p.m.: 20131009-IR-410130346RFA)

410 IAC 1-3-28 Transporting off-site

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 28. (a) All persons and facilities subject to this rule who are transporting infectious waste off-site, whether effectively treated or not shall:

- (1) mark containers of infectious waste with a label that states the name, address, and telephone number of the generating facility and treatment facility, if applicable; and
- (2) provide a form that contains:
 - (A) the name, address, and telephone number of the generating facility and treatment facility, if applicable;
 - (B) a brief description of the waste and the method of effective treatment; and
 - (C) the signature of a responsible person.
- (b) The information required in subsection (a) may be enclosed between the secondary packaging and the outer packaging, when such packaging is used. The outer packaging must contain a biohazard symbol. (Indiana State Department of Health; 410 IAC 1-3-28; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1386; filed Sep 18, 1998, 11:38 a.m.: 22 IR 440; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-3-29 Penalties for violation

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16-10

Sec. 29. Penalties for violation of this rule are set forth in IC 16-41-16-10. (Indiana State Department of Health; 410 IAC 1-3-29; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1386; filed Sep 18, 1998, 11:38 a.m.: 22 IR 440; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

Rule 4. Universal Precautions

410 IAC 1-4-0.5 Applicability of definitions

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 0.5. The definitions in this rule apply throughout this rule. Additionally, the definitions of any other terms contained in the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030) are incorporated by reference. (Indiana State Department of Health; 410 IAC 1-4-0.5; filed Nov 22, 1993, 5:00 p.m.: 17 IR 753; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-1 "Blood" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 1. "Blood" means human blood, human blood components, and products made from human blood. (Indiana State Department of Health; 410 IAC 1-4-1; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 753; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-1.1 "Bloodborne pathogens" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 1.1. "Bloodborne pathogens" means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, HBV, HCV, and HIV. (*Indiana State Department of Health; 410 IAC 1-4-1.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 753; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Mar 28, 2006, 12:45 p.m.: 29 IR 2536; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)*

410 IAC 1-4-1.2 "Contaminated" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 1.2. "Contaminated" means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface. (*Indiana State Department of Health; 410 IAC 1-4-1.2; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA*)

410 IAC 1-4-1.3 "Contaminated laundry" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 1.3. "Contaminated laundry" means laundry which has been soiled with blood or other potentially infectious materials or laundry which may contain sharps. (Indiana State Department of Health; 410 IAC 1-4-1.3; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-1.4 "Covered individual" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11-4

Sec. 1.4. "Covered individual" means any individual covered by IC 16-41-11-4 whose professional, employment, training, or volunteer activities or duties include any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials. (*Indiana State Department of Health; 410 IAC 1-4-1.4; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)*

410 IAC 1-4-1.5 "Decontamination" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 1.5. "Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item which does not require sterilization 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. (*Indiana State Department of Health;* 410 IAC 1-4-1.5; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-2 "Department" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 2. "Department" means the Indiana state department of health. (Indiana State Department of Health; 410 IAC 1-4-2; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-2.1 "Employee" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11; IC 22-8-1.1-1

Sec. 2.1. "Employee" has the meaning set forth in IC 22-8-1.1-1. (*Indiana State Department of Health; 410 IAC 1-4-2.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA*)

410 IAC 1-4-3 "Employer" defined

Authority: IC 16-41-11-9

Affected: IC 16-41-11; IC 22-8-1.1-1

Sec. 3. "Employer" has the meaning set forth in IC 22-8-1.1-1. (*Indiana State Department of Health*; 410 IAC 1-4-3; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-3.1 "ERP" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 3.1. "ERP" means expert review panel, as defined in section 8.1 of this rule. (Indiana State Department of Health; 410 IAC 1-4-3.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-4 "Facility" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 4. "Facility" means a building or location where an individual can be reasonably anticipated in the course of performing his or her professional, employment, training, or volunteer activities or duties to have skin, eye, mucous membrane, or parenteral contact with potentially infectious materials. (*Indiana State Department of Health; 410 IAC 1-4-4; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)*

410 IAC 1-4-4.1 "HBeAg" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 4.1. "HBeAg" means the presence of hepatitis Be antigen in human blood as an indicator of high infectivity for hepatitis

B virus. (Indiana State Department of Health; 410 IAC 1-4-4.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-4.2 "HBsAg" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 4.2. "HBsAg" means the presence of hepatitis B surface antigens in human blood as an indicator of infectivity for hepatitis B virus. (Indiana State Department of Health; 410 IAC 1-4-4.2; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-4.3 "HBV" and "HCV" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 4.3. (a) "HBV" means hepatitis B virus.

(b) "HCV" means hepatitis C virus. (Indiana State Department of Health; 410 IAC 1-4-4.3; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Mar 28, 2006, 12:45 p.m.: 29 IR 2536; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-4.4 "Health care worker" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 4.4. "Health care worker" means any covered individual providing health care for or to a patient during the patient's care or treatment and whose professional, employment, volunteer, or student training duties or activities can be reasonably anticipated to result in skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials. (Indiana State Department of Health; 410 IAC 1-4-4.4; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-4.5 "HIV" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 4.5. "HIV" means human immunodeficiency virus. (Indiana State Department of Health; 410 IAC 1-4-4.5; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-4.6 "Other potentially infectious materials" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 4.6. "Other potentially infectious materials" means the following:

- (1) Human body fluids as follows:
 - (A) Semen.
 - (B) Vaginal secretions.

