Proposed Rule on Accreditation of Third Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications

0910-NEW
SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 307 of FSMA, Accreditation of Third-Party Auditors, amends the FD&C Act to create a new provision, section 808, under the same name (21 U.S.C. 384d). It requires FDA to establish a system, within two years of enactment, for the recognition of accreditation bodies that accredit third-party certification bodies to conduct food safety audits and to issue certifications for eligible foreign food facilities and their products (21 U.S.C. 384d(b)(1)(A)). (While the statute uses the term "auditor" to describe an entity that conducts audits and issues certifications, we propose to use the term "certification body," which better comports with the terminology used by the food industry and the international standards community.)

FSMA section 307 requires FDA to establish a system, within two years of enactment, for FDA recognition of accreditation bodies (ABs) that will accredit third-party certification bodies (CBs) to conduct audits and to issue certifications, with FDA monitoring and oversight of the system (21 U.S.C. 384d(b)(1)(A)). The statute further provides that if FDA has not identified and recognized an accreditation body that meets the requirements of the section within two years after establishing the system for recognition, then FDA may begin to directly accredit third-party certification bodies (21 U.S.C. 384d(b)(1)(A)(ii)). FDA direct accreditation of CBs may occur only when both conditions are met.

FDA must issue implementing regulations for FSMA section 307 within 18 months after enactment (i.e., by July 4, 2012) (21 U.S.C. 384d(c)(5)(C)). The regulations must contain protections against conflicts of interest between accredited third party auditors/certification bodies (and their audit agents) and the entities they audit or certify, including requirements on timing and public disclosure of fees and appropriate limits on financial affiliations (21 U.S.C. 384d(c)(5)(C)(ii) and (iii)). In addition, the regulations must require audits to be unannounced (21 U.S.C. 384d(c)(5)(C)(i)).

FSMA section 307(b)(2) also requires FDA to issue model accreditation standards that third-party certification bodies must meet in order to be qualified for accreditation under FDA's program (21 U.S.C. 384d(b)(2)). The statute specifies that the model accreditation standards must include requirements for regulatory audit reports and must look to existing standards for guidance to avoid unnecessary duplication of efforts and costs (21 U.S.C. 384d(b)(2)).

FSMA section 307 describes two types of certifications that may be issued by accredited third-party certification bodies: facility and food certifications. Facility certifications described in FSMA §§ 302(a) and 307(c)(2) will be used by FDA to help determine whether a facility is eligible to be a facility from which food may be offered for import under the voluntary qualified importer program (VQIP) (21 U.S.C. 384b(d)). The criteria and procedures for VQIP participation are outside the scope of this rulemaking. FDA plans to issue guidance on VQIP and will solicit public comment on VQIP at that time.

Food certifications described in FSMA §§ 303(b) and 307(c)(2) will be used by FDA, in conjunction with any other assurances FDA may require, to help determine whether a food complies with the applicable requirements of the Act and should be admitted into the U.S. (21 U.S.C. 381(q)). FDA may require certification or other assurance of compliance to admit an imported food into the U.S, where FDA determines that such assurance is necessary based on the risk of the food.

Before an accredited third-party certification body may issue either type of certification, the certification body must conduct a regulatory audit and any other activities necessary to establish compliance with the requirements of the §§ 801(q) or 806, respectively (21 U.S.C. 384d(c)(2)(C)(i)).

2. Purpose and Use of the Information Collection

Federal Government: The Third Party proposed rule, along with other proposed rules authorized by the FDA Food Safety Modernization Act (FSMA), aims at strengthening the security of the food supply chain. Under this proposed rule, we will recognize accreditation bodies (ABs) to accredit third-party auditors/certification bodies (CBs), except for limited circumstances in which we may directly accredit CBs to participate in the accredited third-party audits and certification program. Having comprehensive oversight of a credible and reliable program for third-party audits and certifications of foreign food facilities will help FDA prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply. We believe that a trusted program for foreign food safety audits and food and facility certifications--with clear requirements, standards, and procedures and operated under government oversight--will be appealing to accreditation bodies, auditors/certification bodies, and foreign food facilities. Widespread participation and broad acceptance of audits and certifications under the FDA program will help increase efficiency and reduce costs, by eliminating redundant auditing to assess foreign suppliers' compliance with the FD&C Act.

Specifically, we will use certifications issued by accredited third-party auditors/CBs in deciding whether to admit certain imported food into the United States that FDA has determined poses a food safety risk and in deciding whether an importer is eligible to participate in a program for expedited review and entry of food imports.

3. Use of Improved Information Technology and Burden Reduction

The proposed Third Party rule requires ABs and CBs to electronically maintain records and submit reports or notifications to the FDA. We believe that currently all ABs and

CBs have appropriate information technology to comply with the proposed rule's recordkeeping and reporting requirements.

4. Efforts to Identify Duplication and Use of Similar Information
   The Third Party proposed rule is a program for foreign food safety audits and food and facility certifications – with clear requirements, standards, and procedures and operated under government oversight – that would appeal to accreditation bodies, auditors/certification bodies, and foreign food and feed facilities. We believe that participation and acceptance of audits and certifications under the FDA Third Party proposed program will help increase efficiency and reduce cost by eliminating redundant auditing to assess foreign food and feed facilities' compliance with the FD&C Act. The proposed food safety audits and certifications under our program would substitute current food safety audits and certificates that foreign food and feed facilities may use.

5. Impact on Small Businesses or Other Small Entities
   Using the data in Tables B3a and B3b in Appendix B of the combined PRIA for the FSVP and Third Party proposed rules, we estimate that the average incremental cost to eligible entities whose food FDA has determined poses a food safety risk and must be certified to be admitted into the U.S. under §801(q) of the FD&C Act and the Third Party proposed rule is approximately $987 per year for FSVP co-proposal Option 1 ($982 per year for FSVP co-proposal Option 2). Therefore, on average, annual cost to all small businesses whose food is subject to an FDA safety determination and must be certified under §801(q) of the FD&C Act is approximately $9,409,071 ($987/entity x 9,533 entities) for FSVP co-proposal Option 1 ($9,361,406 under FSVP co-proposal Option 2).

