

Accreditation Scheme for Conformity Assessment Pilot Program

0910-NEW

SUPPORTING STATEMENT

Terms of Clearance: N/A.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52) amended section 514 of the FD&C Act (21 U.S.C. 360d(d)) by adding a new subsection (d) titled “Pilot Accreditation Scheme for Conformity Assessment.”¹ Subsection 514(d) requires FDA to establish a pilot program under which testing laboratories may be accredited by accreditation bodies meeting criteria specified by FDA to assess the conformance of a device within certain FDA-recognized standards. Determinations by accredited testing laboratories that a device conforms with an eligible standard included as part of the pilot program shall be accepted by FDA for the purposes of demonstrating such conformity unless FDA finds that a particular such determination shall not be so accepted.²

The statute provides that FDA may review determinations by accredited testing laboratories, including by conducting periodic audits of such determinations or processes of accreditation bodies or testing laboratories.³ Following such a review, or if FDA becomes aware of information materially bearing on safety or effectiveness of a device tested by an accredited testing laboratory, FDA may take additional measures as determined appropriate, including suspension or withdrawal of *ASCA Accreditation* of a testing laboratory, withdrawal of *ASCA Recognition* of an accreditation body, or a request for additional information regarding a specific device.⁴

Also, FDA issued a draft guidance entitled “The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program” (see 84 FR 49741, September 23, 2019) regarding the goals and implementation of the voluntary Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program (hereafter referred to as the ASCA Pilot) in accordance with amendments made to section 514⁵ by FDARA, and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV).⁶ The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Pilot supports the Agency’s continued efforts to use its scientific resources effectively and efficiently to protect and promote public health. FDA believes

¹ See Pub. L. 115-52, section 205.

² See section 514(d)(1)(B).

³ See section 514(d)(2)(A).

⁴ See section 514(d)(2)(A)-(B).

⁵ See section 514(d)(3)(B) of the FD&C Act.

⁶ See also MDUFA IV Commitment Letter:

<https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf>

the voluntary ASCA Pilot may further encourage international harmonization of medical device regulation because it incorporates elements, where appropriate, from a well-established set of international conformity assessment practices and standards (e.g., ISO/IEC 17000 series). The voluntary ASCA Pilot does not supplant or alter any other existing statutory or regulatory requirements governing the decision-making process for premarket submissions.

2. Purpose and Use of the Information Collection

To support its mission of protecting and promoting U.S. public health, FDA aims to minimize unnecessary regulatory burden and efficiently use its scientific resources while ensuring medical devices are safe and effective. The ASCA Pilot contributes to this effort by providing increased confidence in testing results from ASCA-accredited testing laboratories, potentially decreasing the burden of individual premarket submissions when manufacturers rely on testing completed by an ASCA-accredited testing laboratory.

Evidence of conformity to one or more FDA-recognized consensus standards is often a thorough and efficient way for a manufacturer to address certain questions of safety and/or effectiveness. For manufacturers and FDA to benefit from the efficiency, however, FDA must have confidence in the declaration of conformity. Declarations of conformity are discussed in section 514(c)(1)(B) of the FD&C Act and FDA's guidance [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#).⁷ These resources indicate that a device manufacturer may provide a declaration of conformity to one or more FDA-recognized consensus standards in a premarket submission to be reviewed by FDA.

A device manufacturer may declare conformity to an FDA-recognized consensus standard based on test results; however, there may be variability in how this testing is conducted. Given this variability, and because medical devices are increasingly complex and can involve high risks to patients, declarations of conformity are not always sufficient to fully address FDA's questions regarding safety and effectiveness for premarket submissions. As a result, FDA reviewers may need to request additional information and review supplemental documentation as described in FDA's guidance, [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#). In some instances, a device manufacturer may decide to repeat or revise testing based on FDA input. These interactions and requests for modifications in test methodology can result in delays and additional costs, but are needed to provide FDA with the necessary confidence in a declaration of conformity for its intended purpose.

Under the ASCA Pilot's conformity assessment scheme, ASCA-recognized accreditation bodies accredit testing laboratories using ISO/IEC 17025:2017: *General requirements for the competence of testing and calibration laboratories* and the ASCA program specifications associated with each FDA-recognized consensus standard and test method included in the ASCA Pilot. Device manufacturers may then choose to use an ASCA-

⁷ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>

accredited testing laboratory to conduct testing for premarket submissions to FDA. During the ASCA Pilot, FDA generally will accept determinations from ASCA-accredited testing laboratories (i.e., test results) when the standard and test methods are within the testing laboratory's scope of *ASCA Accreditation* at the time of testing. We believe this general approach can help minimize unnecessary regulatory burden and help FDA efficiently use our scientific resources while ensuring there is reasonable assurance of the safety and effectiveness of medical devices intended for human use.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's request.

