



September 1, 2026

Grace R. Graham, Deputy Commissioner
Policy, Legislation, and International Affairs (OPLIA)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: **Docket No FDA-2026-N-7130** for “Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation Scheme for Conformity Assessment Program”

Dear Deputy Commissioner Graham,

The American Association for Laboratory Accreditation (A2LA) appreciates the opportunity to comment on the Food and Drug Administration’s (FDA) information collection associated with the Accreditation Scheme for Conformity Assessment (ASCA) Program.

By way of background, A2LA is among the largest accreditation bodies in the world, and the only independent, nonprofit, internationally recognized accreditation body in the United States that offers a full range of comprehensive conformity assessment accreditation services. Currently, A2LA is an ASCA-recognized accreditation body and provides accreditation services to approximately 60 laboratories in support of the ASCA Program.

Extension of ASCA Recognition

A2LA’s comments relate specifically to Section X, *Processes and Policies for Accreditation Bodies*, Subsection C, *Extension of ASCA Recognition*, together with Appendix A of the ASCA Pilot Program Final Guidance published on September 25, 2020.

The current extension process requires an already recognized accreditation body to follow essentially the same application process used for initial ASCA recognition. As a result, accreditation bodies may be required to resubmit information the FDA has already reviewed during the initial recognition process and again during the biennial renewal of ASCA recognition.

The information required by Appendix A includes substantive documentation regarding the accreditation body’s ASCA activities and accreditation processes. This may include descriptions of how the accreditation body assesses laboratories to ISO/IEC 17025 and applicable ASCA program specifications, how laboratory technical competence is evaluated, the qualifications of technical assessors, and applicable corrective action and complaint processes. Recompiling and resubmitting this information for a scope extension can be burdensome when the information has not changed since the accreditation body’s most recent renewal. It may also require FDA staff to review much of the same material again within a relatively short period of time.

For example, an accreditation body may complete its biennial renewal and then request an extension of its ASCA recognition only several months later. Under the current process, the accreditation body may again be required to assemble information the FDA recently reviewed as part of the renewal, even though the requested change may be limited to the addition of specific FDA-recognized consensus standards or test methods.

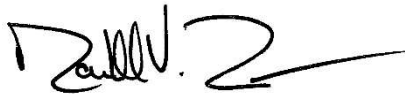
A2LA recommends simplifying the extension process for currently recognized accreditation bodies by limiting the submission requirements to information directly relevant to the requested extension and any information that has materially changed since the accreditation body's most recent recognition or renewal. This would reduce duplicative administrative work for both accreditation bodies and the FDA while preserving the FDA's ability to evaluate whether the accreditation body has demonstrated the competence necessary for the requested extension.

Conclusion

A2LA values its participation in the ASCA Program and supports its continued success. We would welcome further discussion with the FDA regarding opportunities to simplify the extension process while maintaining confidence in ASCA-recognized accreditation bodies and the laboratories they accredit.

If you have any questions or need additional information, please feel free to contact me directly at rquery@A2LA.org.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Randall Query", with a long horizontal flourish extending to the right.

Randall Query
Director of Government Relations
American Association for Laboratory Accreditation (A2LA)