25.00 for BLS, LALS & ALS vehicles
$100.00 for each Aircraft Transport Vehicle (Fixed Wing)
No fee for Medical First Responder for - initial or renewal if received by license renewal expiration date

LATE FEES APPLY AFTER LICENSE RENEWAL EXPIRATION DATE
Late fees are an additional $100.00 per vehicle (MFR – ALS)

Make Check or Money Order Payable To:
STATE OF MICHIGAN
(Please type or print)

VEHICLE LOCATION

8.6.1.2 Submit all documents and fees to Michigan Department of Health and Human Services, Division of EMS and Trauma, PO Box 30437, Lansing, MI 48909. The department must inspect all vehicles that will be added or replaced.

9.0 Vehicle Manufacturing Standards

An ambulance operation must maintain the **Manufacturer's Certificate of Compliance** on file at the time of application for licensure of each ground ambulance. The Certificate of Compliance shall be executed by the final manufacturer of each ground ambulance.

9.1 The manufacturer of a ground ambulance executing a certificate of compliance shall comply with the ambulance structural and mechanical specifications with **one** of the following standards that was in effect at the time of manufacture:

9.1.1 **Federal Triple K-A-1822** standards, excluding the paint scheme, or

9.1.2 **Commission on Accreditation of Ambulance Services (CAAS**) Ground Vehicle Standard for Ambulances (GVSA) in its entirety, or

9.1.3 National Fire Protection Association (NFPA) 1917 Standard for Automotive Ambulances in its entirety and shall maintain test data demonstrating compliance.

9.1.4 Once the vehicle is licensed for service, the ambulance operation shall not be required to meet later modified state vehicle standards during its use by the ambulance operation that obtained the license.

IMPORTANT INFORMATION

A ground ambulance shall not be modified to alter its original design upon which the certificate of compliance was based, unless a new certificate is issued verifying that the modifications have not altered the integrity of the vehicle.

9.2 Remounts

9.2.1 Remounted ambulances are allowed under administrative rule: R 325.22181 (6) – "The patient compartment of a ground ambulance that has met applicable standards at the time of manufacture may be remounted on to a different chassis by a qualified vehicle modifier as designated by the chassis manufacturer.

MODIFYING THE TYPE OF BOX

An ambulance box type cannot be changed to another type. For example, a type III box cannot be changed to a type I box.

9.2.2 A new manufacturer's certificate of compliance shall be issued that identifies the new vehicle identification number and demonstrates compliance with either KKK, GVSA, or NFPA standards in accordance with subrule (2) of this rule. "

9.2.3 **A remounted ambulance is considered a new vehicle at the time it is manufactured. The manufacturer of the ambulance must be a "final stage manufacturer" as defined by the National Highway Traffic Safety Administration (NHTSA) and must be registered with NHTSA . The manufacturer must maintain data demonstrating the structural and mechanical specifications to which the new ambulance was built and be able to produce them upon request.**

9.2.4 A patient compartment box that is being remounted must meet the applicable standards at the time it was originally **manufactured and conform to all current Federal Motor Vehicle Safety Standards**. A **Manufacturers Certificate of Compliance** must be completed before the new remounted ambulance can be considered for licensure. For a list of resources please see Appendix C.

10.0 Minimum Vehicle Equipment Requirements

Each licensed vehicle must have the minimum necessary equipment. All equipment must be clean and functional. Sterile items must be intact in their package, usable, integrity of package must not be compromised, and must not be expired if a manufacturer's expiration is noted. For a specific list of the required equipment by vehicle level, see https://www.michigan.gov/mdhhs/0,5885,7-339-73970_5093_28508_76838---,00.html.

11.0 Violations

Violations are any items that do not fully satisfy the requirements listed on the vehicle or agency inspection forms, as described in the Public Health Code and Administrative Rules.

11.1 On-Site Correctable Violations

11.1.1 On-site correctable violations are violations for which a correction is made while the inspector is on-site, a notation will be made, but a formal violation will not be issued.

11.2 Violations Not Correctible During Inspection

11.2.1 If a violation is not corrected during the inspection, the violation will remain in effect. If one or more violations are found during the inspection, the DET will issue a "statement of violations" clearly indicating the regulation which governs the violation and the items that were in violation of that regulation.

11.2.1.1 If the department determines that a life support vehicle is not in compliance with the requirements of the code and these rules, then the following shall apply:

11.2.1.2 MDHHS makes the determination that a vehicle is non-compliant with equipment items, the agency has 24 hours to make the corrections or the vehicle must be removed from service.

11.2.1.3 A vehicle taken out of service due to non-compliance shall not respond or provide emergency assistance or conduct inter-facility transfers.

11.2.1.4 The vehicle may be returned to service with approval of the DET Agency Licensing Coordinator, written notification that corrections were made must be provided. A re-inspection may occur.

11.2.1.5 If a life support vehicle remains out of compliance for more than 15 calendar days from the date of inspection, then the vehicle license shall be automatically revoked.

11.3 A life support vehicle may be ordered out of immediate service if it is determined that the health, safety, and welfare of a patient may be in jeopardy due to non-compliance with, defective and non-functional equipment, or other applicable reasons. A notice of such action shall be issued to the life support agency by MDHHS based upon the deficiencies identified in the inspection report.

12.0 Enforcement

The department may take any action authorized by sections 20162, 20165, 20168 of the Public Health Code, the Administrative Rules for Life Support Agencies, or other provisions of the code in response to a violation of the code or these rules. Enforcement actions include any of the following:

12.1 Denial, suspension, limitation or revocation of a life support agency license.

12.2 The issuance of a nonrenewable conditional license effective for not more than 1 year.

12.3 A life support agency that is granted a 1-year nonrenewable conditional license must comply with all:

12.3.1 Provide at least 1 vehicle for response to requests for emergency assistance on a 24-hour-a-day, 7-day-a-week basis in accordance with its licensure level.

12.3.2 Submit a statement of the reasons for the life support agency's inability to comply with the code for licensure.

12.3.3 Develop a plan of action to meet all licensure requirements. The plan shall be submitted to the medical control authority and the department.

12.3.4 Submit a monthly report to the medical control authority that outlines the progress made on the plan.

12.3.5 Report all out-of-service time to each involved medical control authority.

12.4 A life support agency that is granted a 1-year non-renewable conditional license shall comply with

12.4.1 The issuance of an administrative order to correct deficiencies and prescribing the actions the department determines to be necessary to obtain compliance with the code or to protect the public health, safety, and welfare.

APPENDICES

APPENDIX A: Division of EMS and Trauma Agency Contacts

EMS Regional Coordinators:

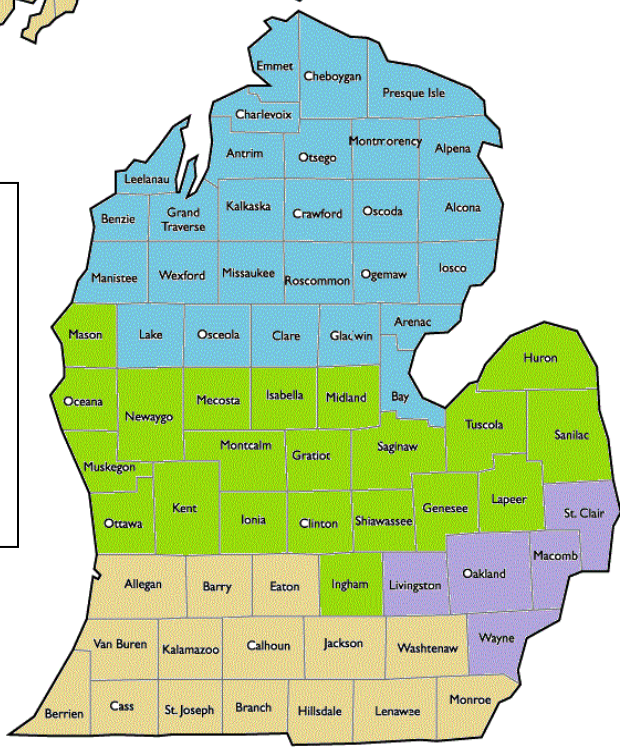
Southwest Region: Matthew Godde

Southeast Region: Allison Biliti

Central Region: Amanda Kinney

Northern Region: Tammy Forbush

Upper Peninsula Region: Lee-Ellen Bailey



Southwest Region	Matt Godde	517-282-1730	goddem@michigan.gov
Southeast Metro Region	Allison Biliti	517-582-5794	bilitia@michigan.gov
Central Region	Amanda Kinney	517-582-5816	armattia@michigan.gov
Northern Region	Tammy Forbush	517-290-0953	forbusht@michigan.gov
Upper Peninsula Region	Lee-Ellen Bailey	517-582-1274	baileyl12@michigan.gov
Agency Licensing Coordinator	Derek Flory	517-335-8382	floryd@michigan.gov
MAIN EMS PHONE LINE		517-241-3025	
EMS Section Manager	Sabrina Kerr	517-241-3024	kerrs3@michigan.gov
Division of EMS & Trauma Director	Kathy Wahl	517-335-8150	wahlk@michigan.gov

APPENDIX B: Agency Requirements Examples of Compliance

ADMINISTRATIVE RULE OR PUBLIC HEALTH CODE (PHC) SECTION	REQUIREMENT	EXAMPLES OF ACCEPTABLE EVIDENCE OF COMPLIANCE
Full Disclosure of the Agency Ownership		
Rule 100(i) Rule 131(g) Rule 141(f)	Documentation of Type of Legal Organization	• Sole Proprietorship • Partnership • Corporation • Subsidiary of another corporation or unit of government Articles of Business Incorporation, City Charter, Township Incorporation papers, Township Board Meeting minutes for incorporation.
Rule 101(ii)	Doing Business As (DBA)	Disclose any doing business as or trade name(s) under which the organization operates, including but not limited to the name(s) by which said organization is known to the public. Officially registered DBA documents from the County Clerk's Office.
Rule 114(iii)	Official Registration of the entity with the State of Michigan	Provide registration in the State of Michigan or other designated official in each state in which the agency is chartered, incorporated or authorized to do business. Registration documents showing registration or license number.
Rule 115(iv)	Parent or Subsidiary Relationships	Disclose any parent, subsidiary or other relationships that involve ambulance or health care business activities; shared overhead or resources; or that have inter-locking directorates. Inter-facility Agreements, Intercept Agreements. Current agreement signed and dated by all parties that is reviewed at least once every 5 years.

ADMINISTRATIVE RULE OR PUBLIC HEALTH CODE SECTION	REQUIREMENT	EXAMPLES OF ACCEPTABLE EVIDENCE OF COMPLIANCE
	Management	
Rule 102 Rule 131(h) Rule 141(g)	Designation of One Operations Leader	Organization has identified one individual (i.e., president, chief, director or coordinator) who is responsible for overall day-to-day operations of the service and serves as the contact person. Position Description; Contract; License Application. Meeting minutes showing appointment to position.
Rule 116 Rule 132(a) Rule 142(a)	Complaints	Written procedure that explains the steps that occur when a complaint is received by the agency Current and reviewed at least once every 3 years.
Rule 104 Rule 111(5)	Response Capabilities	Documentation that demonstrates response capabilities or ensures a response is provided to each request for emergency assistance originating within the bounds of your licensed service area. Mutual aid agreement must be signed and dated by all parties involved. Current agreement that is reviewed, signed, and dated at least once every 3 years.
Rule 117 Rule 132(b) Rule 142(b)	Disaster Plan	Demonstrate inclusion in the county/regional disaster plan and response. This can include a plan, medical control authority protocols, or after-action reports that specifically identify the agency as participating. Current plan that is reviewed at least once every 5 years.

ADMINISTRATIVE RULE OR PUBLIC HEALTH CODE SECTION	REQUIREMENT	EXAMPLES OF ACCEPTABLE EVIDENCE OF COMPLIANCE
	Recordkeeping	
Rule 105 Rule 132(i) Rule 142(i)	Requests for Service	Written policy AND evidence that a record is created to document each request for service that the agency receives, including calls cancelled prior to arrival and incidents which result in no patient being transported. Current policy that is reviewed at least once every 3 years. Evidence Examples: Dispatch log, run log from dispatch center, electronic access.
Rule 106 Rule 132(i) Rule 142(i) Rule 117 Rule 155(2)(b)	Patient Care Record	Written policy AND evidence that a record is created to document all findings and treatment given, if any, whenever contact is made with a patient or one presumed to be a patient regardless of whether or not the patient is ultimately treated or transported in accordance with the Michigan Patient Care Record Protocol (Section 7-15). (identifiable patient information must be protected) Note: A life support agency shall maintain an accurate record of each incident where care is rendered on a form approved by the MCA. All records must be maintained for 5 years. However, records of minors shall be maintained until they reach 23 years of age. **Aircraft Transport Agency** must maintain accurate medical flight records concerning the transportation of an emergency patient in intrastate and interstate flights originating in Michigan. Current policy that is reviewed at least once every 3 years and copy of PCR.

ADMINISTRATIVE RULE OR PUBLIC HEALTH CODE SECTION	REQUIREMENT	EXAMPLES OF ACCEPTABLE EVIDENCE OF COMPLIANCE
Recordkeeping		
PHC Section 20910(1)(i) Rule 132(i) Rule 142(i)	Data Submission to the Michigan EMS Information System (MI-EMSIS)	Written policy AND evidence that all patient care records are uploaded into the Michigan EMS Information System (MI-EMSIS) Database on a monthly basis (by the 15th of the month) for the past year. Current policy that is reviewed at least once every 3 years. Evidence: monthly MI-EMSIS report which will show when the agency last uploaded patient care records to the system. More information about MI EMSIS can be found on the Michigan.gov/ems website
Communications		
Rule 113 Rule 132(k) Rule 142(k)	State MEDCOM Plan	Evidence of compliance with most current State MEDCOM Plan. Evidence: hard copy of plan, online, or electronic. Demonstrate ability to contact hospitals and Central Dispatch from the ambulance.
Safety Policies and Procedures		
Rule 119 Rule 132(d) Rule 142(d)	Maintain written policies and procedures that address safety and accident reduction and comply with all applicable state and federal health and safety laws:	Present current policies and procedures as indicated below. Policies Must be reviewed annually and show date of review on policy (unless otherwise stated).

ADMINISTRATIVE RULE OR PUBLIC HEALTH CODE SECTION	REQUIREMENT	EXAMPLES OF ACCEPTABLE EVIDENCE OF COMPLIANCE
Safety Policies and Procedures		
	Bloodborne Pathogens	The Bloodborne Infectious Diseases Exposure Control Plan must include all of the components of the Part 554 Bloodborne Infectious Diseases Rules, including the following: • Exposure determination • Exposure Control Plan • Universal precautions • Engineering controls • Work practices • Protective work clothing and equipment • Housekeeping • Regulated waste disposal • Laundry • HIV and HBV research laboratories and production facilities • Vaccinations and post-exposure follow-up • Communication of hazards to employees • Recordkeeping • Information and training (annual training) The following resources are also attached to this document for reference: • APPENDIX D: Part 554. Bloodborne Infectious Disease Rules • APPENDIX D-1: Information Sheet • APPENDIX D-2: Hepatitis B Waiver • APPENDIX D-3: Bloodborne Infectious Disease Rule Summary • APPENDIX D-4: Sample Bloodborne Infectious Disease Exposure Control Plan

ADMINISTRATIVE RULE OR PUBLIC HEALTH CODE SECTION	REQUIREMENT	EXAMPLES OF ACCEPTABLE EVIDENCE OF COMPLIANCE
Safety Policies and Procedures		
	Disposal of Medical Waste	The Medical Waste Management Plan must include the components of Part 138 of the Public Health Code - Medical Waste (APPENDIX F), including the following: • The types of medical waste handled • The segregation, packaging, labeling, and collection procedures used • The use and methods of on-site or off-site storage • The use and methods of on-site or off-site decontamination • The use of on-site or off-site incineration • The corporate or other legally recognized business name of solid waste haulers who transport medical waste for the producing facility • The use of sanitary landfills, cemeteries, and other disposal sites • The measures to minimize exposure of the facilities employees to infectious agents throughout the process of handling and disposing of the medical waste, including, where applicable, the use of protocols, procedures and training, personal protective devices and clothing, physical containment or isolation devices or systems, and prevention or control of aerosols. • The name of the individual responsible for the management of the medical waste The plan must be updated each time there is a change in a person or site named in the plan, or the types of medical waste handled or the methods of handling medical waste at the agency within 30 days after the change occurs. A sample Medical Waste Management Plan can be found in APPENDIX F-1.

		If a life support agency brings medical waste back to the agency and stores it for any period of time, please contact EGLE to register the facility as a Medical Waste Producer: Phone: 517-230-9800 Email: MedicalWaste@michigan.gov Website: https://www.michigan.gov/egle/0,9429,7-135-3312_4123_4119---,00.html Medical Waste Registration Memo 8-7-19
ADMINISTRATIVE RULE OR PUBLIC HEALTH CODE SECTION	**REQUIREMENT**	**EXAMPLES OF ACCEPTABLE EVIDENCE OF COMPLIANCE**
Safety Policies and Procedures		
	EEOC (Equal Employment Opportunity Commission)	Current EEOC Posters must be up and there must be an EEOC policy for agency Demonstrate compliance with the Equal Employment Opportunity Law. The EEOC is the federal government agency charged with eliminating workplace discrimination based on race, color, religion, sex, national origin, sexual orientation, gender identity, age, and disabilities. Non-discriminatory policies and practices must be implemented and communicated to all employees. For detailed information, go to https://www.eeoc.gov/employers/ The EEO Law poster can be downloaded from https://www.eeoc.gov/employers/upload/eeoc_self_print_poster.pdf Please refer to the Department of Labor website for more information: EEOC Poster
	General Safety	• MiOSHA safety polices • MSDS data sheets accessible either electronically or in hard copy

ADMINISTRATIVE RULE OR PUBLIC HEALTH CODE SECTION	REQUIREMENT	EXAMPLES OF ACCEPTABLE EVIDENCE OF COMPLIANCE
Safety Policies and Procedures		
	Lab Draws & Blood Glucose CLIA Waiver	• A CLIA Waiver is required for ALL agencies conducting phlebotomy (lab draws) and/or lab testing such as is done with a glucometer or iStat. The CLIA Waiver is required to be submitted at the time of initial and renewal licensing. • At the time of inspection, the Agency must demonstrate compliance with the manufacturer's instructions for quality assurance for equipment used for the waived testing (for example calibration or testing high and low controls etc.) • Policies must be in place to address any testing. Please refer to the CLIA Waiver Memo in APPENDIX G. More information may be found on the Michigan Department of Licensing and Regulatory Affairs website as well: CLIA Waiver
	HAZMAT Response	Policy for responding to HAZMAT incidents.
	Michigan Motor Vehicle Code	Provide Emergency Vehicle Driving Policy for Employees and show where to find P.A. 300 Section 257 commonly known as the Michigan Motor Vehicle Code for Emergency Vehicle Response. Policy should have references to PA 300 within it.
	Respiratory Protection Plan	The following components need to be present in a Respiratory Protection Plan: • Respirator Selection • Employee Medical Evaluation • Employee Fit Testing – Annual • Respirator Use

		• Maintenance, Care, and Disposal of Respirator • Training • Recordkeeping • Storage
ADMINISTRATIVE RULE OR PUBLIC HEALTH CODE SECTION	**REQUIREMENT**	**EXAMPLES OF ACCEPTABLE EVIDENCE OF COMPLIANCE**
Safety Policies and Procedures		
		• Program Evaluation • Assign Responsibility OSHA requires that the program be administered by a suitably trained program administrator. Perform a hazard Evaluation to determine potential exposures that might require the use of respiratory protection including chemical hazards and exposure to infectious diseases. This is an excellent resource for developing a respiratory protection plan and is focused on hospitals, however, it is translatable to an EMS agency: https://www.cdc.gov/niosh/docs/2015-117/pdfs/2015-117.pdf The following resources are also attached to this document for reference: • APPENDIX E: OSHA Respiratory Protection Standards • APPENDIX E-1: Fit Test Procedures • APPENDIX E-2: User Seal Procedures • APPENDIX E-3: Respiratory Cleaning Procedures • APPENDIX E-4: OSHA Respiratory Medical Evaluation Questionnaire • APPENDIX E-5: Information for Employees Using Respirators when Not Required Under the Standard • APPENDIX E-6: Sample Respiratory Protection Program

ADMINISTRATIVE RULE OR PUBLIC HEALTH CODE SECTION	REQUIREMENT	EXAMPLES OF ACCEPTABLE EVIDENCE OF COMPLIANCE
	Personnel	
Rule 122 Rule 132(m) Rule 142(m)	Maintain documentation that each individual operating a licensed life support vehicle during an emergency or patient transport has completed a department approved vehicle operation education and competency assessment.	Provide Emergency Vehicle Driver Training Certificates from MDHHS approved courses: • CEVO • VFIS • MFFTC • EVOC Inspector to randomly select personnel files for review. If your course is not one of the four listed above, you must apply to the DET Education Coordinator for approval to ensure that it meets the appropriate criteria. The driving training criteria may be found website at: Emergency Vehicle Driver Training Criteria
Rule 107 Rule 132(e) Rule 142(e) Rule 108 Rule 207(b) Rule 109 Rule 132(g) Rule 142(g) Rule 120 Rule 132(g) Rule 142(g)	Maintain a list, current license and certification documents of all EMS personnel licensed by MDHHS and employed/registered with life support agency. Assure that agencies are providing clinical competency assessments to emergency medical personnel before the individual provides emergency medical services. Show evidence of an orientation for EMS personnel to familiarize them with the agency's policies and procedures. Orientation must include, at a minimum, a proper introduction to the duties to be performed, equipment used, as well as medical control authority protocols. Show evidence of and maintain documentation that demonstrates that EMS personnel are trained on equipment that is carried by the agency.	Provide current roster of all EMS personnel and the following records: • Current license • Any current certifications, i.e. BLS, ACLS, etc. • Orientation records-including orientation to MCA protocols prior to providing patient care • Clinical competency assessments including competency for any CLIA waived testing • Equipment Training Inspector to randomly select personnel files for review during inspection.

ADMINISTRATIVE RULE OR PUBLIC HEALTH CODE SECTION	REQUIREMENT	EXAMPLES OF ACCEPTABLE EVIDENCE OF COMPLIANCE
	Protocols	
Rule 110 Rule 132(h) Rule 142(h)	Maintain a copy of all applicable protocols for all medical control authorities the agency operates in.	Show current copy of protocols for each MCA your agency operates in and where they are kept. This can include electronic versions on a computer, tablet, or phone, etc. Demonstrate how providers can access the protocols in the field.
	Quality Assurance	
Rule 111 Rule 114 Rule 207(h) Rule 211(1)	Show evidence of participation in an agency based and/or medical control authority quality improvement process.	Participation in agency based or MCA Quality Improvement Process/PSRO Examples of evidence: Internal QA/QI process or policy, MCA letter of compliance, MCA meeting minutes showing participation for QA/QI, etc.
	Equipment and Vehicles	
Rule 112 Rule 132(J) Rule 142(J)	Vehicles inspected are currently licensed and meet equipment requirements established by the department.	Show current, posted copy of the Vehicle license issued by the department, with most current vehicle inspection report that is compliant. All randomly selected vehicles must pass the vehicle inspection requirements at the time of an agency inspection in order to meet compliance with this criterion. See vehicle inspection forms equipment requirements.
Rule 119 Rule 121	A life support agency shall have a written policy in place to ensure vehicles and equipment are operational and provide documentation of not less than a weekly inspection program for all vehicles, communications equipment and mechanical and electronic medical equipment.	Provide written policy for vehicle and equipment inspections. Provide Vehicle Check Sheets that should be dated, signed and completed by employees. Recommend using the MDHHS inspection form as the check sheet. These forms are available for each level of service Policy must be reviewed for updates at least once every 3 years. Inspector will randomly select vehicle inspections date range to review.

APPENDIX C: Vehicle Requirements

Life Support Agency / Vehicle Forms: https://www.michigan.gov/mdhhs/0,5885,7-339-73970_5093_28508_76838---,00.html

CAAS Ground Vehicle Standard for Ambulances: http://www.groundvehiclestandard.org/

National Fire Protection Association Ambulance Standards: https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/detail?code=1917

Triple K Ambulance Standards: safeambulances.org

Triple K Change Notices: safemabulances.org

Federal Motor Vehicle Standards (FMVSS): https://www.nhtsa.gov/laws-regulations/fmvss

NHTSA Manufacture's Information Database: https://vpic.nhtsa.dot.gov/mid/

MIOSHA-STD-1209 (10/15)
14 Pages

For further information
Ph: 517-284-7740
www.michigan.gov/mioshastandards

DEPARTMENT OF LICENSING AND REGULATORY

AFFAIRS DIRECTOR'S OFFICE

OCCUPATIONAL HEALTH STANDARDS

Filed with the Secretary of State on June 30, 1993 (as amended November 14, 1996) (as amended June 28, 2001) **(as amended October 28, 2014)**

These rules become effective immediately upon filing with the Secretary of State unless adopted under section 33, 44, or 45a(6) of 1969 PA 306.

Rules adopted under these sections become effective 7 days after filing with the Secretary of State.

(By authority conferred on the director of the department of licensing and regulatory affairs by sections 14 and 24 of 1974 PA 154, MCL 408.1014 and 408.1024, and Executive Reorganization Order Nos. 1996-1 and 1996-2, 2003-1, 2008-4, and 2011-4, MCL 330.3101, 445.2001, 445.2011, 445.2025 and 445.2030)

R 325.70002, R 325.70003, R 325.70004, R 325.70007, R 325.70008, R 325.70009, R 325.70011, R 325.70013, R 325.70014, R 325.70015, R 325.70016 and R 325.70017 of the Michigan Administrative code are amended, and R 325.70001a is added, and R 325.70017 and R 325.70018 of the Code are rescinded as follows:

PART 554. BLOODBORNE INFECTIOUS DISEASES

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R 325.70001 Scope.

