cultural patrimony, which are subject to the provisions of paragraph (a) of this section) excavated or removed from lands of Indian individuals that are under tribal jurisdiction to a curatorial facility that meets the requirements of 36 CFR part 79. When, however, such consignment constitutes the ultimate disposition of these resources, the tribe having jurisdiction must also grant its consent. Any subsequent exchange or disposition by the facility must have the consent of both the landowner(s) and the tribe.

Dated: September 17, 1993.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

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Part III

Department of Agriculture

Food Safety and Inspection Service

9 CFR Part 318, et al.
Accreditation Fees, Standards, and Procedures for FSIS Accredited Laboratories; Final Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 318, 381, and 391

[Docket No. 92–002F]

RIN 0583–AB49

Accreditation Fees, Standards, and Procedures for FSIS Accredited Laboratories

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to establish user fees and adjust the standards and procedures for the accreditation of non-Federal analytical chemistry laboratories. The Agency's Accredited Laboratory Program (ALP) qualifies non-Federal analytical laboratories to conduct analysis of official meat and poultry samples. These laboratories provide the Agency and the regulated industry with an alternative to reliance on FSIS's own laboratories and often permit more timely analytical results that could otherwise be possible. Accredited laboratories analyze meat and poultry samples for moisture, protein, fat, and salt content and/or certain chemical residues. User fees, which will cover the costs of the FSIS Accredited Laboratory Program, are mandated by the Food, Agriculture, Conservation, and Trade Act of 1990 (the 1990 Farm Bill), as amended.

EFFECTIVE DATE: December 13, 1993.

FOR FURTHER INFORMATION CONTACT: Dr. Jess Rajan, Chief, Quality Systems Branch, Chemistry Division, room 516–A, Annex Building, USDA, FSIS, 300 12th Street SW., Washington, DC 20250–3700, (202) 205–0679.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This final rule has been reviewed under Executive Order 12866.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule (1) establishes user fees for non-Federal analytical chemistry laboratories accredited under the Federal Meat and Poultry Products Inspection Acts and regulations promulgated thereunder, and (2) adjusts the standards and procedures for the accreditation of such laboratories.

States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any requirements with respect to federally inspected premises and facilities, and operations of such establishments, that are in addition to, or different than, those imposed under the FMIA or PPIA. States and local jurisdictions are also preempted under the FMIA and PPIA from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat or poultry products that are in addition to, or different than, those imposed under the FMIA or the PPIA, as well as preempted from imposing, under the PPIA for poultry products, certain storage and handling requirements. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat or poultry products that are misbranded or adulterated under the FMIA or PPIA or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. States and local jurisdictions may also make requirements or take other actions, that are consistent with the FMIA and PPIA, with respect to any other matters regulated under the FMIA and PPIA.

Under the FMIA and the PPIA, States that maintain meat and poultry inspection programs must impose requirements that are at least equal to those required under the FMIA or PPIA. These States may, however, impose more stringent requirements on such State-inspected products and establishments.

This final rule will have no retroactive effect and applicable administrative procedures must be exhausted before any judicial challenge to the application of these provisions. Those administrative procedures are set forth in 9 CFR 306.5, 318.21(h), 381.35, and 381.153(h).

Effect on Small Entities

Most of the entities accredited by FSIS that will be affected by this final rule are large, independent laboratories or official meat packing establishments or States that own or operate accredited laboratories.

There are currently approximately 240 laboratories in the FSIS accredited laboratory program. About three quarters of these are large entities, with respect to the volume of business, or part of such entities as large business corporations, State universities, or State governments. These laboratories provide analytical services to large and small establishments for analysis of official samples.

Participation in the Agency's Accredited Laboratory Program is voluntary. The principal burdens of the final rule on laboratories will be the fee charged for FSIS accreditation ($3,500 per accreditation, of which a laboratory may have more than one) and the minimal billing and accounting costs.

Some large laboratories have multiple accreditations for food chemistry and chemical residues, while many small laboratories are accredited only for food chemistry. Thus, smaller laboratories (small entities) will be expected to pay smaller amounts of accreditation fees than large laboratories. Balanced against these costs are the revenues from analyzing official samples, which are likely to be greater because firms can be expected to pass much of the costs of obtaining accreditation to clients, and the enhancement of income from other services provided by the laboratories because of their status as "accredited by FSIS." As a result, the net effect of this rulemaking on both small and large laboratories will not be significant. The user-fee cost increments for having official samples analyzed by accredited laboratories are likely to be passed on to the establishments doing business with accredited laboratories, or absorbed by the official establishment if the establishment has an in-house accredited laboratory. Establishments using the laboratories will continue to benefit from the earlier marketing of product released from official retention. Overall benefits to the meat and poultry industry, including both small and large establishments, from using accredited laboratories are not expected to change significantly.

Small laboratories that do very little analysis (15 or fewer analyses a year) of official samples may choose to discontinue participating in the ALP. It is expected that a decision to participate would be based on a calculation of the benefits and costs to the firm, including a determination whether the resulting loss of business from not participating in the ALP would be significant.

As a result of nonparticipation in the ALP by some small laboratories, small official establishments doing business with these laboratories would have to seek other facilities for the analysis of official samples. However, there would be relatively few instances of this for small establishments because, by their nature, small establishments rely primarily on FSIS laboratories and seek little assistance from accredited laboratories for the analysis of official samples.

If some of these small accredited laboratories were no longer available, the establishments could, and likely would, have samples tested by other accredited laboratories, such as those operated by States. The Agency is unaware of any cases in which such alternate arrangements could not be made. The affected establishments would still be able to exercise the option of having samples tested at their own expense so that product found to be in compliance with Federal regulations could be released into commerce sooner than it could if the establishments had samples mailed to an analyzed by FSIS laboratories.

Besides the user-fee provisions, the final rule contains adjustments to the accreditation procedures and performance standards. For example, some unit names and addresses and some operational procedures are being changed to conform with Agency practice. Also, the statistical evaluation criteria for determining the effectiveness and consistency of laboratory analytical processes are being adjusted on the basis of comparison data accumulated and analyzed. The Agency is providing, through the final rule, a more equitable and efficient way of determining the qualifications of laboratories in the program. The changes made by the final rule will, by way of providing clearer explanations of the requirements for participation in the program as well as providing more accurate and up-to-date performance criteria, reduce the need for administrative consultations, and increase operational efficiencies in both laboratories and the Agency. The cost savings of such improved efficiencies are likely to be small in most cases, however.

For the reasons given above, the effects of the final rule on the accredited laboratories and on the establishments they serve will not be significant.