- (C) Cerebrospinal fluid.
- (D) Synovial fluid.
- (E) Pleural fluid.
- (F) Pericardial fluid.
- (G) Peritoneal fluid.
- (H) Amniotic fluid.
- (I) Saliva in dental procedures.
- (J) Any body fluid that is visibly contaminated with blood.
- (K) All body fluids where it is difficult or impossible to differentiate between body fluids.
- (2) Any unfixed tissue or organ, other than intact skin, from a human, living or dead.
- (3) HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

(Indiana State Department of Health; 410 IAC 1-4-4.6; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-4.7 "Parenteral" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 4.7. "Parenteral" means piercing the mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, or abrasions. (Indiana State Department of Health; 410 IAC 1-4-4.7; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-4.8 "Sterilize" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 4.8. "Sterilize" means the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores. (Indiana State Department of Health; 410 IAC 1-4-4.8; filed Nov 22, 1993, 5:00 p.m.: 17 IR 756; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-5 "Universal precautions" defined

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 5. "Universal precautions" means an approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. (Indiana State Department of Health; 410 IAC 1-4-5; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 756; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-6 Facility operator responsibilities

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 6. (a) An individual or entity that is a facility operator shall comply with the following:

- (1) Inform all health care workers and covered individuals whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of the facility, that it is strongly recommended by the department that all persons who have reason to believe they are at risk of HIV infection should know their HIV status.
- (2) Inform all health care workers that it is strongly recommended by the department that all those:
 - (A) who perform procedures during which there is a recognized risk of percutaneous injury to the health care worker, and, if such injury occurs, the health care worker's blood may contact the patient's body cavity, subcutaneous tissue, or mucous membranes; and
 - (B) who do not have serologic evidence of immunity to HBV from vaccination or from previous infection should know their HBsAg status and, if that is positive, should also know their HBeAg status.
- (3) Ensure that the training described in the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030) is provided to all covered individuals whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of the facility.
- (4) Ensure that a record is maintained, as required under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030) of an individual's participation in the training that is provided. The record shall be made available to the department for inspection upon request.
- (5) Ensure that each covered individual whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of the facility, is provided appropriate equipment and expendables needed to implement the precautions required under section 8 of this rule and under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030).
- (6) Require all health care workers whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of the facility to provide evidence of compliance with the continuing universal precautions education requirements contained in section 7.1 of this rule.
- (b) The operator of a facility, if providing services to patients or the public in which there is a risk of skin, eye, mucous membrane, or parenteral contact to human blood or other potentially infectious materials, shall display, or make available to the public, a description of compliance with the requirements contained in subsection (a)(6).
- (c) The operator of a facility, if providing services to patients or the public in which there is a risk of skin, eye, mucous membrane, or parenteral contact to human blood or other potentially infectious materials, shall display, or make available to the public, written materials prepared or approved by the department explaining universal precautions and patients' rights under this rule. These materials shall include information on how to report violations of universal precautions and shall include information regarding the department's duties to investigate. (Indiana State Department of Health; 410 IAC 1-4-6; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 756; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-7 Facility operator policies

Authority: IC 16-41-11-9 Affected: IC 16-41-11

- Sec. 7. A facility operator shall develop a written policy in compliance with this rule and the requirements of the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030), that:
 - (1) requires the use of universal precautions by a covered individual when performing those professional, employment, training, or volunteer activities or duties that include any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials;
 - (2) provides sanctions, including discipline and dismissal, if warranted, for failure to use universal precautions; and
 - (3) proscribes the facility operator, or any covered individual acting at or on behalf of the facility, from retaliating against any person, including any professional, employee, trainee, volunteer, or patient, for filing a complaint with the department in good faith under this rule.

(Indiana State Department of Health; 410 IAC 1-4-7; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 757; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-7.1 Covered individuals' minimum training and certification requirements

Authority: IC 16-41-11-9 Affected: IC 16-41-11

Sec. 7.1. All covered individuals shall comply with the following:

- (1) Covered individuals, including health care workers, whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of a facility, must complete the training programs which the facility is required to have employees attend under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030). Approved programs under this rule shall be as follows:
 - (A) A bloodborne pathogen training session provided by a facility or employer under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030).
 - (B) Unless the department makes a specific determination to the contrary, any continuing professional education program on current universal precautions techniques that has been accepted or accredited by the applicable professional credentialing or health licensing entity.
- (2) Covered individuals who are health care workers shall, either individually or through their employer, upon receipt of a written request by the department, employer, or a patient to whom direct services have been provided, provide evidence of compliance with the requirements of this section.

(Indiana State Department of Health; 410 IAC 1-4-7.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 757; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-8 Precautions generally

Authority: IC 16-41-11-9 Affected: IC 16-19; IC 16-41-11

- Sec. 8. (a) All covered individuals and health care workers under this rule shall comply with the requirements imposed under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030).
- (b) The following documents shall be incorporated by reference as guidelines for covered individuals and health care workers under this rule:
 - (1) Centers for Disease Control and Prevention, Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51(No. RR-16).
 - (2) World Health Organization. WHO Guidelines on Hand Hygiene in Health Care. WHO Press: Geneva, Switzerland, 2009.
 - (c) All incorporated material is available for public review at the department.
- (d) The operator and all covered individuals whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of a facility providing services to patients or other members of the public in which there is a reasonably anticipated risk of skin, eye, mucous membrane, or parenteral contact with human blood or other potentially infectious materials shall also comply with the following requirements:
 - (1) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.
 - (2) Heating procedures capable of sterilization must be used when heat stable, nondisposable equipment is sterilized. Monitoring of heat sterilization procedures shall include documentation of the following:
 - (A) Each sterilization cycle.
 - (B) Use of chemical indicators when sterilizing packaged nondisposable equipment.
 - (C) That biological indicators were used within seven (7) days prior to the current sterilization procedure.
 - (D) Routine equipment maintenance according to manufacturer recommendations.

