510(k) Third Party Review Program

Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on: September 14, 2018

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the Third Party Review Program at 3P510K@fda.hhs.gov.

This guidance is a reissuance of the draft guidance titled "510(k) Third Party Review Program – Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations" issued on September 12, 2016.

When final, 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 "Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications" issued on September 28, 2004.

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 CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1500013 to identify the guidance you are requesting.

Table of Contents

510(k) Third Party Review Program

Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

The 510(k) Third Party (3P) Review Program (formally known as the Accredited Persons (AP) Program) is authorized under section 523 of the Federal Food, Drug, and Cosmetic (FD&C) Act.[1] Under this authority, FDA recognizes third parties to review premarket notification (510(k)) submissions and recommend the initial classification of certain devices. FDA's implementation of section 523 establishes a process for recognition of qualified third parties to conduct the initial review of 510(k) submissions for certain low-to-moderate risk devices eligible for review under the 3P Review Program.[2] This guidance document also reflects amendments made to section 523 by the FDA Reauthorization Act of 2017 (FDARA),[3] which directed FDA to issue draft guidance[4] on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person.

[1] Section 523 of the FD&C Act uses the terms "accredited persons," "accredit," "accredited," "accreditation," "reaccredit," "reaccredited," and "reaccreditation." The guidance does not use those statutory terms but rather defines such terms as "recognition," and "rerecognition" as synonymous terms. These alternative terms are used in this guidance to harmonize the terms used by FDA and in the FD&C Act with those in the International Medical Device Regulators Forum (IMDRF) and Medical Device Single Audit Program (MDSAP) documents and are defined in Section IV of this guidance.

[2] Currently, the Center for Biologics Evaluation and Research does not regulate devices of the types subject to this guidance.

[3] Pub. L. 115-52.

[4] See section 523(a)(3)(B)(i).

For the current edition of the FDA-recognized standards referenced in this document, see the FDA Recognized Consensus Standards Database.[5]

The objectives of this draft guidance are:

1. To describe the factors FDA will use in determining device type eligibility for review by 3P Review Organizations
2. To outline FDA's process for the recognition, rerecognition, suspension and withdrawal of recognition for 3P Review Organizations
3. To ensure consistent quality of work among 3P Review Organizations through the Medical Device User Fee Amendments (MDUFA) IV commitments authorized under FDARA.[6]

When finalized, this guidance will supersede FDA's guidance documents titled "Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications" issued on September 28, 2004[7] and "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[8].

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.

II. Background

A. Basis for 3P Review Program

On August 1, 1996, FDA launched a voluntary third party 510(k) review pilot program for selected medical devices. Under this pilot program, all class I devices that were not 510(k) exempt at that time, and 30 class II devices were eligible for 3P review.

On November 21, 1997, the Food and Drug Administration Modernization Act (FDAMA) was signed into law. Section 210 of FDAMA[9] codified and expanded the pilot program by establishing section 523 of the FD&C Act.

---

[5] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] Pub L. 115-52.

[7]The third party guidance document issued in 2004 is available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082191.htm

[8]The third party guidance document issued in 2001 is available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094459.pdf

[9] Pub. L. 105-115

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) [10] was signed into law and required FDA to establish and publish criteria to accredit, reaccredit, and deny reaccreditation of 3P Review Organizations that perform 510(k) reviews of eligible devices.

On August 18, 2017, FDARA[11] was signed into law and required FDA to issue draft guidance on the factors FDA will use in determining whether a class I or class II device type, or subset of such device types, is eligible for review by 3P Review Organizations, including the risk of the device type and whether the device type is permanently implantable, life sustaining, or life supporting, and whether there is a detailed public health justification for permitting the review by an accredited person of such device type. This guidance also addresses several MDUFA IV commitments by including an early interaction consult policy and clarifying criteria for rerecognition of 3P Review Organizations and the suspension or withdrawal of recognition.[12]

B. General Overview of 3P Review Program

The 3P 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 3P Review Organizations, and to provide manufacturers of eligible devices a voluntary alternative review process that may yield more rapid decisions on 510(k)s than from FDA. Figure 1 below provides a schematic overview of the 3P Review Program.[13]

Figure 1 – A General Overview of the 3P Review Program

Under the 3P Review Program, 3P Review Organizations review a 510(k) submission and then forward their review, the 510(k) submission, and a recommendation (e.g., substantially equivalent (SE) or not substantially equivalent (NSE)) to FDA. FDA reviews the 3P Review

[10] Pub. L. 112-144.
[11] Pub. L. 115-52.
[12] Through the MDUFA IV Commitment Letter, FDA commits to improving the 3P Review Program with a goal of eliminating routine re-review by FDA of 3P reviews: https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf
[13] Figure 1 uses IEC/IEC 19510: Information technology – Object Management Group Business Process Model and Notation (2013)

Organization's memo and recommendation and makes a final decision on the submission. Section 523(a)(2) of the FD&C Act requires FDA to make a determination with respect to the initial classification within 30 calendar days[14] after receiving a recommendation from a 3P Review Organization.

FDA recognizes 3P Review Organizations[15] to review 510(k)s for certain device types eligible for the 3P Review Program.[16]

Participation by 510(k) Submitters in the 3P Review Program is entirely voluntary. Manufacturers who do not wish to use a 3P Review Organization may submit their 510(k)s directly to the FDA for review, through either the Traditional, Special or Abbreviated Programs, as appropriate.[17,18]

As described in this draft guidance, the 3P Review Program includes features designed to ensure a high level of quality in the review of 510(k)s by a 3P Review Organization and to minimize risks to public health. A 3P Review Organization must be recognized by FDA under section 523(b) of the FD&C Act to be eligible to participate in the 3P Review Program. In evaluating a 3P Review Organization for recognition or rerecognition, FDA will consider the application, as outlined in Section VIII of this guidance, provided by a 3P Review Organization. In addition, FDA may consider past premarket review performance of the 3P Review Organization as described in Section VIII.B.[19]

III. Scope

This draft guidance outlines FDA's current thinking on key aspects of the 3P Review Program, including:

1. FDA's expectations for 3P Review Organization reviews of 510(k) submissions, including new policy for early interaction consults (see Section VI)
2. New factors used to establish device type eligibility in the 3P Review Program (see Section V)
3. Requirements and recommendations for recognition and rerecognition of 3P Review Organizations under the 3P Review Program (see Section VII)

[14] FDA uses calendar days when measuring on-time performance of user-fee supported premarket medical device submission reviews. See, "MDUFA Performance Goals and Procedures, Fiscal Years 2018 through 2022" at https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf for more information.