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

Based on the guidelines set by the Small Business Administration (SBD) on what constitutes a small business (for manufacturing, a small business cannot exceed 500 employees), we estimate that approximately 95% of U.S. medical device manufacturing establishments may be small businesses.

We estimate that at least 50 % of the testing laboratories and most, if not all, of the accreditation bodies are small businesses.

This is a voluntary program; therefore, ABs are not required to participate in order to accredit TLs outside of the ASCA Pilot and TLs are not required to participate in order to have their testing included in a device manufacturer's premarket submissions to FDA. We are utilizing e-mail for accepting submissions, information requests, etc.

FDA aids small businesses in dealing with the regulations by providing guidance and information through CDRH's Division of International and Consumer Education (DICE). DICE provides technical and non-financial assistance to firms through a comprehensive program including seminars, educational conferences, printed and electronic information materials, and via e-mail and a toll-free telephone number. Other CDRH staff members are also available to respond to questions. Alternatively, the FDA may provide assistance through its Regional Small Business Representatives. FDA has provided a Small Business Guide on the agency's website at <http://www.fda.gov/oc/industry/>.

6. Consequences of Collecting the Information Less Frequently

Respondents will respond to the information collection once when they initially apply for the program and they will request changes regarding their participation on an occasional basis. Additionally, respondents will submit annual status reports.

We are utilizing existing infrastructure set in place by ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories* that testing laboratories already use and ISO/IEC 17011: *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies* that accreditation bodies already use. These standards require annual audits, disclosures, updates, etc. Additionally, section 514(d)(3)(D) of FDARA states that FDA must submit an annual report. Collecting annual status reports from the respondents enables us to provide the annual report on the progress of the pilot as required by FDARA.

There are no legal obstacles to reduce the burden.

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

As part of the ASCA Pilot, ASCA-recognized accreditation bodies and ASCA-accredited testing laboratories agree to notify FDA within 5 business days of any changes that may impact their participation in the program. It is important for FDA to be notified of any changes that will impact an accreditation body or testing laboratory's participation in the ASCA Pilot. Timely notification will allow FDA to update our public website. Manufacturers will use the public website to choose an ASCA-accredited testing laboratory to work with should they choose to participate in the ASCA Pilot, and testing laboratories will use the public website to choose an ASCA-recognized accreditation body to work with to obtain *ASCA Accreditation*. The faster we receive notification that an AB or TL's ability to participate in the ASCA Pilot may be impacted, the faster we can get this information out to the public so that manufacturers and testing laboratories may use their resources appropriately.

There are no other special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of September 5, 2019 (84 FR 46737). We received one comment on the 60-day notice, but it was not related to the information collection or the ASCA Pilot Program. We also considered comments received on the draft guidance, titled "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program" (see 84 FR 49741, September 23, 2019). We have made no changes to the burden estimate as a result of the comments. However, as a result of comments on the draft

guidance and for clarity, we have updated certain terminology used to describe the ASCA Pilot.

FDA has developed the framework of the ASCA Pilot with the support and participation of stakeholders from industry, the conformity assessment community, and the National Institute of Standards and Technology (NIST). The following NIST documents provide an overview of conformity assessment, which FDA considered for the design, development, and implementation of the ASCA Pilot: NIST SP 2000-01 ABCs of Conformity Assessment (2018) and NIST SP 2000-02 Conformity Assessment Considerations for Federal Agencies (2018).

In addition, FDA received and reviewed comments in response to its notice in the Federal Register of May 16, 2017 (82 FR 22548, <https://www.federalregister.gov/documents/2017/05/16/2017-09850/request-for-comments-on-food-and-drug-administration-accreditation-scheme-for-conformity-assessment>).

As required by FDARA,⁸ FDA held a public workshop titled “Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards” on May 22-23, 2018 (see 83 FR 2165, January 16, 2018, <https://www.federalregister.gov/documents/2018/01/16/2018-00551/accreditation-scheme-for-conformity-assessment-of-medical-devices-to-food-and-drug>), to discuss and obtain input and recommendations from stakeholders about the ASCA Pilot, including its goals and scope as well as a suitable framework and procedures to facilitate implementation. The workshop is discussed on [FDA’s “Workshop and Conferences” website](#).⁹

Input from these resources guided the design of the conformity assessment scheme and selection of the standards included in the ASCA Pilot.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

This ICR collects personally identifiable information (PII) or information of a personal nature. PII is collected in the context of the subject individuals’ professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII collected includes name, address, telephone number and email address.

⁸ See section 514(d)(3)(A)

⁹ Available at <https://www.fda.gov/medical-devices/news-events-medical-devices/workshops-conferences-medical-devices>

FDA further determined this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

The project does not require an IRB.