Documents required under this subdivision must be made available to the department upon request.

- (3) Reusable equipment requiring sterilization that is destroyed or altered by heat must be sterilized by chemical means.
- (4) Environmental surfaces and equipment not requiring sterilization that have been contaminated by blood or other

potentially infectious materials shall be cleaned with an absorbent material prior to disinfection. Disinfectant solutions shall be a:

- (A) germicide registered with the Environmental Protection Agency (EPA) for use as a hospital disinfectant and labeled tuberculocidal or registered germicide with specific inactivation claims against HIV and HBV; or
- (B) sodium hypochlorite solution dated and not used after twenty-four (24) hours old as follows:
 - (i) A minimum of 1:100 dilution (one-quarter (1/4) cup of five and twenty-five hundredths percent (5.25%) common household bleach in one (1) gallon of water).
 - (ii) A 1:10 dilution (one (1) part five and twenty-five hundredths percent (5.25%) common household bleach in nine (9) parts water) shall be used when a blood, culture, or OPIM spill occurs in the laboratory setting.
- (5) Hand hygiene shall be performed when there is a risk of skin, eye, mucous membrane, or parenteral contact with human blood or OPIM.
- (6) Hands shall be washed with soap and water when visibly dirty or soiled with blood or OPIM and after using the toilet.
- (7) Hand hygiene shall be performed before and after touching a potential source, before a clean or aseptic procedure, after a risk of body fluid exposure, after contact with inanimate surfaces and objects in the immediate vicinity of a potential source, and after removing gloves.
- (8) The use of gloves shall not replace the need for hand hygiene.
- (9) Gloves shall be worn when contact with blood or OPIM, mucous membranes, or nonintact skin is anticipated.
- (10) Gloves shall be changed or removed during care if moving from a contaminated body site to another body site (including nonintact skin, mucous membrane, or medical device) within the same source or the environment.
- (11) Gloves shall be changed between contact with other individuals.
- (12) If a patient's diagnosis, laboratory analysis, or medical condition requires additional infection control measures or isolation, those specific measures apply in addition to the requirements of this rule and other requirements found at IC 16-19. (Indiana State Department of Health; 410 IAC 1-4-8; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 757; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Mar 28, 2006, 12:45 p.m.: 29 IR 2537; errata filed Aug 16, 2006, 2:30 p.m.: 20060830-IR-410050259ACA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; filed Nov 30,2007, 1:00 p.m.: 20071226-IR-410060426FRA; filed Dec 10, 2010, 10:29 a.m.: 20110105-IR-410090810FRA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-8.1 Expert review panel

Authority: IC 16-41-11-9 Affected: IC 16-41-11

- Sec. 8.1. (a) An HIV infected or HBV infected (and HBeAg positive) health care worker whose practices include digital palpation of a needle tip in a body cavity or the simultaneous presence of the health care worker's finger and needle or other sharp instrument in a poorly visualized or highly confined human anatomic site should either seek the advice of an ERP approved by the department or voluntarily cease these practices.
- (b) As used in this rule, "expert review panel" means a group of experts authorized under this rule to provide confidential consultation and advice to HIV and HBV (and HBeAg) infected health care workers as indicated to promote the highest achievable level of safe, professional care. To be deemed authorized, an ERP must be sponsored by an organization which has been approved by the department under subsection (c).
- (c) Before any public or private medical, surgical, dental, nursing, or other health care organization may sponsor an authorized ERP under this section, the potential sponsor must be approved by the department as having provided credible assurances that:
 - (1) the sponsor is capable of establishing specific ERP protocols and procedures that will accomplish the purposes of an ERP under this section; and
 - (2) it will comply with general protocols to be established and disseminated on request by the department.
 - (d) The ERP will consist of:
 - (1) an expert review entity consisting of:
 - (A) the HIV or HBV infected health care worker's treating physician, either directly or through medical and historical

treatment records:

- (B) an infectious disease specialist knowledgeable in the epidemiology of HIV and HBV infection;
- (C) a health care provider of the same profession as the infected health care provider with expertise in the procedures practiced; and
- (D) an infection control expert or epidemiologist; or
- (2) any other expert review entity expressly authorized by the department.
- (e) An ERP sponsored by an organization approved by the department under subsection (c) will be deemed an authorized ERP.
- (f) An ERP shall advise the health care worker whether and how to modify techniques or to cease performing certain procedures. In rendering this advice, the ERP shall consider the past history of the health care worker's technique, and the extent to which, in the context of other indicated procedures with a measurable and unavoidable significant risk to patients, an indicated invasive procedure in the hands of that health care worker does or does not expose patients to the significant risk of HIV or HBV transmission from the health care worker.
 - (g) The role of the ERP is strictly confidential and advisory to the health care worker.
- (h) All proceedings and communications of the ERP shall be confidential. All communications to an ERP shall be privileged communications. Neither the personnel nor any participant in a panel proceeding shall reveal the identity of any health care worker consulting such panel nor any content of communication to the records of or the outcomes of an ERP outside the panel to any person or other entity, other than the health care worker consulting such panel.
- (i) No person who participates in an ERP proceeding shall be permitted or required to disclose any information acquired in connection with, or in the course of, the proceeding, any opinion, recommendation, or evaluation of the panel or of any panel member.
- (j) The only duty of an ERP is to provide good faith consultation and advice to the HIV or HBV infected health care worker seeking such advice. A health care worker is not, by this rule, relieved of any responsibility, either to himself or herself or to others, for all actions taken or not taken in his or her professional capacity after consulting with an ERP. Neither an ERP nor any member of an ERP is approved by this rule to substitute or assume responsibility for the subsequent actions of the health care worker. No civil or other legal action of any nature shall arise against any member or personnel of an ERP for any good faith act or statement made in the confines of the panel or proceeding thereof.
- (k) Neither an ERP nor any member of an ERP shall, by virtue of their consultation and advice, assume any liability of any kind to the health care worker, his or her patients, or any other person. The personnel and members of an ERP shall be immune from any civil action arising from any determination or recommendation made in good faith in the scope of their duties. (Indiana State Department of Health; 410 IAC 1-4-8.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 759; errata, 17 IR 1009; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 1-4-9 Complaints