6. Consequences of Collecting the Information Less Frequently
   We could not consider regulatory options related to the frequency of recertification, such as requiring recertification every two years rather than annually, because §808(d) of the FD&C Act requires that eligible entities apply for annual recertification if the entity is required to provide to FDA a certification under §801(q)(for any food from such entity.[1]

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
   There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
   As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of July 29, 2013 (78 FR 45781).

9. Explanation of Any Payment or Gift to Respondents
   This information collection does not provide for payment or gifts to respondents.

[1] Under §801(q) of the FD&C Act, FDA may require recertification at any time. Recertification at frequency other than annual recertification under §808 of the FD&C Act is outside the scope of this Third-Party proposed rule.

10. Assurance of Confidentiality Provided to Respondents
This regulation does not specify confidentiality.

11. Justification for Sensitive Questions
This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs
12 a. Annualized Hour Burden Estimate

← Description of Respondents: The coverage of the Third Party proposed rule includes eligible entities seeking audits, certification, and/or recertification by accredited auditors/CBs participating in our program, accreditation bodies (ABs) seeking to comply with the recognition requirements of the Third Party proposed rule, and auditors/CBs seeking to comply with the accreditation requirements of the Third Party proposed rule (including those accredited by recognized ABs and those directly-accredited auditors/CBs to conduct food safety audits). An eligible entity is a foreign entity that offers its food or feed for import to the U.S. and that seeks a food safety audit and possibly certification under the requirements for eligible entities under the Third Party proposed rule.

The eligible entities comprise of an estimate of number of foreign food and feed exporters (5% of all foreign food and feed exporters) that are subject to §801(q) of the Act, and the number of foreign suppliers who would conduct food safety audits under the FSVP proposed rule co-proposal Options 1 and 2. In the economic analysis of the Third Party proposed rule (see Appendix B of the combined FSVP and Third Party RIA), we estimate that under FSVP co-proposal Option 1, there are 57,504 eligible entities (10,035 §801(q) entities + 47,469 FSVP foreign suppliers), 1,336 auditors/CBs and 69 ABs that would respond to the recordkeeping and reporting requirements of the Third Party proposed rule. Under FSVP co-proposal Option 2, we the number of respondents include 53,399 eligible entities (10,035 §801(q) entities + 43,364 FSVP foreign suppliers), 1,273 auditors/CBs and 69 ABs.

Recordkeeping Burden

Recordkeeping burden associated with the Third Party proposed rule includes one-time burden of 335,796 hours and annual burden of 45,274 hours (see Third Party proposed rule PRA; Tables 1a and 2a). In this analysis, we annualize the one-time recordkeeping burden using a 3-year period horizon and zero percent discount rate, or by dividing the number of respondents for each recordkeeping provision of the Third Party proposed rule by three. As a result, under FSVP co-proposal Option 1, we estimate an annual recordkeeping burden of 157,180 hours (see Table 1a). Under FSVP co-proposal Option 2, we estimate an annual recordkeeping burden of 148,625 (see Table 1b).

This PRA analysis is a co-proposal and therefore two different burden options are described. Table 1a (recordkeeping) and Table 2a (reporting) in this document represent

Option 1. Table 1b (recordkeeping) and Table 2b (reporting) in this document represent Option 2.

Since FDA is only able to upload one option as part of the ICR in ICRAS we chose to upload Option 2 (Table 1b and 2b.)

Table 1a: Option 1 - Estimated Annual Recordkeeping Burden[1]

*(**Not** uplodaded into ICRAS/ROCIS)*

21 CFR Part 1, Subpart M	No. of Respondents	No. of Response per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
§1.615 – AB modify recordkeeping protocol	23[2]	1	23	2	46
§1.645 – CB modify recordkeeping protocol	445[2]	1	445	2	890
§1.624(c) – AB public dissemination of information via website (One-time)	23[2]	1	23	68.52	1,576
§1.657(d) – CB public dissemination of information via website (One-time)	445[2]	1	445	68.52	30,491
§1.620, §1.621 – AB contract modification	23[2]	19.3	444	2	888
§1.651 – CB contract modification	445[2]	57	25,365	2	50,730
Unaccredited CBs – accreditation burden (one-time)	255[2]	1	255	107	27,285
§1.625 – AB maintenance of regulatory audit records	69	1,100	75,900	0.25	18,975
§1.624(c) – AB public dissemination of information via website (annual)	69	1	69	8	552
§1.657(d) – CB public dissemination of information via website (Annual)	1,336	1	1,336	8	10,688
§1.656(c) – Report SAHCODHA conditions	1,336	0.25	334	1	334
§1.652 – CB modification of food safety audit report	1,336	57	76,152	0.083	6,321
Unaccredited CBs – accreditation burden (annual)	764	1	764	11	8,404
Total Annual Recordkeeping Burden					**157,180**

1. There are no operations and maintenance costs associated with annual recordkeeping burden.
2. Number of respondents for one-time recordkeeping burden is divided by 3 to convert one-time burden to annual burden.

Table 1b: Option 2 - Estimated Annual Recordkeeping Burden[1]

(Uploaded into ICRAS/ROCIS)

21 CFR Part 1, Subpart M	No. of Respondents	No. of Response per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
§1.615 – AB modify recordkeeping protocol	23[2]	1	23	2	46
§1.645 – CB modify recordkeeping protocol	424[2]	1	424	2	848
§1.624(c) – AB public dissemination of information via website (One-time)	23[2]	1	23	68.52	1,576
§1.657(d) – CB public dissemination of information via website (One-time)	424[2]	1	424	68.52	29,052
§1.620, §1.621 – AB contract modification	23[2]	18.4	423	2	846
§1.651 – CB contract modification	424[2]	57	24,168	2	48,336
§ 1.645 Unaccredited CBs – accreditation burden (one-time)	234[2]	1	234	107	25,038
§1.625 – AB maintenance of regulatory audit records	69	1,049	72,381	0.25	18,095
§1.624(c) – AB public dissemination of information via website (annual)	69	1	69	8	552
§1.657(d) – CB public dissemination of information via website (Annual)	1,273	1	1,273	8	10,184
§1.656(c) – Report SAHCODHA conditions	1,273	0.25	318	1	318
§1.652 – CB modification of food safety audit report	1,273	57	72,561	0.083	6,023
§ 1.645 Unaccredited CBs – accreditation burden (annual)	701	1	701	11	7,711
Total Annual Recordkeeping Burden					**148,625**

1. There are no operations and maintenance costs associated with annual recordkeeping burden.
2. Number of respondents for one-time recordkeeping burden is divided by 3 to convert one-time burden to annual burden.