Paperwork Requirements

This final rule will impose a minimal paperwork burden associated with accounting and payment of bills presented by FSIS to laboratories participating in the ALP. This burden is estimated at about one-half staff hour per laboratory per year. Under current Agency policies, six food chemistry check sample sets per year are being supplied to accredited laboratories.

About 195 laboratories in the ALP are expected to continue their accreditations for food chemistry analysis. In addition, the Agency has updated an existing form, to be used by participating laboratories to report the results of food chemistry check sample analyses for initial accreditation. The burden estimate for collecting and recording the information on the form and mailing it to FSIS is one-half staff hour per laboratory per set of check samples.

Information concerning the paperwork burden associated with the user fee provisions of the final rule has been submitted to OMB. The paperwork requirements under the new and existing FSIS accredited laboratory regulations, including the above form, have been approved under OMB No. 0583–0080.

Background

To assure compliance with regulations promulgated under the Federal Meat Inspection Act (FMIA—21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA—21 U.S.C. 451 *et seq.*), and regulations promulgated thereunder, samples of meat and poultry products are tested periodically to determine protein, moisture, fat, and salt content. Analyses are also conducted to determine the presence of any violative concentrations of drug or other chemical residues.

When FSIS finds that a product is not in compliance, the Agency is required to take appropriate action against the processor of that product. Depending on the type of product and the severity of the noncompliance, such action may range from product reprocessing to litigation proceedings. Because of the critical nature of product testing, it is necessary for FSIS laboratories that analyze official samples of meat and poultry products to maintain a high degree of integrity.

A processor whose sample is to be analyzed generally has the option of using either an FSIS laboratory or an accredited laboratory. The cost of FSIS analysis is borne by the Government while the cost of non-Federal analysis is borne by the processor. Due to the limited number of FSIS laboratories and their heavy workload, many processors prefer to use the non-Federal laboratories either for convenience of location or to obtain test results more quickly.

In 1991, section 1327 (7 U.S.C. 138f) of the Food, Agriculture, Conservation, and Trade Act 1990 (Pub. L. 101–624), known as the 1990 Farm Bill, was amended to require USDA to charge a nonrefundable accreditation fee for laboratories seeking accreditation by the Secretary under the authority of the FMIA or PPIA. The fee established is required to be an amount that will offset the cost of the ALP administered under the authority of the FMIA and PPIA. All fees collected by the Secretary of Agriculture are to be credited to an account from which the expenses of the Accredited Laboratory Program are paid, and are to be available immediately and remain available until expended for the ALP.

On August 19, 1993, FSIS proposed amendments to the Federal meat and poultry inspection regulations to establish accreditation fees and to adjust the standards and procedures for the accreditation of non-Federal analytical chemistry laboratories (58 FR 44236). The adjustments to program standards were proposed to more accurately reflect the performance of participating laboratories. Changes to some administrative procedures were also proposed to enhance FSIS management of the program.

The final rule is effective upon publication. Title I of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriation Act (Pub. L. 103–111) provides—separately from the appropriation for FSIS for services authorized by the FMIA and PPIA—for laboratory accreditation fees to be credited to the account for the FSIS appropriation. Therefore, FSIS must have the revenue from the accreditation fees available to operate the ALP during fiscal year 1994. Only upon promulgation of the final rule can the Agency have funds available for the ALP and operate the program according to the standards and procedures prescribed by the rule. Any delay in adoption of the rule could result in suspension of FSIS laboratory accreditation services and, consequently, a disruption of laboratory support in inspection operation.

In addition to the establishment of accreditation fees, the final rule adjusts standards and procedures for accreditation. Implementation of the accreditation fees in itself changes the procedures for applying for and obtaining an accreditation, so it is necessary to implement such application procedures at the same time that the fee requirement becomes effective.

Further, the final rule defines accreditation as, in part, a determination by the Agency that the applying laboratory meets certain qualifications. These qualifications for the several types of accreditation, including standardizing values, are set forth in the final rule. It would be administratively infeasible to separately implement the qualification criteria and the accreditation fees. Consequently, accreditation fees and adjusted standards and procedures for laboratory accreditation must be implemented simultaneously.

Therefore, in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553), good cause is found for making the final rule effective upon publication.

1. User Fees

Accredited laboratories of record on the effective date of the final rule will be required to reapply to the Agency to continue their accreditations. FSIS will issue bills (Form AD–496–4, Bill for Collection) for their accreditation fees. The fee required for each accreditation sought is $3,500 per year. Laboratories that enter the program after the effective date of the regulation will be billed on the anniversary date of their application. Laboratories that lose their accreditation because of performance considerations and wish to reapply following the mandatory waiting period will be required to pay a new accreditation fee on the date of their application, commensurate with the number of new accreditations requested. Annual fees thereafter will be billed on the anniversary date of each accreditation. A copy or each bill will be forwarded to the National Finance Center, USDA, to record the account receivable in the records for the Agency. Payment of the bill, by money order, check, or bank draft, is due immediately and should be forwarded with a copy of the bill to the address shown on the bill.

Laboratories that wish to become accredited for the first time should submit their request in writing, identifying the specific accreditation(s) they seek. The laboratory will send to FSIS fees commensurate with the accreditation(s) sought along with its written application. Should an applying laboratory be unable to successfully analyze the initial set of accreditation check samples required, it will have an opportunity to analyze a second set of accreditation check samples to demonstrate analytical proficiency. If the laboratory fails to successfully analyze either of these sets of check samples, the laboratory will be required to wait the minimum mandatory time period—60 days—before reapplying for accreditation. The Agency considers this amount of time to be necessary and adequate for a laboratory to make the changes necessary to improve its performance. At that time, the laboratory will again be required to apply for accreditation and to pay the $3,500-per-accreditation fee in the same manner as it did initially.

Each year, the fee for laboratory accreditation and maintenance of accreditation will be reviewed and a cost analysis performed to determine whether the current nonrefundable accreditation fee established will be adequate to recover the costs of providing the accreditation service for the next year. If it is not, a new fee will be established and the regulations will be amended accordingly.

The agency uses the cumulative summation (CUSUM) statistical method ih evaluating the ability of laboratories to maintain satisfactory performance and four types of CUSUM values are used as performance criteria. On the date the user-fee funded accreditation program goes into effect, the Agency will set all CUSUM values at zero for all laboratories in good standing.

2. Standardizing Values

FSIS uses analytical results obtained from FSIS and accredited laboratories on interlaboratory accreditation maintenance check samples and/or split samples to evaluate a laboratory's performance. Check samples are prepared from a large sample at a central location and sent to accredited laboratories. Split samples are splits of randomly selected official samples that are analyzed by an accredited laboratory and an FSIS laboratory.

The Agency's evaluation of a laboratory is based on the difference of a result obtained by that laboratory for a sample and the mean of results obtained by laboratories that analyzed the same sample. Evaluation is based on statistical summaries of these differences over many samples.