[15] For a current list of recognized 3P Review Organizations under the 3P Review Program, please visit FDA's website at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/Accredit.cfm.

[16] For a current list of eligible devices for 3P review under the 3P Review Program, please visit FDA's website at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm.

[17] The guidance document describing the 510(k) Program is available on FDA's website at https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf

[18] The guidance document describing the 510(k) paradigm is available on FDA's website at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf

[19] See section 523(b)(2) and section 523(b)(3)

4. Content and format of a 3P Review Organization's application for initial recognition and rerecognition (see Section VIII)
5. Process for suspension or withdrawal of recognition (see Section IX)
6. Leveraging the International Medical Device Regulators Forum's (IMDRF's) requirements for the Medical Device Single Audit Program (MDSAP) (see Section IX)

Currently accredited 3P Review Organizations should submit their application materials for recognition in the manner described in SectionVIII. of this guidance within six months of finalization of this guidance.

IV. Definitions

The definitions provided below explain the terms used by FDA in the context of this guidance. These terms are not intended to be applied in any context beyond this document and the 3P Review Program.

Device Type: A device type or category as set forth in a section of the Code of Federal Regulations, as well as a subset of such device type, such as that set forth in a product code.

510(k) Submitter: An entity or person that submits scientific and technical data in the form of a 510(k) submission to a 3P Review Organization for demonstrating substantial equivalence (SE) of that device to a legally marketed device that is not subject to premarket approval (PMA).

Final Reviewer: An individual within the 3P Review Organization who oversees the review of a 510(k) submission throughout the entire review process. The Final Reviewer is responsible for ensuring that final recommendations regarding the device made by the Product Specialist (defined separately) are appropriately evaluated, organized, and documented before documents are sent to FDA.This individual has sufficient authority and competence within the 3P Review Organization to independently evaluate the quality and acceptability of the 3P review documentation. The Final Reviewer is a separate individual from the Product Specialist.

IMDRF MDSAP Documents: IMDRF MDSAP WG/N3 FINAL: 2013 – "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition"[20] and IMDRF MDSAP WG/N4 FINAL: 2013 – "Competence and Training Requirements for Auditing Organizations"[21]produced by the International Medical Device Regulators Forum (IMDRF) intended to implement the concept of a Medical Device Single Audit Program (MDSAP).[22] These documents provide criteria for audit programs that FDA believes 3P Review

[20] IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf

[21] IMDRF MDSAP Working Group N4: Competance and Training Requirements for Auditing Organizations can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf

[22] https://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/

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.

IMDRF Medical Device Single Audit Program: An international program, established by IMDRF, specifying a standard set of requirements for the recognition of auditing organizations performing regulatory audits of medical device manufacturers and other related functions.

NSE – Not substantially equivalent

Product Specialist: An individual within the 3P Review Organization 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 their scientific background and competence. This individual is the primary reviewer responsible for leading the 3P Review Organization's review team on a given 510(k) submission. The Product Specialist submits their recommendation and all related documentation to the Final Reviewer.

Recognition: The process of accrediting 3P 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 section 513(f)(1) of the FD&C Act (21 U.S.C. § 360c(f)(1)).

Rerecognition: The process of renewing the accreditation of 3P 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[23] and N4[24], (which include the International Organization for Standardization (ISO)/the International Electrotechnical Commission (IEC) 17021:2011 "Conformity assessment – Requirements for bodies providing audit and certification of management systems", where appropriate and applicable); and the criteria to accredit or deny accreditation announced in the Federal Register.[25]

Recognition Denial: The process of denying an application for accreditation submitted by a potential 3P Review Organization.

[23] IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf

[24] IMDRF MDSAP Working Group N4: Competance and Training Requirements for Auditing Organizations can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf

[25] 63 FR 28388 (May 22, 1998) is available at https://www.gpo.gov/fdsys/pkg/FR-1998-05-22/pdf/98-13799.pdf.

Rerecognition Denial: The process of denying an application for reaccreditation submitted by a recognized 3P Review Organization.

Recognition Withdrawal: The process of withdrawing or suspending accreditation of a 3P Review Organization in accordance with section 523(b)(2) of the FD&C Act.

Safety Signal: A signal represents a new potentially causal association or a new aspect of a known association between a medical device and an adverse event or set of adverse events.[26]

SE – Substantially equivalent or substantial equivalence

Technical Expert: An individual who provides specific knowledge or expertise. This individual may be an employee of a 3P Review Organization or may be external as described below in Sections VI.B and VII.D of this guidance, respectively.

Third Party (3P) Review Organization: An organization recognized by FDA to review 510(k) submissions for certain eligible devices as authorized by section 523 of the FD&C Act.

V. Factors Used in Determining Device Type Eligibility in the 3P Review Program

The factors FDA will consider in determining device type eligibility for the 3P Review Program are as follows:

1. The risk of the device type, or subset of such device type.[27] FDA generally classifies medical devices based on risks associated with the device type and whether general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of the device or there is sufficient information to establish special controls to mitigate such risks and provide such assurance. Devices are classified into one of three regulatory classes: class I, class II, or class III.[28] In accordance with the statute, class III devices are not eligible for 3P review.[29]

[26] See Signal Management Program in "Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health" at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM604690.pdf

[27] See section 523(a)(3)(B)(i)(I)

[28] For more information on the classification of medical devices, please visit FDA's website at https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm378714.htm.

[29] See section 523(a)(3)(A)(i)

2. Whether the device type, or subset of such device type, is permanently implantable, life sustaining, or life supporting. Any 3P Review Organization seeking recognition for review of such device types must provide a detailed public health justification explaining why this device type should be eligible for 3P review[30] and how this will positively impact public health.

3. The extent to which the device type is well understood. For example, devices with novel technological characteristics, including some devices requiring complex special controls initially classified through the De Novo process may be ineligible for 3P review.[31]

4. The extent to which necessary information to make a well-informed recommendation is available to 3P Review Organizations. If information materially relevant to evaluating a device type cannot be shared outside the agency (e.g., it is proprietary), the device type may be ineligible for 3P review.

