years of experience in foodborne pathogen analyses or equivalent qualifications.

(2) Demonstrate the capability to achieve quality assurance levels that are within acceptable limits as determined by evaluation that is consistent with ISO 13528 for the analysis of initial accreditation proficiency testing samples, in the analyte category for which accreditation is sought. FSIS and some Association of Official Analytical Collaboration (AOAC) International analytical test procedures are acceptable for use in this program. FSIS procedures may be found on the U.S. Department of Agriculture (USDA) FSIS website at *www.fsis.usda.gov*. AOAC procedures may be found on the AOAC website at *www.aoac.org*.

(3) Complete a second set of proficiency testing samples if the results of the first set of proficiency testing samples are unsuccessful.

(i) The second set of proficiency testing samples will be provided within 30 days following the date of receipt by FSIS of a request from the applying laboratory. The second set of proficiency testing samples will be analyzed only for the analyte(s) or analyte classes for which unacceptable initial results had been obtained by the laboratory.

(ii) If the results of the second set of proficiency testing samples are unsuccessful, the laboratory may request a third set of proficiency testing samples after a 60-day waiting period, commencing from the date of notification by FSIS of unsuccessful results. The third set of proficiency testing samples will be analyzed only for the analyte(s) or analyte classes for which unacceptable initial results had been obtained by the laboratory.

(iii) If the laboratory is unsuccessful for the third set and still wishes to pursue accreditation, the ALP will require a new application and an application fee if the initial accreditation process is not completed within eleven months. Documentation of corrective action(s) related to the previous unsuccessful accreditation attempt must be submitted to and accepted by the ALP.

(4) Allow inspection of the laboratory facility and pertinent documents by FSIS officials prior to the determination of granting accredited status.

(5) Pay the accreditation fee by the date required.

§ 439.20 Criteria for maintaining accreditation.

(a) *Criteria*. To maintain accreditation, an analytical laboratory must fulfill the requirements of this section.

(b) *Records*. To demonstrate traceable and appropriate application of equipment, standards, procedures, analysts, and approvals related to accreditation, an accredited laboratory must:

(1) Maintain laboratory quality control records for the most recent three years that samples have been analyzed.

(2) Maintain complete records of the receipt, analysis, and disposition of samples for the most recent three years that samples have been analyzed.

(3) Maintain in a secure electronic format or in a standards book, all records, readings, and calculations for prepared standards. Entries are to be dated and the analyst identified at the time of the entry, and manual calculations verified and documented by the supervisor, or by the supervisor's designee, before use of the standard. The standards records are to be retained for three years after the last recorded entry. The certificates of analysis are to be kept on file for purchased standards for at least the period of time that the materials are in use.

(4) Maintain records of instrument maintenance and calibration. The records are to be retained for three years after the last recorded entry.

(5) As provided in paragraph (e) of this section, records are to be made available for review by any duly authorized representative of the Secretary of Agriculture, including ALP personnel or their designees.

(c) *Inter-laboratory accreditation maintenance proficiency testing sample*. (1) An accredited laboratory must analyze inter-laboratory accreditation maintenance proficiency testing samples and return the results to the ALP by the due date, which is usually within approximately three weeks of sample receipt. This must be done whenever requested by FSIS and at no cost to FSIS.

(2) Results must be those of the accredited laboratory. Analyses of proficiency testing samples must not be contracted out by the accredited laboratory.

(d) *Corporate changes.* The ALP must be informed within 30 days of any change of address or in the laboratory's ownership, officers, directors, supervisory personnel, or other responsibly connected individual or entity.

(e) *On-site review.* An accredited laboratory must permit any duly authorized representative of the Secretary to perform both announced and unannounced on-site laboratory reviews of facilities and records, both hard copy and electronic, during normal business hours, and to copy any records pertaining to the laboratory's participation in the ALP.

(f) *Analytical test procedures.* An accredited laboratory must use analytical test procedures designated by the FSIS ALP as being acceptable. FSIS and some AOAC analytical test procedures are acceptable.

(g) *Quality assurance levels.* An accredited laboratory must demonstrate the capability to maintain quality assurance levels that are within acceptable limits as evaluated by the ALP in the analysis of inter-laboratory accreditation maintenance proficiency testing samples for the analyte category for which accreditation was granted. An accredited laboratory will successfully demonstrate the maintenance of these capabilities if its results from inter-laboratory accreditation maintenance proficiency testing samples satisfy ALP evaluation criteria based on the ISO 13528 standard, to include performance evaluation by *z* score statistics.

(h) *Fees.* An accredited laboratory must pay the annual required accreditation fee when it is due.

(i) *Probation.* If placed on probation, an accredited laboratory must meet the ALP requirements as prescribed in this section in order to remove the probation status.

(1) The laboratory must successfully analyze a set of initial accreditation proficiency testing samples for the analyte(s) that triggered the probation and submit the analytical results to FSIS by the due date, which is typically within approximately three weeks of receipt of the samples.

(2) Similarly satisfy criteria for accreditation maintenance proficiency testing samples specified by the ALP in this part.

(3) Provide written corrective action documentation, related to the issue that triggered the probation, to the ALP by the date required.

(j) *Suspension.* If placed on suspension, an accredited laboratory must meet the ALP requirements as prescribed in this section in order to remove the suspension status. If the laboratory is unsuccessful in meeting the requirements to remove the suspension status, accreditation will be revoked.

(1) Laboratories that are suspended due to performance or response issues enter a waiting period of 60 days from the effective date of that action. After the 60-day period has passed, if the laboratory wishes to pursue reinstatement to the ALP, the laboratory must submit a written corrective action plan specifying what corrections were made and illustrate to FSIS that the corrections are effective or would reasonably be expected to be effective.

(i) After the corrective action plan has been accepted by the ALP, the laboratory must successfully analyze a set of initial accreditation proficiency testing samples for the analyte(s) that triggered the suspension and meet all other program requirements including payment of any annual fees that are due. The ALP may perform an on-site inspection at the laboratory's facility and/or require the laboratory to provide documentation to confirm that it meets the requirements of the program.

(ii) The suspended laboratory is allowed two attempts to successfully analyze the initial accreditation proficiency testing set(s) of samples.

(2) Laboratories that are suspended due to indictment or charges as described in § 439.52 may not seek removal of suspension status until being cleared of said indictment or charges.

§ 439.50 Refusal of accreditation.

Upon a determination by the FSIS Administrator (Administrator), a laboratory will be refused accreditation for the following reasons: