DEPARTMENT OF CONSUMER AND INDUSTRY SERVICES

DIRECTOR'S OFFICE

OCCUPATIONAL HEALTH STANDARDS--BLOODBORNE INFECTIOUS DISEASES

(By authority conferred on the director of the department of consumer and industry services 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, MCL 330.3101 and 445.2001)

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.

History: 1993 AACS; 2001 AACS.

R 325.70002 Definitions.

Rule 2. As used in these rules:

(a) "Act" means 1974 PA 154, MCL 408.1001 et seq.

(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 which has been soiled with blood or other potentially infectious materials or which 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 consumer and industry services.

(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 which may take place on the job,

which are neither reasonably nor routinely expected, and which the worker is not required to incur in the normal course of employment.

(o) "Exposure incident" means a specific eye, mouth, other mucous membrane, nonintact 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 a hot-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:

(i) 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 which are caked with dried blood or other potentially infectious material and which are capable of releasing these materials during handling.

(iv) Contaminated sharps.

(v) Pathological and microbiological waste that contains blood or 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

nonneedle sharp or a needle device which is used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, and which has a built-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.

History: 1993 AACS; 1996 AACS; 2001 AACS.

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 determine and document a rationale for an exposure determination.

(4) An employer shall maintain a list of all job classifications which are determined to be category A.

History: 1993 AACS.

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 of the applicable rules of these rules.

(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 R 325.3451 et seq.

(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.

History: 1993 AACS; 1996 AACS; 2001 AACS.

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.

History: 1993 AACS; 1996 AACS.

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.

History: 1993 AACS.

R 325.70007 Work practices.

Rule 7. (1) After implementing appropriate engineering controls, an employer shall further reduce the likelihood of exposure to blood and other potentially infectious material by developing and implementing work practices for each task.

(2) 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) An employee shall wash his or her hands immediately after removing gloves or other protective clothing, as soon as possible after hand contact with blood or other potentially infectious material, and upon leaving the work area. Hand-washing shall be completed using the appropriate facilities, such as utility or rest room sinks. Waterless antiseptic hand cleansers shall be provided on responding units to use when hand-washing facilities are not available. When hand-washing facilities are available, hands shall be washed with warm water and soap or antiseptic cleanser. When hand-washing facilities are not available, a waterless antiseptic hand cleanser shall be used. The manufacturer's recommendations for the product shall be followed. When antiseptic cleaners or towelettes are used, employees shall wash their hands with soap and water as soon as feasible.

(d) An employer shall ensure that employees wash their hands and any other skin with soap and water following contact of such body areas with blood or other potentially infectious material, or flush mucous membranes with water, immediately or as soon as feasible after contamination.

(e) 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.

(f) 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.

(g) 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.

(h) 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.

(i) Mouth pipetting or suctioning is prohibited.

History: 1993 AACS; 1996 AACS.

R 325.70008 Protective work clothing and equipment.

Rule 8. (1) Protective work clothing and equipment shall be provided and used as follows:

(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) Face shields or mask and eye protection.

(vii) Mouthpieces.
(viii) Resuscitation bags.
(ix) Pocket masks.
(x) Other ventilation devices.

Personal protective equipment will be considered as 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 will be 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) Where splashes can be reasonably anticipated, face shields or protective eyewear and masks shall be provided. If the conditions of exposure include the likelihood that clothing will become soaked with blood, protective outer garments, such as impervious gowns, shall be worn. Appropriate personal protective equipment shall be used in all of the following instances:

(i) In performing invasive procedures when the health care worker has cuts, scratches, or other breaks in his or her skin.

(ii) Where there is a high risk of skin or mucous membrane contamination with blood, for example, when performing invasive procedures on an uncooperative patient.

(iii) In phlebotomy when performing finger or heel sticks in infants and children.

(iv) When persons are receiving training in invasive procedures.

(d) 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.

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

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

(g) Gloves shall be worn by an employee 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 (h) of this subrule; and when handling items or surfaces that are soiled with blood or other potentially infectious material. Gloves shall be made of material that is appropriate for a particular task. Disposable (single-use) gloves, such as surgical or examination gloves, shall be replaced as 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. Gloves shall be changed between patient contacts. Utility gloves shall be discarded if they 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. Tear and puncture-resistant gloves shall be provided for procedures which involve a high risk of laceration, but which do not require a high degree of dexterity. See appendix A for supplemental information.

(h) 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.

(i) Masks and eye protection or chin-length face shields shall be worn 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. If there is a significant risk of eye protection breakage or unintended removal, protective eyewear that is suitable for the work to be performed, as required by General Industry Safety Standard Part 33, being R 408.13301 et seq. of the Michigan Administrative Code, and R 325.60001 et seq. of the Michigan Administrative Code, shall be worn.

(j) Gowns, lab coats, aprons, clinic jackets, or similar outer garments shall be worn 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 and characteristics will depend upon the task and degree of exposure anticipated.

(k) Surgical caps or hoods and shoe covers or boots shall be worn where appropriate if there is a reasonable anticipation of gross contamination, for example in autopsies and orthopedic surgery.

(l) To minimize the need for direct mouth-to-mouth resuscitation, pocket masks, resuscitation bags, or other ventilation devices shall be provided in strategic locations and to trained personnel where the need for resuscitation is likely.

History: 1993 AACS; 1996 AACS.