5. The extent to which the review of the device type does not require multifaceted, interdisciplinary expertise. The following are examples of scenarios that would likely be ineligible for 3P review due to the need for such expertise:

    a. the review of some kinds of clinical data or complex non-clinical data (e.g., computational modeling);

    b. a need for consultation across different organizational components, or in cross-modality topics (e.g., a multi-reader clinical study) ;

    c. a combination product or device type that requires review from another Center in the Agency;

    d. if a device type raises novel cross-labeling considerations, such as the potential for off-label use of drugs (e.g., injector needles or syringes). "Cross-labeled" combination products usually refer to any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified drug, device of biological product where both are required to achieve the intended use, indication, or effect.[32]

However, if a device type contains simple clinical data such as sample clinical images or tests using banked specimens, it may be eligible for 3P review. Most in vitro diagnostic (IVD) devices are eligible for 3P review as they typically rely on simple clinical studies to demonstrate SE.

---

[30] See section 523(a)(3)(B)(i)(II)

[31] The guidance document describing the De Novo process is available on FDA's website at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080197.pdf

[32] For more information on "cross-labeled" products, please visit FDA's website at https://www.fda.gov/combinationproducts/aboutcombinationproducts/ucm101496.htm

6. The availability of postmarket data suggesting that the device type is the subject of safety signals. For example, if a device type is the subject of a safety communication, a high-risk recall (Class I)[33], or postmarket data that indicate a safety signal, this device type may be ineligible for 3P review.

   For example, as of the date of issuance of this draft guidance, duodenoscopes have a safety signal associated with their reprocessing.[34] Because of this safety signal, FDA may remove duodenoscopes and accessories from eligibility for the 3P Review Program.

FDA will consider each of the above factors in determining device type eligibility for 3P review. Furthermore, if a device type is considered eligible for 3P review, but a proposed modification to the device type for a specific submission raises different concerns related to the factors listed above, that submission may be determined to be ineligible for third party review.

Upon finalization of this guidance, the product code classification database[35] and FDA's list of devices eligible for 3P review[36] will be updated to reflect the new eligibility factors used to determine 3P eligibility for device types.

VI. Review of 510(k) Submissions by 3P Review Organizations

3P Review Organizations share FDA's mission to protect and promote the public health by ensuring medical devices are safe and effective for their intended uses. 3P Review Organizations are responsible for reviewing and analyzing scientific and technical data in a 510(k) submission to make a recommendation regarding the device to the FDA. 3P Review Organizations should conduct their review of 510(k)s in the manner described in the sections below. Figure 2 identifies the key steps in a 3P Review Organization's review of a 510(k) submission.[37]

Figure 2: Steps in a 3P Review Organization's 510(k) Review

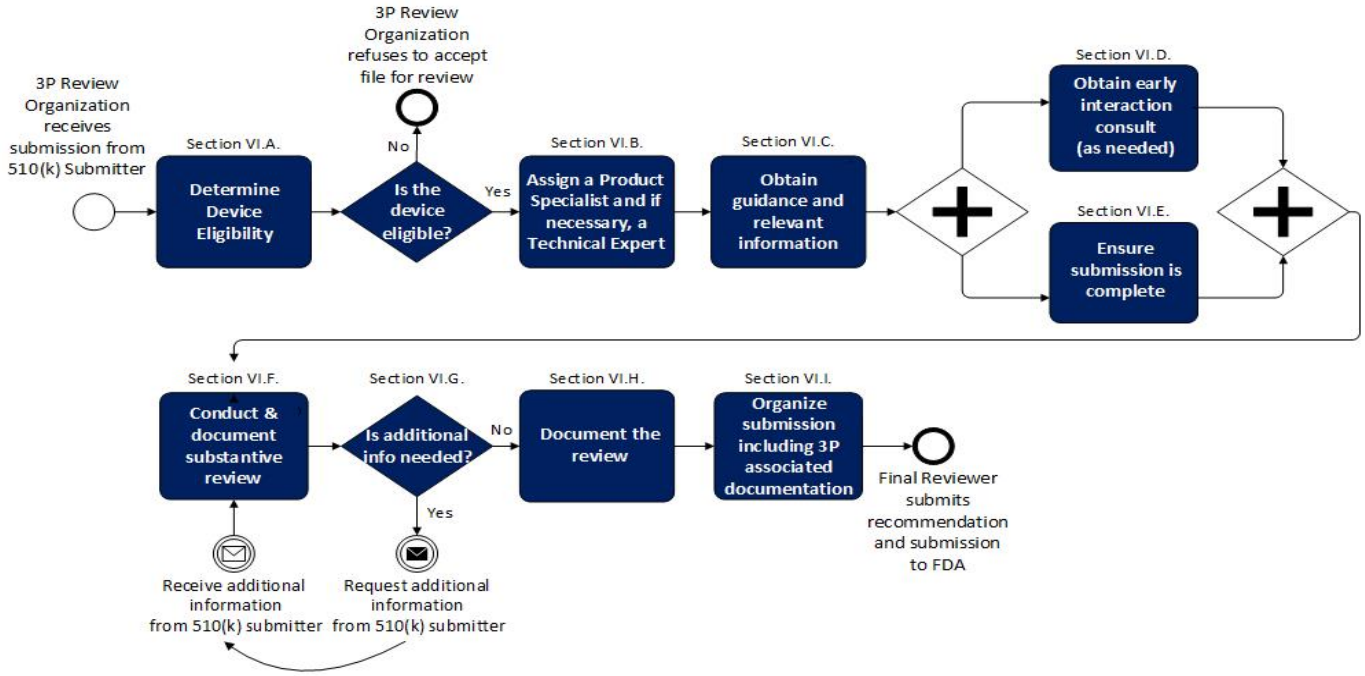
[33] For information on classification of recalls, please visit FDA's website at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm

[34] Information on safety signals associated with duodenoscopes is available on FDA's website at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454630.htm

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

[36] For a current list of eligible devices for 3P review under the 3P Review Program, please visit FDA's website at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm.

[37] Figure 2 uses IEC/IEC 19510: Information technology – Object Management Group Business Process Model and Notation (2013)



A. Determine device eligibility for 3P review

Before reviewing a 510(k) submission, a 3P Review Organization should determine whether a device type is eligible for 3P review based on review of the product code classification database[38] or the FDA Third Party Review public website[39]. If the device is not eligible for 3P review, the 3P Review Organization should not accept the 510(k) for review from the 510(k) Submitter. If the 3P Review Organization determines the device is ineligible for 3P review after it has already accepted the 510(k) submission, the 3P Review Organization should immediately inform the 510(k) Submitter and discontinue the review.