Authority: IC 16-41-11-9 Affected: IC 16-41-11; IC 25

- Sec. 9. A person who believes that this rule has been violated may file a complaint with the department. A complaint must be in writing unless, in the opinion of the department, the violation complained of constitutes an emergency. The department shall reduce an emergency oral complaint to writing. The department shall maintain the confidentiality of the person who files the complaint. The department shall also comply with the following:
 - (1) The department shall promptly investigate, or cause to be investigated with available resources, all complaints received alleging violations of this rule.
 - (2) The department shall not disclose the name or identifying characteristics of the person who files a complaint under this rule:
 - (A) unless the person consents in writing to the disclosure; or
 - (B) the investigation results in an administrative or judicial proceeding and disclosure is ordered by the administrative law judge or the court.

Confidential communication of the complaint information to the Indiana department of labor for compliance purposes shall not constitute disclosure for the purposes of this rule.

- (3) The department shall give a person who files a complaint under this section the opportunity to withdraw the complaint at any time prior to the issuance of an order under subdivision (2)(B).
- (4) A person filing a complaint must make a reasonable attempt to ascertain the correctness of any information to be furnished. Failure to make a reasonable attempt may subject that person to other sanctions available at law.
- (5) A determination of a substantiated and unresolved violation of this rule by a health care provider licensed under IC 25 shall be referred by the department to the appropriate licensing board through notification of the attorney general's consumer protection division.
- (6) In the investigation of a complaint regarding a violation of this rule, the department shall coordinate the investigation, as appropriate, with the state or federal enforcement agency having jurisdiction over the industry or occupation. All complaints alleging violations of the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030) shall be forwarded to the Indiana department of labor.

(Indiana State Department of Health; 410 IAC 1-4-9; filed Oct 6, 1989, 4:20 p.m.: 13 IR 282; filed Nov 22, 1993, 5:00 p.m.: 17 IR 760; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

Rule 5. Sanitary Operation of Tattoo Parlors

410 IAC 1-5-1 Applicability

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 1. The definitions in this rule apply throughout this rule. (*Indiana State Department of Health; 410 IAC 1-5-1; filed May 12, 1998, 10:00 a.m.: 21 IR 3815; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA*)

410 IAC 1-5-2 "Blood" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 2. "Blood" means human blood. (Indiana State Department of Health; 410 IAC 1-5-2; filed May 12, 1998, 10:00 a.m.: 21 IR 3815; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-3 "Bloodborne pathogens" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

- Sec. 3. "Bloodborne pathogens" means pathogenic micro-organisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, the following:
 - (1) HBV.
 - (2) HCV.
 - (3) HIV.

(Indiana State Department of Health; 410 IAC 1-5-3; filed May 12, 1998, 10:00 a.m.: 21 IR 3815; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-3.5 "Body piercer" defined

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 3.5. "Body piercer" means any person who performs body piercing on an individual. (Indiana State Department of Health; 410 IAC 1-5-3.5; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2710; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-3.6 "Body piercing" defined

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 3.6. "Body piercing" means the perforation of any human body part other than ear lobe for the purpose of inserting jewelry or other decoration or for some other nonmedical purpose. (Indiana State Department of Health; 410 IAC 1-5-3.6; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2710; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-4 "Cleaned" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 4. "Cleaned" means removal of all visible dust, soil, or any other foreign material. (*Indiana State Department of Health:* 410 IAC 1-5-4; filed May 12, 1998, 10:00 a.m.: 21 IR 3815; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-5 "Contaminated" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 5. "Contaminated" means the presence or reasonably anticipated presence of blood or OPIM on an item or surface. (Indiana State Department of Health; 410 IAC 1-5-5; filed May 12, 1998, 10:00 a.m.: 21 IR 3815; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-6 "Decontaminated" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 6. "Decontaminated" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item which does not require sterilization 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. (*Indiana State Department of Health;* 410 IAC 1-5-6; filed May 12, 1998, 10:00 a.m.: 21 IR 3815; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-7 "Department" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 7. "Department" means the Indiana state department of health. (Indiana State Department of Health; 410 IAC 1-5-7; filed May 12, 1998, 10:00 a.m.: 21 IR 3815; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010,

12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-7.5 "Facility" defined

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 7.5. "Facility" means a tattoo parlor or a body piercing facility, or both, which is any room or space where tattooing or body piercing, or both, is provided or where the business of tattooing or body piercing, or both, is conducted. (*Indiana State Department of Health; 410 IAC 1-5-7.5; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2710; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)*