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 overtly 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 which is in compliance with the provisions of 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 which are intended for reuse and which 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 leakproof container during collection, handling, processing, storing, transporting, or shipping. If contamination of the outside of a primary container is likely, a second leakproof 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, it shall be placed within a leakproof, puncture-resistant secondary container. All containers shall be labeled or color-coded in accordance with the provisions of R 325.70014.

(g) Reusable items, including reusable sharps, that have been contaminated with blood or other potentially infectious material shall be washed and decontaminated before reprocessing. The order in which washing and decontamination shall be performed shall be chosen so as to minimize exposure to blood or other potentially infectious material. Reusable sharps shall not be stored or processed in a manner that requires reaching by hand into containers where sharps have been placed.

History: 1993 AACS; 1996 AACS.

R 325.70010 Regulated waste disposal.

Rule 10. (1) All regulated waste that is being disposed of shall be placed in closable, leakproof 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 leakproof 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, leakproof, 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 SS333.13801 to 333.13831 of the Michigan Compiled Laws, and known as the medical waste regulatory act.

History: 1993 AACS.

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 the provisions of 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 leakproof bags.

(4) An employer shall ensure that laundry workers wear protective gloves and other appropriate personal protective work clothing while handling contaminated laundry.

(5) An employer shall ensure that all contaminated laundry is cleaned and laundered in such a way that any bloodborne pathogens present are inactivated or destroyed.

(6) 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.

(7) 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 the provisions of R 325.70014.

History: 1993 AACS.

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, leakproof, 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 authorized 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).

History: 1993 AACS; 1996 AACS.

R 325.70013 Vaccinations and postexposure follow-up.

Rule 13. (1) An employer shall assure that all medical evaluations and procedures 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 postexposure 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 provisions of 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 postexposure prophylaxes.

(4) Within 10 working days of the time of initial assignment and after the employee has received training required by the provisions of 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) HBV antibody testing for employees who desire such testing before deciding whether or not to receive HBV vaccination. 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) Acknowledgement 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 for 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) Postexposure 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 which are relevant to the appropriate treatment of the employee, including vaccination status, and which are the employer's responsibility to maintain.

(e) A description of any personal protective equipment used or to be used.

(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) The health care professional's recommended limitations upon the employee's use of personal protective clothing or equipment.

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

(c) 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 which have resulted from exposure to blood or other potentially infectious material and which 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 the provisions of R 325.70015.

History: 1993 AACS; 1996 AACS.

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:

**** For sign see attached file labeled "Figures" ****

[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 (e) or (f) of this subrule.

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

**** For Sign see attached file labeled "Figures" ****

(c) Labels shall be fluorescent orange or orange-red or predominantly 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 which are labeled as to their contents and which 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 with the provisions of 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.

(3) All biologically hazardous conditions shall be identified in an identical manner.

History: 1993 AACS; 1996 AACS; 2001 AACS.

R 325.70015 Recordkeeping.

Rule 15. (1) An employer shall establish and maintain medical records for each category A employee in accordance with R 325.3451 et seq.

(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 the medical history and all results of physical examinations, medical testing, and follow-up procedures as they relate to either of the following:

(i) The employee's ability to wear protective clothing and equipment and receive vaccination.

(ii) Postexposure evaluation after an occupational exposure incident.

(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 R 325.3451 et seq.

(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 R 325.3451 et seq.

(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 R 325.3451 et seq.

(10) An employer shall comply with the requirements that involve the transfer of records set forth in R 325.3451 et seq.

(11) If an employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, then the employer shall notify the director, not less than 3 months before disposing of the records, and shall transmit the records to the director if required by the director to do so within the 3-month period.

(12) All of the following provisions apply to a sharps 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 sharps 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 under R 408.22101 et seq., being Part 11. Recording and Reporting of Occupational Injuries and Illnesses.
(c) A sharps injury log shall be maintained for the period required by R 408.22101 et seq., Part 11. Recording and Reporting of Occupational Injuries and Illnesses.

History: 1993 AACS; 1996 AACS; 2001 AACS.

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 a 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 postexposure 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 the provisions of 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) All employees in category A positions shall receive initial training and annual retraining.

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

(c) The training shall include opportunities for supervised practice with personal protective equipment and other equipment which is designed to reduce the likelihood for exposure and which will be used in the employee's work.

(d) The person or persons who conduct training shall be knowledgeable in all of the following areas:

(i) The information presented in the training session.

(ii) The employer's exposure control plan.

(iii) Conditions of the work environment that affect the implementation of the exposure control plan.

(e) An employer shall maintain written documentation of attendance at training.

(f) An employer may reduce the training specified in subrule (5) of this rule to allow for the previous training of an employee who has received the training from other employment or another academic source. In such cases, the previous training shall be evaluated and documented. At a minimum, an employer shall provide an employee with workplace-specific training that covers the exposure control plan and SOPs.

History: 1993 AACS; 1996 AACS.

R 325.70017 Appendices; effect.

Rule 17. Appendices A and B to these rules are informational and are not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations. Appendices A and B may be obtained from the Michigan Department of Consumer and Industry Services, Division of Occupational Health, Post Office Box 30649, Lansing, Michigan 48909.

History: 1993 AACS; 1996 AACS.

R 325.70018 Availability of rules; permission to reproduce.

Rule 18. (1) Copies of these rules are available to affected employers and employees from the Michigan Department of Consumer and Industry Services, Division of Occupational Health, Post Office Box 30649, Lansing, Michigan 48909.

(2) Permission to reproduce any of these documents in full is granted by the director.

History: 1993 AACS; 1996 AACS.