Rule 1. These rules apply to all employers that have employees with occupational exposure to blood and other potentially infectious material.

R 325.70001a Referenced standards.

Rule 1a. (1) The following Michigan occupational safety and health standards are referenced in these rules. Up to 5 copies of these standards may be obtained at no charge from the Michigan Department of Licensing and Regulatory Affairs, MIOSHA Regulatory Services Section, 7150 Harris Drive, P.O. Box 30643, Lansing, Michigan 48909-8143, or via the internet at website: www.michigan.gov/mioshastandards. For quantities greater than 5, the cost, at the time of adoption of these rules, is 4 cents per page.

(a) Occupational Health Standard Part 470 "Employee Medical Records and Trade Secrets," R 325.3451 to R 325.3476.

(b) MIOSHA Standard Part 11. "Recording and Reporting of Occupational Injuries and Illnesses," R 408.22101 to R 408.22162.

(2) The appendices to these rules are informational only and are not intended to create any additional obligations or requirements not otherwise imposed by these rules or to detract from any established obligations or requirements.

R 325.70002 Definitions.

Rule 2. As used in these rules:

(a) "Act" means Michigan occupational safety and health act (MIOSHA), 1974 PA 154, MCL 408.1001 to 408.1094.

(b) "Biologically hazardous conditions" means equipment, containers, rooms, materials, experimental animals, animals infected with HBV or HIV virus, or combinations thereof that contain, or are contaminated with, blood or other potentially infectious material.

(c) "Blood" means human blood, human blood components, and products made from human blood.

(d) "Bloodborne pathogens" means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

(e) "Clinical laboratory" means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious material.

(f) "Contaminated" means the presence or the reasonably anticipated presence of blood or other potentially infectious material on an item or surface.

(g) "Contaminated laundry" means laundry that has been soiled with blood or other potentially infectious materials or that may contain sharps.

(h) "Contaminated sharps" means any contaminated object that can penetrate the skin, including any of the following:

(i) Needles.

(ii) Scalpels.

(iii) Broken glass.

(iv) Broken capillary tubes.

(v) Exposed ends of dental wires.

(i) "Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

(j) "Department" means the department of licensing and regulatory affairs.

(k) "Director" means the director of the department or his or her designee.

(l) "Disinfect" means to inactivate virtually all recognized pathogenic microorganisms, but not necessarily all microbial forms, on inanimate objects.

(m) "Engineering controls" means controls, for example, sharps disposal containers, self-sheathing needles, or safer medical devices, such as sharps with engineered sharps injury protections and needleless systems that isolate or remove the bloodborne pathogen hazard from the workplace.

(n) "Exposure" means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties. "Exposure" does not include incidental exposures that may take place on the job, that are neither reasonably nor routinely expected, and that the worker is not required to incur in the normal course of employment.

(o) "Exposure incident" means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious material that results from the performance of an employee's duties.

(p) "Handwashing facilities" means facilities that provide an adequate supply of running, potable water, soap, and single-use towels or an air drying machine.

(q) "Licensed health care professional" means a person whose legally permitted scope of practice allows him or her to independently perform the activities required by R 325.70013 concerning hepatitis B vaccination and post-exposure evaluation and follow-up.

(r) "Needleless systems" means a device that does not use needles for any of the following:

(i) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established.

(ii) The administration of medication or fluids.

(iii) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

(s) "Other potentially infectious material" means any of the following:

(i) Any of the following human body fluids:

(A) Semen.

(B) Vaginal secretions.

(C) Amniotic fluid.

(D) Cerebrospinal fluid.

(E) Peritoneal fluid.

(F) Pleural fluid.
(G) Pericardial fluid.
(H) Synovial fluid.
(I) Saliva in dental procedures.
(J) Any body fluid that is visibly contaminated with blood.
(K) All body fluids in situations where it is difficult or impossible to differentiate between body fluids.
(ii) Any unfixed tissue or organ, other than intact skin, from a living or dead human.
(iii) Cell or tissue cultures that contain HIV, organ cultures, and culture medium or other solutions that contain HIV or HBV; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.
(t) "Parenteral" means exposure occurring as a result of piercing mucous membrane or the skin barrier, such as exposure through subcutaneous, intramuscular, intravenous, or arterial routes resulting from needlesticks, human bites, cuts, and abrasions.
(u) "Personal protective equipment" or "PPE" means specialized clothing or equipment that is worn by an employee to protect him or her from a hazard. General work clothes, such as uniforms, pants, shirts, or blouses that are not intended to function as protection against a hazard are not considered to be personal protective equipment.
(v) "Production facility" means a facility that is engaged in the industrial-scale, large-volume production of HIV or HBV or in the high-concentration production of HIV or HBV.
(w) "Regulated waste" means any of the following:
(x) Liquid or semiliquid blood or other potentially infectious material.
(ii) Contaminated items that would release blood or other potentially infectious material in a liquid or semiliquid state if compressed.
(iii) Items that are caked with dried blood or other potentially infectious material and that are capable of releasing these materials during handling.
(iv) Contaminated sharps.
(v) Pathological and microbiological waste that contains blood and other potentially infectious material.
(x) "Research laboratory" means a laboratory that produces or uses research laboratory-scale amounts of HIV or HBV. A research laboratory may produce high concentrations of HIV or HBV, but not in the volume found in a production facility.
(y) "Sharps with engineered sharps injury protections" means a non-needle sharp or a needle device that is used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, and that has a build-in safety feature or mechanism that effectively reduces the risk of an exposure incident.
(z) "Source individual" means any living or dead individual whose blood or other potentially infectious material may be a source of occupational exposure to an employee. Examples of a source individual include all of the following:
(i) A patient of a hospital or clinic.
(ii) A client of an institution for the developmentally disabled.
(iii) A victim of trauma.
(iv) A client of a drug or alcohol treatment facility.
(v) A resident of a hospice or nursing home.
(vi) Human remains.
(vii) An individual who donates or sells his or her blood or blood components.
(aa) "Standard operating procedures (SOPs)" means any of the following that address the performance of work activities so as to reduce the risk of exposure to blood and other potentially infectious material:
(i) Written policies.
(ii) Written procedures.
(iii) Written directives.
(iv) Written standards of practice.
(v) Written protocols.
(vi) Written systems of practice.
(vii) Elements of an infection control program.
(bb) "Sterilize" means the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores.
(cc) "Universal precautions" means a method of infection control that treats all human blood and other potentially infectious material as capable of transmitting HIV, HBV, and other bloodborne pathogens.
(dd) "Work practices" means controls that reduce the likelihood of exposure to bloodborne pathogens by altering the manner in which a task is performed.

R 325.70003 Exposure determination.

Rule 3. (1) An employer shall evaluate routine and reasonably anticipated tasks and procedures to determine whether there is actual or reasonably anticipated employee exposure to blood or other potentially infectious material. Based on this evaluation, an employer shall categorize all employees into category A or B as follows:
(a) Category A consists of occupations that require procedures or other occupation-related tasks that involve exposure or reasonably anticipated exposure to blood or other potentially infectious material or that involve a likelihood for spills or splashes of blood or other potentially infectious material. This includes procedures or tasks conducted in nonroutine situations as a condition of employment.
(b) Category B consists of occupations that do not require tasks that involve exposure to blood or other potentially infectious material on a routine or nonroutine basis as a condition of employment. Employees in occupations in this category do not perform or assist in emergency medical care or first aid and are not reasonably anticipated to be exposed in any other way.
(2) An exposure determination shall be made without regard to the use of personal protective clothing and equipment.
(3) An employer shall maintain a list of all job classifications that are determined to be category A.

R 325.70004 Exposure control plan.

Rule 4. (a) If an employee is determined to be in

category A, then an employer shall establish a written exposure control plan to minimize or eliminate employee exposure.

(b) An exposure control plan shall contain all of the following information:

(i) The exposure determination required by R 325.70003(1).

(ii) The schedule and method of implementation for each applicable rule.

(iii) The contents or a summary of the training program required by R 325.70016.

(iv) The procedures for the evaluation of circumstances surrounding exposure incidents as required by R 325.70013(5).

(v) Task-specific standard operating procedures (SOPs) that address all of the following areas:

(A) Employee recognition of reasonably anticipated exposure to blood and other potentially infectious material.

(B) Appropriate selection, use, maintenance, and disposal of personal protective equipment.

(C) Contingency plans for foreseeable circumstances that prevent following the recommended SOPs.

(c) General employer policies or task-specific SOPs shall address the management of inadvertent exposures such as needlesticks or mucus membrane exposures.

(d) The exposure control plan shall be reviewed at least annually and updated as necessary. A review shall consider changes in employees' tasks and procedures and the latest information from the centers for disease control or the department. See appendix A for addresses of these agencies. The review and update of the exposure control plans shall comply with both of the following provisions:

(i) Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens.

(ii) Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

(e) An employer shall ensure that only a person who has knowledge of applicable control practices is authorized to write and to review an exposure control plan.

(f) An employer shall ensure that the exposure control plan is made available to the director or a representative of the director for examination and copying upon request.

(g) An employer shall ensure that a copy of the exposure control plan is accessible to category A employees in accordance with Occupational Health Standard Part 470 "Employee Medical Records and Trade Secrets," as referenced in R 325.70001a.

(h) An employer who is required to establish an exposure control plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the exposure control plan.

R 325.70005 Universal precautions.

Rule 5. Universal precautions shall be observed to prevent contact with blood and other potentially infectious materials. If differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

R 325.70006 Engineering controls.

Rule 6. (1) Engineering controls shall be used in combination with work practice controls to minimize or eliminate employee exposure to blood and other potentially infectious material. Where exposure remains after use of engineering and work practice controls, personal protective equipment shall also be used.

(2) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(3) An employer shall provide hand-washing facilities which are readily accessible to employees. When provision of hand-washing facilities is not feasible, an employer shall provide an appropriate antiseptic hand cleanser with clean cloth or paper towels or antiseptic towelettes.

R 325.70007 Work practices.

Rule 7. At a minimum, work practices shall ensure all of the following:

(a) All personal protective equipment shall be removed before leaving the work area and shall be placed in an appropriately designated area or container for storage, washing, decontamination, or disposal.

(b) If a garment is penetrated by blood or other potentially infectious materials, the garment shall be removed immediately or as soon as feasible.

(c) Employers shall provide handwashing facilities that are readily accessible to employees. When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, employees shall wash hands with soap and running water as soon as feasible.

(d) Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

(e) Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

(f) Used needles and other contaminated sharps shall not be sheared, bent, or broken and shall not be recapped or resheathed where other disposal methods are practical. Used needles and other sharps shall not be recapped, resheathed, or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical

procedure. Needle recapping or removal shall be accomplished by use of a mechanical device or a 1-handed technique. The disposal of needles and sharps shall be accomplished in accordance with the provisions of R 325.70010.

(g) Eating, drinking, smoking, applying cosmetics or lip balm, or handling contact lenses is prohibited in laboratories and other work areas where there is a reasonable likelihood of exposure.

(h) Food and drink shall not be stored in refrigerators, freezers, shelves, cabinets, or on countertops or benchtops where blood or other potentially infectious material is present or in other areas of possible contamination.

(i) All procedures that involve blood or other potentially infectious material shall be performed in a manner that minimizes splashing, spraying, and aerosolization of blood or other potentially infectious material.

(j) Mouth pipetting or suctioning is prohibited.

R325.70008 Protective work clothing and equipment.

Rule 8. An employer shall provide protective work clothing and equipment used in the following:

(a) When there is occupational exposure, an employer shall provide, at no cost to the employee, and assure that an employee uses, appropriate personal protective clothing and equipment, such as any of the following:

(i) Gloves.
(ii) Gowns.
(iii) Fluid-proof aprons.
(iv) Laboratory coats.
(v) Head and foot coverings.
(vi) Faceshields or mask and eye protection.
(vii) Mouthpieces.
(viii) Resuscitation bags.
(ix) Pocket masks.
(x) Other ventilation devices.

Personal protective equipment is appropriate only if it does not permit blood or other potentially infectious material to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time that the protective equipment is used.

(b) An employer shall ensure that an employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use PPE when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance the use of PPE would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or coworker. When the employee makes this judgment, the circumstances shall be investigated and documented to determine if changes can be made to prevent future occurrences.

(c) An employer shall assure that appropriate protective equipment and clothing in the appropriate sizes are readily accessible at the worksite or issued to employees at no cost to the employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to employees who are allergic to the gloves normally provided. See appendix A for more information.

(d) An employer shall provide for the cleaning, laundering, or disposing of protective clothing and equipment required by this rule.

(e) An employer shall repair or replace required protective clothing and equipment as needed to maintain their effectiveness.

(f) An employee shall wear gloves if there is a reasonable anticipation of direct skin contact with blood, other potentially infectious material, mucous membranes, or nonintact skin of patients; when performing vascular access procedures, except as specified in subdivision (g) of this subrule; and when handling items or surfaces that are soiled with blood or other potentially infectious material.

Disposable (single-use) gloves, such as surgical or examination gloves, shall be replaced a soon as practical if contaminated or as soon as feasible if torn, punctured, or ineffective as barriers. Disposable gloves shall not be washed or decontaminated for reuse. Utility gloves shall be discarded if any are cracked, peeling, discolored, torn, or punctured or exhibit other signs of deterioration, but may be decontaminated for reuse if the integrity of the glove is maintained.

(g) If an employer of a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary, the employer shall do all of the following:

(i) Periodically reevaluate this policy.

(ii) Make appropriate gloves available to all employees who wish to use them for phlebotomy.

(iii) Not discourage the use of gloves for phlebotomy.

(iv) Require that gloves be used for phlebotomy in the following circumstances:

(A) When the employee has cuts, scratches, or other breaks in the skin on his or her hands or wrists.

(B) When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative patient.

(C) When the employee is receiving training in phlebotomy.

(h) Employees shall wear masks and eye protection or chin-length face shields as appropriate if splashes, sprays, spatters, droplets, or aerosols of blood or other potentially infectious material may be generated and if there is a likelihood for eye, nose, or mouth contamination.

(i) Employees shall wear gowns, lab coats, aprons, clinic jackets, or similar outer garments where appropriate if there is a reasonably anticipated exposure. Such clothing shall protect all areas of exposed skin that have a significant likelihood for contamination. The type of characteristics will depend upon the task and degree of exposure anticipated.

(j) Employees shall wear surgical caps or hoods and shoe covers or boots where appropriate if there is a

reasonable anticipation of gross contamination, for example, in autopsies and orthopedic surgery.

R 325.70009 Housekeeping.

Rule 9. (1) An employer shall assure that the worksite is maintained in a clean and sanitary condition. An employer shall determine and implement an appropriate written schedule for cleaning and for the method of decontamination based on all of the following:

(a) The location within a facility.
(b) The type of surface to be cleaned.
(c) The type of soil present.
(d) The tasks or procedures being performed.

(2) All equipment and environmental and working surfaces shall be maintained in a sanitary condition as follows:

(a) Work surfaces shall be cleaned and appropriately decontaminated with an appropriate disinfectant in all of the following instances:

(i) After completion of procedures.
(ii) When surfaces are overtly contaminated.
(iii) Immediately when blood or other potentially infectious material is spilled.
(iv) At the end of the work shift if the surface may have become contaminated since the last cleaning. See appendix A for supplemental information.

(b) Protective coverings such as plastic wrap, aluminum foil, or plastic-backed, absorbent paper may be used to cover equipment and environmental surfaces. These coverings shall be removed and replaced at the end of the work shift if contaminated or as soon as feasible when they become overly contaminated.

(c) Equipment that may become contaminated with blood or other potentially infectious material shall be examined before servicing or shipping and shall be decontaminated as necessary unless the employer can demonstrate that decontamination is not feasible. If decontamination is not feasible, the employer shall ensure that a readily observable label which states the portions of the equipment that remain contaminated and that is in compliance with R 325.70014(2)(h) is attached to the equipment. The employer shall ensure that all affected employees, the servicing representative, or the manufacturer, as appropriate, is notified that equipment decontamination is not feasible and is notified of the portions of the equipment that remain contaminated before handling, servicing, or shipping so that appropriate precautions will be taken.

(d) All bins, pails, cans, and similar receptacles that are intended for reuse and that have a reasonable likelihood for becoming contaminated with blood and other potentially infectious material shall be inspected and decontaminated on a regularly scheduled basis and shall be cleaned and decontaminated immediately, or as soon as possible, upon visible contamination.

(e) Broken glassware that may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, cotton swabs, or forceps.

(f) Specimens of blood or other potentially infectious material shall be placed in a closable leak-proof container during collection, handling, processing, storing, transporting, or shipping. If contamination of the outside of a primary container is likely, a second leak-proof container shall be placed over the outside of the first and closed to prevent leakage during handling, processing, storing, transporting, or shipping. If puncture of the primary container is likely, then the primary container shall be placed within a leak-proof, puncture-resistant secondary container. All containers shall be labeled or color- coded in accordance of R 325.70014.

(g) Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

R 325.70010 Regulated waste disposal.

Rule 10. (1) All regulated waste that is being disposed of shall be placed in closable, leak-proof containers or bags that are color-coded or labeled as required by the provisions of R 325.70014. If outside contamination of the container or bag is likely to occur, then a second leak-proof container or bag that is closable and labeled or color-coded shall be placed over the outside of the first and closed to prevent leakage during handling, storage, and transport.

(2) Immediately after use, contaminated sharps shall be disposed of in closable, leak-proof, puncture-resistant, disposable containers that are labeled or color-coded according to the provisions of R 325.70014. These containers shall be easily accessible to personnel; shall be located in the immediate area of use or where sharps are likely to be found, unless needles are mechanically recapped and transported through nonpublic corridors to the container; and shall be replaced routinely and not allowed to overfill.

(3) The disposal of all medical waste shall be in compliance with the provisions of sections 13801 to 13831 of Act No. 368 of the Public Acts of 1978, as amended, being §§333.13801 to 333.13831 of the Michigan Compiled Laws and known as the medical waste regulatory act.

R 325.70011 Laundry.

Rule 11. (1) Laundry that is or may be soiled with blood or other potentially infectious material or that may contain contaminated sharps shall be treated as if it were contaminated and shall be handled as little as possible with a minimum of agitation.

(2) Contaminated laundry shall be bagged at the location where it was used and shall not be sorted or rinsed in areas where patients are cared for.

(3) Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with R 325.70014. If laundry is wet and presents the likelihood for soaking through or leaking from the bag, it shall be placed and transported in leak-proof bags.

(4) An employer shall ensure that laundry workers

wear protective gloves and other appropriate personal protective work clothing while handling contaminated laundry.

(5) When an employer follows universal precautions in the handling of all soiled laundry, alternative labeling or color coding is sufficient if it permits all employees to recognize the containers that are required to be in compliance with universal precautions.

(6) When an employer ships contaminated laundry off-site to a facility that does not use universal precautions in the handling of all laundry, the shipping employer shall use bags or containers that are labeled or color-coded in accordance with R 325.70014.

R 325.70012 HIV and HBV research laboratories and production facilities.

Rule 12. (1) This rule applies to research laboratories and production facilities that are engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. This rule applies to such laboratories and facilities in addition to the other requirements of these rules. This rule does not apply to clinical or diagnostic laboratories that are engaged solely in the analysis of blood, tissues, or organs.

(2) Research laboratories and production facilities shall be in compliance with all of the following requirements:

(a) All infectious liquid or solid waste shall be incinerated or decontaminated by a method known to effectively destroy bloodborne pathogens before being disposed of.

(b) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

(c) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leak-proof, labeled or color-coded container that is closed before being removed from the work area.

(d) Access to the work area shall be limited to authorize persons only. Written policies and procedures shall be established whereby only persons who have been advised of the biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

(e) When other potentially infectious material or infected animals are present in the work area or containment module, a hazard warning sign that incorporates the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall be in compliance with the provisions of R 325.70014(1).

(f) All activities that involve other potentially infectious material shall be conducted in biological safety cabinets or other physical containment devices within the containment module. Work with such material shall not be conducted on the open bench.

(g) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

(h) Special care shall be taken to avoid skin contamination with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making contact with other potentially infectious materials is unavoidable.

(i) All waste from work areas, including animal rooms, shall be incinerated or decontaminated by a method known to effectively destroy bloodborne pathogens before disposal.

(j) Vacuum lines shall be protected with high-efficiency particulate air (HEPA) filters, or equivalent filters, and liquid disinfectant traps. Filters and traps shall be checked routinely and maintained or replaced as necessary.

(k) Hypodermic needles, syringes, and other sharp instruments shall be used only when a safer alternate technique is not feasible. Only needle-locking syringes or disposable syringe with needle units that have a needle as an integral part of the syringe shall be used for the injection or aspiration of other potentially infectious material. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe after being used. The needle and syringe shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before being discarded or reused.

(l) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or another responsible person. Spills shall immediately be contained and cleaned up by appropriate professional staff who are trained and equipped to work with potentially concentrated infectious material.

(m) A biosafety manual shall be prepared or adopted and reviewed and updated at least annually. Personnel shall be advised of potential hazards and shall be required to read and follow instructions on practices and procedures.

(n) Both of the following containment equipment requirements shall be complied with:

(i) Class I, II, or III certified biological safety cabinets or other appropriate combinations of personal protection or physical containment devices, such as any of the following, shall be used for all activities with other potentially infectious material that poses a threat of exposure to droplets, splashes, spills, or aerosols:

(A) Special protective clothing.

(B) Respirators.

(C) Centrifuge safety cups.

(D) Sealed centrifuge rotors.

(E) Containment caging for animals.

(ii) Biological safety cabinets shall be certified when installed, at least annually, and when they are relocated.

(3) HIV and HBV research laboratories shall be in compliance with both of the following requirements:

(a) Each laboratory shall contain a sink for washing hands and an eye wash station that are readily

available in the work area.

(b) An autoclave for the decontamination of regulated wastes shall be available.

(4) HIV and HBV production facilities shall be in compliance with all of the following requirements:

(a) The work areas shall be separated from areas that are open to an unrestricted traffic flow within the building. Passage through 2 sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored room for changing clothes, an airlock, or other access facility that requires passing through 2 sets of doors before entering the work area. Showers may be included as part of the changing room.

(b) The interior surfaces of walls, floors, and ceilings shall be water-resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination of the work area.

(c) Each work area shall contain a sink for washing hands. The sink shall be foot-operated, elbow operated, or automatically operated and shall be located near the exit door of the work area.

(d) Access doors to the work area or containment module shall be self-closing.

(e) An autoclave for the decontamination of infectious wastes shall be available within, or as near as possible to, the work area.

(f) A ducted exhaust air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow into the work area shall be verified.

(5) Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in R 325.70016(6).

R 325.70013 Vaccinations and post-exposure follow-up.

Rule 13. (1) An employer shall assure that all medical evaluations are procedures that are performed by or under the supervision of a licensed physician or other licensed health care professional and that all laboratory tests are conducted by an accredited laboratory.

(2) An employer shall assure that all evaluations, procedures, vaccinations, and post-exposure prophylaxes are provided without cost to the employee, at a reasonable time and place, and according to current recommendations of the United States public health service, unless in conflict with this rule.

(3) An employer shall assure that all employees will receive appropriate counseling with regard to medical risks and benefits before undergoing any evaluations, procedures, vaccinations, or post-exposure prophylaxes.

(4) Within 10 working days of the time of initial assignment and after the employee has received training required by R 325.70016(5)(i), an employer shall make all of the following available to each category A employee:

(a) A hepatitis B vaccination. If an employee initially declines vaccination, but at a later date, while still covered under these rules, decides to accept the HBV vaccine, the employer shall provide the vaccine at that time. If a booster dose or doses are recommended by the United States public health service at a future date, the booster dose or doses shall be made available.

(b) If an employee has previously received the complete HBV vaccination series, is found to be immune to HBV by virtue of adequate antibody titer, or the vaccine is contraindicated for medical reasons, then the employer is not required to offer the HBV vaccine to that employee.

(c) An employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

(d) An employer shall assure that an employee who declines to accept hepatitis B vaccination signs a waiver statement with all of the following provisions:

(i) Understanding of risk.

(ii) Acknowledgment of opportunity of vaccination at no cost.

(iii) Declining vaccination.

(iv) Future availability of vaccination at no cost if desired, if still in at-risk status. See appendix B for a sample of an acceptable waiver statement.

(5) An employer shall provide each exposed employee with an opportunity to have a confidential medical evaluation and follow-up subsequent to a reported occupational exposure incident to blood or other potentially infectious material. The evaluation and follow-up shall include, at a minimum, all of the following elements:

(a) Documentation of the route or routes of exposure and the circumstances under which the exposure incident occurred.

(b) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law, shall include all of the following:

(i) The source individual's blood shall be tested as soon as feasible and after consent is obtained to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. If the source individual's consent is not required by law, his or her blood, if available, shall be tested and the results documented.

(ii) If the source individual is already known to be infected with HBV or HIV, testing need not be repeated.

(iii) Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(c) Collection and testing of blood or HBV and HIV serological status shall include both of the following:

(i) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

(ii) If the exposed employee consents to baseline blood collection, but not to HIV testing at that time, the sample shall be preserved for not less than 90 days. If within the 90 days the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

(d) Post-exposure prophylaxis, when medically indicated, as recommended by the United States public health service.

(e) Counseling on risk reduction and the risks and benefits of HIV testing in accordance with state law.

(f) Evaluation of reported illnesses.

(6) An employer shall ensure that the health care professional who is responsible for the hepatitis B Vaccination is provided with a copy of these rules and appendices. An employer shall ensure that the health care professional who evaluates an employee after an exposure incident is provided with all of the following information:

(a) A description of the affected employee's duties as they relate to the employee's exposure incident.

(b) Documentation of the route or routes of exposure and the circumstances under which exposure occurred.

