

§ 439.20

9 CFR Ch. III (1–1–10 Edition)

(3) *Individual large deviations*: One hundred times the average of the large deviation measures of the individual samples must be less than 5.0. A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5 and otherwise a measure equal to $1-(2.5/d)$.

(4) For residue analyses, the following additional quality assurance requirements must be met.

(i) *QA recovery*: The average of the QA recoveries of the individual check sample analytical results must lie within ranges established by FSIS.

(ii) *QC recovery*: All QC recoveries must lie within ranges established by FSIS. Supporting documentation must be made available to FSIS upon request.

(iii) *Correct identification*: There must be correct identification of all chemical residues in all samples.

§ 439.20 Criteria for maintaining accreditation.

(a) To maintain accreditation, an analytical laboratory must fulfill the requirements of paragraphs (b) through (i) of this section.

(b) *Official samples*. (1) An accredited laboratory must expeditiously report analytical results, in the analyte category for which accreditation was granted, of official samples on designated forms to the Data Center Staff, USDA/FSIS Eastern Laboratory, Russell Research Center, P.O. Box 6085, Athens, GA 30604 (for U.S. Postal Service delivery), or Data Center Staff, USDA/FSIS Eastern Laboratory, Russell Research Center, 950 College Station Road, Athens, GA 30605 (for commercial carrier delivery). When so provided for by FSIS, analytical results may be reported to the Data Center Staff by facsimile at (706) 546-3589, or electronically. The Federal inspector at any establishment may assign the analysis of official samples to an FSIS laboratory if, in the inspector's judgment, there are delays in receiving test results on official samples from an accredited laboratory.

(2) Every QC recovery associated with reporting of official samples must lie within ranges established by FSIS.

Supporting documentation must be made available to FSIS upon request.

(c) *Records*. An accredited laboratory must:

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

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

(3) Maintain in a secure electronic format or in a standards book, which is preferably a permanently bound book with sequentially numbered pages, all records, readings, and calculations for standard solutions. All entries are to be dated and signed by the analyst immediately upon completion of the entry, and by the supervisor, or in the absence of the supervisor by the supervisor's designee, before use of the standard solution but no later than within one week. The standards book is to be retained for three years after the last recorded entry.

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

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

(d) *Check samples*. (1) An accredited laboratory must analyze interlaboratory accreditation maintenance check samples and return the results to FSIS within 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 maintenance check samples shall not be contracted out by the accredited laboratory.

(3) As provided by the requirements in paragraph (h) of this section, a check sample report will be considered complete only if laboratories report all analytes present in the check sample for the analyte category in which accreditation was granted.

(e) *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.

(f) *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.

(g) *Analytical procedures.* An accredited laboratory must use analytical procedures designated by the FSIS ALP as being acceptable.

(h) *Quality assurance levels.* (1) An accredited laboratory must demonstrate an ability to maintain quality assurance levels that are within acceptable limits for systematic laboratory difference, variability, and individual large deviations in the analysis of interlaboratory check samples for the analyte category for which accreditation was granted. An accredited laboratory will successfully demonstrate the maintenance of these capabilities if its analytical results from interlaboratory accreditation maintenance check samples satisfy the criteria presented in this paragraph (h). All statistical computations are to be rounded to the nearest tenth, except where otherwise noted.

(2) In addition, a laboratory accredited for a specific chemical residue or a chemical residue class:

(i) Must satisfy criteria presented in this paragraph for chemical residue recoveries and proper identification;

(ii) Must demonstrate the maintenance of its capabilities by reporting its analytical results for each specific chemical residue found above the minimum proficiency level; and

(iii) Must, if accredited for the analysis of chlorinated hydrocarbons, obtain analytical results that collectively satisfy the criteria.

(3) *Systematic laboratory difference.* The standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance

check sample is used to determine two CUSUM values, designated as CUSUM-P and CUSUM-N.

(i) When determining compliance with this criterion for all chlorinated hydrocarbon results in a sample collectively, the following statistical procedure must be followed to account for the correlation of analytical results within a sample: The average of the standardized differences of the analytical results within the sample, divided by a constant, is used in place of a single standardized difference to determine the CUSUM-P (or CUSUM-N) value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

(ii) Positive systematic laboratory difference: This value is computed and evaluated as follows:

(A) Determine the CUSUM-P increment for the sample.

(1) The CUSUM-P increment for food chemistry, as defined in §439.1 of this part, is set equal to:

2.0, if the standardized difference is greater than 2.4,

-2.0, if the standardized difference is less than -1.6, or

the standardized difference minus 0.4, if the standardized difference lies between -1.6 and 2.4, inclusive.

(2) The CUSUM-P increment for chemical residues is set equal to:

2.0, if the standardized difference is greater than 2.5,

-2.0, if the standardized difference is less than -1.5, or

the standardized difference minus 0.5, if the standardized difference lies between -1.5 and 2.5, inclusive.

(B) Compute the new CUSUM-P value. The new CUSUM-P value is obtained by adding, algebraically, the CUSUM-P increment to the last previously computed CUSUM-P value. If this computation yields a value smaller than 0, the new CUSUM-P value is set equal to 0.

(C) Evaluate the new CUSUM-P value. The new CUSUM-P value must not exceed:

(1) 5.2 for food chemistry.

(2) 4.8 for chemical residues.

(iii) Negative systematic laboratory difference: This value is computed and evaluated as follows:

(A) Determine the CUSUM–N increment for the sample.