FSIS has amended §§ 318.21 and 381.153 (9 CFR 318.21 and 381.153) of the meat and poultry inspection regulations to change some of the standardizing values used in evaluating laboratory performance.

Review of Comments on the Proposed Rule

Comments on the proposal were received from 17 private laboratories, two State laboratories, one U.S. Congressman and one U.S. Senator (both enclosing constituent correspondence), three trade associations, and two professional associations. Subjects addressed ranged from the issue of charging user fees for laboratory accreditation, to the amount and fairness of the proposed fees, to accreditation standards and procedures. Comments have been grouped by subject, with agency responses, as follows.

Comment: The accredited laboratory program should be financed by appropriations and not by user fees. (Seven comments.)

Response: In the 1990 Farm Bill (7 U.S.C. 138f) as amended, Congress mandated the funding of the Accredited Laboratory Program through the charging of a nonrefundable accreditation fee.

Comment: The amount of the fee proposed is too high. Some laboratories may choose not to participate in the accreditation program. (19 comments.)

Response: The fee required by the 1990 Farm Bill, as amended, must offset the cost of the laboratory accreditation program. The fee proposed is based on the cost of operating the existing program and the estimated participation in the program. The charging of accreditation fees may lead some laboratories to discontinue their participation in the program. FSIS estimates that new enrollments would replace these and that, as a result, the cost of operating the program would not change significantly.

Although FSIS regrets any decision by a laboratory not to participate in the accreditation program for this reason the Agency is bound by the provisions of the Farm Bill to charge an accreditation fee that is based on the costs of the accreditation. The Farm Bill provides for annual adjustment of the fee. The Agency will review each year the level of participation by laboratories and the operating costs to the Agency to assure that the fee charged is fair and in compliance with the legislation.

Comment: The proposed fee is too high compared with fees charged in other, similar, laboratory accreditation programs. (Two comments.)

Response: As previously stated, the basis for the proposed fee is stipulated by the Farm Bill. The Agency does not have latitude in terms of charging a fee. The fee charged is required to offset the costs of the program. The Agency has determined that the fee proposed is necessary to offset the cost of the program.

Comment: The statistical basis for the performance standards proposed is questionable. (Five comments questioned the statistical methodology used; two favored it.)

Response: The Agency is monitoring the analysis of a varying number of check samples and/or split samples for each laboratory. Random numbers of samples are submitted to FSIS over a period of time. Process control statistics are appropriate for evaluating laboratory performance in this kind of situation, and the CUSUM method is among the best of these for this purpose. The comments in general do not call into question the fundamental concepts underlying the agency's approach to measuring laboratory performance. They do, however, criticize the complexity of the statistical treatment of the results and resulting inefficiency in the

Agency's administration of the ALP. The Agency is trying to improve its operations in this area and some of the statistical improvements already achieved, such as revised standardizing values, are reflected in the final rule.

In answer to one commenter who stated that the statistical definition of such terms as CUSUM–V and procedures for evaluating laboratory performance were not given in the proposal, the CUSUM terms were defined. The procedures in the existing regulations for evaluating laboratory performance have been left unchanged by the proposal and this final rule. The proposal focused on changes to the existing regulations. A detailed explanation of the concepts and definitions of the terms used in the existing regulations for CUSUM calculations was published in the 1987 final rule (52 FR 2176). Statistical definitions and the justification of the procedures used in the ALP were presented for public review when the proposal for the existing regulations was published in 1985 (50 FR 15435). The procedures are based on well-known concepts, such as CUSUM, which have been widely used since the 1950's. In addition, a technical addendum, which provided further details on these concepts, was made available for public review in 1985. Thus, FSIS believes that there has been ample opportunity for reviewing and obtaining an understanding of the procedures used.

In answer to one suggestion that a specific range for acceptable results be established for evaluating laboratory performance, the Agency rejected that idea in its 1985 proposal because it could be unfair to participating laboratories. For example, if an acceptable range for protein is plus or minus 1.0 percent from a mean value, then a deviation from the mean of 1.1 percent would count very heavily against a laboratory while one of 1.0 percent would not count at all. That is, in this case, a 0.1 percent marginal difference of results on a single sample, which represents only a scant amount of evidence of a valid difference of performance, would have a very large impact on the assessment of performance. On the other hand, deviations of 0.9 percent and 0.1 percent from the mean would be counted the same, and, similarly, deviations of 1.1 percent and 1.9 percent would be counted the same, and yet these deviations are quite different from one another and would provide evidence of differences in performance between the two laboratories for at least that sample. Thus, instead of using a range of acceptable versus non-acceptable results based on a specific cut-off value, the Agency adopted procedures which use continuous evaluation of performance, so that the effect of a small marginal difference, for example 0.1 percent, has only at most a small effect on the assessment statistics. FSIS believes that using continuous evaluation of performance is more statistically valid and fairer to the participating laboratories than the commenter's proposed procedure of using a specific range of acceptable results.

One commenter remarked that the use of CUSUM's will eventually cause a laboratory to exceed acceptable limits. The Agency has determined that when a CUSUM exceeds acceptable limits, there is deficiency in analytical performance. In addition, a CUSUM penalty for failure to report check sample results could cause a laboratory to exceed acceptable CUSUM limits.

Comment: The proposed fee is unfair to small business. (Seven comments.)

Response: The Agency based its fee strictly on the cost of operating its program. Laboratories with more than a single accreditation must pay more than laboratories with just one accreditation. The Agency determined that smaller laboratories, or smaller entities operating laboratories, would have fewer accreditations than larger entities or laboratories, and hence would pay less in fees. However, in a number of cases, the burden would be comparatively larger for a given small laboratory than for a larger laboratory. Therefore, some small laboratories would choose no longer to participate in the program.

Comment: The fee should be based on the size of a laboratory, annual volume of samples the laboratory analyzes, number of persons employed by the laboratory, or other criteria. (Three comments.)

Response: The 1990 Farm Bill stipulates that the nonrefundable fee charged for laboratory accreditation be established in an amount that offsets the cost of the program administered by the Agency. Such factors as laboratory size, sample volume, and numbers of persons employed by a laboratory do not significantly affect the accreditation status of the laboratory or the costs to FSIS of administering the ADP.

Comment: For the purpose of assessing fees for chemical residue accreditations, accreditation for the analysis of chlorinated hydrocarbons (CHO's) and for that of polychlorinated biphenyls (PCB's) should be considered a single accreditation. (Two comments.)

Response: Different procedures and laboratory equipment are currently in use for analyzing samples for CHC's and PCB's. Samples containing both CHC's and PCB's are subject to different analytical procedures. For this reason, the Agency regards the two compounds as separate classes of chemical residue, requiring different analytical approaches and separate accreditations.

