510(k) Third Party Review Program

Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.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document within 120 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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 the Third Party Review Program at 3P510K@fda.hhs.gov.

This guidance is a reissuance of the draft guidance entitled "Accreditation and Reaccreditation Process for Firms under the Third Party Review Program: Part I – Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Reviewers" issued on February 15, 2013 with updated content.

When final, this document will supersede "Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties" issued on February 2, 2001, and "Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications" issued on September 28, 2004, except for Appendices 2-4.

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

Preface

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Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance provides a comprehensive look into FDA's current thinking regarding the 510(k) Third Party (TP) Review Program (formerly known as the Accredited Persons Program) authorized under section 523 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act).[1] This draft guidance describes the recognition, rerecognition, recognition/rerecognition denial, and recognition withdrawal processes, including the associated criteria.[2] The objective of this guidance is to encourage harmonization by incorporating elements, where appropriate, from the International Medical Device Regulators Forum's (IMDRF) regulatory assessment program called the Medical Device Single Audit Program (MDSAP) into the TP Review Program. In addition, the goal of this guidance is to provide FDA's current thinking on the TP Review Program in the following areas:

- TP Review Organizations review of 510(k) submissions;
- Requirements and recommendations for recognition and rerecognition of TP Review Organizations under the TP Review Program;

[1] Section 523 of the FD&C Act uses the terms "accredited persons," "accredit," "accredited," "accreditation," "reaccredit," "reaccredited," and "reaccreditation." As explained later in this document, the guidance does not use those statutory terms but rather define such terms as "third party review organizations," "recognition," and "rerecognition" as synonymous terms. These alternative terms are used in this guidance in an effort to harmonize the terms used by FDA and in the FD&C Act with those in the IMDRF documents.

[2] The terms "recognition," "rerecognition," "recognition denial," "rerecognition denial," and "recognition withdrawal" are defined in Section II of this guidance.

- Content and format of a TP Review Organization's application for initial recognition and rerecognition; and
- Suspension or withdrawal of recognition

The purpose of the TP Review Program is to implement section 523 of the FD&C Act (21 U.S.C. § 360m). Section 523 authorizes FDA to accredit third parties to review premarket notification (510(k)) submissions and recommend the initial classification of certain devices. FDA's implementation of section 523 includes establishing a process of recognition of qualified third parties to conduct the initial review of 510(k)s for certain low-to-moderate risk devices eligible under the TP Review Program.[3]

In February 2011, the IMDRF was conceived to discuss future directions in medical device regulatory harmonization. The IMDRF is a voluntary group of medical device regulators from around the world, including representatives from the 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.

As one of its initial actions, the IMDRF developed the MDSAP, which is outlined in a collection of documents finalized from 2013 through 2015 and available on the IMDRF website.[4] The IMDRF MDSAP documents provide the fundamental building blocks of an auditing program by providing a common set of criteria to be utilized for the recognition and monitoring of entities that perform regulatory audits and other related functions.

The following IMDRF documents are relevant to this guidance:

- IMDRF MDSAP WG/N3 FINAL: 2013[5] – "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition" and IMDRF MDSAP WG/N4 FINAL: 2013[6] – "Competence and Training Requirements for Auditing Organizations," are complementary documents. These two documents focus on requirements of an auditing organization and individuals performing regulatory audits and other related functions under the respective medical device legislation, regulations, and procedures required in its regulatory jurisdiction.

- IMDRF MDSAP WG/N5 FINAL: 2013[7] – "Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing

[3] At this time, CBER does not regulate devices of the types subject to this guidance.
[4] All the IMDRF documents relevant to this guidance are available on the IMDRF website at http://imdrf.org/documents/documents.asp.
[5] More information is available at http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf.
[6] More information is available at http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf.
[7] More information is available at http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-assessment-method-140901.pdf.

Organizations" and IMDRF MDSAP WG/N6 FINAL: 2013[8] – "Regulatory Authority Assessor Competence and Training Requirements," are complementary documents. These two documents focus on how Regulatory Authorities and their assessors will evaluate or "assess" medical device Auditing Organizations' compliance to the requirements in the IMDRF MDSAP WG/N3 FINAL: 2013 and WG/N4 FINAL: 2013 documents.

- IMDRF MDSAP WG N8 FINAL: 2015[9] –"Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations." The purpose of this document is to complement IMDRF MDSAP WG/N5 and N6 by providing guidance to the Regulatory Authority assessors when conducting the assessment of an Auditing Organization according to the method presented in IMDRF MDSAP WG/N5, chapter 6.

- IMDRF MDSAP WG/N11 FINAL: 2014[10] – "MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization." The purpose of this document is to explain the assessment process and outcomes, including the method to "grade and manage" nonconformities resulting from a recognizing Regulatory Authority(ies)'s assessment of an Auditing Organization; and, to document the decision process for recognizing an Auditing Organization or revoking recognition.

In addition to the above documents, the IMDRF is in the process of developing a document entitled "Competency, Training, and Conduct Requirements for Regulatory Reviewers" which will provide a common set of competency, training, and conduct requirements for personnel involved in reviewing activities.[11]

In an effort to encourage harmonization, this guidance refers to standards described in the IMDRF documents[12] as criteria FDA will consider for recognition, rerecognition, recognition denial, rerecognition denial, and withdrawal of recognition of TP Review Organizations under the TP Review Program. FDA appreciates the advantages of harmonized international standards, and FDA believes that, when finalized, this guidance document will help to further bring the TP Review Program into harmony with such standards, as well as provide clarity and consistency for industry. As there are some differences between terms used by various international organizations, Section II provides definitions of the terms used in the referenced documents for the purposes of this guidance.

[8] More information is available at http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-assessor-competence-and-training-140901.pdf.

[9] More information is available at http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-mdsap-auditing-organizations.pdf.

[10] More information is available at http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-assessment-decision-process-141013.pdf.

[11] This document, when published, will supplement Section V.C on qualifications of personnel involved in 510(k) reviewing activities for TP Review Organizations, if appropriate.

[12] If and when additional documents relevant to the TP Review Program are finalized by IMDRF, FDA will consider if and how to incorporate such documents for the purpose of the TP Review Program.

This draft guidance replaces the draft guidance entitled "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" issued on February 15, 2013, in which the Agency announced its intention to incorporate information from the IMDRF documents in a subsequent draft guidance to the extent appropriate. This draft guidance includes information and recommendations based on the above listed IMDRF documents, to the extent they are consistent with the FD&C Act and other applicable laws and regulations.

When finalized, this guidance will supersede "Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties" issued on February 2, 2001, and supersede in part "Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications" issued on September 28, 2004.[13] The parts from that guidance document that will not be superseded are Appendices 2-4 which are discussed below in Section IV.H. TP Review Organizations should submit their applications for recognition in the manner described in Section VI within six months of finalization of this guidance.

FDA's guidance documents, including this draft 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 guidance means that something is suggested or recommended, but not required.

Please note that the above referenced IMDRF documents include the term "Requirements" in their titles and often use mandatory terms such as "shall." To the extent the IMDRF documents use mandatory language to describe criteria that overlap with requirements in the FD&C Act or FDA's regulations regarding third party review, the use of the mandatory terms is consistent with the FD&C Act and FDA's regulations. However, to the extent that the IMDRF documents refer to requirements or use mandatory language to describe criteria that are not required by the FD&C Act or FDA's regulations, the mandatory language does not represent a requirement for TP Review Organizations under section 523 of the FD&C Act but rather the recommendation of FDA in the relevant context.

