UNITED STATES FOOD & DRUG ADMINISTRATION

Laboratory Accreditation for Analyses of Foods

OMB Control No. 0910-NEW

RIN: 0910-AH31

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

   This information collection supports agency rulemaking. The FDA Food Safety Modernization Act ("FSMA") (Public Law 111-353) section 202(a) added section 422 (codified at 21 U.S.C. 350k) to the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Section 422 of the FD&C Act requires FDA to establish a program for the testing of food by accredited laboratories; to establish a publicly available registry of recognized accreditation bodies and laboratories recognized by an accreditation body; and to require reports to the Secretary of any changes that would affect the recognition of such accreditation body or the accreditation of such laboratory. Accordingly, we are proposing regulations in 21 CFR part 1 subpart R: *Laboratory Accreditation for Analyses of Foods*. Respondents to the information collection are accreditation bodies seeking recognition from FDA, recognized accreditation bodies, laboratories seeking accreditation from recognized accreditation bodies, and accredited laboratories. Participation in this program is voluntary for laboratories and accreditation bodies; however only recognized accreditation bodies would be able to accredit laboratories to conduct food testing as specified in the regulations.

   We therefore request OMB approval for the information collection provisions found in proposed 21 CFR part 1; subpart R, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

   Establishing the laboratory accreditation program will help fulfill FDA's mandate to ensure the safety of the U.S. food supply and protect U.S. consumers by administering appropriate oversight of certain food testing that is of importance to public health. It will also help ensure that the testing is done in accordance with appropriate model standards which will help produce consistently reliable and valid test results.

3. Use of Improved Information Technology and Burden Reduction

   The proposed rule would require respondents to electronically maintain and submit certain test results, reports, notifications, and other records to FDA. We are currently planning and developing information technology improvements to receive, process, and review the information covered by the proposed regulations.

4. Efforts to Identify Duplication and Use of Similar Information

   We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

   Although we estimate that all respondents to the proposed information collection are small businesses, we do not believe it poses undue burden on those entities. At the same time, FDA offers small business assistance through resources on our website at: www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

   The information collection schedule is consistent with current statutory and proposed regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   Section 422(a)(7) of the FD&C Act provides that FDA shall reevaluate accreditation bodies recognized under the program no less than once every 5 years. Accordingly, the proposed rule provides for such a record retention schedule in 21 CFR 1.1124.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 44 U.S.C. 3505(c)(2)(B), we published a notice of proposed rulemaking in the Federal Register of November 4, 2019 (84 FR 59452) soliciting public comment on the information collection. In response to requests from interested parties, FDA extended the comment period to July 6, 2020 (see 85 FR 11893 and 85 FR 19114) to provide additional time for public comment. The agency is continuing to evaluate public comments received and any impact on the proposed information collection.

   On our website we communicate with interested persons regarding implementation of FSMA including the Laboratory Accreditation for Analyses of Foods program. We invite visitors to visit: www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma.

9. Explanation of Any Payment or Gift to Respondents

   This information collection does not provide for payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Confidential commercial information is protected from disclosure under FOIA in accordance with sections 5 U.S.C. 552(a) and (b) and by 21 CFR part 20. To the extent that § 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1--Estimated Annual Reporting Burden

21 CFR Part 1, Subpart R citation; IC Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§§ 1.1113/1.1128(a); Accreditation bodies (ABs) application for recognition (one-time submission)	18	1	18	20	360
§ 1.1123(b) and (c); ABs--general reporting requirements	18	12	216	.5 (30 mins.)	108
§ 1.1128(b); ABs--application for renewal of recognition	18	1	18	3.6	64.8
§§ 1.1138 and 1.1158; laboratories--submission of application for accreditation (one-time submission)	48	1	48	20	960
§ 1.1152(c)(1) and (2); laboratories--Submission of sampling plan, sample collection report, and sampler qualifications	48	88.48	4,247	1.75	7,432
§ 1.1152(d); laboratories--qualification to submit abridged analytical reports (one-time submission).	48	10	480	2	960
§ 1. 1152(c)(3); laboratories--abridged analytical reports submissions	48	88.48	4,247	1.16	4,927
§ 1.1152(c)(4) and (5); laboratories--validation and verification studies submissions	9	1	9	.25 (15 mins.)	2.25
§ 1.1152(i); laboratories--advance notice of sampling submissions	48	3	144	1.5	216
§ 1.1152(j); laboratories--immediate notification	48	1.5	72	.25	18
§§ 1.1165; 1.1171; 1.1173; and 1.1174; requests in response to FDA action	1	1	1	1	1
Total			0		0