Comment: Laboratories should not be required to reimburse FSIS for on-site inspections of their facilities, or only laboratories that are under probation with respect to accreditation for a type of analysis should be required to reimburse the Agency for an on-site inspection. (Five comments.)

Response: The 1990 Farm Bill specifically requires laboratories to reimburse the Agency "for reasonable travel and other expenses necessary to perform onsite inspections of the laboratory." (7 U.S.C. 138f(c).) The Agency accordingly expects laboratories to provide reimbursements that are adequate to cover the costs of such onsite reviews as may be necessary to assure that the laboratories—whatever their status—are capable of analyzing official meat and poultry samples.

Comment: Laboratories should be permitted to pay the annual fee for each accreditation in quarterly or other periodic installments, rather than in one lump sum. (One comment.)

Response: The 1990 Farm Bill, as amended, requires that laboratories participating in the accreditation program pay the nonrefundable fee for each accreditation sought upon filing an application for accreditation and annually thereafter. The legislation further indicates that the fees collected for operating the accreditation program shall be available immediately and remain available until expended to pay for the program. There is no practicable way for the Agency (and the laboratories) to comply with these provisions of the law without non-refundable lump-sum payment upon application for accreditation and at the time of each succeeding fiscal year in which the laboratories are to be eligible to analyze official samples.

Comment: Laboratories agree with the FSIS decision to reset all CUSUM values to zero upon commencement of the user-fee-funded laboratory accreditation program. (Two comments.) Response: FSIS acknowledges the agreement with the policy established.

Comment: The frequency of check sampling should be reduced from six per year to two per year. (One comment.)

Response: FSIS has determined that the current check sampling frequency is reasonable and necessary to maintain the integrity of the accreditation

program. Under the existing regulations (9 CFR 318.21(b)(3)(v) and (c)(3)(v) and 9 CFR 381.153(b)(3)(v) and (c)(3)(v)), which are modified by the final rule, the Agency determines the appropriate check sampling frequency. Check sampling frequency is under continual review and subject to modification by the Agency as necessary to ensure effective monitoring of laboratory performance.

Comment: The fee charged for laboratory accreditation should be set for at least two years in order to permit laboratories to plan and budget their resources with greater confidence. (Two comments.)

Response: FSIS understands the need for some stability in costs to enable administrators and managers to plan their future activities. At the same time, the 1990 Farm Bill authorizes the Agency to make annual adjustments of the fees charged for laboratory accreditation. It also requires that the accreditation fees offset the cost of accreditation. Thus, the Agency must be allowed to provide for annual adjustment of the fees for the ALP.

Comment: Some laboratories commented that it would be unfair for laboratories to have to pay the accreditation fee again during the same year following the required waiting period after having lost or failed to quality for an accreditation. (Two comments.)

Response: A laboratory that has lost its accreditation or that has never obtained one is unaccredited and must apply before it can become accredited (again). The 1990 Farm Bill, as amended, requires that a laboratory, upon applying for accreditation, pay a fee that is nonrefundable. Charging a laboratory an accreditation fee that has been reduced in some proportion to a fee for the same type of accreditation that has been paid less than a year before would be tantamount to granting a partial refund of the original fee.

The accreditation fee is computed as the average cost per accreditation in operating the ALP under the standards and procedures existing prior to this final rule. The Farm Bill requires that the fee offset the cost of the accreditation program. Administrative and other costs to the program for laboratories that have lost or been refused accreditation and tried again to gain accreditation are higher than those for laboratories that have remained in good standing.

The higher-than-average costs associated with laboratories that lose or are refused accreditation and reapply for accreditation vary from year to year according to the number of such laboratories, which is very small. In fiscal year 1993, only four such laboratories reapplied within the year after they had been refused or lost their accreditation. This number can be expected to vary somewhat in the future, but by how much is difficult to estimate, especially considering that, under this final rule, the ALP is operated under revised standards and procedures intended to result in improved accuracy in determining the quality of a laboratory's performance.

A laboratory's decision to apply or reapply for accreditation is entirely voluntary and is based on its own calculation of benefits and costs and the confidence it has in its ability to meet performance and other qualification standards.

Comment: The 30-day period for commenting on the proposal is inadequate and should be extended. (Two comments.)

Response: The 30-day comment period given is consistent with the time period provided for many other FSIS rulemaking documents. FSIS considers this period of time adequate to afford commenters an opportunity to review the proposal and supply meaningful comments. In accordance with the new Executive Order 12866, however, the Agency will in the future provide a 60 day comment period for all proposed rules.

Comment: One commenter suggested that all testing of official samples be conducted by accredited laboratories and that labor savings be used for other Agency purposes, including offsetting the cost of operating the ALP.

Response: Although the use of accredited laboratories provides certain advantages to both the regulated industry and FSIS, the use of savings in one area of the Agency's operations (laboratory testing) cannot be used in this case to offset costs in another (laboratory accreditation). The FSIS appropriation language in Title I of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act (PL 103–111) requires that user fees be used to offset the costs of the accreditation program. Appropriations for other Agency activities cannot be so used.

Comment: One commenter suggested that FSIS commission an outside, independent laboratory to administer the accreditation program at reasonable cost to the Agency and laboratories.

Response: The purpose of accreditation is to provide laboratory analytical resources additional to those operated by the Agency for the analysis of official samples in support of mandatory meat and poultry inspection. FSIS must prescribe the standards for and maintain administrative control of the analysis of these samples to assure the integrity of its program. Although the Agency can and does contract with outside laboratories for technical support of its activities, including the analysis of official samples, it is the Agency that administers the inspection program and ancillary activities. The Agency cannot, therefore, relinquish its administrative role in laboratory accreditation.

Comment: If user fees are charged for accreditation, the response time and accuracy of the reports from FSIS on official samples must be improved to obviate costs to laboratories for outside quality control services.

Response: FSIS is striving to improve the efficiency of its chemistry laboratory quality service operations, including those associated with laboratory accreditation. This effort is being made irrespective of the accreditation fee requirement, which is a legislative mandate. The decision by a private laboratory to contract with firms providing quality control services is, of course, entirely its own.

In addition to the comments submitted, correspondents asked several questions seeking clarification of the terms of the proposal. For example, one question was whether State government laboratories will be required to maintain accreditation to monitor products in intrastate commerce and, if so, will they be required to pay accreditation fees to remain in the ALP. The answer is that State laboratories that are operated in support of State inspection programs (for meat or poultry products distributed solely in intrastate commerce) are not required to be accredited in the ALP. Those State laboratories that wish to remain in the ALP must pay accreditation fees and those that seek new accreditation must pay fees to become accredited.