In the Third Party proposed rule PRA, we estimate that the records requirements for ABs in §1.615 and auditors/CBs in §1.645 would constitute a new one-time burden for 69 ABs, and 1,336 auditors/CBs respectively under FSVP co-proposal Option 1 (1,273 under FSVP co-proposal Option 2). We annualize the one-time burden by estimating the average annual cost of each one-time burden over a three-year period; or equivalently, dividing the number of respondents by three. Therefore, under FSVP co-proposal Option 1, on average, 23 ABs (69 ABs ÷ 3), and 445 auditors/CBs (1,336 CBs ÷ 3) would incur an annual burden for modification of their recordkeeping protocol to satisfy §1.615 and §1.645 of the Third Party proposed rule (see Table 1a). Under FSVP co-proposal Option

2, on average, 23 ABs and 424 auditors/CBs (1,273 CBs ÷ 3) would incur an annual burden satisfy §1.615 and §1.645 of the Third Party proposed rule (see Table 1b). We expect that it would take no more than 2 hours for an AB or an accredited auditor/CB to modify its recordkeeping protocol to comply with the written recordkeeping requirements described in §1.615 and §1.645 of the Third Party proposed rule. Therefore, we estimate that it would take 46 hours (2 hours/AB x 23 ABs) for ABs to comply with §1.615 under both co-proposal options. Under FSVP co-proposal Option 1, we estimate 890 hours (2 hours/CB x 445 CBs) for accredited auditors/CBs, on annual basis, to comply with §1.645 of the Third Party proposed rule (see Table 1a). Under FSVP co-proposal Option 2, we estimate 848 hours (2 hours/CB x 424 CBs) for FSVP co-proposal Option 2 (see Table 1b).

← Section 1.625 of the Third Party proposed rule requires recognized ABs to maintain records pertaining to regulatory audit reports submitted by their accredited auditors/CBs. We expect that it would take no more than 15 minutes (0.25 hour) for a recognized AB to file a regulatory audit report submitted by its auditors/CB. In the economic analysis of the Third Party proposed rule, we estimate that, on average, an AB accredits 19.3 CBs under FSVP co-proposal Option 1 (18.4 CBs/AB under FSVP co-proposal Option 2). Furthermore, each CB, on average, conducts food safety audits for 57 eligible entities. Therefore, there are approximately 1,100 responses (maintenance of records pertaining to regulatory audit reports) (19.3 CBs/AB x 57 regulatory audit report/CB) per AB under FSVP co-proposal Option 1 (1,049 responses under FSVP co-proposal Option 2). Under FSVP co-proposal Option 1, annual recordkeeping burden for 69 recognized ABs to maintain regulatory audit records of their auditors/CBs is estimated at 18,975 hours (18,095 hours under FSVP co-proposal Option 2) (see Tables 1a and 1b).

← We estimate that each AB, on average, would spend approximately a one-time cost of $4,000 to update its webpage to conform with §1.624(c) of the Third Party proposed rule. We expect the hourly wage rate of an IT expert responsible for updating the AB's webpage be equivalent to that of a GS-13, Step 5 employee at $58.38 per hour (includes 50% overhead cost). Hence, we expect that a one-time burden of updating an AB's website to conform with §1.624(c) of the Third Party proposed rule to be equivalent to 68.52 hours ($4,000 ÷ $58.38/hour). In a three-year period, on average, 23 ABs realize the one-time burden of conforming to §1.624(c) of the Third Party proposed rule. Therefore, on average, the annual recordkeeping burden associated with the initial modification of the ABs' webpages is estimated at approximately 1,576 hours (23 ABs x 68.52 hours/AB) (see Tables 1a and 1b). In addition, we estimate that each recognized AB would spend 8 hours annually, following the initial year, to update information as required by §1.624(c) of the Third Party proposed rule. The annual hourly burden for 69 recognized ABs to update their webpages to conform to disclosure of information requirement per §1.624(c) of the Third Party proposed rule is estimated at 552 hours (8 hours/AB x 69 ABs) (see Tables 1a and 1b).

← Similarly, §1.657(d) of the Third Party proposed rule requires an auditor/CB accredited in compliance with the Third Party proposed rule to maintain on its website an up-to-date list of eligible entities which it has issued certifications under this subpart. For each such

eligible entity the website also must identify the duration and scope of the certification and date(s) on which the eligible entity paid the accredited auditor/CB any fee or reimbursement associated with such audit or certification.

←
← In the Third Party proposed analysis, we estimate that following the implementation of the Third Party and FSVP proposed rules, there will be an initial burden to modify webpages of approximately 1,332 auditors/CBs accredited by recognized ABs and 4 directly accredited auditors/CBs under FSVP co-proposal Option 1 (1,269 CBs and 4 directly accredited CBs under FSVP co-proposal Option 2). In a three-year period, on average, 445 auditors/CBs (1,336 CBs ÷ 3) will incur an annual burden of 30,491 hours (68.52 hours/CB x 445 CBs; see Table 1a) under FSVP co-proposal Option 1 (29,052 hours under FSVP co-proposal Option 2; see Table 1b).

←
← In addition, we estimate that each auditor/CB would spend 8 hours annually, following the initial year, to update information as required by §1.657(d) of the Third Party proposed rule. Under FSVP co-proposal Option 1, annual hourly burden for 1,336 auditors/CBs to update their webpages to conform to disclosure of information requirement per §1.624(c) of the Third Party proposed rule is estimated at 10,688 hours (8 hours/CB x 1,336 CBs; see Table 1a) (10,184 hours under FSVP co-proposal Option 2; see Table 1b).