Reporting Burden: Consistent with figures discussed in our Preliminary Regulatory Impact Analysis (PRIA) (see Section II.D, Number of Entities), we estimate a total of 66 respondents. We estimate that five to 80 accreditation bodies would apply for FDA recognition under the rule, with a mean distribution of 17.5 accreditation bodies. For this analysis we round up to 18. Similarly, we estimate of a mean of 48 laboratories will participate in the program, for a total of 66 respondents to the information collection. The reporting burden includes a burden of 8,820 hours associated with one-time submissions. In this analysis, we annualize the one-time submission burden using a 3-year period horizon and zero percent discount rate, for an annualized one-time reporting burden of 2,940 hours. Cumulatively, this results in a total annual reporting burden of 15,049.05 hours.

Proposed § 1.1128(a) would require accreditation bodies that wish to be recognized to submit an application to FDA that demonstrates their qualifications (those qualifications are specified by proposed § 1.1113) to accredit laboratories under this rule. We estimate this process would take one analyst between 40 and 80 hours to compile all the relevant information, prepare for an assessment, and complete initial application process, and submit the application. For this analysis we assume a middle value of 60 hours. Also for this analysis, we use a 3-year period horizon and zero percent discount rate to convert the one-time submission burden to an annualized figure (*i.e.*, 60 hours ÷ by 3 = 20 hours). Annually this results in 360 hours of burden for initial applications submitted by 18 accreditation bodies (18 applications × 20 hours per application), as reflected in row 1.

Proposed § 1.1123 would require a recognized accreditation body to report information, including significant changes affecting its accreditation program or the accreditation status of laboratories it accredits, and ensure FDA has access to these and other records. We estimate recognized accreditation bodies would incur a burden of 1 hour per month, or 12 hours per year, complying with both the reporting requirements of proposed § 1.1123 and the recordkeeping requirements of proposed § 1.1124. For this analysis, we identify recordkeeping and reporting burdens separately and assume 6 of the 12 hours (*i.e.*, 30 minutes per month) would be spent meeting the reporting requirements of § 1.1123. Annually, this results in 108 hours (18 recognized accreditation bodies × 6 hours per year), as reflected in row 2.

Proposed § 1.1128(b) would require accreditation bodies to apply for renewal of recognition at least every 5 years. We believe renewal would take less time than an initial application because much of the information will have already been compiled and therefore assume between 20 and 40 hours. For this analysis we use a middle value and calculate that each recognized accreditation body will spend 30 hours every 5 years to complete and submit an application for renewal of its recognition. This results in 6 hours per year (30 hours ÷ 5 years) for each accreditation body. Because we use a 3-year period horizon and zero percent discount rate for this analysis, we annualize that figure to three-fifths or 3.6. We multiply this figure by 18 accreditations bodies for a total of 64.8 hours annually for the submission of renewal of applications (18 applications × 3.6 hours per application), as reflected in row 3.

Proposed § 1.1158 would require a laboratory seeking accreditation to submit an application for accreditation to a recognized accreditation body, demonstrating that it meets the requirements for accreditation under the proposed rule (those requirements are specified by proposed § 1.1138). We estimate 48 laboratories will apply and assume it would take one analyst an average of 60 hours to compile all the relevant information, however we regard the burden as a one-time burden and therefore have annualized it by 3 years (20 hours annually). This results in an annual reporting burden for initial applications by 48 laboratories would be 960 hours (48 applications × 20 hours per application), as reflected in row 4.

Proposed § 1.1152(a) through (i) would require accredited laboratories to submit testing results of testing conducted under the program and include supporting documentation. However, only a percentage of the testing identified in the PRIA would be defined as information collection under the PRA. For this analysis we assume a mean figure of 4,197, as the basis for factoring a corresponding information collection burden. This figure is derived using lower and upper bound estimates of submissions we expect under the rule. To allow for adjustment and potential increase we have added a count of 50 submissions for a total of 4,247.