410 IAC 1-5-8 "HBV" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 8. "HBV" means the hepatitis B virus. (Indiana State Department of Health; 410 IAC 1-5-8; filed May 12, 1998, 10:00 a.m.: 21 IR 3816; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-9 "HCV" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 9. "HCV" means the hepatitis C virus. (Indiana State Department of Health; 410 IAC 1-5-9; filed May 12, 1998, 10:00 a.m.: 21 IR 3816; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-9.5 "High level disinfection" defined

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 9.5. "High level disinfection" means a process that destroys all micro-organisms, with the exception of high numbers of bacterial spores. (Indiana State Department of Health; 410 IAC 1-5-9.5; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2710; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-10 "HIV" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 10. "HIV" means the human immunodeficiency virus. (Indiana State Department of Health; 410 IAC 1-5-10; filed May 12, 1998, 10:00 a.m.: 21 IR 3816; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-11 "Infectious waste" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 11. "Infectious waste" means waste that epidemiologic evidence indicates is capable of transmitting a dangerous communicable disease. Infectious waste includes, but is not limited to, the following:

- (1) Contaminated sharps or contaminated objects that could potentially become contaminated sharps.
- (2) Infectious biological cultures, infectious associated biologicals, and infectious agent stock.
- (3) Pathological waste.
- (4) Blood and blood products in liquid and semiliquid form.
- (5) Carcasses, body parts, blood and body fluids in liquid and semiliquid form, and bedding of laboratory animals.
- (6) Other waste that has been intermingled with infectious waste.

(Indiana State Department of Health; 410 IAC 1-5-11; filed May 12, 1998, 10:00 a.m.: 21 IR 3816; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-11.2 "Intermediate level disinfection" defined

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 11.2. "Intermediate level disinfection" means a process that inactivates:

- (1) Mycobacterium tuberculosis;
- (2) vegetative bacteria;
- (3) most viruses; and
- (4) most fungi;

but does not necessarily kill bacterial spores. (Indiana State Department of Health; 410 IAC 1-5-11.2; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2710; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-11.5 "Operator" defined

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 11.5. "Operator" means any person who controls, operates, manages, or owns any facility. (*Indiana State Department of Health; 410 IAC 1-5-11.5; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2711; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)*

410 IAC 1-5-12 "Other potentially infectious materials" or "OPIM" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 12. "Other potentially infectious materials" or "OPIM" means the following:

- (1) Human body fluids as follows:
 - (A) Semen.
 - (B) Vaginal secretions.
 - (C) Cerebrospinal fluid.
 - (D) Synovial fluid.
 - (E) Pleural fluid.
 - (F) Pericardial fluid.
 - (G) Peritoneal fluid.
 - (H) Amniotic fluid.
 - (I) Saliva in dental procedures.
 - (J) Any body fluid that is visibly contaminated with blood.
 - (K) All body fluids where it is difficult or impossible to differentiate between body fluids.
- (2) Any unfixed tissue or organ, other than intact skin, from a human, living or dead.
- (3) HIV-containing cell or tissue cultures, and HIV or HBV-containing culture medium or other solutions, and blood, organs,

or other tissues from experimental animals infected with HIV or HBV.

(Indiana State Department of Health; 410 IAC 1-5-12; filed May 12, 1998, 10:00 a.m.: 21 IR 3816; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-13 "Parenteral" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 13. "Parenteral" means piercing the mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, or abrasions. (Indiana State Department of Health; 410 IAC 1-5-13; filed May 12, 1998, 10:00 a.m.: 21 IR 3816; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-14 "Personal protective equipment" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 14. "Personal protective equipment" means specialized clothing or equipment worn for protection against contact with blood or OPIM. (Indiana State Department of Health; 410 IAC 1-5-14; filed May 12, 1998, 10:00 a.m.: 21 IR 3816; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-15 "Secure area" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 15. "Secure area" means an area that is designated and maintained to prevent the entry of unauthorized persons. (Indiana State Department of Health; 410 IAC 1-5-15; filed May 12, 1998, 10:00 a.m.: 21 IR 3816; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-16 "Semiliquid blood, blood products" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 16. "Semiliquid blood, blood products" means blood, blood products that have intermediate fluid properties and are capable of flowing in a manner similar to liquid. (*Indiana State Department of Health; 410 IAC 1-5-16; filed May 12, 1998, 10:00 a.m.: 21 IR 3816; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA*)

410 IAC 1-5-17 "Sterilize" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 17. "Sterilize" means the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores. (Indiana State Department of Health; 410 IAC 1-5-17; filed May 12, 1998, 10:00 a.m.: 21 IR 3817; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-18 "Store" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 18. "Store" means the containment of infectious waste in such a manner as not to constitute collection, treatment, transport, or disposal. (Indiana State Department of Health; 410 IAC 1-5-18; filed May 12, 1998, 10:00 a.m.: 21 IR 3817; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-19 "Tattoo" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 19. "Tattoo" means:

(1) any indelible design, letter, scroll, figure, symbol, or other mark placed with the aid of needles or other instruments; or

(2) any design, letter, scroll, figure, or symbol done by scarring;

upon or under the skin. (*Indiana State Department of Health; 410 IAC 1-5-19; filed May 12, 1998, 10:00 a.m.: 21 IR 3817; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA*)

410 IAC 1-5-20 "Tattoo artist" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 20. "Tattoo artist" means any person who provides a tattoo to an individual. (*Indiana State Department of Health; 410 IAC 1-5-20; filed May 12, 1998, 10:00 a.m.: 21 IR 3817; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)*