If the 3P Review Organization submits a 510(k) submission to FDA for an ineligible device, or a device the 3P Review Organization is not recognized to review (see Section VIII.A), FDA will place the submission on hold and notify the 3P Review Organization of FDA's eligibility assessment. If the 3P Review Organization does not address eligibility concerns or withdraw the submission within 180 days, FDA will delete the file. A 510(k) Submitter cannot submit a 510(k) for the same device directly to FDA until the file is withdrawn voluntarily by the 3P Review Organization or deleted automatically by FDA after 180 days. If a 3P Review Organization is unclear regarding the eligibility status of a device, it should contact the 3P inbox at 3P1510K@fda.hhs.gov to seek clarification.

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

[39] For a list of eligible devices for 3P review under the Third Party Review Program, please visit FDA's website at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm.

B. Assign a Product Specialist(s) and Technical Expert(s) to conduct the substantive review of a 510(k) submission

3P Review Organization personnel should have appropriate education, training, skills, technical knowledge, qualifications, and experience to perform 510(k) reviews for the device type(s) their organization is recognized to review. For additional discussion on FDA's recommendations regarding qualifications of personnel, see Section VII.C of this guidance.

Each 510(k) submission should be assigned to a Product Specialist with appropriate expertise for the type of 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. Particular attention should be given to the expertise and impartiality of any external Technical Experts. For more information on using external Technical Experts, please see Section VII.D of this guidance.

C. Obtain relevant FDA guidance(s) and information

3P Review Organizations should review and be familiar with publicly available information relevant to their review. For example:

1. 3P Review Organizations should review FDA's guidance database to obtain any relevant guidance documents[40] when conducting their reviews, including device-specific and horizontal guidances (e.g., biocompatibility, software, sterility).

2. In addition, 3P Review Organizations should be aware of any special controls, which are regulatory requirements for certain class II devices, that apply to that device type under review. For information on whether a device type has applicable special controls, 3P Review Organizations should review the proposed classification regulation of the device under Title 21 of the Code of Federal Regulations (CFR)[41], which will identify the mandatory special controls for a particular device type.

[40] 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 https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[41] The Code of Federal Regulations Title 21 database is available at https://www.ecfr.gov/cgi-bin/ECFR?page=browse

3. 3P Review Organizations should review FDA's postmarket databases, including recalls, market withdrawals, and safety reports[42]; Medical Device Reports[43]; and MedSun Reports[44] for the predicate device and/or the device type to identify any issues with clinical use of similar devices that should be considered and addressed in the review of the subject device. If potential safety signals are identified by a 3P Review Organization, it should contact FDA for information on current review practice.

4. 3P Review Organizations should review publicly available premarket review information in FDA's 510(k) database for information about the legally marketed device ('predicate') to which a Submitter is comparing its device, or other similar devices,[45], including Indications for Use Statements, 510(k) Summaries[46,47], Decision Summaries (if available), and FDA decision letters. In some instances, a device's product code can also be used to identify a generic category of a device and assist with the identification of similar devices. Product codes can be found in FDA's product code database.[48]

5. If an applicant wishes to utilize standards, the 3P Review Organization should review FDA's guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices".[49]

3P Review Organizations should request that 510(k) Submitters fully inform them of any prior communications with FDA about a device under review, including but not limited to FDA feedback obtained through the Pre-Submission program, unsuccessful marketing applications, and other interactions. 3P Review Organizations should be familiar with the FDA Pre-Submission process through the guidance document titled, "Requests for Feedback on Medical

[42] The recalls database allows users to search for recalls and correction or removal actions initiated by a firm prior to recall classification and is available on FDA's website at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm

[43] The MAUDE database allows users to search for Medical Device Reports and is available on FDA's website at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm

[44] The MedSun database allows users to search for adverse event reports from the Medical Product Safety Network and is available on FDA's website at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/Medsun/searchReportText.cfm

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

[46] 510(k) Summaries should be written in accordance with 21 CFR 807.92 and is available at: https://www.ecfr.gov/cgi-bin/text-idx?SID=7272ad96195b5a401402c8b22c785d10&mc=true&node=se21.8.807_192&rgn=div8

[47] The guidance document describing 510(k) Summaries is available on FDA's website at https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf.

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

[49] The guidance document describing the use of standards to determine substantial equivalence is available on FDA's website at https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm073756.pdf.

Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff"[50]. A 3P Review Organization should request that the authorization letter from the 510(k) Submitter grant FDA permission to discuss previous submissions, identified by submission numbers, with the 3P Review Organization (see Section VI. I). If applicable, the 3P Review Organization should coordinate with the 510(k) Submitter to obtain and review prior submission content for the device, any written feedback or meeting minutes resulting from prior interactions, and any additional data, studies and/or study protocols submitted in response to previous submissions by the 510(k) Submitter prior to submitting the current submission to FDA.

3P Review Organizations should also request that 510(k) Submitters submit only one 510(k) for a specific device at a time.

D. Obtain early interaction consult with FDA (as needed)

3P Review Organizations should consult, as needed, with appropriate FDA staff prior to, and during the review of 510(k) submissions. The early interaction consultation prior to the substantive review by the 3P Review Organization is an important part of the 510(k) review process. These consultations help ensure timely and consistent 510(k) reviews by assisting in device eligibility determinations and identifying relevant issues and contemporary review criteria.

In their initial recognition applications, 3P Review Organizations commit to obtaining early interaction consults from FDA before reviewing a device type they have not previously reviewed (see Section VIII.A). FDA also encourages early interaction consults for all 3P submissions, particularly for the first review of any device type by an individual Product Specialist and for any subset of 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.

Procedures on how to obtain early interaction consults will be available on the FDA Third Party public website. FDA intends to respond to 3P Review Organization requests within 2 business days. If that deadline cannot be met, FDA will work with the 3P Review Organization to establish a reasonable timeline for a response.

E. Ensure a submission is administratively complete

To ensure that a submission is administratively complete, 3P Review Organizations should conduct an acceptance review of the 510(k) submission based on 510(k) regulations from 21 CFR 807.87 to 807.100 to assess whether the 510(k) submission includes all the information necessary to conduct a substantive review and to reach a recommendation (e.g., SE or NSE) as defined under section 513(i) of the FD&C Act (21 U.S.C. § 360c(i)) to submit to FDA. It is

[50]The guidance document describing the Pre-Submission program is available on FDA's website at https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf.

recommended that 3P Review Organizations use the Refuse to Accept (RTA) checklist for 510(k) submissions to make the determination regarding whether a submission is administratively complete. For more information on the RTA checklist, please see FDA's guidance document titled "Refuse to Accept Policy for 510(k)s" [51].