There are certain provisions within the Third Party proposed rule (e.g., §1.620 and §1.621) that would require ABs to modify their contracts with their auditors/CBs in order to comply with the Third Party proposed rule. Therefore, it is expected that recognized ABs will modify their contracts with their accredited auditors/CBs to be able to conduct activities such as conducting unannounced audits of their accredited auditors/CBs. Minor modifications or addenda to contracts with standard language provided by provisions in the Third Party proposed rule would consist of no more than one hour by an AB executive and one hour by a legal counsel representing the AB.

As we discussed, following the implementation of the Third Party proposed rule, we expect that each recognized AB will accredit approximately 19.3 auditors/CBs. Therefore, under FSVP co-proposal Option 1, a total of 1,332 contracts (19.3 contracts/AB x 69 ABs) (1,270 contracts under FSVP co-proposal Option 2) are expected to be modified to reflect changes in contractual obligations between each recognized AB and its accredited auditors/CBs under the Third Party proposed rule. We annualize (average annual cost: total cost spread over three years) the one-time burden of initial modification contracts between ABs and CBs by dividing the number of respondents to this requirement (69 ABs) by three. Therefore, on average, 23 ABs modify their contracts with their respective 19.3 auditors/CBs (18.4 auditors/CB in FSVP co-proposal Option 2) on an annual basis. Under FSVP co-proposal Option 1, annual recordkeeping burden of ABs for initial modification of contracts with their respective accredited auditors/CBs is estimated 888 hours (23 ABs x 19.3 CBs/AB x 2 hours/CB; see Table 1a) (846 hours under FSVP co-proposal Option 2; see Table 1b).

Similarly, auditors/CBs accredited by recognized ABs would need to modify their contracts with their client eligible entities in order to gain access to any records and any area of the facility, its process(es), and food of the eligible entity relevant to the scope and purpose of audit being performed by the auditor/CB (§1.651). Considering that each of the expected 445 accredited auditor/CB (1,336 auditors/CBs ÷ 3), under FSVP co-proposal Option 1, will each have approximately 57 client eligible entities, we expect that approximately 25,365 contracts (57 contracts/CB x 445 CBs) between accredited auditors/CBs and eligible entities will be modified on an annual basis (24,168 contract under FSVP co-proposal Option 2) (see Tables 1a and 1b).

Under FSVP co-proposal Option 1, the one-time burden of initial modification of 25,365 contracts between 445 accredited auditors/CBs and their respective client eligible entities is approximately 50,730 hours (25,365 contracts x 2 hours/contract) (see Table 1a). Under FSVP co-proposal Option 2, the one-time burden of initial modification of 24,168 contracts between 424 accredited auditors/CBs and their respective client eligible entities is approximately 48,336 hours (24,168 contracts x 2 hours/contract) (see Table 1b).

Section 1.652 of the Third Party proposed rule requires that accredited CBs include certain information in reports of food safety audits. We expect that it would take about 5 minutes (0.083 hour), on average, by an accredited CB to include additional information, as required in §1.652, in reports of food safety audits. Therefore, at a minimum, each accredited CB must modify a regulatory audit report for each of its 57 client eligible entities every year. Under FSVP co-proposal Option 1, total annual records of 1,336 accredited CBs modifying regulatory audit reports of their client eligible entities is estimated at 76,152 records (1,336 CBs x 57 eligible entity/CB x 1 record/eligible entity) (72, 561 records under FSVP co-proposal Option 2). Annual recordkeeping burden of accredited CBs, per §1.652 of the Third Party proposed rule, is estimated at 6,321 hours (76,152 records x 0.083 hour/record; see Table 1a) under FSVP co-proposal Option 1 (6,023 hours under FSVP co-proposal Option 2; see Table 1b).

Section 1.656(c) of the Third Party proposed rule requires that an accredited auditor/CB report to us any condition, found during a regulatory or consultative audit of an eligible entity, which could cause or contribute to a serious risk to the public health. We believe that these occurrences are rare and may occur once every 4 years, or 0.25 times per year. Reporting serious hazard conditions would consist of the on-site audit agent of an accredited auditor/CB to document the event as a record and to immediately submit the record to us. Therefore, under FSVP co-proposal Option 1, annual number of records prepared by 1,336 accredited auditors/CBs is estimated at 334 (0.25 records/CB x 1,336 CBs) (318 records under FSVP co-proposal Option 2). It is expected that an accredited auditor/CB would take no more than 1 hour to prepare such record (notification). Under FSVP co-proposal Option 1, annual burden of preparation of records per §1.656(c) of the Third Party proposed rule by 1,336 accredited auditor/CB is estimated at 334 hours (334 records x 1 hour/record; see Table 1a) (318 hours under FSVP co-proposal Option 2; see Table 1b).

In the Third Party proposed analysis, we estimate that in order to become accredited, an unaccredited CB would initially spend, on average, $25,000 to conform to an ABs's scheme (see Appendix E, Table E7). We expect that this cost burden includes initial modification of an unaccredited CB's recordkeeping, reporting and training protocols, and increased personnel to maintain its standards to that of its accrediting AB. We also estimated that following the implementation of the Third Party and FSVP proposed rules, 764 unaccredited CBs (see Appendix B) would choose to become accredited under FSVP co-proposal Option 1 (701 unaccredited CBs under FSVP co-proposal Option 2). Using an average wage rate of GS-13 Step 5 pay level ($58.38/hour including benefits and overhead costs), average initial burden of an unaccredited CB—to modify its practices to conform to an AB's scheme—is approximately 428 hours ($25,000 ÷ $58.38/hour). We assume that the initial burden of 428 hours for an unaccredited CB is equally divided between four categories of recordkeeping, reporting, training and increased personnel hours. Therefore, an unaccredited CB would initially incur a burden of approximately 107 hours (428 hours ÷ 4) for its initial recordkeeping procedures. We annualize the initial recordkeeping burden for unaccredited CBs who choose to become accredited by an AB by dividing the burden over a 3-year period; or divide the number of responding unaccredited CBs by three: 255 CBs (764 ÷ 3). The annual recordkeeping burden for unaccredited CBs that become accredited by an AB is estimated at 27,285 hours (255 unaccredited CBs x 107 hour/unaccredited CB; see Table 1a) under FSVP co-proposal Option 1 (25,038 hours under FSVP co-proposal Option 2; see Table 1b).