410 IAC 1-5-21 "Tattoo operator" defined (Repealed)

Sec. 21. (Repealed by Indiana State Department of Health; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2714)

410 IAC 1-5-22 "Tattoo parlor" defined (Repealed)

Sec. 22. (Repealed by Indiana State Department of Health; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2714)

410 IAC 1-5-23 "Universal precautions" defined

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 23. "Universal precautions" means an approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV, and other bloodborne pathogens. (*Indiana State Department of Health; 410 IAC 1-5-23; filed May 12, 1998, 10:00 a.m.: 21 IR 3817; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)*

410 IAC 1-5-24 Operator training responsibilities

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 24. An individual or entity that is an operator shall comply with the following training responsibilities:

- (1) Ensure that the training described in the Indiana occupational safety and health administration's bloodborne pathogens standard (as found in 29 CFR 1910.1030) is provided to all tattoo artists and body piercers, anyone employed by the facility or anyone acting on behalf of the facility, who has a reasonably anticipated risk for skin, eye, mucous membrane, or parenteral contact with blood or OPIM.
- (2) Ensure that training on the handling of infectious waste is provided to all tattoo artists and body piercers, or anyone

employed by the facility or anyone acting on behalf of the facility who has a reasonably anticipated risk for skin, eye, mucous membrane, or parenteral contact with blood or OPIM.

- (3) Ensure that a record of training described in subdivision (1) is maintained, as required under the Indiana occupational safety and health administration's bloodborne pathogens standard (as found in 29 CFR 1910.1030) of an individual's participation in the training that is provided. The record shall be made available to the department for inspection upon request.
- (4) Ensure that a record of training described in subdivision (2) is maintained.

(Indiana State Department of Health; 410 IAC 1-5-24; filed May 12, 1998, 10:00 a.m.: 21 IR 3817; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2711; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-25 Operator responsibilities

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

- Sec. 25. (a) The operator shall ensure that tattoo artists, body piercers, or anyone employed by the facility or anyone acting on behalf of the facility who has a reasonably anticipated risk for skin, eye, mucous membrane, or parenteral contact with blood have and use personal protective equipment and expendables needed to implement the precautions required by this rule and the Indiana occupational safety and health administration's bloodborne pathogens standard (as found in 29 CFR 1910.1030).
- (b) The operator shall require tattoo artists and body piercers, anyone employed by the facility, or anyone acting on behalf of the facility who has a reasonably anticipated risk for skin, eye, mucous membrane, or parenteral contact with blood to provide evidence of compliance with the universal precautions education requirements contained in section 27 of this rule.
 - (c) The operator shall display a description of compliance with the requirements contained in subsection (d).
- (d) The operator shall display written materials prepared or approved by the department explaining universal precautions and patrons' rights under this rule. These materials shall include information on how to report violations of universal precautions and shall include information regarding the department's duties to investigate. (Indiana State Department of Health; 410 IAC 1-5-25; filed May 12, 1998, 10:00 a.m.: 21 IR 3817; errata filed Aug 31, 1998, 1:08 p.m.: 22 IR 127; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2711; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-26 Operator policies

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

- Sec. 26. The operator shall develop a written policy in compliance with this rule and the requirements of the Indiana occupational safety and health administration's bloodborne pathogen standard (as found in 29 CFR 1910.1030) that:
 - (1) requires the use of universal precautions when performing tattooing or body piercing and any activity or duty that includes any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or OPIM;
 - (2) requires disinfection or sterilization of contaminated reusable items;
 - (3) includes the safe handling of infectious waste; and
 - (4) provides sanctions, including discipline and dismissal, if warranted, for failure to use universal precautions or handle infectious waste safely, or both.

(Indiana State Department of Health; 410 IAC 1-5-26; filed May 12, 1998, 10:00 a.m.: 21 IR 3818; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2711; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-27 Tattoo artist and body piercer minimum training and certification requirements

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

- Sec. 27. (a) All tattoo artists, body piercers, anyone employed by the facility, and anyone acting on behalf of the facility, who has a reasonably anticipated risk for skin, eye, mucous membrane, or parenteral contact with blood or OPIM shall complete the training program that is required under the requirements of the Indiana occupational safety and health administration's bloodborne pathogen standard (as found in 29 CFR 1910.1030). The programs under this section shall be as follows:
 - (1) A bloodborne pathogen training session provided by the operator meeting the requirements under the Indiana occupational safety and health administration's bloodborne pathogens standard (as found in 29 CFR 1910.1030).
 - (2) Any bloodborne pathogen continuing education program provided by a health care agency.
- (b) All tattoo artists, body piercers, anyone employed by the facility, and anyone acting on behalf of the facility, who has a reasonably anticipated risk for skin, eye, mucous membrane, or parenteral contact with blood or OPIM must be trained in the facility's policies on the handling of infectious waste. (*Indiana State Department of Health; 410 IAC 1-5-27; filed May 12, 1998, 10:00 a.m.: 21 IR 3818; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2712; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)*

410 IAC 1-5-28 Patron records

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 28. Records of each patron shall be maintained by the operator for two (2) years. The record shall include the following, but not be limited to:

- (1) Patron's name.
- (2) Address.
- (3) Age.
- (4) Date tattooed or body pierced.
- (5) Design of the tattoo.
- (6) Location of the tattoo or body piercing on the patron's body.
- (7) The name of the tattoo artist or body piercer who performed the work.
- (8) Jewelry or other decoration used.

