

shall be provided to assure that the preparation of the article in no way interferes with the preparation or other handling of the poultry products. Where necessary, separate equipment shall be provided for the preparation of the article. To assure the maintenance of the requisite sanitary conditions in the edible products department, the operations incident to the preparation of the article shall be subject to the same sanitary requirements as apply to the handling of poultry products in the edible products department. Preparation of the article shall be limited to those hours during which the official establishment operates under the supervision of an inspector. The ingredients used in the preparation of the article shall, unless otherwise approved by the Administrator in specific cases, be such as may be used in the preparation of a poultry product. The article may be stored in, and distributed from, the edible products department if the article is properly identified.

(b) *Requirements applicable when prepared in an inedible products department.* When an article (including, but not being limited to, animal food) that is not for use as human food, is prepared in any part of an official establishment other than an edible products department (such part of the establishment being herein referred to as the "inedible products department"), the area in which such article is prepared shall be distinctly separated from all edible products departments. Poultry products and inedible products may be brought from any edible products department into any inedible products department, but no poultry product or inedible product may be brought from an inedible products department into an edible products department except that any such articles as are in sealed containers or are handled under conditions prescribed or approved by the Administrator in specific cases may be brought into an edible products department. Diseased carcasses or diseased parts of any carcass shall not be used in the preparation of any animal food unless they have been treated in the manner prescribed in § 381.95(a). Trucks or containers used for the transportation of poultry products or inedible products into an inedible products de-

partment shall be cleaned before being returned to or brought into an edible products department. Sufficient space shall be allotted and adequate equipment and facilities provided so that the preparation of the article does not interfere with the preparation of poultry products or the maintenance of the requisite sanitary conditions in the official establishment. The preparation of any such article shall be subject to supervision by an inspector.

(c) *Containers to be labeled.* The immediate container of any such article that is prepared in an official establishment shall be conspicuously labeled so as to distinguish it from human food. Such articles are also subject to the requirements under the Federal Food, Drug, and Cosmetic Act.

§ 381.153 Accreditation of chemistry laboratories.

(a) *Definitions:*

Accreditation—Determination by FSIS that a laboratory is qualified to analyze official samples of product subject to regulations in this subchapter and subchapter A of this chapter for the presence and amount of all four food chemistry analytes (protein, moisture, fat, and salt); or a determination by FSIS that a laboratory is qualified to analyze official samples of product subject to regulations in this subchapter and subchapter A of this chapter for the presence and amount of one of several classes of chemical residue, in accordance with the requirements of the Accredited Laboratory Program. Accreditations are granted separately for the food chemistry analysis of official samples and for the analysis of such samples for any one of the several classes of chemical residue. A laboratory may hold more than one accreditation.

Accredited laboratory—A non-Federal analytical laboratory that has met the requirements for accreditation specified in this section and hence, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of official samples is to be made by the establishment using the accredited laboratory.

AOAC methods—Methods of chemical analysis, Chapter 39, Association of Official Analytical Chemists published in the “Official Methods of Analysis of the Association of Official Analytical Chemists”, 15th edition 1990.¹ The “Official Methods of Analysis of the Association of Official Analytical Chemists,” 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

Chemical residue misidentification—see “Correct Chemical Residue Identification” definition.

Coefficient of variation (CV)—The standard deviation of a distribution of analytical values multiplied by 100, and divided by the mean of those values.

Comparison Mean—The average, for a sample, of all accredited and FSIS laboratories’ average results, each of which has a large deviation measure of zero, except when only two laboratories perform the analysis, as in the case of split sample analysis by both an accredited laboratory and an FSIS laboratory. In the latter case, the comparison mean is the average of the two laboratories’ results. For food chemistry, a result for a laboratory is the obtained analytical value; for chemical residues, a result is the logarithmic transformation of the obtained analytical value.

Correct chemical residue identification—Correct identification by a laboratory of a chemical residue whose concentration, in a sample, is equal to or greater than the minimum reporting level for that residue, as determined by the median of all positive analytical values obtained by laboratories analyzing the sample. Failure of a laboratory to report the presence of such a chemical residue is considered a misidentification. In addition, report-

ing the presence of a residue at a level equal to or above the minimum reporting level that is not reported by 90 percent or more of all other laboratories analyzing the sample, is considered a misidentification.

CUSUM—A class of statistical procedures for assessing whether or not a process is “in control”. Each CUSUM value is constructed by accumulating incremental values obtained from observed results of the process, and then determined to either exceed or fall within acceptable limits for that process. The initial CUSUM values for each laboratory whose application for accreditation is accepted are set at zero. The four CUSUM procedures are:

(1) Positive systematic laboratory difference CUSUM (COSUM-P)—monitors how consistently an accredited laboratory gets numerically greater results than the comparison mean;

(2) Negative systematic laboratory difference CUSUM (COSUM-N)—monitors how consistently an accredited laboratory gets numerically smaller results than the comparison mean;

(3) Variability CUSUM (COSUM-V)—monitors the average “total discrepancy” (i.e., the combination of the random fluctuations and systematic differences) between an accredited laboratory’s results and the comparison mean;

(4) Individual large discrepancy CUSUM (COSUM-D)—monitors the magnitude and frequency of large differences between the results of an accredited laboratory and the comparison mean.