II. Definitions

In an effort to provide clarity to industry and TP Review Organizations, the definitions provided below are an attempt to harmonize the terms used by FDA and in the FD&C Act with those in the IMDRF documents. The application of these defined terms is limited for the purposes of this guidance only. These terms are not intended to be applied in any context beyond this document and the TP Review Program.

[13] Available on FDA's website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082191.htm.

510(k) Submitter: An entity or person that submits scientific and technical data in the form of a 510(k) submission to a TP Review Organization for the purpose of demonstrating substantial equivalence of a device to a legally marketed device that is not subject to premarket approval (PMA).

Final Reviewer: An individual within the TP Review Organization who oversees a 510(k) review throughout the entire review process. The Final Reviewer is responsible for ensuring final recommendations regarding substantial equivalence made by Product Specialists are appropriately evaluated, organized, and documented before sending to FDA. This individual should have sufficient authority and competence to independently evaluate the quality and acceptability of the TP review submission. For a 510(k) review, the Final Reviewer should be a separate person from the Product Specialist.

IMDRF Documents: A collection of documents produced by the IMDRF intended to implement the concept of a Medical Device Single Audit Program. These documents provide criteria for audit programs that FDA believes TP Review Organizations should follow, where applicable and to the extent such criteria are appropriate and consistent with the FD&C Act and other applicable laws and regulations.

Medical Device Single Audit Program: A program with a standard set of requirements for the recognition of auditing organizations performing regulatory audits of medical device manufacturers and other related functions.

Product Specialist: An individual within the TP Review Organization appropriately qualified to review and evaluate medical devices within a specific device type(s) and who may also be qualified for a specific technical or clinical specialization (e.g., biocompatibility and Ethylene Oxide (EtO) sterilization), based on one's scientific background and competence. This individual should be the primary reviewer responsible for leading the TP Review Organization's review team on a given 510(k) submission. The Product Specialist should submit the recommendation and all related documentation to the Final Reviewer.

Recognition: The process of accrediting TP Review Organizations under section 523 of the FD&C Act to review premarket notifications submitted under section 510(k) of the FD&C Act (21 U.S.C. § 360k) of certain eligible devices and make recommendations to FDA regarding the initial classification of such devices under sections 513(f)(1) and 513(i) of the FD&C Act (21 U.S.C. §§ 360c(f)(1) and 360c(i)).

Rerecognition: The process of renewing the accreditation of TP Review Organizations under section 523 of the FD&C Act for an additional three years.

Recognition Criteria: The applicable FD&C Act requirements, including the qualification requirements set forth in section 523(b)(3), FDA's recommendations described in this guidance document, including those criteria contained in IMDRF MDSAP WG N3 and N4, which includes the International Organization for Standardization (ISO)/the International

Electrotechnical Commission (IEC) 17021:2011, where appropriate and applicable, and the criteria to accredit or deny accreditation announced in the Federal Register.[14]

Recognition Denial: The process of denying an application for accreditation submitted by a potential TP Review Organization.

Rerecognition Denial: The process of denying an application for reaccreditation submitted by a recognized TP Review Organization.

Recognition Withdrawal: The process of withdrawing or suspending accreditation of a TP Review Organization in accordance with section 523(b)(2) of the FD&C Act.

Technical Expert: An individual who provides specific knowledge or expertise to the TP review team. This person may be an employee of a TP Review Organization or may be outsourced as described below in Sections V.D and V.E of this guidance, respectively.

Third Party Review Organization: A person that is recognized by FDA to review 510(k) submissions for certain eligible devices as authorized by section 523 of the FD&C Act.

Provided below in Table 1 is an explanation of how terms used in the IMDRF documents should be interpreted in relation to FDA personnel and TP Review Organizations for purposes of the TP Review Program.

Table 1. Relationship of different terms used in the IMDRF documents, by Third Party Review Organizations, and by FDA.

IMDRF MDSAP Equivalent	TP Review Organization Equivalent	FDA Equivalent
Auditor	Product Specialist	Lead Reviewer
Regulatory Authority	FDA Representatives	FDA Representatives to the TP Review Program
Audit	Review	Review
Final Reviewer	Final Reviewer	Branch Chief
Technical Expert	Technical Expert	FDA Internal Consultant (e.g., statistician)

III. Background

On August 1, 1996, FDA began a voluntary TP 510(k) review pilot program for selected medical devices. Under the pilot program, all class I devices that were not 510(k) exempt at that time and 30 class II devices were eligible for TP review.

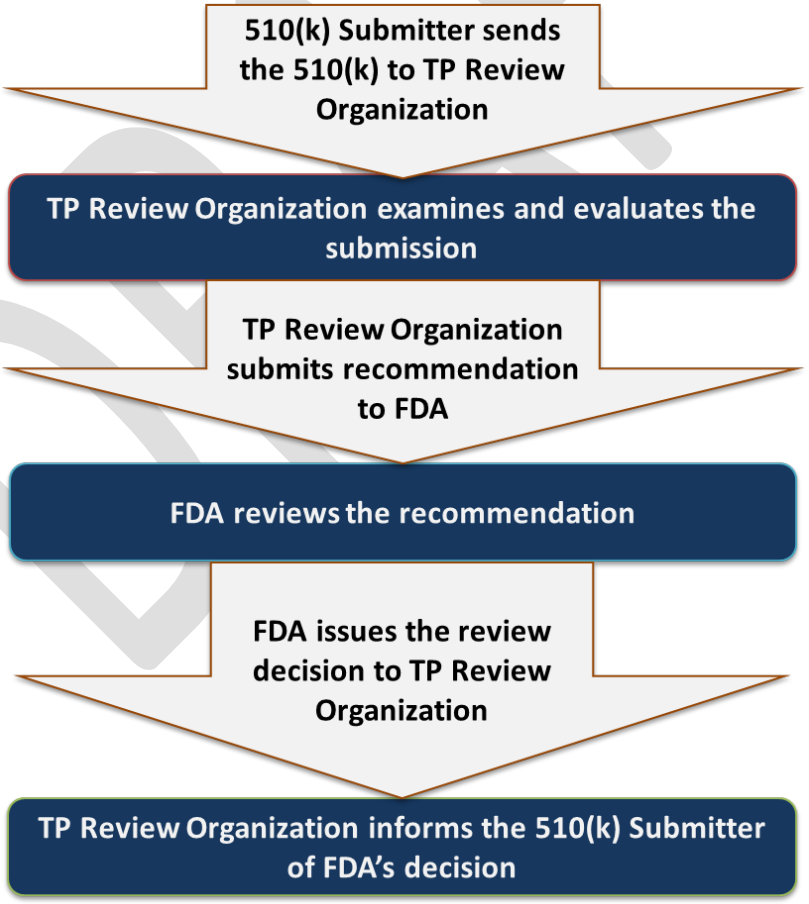
[14] See 63 FR 28388 (May 22, 1998).

On November 21, 1997, the Food and Drug Administration Modernization Act (FDAMA) was signed into law. Section 210 of FDAMA essentially codified and expanded the pilot program by establishing section 523 of the FD&C Act.

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law, and required FDA to establish and publish criteria to reaccredit and deny reaccreditation of TP Review Organizations who perform 510(k) reviews of eligible devices. In accordance with FDASIA, this draft guidance describes the criteria FDA will consider to recognize, rerecognize, deny recognition to, and deny rerecognition to TP Review Organizations under the TP Review Program.

The TP Review Program is intended to enable FDA to focus its internal scientific review resources on 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 TP Review Organizations, and to provide manufacturers of eligible devices a voluntary alternative review process that may yield more rapid 510(k) decisions from FDA. A general overview of the TP Review Program is provided below in Figure 1.