(c) Results of the source individual's blood testing, if available.

(d) All medical records that are relevant to the appropriate treatment of the employee, including vaccination status, and that are the employer's responsibility to maintain.

(7) For each evaluation pursuant to the provisions of this rule, an employer shall obtain, and provide an employee with a copy of, the evaluating health care professional's written opinion within 15 working days of the completion of the evaluation. The written opinion shall be limited to the following information:

(a) Whether hepatitis B vaccination is indicated for an employee and if the employee has received such vaccination.

(b) A statement that the employee has been informed of the results of the medical evaluation and that the employee has been told about any medical conditions that have resulted from exposure to blood or other potentially infectious material and that require further evaluation or treatment. The written opinion obtained by the employer shall not reveal specific findings or diagnoses that are unrelated to the employee's ability to wear protective clothing and equipment or receive vaccinations. Such findings and diagnoses shall remain confidential.

(8) Medical records that are required by these rules shall be maintained in accordance with R 325.70015.

R 325.70014 Communication of hazards to employees.

Rule 14. (1) An employer shall post signs at the entrance to work areas specified in R 325.70012. The signs shall bear the following legend:

[Name of infectious agent]
[Special requirements for entering the area]
[Name and telephone number of the laboratory director or other responsible person]

These signs shall be fluorescent orange-red with lettering and symbols in a contrasting color.

(2) Labels shall be in compliance with all of the following requirements:

(a) Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers that contain blood or other potentially infectious material, and other containers that are used to store or transport blood or other potentially infectious material, except as provided in subdivision € or (f) of this subrule.

(b) Labels that are required pursuant to this rule shall include the follow legend:

(c) Labels shall be fluorescent orange or orange-red or predominately orange or orange-red, with lettering or symbols in a contrasting color.

(d) Labels shall either be an integral part of the container or shall be affixed as close as safely possible to the container by string, wire, or adhesive or by another method that prevents the loss of labels or the unintentional removal of labels.

(e) Red bags or red containers may be substituted for labels.

(f) Containers of blood, blood components, or blood products that are labeled as to their contents and that have been released for transfusion or other clinical use are exempted from the labeling requirements of this rule.

(g) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment, or disposal are exempted from labeling requirements.

(h) Labels required for contaminated equipment shall be in accordance this subrule and shall also describe which portions of the equipment remain contaminated.

(i) Regulated waste that has been decontaminated need not be labeled or color-coded.

R 325.70015 Recordkeeping.

Rule 15. (1) An employer shall establish and maintain medical records for each category A employee in accordance with Occupational Health Standard Part 470 "Employee Medical Records and Trade Secrets," as referenced in R 325.70001a.

(2) An employer shall ensure that medical records contain, at a minimum, all of the following information:

(a) The name and social security number of the employee.

(b) A copy of the employee's hepatitis B vaccination status, including the dates administered and medical records relating to the employee's ability to receive a vaccination as required by R 325.70013.

(c) A copy of all results of examinations, medical testing, and follow-up procedures as required by R 325.70013.

(d) The employer's copy of the physician's written opinion.

(e) A copy of the information provided to the physician as required by R 325.70013(6).

(3) An employer shall assure that employee medical records that are required by this rule are kept confidential and are not disclosed or reported without the employee's express written consent to any person within or outside the workplace, except as required by this rule or as may be required or permitted by law.

(4) An employer shall maintain employee medical records for not less than the duration of employment plus 30 years in accordance with Occupational Health Standard Part 470 "Employee Medical Records and Trade Secrets," as referenced in R 325.70001a.

(5) An employer shall develop and maintain training records for each category A employee. Training records shall be maintained for 3 years beyond the date that the training occurred.

(6) Training records shall include all of the following information:

(a) The dates of the training sessions.

(b) The contents or a summary of the training sessions.

(c) The names and qualifications of persons who conduct the training.

(d) The names and job titles of all persons who attend the training sessions.

(7) An employer shall assure that all records that are required to be maintained by these rules shall be made available, upon request, to representatives of the department or the director for examination and copying.

(8) An employer shall ensure that employee training records are provided, upon request, for examination and copying to employees, employee representatives, and the director in accordance with Occupational Health Standard Part 470 "Employee Medical Records and Trade Secrets," as referenced in R 325.70001a.

(9) An employer shall ensure that employee medical records are provided, upon request, for examination and copying to the subject employee, to anyone who has the written consent of the subject employee, and to the director in accordance with Occupational Health Standard Part 470 "Employee Medical Records and Trade Secrets," as referenced in R 325.70001a.

(10) An employer shall comply with the requirements that involve the transfer of records in Occupational Health Standard Part 470 "Employee Medical Records and Trade Secrets," as referenced in R 325.70001a.

(11) All of the following provisions apply to a sharp's injury log:

(a) An employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharp's injury log shall be recorded and maintained in a manner that protects the confidentiality of the injured employee. At a minimum, a sharps injury log shall contain all of the following information:

(i) The type and brand of device involved in the incident.

(ii) The work unit or work area where the exposure incident occurred.

(iii) An explanation of how the incident occurred.

(b) The requirement to establish and maintain a sharps injury log applies to any employer who is required to maintain a log of occupational injuries and illnesses as prescribed in MIOSHA Standard Part 11. "Recording and Reporting of Occupational Injuries and Illnesses," as referenced in R 325.70001a.

(c) A sharps injury log shall be maintained for the period required as prescribed in MIOSHA Standard Part 11. "Recording and Reporting of Occupational Injuries and Illnesses," as referenced in R 325.70001a.

R 325.70016 Information and training.

Rule 16. (1) An employer shall ensure that all category A employees participate in a training program provided at no cost to the employees and during working hours.

(2) Training shall be provided at the time of initial assignment to category A work or within 90 days after the effective date of these rules, whichever is later, and at least annually thereafter. If an employee has received training on bloodborne pathogens in the year preceding the effective date of these rules, only training with respect to requirements of this rule that were not included in the previous training need to be provided.

(3) An employer shall provide additional training when changes, such as the modification of tasks or procedures or the institution of new tasks or procedures, affect an employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

(4) Material appropriate in content and vocabulary to the educational level, literacy, and language background of employees shall be used.

(5) The training program shall contain all of the following elements:

(a) Accessibility of the copy of these rules and an explanation of the contents of these rules, including appendices.

(b) A general explanation of the epidemiology and symptoms of bloodborne diseases.

(c) An explanation of the modes of transmission of bloodborne pathogens.

(d) An explanation of the employer's exposure control plan, including the standard operating procedures, and how an employee can access the written plan.

(e) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious material.

(f) An explanation of the use and limitations of practices that will prevent or reduce exposure, including appropriate engineering controls, work practices, and personal protective equipment.

(g) Information on all of the following with respect to personal protective clothing and equipment:

(i) Types.

(ii) Proper use.

(iii) Limitations.

(iv) Location.

(v) Removal.

(vi) Handling.

(vii) Decontamination.

(viii) Disposal.

(h) An explanation of the basis for selecting protective clothing and equipment.

(i) Information on the hepatitis B vaccine and post-exposure prophylaxis, including all of the following information:

(i) Availability.

(ii) Efficacy.

(iii) Safety.

(iv) The benefits of being vaccinated.

(v) Method of administration.

(vi) That vaccination is free of charge.

(j) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious material.

(k) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident, and the medical follow-up and counseling that will be made available.

(l) An explanation of the signs and labels or color coding required by R 325.70014.

(6) Employees in HIV or HBV research laboratories and HIV/HBV production facilities shall receive the following initial training in addition to the training requirements specified in subrule (5) of this rule:

(a) Employees shall be trained in, and demonstrate proficiency in, standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV and HBV.

(b) Employees shall be experienced in the handling of human pathogens or tissue cultures before working with HIV and HBV.

(c) A training program shall be provided to employees who have not had experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. An employee shall participate in work activities that involve infectious agents only after proficiency has been demonstrated.

(7) Training shall be conducted in the following manner:

(a) At the time of initial assignment to tasks where occupational exposure may take place and at least annually thereafter.

(b) Training sessions shall afford employees ample opportunity for discussion and the answering of questions by a knowledgeable trainer.

(c) The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

R 325.70017 Rescinded.

R 325.70018 Rescinded.

INFORMATION SHEET

Occupations with Potential for Exposure

The hazard of exposure to infectious materials affects employees in many types of employment and is not restricted to the healthcare industry. In the list below are a number of job classifications that may be associated with tasks that have occupational exposure to blood and other potentially infectious materials. The scope of the standard is not limited to employees in these jobs. At the same time, employees in the following jobs are not automatically covered unless they have reasonably anticipated occupational exposure:

- Barbers Beauticians
- Chiropractors
- Correctional officers
- Day care center workers
- Dental care workers
- Dentists
- Dialysis personnel
- Emergency Medical Technicians
- Firefighters
- Foster home workers
- Health care facility support staff
- Housekeepers
- Institutional home workers
- Janitors
- Laboratory workers
- Laundry workers
- Law enforcement employees assigned to provide emergency first aid
- Maintenance workers
- Medical assistants
- Medical health residential workers
- Morticians
- Nursing personnel (professional and non-professional)
- Optometrists
- Paramedics
- Phlebotomists
- Physician Assistants
- Physicians
- Plumbers
- Podiatrists
- Police officers
- Tattooists

Addresses

Centers for Disease Control CDC and Michigan Department of Licensing and Regulatory Affairs

For current guidelines, contact:

National Prevention Information Network
P.O. Box 6003
Rockville, Maryland 20850
Phone: 1-800-458-5231
Internet Address: www.cdcnpin.org
E-mail Address: info@cdcnpin.org

and

Michigan Department of Licensing and Regulatory Affairs
General Industry Safety & Health Division
P.O. Box 30644
Lansing, Michigan 48909-8144
Phone: (517) 322-1831
Internet Address: www.michigan/miosha

Engineering Controls

Engineering controls including ventilation systems and enclosures such as glove boxes, ventilation cabinets, laboratory hoods and tight fitting lids SHOULD be used to effectively isolate and contain spatters, splashes, mists and aerosols of blood, and other potentially infectious material generated from tissue homogenizers, sonicators, vortex mixers, centrifuges and other items capable of generating splashes, spatters, mists and aerosols. Engineering controls such as self-retracting needles, self-sealing capillary tubes and break resistant tubes should be used to prevent contact with blood or other potentially infectious material.

Disinfectants

Appropriate disinfectants for hospital cleaning including sodium hypochlorite diluted between 1:10 and 1:100 with water or other equally effective disinfectant. Antiseptics available and safe for hands include alcoholic foam cleansers, disposable alcoholic tissue wipes, or even washcloths soaked with 70-90% alcohol. It should be noted that waterless antiseptics are most effective in the absence of gross soil.

Occupations Requiring Tear and Puncture Resistant Gloves

Some occupations which may require tear and puncture resistant gloves are morticians, pathologists, mortuary workers, emergency medical technicians, corrections officers, fire fighters, police officers and other law enforcement occupations.

Gloves

Hypoallergenic gloves may include latex but should not be limited to latex and the new improved glove types (such as vinyl) may be available on the market in the future.

Inappropriate “baggy” gloves, for example, as used by bakers, etc., are not meant for contact with blood of the potentially infectious material.

APPENDIX D-2: Sample Hepatitis B Waiver

SAMPLE WAIVER STATEMENT WHEN AN EMPLOYEE DECLINES THE HEPATITIS B VACCINATION

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Employee Name (print): _____

Employee Signature: _____

Date: _____

LICENSING AND REGULATORY AFFAIRS
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Michigan Occupational Safety and Health
Administration PO Box 30643
Lansing, Michigan 48909-8143
Ph: 517-284-7740

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Michigan Department of Licensing and Regulatory Affairs
Michigan Occupational Safety & Health Administration
Consultation Education & Training Division

Part 554 Bloodborne Infectious Diseases Rules and General Industry First Aid Providers

The bloodborne infectious diseases rules apply to all employers with employees exposed to blood or other potentially infectious material. This will affect employers if they have designated first aid providers on their staff. MIOSHA Part 472 Medical Services and First Aid, Rule 7201(2) states that "In the absence of an infirmary, clinic, or hospital in near proximity to the workplace which is used for the treatment of all injured employees, a person or persons shall be adequately trained to render first aid." This has been interpreted as follows:

> *An employer shall ensure that, in the absence of an infirmary, clinic, or hospital in near proximity to the workplace that is used for the treatment of all injured employees, a person or persons shall be adequately trained to render first aid. Adequate first aid supplies shall be readily available. [Part 472. Rule 325.47201(2)] To determine "near proximity," MIOSHA will apply the following:*
>
> *a) In areas where serious accidents may occur such as those involving falls, electric shock, amputations, or severe chemical exposures that could result in suffocation, severe bleeding, or other life threatening injury or illness, a maximum three- to four-minute response time is required.*
>
> *b) In other circumstances where a life-threatening injury is unlikely (e.g., low hazard workplaces such as offices), a maximum 15-minute response time is acceptable.*
>
> *[Excerpt from the MIOSHA Agency Instruction, MIOSHA-STD-08-3R2 Medical Services and First Aid for General Industry and Construction, January 17, 2012]*

If an employer has employees on staff designated as first aid providers, the requirements of the bloodborne infectious diseases rule, in its entirety, apply. However, if an employee voluntarily administers first aid without being designated by the employer, the action is considered to be a "good Samaritan act" and is not covered by the bloodborne infectious diseases rules.

Hepatitis B Vaccination

The hepatitis B vaccination must be offered free of charge prior to exposure or 24 hours after the first incident involving blood if administering of first aid is a collateral duty of a designated 1st aid provider. If offered within 24 hours after an incident, a reporting procedure must be included in the employee's training. Refer to MIOSHA Agency Instruction MIOSHA-STD-08-3 Medical Services and First Aid for General Industry and Construction for additional information. An employee may choose to decline the vaccine and document that by signing a waiver. If the employee initially declines the vaccination and then decides to accept it, the vaccination must be offered again free of charge.

An exposure incident is an eye, mouth, nose, other mucous membrane, non-intact skin or parenteral (piercing) contact with blood or other potentially infectious material. If this occurs, request consent from the first aid patient (source individual) to have his/her blood tested for HBV and HIV antibody. Offer the same test to the exposed employee. Treatment as prescribed by the U.S. Public Health Service must be followed and a confidential medical examination made available to the employee.

Exposure Control Plan

A requirement of the bloodborne infectious diseases rules is a written exposure control plan which must be reviewed and updated annually. Personal protective equipment (PPE), i.e., what an employee must wear to minimize exposure, is also mandated. During a first aid incident where blood is involved, gloves must be worn by the employee at a minimum. If splashing or splattering of blood is anticipated, protective eyewear and a surgeon's mask or a faceshield must be worn to prevent splattering into the eyes, nose or mouth. If blood contact with street clothing or the skin is anticipated, fluid-resistant clothing must be worn. It is advisable that disposable coveralls be used. If reusable protective clothing is worn and becomes contaminated, the employer is to provide for appropriate laundering. If laundering is necessary, certain requirements outlined in the bloodborne infectious diseases rules must be followed.

Disposal of blood saturated items must be in biohazard bags or color coded red bags. If a blood spill occurs, it must be disinfected with either a 1:10 to 1:100 solution of bleach to water prepared that day or products registered with EPA on Lists A, B or D (not C). The lists of EPA registered products can be accessed online at www.epa.gov/oppad001/chemregindex.htm or call (800) 858-7378.

Work practice controls, primarily handwashing, should also be done. Hands must be washed if there is contact with blood or other potentially infectious material and after glove removal. If handwashing facilities are not feasible, antiseptic cleansers or antiseptic towelettes may be used, until such time as the employee is able to wash his hands with soap and water.

Training of employees must be given both initially and annually. Topics that must be covered are explained in the bloodborne infectious diseases rules.

Medical records and training records must also be maintained. Medical records must be maintained for the duration of employment plus 30 years, and training records must be maintained for 3 years. Content of the records are explained in the rule.

If there are additional questions or concerns regarding the bloodborne infectious diseases rules, please contact the Michigan Department of Licensing and Regulatory Affairs, Michigan Occupational Safety and Health Administration. Consultation Education and Training Division (517) 284-7720.

Michigan Department of Licensing and Regulatory Affairs
Michigan Occupational Safety and Health Administration
Consultation Education and Training Division

"SAMPLE"

BLOODBORNE INFECTIOUS DISEASES EXPOSURE CONTROL PLAN

FOR HEALTH CARE FACILITIES

Note: This guide does not substitute for a full reading of the standard. This document is provided as an informational service under the authority of Public Act 154 of 1974. This program is designed to be adapted to each individual employer's need; forms should be shortened, expanded, or duplicated as needed.

The Model Exposure Control Plan is intended to serve as an employer guide to the MIOSHA Bloodborne Infectious Diseases standard. A central component of the requirements of the standard is the development of an exposure control plan (ECP).

The intent of this model is to provide small employers with an easy-to-use format for developing a written exposure control plan. Each employer will need to adjust or adapt the model for their specific use.

The information contained in this publication is not considered a substitute for the MIOSHA Act or any provisions of MIOSHA standards. It provides general guidance on a particular standard-related topic but should not be considered as the legal authority for compliance with MIOSHA requirements. The reader should consult the MIOSHA standard in its entirety for specific compliance requirements.

POLICY

The *(Facility Name)* is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with MIOSHA Part 554 Bloodborne Infectious Diseases.

The ECP is a key document to assist our firm in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes:

- Determination of employee exposure;
- Implementation of various methods of exposure control, including:
    - Universal precautions;
    - Engineering and work practice controls;
    - Standard operating procedures;
    - Personal protective equipment; and,
    - Housekeeping;
- Hepatitis B vaccination;
- Post-exposure evaluation and follow-up;
- Communication of hazards to employees and training;
- Recordkeeping; and,
- Procedures for evaluating circumstances surrounding an exposure incident

The methods of implementation of these elements of the standard are discussed in the subsequent pages of this ECP.

PROGRAM ADMINISTRATION

(Name of responsible person or department) is responsible for the implementation of the ECP. *(Name of responsible person or department)* will maintain, review, and update the ECP at least annually, and whenever necessary to include new or modified tasks and procedures. Contact location/phone number:_____

Those employees who are determined to have occupational exposure to blood or other potentially infectious materials (OPIM) must comply with the procedures and work practices outlined in this ECP.

(Name of responsible person or department) will maintain and provide all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, and red bags as required by the standard. *(Name of responsible person or department)* will ensure that adequate supplies of the equipment are available in the appropriate sizes. Contact location/phone number: _____

(Name of responsible person or department) will be responsible for ensuring that all medical actions required are performed and that appropriate employee health and MIOSHA records are maintained. Contact location/phone number:_____

(Name of responsible person or department) will be responsible for training, documentation of training, and making the written ECP available to employees, MIOSHA, and NIOSH representatives. Contact location/phone number:_____

I. EMPLOYEE EXPOSURE DETERMINATION

The following is a list of all job classifications at our establishment that have been determined to be Category A:

JOB TITLE	DEPARTMENT/LOCATION
(Example: Phlebotomists)	*(Clinical Lab)*

Part-time, temporary, contract and per diem employees are covered by the standard. How the provisions of the standard will be met for these employees should be described in the ECP.

II. METHODS OF IMPLEMENTATION AND CONTROL

A. Universal Precautions

All employees will utilize universal precautions.

B. Exposure Control Plan

Employees covered by the bloodborne infectious diseases standard receive an explanation of this ECP during their initial training session. It will also be reviewed in their annual refresher training. All employees have an opportunity to review this plan at any time during their work shifts by contacting *(Name of responsible person or department)*.

If requested, we will provide an employee with a copy of the ECP free of charge and within 15 days of the request.

(Name of responsible person, committee or department) is responsible for reviewing and **updating the ECP annually** or more frequently if necessary, to reflect any new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

C. Standard Operating Procedures

Standard operating procedures (S.O.P.'s) provide specific guidance on controls and practices that shall be used when performing tasks involving occupational exposure to bloodborne pathogens. They will be based on the form found in Appendix A and will be utilized in employee training.

D. Contingency Plans

Where circumstances can be foreseen in which recommended standard operating procedures could not be followed, the employer shall prepare contingency plans for employee protection, incident investigation and medical follow-up as part of the standard operating procedures. See Appendix B.

E. Engineering Controls and Work Practices

Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens. The specific engineering controls and work practice controls used are listed in Appendix B.

Sharps disposal containers are inspected and maintained or replaced by

(Name of responsible person or department) every *(list frequency)* or whenever necessary to prevent overfilling.

This facility identifies the need for changes in engineering control and work practices through *(Examples: Review of MIOSHA records, employee interviews, committee activities, etc.)*

We evaluate new procedures or new products by *(Describe the process)*

The following staff are involved in this process: *(Describe how non-managerial employees have their input solicited per 325.0007 (h)).*

(Name of responsible person or department) will ensure effective implementation of these recommendations.

F. Personal Protective Equipment (PPE)

PPE is provided to our employees at no cost to them. Training is provided by *(Name of responsible person or department)* in the use of the appropriate PPE for the tasks or procedures employees will perform.

The types of PPE available to employees are as follows or see Appendix A for PPE required for specific procedures:

(Ex., gloves, eye protection, etc.)

PPE is located ___*(list location)*___ and may be obtained through ___*(Name of responsible person or department)*___. [Specify how employees are to obtain PPE, and who is responsible for ensuring that it is available.]

All employees using PPE must observe the following precautions:

- Wash hands immediately or as soon as feasible after removal of gloves or other PPE. Remove PPE after it becomes contaminated, and before leaving the work area.
- Used PPE may be disposed of in _____(List appropriate containers for storage, laundering, decontamination, or disposal.)
- Wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated items or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.
- Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
- Never wash or decontaminate disposable gloves for reuse.
- Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth.
- Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface. The procedure for handling used PPE is as follows: *(may refer to standard operating procedure by title or number and last date of review)*

  _____

  (For example, how and where to decontaminate face shields, eye protection, resuscitation equipment)

G. Housekeeping

Regulated waste is placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded (see Labels), and closed prior to removal to prevent spillage or protrusion of contents during handling.

The procedure for handling sharps disposal containers is: *(may refer to standard operating procedure by title or number and last date of review)*

_____
_____
_____

The procedure for handling other regulated waste is: *(may refer to standard operating procedure by title or number and last date of review)*

_____
_____
_____

Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leakproof on sides and bottoms, and labeled or color-coded appropriately. Sharps disposal containers are available at *(must be easily accessible and as close as feasible to the immediate area where sharps are used).*

Bins and pails (e.g., wash or emesis basins) are cleaned and decontaminated as soon as feasible after visible contamination.

Broken glassware which may be contaminated is picked up using mechanical means, such as a brush and dust pan, tongs, cotton swabs or forceps.

H. Laundry

The following contaminated articles will be laundered:

_____

_____

Laundering will be performed by ___*(Name of responsible person or department)*___ at ___(time and/or location).

The following laundering requirements must be met:

- Handle contaminated laundry as little as possible, with minimal agitation
- Place wet contaminated laundry in leak-proof and labeled or color-coded containers before transport. Type of bag used: _____
- Wear the following PPE when handling and/or sorting contaminated laundry: ___*(List appropriate PPE or refer to Appendix A SOP)*

III. Labels

The following labeling method(s) is used in this facility:

EQUIPMENT TO BE LABELED	LABEL TYPE (size, color, etc.)
(e.g., specimens, contaminated laundry, etc.)	*(red bag, biohazard label, etc.)* _____
_____	_____
_____	_____

___*(Name of responsible person or department)*___ will ensure warning labels are affixed or red bags are used as required if regulated waste or contaminated equipment is brought into the facility. Employees are to notify _____ if they discover regulated waste containers, refrigerators containing blood or OPIM, contaminated equipment, etc. without proper labels.

IV. HEPATITIS B VACCINATION

Administration

___*(Name of responsible person or department)*___ will provide training to employees on hepatitis B vaccinations according to Section VIII of this plan.

The hepatitis B vaccination series is available at no cost after training and within 10 days of initial assignment to employees identified in the exposure determination section of this plan. Offering the vaccine is not required if: 1) documentation exists that the employee has previously received the series, 2) antibody testing reveals that the employee is immune, or 3) medical evaluation shows that vaccination is contraindicated.

If an employee chooses to decline vaccination, the employee must sign a copy of the declination form (see Appendix C). Employees who decline may request and obtain the vaccination

at a later date at no cost. Documentation of refusal of the vaccination is kept at ___*(List location or person responsible for this recordkeeping).*

Vaccination will be provided by ___*(List Health care Professional who is responsible for this part of the plan)*___ at ___*(location)*___.

Following hepatitis B vaccinations, the health care professional's Written Opinion will be limited to whether the employee requires the hepatitis vaccine, and whether the vaccine was administered.

V. POST-EXPOSURE EVALUATION AND FOLLOW-UP

Should an exposure incident occur, contact ___*(Name of responsible person or department)*___ at the following number:_____.

An immediately available confidential medical evaluation and follow-up will be conducted by

___*(Licensed health care professional)*___. Following the initial first aid (clean the wound, flush

eyes or other mucous membrane, etc.), the following activities will be performed:

- Document the routes of exposure and how the exposure occurred.
- Identify and document the source individual (unless the employer can establish that identification is infeasible or prohibited by state or local law).
- Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that the source individual's test results were conveyed to the employee's health care provider.
- If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.
- Assure that the exposed employee is provided with the source individual's test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
- After obtaining consent, collect exposed employee's blood as soon as feasible after exposure incident, and test blood for HBV and HIV serological status
- If the employee does not give consent for HIV serological testing during collection of blood for baseline testing, preserve the baseline blood sample for at least 90 days; if the exposed employee elects to have the baseline sample tested during this waiting period, perform testing as soon as feasible.