Individual large deviation—An analytical result from a non-Federal laboratory that differs from the sample comparison mean by more than would be expected assuming normal laboratory variability.

Initial accreditation check sample—A sample prepared and sent by an FSIS laboratory to a non-Federal laboratory to ascertain if the non-Federal laboratory’s analytical capability meets the standards for granting accreditation.

Interlaboratory accreditation maintenance check sample—A sample prepared and sent by FSIS to a non-Federal laboratory to assist in determining if acceptable levels of analytical capability

¹A copy of the “Official Methods of Analysis of the Association of Analytical Chemists,” 15th edition, 1990, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists, 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201. 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

are being maintained by the accredited laboratory.

Large deviation measure—A measure that quantifies an unacceptably large difference between a non-Federal laboratory's analytical result and the sample comparison mean.

Minimum proficiency level—The minimum concentration of a residue at which an analytical result will be used to assess a laboratory's quantification capability. This concentration is an estimate of the smallest concentration for which the average coefficient of variation (CV) for reproducibility (i.e., combined within and between laboratory variability) does not exceed 20 percent. (See Table 2)

Minimum reporting level—The number such that if any obtained analytical value equals or exceeds this number, then the residue is reported together with the obtained analytical value.

Official Sample—A sample selected by an inspector or inspection service employee in accordance with FSIS procedures for regulatory use.

Probation—The period commencing with official notification to an accredited laboratory that its check or split sample results no longer satisfy the performance requirements specified in this rule, and ending with official notification that accreditation is either fully restored, suspended, or revoked.

QA (quality assurance) recovery—The ratio of a laboratory's unadjusted analytical value of a check sample residue to the residue level fortified by the FSIS laboratory that prepared the sample, multiplied by 100. (See Table 2.)

QC (quality control) recovery—The ratio of a laboratory's unadjusted analytical value of a quality control standard to the fortification level of the standard, multiplied by 100. (See Table 2.)

Refusal of Accreditation—An action taken when a laboratory which is applying for accreditation is denied the accreditation.

Responsibly connected. Any individual who or entity which is a partner, officer, director, manager, or owner of 10 per centum or more of the voting stock of the applicant or recipient of accreditation or an employee in a managerial or executive capacity or any employee

who conducts or supervises the chemical analysis of FSIS official samples.

Revocation of Accreditation—An action taken against a laboratory which removes its right to analyze official samples.

Split sample—An official sample divided into duplicate portions, one portion to be analyzed by an accredited laboratory (for official regulatory purposes) and the other portion by an FSIS laboratory (for comparison purposes).

Standardizing Constant—The number which is the result of a mathematical adjustment to the "standardized value." Specifically, the number equals the square root of the expected variance of the difference between the accredited or applying laboratory's result and the comparison mean on a sample, taking into consideration the standardizing value, the correlation and number of repeated results by a laboratory on a sample, and the number of laboratories that analyzed the sample.

Standardized Difference—The quotient of the difference between a laboratory's result on a sample and the comparison mean of the sample divided by the standardizing constant.

Standardizing Value—A number representing the performance standard deviation of an individual result (see Tables 1 and 2 and footnotes to the Tables for determining exact procedures for calculation).

Suspension of Accreditation—Action taken against a laboratory which temporarily removes its right to analyze official samples. Suspension of accreditation ends when accreditation is either fully restored or revoked.

Systematic laboratory difference—A comparison of one laboratory's results with the comparison means on samples that shows, 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 and, conversely, numerically smaller results indicate a negative systematic laboratory difference.

Variability—Random fluctuations in a laboratory's processes that cause its analytical results to deviate from a true value.

Variance—The expected average of the squared differences of sample results from an expected sample mean.

TABLE 1—STANDARDIZING VALUES FOR FOOD CHEMISTRY (By analyte)

Moisture	Protein ¹	Fat ²	Salt ³
0.57	0.060	0.26 (0.30)	0.127

¹ To obtain the standardizing value for a sample the appropriate entry in this column is multiplied by $X^{0.65}$ where X is the comparison mean of the sample.

² To obtain the standardizing value for a sample, the appropriate entry in this column is multiplied by $X^{0.25}$, where X is the comparison mean of the sample. The appropriate entry is equal to the value in parentheses when X is equal to or greater than 12.5 percent, otherwise it is equal to 0.26.

³ To obtain the standardizing value for a sample, when the comparison mean of the sample, X, is less than 1.0 percent, the standardizing value equals 0.127, otherwise the appropriate entry is multiplied by $X^{0.25}$. When X is equal to or greater than 4.0 percent for dry salami and pepperoni products, the standardizing value equals 0.22.