Figure 1 – A General Overview of the TP Review Program



Under the TP Review Program, TP Review Organizations conduct the equivalent of an FDA premarket review of a 510(k) submission, and then forward their reviews, recommendations, and 510(k) submissions to FDA for a decision concerning the substantial equivalence of a device. Section 523(a)(2) of the FD&C Act requires FDA to issue a determination within 30 days after receiving a recommendation from a TP Review Organization, which provides manufacturers of eligible devices an alternative review process that may yield more rapid 510(k) decisions. Under the current TP Review Program, FDA has recognized several TP Review Organizations[15] that are authorized to review 510(k)'s for certain devices eligible under the TP Review Program.[16]

A TP Review Organization must be initially recognized by FDA under section 523 of the FD&C Act to participate in the TP Review Program. In determining recognition or rerecognition, FDA will consider the documents, as outlined in Section VI, provided by a TP Review Organization. In addition, in determining rerecognition, FDA may consider past premarket review performance of a TP Review Organization as described in Section VI.B.

Participation by device manufacturers in the TP Review Program is entirely voluntary. Manufacturers who do not wish to use a TP Review Organization may submit their 510(k)s directly to the FDA for review; however, only 510(k)s reviewed by recognized TP Review Organizations will be eligible for review by FDA within 30 days. See section 523(a)(2) of the FD&C Act.

In accordance with section 523 of the FD&C Act, the TP Review Program includes a number of features designed to maintain a high-level of quality in the review of 510(k)s by TP Review Organizations and to minimize risks to the public. These include the exclusion for TP review of all class III devices and any class II devices that are intended to be permanently implantable or life sustaining or life supporting, or which require clinical data, subject to the limitations in section 523(a)(3)(A)(iii) of the FD&C Act. The TP Review Program will not include 510(k)s that require multi-Center review (e.g., 510(k)'s for drug/device combination products), or 510(k) reviews that require multi-center consultation.

The following Sections IV, V, and V.H of this guidance discuss FDA's recommendations regarding TP 510(k) review, Recognition Criteria for TP Review Organizations to be recognized under the TP Review Program, and TP Review Organization recordkeeping, respectively.

[15] For a current list of recognized TP Review Organizations under the Third Party Review Program, please visit FDA's website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/Accredit.cfm.

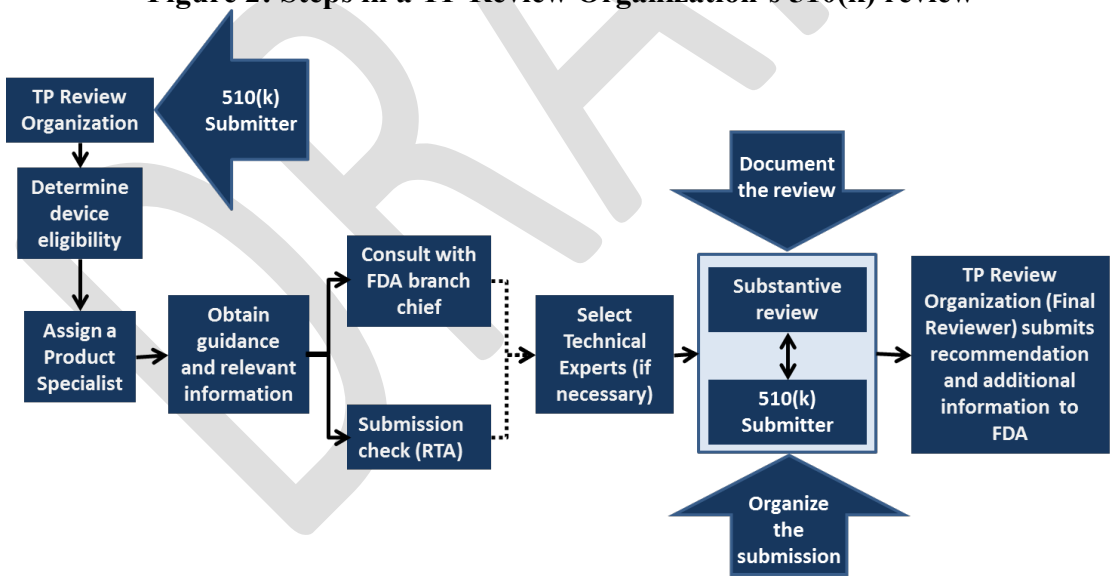
[16] For a list of eligible devices for TP review under the Third Party Review Program, please visit FDA's website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm.

IV. Review of 510(k) Submissions by Third Party Review Organizations

TP Review Organizations should share FDA's mission to protect the public health by ensuring medical devices available on the market are safe and effective for their intended uses. Similar to Reviewers in the Agency, TP Review Organizations are responsible for reviewing and analyzing scientific and technical data submitted in a 510(k) submission to make a recommendation regarding substantial equivalence of a device to a legally marketed medical device prior to its marketing. A TP Review Organization is not responsible for participating in any FDA Pre-Submission meetings that may precede a 510(k) Submitter's submission, but a TP Review Organization should be involved in any discussions with FDA regarding requests for additional information during the pendency of FDA's review of a TP 510(k) submission, and should review any additional studies and study protocols submitted in response by the 510(k) submitter prior to its submission to FDA (see Section IV.J below). However, a TP Review Organization is encouraged to attend in-person or remotely in any relevant FDA Pre-Submission meeting if the device manufacturer consents.

TP Review Organizations should conduct their review of 510(k)s in the manner provided in the subsections below. In addition, Figure 2 describes the steps in a TP Review Organization's review of a 510(k) submission.

Figure 2: Steps in a TP Review Organization's 510(k) review



A. Determining device eligibility for TP review

Prior to beginning review of a 510(k) submission, a TP Review Organization should determine whether a device is eligible for TP review. For information on how to determine whether a device is eligible for TP review, please see Section III of this guidance. If the device is not eligible for TP review, the TP Review Organization should not accept the

510(k) for review. If, however, the TP Review Organization determines the device is ineligible for TP review after it has already accepted the 510(k) submission, the TP Review Organization should immediately inform the 510(k) Submitter and discontinue the review. If the TP Review Organization submits a 510(k) to FDA for an ineligible device, or for a device within a device type for which it is not recognized to review, FDA will place the file on hold and notify the TP Review Organization of FDA's eligibility assessment. If the TP Review Organization does not address the eligibility concerns or withdraw the submission within 180 days, FDA will consider the 510(k) submission to be withdrawn and will delete the submission.

B. Obtain relevant FDA guidance(s) and information

FDA recommends that TP Review Organizations request that 510(k) Submitters fully inform them of any prior communications with FDA about a device under review, including Pre-Submission meetings and unsuccessful premarket applications or submissions. TP Review Organizations should also review CDRH's guidance database to obtain any relevant FDA guidance documents, [17] as well as access CDRH's 510(k) database for information about the legally marketed device a submitter is comparing its device to, or other similar devices.[18] Such information may include the Indications for Use Statement, 510(k) Summary, Decision Summary (if available), and FDA decision letters. In some instances, a device's product code can be helpful in determining a device's eligibility for TP review. Product code classification can be found using FDA's product code classification database.[19]

C. Consult with the relevant FDA Branch Chief (as needed)

FDA recommends that TP Review Organizations consult (via email or telephone), as needed, with the relevant Office of Device Evaluation (ODE) or Office of In Vitro Diagnostics and Radiological Health (OIR) Branch Chief, team leader, or designee. These consultations can help ensure timely and consistent 510(k) reviews by identifying relevant issues and review criteria. FDA expects that TP Review Organizations will consult with the relevant FDA Branch Chief for any device type (i.e., device type by product code) they have not recently reviewed. Generally, FDA considers a recent review to be within the last six months. FDA considers the consultation with the relevant Branch Chief before beginning a review to be an important part of the 510(k) review process by TP Review Organizations (see Section VI.A(iv)).