11. Justification for Sensitive Questions

The information collection does not include questions that are of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Under the ASCA Pilot's conformity assessment scheme, ASCA-recognized accreditation bodies accredit testing laboratories using ISO/IEC 17025:2017: *General requirements for the competence of testing and calibration laboratories* and the ASCA program specifications associated with each FDA-recognized consensus standard and test method included in the ASCA Pilot. ASCA-accredited testing laboratories may conduct testing to provide data used to determine conformance of a device with one or more of the FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot. When an ASCA-accredited testing laboratory conducts testing under the ASCA Pilot, it provides to the device manufacturer all information listed in the relevant ASCA program specifications, which includes an ASCA summary test report. Device manufacturers may choose to use an ASCA-accredited testing laboratory to conduct testing for premarket submissions to FDA. A device manufacturer that uses an ASCA-accredited testing laboratory to perform testing in accordance with the provisions of the ASCA Pilot then includes a declaration of conformity (DOC) with any necessary supplemental documentation (e.g., ASCA summary test report) as part of a premarket submission to FDA.¹⁰ Testing performed by an ASCA-accredited testing laboratory can be used to support a premarket submission for any device if the testing was conducted using an FDA-recognized consensus standard and test method eligible for inclusion in the ASCA Pilot and in accordance with the ASCA Pilot specifications for that standard.

To participate in the ASCA Pilot, accreditation bodies apply to FDA for *ASCA Recognition*. An application includes demonstration that they have the qualifications for

¹⁰ As an element of the premarket submission, Declarations of Conformity are included in the estimated information collection burden for the premarket submission, e.g., a DOC in a premarket notification (510(k) submission) is included in the estimated burden in OMB control number 0910-0120.

ASCA Recognition and agreement to terms of participation. For example, an ASCA-recognized accreditation body agrees to attend training, regularly communicate with FDA, and support periodic FDA audits. When FDA grants *ASCA Recognition*, we will identify the scope of specific standards and test methods to which the accreditation body may accredit testing laboratories as part of the ASCA Pilot.

To participate in the ASCA Pilot, testing laboratories apply to FDA for *ASCA Accreditation*. An application includes demonstration that they have the qualifications for *ASCA Accreditation* and agreement to terms of participation. For example, an ASCA-accredited testing laboratory agrees to attend training, regularly communicate with FDA, and support periodic FDA audits. When FDA grants *ASCA Accreditation*, we will identify the scope of *ASCA Accreditation* of specific standard and test methods to which the testing laboratory may conduct testing as part of the ASCA Pilot.

During the ASCA Pilot, FDA generally intends to rely on the results from ASCA-accredited testing laboratories for the purpose of premarket review without the need for additional information related to conformance with a standard. In addition, FDA does not intend to question the validity of test methods within a testing laboratory's scope of *ASCA Accreditation* except in certain circumstances

Note that *ASCA Accreditation* is separate from any accreditation that an accreditation body may provide to a testing laboratory for purposes other than the ASCA Pilot.

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours ¹
Application by AB for ASCA <i>Recognition</i>	8	1	8	6	48
Request by AB to continue ASCA <i>Recognition</i>	1	1	1	6	6
Request by AB for ASCA <i>Recognition</i> (subsequent to withdrawal)	1	1	1	6	6
Request by AB to expand scope of ASCA <i>Recognition</i>	1	1	1	6	6
AB annual status report	8	1	8	3	24
AB notification of change	8	1	8	1	8
Application by TL for ASCA <i>Accreditation</i>	150	1	150	4	600
Request by TL to continue ASCA <i>Accreditation</i>	15	1	15	4	60
Request by TL for ASCA <i>Accreditation</i> (subsequent to withdrawal or suspension)	5	1	5	4	20
Request by TL to expand scope of ASCA <i>Accreditation</i>	75	1	75	4	300
TL annual status report	150	1	150	1.5	225
TL notification of change	5	1	5	1	5
Request for withdrawal or suspension of ASCA <i>Accreditation</i> (TLs) or request for withdrawal of ASCA <i>Recognition</i> (ABs)	6	1	6	0.08 (5 minutes)	1
Pilot feedback questionnaire (ABs and TLs)	158	1	158	0.5 (30 minutes)	79
Total					1,388

¹ Totals have been rounded to the nearest hour.

Table 2.--Estimated Annual Recordkeeping Burden

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
AB setup documentation (SOPs) & training (one-time burden)	8	1	8	25	200
TL setup documentation (SOPs) & training (one-time burden)	150	1	150	25	3,750
AB record maintenance	8	1	8	1	8
TL record maintenance	150	1	150	1	150
Total					4,108

Table 3.--Estimated Annual Third-Party Disclosure Burden

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Request for Accreditation (TLs requesting accreditation from ABs)	150	1	150	0.5 (30 minutes)	75
Review/Acknowledgement of accreditation request (ABs)	8	22	176	40	7,040
Test Reports (TLs)	880	1	880	1	880
Total					7,995

Our estimate of 8 accreditation bodies (ABs) is based on the number of ILAC signatories in the United States economy.¹¹ We estimate that approximately 150 testing labs will seek accreditation. Our estimate of Test Reports is based on the number of premarket submissions we expect per year with testing from an ASCA-accredited testing laboratory.

