Accreditation and Reaccreditation Process for Firms under the Third Party Review Program: Part I

Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Reviewers

This guidance document is being distributed for comment purposes only.
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You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Scott McFarland at 301-796-6217 or Scott.McFarland@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1815 to identify the guidance you are requesting.

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), requires FDA to establish and publish criteria to reaccredit and deny reaccreditation to third parties under section 523 of the FD&C Act (21 U.S.C. 360m) to perform premarket review of class I and eligible class II premarket notification [510(k)] submissions. This draft guidance describes the accreditation, reaccreditation, and accreditation withdrawal processes, including criteria that will be considered to accredit, reaccredit, deny accreditation to, and deny reaccreditation to firms under the Third Party Review Program (TPRP).

The International Medical Device Regulators Forum (IMDRF) recently issued a proposed draft document entitled "Recognition Criteria for Medical Device Auditing Organizations" ("IMDRF document"). [http://www.imdrf.org/docs/imdrf/final/consultations/imdrf-mdsap-criteria.pdf] The IMDRF was conceived in February 2011, as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world, which includes FDA, who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices. The purpose of the IMDRF is to accelerate international medical device regulatory harmonization and convergence (*see* http://www.imdrf.org/). As one of its initial actions, the

IMDRF is developing the foundations for a Single Audit Program for medical devices that includes criteria for the recognition and re-recognition of third party auditing organizations. The IMDRF document includes criteria used or proposed by member countries for conformity assessment bodies and third party reviewers.

The IMDRF also plans to incorporate specific requirements for competency and considerations for codes of conduct that together will constitute the basis for the recognition of third party auditors under a Single Audit Program. When finalized and adopted, the IMDRF document will represent a harmonized standard for participating countries.

In an effort to develop criteria that could be used in the future for a harmonized TPRP, in this draft guidance we use recognition criteria described in the IMDRF document as part of the criteria for third party accreditation by the FDA. We intend to incorporate information from the IMDRF document in subsequent draft guidance to the extent appropriate as part of the criteria for accreditation and reaccreditation of reviewers under the TPRP.

When final, this draft guidance will replace and supersede any previous accreditation and reaccreditation processes previously announced by FDA.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. General Information about the Third Party Review Program

The purpose of the TPRP is to implement section 523 of the FD&C Act by accrediting third party reviewers (TPR) to review 510(k)s for certain low-to-moderate risk devices. The TPRP is intended to enable FDA to use its scientific review resources for higher-risk and complex devices, while maintaining a high degree of confidence in the review of low-to-moderate risk and less complex devices by TPRs, and to provide manufacturers of eligible devices a voluntary alternative review process that may yield more rapid 510(k) decisions. Participation in the program is entirely voluntary. Manufacturers may continue to submit 510(k)s directly to FDA. Manufacturers may also hire or contract third parties other than those accredited by FDA, but only 510(k)s reviewed by TPRs will be eligible for review within 30 days under section 523 of the FD&C Act. FDA uses the Third Party Recognition

Board (TPRB) to accredit persons to review premarket notifications of certain medical devices.

In accordance with the requirements of section 523 of the FD&C Act, FDA's TPRP includes a number of features designed to maintain a high level of quality in the review of 510(k)s by TPRs and to minimize risks to the public. These include the exclusion of all class III devices and any class II devices that are intended to be permanently implantable or life sustaining or life supporting, or, subject to the limitations of the FD&C Act, that require clinical data.

III. Criteria Used by FDA to Determine Whether an Applicant Qualifies to be a TPR

In determining whether to accredit a TPR, FDA will consider whether a firm has provided to FDA:

(1) administrative information,
(2) a certification/agreement statement signed by the most responsible individual at the firm, including a certification that the firm will at all times while accredited by FDA be in conformity with the IMDRF's document entitled "Recognition Criteria for Medical Device Auditing Organizations," which includes the International Organization for Standardization (ISO)/the International Electrotechnical Commission (IEC) 17021:2011 requirements as indicated in the IMDRF document,
(3) a certification of eCopy understanding, [1]
(4) a certification that the firm has an adequate code of conduct, and
(5) a certification that the firm will ensure competency by meeting general competency requirements for the organization and competency requirements for product assessors or product reviewers.