VI. ADMINISTRATION OF POST-EXPOSURE EVALUATION AND FOLLOW-UP

___*(Name of responsible person or department)*___ ensures that health care professional(s) responsible for employee's hepatitis B vaccination and post-exposure evaluation and follow-up are given a copy of MIOSHA's bloodborne infectious diseases standard.

___*(Name of responsible person or department)*___ ensures that the health care professional evaluating an employee after an exposure incident receives the following:

- A description of the employee's job duties relevant to the exposure incident;
- Route(s) of exposure;
- Circumstances of exposure;
- Results of the source individual's blood test, if available; and,
- Relevant employee medical records, including vaccination status

___*(Name of responsible person or department)*___ provides the employee with a copy of the evaluating health care professional's confidential written opinion within 15 days after completion of the evaluation.

The written opinion obtained by the employer shall <u>not reveal specific findings or diagnoses</u> that are unrelated to the employee's ability to wear protective clothing and equipment or receive vaccinations. Such findings and diagnoses shall <u>remain confidential</u>.

VII. SUGGESTED PROCEDURES FOR EVALUATING THE CIRCUMSTANCES SURROUNDING AN EXPOSURE INCIDENT

___*(Name of responsible person or department)*___ will review the circumstances of all exposure incidents to determine:

- Engineering controls in use at the time
- Work practices followed

- Description of the device being used protective equipment or clothing that was used at the time of the exposure incident *(gloves, eye shields, etc.)*
- Location of the incident *(O.R., E.R., patient room, etc.)*
- Procedure being performed when the incident occurred
- Employee's training

If it is determined that revisions need to be made, ___*(Name of responsible person or department)*___ will ensure that appropriate changes are made to this ECP. *(Changes may include an evaluation of safer devices, adding employees to the exposure determination list, etc.)*

VIII. EMPLOYEE TRAINING

All employees who have occupational exposure to bloodborne pathogens receive training conducted by *(Name of responsible person or department)*. *(Attach a brief description of their qualifications.)*

All employees who have occupational exposure to bloodborne pathogens receive training including the following elements:

- The epidemiology, symptoms, and transmission of bloodborne pathogen diseases;
- A copy and explanation of the standard;
- An explanation of our ECP including SOPs and how to access the written plan;
- An explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident;
- An explanation of the use and limitations of engineering controls, work practices, and PPE;
- An explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE;
- An explanation of the basis for PPE selection;
- Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge;
- Information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM;
- An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the confidential medical evaluation and follow-up that will be made available;
- An explanation of the signs and labels and/or color coding required by the standard and used at this facility; and
- An opportunity for interactive questions and answers with the person conducting the training session.

Training materials for this facility are available at _____.

IX. RECORDKEEPING

A. Training Records

Training records are completed for each employee upon completion of training. These documents will be kept for at least **three years** at ___*(Name of responsible person or location of records)*___.

The training records include:

- The dates of the training sessions;
- The contents or a summary of the training sessions;
- The names and qualifications of persons conducting the training; and,
- The names and job titles of all persons attending the training sessions

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to ____*(Name of responsible person or department)*___.

B. Medical Records

Medical records are maintained for each employee with occupational exposure in accordance with Part 432 Medical Records and Trade Secrets.

(Name of responsible person or department) is responsible for maintenance of the required medical records. These **confidential** records are kept at:

(List location) for at least the **duration of employment plus 30 years.**

Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to *(Name of responsible person or department)*.

C. MIOSHA Recordkeeping

An exposure incident is evaluated to determine if the case meets MIOSHA's Recordkeeping Requirements (Part 11). This determination and the recording activities are done by *(Name of responsible person or department)*.

Appendix A to Part II Recordkeeping lists industries who are partially exempt from keeping the 300 Log and SHARP Log. (e.g. SIC code 801 offices of M.D.s, SIC code 802 Dentist's offices and SIC code 726 Funeral Services are partially exempt).

D. Sharps Injury Log

A sharps injury log is established and maintained for recording percutaneous injuries from contaminated sharps. The log includes:

- Type and brand of device involved in the injury;
- The unit or work area where the exposure occurred; and
- An explanation of how the incident occurred.

The log is recorded and maintained to protect the confidentiality of the injured employee. The Part 11. Recording & Reporting of Occupational Injuries & Illnesses 300 Log of Work Related Injuries and Illnesses may be used to record this information.

_____ is responsible for the maintenance of the sharp's injury log.

APPENDIX A (SOP)

STANDARD OPERATING PROCEDURE

FOR BLOODBORNE INFECTIOUS DISEASE CONTROL MEASURES

Task/Procedure:

Exposure Potential:

Personal Protective Equipment:

Use:

Maintenance/Disinfection:

Disposal:

Engineering Controls:

Work Practice Controls:

Management of Exposure Incidents:

Contingency Plan (if this SOP cannot be followed):

APPENDIX A (SOP) - EXAMPLE

STANDARD OPERATING PROCEDURE (SOP)

FOR BLOODBORNE INFECTIOUS DISEASE CONTROL MEASURES

Task/Procedure: Venipuncture (blood draw) and injections

Exposure Potential: ***Percutaneous Exposure***

Personal Protective Equipment: Wear disposable gloves. Gown, safety glasses and mask if aerosolization or blood spray likely

Use: Don personal protective equipment (PPE) before performing task or procedure.

Maintenance/Disinfection: Gloves, masks and gowns are disposable. Safety glasses may be disinfected with an approved germicidal wipe or spray and reused.

Disposal:

- Discard all sharps in rigid sharps containers (Do not recap)
- Discard PPE in standard waste unless saturated/dripping with blood or OPIM which requires biohazard waste disposal (red bag waste)

Engineering Controls: Sharps with engineered sharps injury protections and sharps disposal containers.

Work Practice Controls:

- Wear disposable exam gloves. Where there is a potential for a splash or spray, see PPE section above.
- Activate safety device after use. Dispose of sharps in rigid sharps container.
- Hands must be washed/sanitized immediately or as soon as feasible after the removal of gloves or other PPE
- Do not reach by hand into containers where sharps have been placed.

Management of Exposure Incidents: Provide immediate first aid to the affected area: clean wound thoroughly, stop bleeding, and follow post exposure incident procedure in exposure control plan.

Contingency Plan: If employees determine that this SOP cannot be followed, they should stop the procedure/work activity and consult with XXXXX on how to proceed (e.g. use bottled water to cleanse hands during utility outage). XXXXX will ensure that needed equipment/supplies, etc. are provided to employees and a revised SOP is developed to address the hazards identified.

EXAMPLE

APPENDIX A - EXAMPLE

STANDARD OPERATING PROCEDURE (SOP)

FOR BLOODBORNE INFECTIOUS DISEASE CONTROL MEASURES

Task/Procedure: **Decontamination of work surfaces/spill cleanup, Routine housekeeping in patient care areas. Handling/queuing biohazard waste for pick-up. Application of ointments/medications. Applying pressure to control bleeding. Routine cleaning of any non-intact skin (e.g. cuts).**

Exposure Potential: ***Non-intact skin exposure to blood or general exposure***

Personal Protective Equipment: Disposable exam gloves.

Use: Don personal protective equipment (PPE) before performing task or procedure

Maintenance/Disinfection: Do not disinfect and reuse disposable gloves.

Disposal:

- Discard PPE in standard trash can unless saturated/dripping with blood or OPIM which requires biohazard waste disposal (red bag waste).
- Sharps containers needing to be disposed of are closed (no employee exposure to contaminated sharps) and placed in back room for pick up by medical waste disposal company. Red bagged waste is removed from trash can, by the loose end of the red bag, and placed in biohazard box supplied by the medical waste disposable company.

Engineering Controls: Safety-tipped scissors and plumbed sinks for hand-washing.

Work Practice Controls:

- Wear PPE as noted above.
- Post-procedures where blood or OPIM exposure is likely/occurred: Decontaminate surfaces using approved EPA registered disinfectant or bleach wipes. Also, disinfection of surfaces may be conducted at the end of a workday.
- Dispose of bleach wipes used on surfaces in the regular trash unless saturated with blood or OPIM
- Hands must be washed/sanitized after removal of gloves or other PPE

General work practice controls:

- Eating drinking, smoking, applying cosmetics are prohibited in work areas where there is reasonable likelihood of occupational exposure
- Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or bench tops where blood or OPIM are present.

EXAMPLE

Management of Exposure Incidents: Provide immediate first aid and follow post exposure follow up procedure in exposure control plan.

Contingency Plan: If employees determine that this SOP cannot be followed, they should stop the procedure/work activity and consult with XXXXX on how to proceed (e.g. use bottled water to cleanse hands during utility outage). XXXXX will ensure that needed equipment/supplies, etc. are provided to employees and a revised SOP is developed to address the hazards identified.

APPENDIX B

SHARPS INJURY AND NEEDLESTICK PREVENTION: USE OF SAFER DEVICES, ENGINEERING CONTROLS AND WORK PRACTICE CONTROLS

The following safer devices and engineering controls are being considered and/or have been implemented:

[List brand and type of each safer medical devices (e.g. sharps with engineered sharps injury protection) used at the facility. Note: Sharps disposal containers and Sinks used for hand hygiene are considered engineering controls]

The following work practice controls are being used to reduce exposure:

[May be contained within Appendix A - Standard Operating Procedures. These would include hand-hygiene procedures]

APPENDIX C

HEPATITIS B VACCINE DECLINATION (MANDATORY)

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Signed: ___*(Employee name)*_____ Date:_____

Date: _____ Performed by: _____

Michigan Occupational Safety and Health Administration

Consultation Education and Training Division

525 W. Allegan Street, P.O. Box 30643

Lansing, Michigan 48909-8143

For further information or to request consultation, education and training services

call 517-284-7720

or

visit our website at www.michigan.gov/miosha

www.michigan.gov/lara

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1910.134 RESPIRATORY PROTECTION

1910.134(a) Permissible practice.

1910.134(a)(1) In the control of those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors, the primary objective shall be to prevent atmospheric contamination. This shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used pursuant to this section.

1910.134(a)(2) A respirator shall be provided to each employee when such equipment is necessary to protect the health of such employee. The employer shall provide the respirators which are applicable and suitable for the purpose intended. The employer shall be responsible for the establishment and maintenance of a respiratory protection program, which shall include the requirements outlined in paragraph (c) of this section. The program shall cover each employee required by this section to use a respirator.

1910.134(b) Definitions.

The following definitions are important terms used in the respiratory protection standard in this section.

Air-purifying respirator means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

Assigned protection factor (APF) means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section.

Atmosphere-supplying respirator means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

Canister or cartridge means a container with a filter, sorbent, or catalyst, or combination of these items, which removes specific contaminants from the air passed through the container.

Demand respirator means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

Emergency situation means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled significant release of an airborne contaminant.

Employee exposure means exposure to a concentration of an airborne contaminant that would occur if the employee were not using respiratory protection.

End-of-service-life indicator (ESLI) means a system that warns the respirator user of the approach of the end of adequate respiratory protection, for example, that the sorbent is approaching saturation or is no longer effective.

Escape-only respirator means a respirator intended to be used only for emergency exit.

Filter or air purifying element means a component used in respirators to remove solid or liquid aerosols from the inspired air:

Filtering facepiece (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium.

Fit factor means 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 means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual. (See also Qualitative fit test QLFT and Quantitative fit test QNFT.)

Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

High efficiency particulate air (HEPA) filter means a filter that is at least 99.97% efficient in removing monodisperse particles of 0.3 micrometers in diameter. The equivalent NIOSH 42 CFR 84 particulate filters are the N100, R100, and P100 filters.

Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Immediately dangerous to life or health (IDLH) means an atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individual's ability to escape from a dangerous atmosphere.

Interior structural firefighting means the physical activity of fire suppression, rescue or both, inside of buildings or enclosed structures which are involved in a fire situation beyond the incipient stage. (See 29 CFR 1910.155)

Loose-fitting facepiece means a respiratory inlet covering that is designed to form a partial seal with the face.

Maximum use concentration (MUC) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator and is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance. The MUC can be determined mathematically by multiplying the assigned protection factor specified for a respirator by the required OSHA permissible exposure limit, short-term exposure limit, or ceiling limit. When no OSHA exposure limit is available for a hazardous substance, an employer must determine an MUC on the basis of relevant available information and informed professional judgment.

Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Oxygen deficient atmosphere means an atmosphere with an oxygen content below 19.5% by volume.

Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide, or be delegated the responsibility to provide, some or all of the health care services required by paragraph (e) of this section.

Positive pressure respirator means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Qualitative fit test (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quantitative fit test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Respiratory inlet covering means that portion of a respirator that forms the protective barrier between the user's respiratory tract and an air-purifying device or breathing air source, or both. It may be a facepiece, helmet, hood, suit, or a mouthpiece respirator with nose clamp.

Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Service life means the period of time that a respirator, filter or sorbent, or other respiratory equipment provides adequate protection to the wearer.

Supplied-air respirator (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

This section means this respiratory protection standard.

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

User seal check means an action conducted by the respirator user to determine if the respirator is properly seated to the face.

1910.134(c) Respiratory protection program.

This paragraph requires the employer to develop and implement a written respiratory protection program with required worksite-specific procedures and elements for required respirator use. The program must be administered by a suitably trained program administrator. In addition, certain program elements may be required for voluntary use to prevent potential hazards associated with the use of the respirator. The Small Entity Compliance Guide contains criteria for the selection of a program administrator and a sample program that meets the requirements of this paragraph. Copies of the Small Entity Compliance Guide will be available on or about April 8, 1998 from the Occupational Safety and Health Administration's Office of Publications, Room N 3101, 200 Constitution Avenue, NW, Washington, DC, 20210 (202-219-4667).

1910.134(c)(1) In any workplace where respirators are necessary to protect the health of the employee or whenever respirators are required by the employer, the employer shall establish and implement a written respiratory protection program with worksite-specific procedures. The program shall be updated as necessary to reflect those changes in workplace conditions that affect respirator use. The employer shall include in the program the following provisions of this section, as applicable:

1910.134(c)(1)(i) Procedures for selecting respirators for use in the workplace;

1910.134(c)(1)(ii) Medical evaluations of employees required to use respirators;

1910.134(c)(1)(iii) Fit testing procedures for tight-fitting respirators;

1910.134(c)(1)(iv) Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;

1910.134(c)(1)(v) Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators;

1910.134(c)(1)(vi) Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators;

1910.134(c)(1)(vii) Training of employees in the respiratory hazards to which they are potentially exposed during

routine and emergency situations;

1910.134(c)(1)(viii) Training of employees in the proper use of respirators, including putting on and removing them, any limitations on their use, and their maintenance; and

1910.134(c)(1)(ix) Procedures for regularly evaluating the effectiveness of the program.

1910.134(c)(2) Where respirator use is not required:

1910.134(c)(2)(i) An employer may provide respirators at the request of employees or permit employees to use their own respirators, if the employer determines that such respirator use will not in itself create a hazard. If the employer determines that any voluntary respirator use is permissible, the employer shall provide the respirator users with the information contained in Appendix D to this section ("Information for Employees Using Respirators When Not Required Under the Standard"); and

1910.134(c)(2)(ii) In addition, the employer must establish and implement those elements of a written respiratory protection program necessary to ensure that any employee using a respirator voluntarily is medically able to use that respirator, and that the respirator is cleaned, stored, and maintained so that its use does not present a health hazard to the user. Exception: Employers are not required to include in a written respiratory protection program those employees whose only use of respirators involves the voluntary use of filtering facepieces (dust masks).

1910.134(c)(3) The employer shall designate a program administrator who is qualified by appropriate training or experience that is commensurate with the complexity of the program to administer or oversee the respiratory protection program and conduct the required evaluations of program effectiveness.

1910.134(c)(4) The employer shall provide respirators, training, and medical evaluations at no cost to the employee.

1910.134(d) Selection of respirators.

This paragraph requires the employer to evaluate respiratory hazard(s) in the workplace, identify relevant workplace and user factors, and base respirator selection on these factors. The paragraph also specifies appropriately protective respirators for use in IDLH atmospheres and limits the selection and use of air-purifying respirators.

1910.134(d)(1) General requirements.

1910.134(d)(1)(i) The employer shall select and provide an appropriate respirator based on the respiratory hazard(s) to which the worker is exposed and workplace and user factors that affect respirator performance and reliability.

1910.134(d)(1)(ii) The employer shall select a NIOSH-certified respirator. The respirator shall be used in compliance with the conditions of its certification.

1910.134(d)(1)(iii) The employer shall identify and evaluate the respiratory hazard(s) in the workplace; this evaluation shall include a reasonable estimate of employee exposures to respiratory hazard(s) and an identification of the contaminant's chemical state and physical form. Where the employer cannot identify or reasonably estimate the employee exposure, the employer shall consider the atmosphere to be IDLH.

1910.134(d)(1)(iv) The employer shall select respirators from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.

1910.134(d)(2) Respirators for IDLH atmospheres.

1910.134(d)(2)(i) The employer shall provide the following respirators for employee use in IDLH atmospheres:

1910.134(d)(2)(i)(A) A full facepiece pressure demand SCBA certified by NIOSH for a minimum service life of thirty minutes, or

1910.134(d)(2)(i)(B) A combination full facepiece pressure demand supplied-air respirator (SAR) with auxiliary self-contained air supply.

1910.134(d)(2)(ii) Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.

1910.134(d)(2)(iii) All oxygen-deficient atmospheres shall be considered IDLH. Exception: If the employer demonstrates that, under all foreseeable conditions, the oxygen concentration can be maintained within the ranges specified in Table II of this section (i.e., for the altitudes set out in the table), then any atmosphere-supplying respirator may be used.

1910.134(d)(3) Respirators for atmospheres that are not IDLH.

1910.134(d)(3)(i) The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory and regulatory requirements, under routine and reasonably foreseeable emergency situations.

1910.134(d)(3)(i)(A) Assigned Protection Factors (APFs) Employers must use the assigned protection factors listed in Table 1 to select a respirator that meets or exceeds the required level of employee protection. When using a combination respirator (e.g., airline respirators with an air-purifying filter), employers must ensure that the assigned protection factor is appropriate to the mode of operation in which the respirator is being used.

TABLE 1.

ASSIGNED PROTECTION FACTORS [5]

Type of respirator [1,2]	Quarter mask	Half mask	Full face-piece	Helmet/ hood	Loose-fitting facepiece
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 this section (29 CFR 1910.134), including training, fit testing, maintenance, and use requirements.

[3] This APF category includes filtering facepieces, and half masks with elastomeric facepieces.

[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 facepiece 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).

1910.134(d)(3)(i)(B) Maximum Use Concentration (MUC)

1910.134(d)(3)(i)(B)(1) The employer must select a respirator for employee use that maintains the employee's exposure to the hazardous substance, when measured outside the respirator, at or below the MUC.

1910.134(d)(3)(i)(B)(2) Employers must not apply MUCs to conditions that are immediately dangerous to life or health (IDLH); instead, they must use respirators listed for IDLH conditions in paragraph (d)(2) of this standard.

1910.134(d)(3)(i)(B)(3) When the calculated MUC exceeds the IDLH level for a hazardous substance, or the performance limits of the cartridge or canister, then employers must set the maximum MUC at that lower limit.

1910.134(d)(3)(ii) The respirator selected shall be appropriate for the chemical state and physical form of the contaminant.

1910.134(d)(3)(iii) For protection against gases and vapors, the employer shall provide:

1910.134(d)(3)(iii)(A) An atmosphere-supplying respirator, or

1910.134(d)(3)(iii)(B) An air-purifying respirator, provided that:

1910.134(d)(3)(iii)(B)(1) The respirator is equipped with an end-of-service-life indicator (ESLI) certified by NIOSH for the contaminant; or

1910.134(d)(3)(iii)(B)(2) If there is no ESLI appropriate for conditions in the employer's workplace, the employer implements a change schedule for canisters and cartridges that is based on objective information or data that will ensure that canisters and cartridges are changed before the end of their service life. The employer shall describe in the respirator program the information and data relied upon and the basis for the canister and cartridge change schedule and the basis for reliance on the data.

1910.134(d)(3)(iv) For protection against particulates, the employer shall provide:

1910.134(d)(3)(iv)(A) An atmosphere-supplying respirator; or

1910.134(d)(3)(iv)(B) An air-purifying respirator equipped with a filter certified by NIOSH under 30 CFR part 11 as a high efficiency particulate air (HEPA) filter, or an air-purifying respirator equipped with a filter certified for particulates by NIOSH under 42 CFR part 84; or

1910.134(d)(3)(iv)(C) For contaminants consisting primarily of particles with mass median aerodynamic diameters (MMAD) of at least 2 micrometers, an air-purifying respirator equipped with any filter certified for particulates by NIOSH.

TABLE I. -- ASSIGNED PROTECTION FACTORS [RESERVED]

TABLE II.

Altitude (ft.)	**Oxygen deficient Atmospheres (% O_2) for which the employer may rely on atmosphere-supplying respirators.**
Less than 3,001	16.0-19.5
3,001-4,000	16.4-19.5
4,001-5,000	17.1-19.5
5,001-6,000	17.8-19.5
6,001-7,000	18.5-19.5
7,001-8,000[1]	19.3-19.5
[1]Above 8,000 feet the exception does not apply. Oxygen-enriched breathing air must be supplied above 14,000 feet.	

1910.134(e) Medical evaluation.

Using a respirator may place a physiological burden on employees that varies with the type of respirator worn, the job and workplace conditions in which the respirator is used, and the medical status of the employee. Accordingly, this paragraph specifies the minimum requirements for medical evaluation that employers must implement to determine the employee's ability to use a respirator.

1910.134(e)(1) General. The employer shall provide a medical evaluation to determine the employee's ability to use a respirator, before the employee is fit tested or required to use the respirator in the workplace. The employer may discontinue an employee's medical evaluations when the employee is no longer required to use a respirator.

1910.134(e)(2) Medical evaluation procedures.

1910.134(e)(2)(i) The employer shall identify a physician or other licensed health care professional (PLHCP) to perform medical evaluations using a medical questionnaire or an initial medical examination that obtains the same information as the medical questionnaire.

1910.134(e)(2)(ii) The medical evaluation shall obtain the information requested by the questionnaire in Sections 1 and 2, Part A of Appendix C of this section.

1910.134(e)(3) Follow-up medical examination.

1910.134(e)(3)(i) The employer shall ensure that a follow-up medical examination is provided for an employee who gives a positive response to any question among questions 1 through 8 in Section 2, Part A of Appendix C or whose initial medical examination demonstrates the need for a follow-up medical examination.

1910.134(e)(3)(ii) The follow-up medical examination shall include any medical tests, consultations, or diagnostic procedures that the PLHCP deems necessary to make a final determination.

1910.134(e)(4) Administration of the medical questionnaire and examinations.

1910.134(e)(4)(i) The medical questionnaire and examinations shall be administered confidentially during the employee's normal working hours or at a time and place convenient to the employee. The medical questionnaire shall be administered in a manner that ensures that the employee understands its content.

1910.134(e)(4)(ii) The employer shall provide the employee with an opportunity to discuss the questionnaire and examination results with the PLHCP.

1910.134(e)(5) Supplemental information for the PLHCP.

1910.134(e)(5)(i) The following information must be provided to the PLHCP before the PLHCP makes a recommendation concerning an employee's ability to use a respirator:

1910.134(e)(5)(i)(A) The type and weight of the respirator to be used by the employee;

1910.134(e)(5)(i)(B) The duration and frequency of respirator use (including use for rescue and escape);

1910.134(e)(5)(i)(C) The expected physical work effort;

1910.134(e)(5)(i)(D) Additional protective clothing and equipment to be worn; and

1910.134(e)(5)(i)(E) Temperature and humidity extremes that may be encountered.

1910.134(e)(5)(ii) Any supplemental information provided previously to the PLHCP regarding an employee need not be provided for a subsequent medical evaluation if the information and the PLHCP remain the same.

1910.134(e)(5)(iii) The employer shall provide the PLHCP with a copy of the written respiratory protection program and a copy of this section.

Note to Paragraph (e)(5)(iii): When the employer replaces a PLHCP, the employer must ensure that the new PLHCP obtains this information, either by providing the documents directly to the PLHCP or having the documents transferred from the former PLHCP to the new PLHCP. However, OSHA does not expect employers to have employees medically reevaluated solely because a new PLHCP has been selected.

1910.134(e)(6) Medical determination. In determining the employee's ability to use a respirator, the employer shall:

1910.134(e)(6)(i) Obtain a written recommendation regarding the employee's ability to use the respirator from the PLHCP. The recommendation shall provide only the following information:

1910.134(e)(6)(i)(A) Any limitations on respirator use related to the medical condition of the employee, or relating to the workplace conditions in which the respirator will be used, including whether or not the employee is medically able to use the respirator;

1910.134(e)(6)(i)(B) The need, if any, for follow-up medical evaluations; and

1910.134(e)(6)(i)(C) A statement that the PLHCP has provided the employee with a copy of the PLHCP's written recommendation.

1910.134(e)(6)(ii) If the respirator is a negative pressure respirator and the PLHCP finds a medical condition that may place the employee's health at increased risk if the respirator is used, the employer shall provide a PAPR if the PLHCP's medical evaluation finds that the employee can use such a respirator; if a subsequent medical evaluation finds that the employee is medically able to use a negative pressure respirator, then the employer is no longer required to provide a PAPR.

1910.134(e)(7) Additional medical evaluations. At a minimum, the employer shall provide additional medical evaluations that comply with the requirements of this section if:

1910.134(e)(7)(i) An employee reports medical signs or symptoms that are related to ability to use a respirator;

1910.134(e)(7)(ii) A PLHCP, supervisor, or the respirator program administrator informs the employer that an employee needs to be reevaluated;

1910.134(e)(7)(iii) Information from the respiratory protection program, including observations made during fit testing and program evaluation, indicates a need for employee reevaluation; or

1910.134(e)(7)(iv) A change occurs in workplace conditions (e.g., physical work effort, protective clothing, temperature) that may result in a substantial increase in the physiological burden placed on an employee.