TABLE 2—MINIMUM PROFICIENCY LEVELS, PERCENT EXPECTED RECOVERIES (QC AND QA), AND STANDARDIZING VALUES FOR CHEMICAL RESIDUES

Class of residues	Minimum proficiency level	Percent expected recovery (QC and QA)	Standardizing value ³
Chlorinated Hydrocarbons:¹			
Aldrin	0.10 ppm	80–110	0.20
Benzene Hexachloride	0.10 ppm	80–110	0.20
Chlordane	0.30 ppm	80–110	0.20
Dieldrin	0.10 ppm	80–110	0.20
DDT	0.15 ppm	80–110	0.20
DDE	0.10 ppm	80–110	0.20
TDE	0.15 ppm	80–110	0.20
Endrin	0.10 ppm	80–110	0.20
Heptachlor	0.10 ppm	80–110	0.20
Heptachlor Epoxide	0.10 ppm	80–110	0.20
Lindane	0.10 ppm	80–110	0.20
Methoxychlor	0.50 ppm	80–110	0.20
Toxaphene	1.00 ppm	80–110	0.20
Hexachlorobenzene	0.10 ppm	80–110	0.20
Mirex	0.10 ppm	80–110	0.20
Nonachlor	0.15 ppm	80–110	0.20
Polychlorinated Biphenyls	0.50 ppm	80–110	0.20
Arsenic ²	0.20 ppm	90–105	0.25
Sulfonamides ²	0.08 ppm	70–120	0.25
Volatile Nitrosamine ²	5 ppb	70–110	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.

(b) *Laboratories accredited for analysis of protein, moisture, fat, and salt content of poultry and poultry products—(1) Applying for accreditation.* Application for accreditation shall be made on designated forms provided by FSIS, or otherwise in writing, by the owner or manager of a non-Federal analytical laboratory and sent to the Accredited Laboratory Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington DC, 20250-3700, and 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 reapply for accreditation after 60 days from the effective date of that action, and must

provide written documentation specifying what corrections were made.

(i) At the time that an Application for Accreditation is filed with the Accredited Laboratory Program, FSIS, and annually thereafter upon receipt of the bill issued by FSIS on the anniversary date of each accreditation, the management of a laboratory shall reimburse the program at the rate specified in 9 CFR 391.5 for the cost of each accreditation that is sought by the laboratory or that the laboratory holds.

(ii) Simultaneously with the initial application for accreditation, the management of a laboratory shall forward 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) sought for the laboratory. Accreditation will not be granted or continued, without further procedure, for failure to pay the accreditation fee(s). The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the laboratory accreditation program are paid.

(iii) Annually on the anniversary date of each accreditation, FSIS will issue a bill in the amount specified in 9 CFR 391.5.

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

(v) The accreditation of a laboratory that was accredited by FSIS on or before December 13, 1993 and was not on probation and whose accreditation on that date was not in suspension or revocation shall be continued, provided that such laboratory reapply for accreditation in accordance with the provisions of this paragraph (b)(1) by January 13, 1994 (30 days of the effective date of this section), and that the reapplication be accepted by the Agency. The CUSUM values for such laboratory will be reset at zero upon acceptance of its reapplication. The accreditation of a laboratory that is on probation shall be continued, provided that the laboratory reapply for accreditation by February 11, 1994 (60 days of the effective date of this section), that the reapplication be accepted by the Agency, and that the laboratory satisfy the terms of the probation.

(2) *Criteria for obtaining accreditation.* Non-Federal analytical laboratories may be accredited for the analyses of moisture, protein, fat, and salt content of poultry and poultry products. Accreditation will be given only if the applying laboratory successfully satisfies the requirements presented below, for all four analytes. This accreditation authorizes official FSIS acceptance of

the analytical test results provided by these laboratories on official samples. To obtain FSIS accreditation for moisture, protein, fat, and salt analyses, a non-Federal analytical laboratory must:

(i) Be supervised by a person holding, as a minimum, a bachelor's degree in either chemistry, food science, food technology, or a related field and having 1 year's experience in food chemistry, or equivalent qualifications, as determined by the Administrator.

(ii) Demonstrate acceptable levels of systematic laboratory difference, variability, and individual large deviations in the analyses of moisture, protein, fat, and salt content using AOAC methods. An applying laboratory will successfully demonstrate these capabilities if its moisture, protein, fat, and salt results from a 36 check sample accreditation study each satisfy the criteria presented below.² If the laboratory's analysis of an analyte (or analytes) from the first set of 36 check samples does not meet the criteria for obtaining accreditation, a second set of 36 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 samples shall be analyzed for only the analyte(s) for which unacceptable initial results had been obtained by the laboratory. If the results of the second set of samples do not meet the accreditation criteria, 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.

(A) *Systematic laboratory difference:* The absolute value of the average standardized difference must not exceed 0.73 minus the product of 0.17 and the standard deviation of the standardized differences.

(B) *Variability:* The estimated standard deviation of the standardized differences must not exceed 1.15.

²All statistical computations are rounded to the nearest tenth, except where otherwise noted.