(Indiana State Department of Health; 410 IAC 1-5-28; filed May 12, 1998, 10:00 a.m.: 21 IR 3818; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2712; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-29 Illness

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 29. Tattoo artists or body piercers who are experiencing symptoms of acute disease that include, but are not limited to:

- (1) diarrhea;
- (2) vomiting;
- (3) fever;
- (4) rash;
- (5) productive cough;
- (6) jaundice; or
- (7) draining (or open) skin infections, boils, impetigo, or scabies;

shall refrain from providing tattoos or body piercing. (*Indiana State Department of Health; 410 IAC 1-5-29; filed May 12, 1998, 10:00 a.m.: 21 IR 3818; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2712; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA*)

410 IAC 1-5-30 Handwashing

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 30. (a) Handwashing facilities shall be readily accessible where tattooing or body piercing, or both, is provided.

- (b) Hands shall be washed with soap and running water immediately before putting on gloves and after removal of gloves or other personal protective equipment.
- (c) Only single-use towels shall be used. (Indiana State Department of Health; 410 IAC 1-5-30; filed May 12, 1998, 10:00 a.m.: 21 IR 3818; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2712; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-31 Personal protective equipment

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 31. Appropriate personal protective equipment shall be worn as follows:

- (1) A clean protective clothing layer shall be worn whenever there is a reasonably anticipated risk of contamination of clothing by blood or OPIM.
- (2) Masks in combination with eye protection devices, such as goggles or glasses with solid side shield, or chin length face shield, shall be worn whenever splashes, spray, splatter, or droplets of blood or OPIM may be generated and eye, nose, or mouth contamination can be reasonably anticipated.
- (3) Disposable gloves, such as surgical or examination type, shall be worn during the tattooing or body piercing process. Gloves shall be changed and properly disposed of each time there is an interruption in the application of the tattoo or body piercing, when the gloves become torn or punctured, or whenever the ability to function as a barrier is compromised. Disposable gloves shall not be reused.
- (4) Gloves shall be worn when decontaminating environmental surfaces and equipment.

(Indiana State Department of Health; 410 IAC 1-5-31; filed May 12, 1998, 10:00 a.m.: 21 IR 3818; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2712; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-32 Tattooing equipment

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 32. (a) Only single-use razors shall be used to shave the area to be tattooed.

- (b) All stencils shall be properly disposed of after a single use.
- (c) If the design is drawn directly onto the skin, it shall be applied with a single-use article only. (*Indiana State Department of Health; 410 IAC 1-5-32; filed May 12, 1998, 10:00 a.m.: 21 IR 3819; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)*

410 IAC 1-5-33 Needles

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 33. (a) Needles shall be individually packaged and sterilized prior to use.

- (b) Needles shall be single-use only.
- (c) Needles shall be discarded in sharps containers immediately after use.
- (d) Contaminated needles shall not be bent or broken or otherwise manipulated by hand. (Indiana State Department of Health; 410 IAC 1-5-33; filed May 12, 1998, 10:00 a.m.: 21 IR 3819; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140;

readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-34 Reusable equipment

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 34. (a) Heating procedures capable of sterilization must be used when heat stable, nondisposable equipment is sterilized.

- (b) Equipment that is to be sterilized shall be put in single-use packaging.
- (c) Records must be maintained to document the following:
- (1) Duration of sterilization technique.
- (2) Determination of effective sterility, such as use of a biological indicator, is performed monthly.
- (3) Equipment is maintained as recommended by the owner's manual, and proof is available that the owner's manual recommendations are reviewed monthly.
- (d) Reusable contaminated equipment shall not be stored or processed in a manner that requires any person to reach by hand into the containers where these sharp items have been placed.
 - (e) Reusable contaminated equipment shall be:
 - (1) placed in puncture-resistant containers;
 - (2) labeled with the biohazard symbol;
 - (3) leakproof on both sides and bottom; and
 - (4) stored in a manner that does not require reaching by hand into the container where the equipment is stored until cleaning prior to sterilization.
 - (f) Reusable contaminated equipment shall be effectively cleaned prior to sterilization or disinfection.
- (g) Any reusable contaminated equipment that comes into direct contact, or is likely to come into direct contact, with an instrument that penetrates the skin other than a piercing gun shall be effectively cleaned and sterilized prior to use.
 - (h) All sterilized equipment shall not be removed from wrappers or sterilizer packaging until immediately prior to use.
- (i) Any reusable equipment that comes into contact with mucus [sic., mucous] membranes shall be effectively cleaned and sterilized prior to use.
- (j) Piercing guns shall be cleaned and undergo, at a minimum, high level disinfection after each use and whenever visibly contaminated.
 - (k) All reusable equipment that has contact with intact skin shall undergo, at a minimum, intermediate level disinfection.
 - (1) All other equipment used during the tattooing or body piercing procedure shall be single use, including corks.
- (m) All body piercers and tattoo artists shall comply with all other equipment manufacturer's recommendations. (Indiana State Department of Health; 410 IAC 1-5-34; filed May 12, 1998, 10:00 a.m.: 21 IR 3819; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2713; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-35 Dyes or pigments or other objects placed under the skin

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

- Sec. 35. (a) All dyes or pigments used in tattooing shall be from professional suppliers specifically providing dyes or pigments for the tattooing of human skin.
- (b) In preparing dyes or pigments to be used by tattoo artists, only nontoxic, sterile materials shall be used. Single-use or individual portions of dyes or pigments in clean, single-use containers shall be used for each patron.
- (c) After tattooing, the remaining unused dye or pigment in single-use or individual containers shall be discarded along with the container.
- (d) Any object placed under the skin shall be sterile. (*Indiana State Department of Health; 410 IAC 1-5-35; filed May 12, 1998, 10:00 a.m.: 21 IR 3819; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2713; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)*

410 IAC 1-5-36 Work environment

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 36. (a) No tattooing or body piercing shall be conducted in any room used as living quarters or in any room that opens directly into living or sleeping quarters.

