**Section 450.50 Incorporated and Referenced Materials**

The following materials are incorporated or referenced in this Part:

a) The following State of Illinois Statutes are referenced in this Part:

1) Illinois Clinical Laboratory and Blood Bank Act [210 ILCS 25]

2) Illinois Dental Practice Act [225 ILCS 25]

3) Hospital Licensing Act [210 ILCS 85]

4) Medical Practice Act of 1987 [225 ILCS 60]

5) Podiatric Medical Practice Act of 1987 [225 ILCS 100]

6) Code of Civil Procedure, Article III (Administrative Review Law) [735 ILCS 5/Art. III]

7) Illinois Controlled Substances Act [720 ILCS 570]

b) The following State of Illinois Regulations are referenced in this Part:

1) Sewer Discharge Criteria (35 Ill. Adm. Code 307)

2) Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities (35 Ill. Adm. Code 724)

3) Solid Waste Disposal: General Provisions (35 Ill. Adm. Code 809)

c) The following federal guidelines, statutes, federal regulations, and other materials are incorporated by reference:

1) Federal Regulations and Statutes:

A) 42 CFR 493, Laboratory Requirements (CLIA regulations) (October 1, 2018)

B) 21 CFR 600-680, Biologics (April 1, 2018)

C) Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, Title II – Preventing Health Care Fraud and Abuse; Administrative Simplification; Medical Liability Reform, Section 264 – Recommendations with Respect to Privacy of Certain Health Information (August 21, 1996), Assistant Secretary for Planning and Evaluation, Room 415F, U.S. Department of Health and Human Services, 200 Independence Avenue, SW, Washington DC 20201

Also available online at: https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996

D) 42 USC 263a, Certification of Laboratories (January 12, 2018)

2) Federal Guidelines and Other Materials:

A) GP17-A3 Clinical Laboratory Safety; Approved Guideline – Third Edition, Clinical and Laboratory Standards Institute (CLSI) (June 2012), 950 West Valley Road, Suite 2500, Wayne PA 10987 Also available online at: https://clsi.org/media/1381/ gp17a3\_sample.pdf

B) Public Health Service Act, Subpart 2, Section 353 – Clinical Laboratories, Certification of Laboratories (1997), Public Health Law, CDC, 1600 Clifton Road, Atlanta GA 30329-4027

Also available online at: https://wwwn.cdc.gov/cliac/pdf/ Addenda/cliac0910/Addendum%20C\_Yost.pdf

C) Reference Volume for Human Cytogeneticists, Molecular Geneticists, Technicians, and Students for the Interpretation and Communication of Human Cytogenetic and Molecular Cytogenomic Nomenclature: ISCN 2016 − An International System for Human Cytogenetic Nomenclature (2016), S. Karger AG, Medical and Scientific Publishers, P.O. Box CH-4009 Basel, Switzerland

d) All incorporations by reference of federal regulations and the standards of nationally recognized organizations refer to the regulation and standards on the date specified and do not include any additions or deletions subsequent to the date specified.

(Source: Amended at 44 Ill. Reg. 20004, effective December 9, 2020)