**Section 450.40 Penalties and Fines**

a) The Department may deny, revoke, or refuse to renew a license or permit for the reasons set forth in Article VIII of the Act. All hearings and appeals shall be conducted in accordance with the procedures set forth in that Article and this Part. Any person holding 5% or more of the ownership in a clinical laboratory who was convicted of violation of Section 8-101(b), (c) or (g) of the Act, shall constitute grounds for denial or revocation of license or permit.

b) In addition to other actions authorized by the Act and this Part, the Department may assess penalties or fines against a licensee or permit holder for violation of any provision of the Act or rules. The Department shall review each inspection report according to criteria provided by this section to determine whether a fine will be assessed, the amount of such fine, and whether each day of violation shall constitute a separate violation for purposes of fine assessment.

1) The Department shall consider the following criteria independently and aggregately to determine whether a fine shall be assessed.

A) Whether the laboratory has previously been cited in the prior two year period for noncompliance in the same area of laboratory testing (e.g. chemistry, hematology, immunohematology, etc.) as currently cited for noncompliance with the Act or this Part.

B) Whether the laboratory has been cited for a violation of the Act or rules and does not correct the violation within the time frame agreed upon by the laboratory and Department in the plan to correct the violation.

C) Whether the laboratory fails to provide an acceptable plan to correct a violation of the Act or this Part.

D) Whether the violation appears to be the result of any failure to carry out duties and responsibilities set forth in this Part and the Act by the laboratory or the laboratory's agents or employees or by any other person responsible for the control or supervision of the laboratory.

E) Whether the laboratory demonstrated good faith efforts (e.g. taking steps to correct or agreeing to correct the cited violation) to correct the violation upon receipt of oral or written notice of the violation and whether such actions in fact corrected the violation.

2) Criteria to determine the amount of a fine are the following, and all amounts determined pursuant to the criteria shall be added together to determine the total fine.

A) For each repeat finding of noncompliance for the same area of laboratory testing, a fine of $100 per work day until the violations upon which noncompliance in that area of testing are based are corrected.

B) For non-correction of a violation within the time frame agreed upon by the laboratory and Department, a fine of $200 per work day for each day subsequent to the inspection which determined that violations were not corrected.

C) For the laboratory to fail to provide an acceptable plan to correct a violation of the Act or rules, a fine of $100 per work day starting on the tenth day after the laboratory received the notice of violation.

3) Each day a violation exists shall constitute a separate violation.

4) The Department shall serve any notice of assessment of fine on the laboratory in the same manner as any notice of license revocation provided pursuant to the Act and this Part (See Section 8-102 of the Act and Section 450.60 of this Part), and the laboratory shall have the same rights and opportunity for hearing as elsewhere provided pursuant to the Act and this Part.

5) All fine assessments which are upheld in whole or in part by final order of the Department shall be due in full at the conclusion of the time period for filing for administrative review pursuant to the Administrative Review Law (Ill. Rev. Stat. 1987, ch. 110, pars. 3-101 et seq.), unless the laboratory has within that time filed proceedings in administrative review specifically appealing the fine assessment and unless the court has stayed the enforcement of the fine assessment.

(Source: Added at 13 Ill. Reg. 11573, effective July 1, 1989)