

TABLE 2 TO PARAGRAPH (aa)—STANDARDIZING VALUES FOR CHEMICAL RESIDUES

Class of residues	Standardizing value ³
Chlorinated Hydrocarbons: ¹	
Aldrin	0.20
Benzene Hexachloride	0.20
Chlordane	0.20
Dieldrin	0.20
DDT	0.20
DDE	0.20
TDE	0.20
Endrin	0.20
Heptachlor	0.20
Heptachlor Epoxide	0.20
Lindane	0.20
Methoxychlor	0.20
Toxaphene	0.20
Hexachlorobenzene	0.20
Mirex	0.20
Nonachlor	0.20
Polychlorinated Biphenyls:	
Arsenic ²	0.25
Sulfonamides ²	0.25
Volatile Nitrosamine ²	0.25

¹ Laboratory statistics are computed over all results (excluding PCB results), and for specific chemical residues.

² Laboratory statistics are only computed for specific chemical residues.

³ The standardizing value of all initial accreditation and probationary check samples computations is 0.15.

(bb) *Suspension of accreditation*—Action taken by FSIS against a laboratory that temporarily removes the laboratory’s right to analyze official samples. Suspension of accreditation ends when accreditation either is fully restored or is revoked.

(cc) *Systematic laboratory difference*—A comparison of one laboratory’s results with the comparison mean for samples that show, on average, a consistent relationship. A laboratory that is reporting, on average, numerically greater results than the comparison mean has a positive systematic laboratory difference. Conversely, numerically smaller results indicate a negative systematic laboratory difference.

(dd) *Variability*—Random fluctuations in a laboratory’s processes that cause its analytical results to deviate from a true value.

(ee) *Variance*—The expected average of the squared differences of sample results from an expected sample mean.

§ 439.5 Applications for accreditation.

(a) Application for accreditation shall be made on designated paper or electronic forms provided by FSIS, or otherwise in writing, by the owner or manager of a non-Federal analytical laboratory. The forms shall be sent to

the ALP or may be submitted electronically when so provided for by FSIS. The application shall specify the kinds of accreditation that are wanted by the owner or manager of the laboratory. A laboratory whose accreditation has been refused or revoked may re-apply for accreditation after 60 days from the effective date of that action, and must provide written documentation specifying what corrections were made.

(b) At the time that an Application for Accreditation is filed with the ALP, the management of a laboratory shall, for each accreditation sought, submit a check, bank draft, or money order in the amount specified in 9 CFR 391.5, made payable to the U.S. Department of Agriculture, along with the completed application for the accreditation(s). When so provided for by FSIS, electronic transfer of funds may be accepted.

(c) Accreditation will not be granted or continued, without further procedure, for failure to pay the accreditation fee(s). The fee(s) paid will be non-refundable and will be credited to the account from which the expenses of the laboratory accreditation program are paid.

(d) Annually on the anniversary date of each accreditation, FSIS will issue a bill in the amount specified in 9 CFR 391.5 for each accreditation held. Bills are payable upon receipt by check, bank draft, or money order made payable to the U.S. Department of Agriculture and become delinquent 30 days from the date of the bill.

(e) Accreditation will be terminated without further procedure for having a delinquent account. The fee(s) paid will be nonrefundable and will be credited to the account from which the expenses of the ALP are paid.

§ 439.10 Criteria for obtaining accreditation.

(a) Analytical laboratories may be accredited for the analyses of food chemistry analytes, as defined in § 439.1 of this part, or a specific chemical residue or a class of chemical residues in raw or processed meat and poultry products.

(b) Accreditation will be given only if the applying laboratory successfully

satisfies the requirements presented below. For food chemistry accreditation, the requirements must be satisfied for all four analytes.

(c) This accreditation authorizes official FSIS acceptance of the analytical test results provided by these laboratories on official samples.

(d) To obtain FSIS accreditation, an analytical laboratory must:

(1) Be supervised by a person holding, at a minimum, a bachelor's degree in chemistry, food science, food technology, or a related field.

(i) For food chemistry accreditation, the supervisor must also have one year's experience in food chemistry analysis, or equivalent qualifications, as determined by the Administrator.

(ii) For chemical residue accreditation, either the supervisor or the analyst assigned to analyze the sample must also have three years' experience determining analytes at or below part per million levels, or equivalent qualifications, as determined by the Administrator.

(2) Demonstrate an ability to achieve quality assurance levels that are within acceptable limits for systemic laboratory difference, variability, and individual large deviations, in the analyte category for which accreditation is sought, using analytical procedures designated by the FSIS ALP as being acceptable. An applying laboratory will successfully demonstrate these capabilities for:

(i) Food chemistry if its results from a 36 check sample accreditation study each satisfy the criteria presented in paragraph (e) of this section.

(ii) Chemical residues if its analytical results for each specific chemical residue provided in a check sample accreditation study containing a minimum of 14 check samples satisfy the criteria presented in paragraph (e) of this section, including criteria for QA and QC recovery and for residue identification. In addition, if the laboratory is requesting accreditation for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria. [Conformance to criteria in paragraph (e) of this section will only be determined when six or more analytical results with associated comparison

means at or above the logarithm of the minimum proficiency level are available.]

(3) Round all check sample statistical computations to the nearest tenth, except where otherwise noted.

(4) Complete a second set of the requisite number of check samples if the results of the first set of check samples do not meet the criteria for obtaining accreditation.

(i) The second set of check 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 food chemistry check samples will be analyzed for only the analyte(s) for which unacceptable initial results had been obtained by the laboratory.

(ii) If the results of the second set of check samples do not meet the criteria for obtaining accreditation, the laboratory may reapply after a 60-day waiting period, commencing from the date of refusal of accreditation by FSIS. At that time, a new application, all fees, and all documentation of corrective action required for accreditation must be submitted.

(5) Allow inspection of the laboratory by FSIS officials prior to the determination of granting accredited status.

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

(e) *Quality assurance levels*—(1) *Systematic laboratory difference*: The absolute value of the average standardized difference must not exceed the following:

(i) For food chemistry, 0.73 minus the product of 0.17 and the standard deviation of the standardized differences; and

(ii) For chemical residues, 1.67 (2.00 if there are less than 12 analytical results) minus the product of 0.29 and the standard deviation of the standardized differences.

(2) *Variability*: The estimated standard deviation of the standardized difference must not exceed the following:

(i) For food chemistry, 1.15; and

(ii) For chemical residues, a computed limit that is a function of the number of analytical results used in the computation of the standard deviation, and of the amount of variability.

§ 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.