(C) *Individual large deviations*: One hundred times the average of the large deviation measures of the individual samples must be less than 5.0.³

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

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

(3) *Criteria for maintaining accreditation*. To maintain accreditation for moisture, protein, fat, and salt analyses, a non-Federal analytical laboratory must:

(i) Report analytical results of the moisture, protein, fat, and salt content of official samples, weekly, on designated forms to the FSIS Eastern Laboratory, College Station Road, P.O. Box 6085, Athens, GA 30604, or to the address designated by the Assistant Administrator, Office of Public Health and Science.

(ii) Maintain laboratory quality control records for the most recent 3 years that samples have been analyzed under this Program.

(iii) Maintain complete records of the receipt, analysis, and disposition of official samples for the most recent 3 years that samples have been analyzed under this Program.

(iv) Maintain a standards book, which is a permanently bound book with sequentially numbered pages, containing all readings and calculations for standardization of solutions, determination of recoveries, and calibration of instruments. All entries are to be dated and signed by the analyst immediately upon completion of the entry and by his/her supervisor within 2 working days. The standards book is to be retained for a period of 3 years after the last entry is made.

(v) Analyze interlaboratory accreditation maintenance check samples and return the results to FSIS within 3 weeks of sample receipt. This must be done whenever requested by FSIS and at no cost to FSIS.

(vi) Inform the Accredited Laboratory Program, Food Safety and Inspect-

³A 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 $1 - (2.5/d)^4$.

tion Service, U.S. Department of Agriculture, Washington, DC 20250-3700, by certified or registered mail, within 30 days of any change in the laboratory's ownership, officers, directors, supervisory personnel, or other responsibly connected individual or entity.

(vii) Permit any duly authorized representative of the Secretary to perform both announced and unannounced on-site laboratory reviews of facilities and records during normal business hours, and to copy any records pertaining to the laboratory's participation in the Accredited Laboratory Program.

(viii) Use official AOAC methods⁴ on official and check samples. The "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(ix) Demonstrate that acceptable limits of systematic laboratory difference, variability, and individual large deviations are being maintained in the analyses of moisture, protein, fat, and salt content. An accredited laboratory will successfully demonstrate the maintenance of these capabilities if its moisture, protein, fat, and salt results from interlaboratory accreditation maintenance check samples and/or split samples satisfy the criteria presented in this paragraph (b)(3)(ix).⁵

(A) *Systematic laboratory difference—(1) Positive systematic laboratory difference*: The standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as COSUM-P. This value is computed and evaluated as follows:

⁴A copy of the "Official Methods of Analysis of the Association of Analytical Chemists," 15th edition, 1990, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Analytical Chemists, Inc., 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201.

⁵All statistical computations are rounded to the nearest tenth, except where otherwise noted.

(j) Determine the CUSUM increment for the sample. The CUSUM increment 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.

(ii) Compute the new COSUM-P value. The new COSUM-P value is obtained by adding, algebraically, the CUSUM increment to the last previously computed COSUM-P value. If this computation yields a value smaller than 0, the new COSUM-P value is set equal to 0. [COSUM-P values are initialized at zero; that is, the COSUM-P value associated with the first sample is set equal to the CUSUM increment for that sample.]

(iii) Evaluate the new COSUM-P value. The new COSUM-P value must not exceed 5.2.

(2) *Negative systematic laboratory difference:* The standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as COSUM-N. This value is computed and evaluated as follows:

(i) Determine the CUSUM increment for the sample. The CUSUM increment 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.

(ii) Compute the new COSUM-N value. The new COSUM-N value is obtained by subtracting, algebraically, the CUSUM increment to the last previously computed COSUM-N value. If this computation yields a value smaller than 0, the new COSUM-N value is set equal to 0. [COSUM-N values are initialized at zero; that is, the COSUM-N value associated with the first sample is set equal to the CUSUM increment for that sample.]

(iii) Evaluate the new COSUM-N value. The new COSUM-N value must not exceed 5.2.

(B) *Variability:* The absolute value of the standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split sample or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as COSUM-V. This value is computed and evaluated as follows:

(1) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the larger of -0.4 and 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.

(2) Compute the new COSUM-V value. The new COSUM-V value is obtained by adding, algebraically, the CUSUM increment to the last previously computed COSUM-V value. If this computation yields a value less than 0, the new COSUM-V value is set equal to 0. [COSUM-V values are initialized at zero; that is, the COSUM-V value associated with the first sample is set equal to the CUSUM increment for that sample.]

(3) Evaluate the new COSUM-V value. The new COSUM-V value must not exceed 4.3.

(C) *Large deviations:* The large deviation measure of the accredited laboratory's result for each split sample or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as COSUM-D.⁶ This value is computed and evaluated as follows:

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

(2) Compute the new COSUM-D value. The new COSUM-D value is obtained by adding, algebraically, the CUSUM increment to the last previously computed COSUM-D value. If this computation yields a value less than 0, the new COSUM-D value is set equal to 0. [COSUM-D values are initialized at zero; that is, the COSUM-D value associated with the first sample is set equal

⁶ See footnote 3.

to the CUSUM increment for that sample.]

(3) Evaluate the new COSUM-D value. The new COSUM-D value must not exceed 1.0.

