

United States Food and Drug Administration

Medical Devices:
Accreditation Scheme for Conformity Assessment Program

OMB Control No. 0910-0889 -- EXTENSION

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of sections 514 and 514(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d and 360d(d)) which provide for the establishment of performance standards and authorizes the *Accreditation Scheme for Conformity Assessment Program* (ASCA Program). As communicated on our website at [FDA Accreditation Scheme for Conformity Assessment Program](#), we announced the implementation of a program under which testing laboratories may be accredited by ASCA-recognized accreditation bodies meeting criteria specified by the Food and Drug Administration (FDA) to assess the conformance of a device to certain FDA-recognized standards. We also provide links to associated instructions and agency guidance intended to assist respondents with participation in the program. 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. Following such a review, or if FDA becomes aware of information materially bearing on safety or effectiveness of a device tested by an ASCA-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.

The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Program continues our efforts to use scientific resources effectively and efficiently to protect and promote public health. We believe the voluntary ASCA Program 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 Program does not supplant or alter any other existing statutory or regulatory requirements governing the decision-making process for premarket submissions.

The information collection includes the following collection instruments, available for download on our website:

- Guidance Documents:
 - o [*The Accreditation Scheme for Conformity Assessment \(ASCA\) Program*](#), (draft, September 2024)
 - o [*Biocompatibility Testing of Medical Devices – Standards Specific Information for the Accreditation Scheme for Conformity Assessment \(ASCA\) Program*](#), (draft, September 2024)
 - o [*Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment \(ASCA\) Program*](#), (draft, September 2024)

2. Purpose and Use of the Information Collection

Under the ASCA Program’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 eligible standard and test method included in the ASCA Program. ASCA-accredited testing laboratories may conduct testing to determine conformance of a device with at least one of the standards eligible for inclusion in the ASCA Program. 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. Declarations of conformity are discussed in section 514(c)(1)(B) of the FD&C Act and FDA’s guidance document [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#).¹ 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.

Respondents to the information collection are accreditation bodies, testing laboratories, and device manufacturers.

3. Use of Improved Information Technology and Burden Reduction

We estimate all respondents will utilize dedicated e-mail to fulfill the information collection. The proposed webforms have been developed through our Center for Devices and Radiological Health (CDRH) Customer Collaboration Portal. We also include training resources on our ASCA webpage.

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

The information collection poses no undue burden on small entities. The ASCA is a voluntary program; therefore, accreditation bodies are not required to participate in order to accredit testing laboratories outside of the ASCA Program and testing laboratories are not required to participate in order to have their testing included in a device manufacturer's premarket submissions to FDA.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is driven by respondents' voluntary participation in the program. We are utilizing the existing framework of 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*, also consistent with ways in which respondents already comply with similar information collection activities.

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 Program, 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. Timely notification allows FDA to update our public website to reflect these changes. Manufacturers utilize the public website to choose an ASCA-accredited testing laboratory to work with should they choose to participate in the ASCA Program, and testing laboratories may use the public website to choose an ASCA-recognized accreditation body to work with to obtain *ASCA Accreditation*. The sooner we receive notification that an accreditation body or testing laboratory's ability to participate in the ASCA Program may be impacted, the sooner we are able to the information publicly 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

FDA published a 60-day notice for public comment in the *Federal Register* of July 17, 2026 (91 FR 44854). Two comments were received. Both comments were determined to be PRA-related.

One commentor recommended that FDA simplify the information collection requirements for the extension of ASCA recognition by limiting submissions to information directly relevant to the requested scope extension and any information that has materially changed since the accreditation body's most recent recognition or renewal. The commentor noted that the current process may require resubmission of information that FDA recently reviewed during an initial recognition or biennial renewal, creating duplicative burden for both accreditation bodies and FDA staff. FDA appreciates the commentor's comment and acknowledges the concern that the current extension process may generate duplicative administrative burden for accreditation bodies and FDA staff. FDA is currently preparing the final version of the ASCA Program Guidance (draft September 20, 2024) that will replace the ASCA Pilot Program Guidance of September 25, 2020, which we believe will address concerns like these. FDA will continue to evaluate opportunities to reduce unnecessary burden while preserving the integrity of the ASCA Program's oversight framework.

A patient commenter addressed the practical utility of the information collected and ways to enhance its quality and clarity. The commenter recommended adding items to the existing feedback questionnaire to gather data on standards outside current ASCA categories, the accessibility of program information to clinicians and patients, and suggested that audit outcomes and the basis for withdrawal of ASCA accreditation be captured in the collection in a comparable format. FDA appreciates the commenter's observations. FDA notes that the PRA burden estimates do not represent an existing or ongoing questionnaire, but rather reflect the time accreditation bodies, testing laboratories, and device manufacturers spend participating in and using the ASCA Program. Expansion of the standards contained in the ASCA Program is an ongoing priority for FDA. FDA notes that remaining comments regarding specific standards families and orthopedic implant testing fall outside the scope of this PRA notice and will not be addressed here.