1910.134(f) Fit testing.

This paragraph requires that, before an employee may be required to use any respirator with a negative or positive pressure tight-fitting facepiece, the employee must be fit tested with the same make, model, style, and size of respirator that will be used. This paragraph specifies the kinds of fit tests allowed, the procedures for conducting them, and how the results of the fit tests must be used.

1910.134(f)(1) The employer shall ensure that employees using a tight-fitting facepiece respirator pass an appropriate qualitative fit test (QLFT) or quantitative fit test (QNFT) as stated in this paragraph.

1910.134(f)(2) The employer shall ensure that an employee using a tight-fitting facepiece respirator is fit tested prior to initial use of the respirator, whenever a different respirator facepiece (size, style, model or make) is used, and at least annually thereafter.

1910.134(f)(3) The employer shall conduct an additional fit test whenever the employee reports, or the employer, PLHCP, supervisor, or program administrator makes visual observations of, changes in the employee's physical condition that could affect respirator fit. Such conditions include, but are not limited to, facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight.

1910.134(f)(4) If after passing a QLFT or QNFT, the employee subsequently notifies the employer, program administrator, supervisor, or PLHCP that the fit of the respirator is unacceptable, the employee shall be given a reasonable opportunity to select a different respirator facepiece and to be retested.

1910.134(f)(5) The fit test shall be administered using an OSHA-accepted QLFT or QNFT protocol. The OSHA-accepted QLFT and QNFT protocols and procedures are contained in Appendix A of this section.

1910.134(f)(6) QLFT may only be used to fit test negative pressure air-purifying respirators that must achieve a fit factor of 100 or less.

1910.134(f)(7) If the fit factor, as determined through an OSHA-accepted QNFT protocol, is equal to or greater than 100 for tight-fitting half facepieces, or equal to or greater than 500 for tight-fitting full facepieces, the QNFT has been passed with that respirator.

1910.134(f)(8) Fit testing of tight-fitting atmosphere-supplying respirators and tight-fitting powered air-purifying respirators shall be accomplished by performing quantitative or qualitative fit testing in the negative pressure mode, regardless of the mode of operation (negative or positive pressure) that is used for respiratory protection.

1910.134(f)(8)(i) Qualitative fit testing of these respirators shall be accomplished by temporarily converting the

respirator user's actual facepiece into a negative pressure respirator with appropriate filters, or by using an identical negative pressure air-purifying respirator facepiece with the same sealing surfaces as a surrogate for the atmosphere-supplying or powered air-purifying respirator facepiece.

1910.134(f)(8)(ii) Quantitative fit testing of these respirators shall be accomplished by modifying the facepiece to allow sampling inside the facepiece in the breathing zone of the user, midway between the nose and mouth. This requirement shall be accomplished by installing a permanent sampling probe onto a surrogate facepiece, or by using a sampling adapter designed to temporarily provide a means of sampling air from inside the facepiece.

1910.134(f)(8)(iii) Any modifications to the respirator facepiece for fit testing shall be completely removed, and the facepiece restored to NIOSH-approved configuration, before that facepiece can be used in the workplace.

1910.134(g) Use of respirators.

This paragraph requires employers to establish and implement procedures for the proper use of respirators. These requirements include prohibiting conditions that may result in facepiece seal leakage, preventing employees from removing respirators in hazardous environments, taking actions to ensure continued effective respirator operation throughout the work shift, and establishing procedures for the use of respirators in IDLH atmospheres or in interior structural firefighting situations.

1910.134(g)(1) Facepiece seal protection.

1910.134(g)(1)(i) The employer shall not permit respirators with tight-fitting facepieces to be worn by employees who have:

1910.134(g)(1)(i)(A) Facial hair that comes between the sealing surface of the facepiece and the face or that interferes with valve function; or

1910.134(g)(1)(i)(B) Any condition that interferes with the face-to-facepiece seal or valve function.

1910.134(g)(1)(ii) If an employee wears corrective glasses or goggles or other personal protective equipment, the employer shall ensure that such equipment is worn in a manner that does not interfere with the seal of the facepiece to the face of the user.

1910.134(g)(1)(iii) For all tight-fitting respirators, the employer shall ensure that employees perform a user seal check each time they put on the respirator using the procedures in Appendix B-1 or procedures recommended by the respirator manufacturer that the employer demonstrates are as effective as those in Appendix B-1 of this section.

1910.134(g)(2) Continuing respirator effectiveness.

1910.134(g)(2)(i) Appropriate surveillance shall be maintained of work area conditions and degree of employee exposure or stress. When there is a change in work area conditions or degree of employee exposure or stress that may affect respirator effectiveness, the employer shall reevaluate the continued effectiveness of the respirator.

1910.134(g)(2)(ii) The employer shall ensure that employees leave the respirator use area:

1910.134(g)(2)(ii)(A) To wash their faces and respirator facepieces as necessary to prevent eye or skin irritation associated with respirator use; or

1910.134(g)(2)(ii)(B) If they detect vapor or gas breakthrough, changes in breathing resistance, or leakage of the facepiece; or

1910.134(g)(2)(ii)(C) To replace the respirator or the filter, cartridge, or canister elements.

1910.134(g)(2)(iii) If the employee detects vapor or gas breakthrough, changes in breathing resistance, or leakage of the facepiece, the employer must replace or repair the respirator before allowing the employee to return to the work area.

1910.134(g)(3) Procedures for IDLH atmospheres. For all IDLH atmospheres, the employer shall ensure that:

1910.134(g)(3)(i) One employee or, when needed, more than one employee is located outside the IDLH atmosphere;

1910.134(g)(3)(ii) Visual, voice, or signal line communication is maintained between the employee(s) in the IDLH atmosphere and the employee(s) located outside the IDLH atmosphere;

1910.134(g)(3)(iii) The employee(s) located outside the IDLH atmosphere are trained and equipped to provide effective emergency rescue;

1910.134(g)(3)(iv) The employer or designee is notified before the employee(s) located outside the IDLH atmosphere enter the IDLH atmosphere to provide emergency rescue;

1910.134(g)(3)(v) The employer or designee authorized to do so by the employer, once notified, provides necessary assistance appropriate to the situation;

1910.134(g)(3)(vi) Employee(s) located outside the IDLH atmospheres are equipped with:

1910.134(g)(3)(vi)(A) Pressure demand or other positive pressure SCBAs, or a pressure demand or other positive pressure supplied-air respirator with auxiliary SCBA; and either

1910.134(g)(3)(vi)(B) Appropriate retrieval equipment for removing the employee(s) who enter(s) these hazardous atmospheres where retrieval equipment would contribute to the rescue of the employee(s) and would not increase the overall risk resulting from entry; or

1910.134(g)(3)(vi)(C) Equivalent means for rescue where retrieval equipment is not required under paragraph (g)(3)(vi)(B).

1910.134(g)(4) Procedures for interior structural firefighting. In addition to the requirements set forth under paragraph (g)(3), in interior structural fires, the employer shall ensure that:

1910.134(g)(4)(i) At least two employees enter the IDLH atmosphere and remain in visual or voice contact with

one another at all times;

1910.134(g)(4)(ii) At least two employees are located outside the IDLH atmosphere; and

1910.134(g)(4)(iii) All employees engaged in interior structural firefighting use SCBAs.

Note 1 to paragraph (g): One of the two individuals located outside the IDLH atmosphere may be assigned to an additional role, such as incident commander in charge of the emergency or safety officer, so long as this individual is able to perform assistance or rescue activities without jeopardizing the safety or health of any firefighter working at the incident.

Note 2 to paragraph (g): Nothing in this section is meant to preclude firefighters from performing emergency rescue activities before an entire team has assembled.

1910.134(h) Maintenance and care of respirators.

This paragraph requires the employer to provide for the cleaning and disinfecting, storage, inspection, and repair of respirators used by employees.

1910.134(h)(1) Cleaning and disinfecting. The employer shall provide each respirator user with a respirator that is clean, sanitary, and in good working order. The employer shall ensure that respirators are cleaned and disinfected using the procedures in Appendix B-2 of this section, or procedures recommended by the respirator manufacturer, provided that such procedures are of equivalent effectiveness. The respirators shall be cleaned and disinfected at the following intervals:

1910.134(h)(1)(i) Respirators issued for the exclusive use of an employee shall be cleaned and disinfected as often as necessary to be maintained in a sanitary condition;

1910.134(h)(1)(ii) Respirators issued to more than one employee shall be cleaned and disinfected before being worn by different individuals;

1910.134(h)(1)(iii) Respirators maintained for emergency use shall be cleaned and disinfected after each use; and

1910.134(h)(1)(iv) Respirators used in fit testing and training shall be cleaned and disinfected after each use.

1910.134(h)(2) Storage. The employer shall ensure that respirators are stored as follows:

1910.134(h)(2)(i) All respirators shall be stored to protect them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals, and they shall be packed or stored to prevent deformation of the facepiece and exhalation valve.

1910.134(h)(2)(ii) In addition to the requirements of paragraph (h)(2)(i) of this section, emergency respirators shall be:

1910.134(h)(2)(ii)(A) Kept accessible to the work area;

1910.134(h)(2)(ii)(B) Stored in compartments or in covers that are clearly marked as containing emergency respirators; and

1910.134(h)(2)(ii)(C) Stored in accordance with any applicable manufacturer instructions.

1910.134(h)(3) Inspection.

1910.134(h)(3)(i) The employer shall ensure that respirators are inspected as follows:

1910.134(h)(3)(i)(A) All respirators used in routine situations shall be inspected before each use and during cleaning;

1910.134(h)(3)(i)(B) All respirators maintained for use in emergency situations shall be inspected at least monthly and in accordance with the manufacturer's recommendations, and shall be checked for proper function before and after each use; and

1910.134(h)(3)(i)(C) Emergency escape-only respirators shall be inspected before being carried into the workplace for use.

1910.134(h)(3)(ii) The employer shall ensure that respirator inspections include the following:

1910.134(h)(3)(ii)(A) A check of respirator function, tightness of connections, and the condition of the various parts including, but not limited to, the facepiece, head straps, valves, connecting tube, and cartridges, canisters or filters; and

1910.134(h)(3)(ii)(B) A check of elastomeric parts for pliability and signs of deterioration.

1910.134(h)(3)(iii) In addition to the requirements of paragraphs (h)(3)(i) and (ii) of this section, self-contained breathing apparatus shall be inspected monthly. Air and oxygen cylinders shall be maintained in a fully charged state and shall be recharged when the pressure falls to 90% of the manufacturer's recommended pressure level. The employer shall determine that the regulator and warning devices function properly

1910.134(h)(3)(iv) For respirators maintained for emergency use, the employer shall:

1910.134(h)(3)(iv)(A) Certify the respirator by documenting the date the inspection was performed, the name (or signature) of the person who made the inspection, the findings, required remedial action, and a serial number or other means of identifying the inspected respirator; and

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1910.134(h)(3)(iv)(B) Provide this information on a tag or label that is attached to the storage compartment for the respirator, is kept with the respirator, or is included in inspection reports stored as paper or electronic files. This information shall be maintained until replaced following a subsequent certification.

1910.134(h)(4) Repairs. The employer shall ensure that respirators that fail an inspection or are otherwise found to be defective are removed from service, and are discarded or repaired or adjusted in accordance with the following procedures:

1910.134(h)(4)(i) Repairs or adjustments to respirators are to be made only by persons appropriately trained to perform such operations and shall use only the respirator manufacturer's NIOSH-approved parts designed for the respirator;

1910.134(h)(4)(ii) Repairs shall be made according to the manufacturer's recommendations and specifications for the type and extent of repairs to be performed; and

1910.134(h)(4)(iii) Reducing and admission valves, regulators, and alarms shall be adjusted or repaired only by the manufacturer or a technician trained by the manufacturer.

1910.134(i) Breathing air quality and use.

This paragraph requires the employer to provide employees using atmosphere-supplying respirators (supplied-air and SCBA) with breathing gases of high purity.

1910.134(i)(1) The employer shall ensure that compressed air, compressed oxygen, liquid air, and liquid oxygen used for respiration accords with the following specifications:

1910.134(i)(1)(i) Compressed and liquid oxygen shall meet the United States Pharmacopoeia requirements for medical or breathing oxygen; and

1910.134(i)(1)(ii) Compressed breathing air shall meet at least the requirements for Grade D breathing air described in ANSI/Compressed Gas Association Commodity Specification for Air, G-7.1-1989, to include:

1910.134(i)(1)(ii)(A) Oxygen content (v/v) of 19.5-23.5%;

1910.134(i)(1)(ii)(B) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

1910.134(i)(1)(ii)(C) Carbon monoxide (CO) content of 10 ppm or less;

1910.134(i)(1)(ii)(D) Carbon dioxide content of 1,000 ppm or less; and

1910.134(i)(1)(ii)(E) Lack of noticeable odor.

1910.134(i)(2) The employer shall ensure that compressed oxygen is not used in atmosphere-supplying respirators that have previously used compressed air.

1910.134(i)(3) The employer shall ensure that oxygen concentrations greater than 23.5% are used only in equipment designed for oxygen service or distribution.

1910.134(i)(4) The employer shall ensure that cylinders used to supply breathing air to respirators meet the following requirements:

1910.134(i)(4)(i) Cylinders are tested and maintained as prescribed in the Shipping Container Specification Regulations of the Department of Transportation (49 CFR part 180);

1910.134(i)(4)(ii) Cylinders of purchased breathing air have a certificate of analysis from the supplier that the breathing air meets the requirements for Grade D breathing air; and

1910.134(i)(4)(iii) The moisture content in the cylinder does not exceed a dew point of -50 deg.F (-45.6 deg.C) at 1 atmosphere pressure.

1910.134(i)(5) The employer shall ensure that compressors used to supply breathing air to respirators are constructed and situated so as to:

1910.134(i)(5)(i) Prevent entry of contaminated air into the air-supply system;

1910.134(i)(5)(ii) Minimize moisture content so that the dew point at 1 atmosphere pressure is 10 degrees F (5.56 deg.C) below the ambient temperature;

1910.134(i)(5)(iii) Have suitable in-line air-purifying sorbent beds and filters to further ensure breathing air quality. Sorbent beds and filters shall be maintained and replaced or refurbished periodically following the manufacturer's instructions.

1910.134(i)(5)(iv) Have a tag containing the most recent change date and the signature of the person authorized by the employer to perform the change. The tag shall be maintained at the compressor.

1910.134(i)(6) For compressors that are not oil-lubricated, the employer shall ensure that carbon monoxide levels in the breathing air do not exceed 10 ppm.

1910.134(i)(7) For oil-lubricated compressors, the employer shall use a high-temperature or carbon monoxide alarm, or both, to monitor carbon monoxide levels. If only high-temperature alarms are used, the air supply shall be monitored at intervals sufficient to prevent carbon monoxide in the breathing air from exceeding 10 ppm.

1910.134(i)(8) The employer shall ensure that breathing air couplings are incompatible with outlets for non-respirable worksite air or other gas systems. No asphyxiating substance shall be introduced into breathing air lines.

1910.134(i)(9) The employer shall use only the respirator manufacturer's NIOSH-approved breathing-gas containers, marked and maintained in accordance with the Quality Assurance provisions of the NIOSH approval for the SCBA as issued in accordance with the NIOSH respirator-certification standard at 42 CFR part 84.

1910.134(j) Identification of filters, cartridges, and canisters.
The employer shall ensure that all filters, cartridges and canisters used in the workplace are labeled and color coded with the NIOSH approval label and that the label is not removed and remains legible.

1910.134(k) Training and information.
This paragraph requires the employer to provide effective training to employees who are required to use respirators. The training must be comprehensive, understandable, and recur annually, and more often if necessary. This paragraph also requires the employer to provide the basic information on respirators in Appendix D of this section to employees who wear respirators when not required by this section or by the employer to do so.

1910.134(k)(1) The employer shall ensure that each employee can demonstrate knowledge of at least the following:

1910.134(k)(1)(i) Why the respirator is necessary and how improper fit, usage, or maintenance can compromise the protective effect of the respirator;

1910.134(k)(1)(ii) What the limitations and capabilities of the respirator are;

1910.134(k)(1)(iii) How to use the respirator effectively in emergency situations, including situations in which the respirator malfunctions;

1910.134(k)(1)(iv) How to inspect, put on and remove, use, and check the seals of the respirator;

1910.134(k)(1)(v) What the procedures are for maintenance and storage of the respirator;

1910.134(k)(1)(vi) How to recognize medical signs and symptoms that may limit or prevent the effective use of respirators; and

1910.134(k)(1)(vii) The general requirements of this section.

1910.134(k)(2) The training shall be conducted in a manner that is understandable to the employee.

1910.134(k)(3) The employer shall provide the training prior to requiring the employee to use a respirator in the workplace.

1910.134(k)(4) An employer who is able to demonstrate that a new employee has received training within the last 12 months that addresses the elements specified in paragraph (k)(1)(i) through (vii) is not required to repeat such training provided that, as required by paragraph (k)(1), the employee can demonstrate knowledge of those element(s). Previous training not repeated initially by the employer must be provided no later than 12 months from the date of the previous training.

1910.134(k)(5) Retraining shall be administered annually, and when the following situations occur:

1910.134(k)(5)(i) Changes in the workplace or the type of respirator render previous training obsolete;

1910.134(k)(5)(ii) Inadequacies in the employee's knowledge or use of the respirator indicate that the employee has not retained the requisite understanding or skill; or

1910.134(k)(5)(iii) Any other situation arises in which retraining appears necessary to ensure safe respirator use.

1910.134(k)(6) The basic advisory information on respirators, as presented in Appendix D of this section, shall be provided by the employer in any written or oral format, to employees who wear respirators when such use is not required by this section or by the employer.

1910.134(l) Program evaluation.
This section requires the employer to conduct evaluations of the workplace to ensure that the written respiratory protection program is being properly implemented, and to consult employees to ensure that they are using the respirators properly.

1910.134(l)(1) The employer shall conduct evaluations of the workplace as necessary to ensure that the provisions of the current written program are being effectively implemented and that it continues to be effective.

1910.134(l)(2) The employer shall regularly consult employees required to use respirators to assess the employees' views on program effectiveness and to identify any problems. Any problems that are identified during this assessment shall be corrected. Factors to be assessed include, but are not limited to:

1910.134(l)(2)(i) Respirator fit (including the ability to use the respirator without interfering with effective workplace performance);

1910.134(l)(2)(ii) Appropriate respirator selection for the hazards to which the employee is exposed;

1910.134(l)(2)(iii) Proper respirator use under the workplace conditions the employee encounters; and

1910.134(l)(2)(iv) Proper respirator maintenance.

1910.134(m) Recordkeeping.
This section requires the employer to establish and retain written information regarding medical evaluations, fit testing, and the respirator program. This information will facilitate employee involvement in the respirator program, assist the employer in auditing the adequacy of the program, and provide a record for compliance determinations by OSHA.

1910.134(m)(1) Medical evaluation. Records of medical evaluations required by this section must be retained and made available in accordance with 29 CFR 1910.1020.

1910.134(m)(2) Fit testing.

1910.134(m)(2)(i) The employer shall establish a record of the qualitative and quantitative fit tests administered to an employee including:

1910.134(m)(2)(i)(A) The name or identification of the employee tested;
1910.134(m)(2)(i)(B) Type of fit test performed;
1910.134(m)(2)(i)(C) Specific make, model, style, and size of respirator tested;
1910.134(m)(2)(i)(D) Date of test; and
1910.134(m)(2)(i)(E) The pass/fail results for QLFTs or the fit factor and strip chart recording or other recording of the test results for QNFTs.
1910.134(m)(2)(ii) Fit test records shall be retained for respirator users until the next fit test is administered.
1910.134(m)(3) A written copy of the current respirator program shall be retained by the employer.
1910.134(m)(4) Written materials required to be retained under this paragraph shall be made available upon request to affected employees and to the Assistant Secretary or designee for examination and copying.

1910.134(n) Effective date.
Paragraphs (d)(3)(i)(A) and (d)(3)(i)(B) of this section become effective November 22, 2006.

1910.134(o) Appendices.
Compliance with Appendix A, Appendix B-1, Appendix B-2, Appendix C, and Appendix D to this section are mandatory.

[63 FR 1152, Jan. 8, 1998; 63 FR 20098, April 23, 1998; 71 FR 16672, April 3, 2006; 71 FR 50187, August 24, 2006; 73 FR 75584, Dec. 12, 2008; 76 FR 33606, June 8, 2011]

Fit Testing Procedures (Mandatory).

Part I. OSHA-Accepted Fit Test Protocols

A. Fit Testing Procedures -- General Requirements

The employer shall conduct fit testing using the following procedures. The requirements in this appendix apply to all OSHA-accepted fit test methods, both QLFT and QNFT.

1. The test subject shall be allowed to pick the most acceptable respirator from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine an acceptable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning of the respirator. This instruction may not constitute the subject's formal training on respirator use, because it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator that provides the most acceptable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each chosen facepiece up to the face and eliminate those that obviously do not give an acceptable fit.

5. The more acceptable facepieces are noted in case the one selected proves unacceptable; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in the following item A.6. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include a review of the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

(a) Position of the mask on the nose

(b) Room for eye protection

(c) Room to talk

(d) Position of mask on face and cheeks

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) Chin properly placed;

(b) Adequate strap tension, not overly tightened;

(c) Fit across nose bridge;

(d) Respirator of proper size to span distance from nose to chin;

(e) Tendency of respirator to slip;

(f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct a user seal check, either the negative and positive pressure seal checks described in Appendix B-1 of this section or those recommended by the respirator manufacturer which provide equivalent protection to the procedures in Appendix B-1. Before conducting the negative and positive pressure checks, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the user seal check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, mustache or sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician or other licensed health care professional, as appropriate, to determine whether the test subject can wear a respirator while performing her or his duties.

11. If the employee finds the fit of the respirator unacceptable, the test subject shall be given the opportunity to select a different respirator and to be retested.

12. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

13. The fit test shall be performed while the test subject is wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with respirator fit.

14. Test Exercises.

(a) Employers must perform the following test exercises for all fit testing methods prescribed in this appendix, except for the CNP quantitative fit testing protocol and the CNP REDON quantitative fit testing protocol. For these two protocols, employers must ensure that the test subjects (**i.e.**, employees) perform the exercise procedure specified in Part I.C.4(b) of this appendix for the CNP quantitative fit testing protocol, or the exercise procedure described in Part I.C.5(b) of this appendix for the CNP REDON quantitative fit-testing protocol. For the remaining fit testing methods, employers must ensure that employees perform the test exercises in the appropriate test environment in the following manner:

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as not to hyperventilate.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his/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.

(4) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(5) 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.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(6) Grimace. The test subject shall grimace by smiling or frowning. (This applies only to QNFT testing; it is not performed for QLFT)

(7) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT or QLFT units that do not permit bending over at the waist.

(8) Normal breathing. Same as exercise (1).

(b) Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds. 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. The respirator shall not be adjusted once the fit test exercises begin. Any adjustment voids the test, and the fit test must be repeated.

B. Qualitative Fit Test (QLFT) Protocols

1. General

(a) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and ensure that test equipment is in proper working order.

(b) The employer shall ensure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol

Note: This protocol is not appropriate to use for the fit testing of particulate respirators. If used to fit test particulate respirators, the respirator must be equipped with an organic vapor filter.

(a) Odor Threshold Screening

Odor threshold screening, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate at low levels.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor-free water (e.g., distilled or spring water) at approximately 25 deg. C (77 deg. F) shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 ml of pure IAA to 800 ml of odor-free water in a 1 liter jar, closing the lid and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well-ventilated to prevent the odor of IAA from becoming evident in the general room air where testing takes place.

(1) The odor test solution is prepared in a second jar by placing 0.4 ml of the stock solution into 500 ml of odor-free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(2) A test blank shall be prepared in a third jar by adding 500 cc of odor-free water.

(3) The odor test and test blank jar lids shall be labeled (e.g., 1 and 2) for jar identification. Labels shall be placed on the lids so that they can be peeled off periodically and switched to maintain the integrity of the test.

(4) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): "The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil."

(5) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(6) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(7) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) Isoamyl Acetate Fit Test

(1) The fit test chamber shall be a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. If no drum liner is available, a similar chamber shall be constructed using plastic sheeting. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well-ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 ml of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber. An IAA test swab or ampule may be substituted for the IAA wetted paper towel provided it has been demonstrated that the alternative IAA source will generate an IAA test atmosphere with a concentration equivalent to that generated by the paper towel method.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the test exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana-like odor of IAA, the test is failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test is failed, the subject shall return to the selection room and remove the respirator. The test subject shall repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in (b) (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait at least 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) If the subject passes the test, the efficiency of the test procedure shall be demonstrated by having the subject break the respirator face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so that there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self-sealing plastic bag to keep the test area from being contaminated.

3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(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, subjects 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 s hall breathe through his/her slightly open mouth with tongue extended. The subject is instructed to report when he/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 to paragraph 3. (a): If the test subject eats or drinks something sweet before the screening test, he/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 in 3(a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I. A. of this appendix. 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/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 in section I. A. 14. of this appendix.

(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.

4. Bitrex™ (Denatonium Benzoate) Solution Aerosol Qualitative Fit Test Protocol

The Bitrex™ (Denatonium benzoate) solution aerosol QLFT protocol uses the published saccharin test protocol because that protocol is widely accepted. Bitrex is routinely used as a taste aversion agent in household liquids which children should not be drinking and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste Threshold Screening.

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

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches (30.5 cm) in diameter by 14 inches (35.6 cm) tall. The front portion of the enclosure shall be clear from the respirator and allow free movement 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 open mouth with tongue extended. The subject is instructed to report when he/she detects a bitter taste

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the Threshold Check Solution into the enclosure. This Nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The Threshold Check Solution is prepared by adding 13.5 milligrams of Bitrex to 100 ml of 5% salt (NaCl) solution in distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that the bulb collapses completely, and is then released and allowed to fully expand.