Proposed § 1.1152(c)(1) would require accredited laboratories to obtain, or develop, and submit a sample collection plan and sample collection report (the contents of which would be prescribed by proposed § 1.1149) with each test result. Under proposed § 1.1152(c)(2), laboratories would also be required to include documentation of the sampler's qualifications the first time the sampler collects a sample, or when the sampler's qualifications have significantly changed. We assume that it would take 30 minutes to 1 hour to compile a sampling plan, 30 minutes to one hour to compile a sample collection report, and an average of 10 to 20 minutes to obtain the sampling plan, sample collection report, and sampler's credentials. Using a middle value of 1.5 hours to generate the sampling plan and the sample collection report, and a middle value of 15 minutes (.25 hours) to obtain those two documents and documentation of the sampler's qualifications, we calculate a total of time per test results of 1.75 hours (1.5 + .25). When multiplied together the total reporting burden for the submission of sampling plans, sample collection reports, and sampler credential requirements (48 accredited laboratories × 88.48 sampling plans and sample collection reports × 1.75 hours) is 7,432 hours, as reflected in row 5.

Proposed § 1.1152(d) would allow accredited laboratories to qualify to submit abridged analytical reports in lieu of full analytical reports. At this time we expect this would be a one-time burden, but we may revisit this assumption in the future based on actual disqualification rates if the proposed rule is finalized and implemented. We assume that each accredited laboratory would submit 10 consecutive full analytical reports to qualify to submit abbreviated reports. We also assume accredited laboratories spend 4 to 8 hours to compile and submit a full analytical report, and we use the middle value of 6 hours for this analysis. For initial or one-time burdens we use a 3-year period horizon and zero percent discount rate to convert the one-time burden to an annualized figure (2 hours). When multiplied together, this results in a total reporting burden for the accredited laboratories to qualify to submit abridged analytical reports of 960 hours (48 laboratories × 10 full analytical reports each × 2 hours per analytical report), as reflected in row 6.

After an accredited laboratory qualifies to submit abridged analytical reports, we assume it would submit abridged analytical reports to us thereafter. We may revisit this assumption in the future based on actual disqualification rates if the proposed rule is finalized and implemented. We estimate the burden to compile and submit an abridged analytical report to be between 25 percent and 33 percent of the burden of compiling and submitting a full analytical report, and we use a middle value of 29 percent here. Thus, using these figures we calculate it would take an accredited laboratory 1.74 hours to compile and submit an abridged analytical report (29 percent × 6 hours). This results in an annual total reporting burden for the 48 accredited laboratories to compile and submit abridged analytical reports of approximately 4,927 hours (48 laboratories × 88.48 abridged analytical reports × 1.16 hours per abridged analytical report), as reflected in row 7.

The proposed rule would also require the participating lab to submit verification and validation studies to FDA as part of an analytical report, or to an accreditation body as a prerequisite for participation in the labs program. The ISO/IEC 17025 standard requires the use of validated and verified methods for testing foods. However, the proposed rule, if finalized, would require additional verification studies over and above the requirements of ISO/IEC 17025. Additional studies may include information to verify that a method previously validated for a specific food item is also valid for a different food item, in what is called a "matrix extension." We estimate that the additional time burden of requiring laboratories to submit verification studies such as matrix extensions under this proposed rule to be a middle value of approximately 3 percent of the time burden incurred by laboratories to maintain accreditation to ISO/IEC 17025 (the PRIA estimates a range of 1 percent to 5 percent). In the PRIA we also note that internal FDA experts suggest that between 5 percent and 30 percent of import food testing results require verification studies such as matrix extensions. We use a middle value of 17.5 percent for this analysis.

With regard to validation requirements, we assume that methods used to test shell eggs, sprouts, and bottled water are either already validated or the costs to doing so would be included in the costs to maintain accreditation to the ISO/IEC 17025 standard. Consequently, we assume that shell eggs, sprouts, and bottled water producers would incur no burden from this requirement beyond the burden of the proposed rule's requirements to meet the validation requirements of ISO/IEC 17025.