Our estimates for the Average Burden per Response, Recordkeeping, and Disclosure are based on the burden for similar programs.

The ASCA Pilot does not address specific content for a particular premarket submission. Information collections associated with premarket submissions have been previously approved as follows: The collections of information in 21 CFR part 807, subpart E (premarket notification) have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814, subparts A through E (premarket approval) have been approved under

¹¹ <https://ilac.org/signatory-search/> accessed on 7/8/19.

OMB control number 0910-0231; the collections of information in 21 CFR part 814, subpart H (humanitarian device exemption) have been approved under OMB control number 0910-0332; the collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910-0844; the collections of information in 21 CFR part 312 (investigational new drug application) have been approved under OMB control number 0910-0014; and the collections of information in 21 CFR part 601 (biologics license application) have been approved under OMB control number 0910-0338.

12b. Annualized Cost Burden Estimate

FDA estimates the annualized cost burden as \$608,393. We believe that work will be performed by several types of worker. For Accreditation Bodies, we believe the work will be performed by Program Managers, Technical and/or Quality Assessors, and Secretaries or Administrative workers. For Testing Laboratories, we believe the work will be performed by Test Lab Managers, Test Lab Technical Personnel, and Secretaries or Administrative workers.

The information collections (ICs) in the burden tables in section 12a of this document for “*Request for withdrawal or suspension of ASCA Accreditation (TLs) or request for withdrawal of ASCA Recognition (ABs)*” and “*Pilot feedback questionnaire (ABs and TLs)*” include work performed by both TLs and ABs. For purposes of calculating the number of burden hours performed by ABs and TLs, respectively, we assume that the No. of Respondents for those ICs are equally distributed between ABs and TLs. Respondents for all other ICs are either ABs or TLs. Therefore, we estimate that the Total burden hours for ABs are 7,386 and the Total burden hours for TLs are 6,105, for a combined total of 13,491 burden hours.

As indicated in the table below, we used occupational categories and updated wage rates from the Bureau of Labor and Statistics data to determine the cost burden estimate.

Type of Respondent— % of Burden Hours for Respondent Type	Burden Hours ¹	BLS Occupation Code ²	Hourly Wage Rate ²	Total Respondent Costs ¹
Accreditation Bodies				
AB Program Manager —45%	3,324	11-1021 General & Operations Managers	\$59.56	\$197,977
Technical and/or Quality Assessor— 50%	3,693	13-1041 Compliance Officers	\$34.86	\$128,738
Secretary or Admin. —5%	369	43-6010 Secretaries and Administrative Assistants	\$20.34	\$7,505
Total ABs	7,386			\$334,220
Testing Laboratories				
Test Lab Technical Personnel—30%	1,832	29-2010 Clinical Laboratory Technologists and Technicians	\$25.91	\$47,467
Test Lab Manager— 65%	3,968	11-9199 Managers, All Other	\$55.57	\$220,502
Secretary or Admin. —5%	305	43-6010 Secretaries and Administrative Assistants	\$20.34	\$6,204
Total TLs	6,105			\$274,173
Total All	13,491			\$608,393
¹ Rounded to the nearest whole number.				
² Hourly wage rate is based on the Bureau of Labor and Statistics' May 2018 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm).				

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

FDA estimates that a total of 5 full time equivalent (FTE) positions are used for the ASCA Pilot. Based on a cost of \$270,305 per position (which is the agency's projected average cost of an FTE including benefits*), the estimated annual Federal cost is \$1,351,525.

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2018, as provided by agency economists.

Additional funding for ASCA includes a one-time operating cost for IT support (\$700,000) and \$1.5M operating costs over 5 years. Therefore, the average estimated Federal cost is \$1,791,525 per year.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

As part of the enactment of MDUFA IV, FDA committed to publish the following information on FDA's ASCA website (see <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca>)

- A list of ASCA-recognized accreditation bodies including the FDA-recognized consensus standards and test methods within their scopes of *ASCA Recognition*; an expiration date for each accreditation body's *ASCA Recognition* will also be provided.
- A list of ASCA-accredited testing laboratories including the FDA-recognized consensus standards and test methods within their scopes of *ASCA Accreditation*; an expiration date for each testing laboratory's *ASCA Accreditation* will also be provided.

Device manufacturers may choose to use an ASCA-accredited testing laboratory to conduct testing for premarket submissions to FDA. There are no other plans for tabulation or publication. We anticipate that the program will remain in pilot during the 36-month OMB approval period and we will update the ICR upon transition to an ongoing program.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.