(7) An initial ten squeezes are repeated rapidly and then the test subject is asked whether the Bitrex can be tasted. If the test subject reports tasting the bitter 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 Bitrex is tasted. If the test subject reports tasting the bitter 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 Bitrex is tasted. If the test subject reports tasting the bitter 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 Bitrex is not tasted after 30 squeezes (step 10), the test subject is unable to taste Bitrex and may not perform the Bitrex fit test.

(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 to dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Bitrex 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 as that described in 4(a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected according to section I. A. of this appendix. The respirator shall be properly adjusted and equipped with any type 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 337.5 mg of Bitrex to 200 ml of a 5% salt (NaCl) solution in warm water.

(6) As before, the test subject shall breathe through his or her slightly open mouth with tongue extended, and be instructed to report if he/she tastes the bitter taste of Bitrex.

(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of the 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.

(8) After generating the aerosol, the test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the 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 Bitrex is detected. If the test subject does not report tasting the Bitrex, the test is passed.

(11) If the taste of Bitrex 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).

5. 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.

(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 build-up 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/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/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/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/her eyes closed.

(3) The test operator shall direct the stream of irritant smoke from the smoke tube toward the faceseal 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 facepiece 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 exercises identified in section I.A. 14. of this appendix shall be performed by the test subject while the respirator seal is being continually challenged by the smoke, directed around the perimeter of the respirator at a distance of six inches.

(6) 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.

(7) 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/she still reacts to the smoke. Failure to evoke a response shall void the fit test.

(8) If a response is produced during this second sensitivity check, then the fit test is passed.

C. Quantitative Fit Test (QNFT) Protocols

The following quantitative fit testing procedures have been demonstrated to be acceptable: Quantitative fit testing using a non-hazardous test aerosol (such as corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator; Quantitative fit testing using ambient aerosol as the test agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit; Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.

1. General

(a) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and ensure that test equipment is in proper working order.

(b) The employer shall ensure that QNFT equipment is kept clean, and is maintained and calibrated according to the manufacturer's instructions so as to operate at the parameters for which it was designed.

2. Generated Aerosol Quantitative Fit Testing Protocol

(a) Apparatus.

(1) Instrumentation. Aerosol generation, dilution, and measurement systems using particulates (corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS] or sodium chloride) as test aerosols shall be used for quantitative fit testing.

(2) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the test agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the test agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(3) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high efficiency particulate air (HEPA) or P100 series filter supplied by the same manufacturer.

(4) The sampling instrument shall be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the test agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers that integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(5) The combination of substitute air-purifying elements, test agent and test agent concentration shall be such that the test subject is not exposed in excess of an established exposure limit for the test agent at any time during the testing process, based upon the length of the exposure and the exposure limit duration.

(6) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g., where the respirator is probed), a free air flow is allowed into the sampling line at all times, and there is no interference with the fit or performance of the respirator. The in-mask sampling device (probe) shall be designed and used so that the air sample is drawn from the breathing zone of the test subject, midway between the nose and mouth and with the probe extending into the facepiece cavity at least 1/4 inch.

(7) The test setup shall permit the person administering the test to observe the test subject inside the chamber during the test.

(8) The equipment generating the test atmosphere shall maintain the concentration of test agent constant to within a 10 percent variation for the duration of the test.

(9) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event and its being recorded.

(10) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(11) The exhaust flow from the test chamber shall pass through an appropriate filter (i.e., high efficiency particulate filter) before release.

(12) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(13) The limitations of instrument detection shall be taken into account when determining the fit factor.

(14) Test respirators shall be maintained in proper working order and be inspected regularly for deficiencies such as cracks or missing valves and gaskets.

(b) Procedural Requirements.

(1) When performing the initial user seal check using a positive or negative pressure check, the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these pressure checks.

(2) The use of an abbreviated screening QLFT test is optional. Such a test may be utilized in order to quickly identify poor fitting respirators that passed the positive and/or negative pressure test and reduce the amount of QNFT time. The use of the CNC QNFT instrument in the count mode is another optional method to obtain a quick estimate of fit and eliminate poor fitting respirators before going on to perform a full QNFT.

(3) A reasonably stable test agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain types of test units, the determination of the test agent's stability may be established after the test subject has entered the test environment.

(4) Immediately after the subject enters the test chamber, the test agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(5) A stable test agent concentration shall be obtained prior to the actual start of testing.

(6) Respirator restraining straps shall not be over-tightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonably comfortable fit typical of normal use. The respirator shall not be adjusted once the fit test exercises begin.

(7) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested.

(8) Calculation of fit factors.

(i) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

(ii) The average test chamber concentration shall be calculated as the arithmetic average of the concentration measured before and after each test (i.e., 7 exercises) or the arithmetic average of the concentration measured before and after each exercise or the true average measured continuously during the respirator sample.

(iii) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(A) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers that calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

(B) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(C) Integration by calculation of the area under the individual peak for each exercise except the grimace exercise. This includes computerized integration.

(D) The calculation of the overall fit factor using individual exercise fit factors involves first converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor. This procedure is described in the following equation:

$$\text{Overall Fit Factor} = \frac{\text{Number of exercises}}{1/ff_1 + 1/ff_2 + 1/ff_3 + 1/ff_4 + 1/ff_5 + 1/ff_6 + 1/ff_7 + 1/ff_8}$$

Where ff_1, ff_2, ff_3, etc. are the fit factors for exercises 1, 2, 3, etc.

(9) The test subject shall not be permitted to wear a half mask or quarter facepiece respirator unless a minimum fit factor of 100 is obtained, or a full facepiece respirator unless a minimum fit factor of 500 is obtained.

(10) Filters used for quantitative fit testing shall be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media.

3. Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol.

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 probed respirator is required for each make, style, model, and size that the employer uses and can be obtained from the respirator manufacturer or distributor. The CNC instrument manufacturer, TSI Inc., also provides probe attachments (TSI sampling adapters) that permit fit testing in an employee's own respirator. 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 facepiece negative pressure respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Portacount Fit Test Requirements.

(1) Check the respirator to make sure the sampling probe and line are properly attached to the facepiece and that the respirator is fitted with a particulate filter capable of preventing significant penetration by the ambient particles used for the fit test (e.g., NIOSH 42 CFR 84 series 100, series 99, or series 95 particulate filter) per manufacturer's instruction.

(2) 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.

(3) 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.

(4) 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 facepiece, try another size of the same model respirator, or another model of respirator.

(5) Follow the manufacturer's instructions for operating the Portacount and proceed with the test.

(6) The test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(7) 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.

(b) Portacount Test Instrument.

(1) 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 was a Pass, the fit test is over.

(2) Since the pass or fail criterion of the Portacount is user programmable, the test operator shall ensure that the pass or fail criterion meet the requirements for minimum respirator performance in this Appendix.

(3) 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.

4. Controlled negative pressure (CNP) quantitative fit testing protocol.

The CNP protocol provides an alternative to aerosol fit test methods. The CNP fit test method technology is based on exhausting air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The rate of air exhaust is controlled so that a constant negative pressure is maintained in the respirator during the fit test. The level of pressure is selected to replicate the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is equal to air flow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage air flow into the respirator. The CNP fit test method measures leak rates through the facepiece as a method for determining the facepiece fit for negative pressure respirators. The CNP instrument manufacturer Occupational Health Dynamics of Birmingham, Alabama also provides attachments (sampling manifolds) that replace the filter cartridges to permit fit testing in an employee's own respirator. To perform the test, the test subject closes his or her mouth and holds his/her breathe, after which an air pump removes air from the respirator facepiece at a pre-selected constant pressure. The facepiece fit is expressed as the leak rate through the facepiece, expressed as milliliters per minute. The quality and validity of the CNP fit tests are determined by the degree to which the in-mask pressure tracks the test pressure during the system measurement time of approximately five seconds. Instantaneous feedback in the form of a real-time pressure trace of the in-mask pressure is provided and used to determine test validity and quality. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full facepiece respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) CNP Fit Test Requirements.

(1) The instrument shall have a non-adjustable test pressure of 15.0 mm water pressure.

(2) The CNP system defaults selected for test pressure shall be set at -- 15 mm of water (-0.58 inches of water) and the modeled inspiratory flow rate shall be 53.8 liters per minute for performing fit tests.

(Note: CNP systems have built-in capability to conduct fit testing that is specific to unique work rate, mask, and gender situations that might apply in a specific workplace. Use of system default values, which were selected to represent respirator wear with medium cartridge resistance at a low-moderate work rate, will allow inter-test comparison of the respirator fit.)

(3) The individual who conducts the CNP fit testing shall be thoroughly trained to perform the test.

(4) The respirator filter or cartridge needs to be replaced with the CNP test manifold. The inhalation valve downstream from the manifold either needs to be temporarily removed or propped open.

(5) The employer must train the test subject to hold his or her breath for at least 10 seconds.

(6) The test subject must don the test respirator without any assistance from the test administrator who is conducting the CNP fit test. The respirator must not be adjusted once the fit-test exercises begin. Any adjustment voids the test, and the test subject must repeat the fit test.

(7) The QNFT protocol shall be followed according to section I. C. 1. of this appendix with an exception for the CNP test exercises.

(b) CNP Test Exercises.

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject needs to hold head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, being careful not to hyperventilate. After the deep breathing exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during test measurement.

(3) 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 for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side. After the turning head side to side exercise, the subject needs to hold head full left and hold his or her breath for 10 seconds during test measurement. Next, the subject needs to hold head full right and hold his or her breath for 10 seconds during test measurement.

(4) Moving head up and down. Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling). After the moving head up and down exercise, the subject shall hold his or her head full up and hold his or her breath for 10 seconds during test measurement. Next, the subject shall hold his or her head full down and hold his or her breath for 10 seconds during test measurement.

(5) 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 for 1 minute. After the talking exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(6) Grimace. The test subject shall grimace by smiling or frowning for 15 seconds.

(7) Bending Over. The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud-type QNFT units that prohibit bending at the waist. After the bending over exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(8) Normal Breathing. The test subject shall remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement. 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 a respirator shall be tried.

(c) CNP Test Instrument.

(1) The test instrument must have an effective audio-warning device, or a visual-warning device in the form of a screen tracing, that indicates when the test subject fails to hold his or her breath during the test. The test must be terminated and restarted from the beginning when the test subject fails to hold his or her breath during the test. The test subject then may be refitted and retested.

(2) A record of the test shall 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.

5. Controlled negative pressure (CNP) REDON quantitative fit testing protocol.

(a) When administering this protocol to test subjects, employers must comply with the requirements specified in paragraphs (a) and (c) of Part I.C.4 of this appendix ("Controlled negative pressure (CNP) quantitative fit testing protocol"), as well as use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in paragraph (b) of Part I.C.4 of this appendix.

(b) Employers must ensure that each test subject being fit tested using this protocol follows the exercise and measurement procedures, including the order of administration, described below in Table A-1 of this appendix.

Table A-1.
CNP REDON Quantitative Fit Testing Protocol

Exercises[1]	Exercise procedure	Measurement procedure
Facing Forward	Stand and breathe normally, without talking, for 30 seconds.	Face forward, while holding breath for 10 seconds.
Bending Over	Bend at the waist, as if going to touch his or her toes, for 30 seconds.	Face parallel to the floor, while holding breath for 10 seconds
Head Shaking	For about three seconds, shake head back and forth vigorously several times while shouting.	Face forward, while holding breath for 10 seconds.
REDON 1	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask.	Face forward, while holding breath for 10 seconds.
REDON 2	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask again.	Face forward, while holding breath for 10 seconds.

[1] Exercises are listed in the order in which they are to be administered.

(c) After completing the test exercises, the test administrator must question each test subject regarding the comfort of the respirator. When a test subject states that the respirator is unacceptable, the employer must ensure that the test administrator repeats the protocol using another respirator model.

(d) Employers must determine the overall fit factor for each test subject by calculating the harmonic mean of the fit testing exercises as follows:

$$\text{Overall Fit Factor} = \frac{N}{[1/FF_1 + 1/FF_2 + \ldots 1/FF_N]}$$

Where:

N = The number of exercises;

FF_1 = The fit factor for the first exercise;

FF_2 = The fit factor for the second exercise; and

FF_N = The fit factor for the nth exercise.

Part II. New Fit Test Protocols

A. Any person may submit to OSHA an application for approval of a new fit test protocol. If the application meets the following criteria, OSHA will initiate a rulemaking proceeding under section 6(b)(7) of the OSH Act to determine whether to list the new protocol as an approved protocol in this Appendix A.

B. The application must include a detailed description of the proposed new fit test protocol. This application must be supported by either:

1. A test report prepared by an independent government research laboratory (e.g., Lawrence Livermore National Laboratory, Los Alamos National Laboratory, the National Institute for Standards and Technology) stating that the laboratory has tested the protocol and had found it to be accurate and reliable; or

2. An article that has been published in a peer-reviewed industrial hygiene journal describing the protocol and explaining how test data support the protocol's accuracy and reliability.

C. If OSHA determines that additional information is required before the Agency commences a rulemaking proceeding under this section, OSHA will so notify the applicant and afford the applicant the opportunity to submit the supplemental information. Initiation of a rulemaking proceeding will be deferred until OSHA has received and evaluated the supplemental information.

[63 FR 20098, April 23, 1998; 69 FR 46993, August 4, 2004]

APPENDIX E-2: User Seal Check Procedures (Mandatory)

User Seal Check Procedures (Mandatory)

The individual who uses a tight-fitting respirator is to perform a user seal check to ensure that an adequate seal is achieved each time the respirator is put on. Either the positive and negative pressure checks listed in this appendix, or the respirator manufacturers recommended user seal check method shall be used. User seal checks are not substitutes for qualitative or quantitative fit tests.

I. Facepiece Positive and/or Negative Pressure Checks

A. Positive pressure check. Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

B. Negative pressure check. Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. The design of the inlet opening of some cartridges cannot be effectively covered with the palm of the hand. The test can be performed by covering the inlet opening of the cartridge with a thin latex or nitrile glove. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

II. Manufacturer's Recommended User Seal Check Procedures

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

[63 FR 1152, Jan. 8, 1998]

Respirator Cleaning Procedures (Mandatory)

These procedures are provided for employer use when cleaning respirators. They are general in nature, and the employer as an alternative may use the cleaning recommendations provided by the manufacturer of the respirators used by their employees, provided such procedures are as effective as those listed here in Appendix B-2. Equivalent effectiveness simply means that the procedures used must accomplish the objectives set forth in Appendix B-2, i.e., must ensure that the respirator is properly cleaned and disinfected in a manner that prevents damage to the respirator and does not cause harm to the user.

I. Procedures for Cleaning Respirators

A. Remove filters, cartridges, or canisters. Disassemble facepieces by removing speaking diaphragms, demand and pressure- demand valve assemblies, hoses, or any components recommended by the manufacturer. 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 facepieces 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 facepiece, replacing filters, cartridges, and canisters where necessary.

H. Test the respirator to ensure that all components work properly.

[63 FR 1152, Jan. 8, 1998]

OSHA Respirator Medical Evaluation Questionnaire (Mandatory)

To the employer:
Answers to questions in Section 1, and to question 9 in Section 2 of Part A, do not require a medical examination.

To the employee:
Your employer must allow you to answer this questionnaire during normal working hours, or at a time and place that is convenient to you. To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the health care professional who will review it.

Part A. Section 1. (Mandatory) The following information must be provided by every employee who has been selected to use any type of respirator (please type or print).

1.	Today's date:		
2.	Your name:		
3.	Your age (to nearest year):		
4.	Sex (circle one):	Male	Female
5.	Your height:	ft.	in.
6.	Your weight:	lbs.	
7.	Your job title:		
8.	A phone number where you can be reached by the health care professional who reviews this questionnaire (include the Area Code):		
9.	The best time to phone you at this number:		
10.	Has your employer told you how to contact the health care professional who will review this questionnaire (check one):	Yes	No
11.	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-facepiece type, powered-air purifying, supplied-air, self-contained breathing apparatus).	
12.	Have you worn a respirator (check one):	Yes	No
	If "yes," what type(s):		

Part A. Section 2. (Mandatory) Questions 1 through 9 below must be answered by every employee who has been selected to use any type of respirator (please check "yes" or "no").

1.	Do you *currently* smoke tobacco, or have you smoked tobacco in the last month:	Yes	No
2.	Have you *ever had* any of the following conditions?		
a.	Seizures:	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

3.	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
4.	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
5.	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

6.	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
7.	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:	Yes	No
8.	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 9:)		
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
9.	Would you like to talk to the health care professional who will review this questionnaire about your answers to this questionnaire:	Yes	No
Questions 10 to 15 below must be answered by every employee who has been selected to use either a full-facepiece 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. (Please check “yes” or “no”).			
10.	Have you *ever lost* vision in either eye (temporarily or permanently):	Yes	No
11.	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
12.	Have you *ever had* an injury to your ears, including a broken ear drum:	Yes	No
13.	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
14.	Have you *ever had* a back injury:	Yes	No

15.	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 or 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
Part B. Any of the following questions, and other questions not listed, may be added to the questionnaire at the discretion of the health care professional who will review the questionnaire. (Please check “yes” or “no”).			
1.	In your present job, are you working at high altitudes (over 5,000 feet) or in a place that has lower than normal amounts of oxygen:	Yes	No
	If "yes," do you have feelings of dizziness, shortness of breath, pounding in your chest, or other symptoms when you're working under these conditions:	Yes	No
2.	At work or at home, have you ever been exposed to hazardous solvents, hazardous airborne chemicals (e.g., gases, fumes, or dust), or have you come into skin contact with hazardous chemicals:	Yes	No
	If "yes," name the chemicals if you know them:		
3.	Have you ever worked with any of the materials, or under any of the conditions, listed below:		
a.	Asbestos:	Yes	No
b.	Silica (*e.g.*, in sandblasting):	Yes	No
c.	Tungsten/cobalt (e.g., grinding or welding this material):	Yes	No
d.	Beryllium:	Yes	No
e.	Aluminum:	Yes	No
f.	Coal (for example, mining):	Yes	No
g.	Iron:	Yes	No
h.	Tin:	Yes	No
i.	Dusty environments:	Yes	No
j.	Any other hazardous exposures:	Yes	No
	If "yes," describe these exposures:		
4.	List any second jobs or side businesses you have:		
5.	List your previous occupations:		
6.	List your current and previous hobbies:		

7.	Have you been in the military services?	Yes	No
	If "yes," were you exposed to biological or chemical agents (either in training or combat):	Yes	No
8.	Have you ever worked on a HAZMAT team?	Yes	No
9.	Other than medications for breathing and lung problems, heart trouble, blood pressure, and seizures mentioned earlier in this questionnaire, are you taking any other medications for any reason (including over-the-counter medications):	Yes	No
	If "yes," name the medications if you know them		
10.	Will you be using any of the following items with your respirator(s)?		
a.	HEPA Filters:	Yes	No
b.	Canisters (for example, gas masks):	Yes	No
c.	Cartridges:	Yes	No
11.	How often are you expected to use the respirator(s) (circle "yes" or "no" for all answers that apply to you)?:		
a.	Escape only (no rescue):	Yes	No
b.	Emergency rescue only:	Yes	No
c.	Less than 5 hours *per week:*	Yes	No
d.	Less than 2 hours *per day:*	Yes	No
e.	. 2 to 4 hours per day:	Yes	No
f.	Over 4 hours per day:	Yes	No
12.	During the period you are using the respirator(s), is your work effort:		
a.	*Light* (less than 200 kcal per hour):	Yes	No
	If "yes," how long does this period last during the average shift:	hrs	mins
	Examples of a light work effort are *sitting* while writing, typing, drafting, or performing light assembly work; or *standing* while operating a drill press (1-3 lbs.) or controlling machines.		
b.	*Moderate* (200 to 350 kcal per hour): Yes/No	Yes	No
	If "yes," how long does this period last during the average shift:	hrs	mins
	Examples of moderate work effort are *sitting* while nailing or filing; *driving* a truck or bus in urban traffic; *standing* while drilling, nailing, performing assembly work, or transferring a moderate load (about 35 lbs.) at trunk level; *walking* on a level surface about 2 mph or down a 5-degree grade about 3 mph; or *pushing* a wheelbarrow with a heavy load (about 100 lbs.) on a level surface.		
c.	*Heavy* (above 350 kcal per hour):	Yes	No
	If "yes," how long does this period last during the average shift:	hrs	mins
	Examples of heavy work are *lifting* a heavy load (about 50 lbs.) from the floor to your waist or shoulder; working on a loading dock; *shoveling; standing* while bricklaying or chipping castings; *walking* up an 8-degree grade about 2 mph; climbing stairs with a heavy load (about 50 lbs.).		
13.	Will you be wearing protective clothing and/or equipment (other than the respirator) when you're using your respirator:	Yes	No
	If "yes," describe this protective clothing and/or equipment:		
14.	Will you be working under hot conditions (temperature exceeding 77 deg. F):	Yes	No
15.	Will you be working under humid conditions:	Yes	No
16.	Describe the work you'll be doing while you're using your respirator(s):		

17.	Describe any special or hazardous conditions you might encounter when you're using your respirator(s) (for example, confined spaces, life-threatening gases):
18.	Provide the following information, if you know it, for each toxic substance that you'll be exposed to when you're using your respirator(s)
	Name of the first toxic substance:
	Estimated maximum exposure level per shift:
	Duration of exposure per shift:
	Name of the second toxic substance:
	Estimated maximum exposure level per shift:
	Duration of exposure per shift:
	Name of the third toxic substance:
	Estimated maximum exposure level per shift:
	Duration of exposure per shift:
	The name of any other toxic substances that you'll be exposed to while using your respirator:
19.	Describe any special responsibilities you'll have while using your respirator(s) that may affect the safety and well-being of others (for example, rescue, security):
20.	Employee Name (Please print): Employee Signature:
21.	Physician Name (Please print): Physician Signature:
22.	Date:

APPENDIX E-5: Information for Employees Using Respirators When Not Required Under the Standard (Mandatory)

Information for Employees Using Respirators When Not Required Under the Standard (Mandatory)

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. Sometimes, workers may wear respirators to avoid exposures to hazards, even if the amount of hazardous substance does not exceed the limits set by OSHA standards. If your employer provides respirators for your voluntary use, or if you provide your own respirator, you need to take certain precautions to be sure that the respirator itself does not present a hazard.

You should do the following:

1. Read and heed all instructions provided by the manufacturer on use, maintenance, cleaning and care, and warnings regarding the respirators limitations.
2. Choose respirators certified for use to protect against the contaminant of concern. NIOSH, the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services, certifies respirators. A label or statement of certification should appear on the respirator or respirator packaging. It will tell you what the respirator is designed for and how much it will protect you.
3. Do not wear your respirator into 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. [63

FR 1152, Jan. 8, 1998; 63 FR 20098, April 23, 1998]

LICENSING AND REGULATORY AFFAIRS
CUSTOMER DRIVEN. BUSINESS MINDED.

Michigan Occupational Safety and Health Administration PO Box 30643
Lansing, Michigan 48909-8143
Ph: 517-284-7740

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Michigan Department of Licensing and Regulatory Affairs
Michigan Occupational Safety & Health Administration
Consultation Education & Training Division

Sample

(Insert Company Name)

Respiratory Protection Program

Program Administrator: **(Insert Name)**

Provided by:
Michigan Department of Licensing and Regulatory Affairs
Michigan Occupational Safety & Health Administration
Consultation Education & Training Division
(517) 284-7720

NOTICE:

The purpose of this document is to aid in the development of written programs related to respiratory protection. There is no regulation requiring that an employer use this exact format in setting up a respiratory protection program. In order to be in compliance with 1910.134 as adopted by the Michigan Occupational Health Standards Commission, an employer may use this or any other format that will satisfy all the requirements of the standard. This program is designed to be adapted to each individual employer's need; forms should be shortened, expanded, or duplicated as needed. It does not substitute for a full reading of the standard.

PURPOSE

It is the policy of **(YOUR COMPANY NAME)** to provide its employees with a safe and healthy work environment. The guidelines established in this program are designed to help reduce employee exposure to occupational air contaminants. The primary objective is to provide employee protection from exposure to any respiratory hazard that may be encountered while performing various work assignments for this company. These hazards include: (i.e., **wood dusts, welding fumes, particulates, and organic vapors - add or subtract as necessary to reflect your site-specific hazards).**

Controlling employee exposures through engineering controls, such as ventilation and substitution of less toxic materials followed by proper work practices that reduce employee exposure are to be implemented first and foremost. When effective engineering controls are not feasible, or while they are being implemented or evaluated, respiratory protection may be required to achieve this goal.

In addition, certain program elements are required for voluntary use of disposable filtering face-piece respirators. In all applicable situations, respiratory protection and the expenses associated with training and medical evaluations is provided at no cost to the employee per the MIOSHA Part 451. Respiratory Protection Standard.

SCOPE & APPLICATION

This policy applies to all (**COMPANY NAME HERE)** employees who may be required to work in hazardous atmospheres in which contaminants that cannot be reduced by engineering controls and requires the utilization of respirators. This may include normal work processes/operations, maintenance activities and during some non-routine or emergency operations such as a spill of a hazardous chemical. All employees working in areas that require the need for respiratory protection (as outlined in the table below) must be enrolled in the company's respiratory protection program.

In addition, any employee who voluntarily wears a respirator when a respirator is not required (i.e., in certain maintenance and coating operations) is subject to the medical evaluation, cleaning, maintenance, and storage elements or this program, and must be provided with certain information specified in this section of the program. Employees participating in the respiratory protection program do so at no cost to them. The expense associated with training, medical evaluations and respiratory protection equipment will be borne by the company.