3P Review Organizations should not act as a consultant for the 510(k) Submitter. It is the responsibility of the 510(k) Submitter to be familiar with the content and format requirements of a 510(k) prior to submitting to a 3P Review Organization. If a Submitter is not familiar with the 510(k) regulatory pathway, 3P Review Organizations should direct them to resources such as FDA's guidance documents titled, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] – Guidance for Industry and FDA Staff",[52] and "Format for Traditional and Abbreviated 510(k)s – Guidance for Industry and FDA staff" [53] or the Division of Industry and Consumer Education in the Office of Communication and Education.[54]

If the 3P Review Organization determines that a submission is administratively complete, the organization should begin its substantive review of the 510(k) submission. If the 3P Review Organization identifies any deficiencies in the 510(k) submission, it should contact the 510(k) Submitter to request the missing information.

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

Substantive review focuses on the evaluation of SE 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 making an SE determination under the 510(k) program, please see FDA's guidance document titled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]".[55] For information on Abbreviated and Special 510(k)s, see FDA's guidance document titled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications".[56]

3P Review Organizations should identify at least one independent Final Reviewer within its organization who is responsible for providing a final supervisory assessment of the Product

[51] The guidance document for Refuse to Accept policy is available on FDA's website at https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf.
[52] The guidance document for the 510(k) Program is available on FDA's website at https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf.
[53] The guidance document on the content of a 510(k) is available on FDA's website at (https://www.fda.gov/RegulatoryInformation/Guidances/ucm084365.htm
[54] The contact information for the Division of Industry and Consumer Education is available on FDA's website at https://www.fda.gov/medicaldevices/deviceregulationandguidance/contactdivisionofindustryandconsumereducation/default.htm
[55] The guidance document used to determine the substantial equivalence of a device is available on FDA's website at https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf.
[56] The guidance document for abbreviated and special 510(k) submissions is available on FDA's website at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf

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 3P Review Organizations identify any deficiencies during their substantive review, they should contact the 510(k) Submitter with a request that the deficiencies be addressed. Section VI.G below provides further instruction on how to identify deficiencies in a 510(k) submission. When the substantive review is complete, the Product Specialist(s), Technical Expert(s), if applicable, and Final Reviewer should reach an agreement on a final recommendation (e.g., SE or NSE) to a predicate device before submitting the recommendation to FDA.

G. Identify deficiencies in a 510(k) submission

If a 3P Review Organization identifies any deficiencies during their review, it should contact the 510(k) Submitter. 3P Review Organizations may use any form of communication (i.e., telephone, facsimile, electronic mail, or letter) to resolve the matter provided confidentiality is maintained and the interaction is documented. 3P 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.

When requesting additional information from a 510(k) Submitter, 3P Review Organizations should structure their additional information requests as described in FDA's guidance document titled "Developing and Responding to Deficiencies in Accordance with Least Burdensome Provisions". [57] This guidance document has examples of well-constructed deficiencies and responses to FDA's requests.

3P Review Organizations should document the deficiencies, the 510(k) Submitter's response to the deficiencies, and the discussion on the adequacy of the response. 3P Review Organizations should also provide a copy of all written communications between the 510(k) Submitter and the 3P Review Organization (e.g., electronic mail, letters, summary of teleconferences). If the 510(k) Submitter made any modifications to the submission in response to a deficiency (e.g., revised 510(k) summary), the 3P Review Organization should document this modification and request that the 510(k) Submitter provide the latest version of the 510(k) submission prior to submitting to FDA. For example, if the Product Specialist requested an updated device description, the latest version should be in the 510(k) submission to FDA. However, the original device description and the deficiency requesting an updated device description should be found in the review memo. This will ensure that FDA has the correct version of the 510(k) submission on record. Proper documentation will ensure that the 3P Review Organization does not have or appear to have the role of a consultant.

[57] The guidance document on developing and responding to deficiencies is available on FDA's website at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073680.pdf

H. Document a 510(k) review

Once a 3P Review Organization has made a final recommendation, it should prepare their review documentation specifying the reasoning and steps that led to their final recommendation. 21 CFR 10.70 ("Documentation of significant decisions in administrative file") provides a framework that should be utilized by 3P Review Organizations. The content of the review documentation will vary based on the type of 510(k) submission and device. Recommended review memorandum examples for documentation purposes will be available on the FDA Third Party public website.[58]

If standards are referenced in a submission, FDA recommends 3P Review Organizations discuss how they were utilized in the 510(k) submission in their review memorandum. A Submitter may rely upon an FDA-recognized standard in their submission either 'in general use' or with a Declaration of Conformity. 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 to submit a Declaration of Conformity to an FDA-recognized consensus standard, they should state that all requirements were met and identify all inapplicable requirements in a separate section in the Declaration of Conformity and in the submission.

In addition to the necessary information required in a 510(k) submission[59], the review memorandum should also convey how a 3P Review Organization made their recommendation regarding the device. A thorough and substantive review memorandum should discuss the adequacy of each section of the submission. It is not sufficient to state that a section of the 510(k) submission or a response to a deficiency was adequate without providing an explanation of how the 3P Review Organization came to that determination.

To facilitate FDA's review process, 3P Review Organizations should reference sections and page numbers of the 510(k) submission in their review memorandum where possible. 3P Review Organizations should also clearly document any deficiencies, the response to the deficiencies, and the 3P Review Organization's review of the response as indicated in Section VI.G.

The review memorandum is the only means by which FDA can understand how and why a 3P Review Organization recommended a device to be SE (or NSE) to the predicate device. Thorough and clear documentation will reduce the need for FDA to re-review the submission itself and increase the efficiency of FDA's final review.[60]

---

[58]Review examples will be available on FDA's third party website: https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/thirdparyreview/default.htm

[59] See 21 CFR 807 Subpart E

[60] Through the MDUFA IV Commitment Letter, FDA commits to improving the 3P Review Program with a goal of eliminating routine re-review by FDA of 3P reviews: https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf

I. Organize and submit a 510(k) submission including associated 3P review documentation

Upon completing the review of a 510(k) submission, the Final Reviewer should submit two separate eCopy documents to FDA's Document Control Center[61], the 510(k) submission generated by the 510(k) Submitter and the 3P review documentation generated by the 3P Review Organization.

Since there are two distinct parties involved in the generation of a 3P 510(k) submission, the 3P Review Organization and the 510(k) Submitter, each is subject to the eCopy requirements and each must provide their 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)). The 510(k) Submitter should take care to submit the latest version of the 510(k) submission. This version should include any documents that have been updated in response to deficiencies from the 3P Review Organization. Please refer to FDA's guidance titled "eCopy Program for Medical Device Submissions"[62] for more information on how to submit through the eCopy program.