We also assume that the annual increase in recordkeeping, reporting, training and increase in personnel of an unaccredited CB which chooses to become accredited will amount to 10% of the initial burden, or 11 hours per CB per year (107 hour/unaccredited CB x 10%). The annual recordkeeping burden for unaccredited CBs that become accredited by a recognized AB is estimated at 8,404 hours (764 unaccredited CBs x 11 hour/unaccredited CB; see Table 2a) under FSVP co-proposal Option 1 (7,711 hours under FSVP co-proposal Option 2; see Table 1b). We request comments on our one-time and annual recordkeeping burden estimates of unaccredited CBs who choose to become accredited.

Reporting Burden

Reporting burden associated with the Third Party proposed rule includes one-time burden of 88,924 hours and annual burden of 73,309 hours (see Third Party proposed rule PRA; Tables 3a and 4a). In this analysis, we annualize the one-time recordkeeping burden using a 3-year period horizon and zero percent discount rate, or by dividing the number of respondents for each recordkeeping provision of the Third Party proposed rule by three. As a result, under FSVP co-proposal Option 1, we estimate an annual recordkeeping burden of 83,921 hours (see Table 2a). Under FSVP co-proposal Option 2, we estimate an annual recordkeeping burden of 78,823 (see Table 2b).

Table 2a: Option 1 - Estimated Annual Reporting Burden[1]

*(**Not** uplodaded into ICRAS/ROCIS)*

21 CFR Part 1, Subpart M	No. of Respondents	No. of Response per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
§1.630 – AB application for recognition	23[2]	1	23	80	1,840
§1.653(b)(2) – CB modification of certification design	445[2]	1	445	1	445
§1.670(a-b) – CB application for direct accreditation	1[2]	1	1	80	80
§1.656 Unaccredited CBs – Additional one-time reporting burden	255[2]	1	255	107	27,285
§1.634 – AB application for renewal of recognition	69	1	69	8	552
§1.673 – CB application for renewal of direct accreditation	4	1	4	10	40
§1.623(a) – AB submission of assessment of its CBs	69	19.3	1,332	0.25	333
§1.623(b) – AB submission of self-assessments	69	1	69	0.25	17
§1.653(b)(2) – CB completion of additional information on certificates	1,336	57	76,152	0.083	6,321
§1.656(a) – CB submission of regulatory audit report to its AB	1,332	57	75,924	0.25	18,981
§1.656(a) – CB submission of regulatory audit report to FDA	1,332	57	75,924	0.25	18,981
§1.656(a) – Directly-accredited CB submission of regulatory audit report to FDA	4	57	228	0.25	57
§1.656(b) – CB submission of self-assessment to its AB	1,332	1	1,332	0.25	333
§1.656(b) – Directly-accredited CB submission of self-assessment to FDA	4	1	4	0.25	1
§1.656(c) – CB reporting conditions that could contribute to serious risk to public health to FDA	1,336	0.25	334	0.25	84
§1.656(e) – CB reporting conditions that could contribute to serious risk to public health to its eligible entities clients	1,336	0.25	334	0.25	84
§1.656(e) – CB reporting conditions that could contribute to serious risk to public health to its ABs	1,332	0.25	333	0.25	83
§ 1.656 Unaccredited CBs – Additional annual reporting	764	1	764	11	8,404

burden					
Total Annual Reporting Burden					**83,921**

1. There are no operations and maintenance costs associated with annual reporting burden.
2. Number of respondents for one-time reporting burden is divided by 3 to convert one-time burden to annual burden.

Table 2b: Option 2 - Estimated Annual Reporting Burden[1]

(Uploaded into ICRAS/ROCIS)

21 CFR Part 1, Subpart M	No. of Respondents	No. of Response per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
§1.630 – AB application for recognition	23[2]	1	23	80	1,840
§1.653(b)(2) – CB modification of certification design	424[2]	1	424	1	424
§1.670(a-b) – CB application for direct accreditation	1[2]	1	1	80	80
Unaccredited CBs – Additional one-time reporting burden	234[2]	1	234	107	25,038
§1.634 – AB application for renewal of recognition	69	1	69	8	552
§1.673 – CB application for renewal of direct accreditation	4	1	4	10	40
§1.623(a) – AB submission of assessment of its CBs	69	18.4	1,270	0.25	317
§1.623(b) – AB submission of self-assessments	69	1	69	0.25	17
§1.653(b)(2) – CB completion of additional information on certificates	1,273	57	72,561	0.083	6,023
§1.656(a) – CB submission of regulatory audit report to its AB	1,269	57	72,333	0.25	18,083
§1.656(a) – CB submission of regulatory audit report to FDA	1,269	57	72,333	0.25	18,083
§1.656(a) – Directly-accredited CB submission of regulatory audit report to FDA	4	57	228	0.25	57
§1.656(b) – CB submission of self-assessment to its AB	1,273	1	1,273	0.25	318
§1.656(b) – Directly-accredited CB submission of self-assessment to FDA	4	1	4	0.25	1
§1.656(c) – CB reporting conditions that could contribute to serious risk to public health to FDA	1,273	0.25	318	0.25	80
§1.656(e) – CB reporting conditions that could contribute to serious risk to public health to its eligible entities clients	1,273	0.25	318	0.25	80
§1.656(e) – CB reporting	1,269	0.25	317	0.25	79

conditions that could contribute to serious risk to public health to its ABs					
Unaccredited CBs – Additional annual reporting burden	701	1	701	11	7,711
Total Annual Reporting Burden					**78,823**

1. There are no operations and maintenance costs associated with annual reporting burden.
2. Number of respondents for one-time reporting burden is divided by 3 to convert one-time burden to annual burden.

