§ 439.5

(a) *Standardizing value*—A number representing the performance standard deviation of an individual result. The number is given, or computed by, the information provided in Tables 1 and 2 to this paragraph (aa).

<table>
<thead>
<tr>
<th>Product/class</th>
<th>Moisture</th>
<th>Protein</th>
<th>Fat</th>
<th>Salt</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;12.5%</td>
<td>&gt;12.5%</td>
<td>&lt;1%</td>
<td>1–4%</td>
</tr>
<tr>
<td>Cured Pork</td>
<td>0.50</td>
<td>0.060 (X&lt;sub&gt;1&lt;/sub&gt;)</td>
<td>0.26 (X&lt;sub&gt;2&lt;/sub&gt;)</td>
<td>0.30 (X&lt;sub&gt;3&lt;/sub&gt;)</td>
</tr>
<tr>
<td>Canned Ham</td>
<td>0.50</td>
<td>0.060 (X&lt;sub&gt;1&lt;/sub&gt;)</td>
<td>0.26 (X&lt;sub&gt;2&lt;/sub&gt;)</td>
<td>0.30 (X&lt;sub&gt;3&lt;/sub&gt;)</td>
</tr>
<tr>
<td>Other Meat Products</td>
<td>0.57</td>
<td>0.060 (X&lt;sub&gt;1&lt;/sub&gt;)</td>
<td>0.26 (X&lt;sub&gt;2&lt;/sub&gt;)</td>
<td>0.30 (X&lt;sub&gt;3&lt;/sub&gt;)</td>
</tr>
<tr>
<td>Poultry Products</td>
<td>0.57</td>
<td>0.060 (X&lt;sub&gt;1&lt;/sub&gt;)</td>
<td>0.26 (X&lt;sub&gt;2&lt;/sub&gt;)</td>
<td>0.30 (X&lt;sub&gt;3&lt;/sub&gt;)</td>
</tr>
</tbody>
</table>

1 The standardizing value is either the value given in the table or is computed by the formula set forth in the table, where X is the comparison mean of the sample. Standardizing values are provided for different percentages of fat and salt as indicated in the table.

2 For dry salami and pepperoni products.

(b) *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.

§ 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 reapply 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,
(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. 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.

(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