A 3P Review Organization's 510(k) documentation 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 3P 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 regulation name, classification regulation number, and product code, as applicable)

   f. The 3P Review Organization's recommendation (SE or NSE) with respect to the device

   g. The date the 3P Review Organization first received the 510(k) from the Submitter

(2) A letter signed by the 510(k) Submitter authorizing the 3P Review Organization to submit the 510(k) to FDA on their behalf and authorizing the 3P Review Organization to

[61] The address for CDRH's Document Control Center is available on FDA's website at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

[62] The guidance document on eCopies is available on FDA's website at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

discuss the contents of the 510(k) with FDA on their behalf. This letter should also authorize FDA to discuss other related submission(s) with the 3P Review Organization and should include a list of these submission numbers.

(3) A signed certification that the reported information accurately reflects the data reviewed and that no material fact has been omitted. This certification should also state that the 3P Review Organization continues to meet personnel qualifications and prevention of conflicts of interest criteria reviewed by FDA; that the 3P Review Organization's review is based on the 510(k) that it is submitting with the review; and that the 3P Review Organization understands that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

(4) A table of contents listing the sections where the 510(k) submission and associated 3P review documentation are located, along with the corresponding page numbers.

(5) A summary of any early interaction consults that occurred prior to the 510(k) submission to FDA with the appropriate FDA staff, if appropriate (see Section VI.D of this guidance).

(6) The 510(k) Submitter's complete 510(k) submission that conforms to FDA's requirements for content and format as provided in 21 CFR part 807 subpart E. The 510(k) submission should be prepared by the 510(k) Submitter, not the 3P Review Organization. This information should be separate from the 3P Review Organization's documentation and should be the latest version. Please see Section VI.G for more information. Proper documentation will ensure that the 3P Review Organization does not have or appear to have the role of a consultant.

(7) An acceptance review of the 510(k) submission based on objective criteria using the RTA checklist, discussed in Section VI.E of this guidance, to assess whether the submission is administratively complete and includes all of the information necessary for the 3P Review Organization to conduct a substantive review on FDA's behalf.

(8) A review memorandum including complete documentation of the 3P Review Organization's review of the 510(k) submission as described in Section VI.H of this guidance, signed by all personnel who conducted the review (generally the Product Specialist(s), Technical Expert(s), when applicable, and Final Reviewer), with a decision recommendation.

FDA will begin its review only after it receives all documentation listed above.

J. Submit additional information upon FDA's request

After a 3P Review Organization has submitted their 510(k) recommendation, including the associated 3P review documentation, FDA will begin to review the 3P review documentation, and if necessary, the 510(k) submission. If FDA determines that additional information is needed

to make an SE determination, it will contact the 3P Review Organization either by telephone or email.[63] Such requests will describe FDA's concerns with a 510(k) submission, and identify the information needed to address those concerns.

If FDA places a 510(k) submission "on hold" (i.e., officially suspends review of the submission pending FDA's receipt of additional information), it will send an email informing the 3P Review Organization of the "on hold" status and request additional information. For more information on a request for additional information, please see FDA's guidance titled "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals".[64]

Upon receiving a request from FDA for additional information, the 3P Review Organization should:

(1) Promptly inform the 510(k) Submitter of FDA's request for additional information relating to the 510(k) submission and request that the 510(k) Submitter provide responses to the 3P Review Organization in writing.

    The 3P Review Organization should be involved in any discussions with FDA regarding the request for additional information, such as if the 510(k) Submitter seeks clarification or a Submission Issue Meeting with FDA;

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

(3) Document their review of the response to the deficiency by providing a clear and thorough assessment of whether and how the response adequately addresses FDA's deficiency;

(4) Prepare a cover letter referencing the 510(k) number previously assigned by FDA and identifying the purpose of the new submission (i.e., response to deficiencies);

(5) Send the cover letter, their additional or revised review documentation, and any additional information received from the 510(k) Submitter to FDA's Document Control Center[65].

[63] Through the MDUFA IV Commitment Letter, FDA commits to improving the 3P Review Program with a goal of eliminating routine re-review by FDA of 3P reviews: https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf

[64] The guidance document on FDA review clocks is available on FDA's website at https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089738.pdf

[65] The address for CDRH's Document Control Center is available on FDA's website at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

The 3P Review Organization must provide the two separate eCopy documents[66] (the new submission eCopy document generated by the 510(k) Submitter and the eCopy document generated by the 3P Review Organization). Each eCopy should be clearly marked as belonging to the 3P Review Organization or the 510(k) Submitter as appropriate. For information on the eCopy program, see Section VI.I of this guidance.

FDA will begin its review only after it receives the 510(k) Submitter's response to the additional information request, documentation of the 3P Review Organization's review, and the 3P Review Organization's determination of the adequacy of the response to additional information requests.

K. 510(k) submission dispute resolution

FDA has developed guidance documents that provide an overview of the appeals processes available for medical devices (see FDA's guidances titled "Center for Devices and Radiological Health Appeals Processes"[67] and "Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A"[68]). The processes for reviewing and reconsidering FDA decisions or actions on other 510(k) submissions are also available for 3P submissions when a dispute between FDA and a 510(k) Submitter arises.

Disputes are often the result of misunderstanding or miscommunication, and FDA encourages 3P Review Organizations to seek clarification, as needed, from FDA or the 510(k) Submitter during a review. If the 510(k) Submitter disagrees with an FDA decision or action, the 3P 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.

If a 510(k) Submitter would like to issue a complaint against a 3P Review Organization, communication should be sent to 3P510K@fda.hhs.gov.

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

In this section of the guidance, FDA describes the criteria considered in recognizing 3P Review Organizations to conduct premarket reviews of eligible 510(k)s as established by FDASIA.

[66] The guidance document describing the eCopy Program is available on the FDA's website at https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313794.pdf

[67] The guidance document describing the CDRH appeaks process is available on FDA's website at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284670.pdf

[68] The guidance document on the CDRH appeals process, specifically regarding 517A is available on FDA's website at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM352254.pdf

In accordance with section 523(b)(3) of the FD&C Act, a 3P Review Organization shall, at a minimum, meet the following qualification requirements. Such person:

(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) The operations of such person shall be in accordance with generally accepted professional and ethical business practices

(6) Shall agree, at a minimum, to include in its request for accreditation a commitment to, at the time of accreditation, and at any time it is performing any review pursuant to section 523, it will: -

a. Certify that reported information accurately reflects data reviewed

b. Limit work to that for which competence and capacity are available

c. Treat information received, records, reports, and recommendations as proprietary information

d. Promptly respond and attempt to resolve complaints regarding its activities for which it is recognized

e. 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 of the person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the 3P Review Organization, and the officers and employees of the 3P Review Organization, have maintained compliance with requirements relating to financial conflicts of interest

In addition to these minimum requirements set forth in the FD&C Act, a 3P Review Organization should meet additional qualifications announced in the Federal Register.[69] These qualifications include establishing policies designed to identify, prevent, and ensure reporting to FDA, of instances of forum shopping by 510(k) Submitters. Other qualifications listed in the Federal Register or that have been previously identified through guidance are discussed below.