A second question was whether results of analysis of split samples are provided to in-plant inspectors. The Agency's answer is "no." This information, which is used for quality assurance, is sent to the Agency's Eastern Laboratory in Athens, Georgia.

A third question was whether the same CUSUM limits would be applied under the new regulations as under the existing regulations. The Agency's answer is "yes."

A fourth question was what were the qualification requirements for laboratory analysts working with samples containing the compounds of interest in the proposal. Qualification requirements of laboratory analysts remain the same

under the new regulations as under the existing regulations.

A fifth question was whether the number of split samples analyzed by laboratories could be limited to a certain maximum number per year. Split sampling frequency is under continual review and subject to modification by the Agency as necessary to assure effective monitoring of laboratory performance.

A sixth question was whether FSIS laboratories participating in the check sample phase of the ALP would be subject to the same requirements for maintaining accreditation as commercial or industrial laboratories. FSIS laboratories are not accredited laboratories but they must adhere to exactly the same standards as accredited laboratories for the same types of analysis.

In addition to comments and questions on the proposed rule, there were a number of suggestions for minor technical changes in the operation of the ALP, such as, for example, improving the timeliness of reports. FSIS is always interested in ways to improve the program and will take these suggestions into consideration. They are not addressed in this rulemaking, however.

The Final Rule

FSIS has concluded that no significant changes based on comments received on the proposal are necessary in the final rule. The Agency is, however, making a number of editorial changes to correct oversights in the proposal. These changes in the amendments to both 9 CFR 318.21 and 9 CFR 381.153 will make certain provisions more clear. A discussion of these changes follows.

The wording of the definition of "comparison mean" is being changed to show clearly that the reference to a case in which two laboratories are analyzing a sample is that of a split sample analysis by an accredited laboratory and an FSIS laboratory. This change alleviates a possible misinterpretation of provisions in the existing regulations that address the four CUSUM procedures (CUSUM's –P, –N, –V, –D).

The wording of the definition of "interlaboratory accreditation maintenance check sample" is being changed to show that the check sample is provided by FSIS and not necessarily by an FSIS laboratory. Check samples may be provided by contract facilities or by those operated by the Agency.

The wording of the definition of "official sample" in 9 CFR 318.21(a) is being changed by substituting the term "Program employee" for "FSIS employee" to show that official samples may be collected by personnel of agencies other than FSIS who perform Federal inspection under cooperative agreements with FSIS.

The wording of the definition of "systematic laboratory difference" is being changed by substituting the term "a negative systematic laboratory difference" for the term "negative systematic values." The terms mean the same thing in the context of the definition but uniform use of the term "systematic laboratory difference" eliminates possible confusion.

The wording of the definition of "variance" is being changed by substituting the term "an expected sample mean" for "a true sample mean." The reworded phrase is more statistically accurate than the original but its intended meaning is the same.

Footnote 2 to Table 1, which follows the list of definitions in paragraph (a), has been clarified to explain that the quantity X is the comparison mean of the sample.

Table 2, which follows Table 1 at the end of the list of definitions in paragraph (a), has been revised to show more clearly the specific classes of chemical residue. The list of individual compounds under "chlorinated hydrocarbons" has been indented. The table shows chlorinated hydrocarbons, polychlorinated biphenyls, arsenic, sulfonamides, and volatile nitrosamine as separate classes of residue. This was the original intention of the Agency in its proposal and reflects current ALP practice. Further, the placement of footnote numbers is being corrected so that a footnote superscript 1 appears next to "Chlorinated Hydrocarbons:"; superscript 2 appears next to "Arsenic," "Sulfonamides," and "Volatile Nitrosamine"; and superscript 3 appears next to "Standardizing value," in the heading for the fourth column of the table. The footnote placements in Table 2 in both 9 CFR 318.21 and 9 CFR 381.153 will now be the same, as was originally intended. In addition, the term "Percent Expected Recoveries (QC)" in the title of the table has been corrected to read "Percent Expected Recoveries (QC and QA)" and a similar correction has been made in the third column heading because reference to quality assurance (QA) was inadvertently omitted.

The introductory texts of paragraph (b)(1) and (c)(1) of 9 CFR 318.21 and 381.153 have been revised to show that applications can be made on designated FSIS forms or otherwise in writing. Paragraphs (b)(1)(i) and (c)(1)(i) of 9 CFR 318.21 and 381.153 have been revised to show that accreditation fees are payable through a billing process. Paragraphs (b)(1)(ii) and (c)(1)(ii) of 9 CFR 318.21 and 381.153 have been revised to show that fees for accreditation are payable by check, bank draft, or money order. The proposal neglected to show explicitly that the fees are "for accreditation" and that they may be paid by check. The proposal inadvertently failed to state that accreditation will not be granted or continued without further procedure when laboratories do not pay accreditation fee(s). Paragraphs (b)(1)(iv) and (c)(1)(iv) of 9 CFR 318.21 and 381.153 have been revised to show that bills for accreditation fees are payable by check, bank draft, or money order. In addition, these paragraphs now include the information that the fees paid are non-refundable and credited to the account from which ALP expenses are paid.

The last sentence in paragraphs (b)(2)(ii) and (c)(2)(ii) of 9 CFR 318.21 and 381.153 is being revised by replacing the words "and all documents" to "and all documentation of corrective action." The new wording is more precise.

Paragraphs (b)(3)(i), (b)(3)(xi), and (c)(3)(xi) of 9 CFR 318.21 and 381.153 are being changed by substituting the words "or to the address designated" for "unless otherwise directed" to show that the meaning intended is that another address than that shown for reporting analytical results could be chosen by FSIS.

Paragraphs (b)(3)(ix) and (c)(3)(ix) of 9 CFR 318.21 and 381.153 have been changed by reversing the word order in the phrase "split samples and interlaboratory accreditation maintenance check samples" and by replacing "and" with "and/or" in paragraph (c)(3)(ix). The phrase now reads "interlaboratory accreditation maintenance check samples and/or split samples."

Paragraph (g)(1) of 9 CFR 318.21 and 381.153 has been changed by the insertion of the phrase "and/or split samples" after the phrase "such interlaboratory accreditation maintenance check samples." The phrasing in these paragraphs now more accurately reflects the current practice of the ALP.

In paragraph (c)(1) of 9 CFR 318.21 and 381.153 introductory text, the phrase "refused or withdrawn" is being changed to "refused or revoked" to make the reference to the status of laboratories applying for chemical residue accreditation consistent with the similar reference in paragraph (b)(1) of 9 CFR 318.21 and 381.153 to laboratories applying for food chemistry accreditation.