[17] The guidance database search engine allows users to search the inventory of guidances available by title, words, or origin and is available on FDA's website at http://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[18] The 510(k) database search engine allows users to search all previously cleared 510(k) submissions by 510(k) number, applicant name, device name, etc., and is available on FDA's website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

[19] The product code classification database is available on FDA's website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

D. Ensure a submission is administratively complete

To ensure that a submission is administratively complete, FDA recommends an acceptance review of the 510(k) submission by the TP Review Organization based on 510(k) regulations from 21 CFR 807.87 to 807.100 to assess whether the 510(k) submission includes all of the information necessary to conduct a substantive review and to reach a recommendation regarding substantial equivalence as defined under section 513(i) of the FD&C Act (21 U.S.C. § 360c(i)). FDA reviewers use the Refuse to Accept (RTA) checklist for 510(k) submissions to make this determination. FDA recommends that TP Review Organizations use the same RTA checklist upon receiving a 510(k) submission to ensure it is administratively complete. For more information on the RTA checklist, please see FDA's guidance entitled "Refuse to Accept Policy for 510(k)s."[20]

If the TP Review Organization determines that a submission is administratively complete, it should begin its substantive review of the 510(k) submission. If the TP Review Organization identifies any deficiencies in the 510(k) submission, it should contact the 510(k) Submitter to request the missing information.

E. Select the appropriate Product Specialist(s) and Technical Expert(s) to conduct the substantive review of a 510(k) submission

FDA recommends that TP Review Organizations maintain personnel with the appropriate education, training, skills, and experience to perform 510(k) reviews for the device type(s) for which the TP Review Organizations are recognized by FDA to perform. For additional discussion on FDA's recommendations regarding qualifications of personnel, see Section V.C of this guidance.

To assure technically competent reviews, each 510(k) submission should be assigned to a Product Specialist with appropriate expertise for the device under review. The Product Specialist may add qualified Technical Experts to the review team to ensure sufficient competency in the review, if necessary. The Product Specialist should document the competencies of and the rationale for choosing to use any Technical Experts. When using external Technical Experts, particular attention should be given to the expertise level and impartiality of these external experts. For more information on using external Technical Experts, please see Section V.D of this guidance.

[20] Available on FDA's website at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf.

F. Conduct the substantive review of a 510(k) submission

Substantive review focuses on substantial equivalence as defined in section 513(i) of the FD&C Act. 21 CFR 807.100(b) sets forth the criteria that FDA uses to determine whether a device is substantially equivalent to a legally marketed device. For information on determining substantial equivalence of a device under the 510(k) program, please see FDA's guidance entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]."[21]

For information on Abbreviated and Special 510(k)s, please see FDA's guidance entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications."[22]

For information on the use of standards in a 510(k) submission to demonstrate substantial equivalence, please see FDA's guidance entitled "Use of Standards in Substantial Equivalence Determinations."[23]

TP Review Organizations should refer to these guidance documents when conducting their substantive review of 510(k) submissions, including any device specific guidances or horizontal guidances (e.g., biocompatibility, software, sterility). In addition, TP Review Organizations should be aware of any special controls that apply to a device under review, which are regulatory requirements for class II devices. For information on whether a device has special controls, TP Review Organizations should review the classification regulation of the device under21 CFR parts 862 to 892, which would reference any applicable special controls for a particular device type.

TP Review Organizations should identify at least one independent Final Reviewer, within the TP Review Organization, responsible for providing a final supervisory assessment of the Product Specialist's work before it is submitted to FDA. This individual should have sufficient authority and competence to independently assess the quality and acceptability of the Product Specialist's review of the 510(k) submission.

If TP Review Organizations identify any deficiencies during their review, they should contact the 510(k) Submitters. Section IV.G below provides further instruction on how to identify deficiencies in a 510(k) submission. When the substantive review is complete, a TP Review Organization should reach an agreement between persons involved with the TP Review (e.g., product specialist, technical expert(s), and final reviewer) and make a final recommendation on whether the device is substantially equivalent to a predicate device.

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[21] Available on FDA's website at http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf.
[22] Available on FDA's website at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf.
[23] Available on FDA's website at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm073756.pdf.

G. Identifying deficiencies in a 510(k) submission

If a TP Review Organization identifies any deficiencies in a 510(k) submission during its substantive review, it should contact the 510(k) Submitter. TP Review Organizations may use any form of communication (i.e., telephone, facsimile, electronic mail, or letter) to resolve the matter as long as confidentiality is maintained. TP Review Organizations should, however, avoid the exchange of substantive data and information solely over the telephone to avoid errors that may arise in the absence of a written request and response. FDA recommends that TP Review Organizations document any deficiencies in writing and summarize in their review memorandum any modifications the 510(k) Submitter may have made to the submission as a result of being notified of deficiencies.

When requesting additional information from a 510(k) Submitter, FDA recommends that TP Review Organizations structure their additional information requests in the manner described below. For examples of well-constructed deficiencies and responses to FDA's requests, please see FDA's guidance entitled "Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA."[24]

A TP Review Organization's request for additional information as a result of identified deficiencies should include the following:

1. Clear identification of the specific issue(s) or question(s);
2. Acknowledgement of the information submitted and explanation of why the information provided did not adequately address the issue;
3. Explanation of the relevance of the request for additional information to the substantial equivalence determination; and
4. Recommendations regarding additional information needed to adequately address the issue or question and, when possible, suggestions of alternate ways to address the deficiency

H. Documenting a 510(k) review

Once a TP Review Organization has made a final recommendation regarding substantial equivalence, it should prepare its review documentation which documents the reasons and steps that led to its final recommendation. 21 CFR 10.70 ("Documentation of significant decisions in administrative file") provides a framework for documentation that should be utilized by TP Review Organizations in documenting their review. The content of a review documentation will vary based on the type of 510(k) submission and device. The review documentation formats identified in Table 2 below are the tools FDA reviewers typically use for each submission type shown. These tools may be used by the assigned Product Specialist of a TP Review Organization in preparing the review documentation.

[24] Available on FDA's website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073679.htm.

Table 2. FDA Review Formats

Submission Type	Review Formats			
	Refuse to Accept (RTA) Checklist	510(k) Decision-Making Documentation	Review Memorandum	Special 510(k) Device Modification Review Memo
Traditional	yes	yes	yes*	no
Abbreviated	yes	yes	yes*	no
Special	yes	yes	no	yes

***** Product Specialists should use the ODE Review Memorandum for Traditional and Abbreviated 510(k) Submissions in preparing their review documentation for traditional and abbreviated 510(k) submissions reviewed by ODE or for radiological devices reviewed by OIR, and the OIR Review Templates for in vitro diagnostic (IVD) devices reviewed by OIR.

Each review format is explained in further detail below.

1. **RTA Checklist**
   See Section IV.D of this guidance for information on determining whether a 510(k) submission is administratively complete and how to utilize the RTA checklist.

2. **510(k) Decision-Making Documentation**
   FDA uses this format to document the key decision points leading to a determination on substantial equivalence. See Section IV.F of this guidance for a discussion on substantive review.

3. **ODE Review Memorandum for Traditional and Abbreviated 510(k) Submissions**
   For information on what ODE reviewers typically provide in a review memorandum for a traditional and abbreviated 510(k) submission, please see FDA's guidance entitled "Third Party Review of Premarket Notifications: Appendix 2: ODE Review Memorandum for Traditional and Abbreviated 510(k) Submissions."[25]

   Note that the review documentation for radiological medical devices should also follow this format.