ASCA Workshop and Webinar Materials

- April 17, 2024: [ASCA Expansion Workshop](#)
- November 6, 2024: [Public Workshop – Accreditation Scheme for Conformity Assessment and Use of Chemical Analysis to Support Biocompatibility of Medical Devices](#)

Annual Reports

- [ASCA 2024 Annual Report](#)
- [ASCA Consolidated Pilot Final Report and 2023 Annual Report](#)
- [ASCA 2022 Annual Report](#)

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This ICR does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports a 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. Because neither FDA nor any party acting on behalf of the agency collects PII, the ICR is not subject to the Privacy Act of 1974 and the requirements of the Privacy Act such as displaying a Privacy Act Statement on a collection form do not apply.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. *Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Request by AB to continue ASCA Recognition	2	1	2	6	12
Request by AB for ASCA Recognition (subsequent to withdrawal)	1	1	1	6	6
Request by AB to expand scope of ASCA Recognition	1	1	1	6	6
AB annual status report	5	1	5	3	15
AB notification of change	5	1	5	1	5
Application by TL for ASCA Accreditation	50	1	50	4	200
Request by TL to continue ASCA Accreditation	75	1	75	1	75
Request by TL for ASCA Accreditation (subsequent to withdrawal or suspension)	5	1	5	4	20
Request by TL to expand scope of ASCA Accreditation	75	1	75	4	300
TL annual status report	100	1	100	1.5	150
TL notification of change	5	1	5	1	5
Voluntary Request for withdrawal or suspension of ASCA Accreditation (TLs) or request for withdrawal of ASCA Recognition (ABs)	6	1	6	0.08 (5 mins.)	1
TOTAL					795

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)	3	1	3	25	75
TL setup documentation (SOPs) & training (one-time burden)	20	1	20	25	500
AB record maintenance	8	1	8	1	8
TL record maintenance	150	1	150	1	150
TOTAL			181		733

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

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
Review/Acknowledgement of accreditation request (ABs)	8	22	176	40	7,040
Test Reports (TLs)	880	1	880	1	880
TOTAL			1,206		7,995

Our estimate of eight accreditation bodies was based on the number of ILAC signatories in the United States economy.¹ However, during the pilot, we learned that there are only five medical device accreditation bodies. Therefore, all five have applied and been granted approval, no further applications for accrediting bodies will be received. We estimate that approximately 50 new testing labs will seek accreditation, given that over 100 have already received 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 No. of Respondents and Average Burden per Response, Recordkeeping, and Disclosure are based on our experience with the pilot program.

12b. Annualized Cost Burden Estimate

We estimate an annualized cost burden of \$497,288. We assume collection activities applicable to the elements “*Request for withdrawal or suspension of ASCA Accreditation (TLs) or request for withdrawal of ASCA Recognition (ABs)*”. We assume that the remaining collection activities are distributed among ABs and TLs and account for a total of 9,523 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 corresponding cost estimate.

¹ <https://ilac.org/signatory-search/>. Initially accessed in 2019, as of 5/9/23, the number of ILAC signatories in the U.S. economy is six. Upon evaluation of this ICR, we retain eight for our estimate of respondents.

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%	3,225	11-1021 General & Operations Managers	\$64	\$206,400
Technical and/or Quality Assessor—50%	3,584	13-1041 Compliance Officers	\$40.86	\$146,442
Secretary or Admin.— 5%	358	43-6010 Secretaries and Administrative Assistants	\$25.03	\$8,961
Total Abs	7,167			\$361,803
Testing Laboratories				
Test Lab Technical Personnel—30%	707	29-2010 Clinical Laboratory Technologists and Technicians	\$31.41	\$22,207
Test Lab Manager— 65%	1531	11-9199 Managers, All Other	\$72.06	\$110,324
Secretary or Admin.— 5%	118	43-6010 Secretaries and Administrative Assistants	\$25.03	\$2,954
Total TLs	2,356			\$135,485
Total All	9,523			\$497,288

¹ Rounded to the nearest whole number.

² Hourly wage rate is based on the Bureau of Labor and Statistics' May 2024 National Occupational Employment and Wage Estimates (<https://data.bls.gov/oes/#/industry/000000>), then doubled to account for benefits and overhead.

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

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

14. Annualized Cost to the Federal Government

Assuming 13 full time equivalent (FTE) positions are allocated to administer the information collection, we calculate annual costs of \$4,709,536. Based on an internal cost model, we assume a fully-loaded cost of \$362,272 (rounded) per position.

15. Explanation for Program Changes or Adjustments*

We have decreased the estimated annual burden by 839 hours to reflect updated participation and completion-time estimates as the ASCA Program has matured. This decrease is attributable to adjustments in estimates rather than a program change. The estimated recordkeeping and third-party disclosure burdens remain unchanged.

The reporting burden decrease includes:

- 48 hours from removing initial applications for ASCA Recognition;
- 400 hours from reducing anticipated applications for ASCA Accreditation from 150 to 50 annually;
- 225 hours from reducing the estimated time for TL continuation requests from 4 hours to 1 hour;
- 12 hours from reducing estimated AB participation in annual status reports and notifications of change from 8 to 5;
- 75 hours from reducing the estimated burden for TL annual status reports from 225 to 150 hours;
- and
- 79 hours from removing feedback questionnaires used during the pilot.

16. Plans for Tabulation and Publication and Project Time Schedule

In meeting one of our commitments under MDUFA IV, we publish the following information on our 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*.
- A list of ASCA-accredited testing laboratories including the FDA-recognized consensus standards and test methods within their scopes of *ASCA Accreditation*.

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.

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

Consistent with established practice, FDA publishes a *Federal Register* notice announcing OMB approval of information collection found in guidance documents applicable to the information collection and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.