[69] 63 FR 28388 (May 22, 1998) is available at https://www.gpo.gov/fdsys/pkg/FR-1998-05-22/pdf/98-13799.pdf.

A. Operational considerations

All submissions and communications with FDA and all documentation pertaining to the review of a 510(k) submitted to FDA should be in English. For foreign 3P Review Organizations, a United States representative should be designated so that FDA can efficiently communicate with the 3P Review Organization while conducting its review (see Section (1))

B. Management of impartiality

FDA expects 3P 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. Therefore, FDA will consider whether the potential 3P 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 their external Technical Experts. Policies and procedures intended to address this issue should be consistent with IMDRF MDSAP WG/N3 FINAL: 2013– "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition"[70] and IMDRF MDSAP WG/N4 FINAL: 2013– "Competence and Training Requirements for Auditing Organizations" [71]. For more information on the IMDRF MDSAP, see Section IX of this guidance below.

FDA recommends that 3P Review Organizations also address the following to prevent a potential conflict of interest:

(1) 3P Review Organizations should not participate in the preparation of 510(k)s when involved in 510(k) reviews. For more information, see Section VI.E of the guidance.

(2) 3P Review Organizations should not hire or contract with individuals who were employed within the last twelve months by a firm who submitted a 510(k) submission to either FDA or a recognized 3P Review Organization for its review. Personnel should not review a medical device that they developed or helped develop.

(3) 3P 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

[70] IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf

[71] IMDRF MDSAP Working Group N4: Competance and Training Requirements for Auditing Organizations can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf

Branch."[72] 3P Review Organizations are encouraged to refer to these standards in safeguarding their operations against conflicts of interest.

The conflict of interest policies for a 3P 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. When using external technical experts, see Section VII.D regarding conflicts of interest safeguards.

C. Personnel involved in reviewing activities[73]

FDA expects that 3P Review Organizations and their personnel should demonstrate knowledge and experience with the following:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)

(2) The Public Health Service Act (42 U.S.C. 201 et seq.), as applicable

(3) Regulations in the Code of Federal Regulations implementing these statutes, particularly 21 CFR Parts 800 through 1299.

Additionally, the 3P Review Organization should:

(4) Establish, document, and execute policies and procedures to ensure that 510(k)s are reviewed by qualified personnel.

(5) Maintain records on the relevant education, training, skills, and experience of all personnel who contribute to the technical review of a 510(k).

(6) Make clear written instructions for duties and responsibilities with respect to 510(k) reviews available to its personnel.

(7) Employ personnel who are qualified in all the scientific disciplines addressed by the 510(k)s that the 3P Review Organization accepts for review.

(8) 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.

[72] 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%2081641%20FINAL.pdf

[73] Additional information on the criteria for personnel qualifications is available in the Federal Register notice published on 63 FR 28388 (May 22, 1998) at https://www.gpo.gov/fdsys/pkg/FR-1998-05-22/pdf/98-13799.pdf.

In addressing the items enumerated above in this section, 3P Review Organizations should be consistent with IMDRF MDSAP WG/N3 FINAL: 2013 – "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition"[74] and IMDRF MDSAP WG/N4 FINAL: 2013 – "Competence and Training Requirements for Auditing Organizations"[75]. For more information on the IMDRF MDSAP, see Section IX of this guidance below.

In addition, 3P Review Organizations will be expected to consult national and/or international standards recognized by FDA as well as FDA guidance documents. 3P Review Organizations should have the capability to interface with FDA's electronic data systems and websites through which the 3P Review Organization can search for relevant guidance documents, recognized standards, predicate summaries, and publicly available information regarding adverse events and recalls to provide supporting risk information when performing premarket review of similar devices.

3P Review Organizations must certify in their application that designated personnel will attend FDA's training for recognition and rerecognition (see Section VIII.A of this guidance and the Federal Register notice published on May 22, 1998 (63 FR 28388)). 3P Review Organizations are expected to complete training before conducting any 510(k) reviews under the program. FDA will not accept 510(k) reviews and recommendations from 3P Review Organizations that have failed to have at least one designated person attend a FDA training session for recognition.

3P Review Organizations should be prepared to conduct technically competent 510(k) reviews before requesting recognition by FDA. FDA recommends persons involved in a 510(k) submission review at a 3P Review Organization meet the appropriate qualifications (i.e., specialized education or experience) provided in this guidance. When a 3P Review Organization requests to expand the scope of device types for which it may review 510(k) submissions, it should ensure through its policies and procedures in place that its staff are qualified in the scientific disciplines for the new device types.

D. Use of external Technical Experts

The following are FDA's recommendations when 3P Review Organizations use an external Technical Expert:

(1) External Technical Experts should meet the same standards as those who work within the 3P Review Organization, such as freedom from conflicts of interest

(2) External Technical Experts should be discouraged from subcontracting parts of their contract to subcontractors

[74] IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf

[75] IMDRF MDSAP Working Group N4: Competance and Training Requirements for Auditing Organizations can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf

(3) 3P Review Organizations should maintain records of the qualifications of external Technical Experts, in addition to evidence of regular monitoring of the established competence and the degree of fulfillment of the outsourced work

To ensure that 3P Review Organizations have sufficient competence among their own staff, there should be at least one qualified Product Specialist per device type that the 3P Review Organization is recognized to review. This is to ensure that there is not excessive reliance on external expertise by a 3P Review Organization and to enable appropriate oversight of the qualifications of external Technical Experts by 3P Review Organizations.

In addressing the items above, 3P Review Organizations should be consistent with IMDRF MDSAP WG/N3 FINAL: 2013 – "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition"[76] and IMDRF MDSAP WG/N4 FINAL: 2013 – "Competence and Training Requirements for Auditing Organizations"[77]. For more information on the IMDRF MDSAP, see Section IX of this guidance below.