- (b) Live animals shall be excluded from areas where tattooing or body piercing is being conducted. This exclusion does not apply to the following:
 - (1) Patrol dogs accompanying security or police officers.
 - (2) Guide dogs accompanying the following:
 - (A) Blind persons.
 - (B) Partially blind persons.
 - (C) Physically disabled persons.
 - (D) Guide dog trainers.
 - (E) Persons with impaired hearing.
- (c) Eating, drinking, smoking, applying cosmetics, or handling contact lenses shall not be allowed in work areas where there is a likelihood of exposure to blood or OPIM.
 - (d) Food and drink shall not be kept in areas where there is a reasonably anticipated risk of exposure to blood or OPIM.
 - (e) All equipment and environmental surfaces shall be cleaned and disinfected after contact with blood or OPIM.
- (f) Environmental surfaces and equipment not requiring sterilization that have been contaminated by blood shall be cleaned and disinfected.
 - (g) All work surfaces shall be:
 - (1) nonabsorbent:
 - (2) easily cleanable;
 - (3) smooth; and
 - (4) free of:
 - (A) breaks:
 - (B) open seams;
 - (C) cracks;
 - (D) chips;
 - (E) pits; and
 - (F) similar imperfections.
 - (h) Disinfectant solutions shall be:
 - (1) a hospital grade, tuberculocidal Environmental Protection Agency (EPA) registered disinfectant; or
 - (2) sodium hypochlorite, five-tenths percent (0.5%) concentration, by volume (common household bleach in ten percent

(10%) concentration in water); the solution shall be dated and shall not be used if it is more than twenty-four (24) hours old. (Indiana State Department of Health; 410 IAC 1-5-36; filed May 12, 1998, 10:00 a.m.: 21 IR 3821; errata filed Aug 31, 1998, 1:08 p.m.: 22 IR 127; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2713; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-37 Infectious waste containment

Authority: IC 16-19-3-4.1 Affected: IC 16-19-3-4.1

Sec. 37. (a) Contaminated disposable needles or instruments shall be:

(1) stored in:

(A) leak-resistant; and

(B) puncture-resistant;

containers:

- (2) tightly sealed to prevent expulsion;
- (3) labeled with the biohazard symbol; and
- (4) effectively treated in accordance with this rule prior to being stored in an unsecured area and sent for final disposal.
- (b) Infectious wastes that are not contaminated sharps or objects that could potentially become contaminated sharps shall be placed in containers that meet the following requirements:
 - (1) Impervious to moisture.
 - (2) Sufficient strength and thickness to prevent expulsion.
 - (3) Secured to prevent leakage expulsion.
 - (4) Labeled with the biohazard symbol.
 - (5) Effectively treated in accordance with this rule prior to being placed in an unsecured area and sent for final disposal.
- (c) If infectious waste is stored prior to final disposal, all persons subject to this rule shall store infectious waste in a secure area that:
 - (1) is locked or otherwise secured to eliminate access by or exposure to the general public;
 - (2) affords protection from adverse environmental conditions and vermin; and
 - (3) has a prominently displayed biohazard symbol.
- (d) Infectious waste shall be stored in a manner that preserves the integrity of the container and is not conducive to rapid microbial growth and putrefaction.
- (e) Disinfect reusable containers for infectious waste each time that they are emptied unless the surfaces of the reusable containers have been protected from contamination by disposable liners, bags, or other devices that are removed with the infectious waste. (Indiana State Department of Health; 410 IAC 1-5-37; filed May 12, 1998, 10:00 a.m.: 21 IR 3820; errata filed Aug 31, 1998, 1:08 p.m.: 22 IR 127; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

410 IAC 1-5-38 Treatment and transport of infectious waste

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2

Affected: IC 16-19-3

Sec. 38. (a) All operators shall ensure that infectious waste is either treated on-site in accordance with this rule or transported off-site for treatment in accordance with this rule.

- (b) A treatment is effective if it reduces the pathogenic qualities of infectious waste for safe handling, is designed for the specific waste involved, and is carried out in a manner consistent with this rule. Effective treatment may include:
 - (1) incineration in an incinerator designed to accommodate infectious waste;
 - (2) steam sterilization:
 - (3) chemical disinfection under circumstances where safe handling of the waste is assured;
 - (4) thermal inactivation;
 - (5) irradiation; or
 - (6) discharge in a sanitary sewer or septic system that is properly installed and operating in accordance with state and local laws.
 - (c) All persons subject to this rule shall:
 - (1) transport infectious waste in a manner that reasonably protects waste haulers and the public from contracting a dangerous communicable disease; and
 - (2) effectively treat infectious waste in accordance with this rule before it is compacted.
- (d) The operator shall ensure that infectious waste, effectively treated or not is transported off-site in compliance with 410 IAC 1-3. (Indiana State Department of Health; 410 IAC 1-5-38; filed May 12, 1998, 10:00 a.m.: 21 IR 3821; errata filed Aug 31, 1998, 1:08 p.m.: 22 IR 127; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2714; readopted filed Jul 21, 2004, 5:00 p.m.: 27 IR 4140; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA)

Rule 6. Offering of Human Immunodeficiency Virus Information and Counseling and Human Immunodeficiency Virus Testing