(1) The CUSUM–N increment for food chemistry is set equal to:

2.0, if the standardized difference is greater than 1.6,

–2.0, if the standardized difference is less than –2.4, or

the standardized difference plus 0.4, if the standardized difference lies between –2.4 and 1.6, inclusive.

(2) The CUSUM–N increment for chemical residues is set equal to:

2.0, if the standardized difference is greater than 1.5,

–2.0, if the standardized difference is less than –2.5, or

the standardized difference plus 0.5, if the standardized difference lies between –2.5 and 1.5, inclusive.

(B) Compute the new CUSUM–N value. The new CUSUM–N value is obtained by subtracting, algebraically, the CUSUM–N increment from the last previously computed CUSUM–N value. If this computation yields a value smaller than 0, the new CUSUM–N value is set equal to 0.

(C) Evaluate the new CUSUM–N value. The new CUSUM–N value must not exceed:

(1) 5.2 for food chemistry.

(2) 4.8 for chemical residues.

(4) *Variability*: The absolute value of the standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–V.

(i) When determining compliance with this criterion for all chlorinated hydrocarbon results in a sample collectively, the following statistical procedure must be followed to account for the correlation of analytical results within a sample: The square root of the sum of the within sample variance and the average standardized difference of the sample, divided by a constant, is used in place of the absolute value of the standardized difference to determine the CUSUM–V value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

(ii) The variability value is computed and designated as follows:

(A) Determine the CUSUM–V increment for the sample. The CUSUM increment is set equal to the larger of –0.4 or the absolute value of the standardized difference minus 0.9. If this computation yields a value larger than 1.6, the increment is set equal to 1.6.

(B) Compute the new CUSUM–V value. The new CUSUM–V value is obtained by adding, algebraically, the CUSUM–V increment to the last previously computed CUSUM–V value. If this computation yields a value less than 0, the new CUSUM–V value is set equal to 0.

(C) Evaluate the new CUSUM–V value. The new CUSUM–V value must not exceed 4.3.

(5) *Large deviations*: The large deviation measure of the accredited laboratory's result for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–D.

(i) A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5, and otherwise a measure equal to $1 - (2.5/d)$.

(ii) The large deviation value is computed and evaluated as follows:

(A) Determine the CUSUM–D increment for the sample. The CUSUM increment is set equal to the value of the large deviation measure minus 0.025.

(B) Compute the new CUSUM–D value. The new CUSUM–D value is obtained by adding, algebraically, the CUSUM–D increment to the last previously computed CUSUM–D value. If this computation yields a value less than 0, the new CUSUM–D value is set equal to 0.

(C) Evaluate the new CUSUM–D value. The new CUSUM–D value must not exceed 1.0.

(6) For chemical residues:

(i) Each QC recovery must lie within ranges established by FSIS.

Supporting documentation must be made available to FSIS upon request.

(ii) Not more than one residue misidentification may be made in any two consecutive check samples.

(iii) Not more than two residue misidentifications may be made in any eight consecutive check samples.

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

(j) *Probation.* An accredited laboratory must meet the following requirements if placed on probation pursuant to § 439.51 of this part:

(1) Send all official samples that have not been analyzed as of the date of written notification of probation to a specified FSIS laboratory by certified mail or private carrier or, as an alternative and as directed by FSIS, to a laboratory accredited by FSIS for the designated analyte(s). Mailing expenses will be paid by FSIS.

(2) Analyze a set of check samples similar to those used for initial accreditation, and submit the analytical results to FSIS within three weeks of receipt of the samples.

(3) Satisfy criteria for accreditation check samples specified in § 439.10 of this part.

§ 439.50 Refusal of accreditation.

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

(a) A laboratory will be refused accreditation for failure to meet the requirements of § 439.5 or § 439.10 of this part.

(b) A laboratory will be refused subsequent accreditation for failure to return to an FSIS laboratory, by certified mail or private carrier, or, as an alternative and as directed by FSIS, to a laboratory accredited by FSIS for the designated analytes, all official samples that have not been analyzed as of the notification of a loss of accreditation.

(c) A laboratory will be refused accreditation if the laboratory or any individual or entity responsibly connected with the laboratory has been convicted of, or is under indictment for, or has charges on an information brought against them in a Federal or State court concerning any of the following violations of law:

(1) Any felony.

(2) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(3) Any misdemeanor based upon a false statement to any governmental agency.

(4) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

§ 439.51 Probation of accreditation.

Upon a determination by the Administrator, a laboratory will be placed on probation for the following reasons:

(a) If the laboratory fails to complete more than one interlaboratory accreditation maintenance check sample analysis as required by § 439.20(d) of this part within 12 consecutive months, unless written permission is granted by the Administrator.

(b) If the laboratory fails to meet any of the criteria set forth in §§ 439.20(d) and 439.20(h) of this part.

§ 439.52 Suspension of accreditation.

The accreditation of a laboratory will be suspended if the laboratory or any individual or entity responsibly connected with the laboratory is indicted or has charges on information brought against them in a Federal or State court for any of the following violations of law:

(a) Any felony.

(b) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(c) Any misdemeanor based upon a false statement to any governmental agency.

(d) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

§ 439.53 Revocation of accreditation.

The accreditation of a laboratory will be revoked for the following reasons:

(a) An accredited laboratory that is accredited to perform analysis under §§ 439.5, 439.10 and 439.20 of this part will have its accreditation revoked for failure to meet any of the requirements of § 439.20 of this part, except for the following circumstances. If the accredited laboratory fails to meet any of the criteria set forth in §§ 439.20(d) and 439.20(h) of this part and it has not failed during the 12 months preceding