[25] Available on FDA's website at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM082216.pdf.

4. **IVD Devices OIR Review Templates**
   Templates and instructions provided to FDA reviewers of 510(k) submissions for IVD devices are in three documents depending on the type of device reviewed. For assay and instrument combination 510(k) submissions, please see FDA's guidance entitled "Third Party Review of Premarket Notifications: Appendix 3A: Review Memorandum Template and Instructions for Assay and Instrument Combination Submissions."[26]

   For instrument only 510(k) submissions, please see FDA's guidance entitled "Third Party Review of Premarket Notifications: Appendix 3C: Review Memorandum Template and Instructions for Instrument Only Submissions."[27]

   For assay only 510(k) submissions, please see FDA's guidance entitled "Third Party Review of Premarket Notifications: Appendix 3B: Review Memorandum Template and Instructions for Assay Only Submissions."[28]

   Numerous examples of completed templates used in previous 510(k) decision summaries are available through the 510(k) database.[29]

5. **Special 510(k) Device Modification Review Memo**
   FDA uses the Special 510(k) Device Modification Review Memo to summarize the information provided in a Special 510(k) submission and FDA's determination on substantial equivalence. For information on what is contained in a Special 510(k) review memorandum, please see FDA's guidance entitled "Third Party Review of Premarket Notifications: Appendix 4: Special 510(k): Device Modification Review Memo."[30]

FDA recommends TP Review Organizations discuss in their review memo how standards are utilized in a 510(k) submission, if applicable. A 510(k) submitter may use consensus standards in its submission in two ways: general use and Declaration of Conformity in accordance with section 514(c)(1)(B) of the Act. General use of a consensus standard in any premarket submission refers to situations where a submitter chooses to conform to a consensus standard, but does not submit a Declaration of Conformity. If a submitter intends

[26] Available on FDA's website at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM082222.pdf.
[27] Available on FDA's website at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM082230.pdf.
[28] Available on FDA's website at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM082224.pdf.
[29] Available on FDA's website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
[30] Available on FDA's website at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM082232.pdf.

to submit a Declaration of Conformity to an FDA-recognized consensus standard, the submitter should certify that all requirements were met, except for inapplicable requirements which should be identified in a separate section in the Declaration of Conformity and in the 510(k) submission. A submitter may not submit a Declaration of Conformity if the submitter chooses to rely on a consensus standard that has not been recognized by FDA or if the submitter has deviated from an FDA-recognized standard. For further guidance on the use of consensus standards, please visit FDA's website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm.

I. Organizing and submitting a 510(k) submission including associated TP Review documentation

There are two distinct parties involved in the generation of a TP 510(k): the TP Review Organization and 510(k) Submitter. Each party is subject to the eCopy requirements. Accordingly, each party must provide its own eCopy and company cover letter with an eCopy statement and signature. See section 745A(b) of the FD&C Act (21 U.S.C. § 379k-1). Upon completing the review of a 510(k) submission, the Final Reviewer of the TP Review Organization should submit both eCopies together to CDRH's Document Control Center[31] in order to expedite timely review by the Agency, but should not consult in the preparation of the 510(k) Submitter's eCopy. FDA intends to hold the TP Review Organization responsible for resolving any eCopy holds concerning any issues with either eCopy. For information on the eCopy program, please see FDA's guidance entitled "eCopy Program for Medical Device Submissions."[32]

A TP Review Organization's 510(k) submission should include the following:

1. A cover letter signed by the Final Reviewer that clearly identifies:
   a. The purpose of the submission;
   b. The name and address of the TP Review Organization and the contact person;
   c. The name, email address, and telephone number of the Final Reviewer;
   d. The name and address of the 510(k) Submitter;
   e. The name of the device (trade name, common or usual name, FDA classification name, classification regulation number, and product code, as applicable);
   f. The TP Review Organization's recommendation with respect to the substantial equivalence of the device; and
   g. The date the TP Review Organization first received the 510(k) from the Submitter

[31] The address for CDRH's Document Control Center is available on FDA's website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm.

[32] Available on FDA's website at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

2. A letter signed by the 510(k) Submitter authorizing the TP Review Organization to submit the 510(k) to FDA on its behalf and authorizing the TP Review Organization to discuss the contents of the 510(k) with FDA on its behalf.

3. A signed certification that the reported information accurately reflects the data reviewed.

4. A table of contents listing the sections where the 510(k) submission and associated TP Review Organization's documentation are located, along with the corresponding page numbers.

5. A summary of any discussion that occurred prior to the 510(k) submission to FDA with the appropriate ODE/OIR branch chief or designee, if appropriate (see Section IV.C).

6. The 510(k) Submitter's complete 510(k) submission that conforms to FDA's requirements for content and format of 510(k) submissions as provided in 21 CFR part 807 subpart E. This information should be separate from the TP Review Organization's documentation.

7. An acceptance review of the 510(k) submission based on the RTA checklist, discussed in Section IV.D, to assess whether the submission is administratively complete and that it includes all of the information necessary for the TP Review Organization to conduct a substantive review on FDA's behalf and for FDA to reach a determination regarding substantial equivalence under section 513(i) of the FD&C Act.

8. A complete documentation of the TP Review Organization's review of the 510(k) submission as described in Section IV.H of this guidance, signed by all personnel who conducted the review (generally the Product Specialist(s) and Technical Expert(s)) and by the individual responsible for supervising 510(k) reviews (Final Reviewer), with a recommendation concerning the substantial equivalence of the device under review. TP Review Organizations must provide their eCopy documentation[33] and should prepare their review documentation for posting, as applicable and appropriate.

FDA may not be able to process a 510(k) submitted by a TP Review Organization if the review material discussed above is not included with the submission. FDA will begin its review only after it receives the necessary information.

J. Submitting additional information upon FDA's request

After a TP Review Organization has submitted the 510(k) and its recommendation, including the associated TP Review documentation, FDA will begin to review the submission. If FDA determines that additional information is needed to make a substantial equivalence determination, FDA plans to contact the TP Review Organization. FDA may request additional information by either telephone or electronic mail. Such requests will

[33] See section 745A(b) of the FD&C Act.

describe FDA's concerns with a 510(k) submission, and identify the information that FDA believes is needed to address its concerns. In addition, if FDA places a 510(k) submission "on hold" (i.e., officially suspend processing of the submission pending FDA's receipt of additional information), FDA will send an email informing the TP Review Organization of the "on hold" status and request for additional information. For more information, please see FDA's guidance entitled "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals."[34]

Upon receiving a request from FDA for additional information, the TP Review Organization should:

1. promptly inform the 510(k) Submitter of FDA's request for additional information relating to the 510(k) submission;

2. thoroughly review any additional information provided by the 510(k) Submitter to ensure that it adequately responds to FDA's concerns;

3. revise its 510(k) review documentation to resolve any deficiencies FDA identified in the previously submitted documentation;

4. add or incorporate the review of the additional information, if any, provided by the 510(k) Submitter into its review documentation;

5. prepare a cover letter referencing the 510(k) number previously assigned by FDA and identifying the purpose of the new submission; and

6. send the cover letter, its additional or revised review documentation, and any additional information received from the 510(k) Submitter to FDA to CDRH's Document Control Center[35]

The TP Review Organization must provide two separate eCopy documents (i.e., eCopy of the additional information provided by the 510(k) submitter and eCopy of documentation generated by the TP Review Organization).[36] Each eCopy should be clearly marked as belonging to the TP Review Organization or the 510(k) Submitter, as appropriate. For information on the eCopy program, see Section IV.I.