Section 1.630 of the Third Party proposed rule allows for any AB to apply for recognition. We estimate that approximately 69 ABs would apply for recognition. We annualize the one-time burden by estimating the average annual cost of each one-time burden over a three-year period; or equivalently, dividing the number of respondents by three. Therefore, on average, 23 ABs (69 ABs ÷ 3) would incur an annual burden for applying for recognition from FDA (see Tables 2a and 2b). We estimate that it will take 80 person-hours to compile all the relevant information and complete the application for recognition. Consequently, under FSVP co-proposal Options 1 and 2, the annualized reporting burden of the initial application for 69 ABs is estimated at 1,840 hours (23 applications x 80 hours/application) (see Tables 2a and 2b).

The duration of recognition for a recognized AB will not exceed 5 years per §1.632 of the Third Party proposed rule. Therefore, it is expected that each of the expected 69 recognized ABs would apply to renew its recognition every 5 years per §1.634 of the Third Party proposed rule. We expect that applications for renewal of recognition will take significantly less time to prepare. We use 50% of the amount of effort to prepare and submit an application for renewal of recognition. Therefore, it is expected that, on average, each recognized AB will spend 40 hours every 5 years to complete and submit an application for renewal of its recognition, or approximately 8 hours per year (40 hours ÷ 5 years) for each AB. Therefore, the annual burden of completing the renewal of recognition application by 69 ABs is 552 hours (69 applications x 8 hours/application) per year (see Tables 2a and 2b).

Similarly, §1.670(a-b) of the Third Party proposed rule allows for auditors/CBs to apply to us for direct accreditation, when the criteria for direct accreditation are met. We estimate that approximately 4 auditors/CBs would apply for direct accreditation. It is expected that the application for direct accreditation would require the same amount of effort as does an AB's application for recognition. Hence, we estimate that the initial application for direct accreditation would take 80-person hours. We annualize the one-time burden by dividing the number of respondents (4 auditors/CBs) by three, or 1.33 auditors/CBs. In this document, we round 1.33 auditors/CBs to 1 auditor/CB. The annualized reporting burden of the initial application for 1 auditors/CBs is estimated at 80 hours (1 applications x 80 hours/application) (see Tables 2a and 2b). The duration of accreditation for a directly-accredited CB will not exceed 4 years, per §1.671 of the Third Party proposed rule. Therefore, it is expected that each of the expected 4 directly-accredited auditors/CBs would apply to renew its accreditation every 4 years, per §1.673 of the Third Party proposed rule. We expect that directly-accredited auditors/CBs use 50% amount of effort, or 40 person-hours, for their initial application for direct

accreditation, yielding an average of 10 hours per year. Therefore, the annual burden of completing the application for renewal by 4 directly-accredited auditors/CBs is 40 hours (4 applications x 10 hours/application) per year (see Tables 2a and 2b).

Section 1.623(a) of the Third Party proposed rule requires that recognized ABs annually conduct comprehensive assessments of the performance of auditors/CBs they have accredited and submit the results of the assessments to us within 45 days of their completion. We expect that it would take no more than 15 minutes (0.25 hour) for an AB to electronically submit the assessment of each its accredited auditors/CBs. Following the implementation of the Third Party proposed rule and FSVP co-proposal Option 1, we expect, on average, each recognized AB would accredit approximately 19.3 auditors/CBs (18.4 auditors/CBs under FSVP co-proposal Option 2). Therefore, under FSVP co-proposal Option 1, each recognized AB would submit, on average, approximately 1,332 copies of assessments of performance of their accredited auditors/CBs (19.3 assessments/AB x 69 ABs) (1,270 assessments under FSVP co-proposal Option 2). Under FSVP co-proposal Option 1, annual reporting of 1,332 assessments by 69 recognized ABs is estimated at 333 hours (1,332 submission of assessments x 0.25 hour/submission; see Table 2a) (317 hours under FSVP co-proposal Option 2; see Table 2b).

Section 1.623(b) of the Third Party proposed rule requires that recognized ABs annually conduct a self-assessment and submit the assessments within 45 days of their completion. We expect that it would take no more than 15 minutes for an AB to electronically submit a copy of its self-assessment. Annual reporting of 69 self-assessments by 69 recognized ABs is estimated at 17 hours (69 submission of self-assessments x 0.25 hour/submission) (see Tables 2a and 2b).

Section 1.653(b)(2) requires that certifications issued by accredited CBs contain information such as the DUNS number of the eligible entity to which the certification was issued. We assume that certifications that are currently issued by accredited CBs need to be modified so that they comply with the requirements of §1.653(b)(2). We expect that it will take no more than 1 hour, on average, to change the design of certifications issued by accredited CBs. Under FSVP co-proposal Option 1, we estimate annualized reporting burden of of modifying the design of the certifications of 445 accredited CBs (1,336 accredited CBs ÷ 3) at 445 hours (445 CBs x 1 hour/CB; see Table 2a) (424 hours under FSVP co-proposal Option 2; see Table 2b).

We expect that the burden to fill additional information on a certification that is issued is 5 minutes (0.083 hour). Therefore, under FSVP co-proposal Option 1, the annual burden of §1.653(b)(2) is estimated at 6,321 hours (1,336 CBs x 1 certificate/entity x 57 entities/CB x 0.083 hour/certificate; see Table 2a) (6,023 hours under FSVP co-proposal Option 2; see Table 2b).

Section 1.656(a) of the Third Party proposed rule requires that an accredited auditor/CB must submit the regulatory audit reports it conducts to us and to the AB that granted its accreditation (where applicable) within 45 days after completing such audit. In the Third

Party proposed analysis, we estimated that following the implementation of the Third Party proposed rule, there will be 69 recognized ABs that accredit 1,332 auditors/CBs (1,269 auditors/CBs under FSVP co-proposal Option 2), and we will directly accredit 4 auditors/CBs. In addition, we estimated that each accredited auditor/CB, on average, conducts food safety audits and certifies 57 eligible entities. Therefore, auditors/CBs accredited by recognized ABs will annually submit 75,924 regulatory audit reports (1,332 CBs x 57 reports/CB) to their accrediting ABs and 75,924 reports to us (see Table 2a) (72,333 reports under FSVP co-proposal Option 2; see Table 2b). The directly-accredited auditors/CBs will annually submit 228 regulatory audit reports (4 CBs x 57 reports/CB) (see Table 2a and 2b). We expect that it would take no more than 15 minutes (0.25 hour) for an accredited auditor/CB to electronically submit a copy of the regulatory report it conducts to us and to its AB (where applicable).