FDA will also consider any past performance as a TPR.

IV. Format and Content of an Initial TPR Application

Persons wishing to become TPRs under section 523 of the FD&C Act should apply to the CDRH TPRB. We are required to respond to your request for accreditation within 60 days of receiving your application. Three complete copies of your application, with all attachments, should be sent to the address below by a method such as registered mail that returns to you proof of delivery. You should keep a complete copy for your files. FDA will

[1] Guidance on the eCopy program can be found in the guidance entitled "eCopy Program for Medical Device Submissions" and found at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

accept electronic submissions from any applicant that wishes to voluntarily submit a .pdf file format version of the submission.

William Sutton, Chairman
Third Party Recognition Board (TPRB)
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue,
Bldg. 66, rm. 4626
Silver Spring, Maryland 20993 USA.

We will fax a date-stamped acknowledgment letter to your contact person when we receive your application. The TPRB will review these materials and respond within 60 days of the date of the receipt of the application with a letter of accreditation, a denial of accreditation, or a request for additional information. We may deem incomplete and deny your request for accreditation if you fail to respond to a request for additional information in a timely manner. You may make a written request to the Director, Office of Communication and Education (OCE), CDRH, for reconsideration of a decision to deny your request for recognition or to withdraw your request for recognition.

You should include the following information in an application to demonstrate that you meet the qualifications addressed in this section.

A. Administrative Information

1. Name and address of the firm seeking accreditation;
2. Telephone number and FAX number of the contact person. The contact person should be the person to whom questions about the content of the application may be addressed and the person to whom a letter of determination and general correspondence will be directed;
3. Name and title of the most responsible individual at the firm. Foreign firms should also identify the name, address, telephone number, and FAX number of an authorized representative located within the United States who will serve as the TPR's contact with FDA;
4. Brief description of the firm, including: type of organization (e.g., not-for-profit institution, commercial business, other type of organization); size of organization (number of employees); number of years in operation; nature of work (e.g., testing or certification laboratory); and information regarding ownership, operation, and control of organization sufficient to assess its degree of independence from device manufacturers and distributors; and
5. Listing of any national, state, local, or other accreditations.

B. Certification/Agreement Statement

You should provide a statement, signed by the most responsible individual at the firm, certifying that the TPR will:

1. Report information that accurately reflects data reviewed;
2. Limit work to that for which competence and capacity are available;
3. Treat information received, records, reports, and recommendations as proprietary information;
4. Be in conformity at all times while accredited by FDA with the IMDRF's document entitled "Recognition Criteria for Medical Device Auditing Organizations," which includes the ISO/ IEC 17021:2011 requirements as indicated in the IMDRF document to the extent such criteria are consistent with the FD&C Act and other applicable laws and regulations;
5. Have a code of conduct that meets any requirements defined in the IMDRF document; and
6. Ensure general competency requirements for the organization and competency requirements for product assessors or product reviewers as defined in the IMDRF document.

C. Certification of eCopy Understanding

You should include a statement that you will comply with the eCopy requirements for premarket submissions as described in the guidance titled, "eCopy Program for Medical Device Submissions."1

V. Accreditation Denial

If you wish a reconsideration of a decision by the TPRB, a written request should be submitted to:

CDRH Ombudsman
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland, 20993 USA

VI. Reaccreditation

After obtaining accreditation by FDA, a TPR's accreditation by FDA will sunset 3 years from the date the accreditation was granted. If a TPR wants to continue to be a TPR, then the TPR will need to obtain a new accreditation every three years. A TPR can request a new accreditation earlier if it so chooses. FDA will need to approve or deny reaccreditation requests within 60 days.

To ensure that a TPR continues to meet accreditation standards, FDA will consider past premarket review performance as a TPR and any information that comes to FDA's attention about a TPR's adherence to expected TPR policies and commitments. Aside from this additional criteria, we believe reaccreditation requests should be handled the same as initial accreditation requests and plan to process reaccreditations accordingly. Reaccreditation

applications should follow the format described in **Section IV, Format and Content of an Initial TPR Application**.