[34] Available on FDA's website at http://www.fda.gov/RegulatoryInformation/Guidances/ucm089735.htm.
[35] The address for CDRH's Document Control Center is available on FDA's website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm.
[36] See section 745A(b) of the FD&C Act.

K. 510(k) submission dispute resolution

FDA has developed guidance documents that provide an overview of the appeals processes available for medical devices. For information about the appeals processes, please see FDA's guidance entitled "Center for Devices and Radiological Health Appeals Processes"[37] and FDA's guidance entitled "Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A."[38] The processes available for reviewing and reconsidering FDA decisions or actions on other 510(k) submissions are also available for TP 510(k) submissions when a dispute between FDA and a 510(k) Submitter arises.

FDA believes disputes are often the result of misunderstanding or miscommunication. FDA encourages TP Review Organizations to seek clarification, as needed, from FDA or the 510(k) Submitter during the course of a review. If the 510(k) Submitter disagrees with an FDA decision or action, the TP Review Organization should maintain impartiality and exercise care to avoid the appearance of conflict of interest that may result from acting as an advocate on the 510(k) Submitter's behalf.

V. Requirements and Recommendations for Recognition and Rerecognition of Third Party Review Organizations

In this Section of the guidance, FDA describes the Recognition Criteria considered in recognizing TP Review Organizations under section 523 of the FD&C Act to conduct premarket reviews of 510(k)s of devices eligible under the TP Review Program. In accordance with section 523(b)(3) of the FD&C Act, a TP Review Organization must, at a minimum, meet the following qualification requirements:

1. May not be an employee of the Federal Government.
2. Shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of devices and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.
3. Shall be a legally constituted entity permitted to conduct the activities for which it seeks recognition.
4. Shall not engage in the design, manufacture, promotion, or sale of devices.
5. Its operations shall be in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will:
    i. certify that reported information accurately reflects data reviewed;
    ii. limit work to that for which competence and capacity are available;

[37] Available on FDA's website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm284651.htm.

[38] Available on FDA's website at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM352254.pdf.

iii. treat information received, records, reports, and recommendations as proprietary information;

iv. promptly respond and attempt to resolve complaints regarding its activities for which it is recognized; and

v. protect against the use, in carrying out the review of a 510(k) submission and initial classification of a device, of any officer or employee who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the TP Review Organization, and the officers and employees of the TP Review Organization, have maintained compliance with requirements relating to financial conflicts of interest.

In addition to the minimum requirements for TP Review Organizations set forth in the FD&C Act, a TP Review Organization should meet those qualifications announced in the Federal Register, many of which are discussed below.[39] These qualifications include having in place policies to identify, prevent, and ensure reporting to FDA of instances of forum shopping by 510(k) submitters.

The IMDRF's MDSAP qualifications for recognition and rerecognition of auditing organizations are provided in the IMDRF MDSAP Document WG N3 FINAL: 2013 and IMDRF MDSAP Document WG N4 FINAL: 2013. FDA intends to refer to the standards presented in these IMDRF Documents as criteria in the recognition of TP Review Organizations to the extent such criteria are appropriate and consistent with the FD&C Act and other applicable laws and regulations.[40] In addition to the criteria provided in these IMDRF Documents, a TP Review Organization should meet additional FDA criteria provided below.

For the purpose of initial recognition and rerecognition, TP Review Organizations should develop policies and procedures consistent with the following subsections, and be prepared to submit copies to FDA upon request for consideration in the recognition decision making process. See Section VI for more information on the application process. In addition, TP Review Organizations should ensure that any documentation or records developed for the purpose of the TP review program are reasonably available upon request by FDA or made available to FDA during an on-site assessment as described below in Sections V.H and VII.

A. Operational considerations

All applications and communications with FDA and all documentation pertaining to the review of a 510(k) submitted to FDA should be in English, and for foreign TP Review

[39] See 63 FR 28388 (May 22, 1998).

[40] As stated earlier, requirements in the IMDRF documents that do not reflect requirements in the FD&C Act or FDA's regulations are recommendations under this guidance. In addition, refer to section 523 of the FD&C Act, 63 FR 28288, or the additional FDA criteria described in this guidance when there is any overlap in criteria with the IMDRF documents and they are inconsistent.

Organizations, a United States representative should be designated so that FDA can efficiently communicate with the TP Review Organization while conducting its review (see Section VI.A(i)).

B. Management of impartiality

FDA expects TP Review Organizations to be impartial and free from any commercial, financial, and other pressures that might present a conflict of interest or an appearance of a conflict of interest. To that end, as part of FDA's consideration in recognizing TP Review Organizations, FDA will consider whether the potential TP Review Organization has established, documented, and executed policies and procedures to prevent any individual or organizational conflict of interest, or the appearance of a conflict of interest including conflicts of interests pertaining to its contractors, including individual contract employees. FDA recommends that TP Review Organizations, in addition to the criteria set forth in the abovementioned IMDRF Documents, including ISO/IEC 17021:2011, meet the following to prevent a potential conflict of interest:

A. TP Review Organizations should not participate in the preparation of 510(k)s when involved in TP 510(k) reviews. However, TP Review Organizations can provide general information on 510(k) requirements to permit a 510(k) Submitter to improve the format or content of a 510(k) that it is reviewing.

B. TP Review Organizations should not use personnel who were employed within the last twelve months by a firm who submitted a 510(k) submission for its review.

C. TP Review Organizations should not promise or advertise any guarantees for FDA clearance.

Information on the conflict of interest standards FDA applies to its own review personnel is included in the document, titled "Standards of Ethical Conduct for Employees of the Executive Branch."[41] TP Review Organizations are encouraged to refer to these standards in safeguarding their operations against conflicts of interest.

The conflict of interest policies for a TP Review Organization should be fully implemented and signed off by the most responsible individual at the organization before any 510(k) is accepted for review. As a reminder, when using external consultants or outsourcing, see Sections V.D and V.E respectively, regarding conflicts of interest safeguards.

[41] Standards of Ethical Conduct for Employees of the Executive Branch is available at: https://www.oge.gov/Web/oge.nsf/0/076ABBBFC3B026A785257F14006929A2/$FILE/SOC%20as%20of%2081%20FR%2048687.pdf

C. Personnel involved in reviewing activities

Below describes FDA's recommendations regarding qualifications of personnel involved in reviewing activities for TP Review Organizations, in addition to the criteria set forth in the abovementioned IMDRF Documents, including ISO/IEC 17021:2011.

FDA expects that TP Review Organizations and their personnel should have proven knowledge and experience with the following:

- The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);
- The Public Health Service Act (42 U.S.C. 201 et seq.), as applicable; and
- Regulations in the Code of Federal Regulations implementing these statutes, particularly 21 CFR parts 800 through 1299

Additionally, the TP Review Organization should

- establish, document, and execute policies and procedures to ensure that 510(k)'s are reviewed by qualified personnel;
- maintain records on the relevant education, training, skills, and experience of all personnel who contribute to the technical review of a 510(k);
- make written instructions for duties and responsibilities with respect to 510(k) reviews available to its personnel;
- employ personnel who, as a whole, are qualified in all of the scientific disciplines addressed by the 510(k)s the TP Review Organization accepts for review; and
- identify at least one individual who is responsible for providing supervision over 510(k) reviews and who has sufficient authority and competence to assess the quality and acceptability of these reviews.

For appropriate review of a particular class II device, FDA will expect specialized education and experience to assure a technically competent review. These may include expertise and experience in specific scientific, engineering, statistical, and/or clinical disciplines. FDA typically assembles a team with a range of expertise and experience necessary to assure a thorough and well-informed review of a particular submission.