Finally, the revised authority citation for 9 CFR 391.5 is being changed to include 21 U.S.C. 451 *et seq.* instead of 21 U.S.C. 460 *et seq.* and also to include 7 CFR 2.17(g) and (i), 2.55. The PPIA citation in both the current 9 CFR part 391 and the proposed revised citation are in error and the error is being corrected. The 7 CFR citations, which are delegations of authority to FSIS, are in the current 9 CFR part 391 authority citation and are intended to be left unchanged.

In summary, to comply with a mandate through amendments to the 1990 Farm Bill, FSIS is charging a fee of $3,500 per accreditation to participants in its voluntary ALP. The Agency has amended 9 CFR 318.21 and 381.153 to implement the fee-based program. Costs associated with the program will be reviewed each year to determine if the fee should be adjusted.

FSIS has also amended 9 CFR 318.21 and 381.153 to change the standardizing values used in evaluating laboratory performance.

List of Subjects

9 CFR Part 318

Accreditation of chemistry laboratories, Meat inspection.

9 CFR Part 381

Accreditation of chemistry laboratories, Poultry products inspection.

9 CFR Part 391

Fees and charges for inspection services, Laboratory accreditation fees.

For the reasons discussed in the preamble, FSIS is amending 9 CFR parts 318, 381, and 391 to read as follows:

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

1. The authority citation for part 318 is revised to read as follows:

Authority: 7 U.S.C. 138f; 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Paragraph (a) of § 318.21 is amended by removing the definition for "Accredited Laboratory Coordinator"; by revising the definitions for "AOAC Methods," "Comparison Mean," "Correct Chemical Residue Identification," "CUSUM," "Interlaboratory Accreditation Maintenance Check Sample," "Minimum Proficiency Level," "Official Sample" "Standardized Difference," "Standardizing Value," and "Systematic Laboratory Difference"; by adding, in alphabetical order, new definitions for "Accreditation," "Refusal of Accreditation," "Revocation of Accreditation," "Standardizing Constant," "Suspension of Accreditation," and "Variance"; and by revising Tables 1 and 2, to read as follows:

§ 318.21 Accreditation of chemistry laboratories.

(a) * * *

Accreditation—Determination by FSIS that a laboratory is qualified to analyze official samples of product subject to regulations in this subchapter and part 381 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 part 381 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.

* * * * *

AOAC methods—Methods of chemical analysis, section 24.001 through 24.071, AOAC International; in the "Official Methods of Analysis of AOAC International," 15th edition 1990; published by AOAC International, 2200 Wilson Boulevard, Suite 400, Arlington, VA 22207. This publication is incorporated by reference and was originally approved by the Director, Office of the Federal Register, on February 19, 1987.[1]

* * * * *

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.

[1] Copies of this publication are on file with the Director, Office of the Federal Register, and may be purchased from AOAC International at the address indicated.

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 such a chemical residue is considered a misidentification. In addition, reporting 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 systemic laboratory difference CUSUM (CUSUM–P)—monitors how consistently an accredited laboratory gets numerically greater results than the comparison mean;

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

(3) Variability CUSUM (CUSUM–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 (CUSUM–D)—monitors the magnitude and frequency of large differences between the results of an accredited laboratory and the comparison mean.

* * * * *

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 are being maintained by the accredited laboratory.

* * * * *

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)

* * * * *

Official Sample—A sample selected by a Program employee in accordance with FSIS procedures for regulatory use.

* * * * *

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

* * * * *

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

* * * * *

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.

* * * * *

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

TABLE 1.—STANDARDIZING VALUES FOR FOOD CHEMISTRY

[By product class and analyte]

Product/Class	Moisture	Protein [1]	Fat [2]	Salt [3]
Cured Pork/Canned Ham	0.50	0.060	0.26 (0.30)	0.127
Ground Beef	0.71	0.060	(0.35)	0.127
Other	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 ppm	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.

3. Paragraph (b)(1) of § 318.21 is revised to read as follows:

§ 318.21 Accreditation of chemistry laboratories.

* * * * *

(b) * * *

(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, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street SW., 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 for 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 (b)(1) by January 12, 1994 (30 days after 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 after the effective date of this section), that the reapplication be accepted by the Agency, and that the laboratory satisfy the terms of the probation.

* * * * *

4. Paragraphs (b)(2) (ii) introductory text, (b)(3)(i), (b)(3)(vi), (b)(3)(vii), (b)(3)(ix) introductory text, (b)(3)(x)(C), (b)(3)(xi) of § 318.21 are revised; and new paragraphs (b)(2)(iv) and (b)(3)(xii) and added to read as follows:

§ 318.21 Accreditation of chemistry laboratories.

* * * * *

(b) * * *

(2) * * *

(ii) Demonstrate acceptable levels of systematic laboratory difference, variability, and individual large deviations in the analyses of moisture, protein, fat, and salt content using AOC 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.

* * * * *

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

(3) * * *

(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 Quality Systems Branch, FSIS Chemistry Division.

* * * * *

(vi) Inform the Accredited Laboratory Program, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street, SW., 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 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.

* * * * *

(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 below.[5]

* * * * *

(x) * * *

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

(xi) Expeditiously 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 Quality Systems Branch, FSIS Chemistry Division. The Federal

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

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

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.

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

* * * * *

5. Footnote 4 to paragraph (b)(2)(ii)(C) of § 318.21 is renumbered as footnote 3; and footnote 5 to paragraph (b)(3)(viii) of § 318.21 is renumbered as footnote 4 and revised to read as follows:

[4] Copies of the "Official Methods of Analysis of AOAC International," 15th edition, 1990, are on file with the Director, Office of the Federal Register, and may be purchased from AOAC International, 2200 Wilson Boulevard, Suite 400, Arlington, VA 22201.

6. Footnote 4 to paragraph (b)(3)(ix)(C) introductory text is renumbered as footnote 6 and revised to read as follows:

[6] *See* footnote 3.

7. Paragraph (c)(1) of § 318.21 is revised to read as follows:

§ 318.21 Accreditation of chemistry laboratories.

* * * * *

(c) * * *

(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, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street, SW., 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 for 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 (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 such 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.

* * * * *

8. Paragraph (c)(2)(ii) introductory text of § 318.21 is revised and a new paragraph (c)(2)(iv) is added to read as follows:

§ 318.21 Accreditation of chemistry laboratories.

* * * * *

(c) * * *

(2) * * *

(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) 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.

* * * * *

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

* * * * *

9. Footnote 9 to paragraph (c)(2)(ii)(C) of § 318.21 is renumbered as footnote 8; footnotes 10 and 11 to § 318.21(c)(3)(ix) introductory text of § 318.21 are renumbered as footnotes 9 and 10, respectively; and footnote 12 to § 318.21 (c)(3)(ix)(A)(*1*) introductory text is renumbered as footnote 11.