(x) Meet the following requirements if placed on probation pursuant to paragraph (e) of this section:

(A) 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, to an accredited laboratory approved for food chemistry. Mailing expenses will be paid by FSIS.

(B) Analyze a set of check samples similar to those used for initial accreditation, and submit the analytical results to FSIS within 3 weeks of receipt of the samples.

(C) Satisfy criteria for check samples specified in paragraphs (b)(2)(i) (A), (B), and (C) of this section.

(xi) Exeditiously report analytical results of official samples to the FSIS Eastern Laboratory, College Station Road, P.O. Box 6085, Athens, GA 30604, or to the address designated by the Assistant Administrator, Office of Public Health and Science. The Federal inspector at any establishment may assign the analysis of official samples of an FSIS laboratory if, in the inspector's judgment, there are delays in receiving test results on official samples from an accredited laboratory.

(xii) Pay the required accreditation fee when it is due.

(c) *Laboratories accredited for analysis of a class of chemical residues in poultry and poultry products*—(1) *Applying for accreditation.* Application for accreditation shall be made on designated forms provided by FSIS, or otherwise in writing, by the owner or manager of the non-Federal analytical laboratory and sent to the Accredited Laboratory Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700, and 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 reapply for accreditation after 60 days from the effective date of that action, and must provide

written documentation specifying what corrections were made.

(i) At the time that an Application for Accreditation is filed with the Accredited Laboratory Program, FSIS, and annually thereafter upon receipt of the bill issued by FSIS on the anniversary date of each accreditation, the management of a laboratory shall reimburse the program at the rate specified in 9 CFR 391.5 for the cost of each accreditation that is sought by the laboratory or that the laboratory holds.

(ii) Simultaneously with the initial application for accreditation, the management of a laboratory shall forward 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) sought by the laboratory. Accreditation will not be granted or continued, without further procedure, for failure to pay the accreditation fee(s). The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the laboratory accreditation program are paid.

(iii) Annually on the anniversary date of each accreditation, FSIS will issue a bill in the amount specified in 9 CFR 391.5.

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

(v) The accreditation of a laboratory that was accredited by FSIS on or before December 13, 1993 and was not on probation and whose accreditation on that date was not in suspension or revocation shall be continued, provided that such laboratory reapply for accreditation in accordance with the provisions of this paragraph (c)(1) by January 12, 1994 (30 days of the effective date of this section), and that the reapplication be accepted by the Agency. The CUSUM values for such laboratory will be reset at zero upon acceptance of

its reapplication. The accreditation of a laboratory that is on probation shall be continued, provided that the laboratory reapply for accreditation by February 11, 1994 (60 days of the effective date of this section), that the reapplication be accepted by the Agency, and that the laboratory satisfy the terms of the probation.

(2) *Criteria for obtaining accreditation.* Non-Federal analytical laboratories may be accredited for the analysis of a class of chemical residues in poultry and poultry products. Accreditation will be given only if the applying laboratory successfully satisfies the requirements presented below. This accreditation authorizes official FSIS acceptance of the analytical test results provided by these laboratories on official samples. To obtain FSIS accreditation for the analysis of a class of chemical residues, a non-Federal analytical laboratory must:

(i) Be supervised by a person holding, as a minimum, a bachelor's degree in either chemistry, food science, food technology, or a related field and either the supervisor or the analyst assigned to analyze the sample has 3 years' experience determining analytes at or below part per million levels, or equivalent qualifications, as determined by the Administrator.

(ii) Demonstrate acceptable limits of systematic laboratory difference, variability, individual large deviations, recoveries, and proper identification in the analysis of the class of chemical residues for which application was made, using FSIS approved procedures. An applying laboratory will successfully demonstrate these capabilities if its analytical results for each specific chemical residue provided in a check sample accreditation study containing a minimum of 14 samples satisfy the criteria presented in this paragraph (c)(2)(ii).⁷ 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 (c)(2)(ii) (A), (B), (C), (D), (E), and (F) 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.] If the results of the first set of check samples do not meet these criteria for obtaining accreditation, a second set of at least 14 samples will be provided within 30 days following the date of receipt by FSIS of a request from the applying laboratory. If the results of the second set of samples do not meet accreditation criteria, 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.

(A) *Systematic laboratory difference:* The absolute value of the average standardized difference must not exceed 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.

(B) *Variability:* The standard deviation of the standardized differences must not exceed a computed limit. This limit is a function of the number of analytical results used in the computation of the standard deviation, and of the amount of variability associated with the results from the participating FSIS laboratories.

(C) *Individual large deviations:* One hundred times the average of the large deviation measures of the individual analytical results must be less than 5.0.⁸

(D) *QA recovery:* The average of the QA recoveries of the individual analytical results must lie within the range given in Table 2 under the column entitled "Percent Expected Recovery."

(E) *QC recovery:* All QC recoveries must lie within the range given in Table 2 under "Percent Expected Recovery." Supporting documentation must be made available to FSIS upon request.

⁸A 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 $1-(2.5/d)^4$.

⁷All statistical computations are rounded to the nearest tenth, unless otherwise noted.