We estimate the time required to perform a matrix extension is a middle value of 34 hours (the PRIA estimates a range of 22 to 46 hours). We do not distinguish between the burden of reporting the study and the burden of conducting the study. We assume 25 percent of the 34 hours (8.5 hours) is attributable to the associated reporting burden. Because we estimate that the additional time burden of requiring laboratories to submit verification studies such as matrix extensions under this proposed rule would be approximately 3 percent of the time burden incurred by laboratories to maintain accreditation to ISO 17025, we multiply 8.5 hours by 3 percent to get the additional reporting burden of .255 hours (15.3 minutes, which we round to 15 minutes, which is .25 hours) per study imposed by the verification study submission requirements of the proposed rule. To estimate the number of test results that would require matrix extensions, we multiply the number of import testing results that would

be submitted to us under this rule annually that are subject to PRA requirements (50) by the share of test results submitted to us for import food testing that require matrix extensions (17.5 percent), for a total of 8.75 matrix extensions per year. This equates to an average of .17708 matrix extensions per accredited laboratory (8.5 ÷ 48). Because the number of respondents and the annual responses per respondent in a PRA analysis must be whole numbers, we instead estimate that nine accredited laboratories (48 × .17708, rounded to 9 from 8.5) will submit one full verification study to FDA annually. Therefore, the annual reporting burden of requiring the submission of validation and verification studies under this proposed rule is 2.25 hours (9 accredited laboratories × 1 verification studies × .25 hours per study), as reflected in row 8.

Proposed § 1.1152(i) would provide that, under certain circumstances, FDA may require one or more accredited laboratories to submit an advance notice of sampling to FDA before each of the next several occasions that the sampler will a collect a sample that the accredited laboratory will analyze under this program. We assume that it would take a laboratory analyst between 1 and 2 hours to compile the required information and submit the information, and we assume that between one percent and five percent of all test results submitted annually under this program would be subject to the notice of sampling requirement. For this analysis we assume middle values of 1.5 hours and three percent, respectively. Thus, we estimate that 127.41 test results (4,247 × 3%) would require submission of advance notice of sampling under the proposed rule. For this analysis we assume that each of the estimated 48 accredited laboratories would be required to submit three notices of advance sampling annually under the proposed rule (127.41 ÷ 48 = 2.65; rounded to 3). Thus, the annual reporting burden on accredited laboratories due to the proposed advance notice of sampling requirement would be 216 hours (48 laboratories × 3 advance notices of sampling × 1.5 hours), as reflected in row 9.

Proposed § 1.1152(j) would require accredited laboratories to notify FDA and the accreditation body of any changes that affect the laboratory's accreditation. Note, however, that under § 1.1123(c), recognized accreditation bodies also have a duty to immediately notify FDA of changes in an accredited laboratory's status. Thus, an accredited laboratory is not required to notify FDA of changes that fall under § 1.1123(c). To be conservative we estimate that every lab that participates will have some change about which it must notify its accreditation body, and for half of those changes the accredited laboratory will also need to notify FDA. We estimate it will take an accredited laboratory 15 minutes per notification. Thus we estimate the burden associated with § 1.1152(j) would be 18 hours (48 accredited laboratories × 1.5 notifications × 0.25 hours per notification), as reflected in row 10.

Proposed §§ 1.1165, 1.1171, 1.1173, and 1.1174 provide for requests to FDA. Specifically, § 1.1165 provides for requests for reinstatement of accreditation; § 1.1171 provides for requests for reconsideration of denials; and §§ 1.1173 and 1.1174 provide for requests for hearings. Because this is a new collection, we are estimating a cumulative total of 1 respondent and 1 burden hour, as reflected in row 11, however we invite specific comment in this regard. Upon implementation of any final rule, we will reevaluate our burden estimate in light of overall submissions to the Agency and public comments received.

Table 2--Estimated Annual Recordkeeping Burden

Proposed 21 CFR part 1, subpart R; IC Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
§§ 1.1113 and 1.1118; recordkeeping associated with ISO/IEC 17011	18	1	18	1	18
§ 1.1124; ABs--additional recordkeeping requirements	18	1	18	6	108
§ 1.1138; laboratories--becoming accredited to ISO/IEC 17025 (one-time)	5	1	5	91.06	455.35
§ 1.1146; laboratories--maintaining ISO/IEC 17025 accreditation	48	1	48	889.53	42,697.44
Total			0		43,278.79

Recordkeeping Burden: Recordkeeping requirements associated with the proposed rule include a one-time burden of 1,366.05 hours and annual burden of 41,912.74 hours. In this analysis, we annualize the one-time recordkeeping burden using a 3-year period horizon and zero percent discount rate, for an annualized one-time recordkeeping burden of 455.35. Cumulatively, we estimate an annual recordkeeping burden under this proposed rule of 43,278.79 hours.