10. Footnote 13 to § 318.21(c)(3)(ix)(A)(*2*) introductory text is renumbered as footnote 12 and revised to read:

[12] *See* footnote 11.

11. Footnote 14 to § 318.21(c)(3)(ix)(B) introductory text is renumbered as footnote 13 and footnote 15 to paragraph (c)(3)(ix)(C) introductory text is renumbered as footnote 14.

12. Footnote 16 to § 318.21(c)(3)(xiii)(A)(*1*) introductory text is renumbered as footnote 15 and footnote 17 to paragraph (c)(3)(xiii)(A)(*2*) introductory text is renumbered as footnote16; and the text of each of these footnotes is revised to read "*See* footnote 11."

[7] All statistical computations are rounded to the nearest tenth, except where otherwise noted.

13. Footnote 18 to § 318.21(c)(3)(xiii)(B) introductory text is renumbered as footnote 17 and the text of this footnote is revised to read "*See* footnote 13."

14. Footnote 19 to § 318.21(c)(3)(xiii)(C) introductory text is renumbered as footnote 18.

15. Paragraph (c)(3)(i) of § 318.21 is removed and reserved.

16. Paragraphs (c)(3)(vi), (c)(3)(vii), (c)(3)(ix) introductory text, (c)(3)(x)(C), and (c)(3)(xi) of § 318.21 are revised and a new paragraph (c)(3)(xiv) added to read as follows:

§ 318.21 Accreditation of chemistry laboratories.

* * * * *

(c) * * *

(3) * * *

(vi) Inform the Accredited Laboratory Program, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street, SW., 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 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.

* * * * *

(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 in this paragraph (c)(3)(ix).[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.

* * * * *

(x) * * *

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

(xi) Expeditiously report analytical results of official samples to the Eastern Laboratory, College Station Road, P.O. Box 6085, Athens, GA 30604, or to the address designated by the Quality Systems Branch, FSIS Chemistry Division. 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.

* * * * *

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

* * * * *

17. Paragraphs (g)(1), (g)(2), (g)(3)(ii) of § 318.21 are revised to read as follows:

§ 318.21 Accreditation of chemistry laboratories.

* * * * *

(g) * * *

(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) of this section 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) * * *

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

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

18. The authority citation for part 381 is revised to read as follows:

Authority: 7 U.S.C. 138F; 7 U.S.C. 450; 21 U.S.C. 451–470; 7 CFR 2.17, 2.55.

19. Paragraph (a) of § 381.153 is amended by removing the definitions for "Accredited Laboratory Coordinator"; by revising the definitions for "AOAC Methods," "Comparison Mean," "Correct Chemical Residue Identification," "CUSUM," "Interlaboratory Accreditation Maintenance Check Sample," "Minimum Proficiency Level," "Official Sample," "Standardized Difference," "Standardizing Value," and "Systematic Laboratory Difference"; by adding, in alphabetical order, new definitions for "Accreditation," "Refusal of Accreditation," "Revocation of Accreditation," "Standardizing Constant," "Suspension of Accreditation," and "Variance"; and by revising Tables 1 and 2 to read as follows:

§ 381.153 Accreditation of chemistry laboratories.

(a) * * *

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.

* * * * *

AOAC methods—Methods of chemical analysis, section 24.001 through 24.071, AOAC International; in the "Official Methods of Analysis of AOAC International," 15th edition 1990; published by AOAC International, 2200 Wilson Boulevard, Suite 400, Arlington, VA 22207. This publication is incorporated by reference and was

originally approved by the Director, Office of the Federal Register, on February 19, 1987.[1]

* * * * *

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, reporting 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 (CUSUM–P)—monitors how consistently an accredited laboratory gets numerically greater results than the comparison mean;

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

(3) Variability CUSUM (CUSUM–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 (CUSUM–D)—monitors the magnitude and frequency of large differences between the results of an accredited laboratory and the comparison mean.

* * * * *

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 are being maintained by the accredited laboratory.

* * * * *

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)

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

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.

* * * * *

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.

[1] Copies of this publication are on file with the Director, Office of the Federal Register, and may be purchased from AOAC International at the address indicated.

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.

20. Paragraph (b)(1) of § 381.153 is revised to read as follows:

§ 381.153 Accreditation of chemistry laboratories.

* * * * *

(b) * * *

(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, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street SW., 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.

* * * * *

21. Paragraphs (b)(2)(ii) introductory text, (b)(3)(i), (b)(3)(vi), (b)(3)(vii), (b)(3)(ix), introductory text, (b)(3)(x)(C), (b)(3)(xi) of § 381.152 are revised; and new paragraphs (b)(2)(iv) and (b)(3)(xii) are added to read as follows:

§ 381.153 Accreditation of chemistry laboratories.

* * * * *

(b) * * *

(2) * * *

(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.

* * * * *

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

(3) * * *

(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 Quality Systems Branch, FSIS Chemistry Division.

* * * * *

(vi) Inform the Accredited Laboratory Program, Room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street, SW., 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.

* * * * *

(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]

* * * * *

(x) * * *

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

(xi) Expeditiously 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 Quality Systems Branch, FSIS Chemistry Division. 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.

* * * * *

22. Footnote 4 to paragraph (b)(2)(ii)(C) of § 381.153 is renumbered as footnote 3; and footnote 5 to paragraph (b)(3)(viii) of § 381.153 is renumbered as footnote 4 and revised to read as follows:

[4] Copies of the "Official Methods of Analysis of AOAC International," 15th edition, 1990, are on file with the Director, Office of the Federal Register, and may be purchased from AOAC International, 2200 Wilson Boulevard, Suite 400, Arlington, VA 22201.

23. Footnote 6 to § 381.153(b)(3)(ix) introductory text is renumbered as footnote 5 and footnote 4 to paragraph (b)(3)(ix)(C) introductory text is renumbered as footnote 6 and revised to read as follows:

[6] *See* footnote 3.

24. Paragraph (c)(1) of § 381.153 is revised to read as follows:

§ 381.153 Accreditation of chemistry laboratories.

* * * * *

(c) * * *

(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, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street, SW., 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

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

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

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.

* * * * *

25. Paragraph (c)(2)(ii) introductory text of § 381.153 is revised and a new paragraph (c)(2)(iv) is added to read as follows:

§ 381.153 Accreditation of chemistry laboratories.

* * * * *

(c) * * *

(2) * * *

(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.

* * * * *

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

* * * * *

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

26. Footnote 9 to paragraph (c)(2)(ii)(C) of § 381.153 is renumbered as footnote 8; footnotes 10 and 11 to § 381.153 (c)(3)(ix) introductory text are renumbered as footnotes 9 and 10, respectively; and footnote 12 to § 381.153 (c)(3)(ix)(A)(*1*) introductory text is renumbered as footnote 11.