In addition, TP Review Organizations will be expected to consult national and/or international standards recognized by FDA as well as FDA guidance documents. As such, TP Review Organizations should have the capability to interface with FDA's electronic data systems, including FDA's website through which TP Review Organizations can search for relevant guidance documents, recognized standards, device predicate summaries, and information regarding adverse events and recalls to provide supporting risk information when performing premarket review of similar devices.

TP Review Organizations are expected to complete FDA training before conducting any 510(k) reviews under the TP Review Program. FDA will not accept 510(k) reviews and

recommendations from TP Review Organizations that have failed to have at least one designated personnel attend a FDA training session. TP Review Organizations should ensure their personnel participate in such training (see Section VI.A(iv) of this guidance).

TP Review Organizations should be prepared to conduct technically competent 510(k) reviews at the time of requesting recognition by FDA. FDA recommends persons involved in a 510(k) submission review at a TP Review Organization meet the appropriate qualifications provided in this guidance. When a TP Review Organization requests to expand its scope of device types for which it may review 510(k) submissions, it should ensure that it has personnel qualified in the scientific disciplines for the new device types and apply for recognition for these new device types in accordance with Section VI of this guidance.

D. Use of external Technical Expert(s)

In addition to the criteria set forth in the abovementioned IMDRF Documents, including ISO/IEC 17021:2011, the following are FDA's recommendations when TP Review Organizations use an external Technical Expert:

- External Technical Experts should meet the same standards as those expected of personnel who work within the TP Review Organization, such as freedom from conflicts of interest;

- External Technical Experts are discouraged from subcontracting parts of their contracts to subcontractors; and

- Records of the qualifications of external Technical Experts should be kept by the TP Review Organization, in addition to evidence of regular monitoring on the established competence and the degree of fulfillment of the outsourced work

To ensure that TP Review Organizations have sufficient competence among their own staff, there should be at least one qualified Product Specialist per device type for which the TP Review Organization is recognized to review. This is to ensure that there is not excessive reliance on external expertise by a TP Review Organization and to ensure appropriate oversight of the qualifications of external Technical Experts by TP Review Organizations.

E. Outsourcing

FDA considers a TP Review Organization's use of any external organization to be outsourcing. In addition to the criteria set forth in the abovementioned IMDRF Documents, including ISO/IEC 17021:2011, the following are FDA's recommendations for TP Review Organizations regarding outsourcing:

- Outsourced organizations should meet the same standards as those met by recognized TP Review Organizations, such as freedom from conflicts of interest;

- Outsourced organizations may subcontract parts of their contracts to other subcontractors, if appropriate, but those subcontractors should be from another recognized TP Review Organization; and

- Records of the qualifications of outsourced organizations should be kept by the TP Review Organization, in addition to evidence of regular monitoring of the established competence of the outsourced organization and the degree of fulfillment of the outsourced work

F. Confidential information

A TP Review Organization is required to treat information received, records, reports, and recommendations as proprietary information. See sections 301(y)(2) and 523(b)(3)(E)(iii) of the FD&C Act (21 U.S.C. § 331(y)(2); 21 U.S.C. § 360m(b)(3)(E)(iii)). Also, in accordance with 21 CFR 807.95, when a 510(k) is submitted to FDA, FDA will in general not publicly disclose the existence of a 510(k) submission for a device. As such, a TP Review Organization should not publicly disclose a 510(k) submission for a device that is not currently on the market and where the intent to market the device has not been disclosed.

FDA will determine the releasability of review information submitted to FDA by a TP Review Organization in accordance with the Agency's regulations implementing the Freedom of Information Act (21 CFR part 20) and 21 CFR 807.95, regarding confidentiality of information in 510(k)s. In general, 510(k) reviews submitted by TP Review Organizations will be available for disclosure by FDA after the agency has issued a substantial equivalence decision for a device, unless the information is exempt from public disclosure under 21 CFR part 20 or 21 CFR 807.95.

In addition, information submitted by a TP Review Organization to obtain recognition or rerecognition from FDA will be available for disclosure, unless exempted under 21 CFR part 20.

G. Complaints regarding 510(k) Submitters

The TP Review Organization should follow the criteria set forth in the abovementioned IMDRF Documents, including ISO/IEC 17021: 2011 in forwarding to FDA information on any complaint (e.g., whistleblowers) it receives about a 510(k) Submitter that could indicate an issue related to the safety or effectiveness of a medical device or a public health risk.

H. Third Party Review Organization recordkeeping

Pursuant to section 704(f) of the FD&C Act (21 U.S.C. § 374(f)), a TP Review Organization must maintain records that support its initial and continuing qualifications to receive FDA recognition. These records must include the following:

1) documentation of the training and qualifications of the TP Review Organization and its personnel;

2) the procedures used by the TP Review Organization for handling confidential information;

3) the compensation arrangements made by the TP Review Organization; and

4) the procedures used by the TP Review Organization to identify and avoid conflicts of interest

In accordance with section 704(f)(1) of the FD&C Act, TP Review Organizations must make these records available upon request by an officer or employee of FDA. TP Review Organizations shall permit the officer or employee at all reasonable times, to have access to, to copy, or to verify, these records. Within 15 days of receipt of a written request from FDA, TP Review Organizations must make copies of the requested records available at the place FDA designates. See section 704(f)(2) of the FD&C Act. If FDA's monitoring of the TP Review Program, such as a review of compensation arrangements between TP Review Organizations and 510(k) submitters, reveals that 510(k) Submitters are developing business relationships with TP Review Organizations that call into question the independence or objectivity of TP Review Organizations, FDA will consider implementing a process that limits a submitter's choice of TP Review Organizations. Business relationships that may undermine the independence or objectivity of a TP Review Organization include contracts between a manufacturer and a TP Review Organization that represent a significant share of the TP Review Organization's income from all activities including the TP Review Program over the period of the contract, such that continuation or termination of the contract may create the appearance of an undue financial influence.

In addition to these recordkeeping requirements, TP Review Organizations should keep, maintain, and make reasonably available upon request by FDA or during an onsite assessment of any policies and procedures developed consistent with this Section.

Further, TP Review Organizations should retain the following records for at least three years following the submission of a 510(k) for review to FDA:

1) copies of all 510(k) reviews and associated correspondence;

2) information on the identity and qualifications of all personnel who contributed to the technical review of each 510(k); and

3) other relevant records

Section 523(b)(3)(E)(iv) requires TP Review Organizations to agree in writing that they will promptly respond and attempt to resolve complaints regarding its activities for which it is recognized. FDA recommends that TP Review Organizations establish a recordkeeping

system for tracking the submission of those complaints and how those complaints were resolved, or attempted to be resolved.

VI. Content and Format of an Application for Initial Recognition and Rerecognition as a TP Review Organization

This section of the guidance provides FDA's recommendations on how TP Review Organizations should apply for recognition and rerecognition, as well as what should be included in an application to FDA to avoid recognition denial or rerecognition denial.

Note that when a TP Review Organization suspends, withdraws, cancels, or reduces the scope of its recognition, the TP Review Organization should inform FDA promptly.

A. Initial recognition

Organizations that wish to become TP Review Organizations recognized under section 523 of the FD&C Act should send their applications to FDA. Three complete copies of the application should be sent to the following address. To facilitate review of the application, FDA also encourages submission of an eCopy.[42]

CDRH Third Party Premarket Review Program
Food and Drug Administration
10903 New Hampshire Avenue,
Silver Spring, Maryland 20993 USA
3P510K@fda.hhs.gov

FDA will acknowledge receipt with an email to the applicant's designated contact person when the application is received. FDA will review these materials and respond within 60 days of the date of receipt of the application with a decision to recognize or deny recognition, or a request for additional information. FDA may deem the application incomplete and deny recognition if the applicant fails to respond to FDA's request for additional information in a timely manner.