PROGRAM ADMINISTRATOR

This respiratory protection program is administered by the (**EMPLOYEE'S JOB TITLE** (i.e., **Safety Manager**)). This individual has the authority to act on any and all matters relating to the operation and administration of this program and is referred to as the Respiratory Protection Program Administrator. This person is responsible for monitoring or conducting exposure assessments of the respiratory hazard, selection of respiratory protection options, developing standard operating procedures and maintaining all records associated with the program. Other responsibilities also include administering the medical surveillance program, training employees of proper use, selection, donning/doffing of the respiratory protection, proper storage and maintenance of respiratory protection equipment, conducting annual program evaluations, conducting annual fit testing and updating this program as necessary.

RESPONSIBILITIES

Management/Supervisors

Supervisors are responsible for ensuring that the Respiratory Protection Program is implemented and followed in their particular areas and ensuring that the program requirements are understood by all employees. Additional duties of the supervisor include:

- Ensuring that employees under their supervision (including new hires) have received the medical evaluation, appropriate training and annual fit testing.
- Ensuring the availability of appropriate respirators and accessories.
- Being aware of tasks requiring the use of respiratory protection.
- Enforcing the proper use of respiratory protection when necessary.
- Ensuring that respirators are properly cleaned, maintained, and stored according to the respiratory protection program.
- Ensuring that respirators fit well and do not cause discomfort.
- Continually monitor their work areas and operations to identify hazards.

Employees

Each employee has the responsibility to wear his/her respirator when and where required and in a manner in which they were trained.

Additional responsibilities of the employee include:

- Maintain and store their respirators as instructed in a clean sanitary location.
- Inform their supervisor if the respirator no longer fits well, or new medical conditions arise and request a new evaluation when this occurs.
- Inform their supervisor or the Program Administrator of any respiratory hazards that they feel are not adequately addressed in the workplace.

SELECTION PROCEDURES

The Program Administrator will select respirators to be used on site based on the hazards to which workers are exposed and in accordance with all MIOSHA standards. The Program Administrator will **conduct a hazard evaluation** for each operation, process, or work area where airborne contaminants may be present in routine operations or during an emergency. The hazard evaluation will include: an identification of the hazardous substances used in the workplace, by department, or work process and a review of work processes to determine where potential exposures to these hazardous substances may occur. This review shall be conducted by surveying the workplace, reviewing process records, and talking with employees and supervisors. An employee exposure assessment (i.e., breathing zone air sampling) will be conducted to ensure proper respirator selection. In order to determine the employees' exposure level, air samples of the work place representative of the employee exposure will be used. Personal sampling equipment will be used in accordance with accepted industrial hygiene standards. Respiratory protection has been selected based on recent air sampling results.

The exposure assessment will be performed prior to the task requiring respiratory protection. A review of the assessment will be performed periodically to determine if respiratory protection is still required. If respiratory protection is still necessary, respirator selections will be reviewed to assure their continued suitability. Additionally, all respirators must be certified by the National Institute for Occupational Safety and Health (i.e., NIOSH) and shall be used in accordance with the terms of that certification. Respirators are selected and approved for use by the Program Administrator. The selection is based upon the type and concentration of contaminant to be encountered by the employee. Assigned protection factors (APFs) and maximum use concentrations (MUCs) must be determined when determining the appropriate type of respirator.

(NOTE: The employer must describe areas that require the use of respiratory protection here. This should include a brief description of the process, any engineering controls utilized and a description of employee exposure levels.)

AIR SAMPLING TESTING (Sample language to follow)

Air sampling was conducted in the breathing zone of employee(s) working at the **(describe operation)** to evaluate the employee(s) exposure to **(list contaminants)**. The testing results are shown on the attached Air Contaminant Data Sheet(s). These results indicate that the employee(s) **(was/ or was not – choose one)** exposed to air contaminant(s) in excess of permissible exposure limits (PELs). Employee exposures were equal to _____ mg/m³ or ppm **(circle one)**. Employees will be required to wear (**DESCRIBE RESPIRATORY PROTECTION)** as noted in Table 1. Local exhaust ventilation (**choose one – is OR is not)** available for this process.

RESPIRATOR USE

The results of the hazard evaluation are shown in Table 1.

TABLE 1: VOLUNTARY AND REQUIRED RESPIRATOR USE

Respirator	*Required OR Voluntary* (circle one)	*Department/Process*
Filtering face-piece (disposable dust mask)	**required OR voluntary**	Job description + contaminant (i.e., Maintenance – light end of shift sweeping activities)
Half-face (elastomeric) air purifying respirator (APR) with N100 filters (i.e., 99.97% efficient	**required OR voluntary**	Job description + contaminant (i.e., asbestos, lead, arsenic, cadmium)

Half-face (elastomeric) air purifying respirator (APR) with N95 filters (i.e. 95% efficient)	**required OR voluntary**	Job description + contaminant (i.e., welding fume, wood dust, crystalline silica (could also use a N100))
Half-face (elastomeric) respirator with organic vapor (OV) cartridges	**required OR voluntary**	Job description + contaminant (i.e., solvents, paint thinner, xylene, glutaraldehyde)
Supplied-air respirator (SAR)	**required OR voluntary**	Job description + contaminant (i.e., carbon monoxide, cyanides, spraying isocyanate containing coatings)
Self-contained breathing apparatus (SCBA) or Escape SCBA	**required OR voluntary**	Job description + contaminant (i.e., fire-fighting, emergency response, emergency escape)
	required OR voluntary	Job description + contaminant (i.e.,
	required OR voluntary	Job description + contaminant (i.e.,

(NOTE: These are samples only. The employer must select and utilize the appropriate respiratory protection for the contaminants present at their worksite. Consult the manufacturers' respirator selection guide when selecting respirators. Customize the table above by listing site-specific operations and types of respiratory protection that are used at your facility.)

The Program Administrator will provide all employees who ***voluntarily*** choose to wear either a filtering face-piece or elastomeric style respirator with the information contained in **Appendix D** of the standard (see below).

Appendix D (for voluntary use respirators)

Respirators are an effective method of protection against designated hazards when properly selected and worn. Respirator use is encouraged, even when employee 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. Sometimes, workers may wear respirators to avoid exposures to hazards, even if the amount of hazardous substances does not exceed the limits set by OSHA/MIOSHA standards. If your employer provides respirators for your voluntary use, or if you provide your own respirator, you need to take certain precautions to be sure that the respirator itself does not present a hazard.

You should do the following:

1. Read and heed all instructions provided by the manufacturer on use, maintenance, cleaning and care, and warnings regarding the respirators' limitations.
2. Choose respirators certified for use to protect against the contaminant of concern. NIOSH, the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services,

certifies respirators. A label or statement of certification should appear on the respirator or respirator packaging. It will tell you what the respirator is designed for and how much it will protect you.

3. Do not wear your respirator into 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.

Employees voluntarily choosing to wear a half-face-piece APR must also comply with the sections of this program relating to medical evaluation, respirator use, cleaning, maintenance and storage. The Program Administrator shall authorize all voluntary use of respiratory protective equipment as requested by workers on a case-by-case basis. Approval to wear a respirator will depend on specific workplace conditions and the results of the medical evaluation.

Respirators will be purchased from **(SUPPLY COMPANY NAME HERE).** The following respirators have been approved:

1. 3M Particulate Respirator #8210 - N95 **(example - enter respirators used here)**

2. 3M Particulate Respirator #8233 - N100

3. _____

Replacement respirators, disposable filtering face-piece APRs and cartridges/filters will be available in/at the (**DESCRIBE LOCATIONS HERE).**

EMERGENCY PROCEDURES:

(NOTE: Employer should add/subtract these headings as deemed necessary.)

The following work areas have been identified as having potential emergencies:

(_____)

When the emergency alarm sounds/evacuation command given, employees in the affected area must immediately don their emergency escape respirator, shut down their process equipment, and exit the work area to a safe and secure area. All other employees must immediately evacuate the building. (**YOUR COMPANY NAME HERE)** Emergency Action Plan describes these procedures (including proper evacuation routes and safe head-count locations) in greater detail.

Emergency escape respirators are located:

(**Describe locations of emergency escape respirators here, if applicable)**

(_____)

Employees of (**YOUR COMPANY NAME HERE)** that use escape only respirators, are **not** trained as emergency responders, and are not authorized to act in such a manner. When the evacuation alarm or command is given, all employees will leave the building, gather at the designated safe area or head-count location and wait for an all clear from the designated emergency responders. Once an evacuation command is given employees **are not** permitted to enter back into the building until an all clear command has been established.

If self-contained breathing apparatus (SCBA) respirators are maintained for use in emergency situations they shall be inspected at least monthly. Required documentation of this inspection must include: the unit's identification number, inspection date, inspector's name, findings and any required action.

BREATHING AIR QUALITY

For supplied-air respirators (i.e., SAR), only Grade D breathing air shall be used. Grade D breathing air may be provided in cylinders or by an air compressor system that has routine air quality checks, to ensure the quality of the breathing air being provided. Compressors used to supply breathing air must have suitable in-line air-purifying sorbent beds and filters and must have high heat alarms/shut-off, carbon monoxide monitor/alarm, oil filter/trap, and a water removal trap; in accordance with Part 451. Respiratory Protection. A tag noting the date of most recent filter change must be signed by the employee who performed the change.

MEDICAL EVALUATION

Employees who are either required to wear respirators, or who choose to wear an APR voluntarily, must pass a medical exam before being permitted to wear a respirator on the job. Employees are **not** permitted to wear respirators until a physician or other licensed health care professional (PLHCP) has determined that they are medically able to do so. The only exception to this is the voluntary use of filtering face-piece style (dust mask) respirators. Any employee refusing the medical evaluation will not be allowed to work in an area requiring respirator use.

A PLHCP at **(INSERT NAME OF MEDICAL CLINIC)** will provide the required respirator medical evaluations. The medical evaluation procedure is as follows:

- The medical evaluation will be conducted using the questionnaire provided in **Appendix C** of Part 451. Respiratory Protection. The Program Administrator will provide a copy of this questionnaire to all employees requiring medical evaluations. Employees will be permitted to fill out the questionnaire on company time.
- To the extent feasible, the company will assist employees who are unable to read the questionnaire (by providing help in reading the questionnaire). When this is not possible, the employee will be sent directly to the PLHCP for medical evaluation.
- All affected employees will be given a copy of the medical questionnaire to fill out, along with a stamped and addressed envelope for mailing the questionnaire to the company PLHCP.
- Follow-up medical exams will be granted to employees as deemed necessary by the PLHCP.
- The Program Administrator has provided the medical clinic PLHCP with a copy of this program, a copy Part 451. Respiratory Protection, the list of hazardous substances by work area, and for each employee requiring evaluation: his or her work area or job title, proposed respirator type and weight, length of time required to wear respirator, expected physical work load (light, moderate, or heavy), potential temperature and humidity extremes, and any additional protective clothing required.

- Any employee required for medical reasons to wear a positive pressure air-purifying respirator will be provided with a powered air-purifying respirator.
- After an employee has received clearance and begun to wear his or her respirator, additional medical evaluations will be provided under the following circumstances:
  - Employee reports signs and/or symptoms related to their ability to use a respirator, such as shortness of breath, dizziness, chest pains, or wheezing.
  - The medical clinic PLHCP or supervisor informs the Program Administrator that the employee needs to be reevaluated.
  - Information from this program, including observations made during fit testing and program evaluation, indicates a need for reevaluation.
  - A change occurs in workplace conditions that may result in an increased physiological burden on the employee.

All examinations and questionnaires are to remain confidential between the employee and the PLHCP.

FIT TESTING

Fit testing is required for employees who are required to wear any tight-fitting respirator and shall be conducted:

- Prior to the employee being allowed to use that type of respirator.
- Annually.
- When there are changes in the employee's physical condition that could affect respiratory fit (i.e., obvious change in body weight, facial scarring, etc.).

Employees will be fit tested with the make, model, and size of respirator that they will actually wear. Employees will be provided with several models and sizes of respirators so that they may find an optimal fit. Fit testing of PAPRs is to be conducted in the negative pressure mode.

The Program Administrator will conduct qualitative (pass or fail) fit testing using the following the approved protocol **(INSERT FIT TESTING METHOD HERE (**i.e., **Bitrex Solution Aerosol QLFT)).** Approved fit-testing protocols can be found in **Appendix A** of the Standard. The Program Administrator will evaluate on a case-by-case basis whether quantitative fit testing (QNFT) is required.

USE, MAINTENANCE & STORAGE

Employees assigned to jobs requiring the use of respirators will be instructed by their supervisor relative to their responsibilities in the respiratory protection program. They will be instructed in the need, use, limitations, and care/maintenance of their respirator. If additional information/training is required contact the Program Administrator.

- Employees will use their respirators under conditions specified by this program, and in accordance with the training they receive on the use of each particular model. In addition, the respirator shall not be used in a manner for which it is not certified by NIOSH or by its manufacturer.
- All employees shall conduct **"user seal checks"** (this is **NOT** the same as a "fit test") **each time** that they wear their respirator. Employees shall use either the positive or negative pressure check (depending on which test works best for them) specified in **Appendix B-1 of the Respiratory Protection Standard**.
- Employees are **not** permitted to wear tight-fitting respirators if they have any condition, such as facial scars, facial hair, or any condition that prevents them from achieving a good seal.

Employees are not permitted to wear headphones, jewelry, or other articles that may interfere with the face to face-piece seal.

Respirators must be properly maintained to retain their original effectiveness. The maintenance program will consist of daily inspection, any necessary repairs, cleaning and proper storage. The wearer of the respirator will inspect it daily prior to use. Supervisors will periodically spot check respirators for fit, usage, proper storage and the respirator's overall condition. The use of a defective respirator is not permitted and must be replaced or repaired.

The following checklist will be used when inspecting respirators:

- **Face-piece:** Examine for cracks, tears, holes, facemask distortion, cracked or loose lenses/face-shield. Head straps: Examine for breaks or tears and broken buckles/connectors.
- **Valves**: Examine for residue or dirt, cracks or tears in valve material.
- **Filters/Cartridges:** Examine for approval designation (i.e., proper cartridge for the hazard), gaskets, cracks or dents in housing.
- **Supplied Air Systems (SAR)**: Confirm breathing air quality is at least Grade D, examine the condition of the supply hoses, hose connections and the settings on the regulators, valves and alarms.

For any malfunction of an APR (i.e., such as chemical breakthrough, face-piece leakage, or improperly working valves), the respirator wearer will inform their supervisor that the respirator no longer functions as intended. The supervisor must ensure that the employee receives the needed parts to repair the respirator or is provided with a new respirator. Chemical breakthrough **is not acceptable** and cartridge type respirators **must be changed prior to breakthrough occurring**. Please review the Respirator Cartridge Change-out Schedule.

During cleaning and maintenance, respirators that do not pass inspection will be removed from service and will be discarded or repaired. Repairs must be done with parts designed for the specific respirator in accordance with the manufacturers' recommendations. Respirators (except filtering face-piece types) will be cleaned according to the manufacturer's instructions or at a minimum at described in Appendix B-2 of Part 451. Respiratory Protection.

The following procedure shall be used for cleaning and disinfecting all respirators:

- Disassemble respirator, removing any filters, canisters, or cartridges.
- Wash the face-piece and associated parts in mild detergent with warm water.
  (Do not use organic solvents. They will deteriorate the face-piece.)
- Rinse completely in clean warm water.
- Wipe the respirator with a disinfectant wipe to kill germs.
- Allow to air dry in a clean area or hand dry with a clean lint-free cloth.
- Reassemble the respirator and replace any defective parts.
- Place in a clean, dry plastic bag or other air tight container.

(NOTE: The Program Administrator will ensure an adequate supply of appropriate cleaning and disinfection materials at the cleaning station. If supplies are low, employees should contact their supervisor, who will inform the Program Administrator.)

Respirators must be stored in a location where they are protected from sunlight, dust, heat, cold, moisture and damaging chemicals. They shall be stored in a manner to prevent deformation of the face-piece and exhalation valve. APRs will be stored in re-sealable bags (i.e., a Ziploc gallon size bag). If the respirator is used by more than one employee, the respirator will be cleaned immediately after each use and properly stored for the next user.

RESPIRATOR CARTRIDGE CHANGE-OUT SCHEDULE

Employees wearing elastomeric face-piece (i.e., rubber or silicone) APRs with particulate filters shall change the cartridges on their respirators when they first begin to experience difficulty breathing (i.e., breathing resistance).
Employees wearing elastomeric face-piece (i.e., rubber or silicone) APRs **with chemical cartridges** shall change the filter cartridges **before** chemical break-through occurs. Break-through is the ability to detect/smell/sense the contaminant while the respirator is in place on the operator's face with an appropriate seal between the employee's face and the respirator's face-piece. Break-through occurs when the chemical cartridge is saturated with the contaminant. This condition allows the contaminant to pass through the cartridge along with the operator's inhaled breath to the inside of the respirator mask and eventually into the operators' lungs/body. The purpose of this change-out schedule is to remove the used chemical cartridges before break-through occurs while the operator is wearing the respirator. Employee exposure levels must be known prior to the development of a proper change-out schedule.

Exposure levels have been evaluated at the **(Describe operation)**.

The main chemical contaminant of concern is: **(Chemical name)**.

Exposure levels for this operation/facility were determined to be **(Customize and select from below):**

1. None Detected, Trace levels or < 20 ppm (i.e., parts per million).

If the concentrations of contaminants are none detected, trace levels or < 20 ppm then the respirator chemical cartridges must be changed weekly.

2. < 200 ppm.

If the concentrations of contaminants are < 200 ppm then the respirator chemical cartridges must be changed after every 8 hours of use.

3. At or in excess of the established limits. Exposure Level = _____.

If the concentrations of contaminants are near, at, or in excess of an established limit, then the chemical cartridges must be changed per the manufacturer's recommendations. These higher levels of contaminants in an operator's breathing zone will require more frequent chemical cartridge change-out to occur (i.e., less than eight hours, possibly as low as one hour maximum, dependent on contaminant, concentration, breathing rate and manufacturer of the cartridges used).

The chemical cartridge change-out requirements for the **(Describe operation(s) and then choose one from list below)** will be:

1. Cartridges changed every week (i.e., 40 hours of use).
2. Cartridges changed at the end of 8 hours.

3. Other (per manufacturers' calculations):_____

Other considerations for cartridge change-outs that can be utilized:

- If the chemical's boiling point is less than 65C (149F), regardless of low level exposures, the cartridges must be changed at shift end (after every eight hours). Chemicals with this characteristic can desorb from the charcoal overnight and cause exposure to employees donning the respirator the next day.
- If the chemical's boiling point is > 70C (158F) and the concentration is less than 200 ppm, you can expect a cartridge service life of eight hours at a normal work rate.
- Cartridge service life is inversely proportional to work rate. Heavy work efforts will speed up the service life of a chemical cartridge thus reducing its time of usage.
- Reducing concentration by a factor of ten will increase cartridge service life by a factor of five.
- Humidity above 85% will reduce cartridge service life by 50%.
- Some chemical cartridges may be available with an end-of-service life indicator on them.

Mixtures of chemicals currently cannot be utilized to determine a chemical cartridge's change-out schedule. It is recommended to utilize the most toxic component at the highest concentration for the change-out determination and provide additional protection (i.e., reduce the time in use). Use the supplying manufacturers recommended service life. Do not use another manufacturers' recommendation for a chemical cartridge's service life other than that provided by the specific manufacturer.

When chemicals with poor warning properties are present, employees should not utilize air-purifying respirators and an air supplying respirator is the respirator of choice.

TRAINING

The Program Administrator will provide training to respirator users and their supervisors on the contents of this Respiratory Protection Program. Employees will be trained prior to using a respirator in the workplace. Supervisors will also be trained prior to using a respirator in the workplace or prior to supervising employees that must wear respirators.

The training course will cover the following topics:

- The site-specific Company Respiratory Protection Program
- Part 451. MIOSHA's Respiratory Protection standard
- Workplace respiratory hazards encountered and their health effects
- Proper selection and use of respirators
- Limitations of respirators
- Respirator donning and user seal (fit) checks
- Fit testing
- Emergency use procedures
- Maintenance and storage
- Medical signs and symptoms limiting the effective use of respirators

Employees will be retrained annually or as needed (i.e., if they change departments and need to use a different respirator). Employees must demonstrate knowledge in that the training they received was effective (i.e., through hands-on exercises, written test). Respirator training will be documented by the Program Administrator.

PROGRAM EVALUATION

The Program Administrator will conduct periodic evaluations of the workplace to ensure that the provisions of this program are being implemented. The evaluations will include regular consultations with employees who use respirators and their supervisors, site inspections, air monitoring and a review of records

DOCUMENTATION & RECORDKEEPING

A written copy of this program and the MIOSHA standard is kept in the Program Administrator's office and is available to all employees who wish to review it. Also maintained are copies of training and fit test records. These records will be updated as new employees are trained, as existing employees receive refresher training, and as new fit tests are conducted.

The Program Administrator will also maintain a copy of the PLHCP written recommendation regarding each employee's ability to wear a respirator (medical evaluation) for all employees covered under the respirator program. The completed medical questionnaire and the PLHCP documented findings are confidential and will remain at the medical clinic.

RESPIRATOR FIT TESTING FORM

IMPORTANT NOTE: Fit testing will **NOT** be performed if there is any interference with the respirator's face-to-face-piece seal (i.e., beards/facial hair growth where face and respirator seal).

Company Name: _____

Employee Name: _____ **Employee Number: _____**

Job Title: _____ **Work Area: _____**

Test Date: _____ **Test Conductor: _____**

Test Location: _____ **Supervisor: _____**

Respirator Brand/Type/ Model Number: _____

Cartridge/Pre-Filter Type Used: _____

Respirator Size (circle one): S M L XL one-size

Frequency of use (i.e., hours/day, times/month): _____

Expected Physical Workload (circle one): Light Moderate Heavy

High Temperature & Humidity Extremes (circle one): Yes No

Additional Personal Protective Equipment Required: _____

Fit Testing Protocol (circle one below):

Qualitative (QLFT): BitrexTM, Isoamyl Acetate, Irritant Smoke, Saccharin Aerosol

Quantitative (QNFT): Portacount System Other:_____

NOTE: The fit testing methodology used should be described in the written respirator program.

Has a proper face fit been obtained (circle one): **Yes** **No**

If at any time you notice that the respirator is damaged, you can taste or smell contaminants, an irritation develops, breathing becomes difficult, or you experience dizziness or distress, please leave the unsafe atmosphere immediately and then remove the respirator. Consult your supervisor immediately. You may have a leak in your respirator, the cartridges may need replacement, or there may be some other problem.

Employee Signature:_____ Date: _____

Michigan Occupational Safety & Health Administration

Consultation Education & Training Division

530 W. Allegan Street, P.O. Box 30643

Lansing, Michigan 48909-8143

For further information or to request consultation, education and training services

call (517) 284-7720

or

visit our website at www.michigan.gov/miosha

www.michigan.gov/lara

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APPENDIX F: Medical Waste

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978
PART 138
MEDICAL WASTE

333.13801 Short title. Sec. 13801. This part shall be known and may be cited as the "medical waste regulatory act".

History: Add. 1990, Act 18, Eff. May 31, 1990.

Popular name: Act 368

333.13803 Meanings of words and phrases; general definitions and principles of construction.
Sec. 13803. (1) For purposes of this part, the words and phrases defined in sections 13805 and 13807 have the meanings ascribed to them in those sections.
In addition, article 1 contains general definitions and principles of construction applicable to all articles in this code.

History: Add. 1990, Act 21, Eff. June 4, 1990.

Popular name: Act 368

333.13805 Definitions; A to M.
Sec. 13805. (1) "Advisory council" means the interdepartmental medical waste advisory council created in section 13827.
(2) "Autoclave" means to sterilize using superheated steam under pressure.
(3) "Decontamination" means rendering medical waste safe for routine handling as solid waste.
(4) "Fund" means the medical waste emergency response fund created in section 13829.
(5) "Health facility or agency" means that term as defined in section 20106.
(6) "Household" means a single detached dwelling unit or a single unit of a multiple dwelling.
(7) "Infectious agent" means a pathogen that is sufficiently virulent so that if a susceptible host is exposed to the pathogen in an adequate concentration and through a portal of entry, the result could be transmission of disease to a human.
(8) "Medical waste" means any of the following that are not generated from a household, a farm operation or other agricultural business, a home for the aged, or a home health care agency:
(a) Cultures and stocks of infectious agents and associated biologicals, including laboratory waste, biological production wastes, discarded live and attenuated vaccines, culture dishes, and related devices.
(b) Liquid human and animal waste, including blood and blood products and body fluids, but not including urine or materials stained with blood or body fluids.
(c) Pathological waste.
(d) Sharps.
(e) Contaminated wastes from animals that have been exposed to agents infectious to humans, these being primarily research animals.

History: Add. 1990, Act 21, Eff. June 4, 1990.

Popular name: Act 368

333.13807 Definitions; P to T.
Sec. 13807. (1) "Pathogen" means a microorganism that produces disease.
(2) "Pathological waste" means human organs, tissues, body parts other than teeth, products of conception, and fluids removed by trauma or during surgery, autopsy, or other medical procedure, and not fixed in formaldehyde. Pathological waste does not include a fetus or fetal body parts.
(3) "Point of generation" means the point at which medical waste leaves the producing facility site.
(4) "Producing facility" means a facility that generates, stores, decontaminates, or incinerates medical waste.
(5) "Products of conception" means any tissues or fluids, placenta, umbilical cord, or other uterine contents resulting from a pregnancy. Products of conception do not include a fetus or fetal body parts.
(6) "Release" means any spilling, leaking, pumping, pouring, emitting, emptying, discharging,

injecting, escaping, leaching, dumping, or disposing of medical waste into the environment in violation of this part.