Under FSVP co-proposal Option 1, annual reporting burden for auditors/CBs accredited by recognized ABs is estimated at 18,981 hours (75,924 reports x 0.25 hours/report) for submitting copies of regulatory audit reports they have conducted to their accrediting ABs and 18,981 hours for submitting the same records to us (see Table 2a). Under FSVP co-proposal Option 2, annual reporting burden for auditors/CBs accredited by recognized ABs is estimated at 18,083 hours (75,333 reports x 0.25 hours/report) for submitting copies of regulatory audit reports they have conducted to their accrediting ABs and 18,083 hours for submitting the same records to us (see Table 2b). Annual burden for submission of regulatory audit reports by directly-accredited auditors/CBs is estimated at 57 hours (228 reports x 0.25 hours/report) (see Tables 2a and 2b).

Section 1.656(b) of the Third Party proposed rule requires accredited auditors/CBs to submit reports of their annual self-assessments electronically to their ABs, or in the case of direct accreditation to us, within 45 days of the anniversary date of their accreditation under subpart M. We expect that it would take no more than 15 minutes (0.25 hour) for an accredited auditor/CB to electronically send a copy of its annual self-assessment to its AB or us (as applicable). Under FSVP co-proposal Option 1, the annual burden for auditors/CBs accredited by recognized ABs is estimated at 333 hours (1,332 self-assessments x 0.25 hour/self-assessment; see Table 2a) (318 hours under FSVP co-proposal Option 2; see Table 2b). Annual burden for submission of self-assessments by directly-accredited auditors/CBs is estimated at 1 hour (4 self-assessments x 0.25 hour/self-assessment; see Tables 2a and 2b).

As we discussed, §1.656(c) of the Third Party proposed rule requires that an accredited auditor/CB report to us any condition, found during a regulatory or consultative audit of an eligible entity, which could cause or contribute to a serious risk to the public health. In the Recordkeeping Burden section above, we estimated that such events are expected to occur once every 4 years, or 0.25 per year. We expect that it would take no more than 15 minutes (0.25 hour) for an accredited auditor/CB to electronically send a copy of its notification documenting serious risk to the public health to us. Therefore, under FSVP co-proposal Option 1, the total number of notification sent to us on an annual basis per §1.656(c) of the Third Party proposed rule is estimated at 334 (1,336 CBs x 0.25 records/CB) (318 notifications under FSVP co-proposal Option 2). Under FSVP co-

proposal Option 1, annual burden for submitting serious risk to the public health notification per §1.656(c) of the Third Party proposed rule to us by accredited auditors/CBs is estimated at 84 hours (334 records x 0.25 hour/record; see Table 2a) (80 hours under FSVP co-proposal Option 2; see Table 2b).

Following reporting of a serious risk to the public health hazard condition to us, an accredited auditor/CB is required under §1.656(e) of the Third Party proposed rule to immediately notify the eligible entity and its accrediting AB of any conditions identified during the audit which triggered the reporting requirement per §1.656(c) of the Third Party proposed rule. Under FSVP co-proposal Option 1, total number of notification sent to eligible entities by 1,336 accredited auditors/CBs is estimated at 334 (1,336 CBs x 0.25 records/CB) (318 notifications under FSVP co-proposal Option 2) while the number of notifications sent to ABs by their accredited auditors/CBs is estimated at 333 (1,332 CBs x 0.25 records/CB) (317 hours under FSVP co-proposal Option 2). Under FSVP co-proposal Option 1, annual burden of submitting serious risk to the public health notification per §1.656(e) of the Third Party proposed rule to affected eligible entities and ABs by accredited auditors/CBs is estimated at 84 hours and 83 hours, respectively (see Table 2a) (80 hours and 79 hours under FSVP co-proposal Option 2; see Table 2b).

In the Recordkeeping Burden section, we estimated that, initially, the increased reporting burden by 764 unaccredited CB who chooses to become accredited is approximately 107 hours per CB. Annualizing the reporting burden of 764 CBs, we estimate that approximately 255 CBs (764 CBs ÷ 3) would incur additional reporting burden per year. Estimated annualized one-time reporting burden of 255 unaccredited CBs, under FSVP co-proposal Option 1, is estimated at 27,285 hours (255 unaccredited CBs x 107 hour/unaccredited CB; see Table 2a) (25,038 hours under FSVP co-proposal Option 2; see Table 2b). Annual increase in reporting burden of an unaccredited CB is calculated as 10% of initial burden, or 11 hours. Estimated annual reporting burden of 764 unaccredited CBs, under FSVP co-proposal Option 1, is estimated at 8,404 hours (764 unaccredited CBs x 11 hour/unaccredited CB; see Table 2a) (7,711 hours under FSVP co-proposal Option 2; see Table 2b).