27. Footnote 13 to § 381.153 (c)(3)(ix)(A)(*2*) introductory text is renumbered as footnote 12 and revised to read:

[12] *See* footnote 11.

28. Footnote 14 to § 381.153 (c)(3)(ix)(B) introductory text is renumbered as footnote 13 and footnote 15 to paragraph (c)(3)(ix)(C) introductory text of § 381.153 is renumbered as footnote 14.

29. Footnote 16 to § 381.153 (c)(3)(xiii)(A)(*1*) introductory text is renumbered as footnote 15 and footnote 17 to paragraph (c)(3)(xiii)(A)(*2*) introductory text is renumbered as footnote 16; and the text of each of these footnotes is revised to read, "*See* footnote 11."

30. Footnote 18 to § 381.153 (c)(3)(xiii)(B) introductory text is renumbered as footnote 17 and the text of this footnote is revised to read, "*See* footnote 13."

31. Footnote 19 to § 381.153 (c)(3)(xiii)(C) is renumbered as footnote 18.

32. Paragraph (c)(3)(i) of § 381.153 is removed and reserved.

33. Paragraphs (c)(3)(vi), (c)(3)(vii), (c)(3)(ix) introductory text, (c)(3)(x)(C), and (c)(3)(xi) of § 381.153 are revised and a new paragraph (c)(3)(xiv) added to read as follows:

§ 381.153 Accreditation of chemistry laboratories.

* * * * *

(c) * * *

(3) * * *

(vi) Inform the Accredited Laboratory Program, Room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street, SW., 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.

* * * * *

(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.

* * * * *

(x) * * *

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

(xi) Expeditiously 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 Quality Systems Branch, FSIS Chemistry Division. 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.

* * * * *

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

* * * * *

34. Paragraphs (g)(1), (g)(2), (g)(3)(ii) of § 381.153 are revised to read as follows:

§ 381.153 Accreditation of chemistry laboratories.

* * * * *

(g) * * *

(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

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

[10] An 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.

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) * * *

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

* * * * *

PART 391—FEES AND CHARGES FOR INSPECTION SERVICES AND LABORATORY ACCREDITATION

35. The part heading is revised to read as shown above.

36. The authority citation for part 391 is revised to read as follows:

Authority: 7 U.S.C. 138f; 7 U.S.C. 394, 1622, 1624; 21 U.S.C. 451 *et seq.*; 21 U.S.C. 601–695; 7 CFR 2.17 (g) and (i), 2.55.

37. Part 391 is amended by adding a new § 391.5 to read as follows:

§ 391.5 Laboratory accreditation fees.

(a) The annual fee for the initial accreditation and maintenance of accreditation provided pursuant to §§ 318.21 and 381.153 shall be $3,500 per accreditation.

(b) Laboratories that request special onsite inspections shall pay FSIS the actual cost of reasonable travel and other expenses necessary to perform the unscheduled or non-routine onsite inspections.

Done at Washington, DC, on December 6, 1993.

Eugene Branstool,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–30211 Filed 12–10–93; 8:45 am]

BILLING CODE 3410–DM–M

federal register

Monday
December 13, 1993

Part IV

Department of the Interior

Bureau of Indian Affairs

Indian Gaming; St. Regis Mohawk Tribe and State of New York; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming; St. Regis Mohawk Tribe and State of New York

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of approved Tribal-State Compact.

SUMMARY: Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the Federal Register, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gaming on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved the Tribal State Compact Between the St. Regis Mohawk Tribe and the State of New York, which was executed on June 9, 1993.

DATES: This action is effective December 13, 1993.

FOR FURTHER INFORMATION CONTACT: Hilda Manuel, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, DC 20240, (202) 219–4066.

Dated: December 4, 1993.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 93–30377 Filed 12–10–93; 8:45 am]

BILLING CODE 4310–02–P

federal register

Monday
December 13, 1993

Part V

Federal Emergency Management Agency

Fee for Services to Support FEMA's Offsite Radiological Emergency Preparedness (REP) Program; Notice

FEDERAL EMERGENCY MANAGEMENT AGENCY

Fee for Services to Support FEMA's Offsite Radiological Emergency Preparedness (REP) Program

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: In accordance with FEMA's interim rule, 44 CFR part 354, published in the **Federal Register** on July 1, 1993 (58 FR 35770), FEMA has established a fiscal year (FY) 1993 hourly rate of $122.88 for assessing and collecting fees from Nuclear Regulatory Commission (NRC) licensees for services provided by FEMA personnel for FEMA's REP Program.

DATES: The user fee hourly rate is effective for FY 1993 (October 1, 1992 to September 30, 1993).

FOR FURTHER INFORMATION CONTACT: Linda Vasta, Chief, Regulatory Services Coordination Unit, Preparedness, Training and Exercises Directorate, Federal Emergency Management Agency, Washington, DC 20472 (202) 646–4570.

SUPPLEMENTARY INFORMATION: As authorized by Public Law 102–389 (106 Stat. 1571–1619), an hourly user fee rate of $122.88 will be charged to NRC licensees of commercial nuclear power plants for all site-specific and generic services provided by FEMA personnel for FEMA's REP Program under the interim rule, 44 CFR part 354, published in the **Federal Register** on July 1, 1993, 58 FR 35770. All funds collected under this rule will be deposited in the U.S. Department of the Treasury to offset appropriated funds obligated by FEMA for its REP Program.

The hourly rate is established on the basis of the methodology set forth in the referenced FEMA interim rule at 44 CFR 354.4(a), "Determination of costs for FEMA personnel," and will be used to assess and collect fees for site-specific and generic services rendered by FEMA personnel. For FY 1993, the total Salaries and Expenses funds obligated for FY 1993 was $5,893,031.94 and the total number of site-specific hours expended was 47,958.5. Applying the formula set forth in the interim rule, the FY 1993 hourly rate is $122.88.

The establishment of this hourly rate is intended only to address charges for services provided by FEMA personnel, not charges for services provided by FEMA contractors. Contractor services will be charged under the interim rule at 44 CFR 354.4 (b) and (c) for the recovery of appropriated funds obligated for the Emergency Management Planning and Assistance (EMPA) portion of FEMA's REP Program budget.

In light of FEMA's reorganization, effective November 28, 1993, and the NRC's reexamination of its own user fee policy and rule, which FEMA used as a model for its interim rule, FEMA does not plan to publish a final rule at this time. Comments submitted in response to the publication of the interim rule, including those addressing the determination of the hourly rate and its use in assessing user fees, will be addressed and incorporated in either a final rule or a new proposed rule.

Dated: December 3, 1993.

Dennis H. Kwiatkowski,

Deputy Associate Director.

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