The following information should be submitted in an application for FDA's consideration:

(i) Administrative information

1. The name and address of the TP Review Organization seeking recognition;

[42] For information on the eCopy program, please see FDA's guidance entitled "eCopy Program for Medical Device Submissions" available on FDA's website at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

2. The telephone number, email address, 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. Foreign organizations should also identify the name, address, telephone number, email address, and fax number of an authorized representative located within the United States that will serve as the TP Review Organization's contact with FDA (see also Section V.A);

3. The name and title of the most responsible individual at the organization;

4. A brief description of the organization, 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, control of organization, and other related information sufficient for FDA to assess its degree of independence from entities such as device manufacturers and distributors;

5. A listing of any national, state, local, or other recognition; and

6. A list of the device types the applicant seeks to review. Applicants should identify the device types by, for example, product codes or classification name and regulation

(ii) Prevention of conflicts of interest

1. A copy of the written policies and procedures established by the TP Review Organization to ensure that the TP Review Organization and its employees (including contractors) involved in the evaluation of 510(k)s are free from conflicts of interest, and to prevent any individual or organizational conflict of interest, or appearance of conflict of interest that might affect the review process.

(iii) Personnel qualifications

1. A list of personnel that will be involved in the TP 510(k) review, including Product Specialists, Technical Experts, and Final Reviewers. Applicants should demonstrate that these personnel are technically competent to conduct 510(k) reviews and should document the following in their applications:

   (i) the written policies and procedures established to ensure 510(k)s are reviewed by qualified personnel;

   (ii) the written instructions for the duties and responsibilities of personnel with respect to 510(k) reviews;

   (iii) the written personnel standards established to ensure that designated personnel are

qualified in all of the scientific disciplines addressed by the 510(k)s for devices for which the TP Review Organization is applying for its review;

(iv) the documentation (e.g., CVs) to establish that the reviewers of 510(k)s (i.e., Product Specialists and Technical Experts) and other involved non-supervisory personnel meet the Recognition Criteria for qualified personnel. This includes documentation of education, training, skills, abilities, and experience, including specialized education and experience needed for the review of class II devices for which the TP Review Organization is applying for its review;

(v) the documentation (e.g., CVs) to establish that the supervisor(s) of 510(k) reviewers (i.e., Final Reviewer) have sufficient authority and meet the Recognition Criteria for qualified supervisory personnel. This includes documentation of education, training, skills, abilities, and experience, including specialized education and experience needed for the review of class II devices for which the TP Review Organization is applying for its review;

(vi) a description of the management structure, or, if a contractor is used for 510(k) reviews, the contractor's management structure. The application should describe the position of the individual(s) providing supervision within the management structure and explain how that structure provides for the supervision of 510(k) reviewers and other personnel involved in the review process.

(iv) Certification statements

Pursuant to section 523(b)(3)(E), the applicant must provide a statement in its application, signed by the most responsible individual at the organization, certifying that it, at all times:

1. will report information that accurately reflects data reviewed;

2. will limit its work and reviews to that for which competence and capacity are available, including conduct 510(k) reviews in accordance with the policies and procedures it has established regarding review of 510(k)s by qualified personnel;

3. will treat any information, records, reports, and recommendations that it may receive as proprietary and confidential information;

4. will promptly respond and attempt to resolve complaints regarding its activities for which it is recognized;

5. will protect against financial conflicts of interests in accordance with policies and procedures it has established relating to prevention of financial conflicts of interests.

FDA also expects the applicant to certify in its application that at all times it:

1. will be in conformity while recognized by FDA with the requirements of section 523 of

the FD&C Act;

2. will protect against conflicts of interests in accordance with policies and procedures it has established relating to prevention of conflicts of interests;

3. will keep and maintain documentation of any organizational policies and procedures developed consistent with Section V and commits to ensuring these documents are reasonably available upon request by FDA (including during FDA's review of an application for recognition or rerecognition) or made available to FDA during an on-site assessment (see Section VII);

4. will keep and maintain records in a manner consistent with Section V.H of this guidance;

5. will comply with the eCopy requirements[43] for TP 510(k) submissions as described in the guidance document titled, "eCopy Program for Medical Device Submissions," as discussed in Section IV.I of this guidance;

6. commits that its most responsible person or designee(s) will have completed FDA training prior to the TP Review Organization performing any 510(k) reviews, and agrees that its most responsible person or designee(s) will attend such training at least every three years; and

7. will contact the relevant Branch Chief or designee for consultation before reviewing any device type (by respective product code) that it has not recently reviewed.

B. Rerecognition

In accordance with section 523(b)(2)(E) of the FD&C Act, a TP Review Organization's recognition by FDA will sunset 3 years from the date of recognition under section 523 of the FD&C Act. To continue conducting TP 510(k) reviews, the TP Review Organization must obtain rerecognition.

Requests for rerecognition will be handled in the same manner as initial recognition requests. Accordingly, rerecognition applications should follow the format described in Section VI.A . For the purpose of rerecognition, FDA may also consider the past premarket review performance of the TP Review Organization and any information that comes to FDA's attention about the status of the TP Review Organization's recognition.

FDA intends to perform assessments of the TP Review Program and TP Review Organizations in accordance with the criteria set forth in the IMDRF Documents, specifically IMDRF MDSAP WG N5, N6, and N11, to the extent such criteria are appropriate and consistent with the FD&C Act and other applicable laws and regulations, and depending on the availability of FDA resources.

[43] See section 745A(b) of the FD&C Act.

TP Review Organizations should account for FDA's 60 day review period in determining when to submit their applications in order to prevent any lapse in recognition. A TP Review Organization may request rerecognition earlier if it so chooses.

C. Recognition or rerecognition denial

A TP Review Organization that wishes to request a reconsideration of a recognition denial or rerecognition denial may make a written request to FDA. For information about the appeals processes, please see FDA's guidance entitled "Center for Devices and Radiological Health Appeals Processes."[44] A written appeal should be submitted to the CDRH Ombudsman at:

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

VII. Recognition Suspension or Withdrawal

Section 523(b)(2)(B) of the FD&C Act authorizes FDA to suspend or withdraw accreditation of any TP Review Organization, after providing notice and an opportunity for an informal hearing, when the TP Review Organization is substantially not in compliance with the requirements of section 523 of the FD&C Act, poses a threat to public health or fails to act in a manner that is consistent with the purposes of section 523 of the FD&C Act.

FDA will perform an assessment of each TP Review Organization on a periodic or "for cause" basis as part of its auditing to ensure TP Review Organizations continue to meet the standards of recognition. See section 523(b)(2)(C) of the FD&C Act. This may include unannounced on-site audits conducted by the Agency. Generally, assessments will involve inspecting a TP Review Organization's facility to ensure that the TP Review Organization has maintained records and is operating in accordance with the procedures, qualifications, and certifications as specified in the TP Review Organization's application and the FD&C Act. Furthermore, FDA will periodically evaluate completed premarket reviews of 510(k)s submitted to FDA under the TP Review Program and will provide periodic feedback to Product Specialists of TP Review Organizations as part of its auditing. TP Review Organizations should continue to demonstrate technical competency in order to maintain recognition. If monitoring of a TP Review Organization reveals nonconformity with section 523, a threat to the public health or a failure to act in a manner that is consistent with the purposes of section 523 of the FD&C Act, FDA may take steps to suspend or withdraw

[44] Available on FDA's website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm284651.htm.

recognition of the TP Review Organization, after providing notice and an opportunity for an informal hearing. See section 523(b)(2)(B) of the FD&C Act.