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

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

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

(3) *Criteria for maintaining accreditation*. To maintain accreditation for analysis of a class of chemical residues, a non-Federal analytical laboratory must:

(i) [Reserved]

(ii) Maintain laboratory quality control records for the most recent 3 years that samples have been analyzed under this Program.

(iii) Maintain complete records of the receipt, analysis, and disposition of official samples for the most recent 3 years that samples have been analyzed under the Program.

(iv) Maintain a standards book, which is a permanently bound book with sequentially numbered pages, containing all readings and calculations for standardization of solutions, determination of recoveries, and calibration of instruments. All entries are to be dated and signed by the analyst immediately upon completion of the entry and by his/her supervisor within 2 working days. The standards book is to be retained for a period of 3 years after the last entry is made.

(v) Analyze interlaboratory accreditation maintenance check samples and return the results to FSIS within 3 weeks of sample receipt. This must be done whenever requested by FSIS and at no cost to FSIS.

(vi) Inform the Accredited Laboratory Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700, by certified or registered mail, within 30 days when there is any change in the laboratory's ownership, officers, directors, supervisory personnel, or any other responsibly connected individual or entity.

(vii) Permit any duly authorized representative of the Secretary to perform both announced and unannounced on-site laboratory reviews of facilities and records during normal business hours, and to copy any records pertaining to

the laboratory's participation in the Accredited Laboratory Program.

(viii) Use analytical procedures designated and approved by FSIS.

(ix) Demonstrate that acceptable limits of systematic laboratory difference, variability, and individual large deviations are being maintained in the analysis of samples, in the chemical residue class for which accreditation was granted. A laboratory will successfully demonstrate the maintenance of these capabilities if its analytical results for each specific chemical residue found in interlaboratory accreditation maintenance check samples and/or split samples satisfy the criteria presented below.^{9 10} In addition, if the laboratory is accredited for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria.

(A) *Systematic laboratory difference*:

(1) *Positive systematic laboratory difference*: The standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split and/or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as COSUM-P.¹¹ This value is computed and evaluated as follows:

(j) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to:

⁹All statistical computations are rounded to the nearest tenth, except where otherwise noted.

¹⁰An analytical result will only be used in the statistical evaluation of the laboratory if the associated comparison mean is equal to or greater than the logarithm of the minimum proficiency level for the residue.

¹¹When 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 COSUM-P (or COSUM-N) value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

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.

(ii) Compute the new COSUM-P value. The new COSUM-P value is obtained by adding, algebraically, the CUSUM increment to the last previously computed COSUM-P value. If this computation yields a value smaller than 0, the new COSUM-P value is set equal to 0. [COSUM-P values are initialized at zero; that is, the COSUM-P value associated with the first sample is set equal to the CUSUM increment for that sample.]

(iii) Evaluate the new COSUM-P value. The new COSUM-P value must not exceed 4.8.

(2) *Negative systematic laboratory difference:* The standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split and/or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as COSUM-N.¹² This value is computed and evaluated as follows:

(i) Determine the CUSUM increment for the sample. The CUSUM increment 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.

(ii) Compute the new COSUM-N value. The new COSUM-N value is obtained by subtracting, algebraically, the CUSUM increment to the last previously computed COSUM-N value. If this computation yields a value smaller than 0, the new COSUM-N value is set equal to 0. [COSUM-N values are initialized at zero; that is, the COSUM-N value associated with the first sample is set equal to the CUSUM increment for that sample.]

(iii) Evaluate the new COSUM-N value. The new COSUM-N value must not exceed 4.8.

(B) *Variability:* The absolute value of the standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split and/or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as COSUM-V.¹³ This value is computed and evaluated as follows:

(1) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the larger of -0.4 and 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.

(2) Compute the new COSUM-V value. The new COSUM-V value is obtained by adding, algebraically, the CUSUM increment to the last previously computed COSUM-V value. If this computation yields a value less than 0, the new COSUM-V value is set equal to 0. [COSUM-V values are initialized at zero; that is, the COSUM-V value associated with the first sample is set equal to the CUSUM increment for that sample.]

(3) Evaluate the new COSUM-V value. The new COSUM-V value must not exceed 4.3.

(C) *Large Deviations:* The large deviation measure of the accredited laboratory's result for each split and/or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as COSUM-D.¹⁴ This value is computed and evaluated as follows:

¹³When 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 COSUM-V value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

¹⁴A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference,

¹² See footnote 11.

Continued

(1) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the large deviation measure minus 0.025.

(2) Compute the new COSUM-D value. The new COSUM-D is obtained by adding, algebraically, the CUSUM increment to the last previously computed COSUM-D value. If this computation yields a value less than 0, the new COSUM-D value is set equal to 0. [COSUM-D values are initialized at zero; that is, the COSUM-D value associated with the first sample is set equal to the CUSUM increment for that sample.]

(3) Evaluate the new COSUM-D value. The new COSUM-D value must not exceed 1.0.