(7) "Response activity" means an activity necessary to protect the public health, safety, welfare, and the environment, and includes, but is not limited to, evaluation, cleanup, removal, containment, isolation, treatment, monitoring, maintenance, replacement of water supplies, and temporary relocation of people.

(8) "Sharps" means needles, syringes, scalpels, and intravenous tubing with needles attached.

(9) "Storage" means the containment of medical waste in a manner that does not constitute disposal of the medical waste.

(10) "Transport" means the movement of medical waste from the point of generation to any intermediate point and finally to the point of treatment or disposal. Transport does not include the movement of medical waste from a health facility or agency to another health facility or agency for the purposes of testing and research.

History: Add. 1990, Act 21, Eff. June 4, 1990;□Am. 2012, Act 499, Eff. Mar. 31, 2013.

Popular name: Act 368

333.13809 Producing facility not incinerating medical waste on site; containment of medical waste.

Sec. 13809. A producing facility that does not incinerate medical waste on site shall do all of the following to contain medical waste:

(a) Package, contain, and locate medical waste in a manner that protects and prevents the medical waste from release at the producing facility or at any time before ultimate disposal.

(b) Separate the categories of medical waste at the point of origin into appropriate containers that are labelled as required under subdivision (c).

(c) Label the containers required under subdivision (b) with a biohazard symbol or the words "medical waste" or "pathological waste" in letters not less than 1 inch high.

(d) Not compact or mix medical waste with other waste materials before decontamination, incineration, and disposal.

(e) If decontaminated medical waste is mixed with other solid waste, clearly label the container to indicate that it contains decontaminated medical waste.

(f) Store medical waste in such a manner that prevents putrefaction and also prevents infectious agents from coming in contact with the air or with individuals.

(g) If medical waste is stored outside of the producing facility, store the medical waste in a secured area or locked in a container that weighs more than 500 pounds and prevent access to the area or container by vermin or unauthorized individuals.

(h) Not store medical waste on the premises of the producing facility for more than 90 days.

History: Add. 1990, Act 21, Eff. June 4, 1990.

Popular name: Act 368

333.13810 Producing facility incinerating medical waste on site; containment of medical waste.

Sec. 13810. A producing facility that incinerates medical waste on site shall do all of the following to contain medical waste:

(a) Package, contain, and locate medical waste in a matter that protects and prevents the medical waste from release at the producing facility or at any time before ultimate disposal.

(b) Separate and dispose of sharps in the manner described in section 13811(d).

(c) Label the containers required under subdivision (a) with a biohazard symbol or the words "medical waste" or "pathological waste" in letters not less than 1 inch high.

(d) Not store medical waste on premises of the producing facility for more than 90 days.

History: Add. 1990, Act 21, Eff. June 4, 1990.

Compiler's note: In subdivision (a), the words "Package, contain, and locate medical waste in a matter" evidently should read "Package, contain, and locate medical waste in a manner."

Popular name: Act 368

333.13811 Storage, decontamination, and disposal of medical waste.

Sec. 13811. A producing facility shall store, decontaminate, and dispose of medical waste pursuant to

the following:

(a) Cultures and stocks of material contaminated with an infectious agent shall be stored in closed, puncture-resistant containers, decontaminated by autoclaving or incineration, and disposed of in a sanitary landfill.

(b) Blood and blood products and body fluids shall be disposed of by 1 or more of the following methods:

(i) Flushing down a sanitary sewer.

(ii) Decontaminating by autoclaving or incineration.

(iii) Solidifying.

(iv) If not in liquid form, transferring to a sanitary landfill.

(v) A process approved by the department.

(c) Pathological waste shall be disposed of by 1 or more of the following methods:

(i) Incineration or cremation.

(ii) Grinding and flushing into a sanitary sewer.

(iii) Burial in a cemetery, if transported in leak-proof containers of sufficient integrity to prevent rupture.

(iv) Grinding until rendered unrecognizable, stored in closed, puncture-resistant, properly labeled containers, and, if not in liquid form, disposed of in a sanitary landfill.

(v) A process approved by the department.

(d) Sharps shall be disposed of by 1 of the following methods:

(i) Placement in rigid, puncture-resistant containers that are appropriately labeled and transported to a sanitary landfill in a manner that retains the integrity of the container.

(ii) Incineration or decontamination and grinding that renders the objects unrecognizable. Ground sharps shall be placed in a sealed, rupture-resistant container and transported to a sanitary landfill.

(iii) A process approved by the department.

(e) Animal waste contaminated with organisms infectious to humans shall be disposed of by incineration or by burial in a sanitary landfill in properly labeled, double containers that are leak-proof and puncture-resistant and are tightly sealed to prevent escape of fluids or material. Contaminated animal organs disposed of separately shall be rendered unrecognizable.

History: Add. 1990, Act 21, Eff. June 4, 1990.

Popular name: Act 368

333.13813 Producing facility; registration; form; medical waste management plan required; registration fee; certificate of registration; investigation of complaint; inspection of facility; disposition of fees.

Sec. 13813. (1) Each producing facility shall register with the department on a form prescribed by the department. A producing facility shall have a written medical waste management plan that contains information required in section 13817 on file on the premises within 90 days after registration.

(2) A producing facility shall submit the following registration fee with the registration form:

(a) For a producing facility that is a private practice office with fewer than 4 licensees under article 15 who are physicians, dentists, podiatrists, certified nurse practitioners, certified nurse midwives, or veterinarians employed by, under contract to, or working at the producing facility, a registration fee of $50.00.

(b) For a producing facility that is a private practice office with 4 or more licensees under article 15 who are physicians, dentists, podiatrists, certified nurse practitioners, certified nurse midwives, or veterinarians employed by, under contract to, or working at the producing facility, a registration fee of $20.00 for each licensee, up to a maximum total registration fee of $80.00.

(3) Upon receipt of a complete registration form and registration fee under this section or section 13815, the department shall issue a certificate of registration to the producing facility. A certificate of registration issued under this section is valid for 3 years from its date of issuance. The department shall investigate each complaint received and may inspect a producing facility registered under this section pursuant to the receipt of a complaint.

(4) Registration fees collected pursuant to this section and section 13815 shall be forwarded to the state treasury and deposited pursuant to section 13829.

History: Add. 1990, Act 18, Eff. May 31, 1990.

Popular name: Act 368

333.13815 Registration fee.

Sec. 13815. A producing facility shall submit the following registration fee with the registration form required under section 13813:

(a) For a producing facility that is a health facility or agency other than a hospital described in subdivision

(b) And for a producing facility that is not a health facility or agency, a registration fee of $75.00.

For a producing facility that is a health facility or agency that is a hospital with 150 or more licensed beds or a clinical laboratory, a registration fee of $150.00.

History: Add. 1990, Act 21, Eff. June 4, 1990.

Popular name: Act 368

333.13817 Medical waste management plan; contents; compliance; update; availability.

Sec. 13817. (1) The medical waste management plan required in section 13813 shall contain information relating to the handling of all medical waste generated, stored, decontaminated, or incinerated at each producing facility or transported from the producing facility for handling by another facility for storage, decontamination, incineration, or for disposal in a sanitary landfill, cemetery, or other disposal site. A professional corporation may identify and prepare a common medical waste management plan for all producing facilities owned and operated by the corporation. The medical waste management plan shall describe each of the following, to the extent the information is applicable to the producing facility:

(a) The types of medical waste handled.

(b) The segregation, packaging, labeling, and collection procedures used.

(c) The use and methods of on-site or off-site storage.

(d) The use and methods of on-site or off-site decontamination.

(e) The use of on-site or off-site incineration.

(f) The corporate or other legally recognized business name of solid waste haulers who transport medical waste for the producing facility.

(g) The use of sanitary landfills, cemeteries, and other disposal sites.

(h) The measures to minimize exposure of the facility's employees to infectious agents throughout the process of handling and disposing of the medical waste, including, where applicable, the use of protocols, procedures and training, personal protective devices and clothing, physical containment or isolation devices or systems, and prevention or control of aerosols.

(i) The name of the individual responsible for the management of the medical waste.

(2) A medical waste management plan shall comply with the requirements of this act.

(3) A producing facility shall update a medical waste management plan each time there is a change in either of the following, within 30 days after the change occurs:

(a) A person or site named in the plan.

(b) The types of medical waste handled or the methods of handling medical waste at the facility.

(4) Upon request, a producing facility shall make its medical waste management plan available to the department pursuant to a routine or unannounced inspection or the investigation of a complaint.

(5) Upon receipt of 24 hours' advance notice, a producing facility shall make its medical waste management plan available to an employee of the producing facility for inspection on the premises or provide a copy of the medical waste management plan to the employee.

(6) A producing facility shall comply with its medical waste management plan.

History: Add. 1990, Act 18, Eff. May 31, 1990.

Popular name: Act 368

333.13819 Medical waste management plan; modification; warning.

Sec. 13819. (1) Upon review of a medical waste management plan under section 13817(4), the department may require a producing facility to modify the medical waste management plan at any time the department determines the plan is not adequate to protect the public health or is inconsistent with state or federal law. Upon determining that the plan is inadequate or inconsistent under this section, the department shall notify the producing facility in writing of its determination and the specific modifications necessary for compliance. The producing facility shall modify the plan within 10 days after receipt of the notice from the department.

(2) The department may issue a warning to a producing facility that fails to modify a plan within the 10-day period.

History: Add. 1990, Act 18, Eff. May 31, 1990.

Popular name: Act 368

333.13821 Manner of packaging medical waste.

Sec. 13821. A producing facility that transports medical waste off the premises of the producing facility shall package the medical waste in the following manner:

(a) Sharps that are not ground or incinerated as described in section 13811(d) shall be contained for disposal in individual leak-proof, rigid, puncture-resistant containers that are secured to preclude loss of the contents. In addition, a container used to store or transport a number of individual sharps containers shall be leak-proof. These containers shall be conspicuously labeled with the word “sharps”. Sharps that are contained pursuant to this subdivision may be disposed of as solid waste pursuant to part 115 (solid waste management) of the natural resources and environmental protection act, Act No. 451 of the Public Acts of 1994, being sections 324.11501 to 324.11549 of the Michigan Compiled Laws. However, sharps shall not be compacted or handled during transport in a manner that will result in breakage of a sharps container.

(b) Medical waste other than sharps shall be contained in bags other than body pouches or other containers that are impervious to moisture and have a strength sufficient to resist ripping, tearing, breaking, or bursting under normal conditions of usage or handling. The bags or containers shall be secured so as to prevent leakage during storage, handling, or transport.

History: Add. 1990, Act 18, Eff. May 31, 1990; Am. 1996, Act 67, Imd. Eff. Feb. 26, 1996.

Popular name: Act 368

333.13823 Investigation and confirmation of reported medical waste on land or water; report; protective measures; consultations; information on results of investigation.

Sec. 13823. (1) If suspected medical waste is discovered on any land or water in the state and reported to the department of natural resources, the department of public health, a local health department, the department of state police, or any other state or local governmental agency, the agency or department receiving the report shall promptly investigate to confirm the existence of medical waste. If the existence of medical waste is confirmed by a department or agency other than the department of natural resources, a report shall be transmitted immediately to the department of natural resources. The department of natural resources may if appropriate take measures to contain the medical waste, to close off the area, to remove the medical waste from the environment, and to do all things necessary to protect the public health, safety, and welfare and the environment. The department of natural resources may if appropriate conduct an investigation to determine the source of the medical waste.

(2) The department of natural resources may consult with the department of public health, the appropriate local health department, the department of state police, and the department of attorney general on the actions taken by the department of natural resources under this section.

(3) After the department of natural resources confirms the existence of medical waste under this section, the department of natural resources shall inform the legislature, the governor, the advisory council, and the public on the results of any investigation conducted within 30 days after the investigation is completed.

History: Add. 1990, Act 18, Eff. May 31, 1990.

Popular name: Act 368

333.13825 Investigation and confirmation of violation; report; corrective and protective measures; consultations; assistance; information on results of investigation.

Sec. 13825. (1) If there is a suspected violation of this part on the premises of a health facility or agency or on the premises of an incinerator owned and operated by a health facility or agency, the department of public health shall promptly conduct an investigation to confirm the violation. If the suspected violation is reported to the department of natural resources, a local health department, the department of state police, or any other state or local governmental agency, the report immediately shall be transmitted to the department of public health. If the investigation confirms the existence of a violation of this part, the department of public health may if appropriate take measures to correct the violation and to do all things necessary to protect the public health, safety, and welfare and the environment.

(2) The department of public health may consult with the department of natural resources, the appropriate local health department, the department of state police, and the department of attorney general on the actions taken by the department of public health under this section. If the suspected

violation of this part is at an incinerator owned and operated by a health facility or agency, the department of public health immediately shall notify the department of natural resources and request the assistance of the department of natural resources in conducting the investigation.

(3) If the department of public health confirms the existence of a violation under this section, the department of public health shall inform the legislature, the governor, the advisory council, and the public on the results of the investigation conducted within 30 days after the investigation is completed.

History: Add. 1990, Act 18, Eff. May 31, 1990.

Popular name: Act 368

333.13827 Interdepartmental medical waste advisory council; creation; appointment and qualifications of members; chairperson; duties of advisory council.

Sec. 13827. (1) The interdepartmental medical waste advisory council is created in the department. The council shall consist of the following members appointed as follows:

(a) One individual appointed by the director of public health representing the department.

(b) One individual appointed by the director of the department of natural resources representing the department of natural resources.

(c) One individual appointed by the director of the department of state police representing the department of state police.

(d) One individual appointed by the director of commerce representing the department of commerce, who has knowledge of tourism in the state.

(e) One individual appointed by the attorney general representing the department of the attorney general.

(2) The representative of the department shall serve as chairperson.

(3) The advisory council shall do all of the following:

(a) Collect data pertaining to medical waste reports and investigations under this part.

(b) Annually report to the governor, the standing committees in the senate and house of representatives with jurisdiction over public health matters, the department of public health, and the department of natural resources on all of the following:

(i) The number of medical waste reports received and investigations conducted under this part.

(ii) The implementation and effectiveness of this part.

(iii) Changes in the overall regulatory scheme pertaining to medical waste, including, but not limited to, the enactment of pertinent federal law.

(iv) Recommendations, if any, that the advisory council has for changes to this part or any other state statute or rule that pertains to medical waste.

(v) Coordinate reports and investigations under this part between the department of public health and the department of natural resources.

History: Add. 1990, Act 18, Eff. May 31, 1990.

Popular name: Act 368

333.13829 Medical waste emergency response fund; creation; deposits; investments; interest and earnings; no reversion to general fund; use of fund.

Sec. 13829. (1) The medical waste emergency response fund is created in the state treasury.

(2) The state treasurer shall deposit in the fund all money received pursuant to this act and all money received by the fund as otherwise provided by law.

(3) The state treasurer shall direct the investment of the fund. Interest and earnings of the fund shall be credited to the fund. Money in the fund at the close of the fiscal year shall remain in the fund and shall not revert to the general fund.

(4) Not more than 80% of the total amount in the fund shall be used by the department of public health for administrative expenses related to the implementation of this part, and the balance may be used by the department of natural resources for response activities necessitated by the release of medical waste into the environment.

History: Add. 1990, Act 18, Eff. May 31, 1990.

Popular name: Act 368

333.13830 Rules to prescribe training standards.

Sec. 13830. (1) The department shall promulgate rules to prescribe training standards for both medical and nonmedical personnel who handle medical waste in producing facilities.

(3) Each producing facility shall train its personnel who handle medical waste pursuant to the rules promulgated under subsection (1).

History: Add. 1990, Act 18, Eff. May 31, 1990.

Popular name: Act 368

Administrative rules: R 325.1541 et seq. of the Michigan Administrative Code.

333.13831 Violation; administrative fine; failure to register or have plan available for inspection; injunction.

Sec. 13831. (1) Except as provided in subsection (2), a person who violates this part or a rule promulgated under this part is subject to an administrative fine of not more than $2,500.00 for each violation and an additional fine of not more than $1,000.00 for each day during which the violation continues. For a first offense, the department of public health or the department of natural resources may postpone the levying of a fine under this subsection for not more than 45 days or until the violation is corrected, whichever occurs first.

(2) A person who fails to register with the department or have a medical waste management plan available for inspection in compliance with sections 13813 and 13817 is subject to an administrative fine of $500.00.

(3) A person who violates this act may be enjoined by a court of competent jurisdiction from continuing the violation.

History: Add. 1990, Act 18, Eff. May 31, 1990.

Popular name: Act 368

333.13832 Part subject to MCL 324.1401 to 324.1429.

Sec. 13832. This part is subject to part 14 of the natural resources and environmental protection act, 1994 PA 451, MCL 324.1401 to 324.1429.

History: Add. 2012, Act 556, Imd. Eff. Jan. 2, 2013.

MEDICAL WASTE MANAGEMENT PLAN

Note: This form is provided to assist the user in developing a medical waste management plan that complies with Sections 13813(1) and 13817 of the Medical Waste Regulatory Act (MWRA), Part 138 of the Public Health Code, 1978 PA 368, as amended. You are not required to use this form. You may generate your plan using any format desired as long as it complies with the requirements of the MWRA. You may also include attachments with additional information if needed.

Facility Name:

Address:

City: State: Zip Code:

E-Mail:

Owner(s):

Individual Responsible for Management of Medical Waste:

Types of Medical Waste Produced at this Facility: (Check all that apply)

☐ **Sharps (needles, syringes, scalpels, tubing with needle attached)**

☐ **Cultures and stocks (lab waste, biological production waste, live/attenuated vaccines, culture dishes, and related devices)**

☐ **Pathological Waste (human organs, tissues, body parts other than teeth, products of conception, or fluids removed during trauma or other surgical procedure, and not fixed in formaldehyde)**

☐ **Liquid human and animal waste, including blood and blood products and body fluids, but not including urine or materials stained with blood or body fluids**

☐ **Contaminated wastes from animals that have been exposed to agents infectious to humans, these being primarily research animals**

Indicate the segregation, packaging, labeling, and collection procedures used for each type of medical waste generated facility:

Sharps:

☐ **Not Applicable (sharps not generated at this facility)**

☐ **Sharps are placed into an appropriately labeled sharps container before being stored and/or removed by our medical waste disposal service, and are stored at the facility no longer than 90 days (the storage period begins when the use of the container is initiated)**

☐ **Placed in rigid, puncture-resistant containers that are appropriately labeled and transported to a sanitary landfill in a manner that retains the integrity of the container**

☐ **Other Approved Method (Specify)**

Blood and Body Fluids:

☐ **Not Applicable (blood and body fluids not generated at this facility)**

☐ **Flushed into a sanitary sewer system using appropriate personal protection equipment (PPE) and universal precautions**

- ☐ **Saturated and solidified blood items are placed into a red biohazard bag prior to removal by our medical waste disposal company**
- ☐ **Other Approved Method (Specify)**

Cultures and Stocks:

- ☐ **Not Applicable (cultures and stocks are not generated at this facility)**
- ☐ **Stored in closed, puncture resistant containers and removed by our medical waste disposal company for autoclaving or incineration prior to disposal in a sanitary landfill**

Pathological Waste:

- ☐ **Not Applicable (pathological waste not generated at this facility)**
- ☐ **Removed and incinerated by our medical waste disposal company or other company or cremated (mortuaries)**
- ☐ **Ground and flushed into a sanitary sewer using appropriate PPE and universal precautions to protect from splashing**
- ☐ **Burial in a cemetery (placed in leak-proof, rupture-proof container prior to burial)**
- ☐ **Ground until rendered unrecognizable, stored in closed, puncture-resistant, properly labeled containers, and, if not in liquid form, disposed of in a landfill**
- ☐ **Other Approved Method (Specify)**

Contaminated Animal Waste:

- ☐ **Not Applicable (contaminated animal waste not generated at this facility)**
- ☐ **Burial in a sanitary landfill in properly labeled, double containers that are leak-proof and puncture-resistant and are tightly sealed to prevent escape of fluids or material**
- ☐ **Placed into appropriately labeled containers and removed by our medical waste disposal company. The waste is incinerated prior to disposal in a sanitary landfill**

Use and methods of on-site or off-site storage (check all that apply)

- ☐ **Stored in appropriate containers (biohazard bin, box) in a designated storage area until removed by our medical waste disposal company**
- ☐ **Kept in a outdoor storage unit that complies with Section 13809(g) of the MWRA, and removed by our medical waste disposal company**
- ☐ **Other Approved Method (Specify)**

Use and methods of on-site or off-site decontamination (check all that apply)—check with your medical waste disposal company to obtain this information

- ☐ **Not Applicable – All medical waste generated at this facility is incinerated by our medical waste disposal company prior to disposal in a sanitary landfill**
- ☐ **Medical waste generated at this facility (sharps, blood, body fluids, and cultures and stocks only) is decontaminated on-site by autoclaving or other method specified below by a medical waste treatment facility prior to disposal in a sanitary landfill**

☐ **Medical waste generated at this facility (sharps, blood, body fluids, and cultures and stocks only) is decontaminated off-site by autoclaving prior to disposal in a sanitary landfill (medical waste treatment facility)**

☐ **Other Approved Method (Specify)**

Use of on-site or off-site incineration (check all that apply) – check with your medical waste disposal company to obtain this information

☐ **Not Applicable – None of the medical waste general at this facility in incinerated**

☐ **Pathological and/or contaminated animal waste (if applicable) is incinerated off-site by our medical waste disposal company or treatment facility prior to disposal in a sanitary landfill – other medical waste is treated by autoclaving or another approved technology**

☐ **All medical waste generated at this facility is incinerated off-site by our medical waste disposal company or treatment facility prior to disposal in a sanitary landfill**

☐ **All medical waste generated at this facility is incinerated on-site prior to disposal in a sanitary landfill (medical waste treatment facility)**

☐ **Other Approved Method (Specify)**

Corporate or other legally recognized business address and telephone number of our medical waste disposal company

Name:

Address:

City: State: Zip Code:

Phone Number:

Not Applicable (Explain)

Use of sanitary landfills, cemeteries, and other disposal sites

☐ **Not Applicable – We do not transport any of our medical waste directly to a sanitary landfill**

☐ **Decontaminated and/or appropriately packaged medical waste is transported to the following sanitary landfill:**

Facility Name:

Address:

City: State: Zip Code:

The measures to minimize exposure of the facility's employees to infectious agents throughout the process of handling and disposing of the medical waste (check all that apply)

☐ **Bloodborne Pathogens training is required for each employee with potential exposure initially upon hire, and refresher training is provided on an annual basis. These records are maintained at the facility.**

☐ **Training is provided upon hire regarding proper handling of medical waste, and is performed before the employee assumes duties that involve handling of medical waste as required by R 325.1547 of the MWRA. All employees receive refresher training when a change in the medical waste management plan directly affects the employee's**

duties. Records are maintained at the facility, which includes the employee's name, job classification, and dates of training as required. Training records are maintained for a minimum of 3 years.

☐ **Personal protection equipment available and universal precautions employed at the facility (specify)**

Note: A producing facility shall update this medical waste management plan (Plan) each time there is a change in either of the following within 30 days after the change occurs: 1) A person or site named in the plan, or 2) The types of medical waste handled or the methods of handling medical waste at the facility. Upon request, a producing facility shall make its plan available to the Department of Environmental Quality pursuant to an inspection of the facility. Upon receipt of 24 hours advance notice, a producing facility shall make its plan available to an employee of the facility for inspection on the premises or provide a copy of the plan to the employee.

APPENDIX G: CLIA Waiver Communication

CLIA WAIVER COMMUNICATION

STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

RICK SNYDER
GOVERNOR

NICK LYON
DIRECTOR

Date: November 30, 2016

To: EMS Agencies

From: Kathy Wahl, Director Division of EMS and Trauma

Subject: CLIA Certificate of Waiver for Blood Glucose Testing

As EMS agency administrators, if your service provides blood glucose readings, it is imperative that you understand what a CLIA Certificate of Waiver is. The Clinical Laboratory Improvement Amendments (CLIA) of 1988 law requires any facility performing examinations of human specimens, including blood glucose for diagnostic or treatment purposes to be certified by the Secretary of the U.S. Department of Health and Human Services. Waived tests are those tests that are determined by the CDC or the FDA to be simple tests with a low risk of error. However, the potential for error resulting in harm still exists if a procedure is not performed correctly according to manufacturers' instructions.

According to the Michigan Department of Licensing and Regulatory Affairs, "You must have a CLIA certificate even if you perform only one basic test. It does not matter if you charge for the test or not, you must have a CLIA certificate. **If you perform a test and do not have a CLIA certificate you will be in violation of federal law**." Please see http://www.michigan.gov/lara/0,4601,7-154-63294_63302-47093--,00.html for further clarification.

Therefore, effective immediately, when an EMS Regional Coordinator conducts an agency inspection, your agency will be expected to:

- Produce the CLIA Certificate of Waiver. If the agency is owned by a corporation such as a hospital or a service with multiple sites that holds the waiver, you will be expected to show a copy of the corporate waiver.
- Provide a policy/procedure that incorporates the manufacturer's instructions for use of the equipment, calibration (if the glucometer requires calibration), storage of reagents used for quality control checks if applicable, a log demonstrating that quality control checks have been completed if applicable.
- Proof of initial staff training on the glucometer and competency verification of staff utilizing the glucometer if the model has changed.

If you do not have a CLIA certificate at the time of the inspection, you must stop testing immediately since you will be in violation of federal law. You will need to obtain a CLIA certificate as soon as possible by visiting www.michigan.gov/clia. If after 30 days you have not obtained a CLIA certificate, you will be reported to the Michigan Department of Licensing and Regulatory Affairs-Laboratory Improvement Section for further investigation. If you have any questions, or need assistance, please feel free to contact me at wahlk@michigan.gov, or your assigned EMS Regional Coordinator.

1001 TERMINAL ROAD • LANSING, MICHIGAN 48906
www.michigan.gov/mdhhs • 517-335-8150