12b. Annualized Cost Burden Estimate

We believe that recordkeeping and reporting requirements of the Third Party proposed rule are conducted by personnel with differing wage rates. We expect that recordkeeping burden under §1.615, §1.625, and §1.645 of the proposed rule (see Tables 1a and 1b) are conducted by management personnel with wage rate equivalent to GS 14, Step 1, or $38.92 per hour. Including 50% overhead cost to the GS 14-1 wage rate, we estimate that wage rate for personnel conducting these activities is approximately $61 ($38.92 x 150%). Recordkeeping burden under §1.624(c), §1.652, §1.656 (c), §1.657(d), and for unaccredited CBs who choose to become accredited by recognized ABs (see Tables 1a and 1b) are expected to be conducted by staff-level personnel with wage rate equivalent to GS 13, Step 5, or $40.58 per hour. Including 50% overhead cost to the GS 13-5 wage rate, we estimate that wage rate for personnel conducting these activities is approximately $58 ($40.58 x 150%). U.S. government GS personnel rates are obtained from Salary

Table 2012-GS.[2] We expect that executive management and attorneys would modify existing contracts between ABs and CBs (per §1.620 and §1.621), and between CBs and eligible entities (per §1.651). According to Bureau of Labor Statistics, an executive management in the scientific and technical consulting services earns approximately $62.69 per hour, or approximately $94.03 per hour including 50% overhead costs.[3] Attorneys who manage companies and enterprises earn approximately $70.08 per hour, or approximately $105.12 per hour including 50% overhead costs.[4] We expect that executive managers and attorneys spend equal amount of thime modifying contracts; hence, on average, we expect a mean hourly wage of approximately $100 (($94.03 + $105.12) ÷ 2).

In Tables 3a and 3b, we provide total burden hours for appropriate personnel (see Tables 1a, and 1b), their wage rates and total respondent costs for the recordkeeping burden of the proposed rule. For FSVP co-proposal Option 1, we estimate the total recordkeeping burden cost at $11,344,129 (see Table 3a). For Option 2, we estimate total recordkeeping burden cost of $10,742,861 (see Table 3b).

Table 3a: Option 1 - Estimated Annual Recordkeeping Burden Cost

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manager equivalent to GS 14-1	19,911	$61	$1,214,571
Staff equivalent to GS 13-5	85,651	$58	$4,967,758
Executive management/Attorney	51,618	$100	$5,161,800
Total Recordkeeping Cost			**$11,344,129**

Table 3b: Option 2 - Estimated Annual Recordkeeping Burden Cost

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manager equivalent to GS 14-1 §1.615, §1.625, §1.645	18,989	$61	$1,158,329
Staff equivalent to GS 13-5 §1.624(c), §1.652, §1.656(c), §1.657(d), 1.645 (unaccredited CBs who choose to become accredited by recognized ABs	80,454	$58	$4,666,332
Executive management/Attorney §1.620, §1.621, and between CBs and eligible entities (per §1.651)	49,182	$100	$4,918,200
Total Recordkeeping Cost			**$10,742,861**

We expect that reporting burden under §1.630, §1.634, §1.670(a-b), and §1.673 of the proposed rule (see Tables 1a and 1b) are conducted by management personnel with wage

[2] http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2012/general-schedule/
[3] http://www.bls.gov/oco/ocos012.htm#earnings
[4] http://www.bls.gov/oco/ocos053.htm

rate equivalent to GS 14, Step 1, or $61per hour including 50% overhead cost. Reporting burden under §1.653(b)(2), and for unaccredited CBs who choose to become accredited by recognized ABs (see Tables 1a and 1b) are expected to be conducted by staff-level personnel with wage rate equivalent to GS 13, Step 5, or $58 per hour including 50% overhead cost. We expect that executive secretaries would submit appropriate reports and notifications per §1.623(a), §1.623(b), and §1.656 (a-e) of the proposed rule. According to Bureau of Labor Statistics, an executive secretary earns approximately $19.25 per hour, or approximately $29 per hour including 50% overhead costs.[5]

In Tables 4a and 4b, we provide total burden hours for appropriate personnel (see Tables 1a, and 1b), their wage rates and total respondent costs for reporting burden of the proposed rule. For FSVP co-proposal Option 1, we estimate the total reporting burden cost at $3,745,288 (see Table 4a). For Option 2, we estimate total reporting burden cost of $3,502,935 (see Table 4b).

Table 4a: Option 1 - Estimated Annual Reporting Burden Cost

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manager equivalent to GS 14-1	2,512	$61	$153,232
Staff equivalent to GS 13-5	42,455	$58	$2,462,390
Executive secretary	38,954	$29	$1,129,666
Total Recordkeeping Cost			**$3,745,288**

Table 4b: Option 2 - Estimated Annual Reporting Burden Cost

Uploaded into ICRAS/ROCIS.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manager equivalent to GS 14-1 §1.630, §1.634, §1.670(a)-(b), §1.673	2,512	$61	$153,232
Staff equivalent to GS 13-5 §1.653(b)(2), unaccredited CBs who choose to become accredited by recognized ABs	39,196	$58	$2,273,368
Executive management/Attorney §1.623(a), §1.623(b), §1.656(a)-(e)	37,115	$29	$1,076,335
Total Recordkeeping Cost			**$3,502,935**

Overall, the cost of recordkeeping and reporting burden of the Third Party proposed rule and FSVP co-proposal Option 1 is estimated at $15,089,417. The cost of recordkeeping

[5] http://www.bls.gov/oco/ocos151.htm#earnings

and reporting burden of the Third Party proposed rule and FSVP co-proposal Option 2 is estimated at $14,245,796. Option 2 is uploaded into ICRAS/ROCIS.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs
    There are no capital costs associated with this information collection.

14. Annualized Cost to the Federal Government
    In the economic analysis of the Third Party proposed rule, we estimate the annualized cost to the FDA to administer the proposed program. The administration of the Third Party proposed program includes review of initial and renewal applications for recognition and accreditation, monitoring ABs and CBs under the proposed program, and collection and dissemination of information. Under FSVP co-proposal Option 1, annualized cost to the FDA to administer the Third Party program is estimated at approximately $17.6 million (see Appendix B of the FSVP Third Party combined economic analysis; Table B10a). Under FSVP co-proposal Option 2, annualized cost to the FDA is estimated at approximately $17.0 million (see Appendix B; Table B10b).

15. Explanation for Program Changes or Adjustments
    This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule
    FDA will make available on its website a publicly available registry of recognized accreditation bodies and of accredited auditors/certification bodies, including the name of and contact information for such bodies. Such registry may provide information on auditors/certification bodies accredited by recognized accreditation bodies through links to the websites of such accreditation bodies.

17. Reason(s) Display of OMB Expiration Date is Inappropriate
    We are not seeking approval not to display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions
    There are no exceptions to the certification.