(x) Meet the following requirements if placed on probation pursuant to paragraph (e) of this section:

(A) Send all official samples that have not been analyzed as of the date of written notification of probation to a specified FSIS Science Laboratory by certified mail or private carrier or, as an alternative, to an accredited laboratory accredited for this specific chemical residue. Mailing expenses will be paid by FSIS.

(B) Analyze a set of check samples similar to those used for initial accreditation, and submit analytical results to FSIS within 3 weeks of receipt of the samples.

(C) Satisfy criteria for check samples as specified in paragraphs (c)(2)(ii) (A), (B), (C), (D), (E), and (F) of this section.

(xi) Expediently report analytical results of official samples to the FSIS Eastern Laboratory, College Station Road, P.O. Box 6085, Athens, GA 30604, or to the address designated by the Assistant Administrator, Office of Public Health and Science. The Federal inspector at any establishment may assign the analysis of official samples to an FSIS laboratory if, in the judgment of the inspector, there are delays in receiving test results on official samples from an accredited laboratory.

(xii) Every QC recovery associated with reporting of official samples must be within the appropriate range given in Table 2 under "Percent Expected Re-

(d), is less than 2.5, and otherwise a measure equal to $1 - (2.5/d)^4$.

covery." Supporting documentation must be made available to FSIS upon request.

(xiii) Demonstrate that acceptable levels of systematic laboratory difference, variability, individual large deviations, recoveries, and proper identification are being maintained in the analysis of interlaboratory accreditation maintenance check samples, in the chemical residue class for which accreditation was granted. A laboratory will successfully demonstrate the maintenance of these capabilities if its analytical results for each specific chemical residue found in interlaboratory accreditation maintenance check samples satisfy the criteria presented below. In addition, if the laboratory is accredited for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria.

(A) *Systematic laboratory difference—*
(1) *Positive 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 a CUSUM value, designated as COSUM-P.¹⁵ This value is computed and evaluated as follows:

(i) Determine the CUSUM increment for the sample. The CUSUM increment 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.

(ii) Compute the new COSUM-P value. The new COSUM-P value is obtained by adding, algebraically, the CUSUM increment to the last previously computed COSUM-P value. If this computation yields a value smaller than 0, the new COSUM-P value is set equal to 0. [COSUM-P values are initialized at zero; that is, the COSUM-P value associated with the first sample is set equal to the CUSUM increment for that sample.]

¹⁵ See footnote 11.

(iii) Evaluate the new COSUM-P value. The new COSUM-P value must not exceed 4.8.

(2) *Negative 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 a CUSUM value, designated as COSUM-N.¹⁶ This value is computed and evaluated as follows:

(i) Determine the CUSUM increment for the sample. The CUSUM increment 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.

(ii) Compute the new COSUM-N value. The new COSUM-N value is obtained by subtracting, algebraically, the CUSUM increment to the last previously computed COSUM-N value. If this computation yields a value smaller than 0, the new COSUM-N value is set equal to 0. [COSUM-N values are initialized at zero; that is, the COSUM-N value associated with the first sample is set equal to the CUSUM increment for that sample.]

(iii) Evaluate the new COSUM-N value. The new COSUM-N value must not exceed 4.8.

(B) *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 COSUM-V.¹⁷ This value is computed and evaluated as follows:

(i) Determine the CUSUM 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.

(2) Compute the new COSUM-V value. The new COSUM-V value is obtained by

adding, algebraically, the CUSUM increment to the last previously computed COSUM-V value. If this computation yields a value less than 0, the new COSUM-V value is set equal to 0. [COSUM-V values are initialized at zero; that is, the COSUM-V value associated with the first sample is set equal to the CUSUM increment for that sample.]

(3) Evaluate the new COSUM-V value. The new COSUM-V value must not exceed 4.3.

(C) *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 COSUM-D.¹⁸ This value is computed and evaluated as follows:

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

(2) Compute the new COSUM-D value. The new COSUM-D is obtained by adding, algebraically, the CUSUM increment to the last previously computed COSUM-D value. If this computation yields a value less than 0, the new COSUM-D value is set equal to 0. [COSUM-D values are initialized at zero; that is, the COSUM-D value associated with the first sample is set equal to the CUSUM increment for that sample.]

(3) Evaluate the new COSUM-D value. The new COSUM-D value must not exceed 1.0.

(D) Each QC Recovery is within the range given in Table 2 under "Percent Expected Recovery". Supporting documentation must be made available to FSIS upon request.

(E) Not more than 1 residue misidentification in any 2 consecutive check samples.

(F) Not more than 2 residue misidentifications in any 8 consecutive check samples.

(xiv) Pay the accreditation fee when it is due.

¹⁸A 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 $1 - (2.5/d)^4$.

¹⁶ See footnote 11.

¹⁷ See footnote 13.

(d) *Refusal of accreditation.* Upon a determination by the Administrator, a laboratory will be refused accreditation for the following reasons:

(1) A laboratory shall be refused accreditation for moisture, protein, fat, and salt analysis for failure to meet the requirements of paragraph (b)(1) or (b)(2) of this section.

(2) A laboratory shall be refused accreditation for chemical residue analysis for failure to meet the requirements of paragraph (c)(1) or (c)(2) of this section.

