

Section 808(b)(2) of the FD&C Act requires FDA to develop model accreditation standards that recognized accreditation bodies shall use to qualify third-party auditors/certification bodies for accreditation, and in so doing, to look to existing standards for certification bodies (as of the date of enactment of FSMA) to avoid unnecessary duplication of efforts and costs. This draft guidance, when finalized, will constitute the model accreditation standards referred to in section 808(b)(2) of the FD&C Act. The draft guidance contains FDA recommendations on third-party auditor/certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under an FDA program required by FSMA.

FDA was guided in developing this draft guidance, in part, by the National Technology Transfer and Advancement Act of 1995, which directs Federal Agencies to use voluntary consensus standards in lieu of government-unique standards, except where inconsistent with law or otherwise impractical.

In developing the draft guidance, FDA considered several voluntary consensus standards for their relevance to the qualifications of third-party auditors/certification bodies that would certify foreign food facilities and/or their foods for conformance with the requirements of the FD&C Act. FDA also sought to identify the standards most commonly used by stakeholders (e.g., other governments, public and private accreditation bodies, the food industry, and the international standards community) in qualifying third-party auditors/certification bodies for conducting food safety audits. As a result, FDA was guided in developing the draft model accreditation standards guidance document by International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) ISO/IEC 17021: *Conformity Assessment—Requirements for bodies providing audit and certification management systems* (2011) (“ISO/IEC 17021:2011”) and included an appendix containing a crosswalk between ISO/IEC 17021:2011 and ISO/IEC 17065: *Conformity assessment—Requirements for bodies certifying products, processes and services* (“ISO/IEC 17065:2012”).

The draft guidance document is issued as a companion to the proposed rule “Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications” that was published in the **Federal Register** of July 29, 2013 (78 FR 45781). When this guidance is

finalized, it will serve as a companion guidance document to the final rule.

II. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA’s July 29, 2013, proposed rule on Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, which this draft guidance is intended to interpret. The proposed collections of information in the proposed rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule (see 78 FR 45781 at 45825, reference 25, pages 216–239, available at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>) and has submitted the proposed collections to OMB for approval.

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: July 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality: Change in Meeting Dates

ACTION: Notice of change in meeting dates.

SUMMARY: Health Resources and Services Administration is issuing this notice to change the meeting dates for the Notice is hereby given of a change in the meeting of the Secretary’s Advisory Committee on Infant Mortality (SACIM). The meeting was originally scheduled for July 13–14, 2015 and was published in the **Federal Register** on June 26, 2015, 80 FR 123 (page 36826).

DATES: The meeting dates have changed to August 10, 2015, starting at 8:30 a.m. (EST) and ending at 5 p.m. (EST) and August 11, 2015, starting at 8:30 a.m. (EST) and ending at 3:30 p.m. (EST).

The meeting remains virtual via webinar and phone using the following links: URL: https://hrsconnectsolutions.com/sacim_seminar_200/. Call-In Number: 1.888.942.8170. Passcode: 3494113.

For more details, please visit the ACIM Web site: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/InfantMortality/index.html>. The meeting is open to the public with attendance limited to availability of call-in lines.

FOR FURTHER INFORMATION CONTACT:

Anyone requiring information regarding the Committee should contact Michael C. Lu, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration, Room 18 W, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–2170.

Individuals who are submitting public comments or who have questions regarding the meeting and location should contact David S. de la Cruz, Ph.D., M.P.H., SACIM Designated Federal Official, HRSA, Maternal and Child Health Bureau, telephone: (301) 443–0543, email: David.delaCruz@hrs.hhs.gov. Public comments must be submitted to Dr. de la Cruz by email no later than August 3, 2015.

Jackie Painter,

Director, Division of the Executive Secretariat.

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