Proposed § 1.1113 and § 1.1118 would require accreditation bodies to meet the requirements of ISO/IEC 17011 to be recognized. While ISO/IEC 17011 includes recordkeeping requirements, as noted above we estimate that all of the 18 accreditation bodies that would become recognized under the proposed rule currently adhere to ISO/IEC 17011. We therefore regard these activities as usual and customary, however we include a place holder of one response and one burden hour for each respondent, as reflected in row 1.

Proposed § 1.1124, however, provides for the maintenance of certain records in addition to those required by ISO/IEC 17011. We estimate recognized accreditation bodies would incur a burden of 12 hours per year to comply with both the recordkeeping requirements of proposed § 1.1124 and the reporting requirements of proposed § 1.1123. For this analysis, we identify the recordkeeping and reporting burdens separately, assuming six of those 12 annual hours would be spent complying with the recordkeeping requirements of proposed § 1.1124. Thus, the annual recordkeeping burden for the 18 recognized accreditation bodies to meet the additional recordkeeping requirements of proposed § 1.1124 would be 108 hours, as reflected in row 2.

Proposed § 1.1138 would require laboratories to meet certain requirements of ISO/IEC 17025, including its recordkeeping requirements, to be accredited under the proposed rule. We estimate that between two to eight laboratories not currently accredited to ISO/IEC 17025 would become accredited. We use a middle estimate of five laboratories and also estimate that it would take a mean of 91.06 hours for the associated recordkeeping activities. This results in an annualized burden of 455.35, as reflected in row 3.

Proposed § 1.1146 would require laboratories to maintain conformance with ISO/IEC 17025, including its recordkeeping requirements. Based on available data, and as discussed in our PRIA, we estimate a mean of 889.53 hours for this recordkeeping. This results in an annual burden of 42,697.44 hours, as reflected in row 4.

12b. Annualized Cost Burden Estimate

We estimate that the annualized reporting cost burden under the proposed rule would be $1,916,962.09 (see Table 3 below) and the annualized recordkeeping cost burden under the proposed rule would be $347,526.70 (see Table 4 below), for a total annualized information collection burden cost estimate of $2,264,488.79.

We believe that recordkeeping and reporting requirements of the proposed rule are conducted by personnel with differing wage rates, in accordance with the PRIA. With respect to the reporting burden on accreditation bodies under the proposed rule:

- We expect the reporting burden on accreditation bodies under proposed § 1.1128(a) (the application for recognition) and proposed § 1.1128(b) (the application for renewal of recognition) to be conducted by personnel at the level of a Lawyer (see PRIA at p. 73), as reported in the Bureau of Labor Statistics, May 2017 National Occupational Survey under occupation code 23-1011. We multiply the wage by two to account for overhead to obtain a fully loaded hourly wage of $136.44 for a Lawyer.

- We expect the reporting burden on accreditation bodies under proposed § 1.1123(b) (the general reporting requirements) to be conducted by accreditation body personnel at the level of Microbiologist (see PRIA at p. 77), as reported in the Bureau of Labor Statistics, May 2017 National Occupational Survey under occupation code 19-1022. We multiply the wage by two to account for overhead to obtain a fully loaded hourly wage of $75.38 for a Microbiologist.

With respect to the reporting burden on laboratories under the proposed rule:

- We expect the reporting burden on laboratories under proposed § 1.1158 (the application for accreditation) to be conducted by laboratory personnel at the level of a Food Scientist and Technologist (see PRIA at p. 80), as reported in the Bureau of Labor Statistics, May 2017 National Occupational Survey under occupation code 11-9121, at the fully loaded hourly wage of $69.22.

- We expect the reporting burden on laboratories under proposed §§ 1.1152(c), (d), and (i) (submission of sampling plans, sample collection reports, sampler qualifications, analytical reports (including qualifying to submit abridged analytical reports and submission of abridged analytical reports), validation studies, verification studies, and advance notices of sampling) to be conducted by laboratory personnel at the level of a Food Scientist and Technologist (see PRIA at p. 91), as reported in the Bureau of Labor Statistics, May 2017 National Occupational Survey under occupation code 11-

9121. We multiply the wage by two to account for overhead to obtain a fully loaded hourly wage of $69.22 for a Food Scientist and Technologist.