(3) A laboratory shall be refused subsequent accreditation for failure to return to an FSIS laboratory, by certified mail or private carrier, all official samples which have not been analyzed as of the notification of a loss of accreditation.

(4) A laboratory shall be refused accreditation if the applicant or any individual or entity responsibly connected with the applicant has been convicted of or is under indictment or if charges on an information have been brought against the applicant or responsibly connected individual or entity in any Federal or State court concerning the following violations of law:

(i) Any felony.

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

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

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

(e) *Probation of accreditation.* Upon a determination by the Administrator, a laboratory shall be placed on probation for the following reasons:

(1) If the laboratory fails to complete more than one interlaboratory accreditation maintenance check sample analysis within 12 consecutive months as required by paragraphs (b)(3)(v) and (c)(3)(v) of this section, unless written permission is granted by the Administrator to exceed the time limit.

(2) If the laboratory fails to meet any of the criteria set forth in paragraphs (b)(3)(v) and (b)(3)(ix) and (c)(3)(v) and (c)(3)(ix) of this section.

(f) *Suspension of accreditation.* The accreditation of a laboratory shall be suspended if the laboratory or any individual or entity responsibly connected with the laboratory is indicted or if charges on an information have been brought against the laboratory or responsibly connected individual or entity in any 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.

(g) *Revocation of accreditation.* The accreditation of a laboratory shall be revoked for the following reasons:

(1) An accredited laboratory which is accredited to perform analysis under paragraph (b) of this section shall have its accreditation revoked for failure to meet any of the requirements of paragraph (b)(3) except for the following circumstances. If the accredited laboratory fails to meet the criteria for reporting the analytical results on interlaboratory accreditation maintenance check samples as set forth in paragraph (b)(3)(v) of this section or if, at any time, the CUSUM results from the analysis of such interlaboratory accreditation maintenance check samples and/or split samples have not satisfied the criteria specified in paragraph (b)(3)(ix) of this section and there have been, during the previous 12 months, no other occasions on which such CUSUM results have not satisfied such criteria, the laboratory shall be placed on probation; but if there have been such other occasions during those 12 months, the laboratory's accreditation will be revoked.

(2) An accredited laboratory which is accredited to perform analysis for a class of chemical residues under paragraph (c) of this section shall have the accreditation to perform this analysis revoked if it fails to meet any of the requirements in paragraph (c)(3) of this

section except for the following circumstances. If the accredited laboratory fails to meet any of the criteria set forth in paragraphs (c)(3)(v), (c)(3)(ix), and (c)(3)(xiii) of this section and it has not so failed during the 12 months preceding its failure to meet the criteria, it shall be placed on probation, but if it has so failed at any time during those 12 months, its accreditation will be revoked.

(3) An accredited laboratory shall have its accreditation revoked if the Administrator determines that the laboratory or any responsibly connected individual or any agent or employee has:

(i) Altered any official sample or analytical finding, or,

(ii) Substituted any analytical result from any other laboratory for its own.

(4) An accredited laboratory shall have its accreditation revoked if the laboratory or any individual or entity responsibly connected with the laboratory is convicted in a Federal or State court of any of the following violations of law:

(i) Any felony.

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

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

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

(h) *Notification and hearings.* Accreditation of any laboratory shall be refused, suspended, or revoked under the conditions previously described herein. The owner or operator of the laboratory shall be sent written notice of the refusal, suspension, or revocation of accreditation by the Administrator. In such cases, the laboratory owner or operator will be provided an opportunity to present, within 30 days of the date of the notification, a statement challenging the merits or validity of such action and to request an oral hearing with respect to the denial, suspension, or revocation decision. An oral hearing shall be granted if there is any dispute of material fact joined in such responsive statement. The proceeding shall

thereafter be conducted in accordance with the applicable rules of practice which shall be adopted for the proceeding. Any such refusal, suspension, or revocation shall be effective upon the receipt by the laboratory of the notification and shall continue in effect until final determination of the matter by the Administrator.

(Reporting and recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0015)

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Subpart P—Definitions and Standards of Identity or Composition

§ 381.155 General.

(a) *Authorization to establish specifications.* (1) The Administrator is authorized to establish specifications or definitions and standards of identity or composition, covering the principal constituents of any poultry product with respect to which a specified name of the product or other labeling terminology may be used, whenever he determines such action is necessary to prevent sale of the product under false or misleading labeling. Further, the Administrator is authorized to prescribe definitions and standards of identity or composition for poultry products whenever he determines such action is otherwise necessary for the protection of the public. The requirements of this subpart are hereby found to be necessary for these purposes and standards are hereby established as set forth in this subpart.

(2) Where cooked poultry meat is specified in this subpart as an ingredient of poultry products, this means poultry meat derived from poultry processed, cooked, and cooled in a manner approved by the Administrator in specific cases without use of liquid or moisture in direct contact with the poultry meat following the cooking and cooling of the poultry.

(3) If, following cooking and cooling of poultry meat to be used in poultry products, liquid or moisture is used in direct contact with such poultry meat