With respect to the recordkeeping burden on accreditation bodies under the proposed rule:

- We expect the recordkeeping burden on accreditation bodies under proposed § 1.1124 (the recordkeeping requirements in addition to those of ISO/IEC 17011) to be conducted by accreditation body personnel at the level of Microbiologist (see PRIA at p. 77), as reported in the Bureau of Labor Statistics, May 2017 National Occupational Survey under occupation code 19-1022, at the fully loaded hourly wage of $75.38.

With respect to the recordkeeping burden on laboratories under the proposed rule:

- We expect the recordkeeping burden on laboratories under proposed § 1.1138 (becoming accredited to ISO/IEC 17025) and § 1.1146 (maintaining accreditation to ISO/IEC 17025) to be conducted by laboratory personnel at the level of Food Scientist and Technologist (in accordance with the PRIA's assumptions about who would conduct analytical activities for accredited laboratories, see PRIA at p. 87), as reported in the Bureau of Labor Statistics, May 2017 National Occupational Survey under occupation code 11-9121, at the fully loaded hourly wage of $69.22.

Table 3--Estimated Annual Reporting Burden Cost

Type of Respondent	**Total Burden Hours**	**Fully Loaded Hourly Wage**	**Total Respondent Costs**
Lawyer	424.80	$136.44	$57,959.71
Microbiologist	928	$75.38	$69,952.64
Food Scientists and Technologist	25,845.85	$69.22	$1,789,049.74
Total			**$1,916,962.09**

Table 4--Estimated Annual Recordkeeping Burden Cost

Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Microbiologist	108	$75.38	$8,141.04
Food Scientists and Technologist	4,447.63	$69.22	$339,385.66
Total			**$347,526.70**

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

For estimating the costs to FDA that would be imposed by the proposed rule we use a fully loaded hourly wage of $116.75, which is derived from the 2018 annual fully loaded salary for agency personnel of $242,838 used by FDA for budgeting purposes. We estimate the mean

annualized cost to FDA imposed by the proposed rule, annualized at seven percent over 10 years, to be $1,308,178.00.

15. Explanation for Program Changes or Adjustments

This is a new information collection request.

16. Plans for Tabulation and Publication and Project Time Schedule

Upon implementation of a final rule, and consistent with requirements set forth in section 422(a)(1)(B) of the FD&C Act and proposed 21 CFR 1.1109, FDA will make available on its website a publicly available registry of recognized accreditation bodies and accredited laboratories.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

As described above in Question 3, upon implementation of a final rule, respondents will need to electronically maintain and submit certain test results, reports, notifications, and other records to FDA. The OMB control number and expiration date will be displayed in connection with the information technology components (e.g., submission forms, website) used to implement this program.

However, the proposed regulations also seek to incorporate proprietary standards, and the OMB control number and expiration date would not appear on those documents themselves. We explain in further detail below which standards will be incorporated by reference, as well as FDA's work to ensure public availability of these standards during the comment period.

If finalized, the regulations will incorporate by reference the following proprietary standard(s):

- ISO/ IEC 17011:2017, "*Conformity Assessment--Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*," Second edition, November 2017; and

- ISO/IEC 17025:2017, "*General Requirements for the Competence of Testing and Calibration Laboratories*," Third edition, November 2017.

During the comment period, we made these standards available via the following sources:

- The American National Standards Institute (ANSI), a private non-profit organization that supports the U.S. voluntary standards and conformity assessment system has created a link where ISO/IEC 17011:2017 and ISO/IEC 17025:2017 are available to view free of charge during the comment period. This link is available from our website at: https://www.surveymonkey.com/r/KFJMZ67. Users will need to register to view these documents; and to return to the documents users may access the ANSI website directly and use the log-in information developed during registration.

- The standards can also be accessed at the National Archives and Records Administration (NARA) or at Dockets Management Staff at FDA. For information on the availability of this material at NARA, call 202-741-6030 or visit at the NARA website at www.archives.gov.

- Finally, copies of the standards may be purchased from ISO or from IEC or from any other source from which the user is assured that the copy to be received is an accurate and current version of the standard.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.