E. Confidential information

A 3P Review Organization is required to treat information received, records, reports, and recommendations as proprietary information (see sections 301(y)(2) and 523(b)(3)(F)(iii) of the FD&C Act). Also, in accordance with 21 CFR 807.95, when a 510(k) is submitted by a device manufacturer to FDA, FDA will in general not publicly disclose that submission. Thus, a 3P 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 whether information submitted to FDA by a 3P Review Organization can be released in accordance with 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 3P Review Organizations will be available for disclosure by FDA after the agency has issued an SE decision for a device, unless the information is exempt from public disclosure under 21 CFR part 20 or 21 CFR 807.95. If necessary, a copy of the 510(k) will be provided to the manufacturer for predisclosure notification according to§20.61.

In addition, information submitted by a 3P Review Organization to obtain recognition or rerecognition from FDA will be available for disclosure, unless exempted under 21 CFR part 20.

[76] IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf

[77] IMDRF MDSAP Working Group N4: Competance and Training Requirements for Auditing Organizations can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf

F. Complaints regarding 510(k) Submitters

The 3P Review Organization should send to FDA via e-mail to 3P510K@fda.hhs.gov information on any complaint (e.g., whistleblowing) 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.

G. Third Party Review Organization recordkeeping

Pursuant to section 704(f) of the FD&C Act, a 3P Review Organization must maintain records that support their initial and continuing qualifications to receive FDA recognition. These records must include the following:

(1) Documentation of the training and qualifications of the 3P Review Organization and its personnel;

(2) The procedures used by the 3P Review Organization for handling confidential information;

(3) The compensation arrangements made by the 3P Review Organization; and

(4) The procedures used by the 3P Review Organization to identify and avoid conflicts of interest.

In addition to these recordkeeping requirements, 3P Review Organizations should retain the following records for at least three years (3) 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.

In addressing the items enumerated above, 3P Review Organizations should be consistent with IMDRF MDSAP WG/N3 FINAL: 2013 – "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition"[78] and IMDRF MDSAP WG/N4 FINAL:

[78] IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf

2013 – "Competence and Training Requirements for Auditing Organizations"[79]. For more information on the IMDRF MDSAP, see Section IX of this guidance.

In accordance with section 704(f)(1) of the FD&C Act, 3P Review Organizations must make the records specified in that section available upon request by an officer or employee of FDA. 3P Review Organizations shall permit the FDA officer or employee at all reasonable times to have access to, copy, and/or verify these records. Within 15 days of receipt of a written request from FDA, 3P 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 3P Review Program, such as a review of compensation arrangements between 3P Review Organizations and 510(k) Submitters, reveals that 510(k) Submitters are developing business relationships with 3P Review Organizations that call into question the independence or objectivity of a 3P Review Organizations, FDA will consider limiting a Submitter's choice of 3P Review Organizations. Business relationships that may undermine the independence or objectivity of a 3P Review Organization include, for example, contracts between a manufacturer and a 3P Review Organization that represent a significant share of the 3P Review Organization's income.

Section 523(b)(3)(F)(iv) requires 3P Review Organizations to agree that they will promptly respond and attempt to resolve complaints regarding its activities for which it is accredited. FDA recommends that 3P Review Organizations establish a recordkeeping system for tracking the submission of those complaints and how those complaints were resolved, or attempted to be resolved.

VIII. Content and Format of an Application for Initial Recognition and Rerecognition as a 3P Review Organization

This section of the guidance provides FDA's recommendations on what should be included in an application to FDA for recognition as a 3P Review Organization.

The 3P Review Organization should inform FDA promptly if they would like to suspend, withdraw, cancel or reduce the scope of their program. FDA will adjust recognition or rerecognition as appropriate.

A. Initial Recognition

[79] IMDRF MDSAP Working Group N4: Competance and Training Requirements for Auditing Organizations can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf

Organizations that wish to become recognized as 3P Review Organizations under section 523 of the FD&C Act should send their applications to FDA at the following address. To facilitate review of the application, FDA strongly encourages submission of an eCopy.[80]

CDRH Third Party Premarket Review Program
U.S. Food and Drug Administration
Document Control Center (DCC) – WO66-G609
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 calendar days[81] of the date of the 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:

(1) Administrative information

a. The name and mailing address of the 3P Review Organization seeking recognition;

b. 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 3P

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

[81] FDA uses calendar days when measuring on-time performance of user-fee supported premarket medical device submission reviews. See, "MDUFA Performance Goals and Procedures, Fiscal Years 2018 through 2022" at https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf for more information.

Review Organization's contact with FDA (see also Section VII.A of this guidance);

c. The name and title of the most responsible individual at the 3P Review Organization;

d. A brief description of the 3P Review 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 (i.e., name of owner(s) and extent of 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;

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

f. A list of the device types the applicant seeks to review by product codes or classification regulation name and regulation. Please refer to the FDA Third Party public website[82] for devices that are eligible for 3P review.

(2) Prevention of conflicts of interest

A copy of the written policies and procedures established by the 3P Review Organization to ensure that the 3P Review Organization and its employees (including external technical experts, contractors and individual contract employees) 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.

(3) Personnel qualifications

A list of personnel who will be involved in the preparation of the 3P Review Organization's 510(k) recommendations, including Product Specialists, Technical Experts, external 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 application:

[82] Information on third party eligible device types is available on FDA's website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm

a. The written policies and procedures established to ensure 510(k)s are reviewed by qualified personnel;

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

c. The written personnel standards established to ensure that designated personnel are qualified in all of the scientific disciplines presented by the 510(k)s for devices for which the 3P Review Organization is applying for its review;

d. The documentation (e.g., curricula vitae or 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 devices for which the 3P Review Organization is applying for its review;

e. 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 3P Review Organization is applying for its review; and

f. A description of the management structure, or, if an external technical expert is used for 510(k) reviews, the external technical expert'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.

(4) Certification statements

In order to address all relevant statutory requirements, and to support FDA's commitment to eliminate routine re-review of 3P submissions, the applicant must provide a statement in their application, signed by the most responsible individual at the organization, certifying that the 3P Review Organization has committed at the time of accreditation and at any time it is performing any 3P review that it:

a. Will report information that accurately reflects data reviewed;

b. Will limit work and reviews to that for which competence and capacity are available, including conducting 510(k) reviews in accordance with

the policies and procedures it has established regarding review of 510(k)s by qualified personnel;

c. Will treat any information, records, reports, and recommendations that they may receive as proprietary and confidential information;

d. Will promptly respond and attempt to resolve complaints regarding the activities for which it is recognized;

e. Will protect against conflicts of interests in accordance with policies and procedures it has established relating to prevention of financial conflicts of interests, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements relating to financial conflicts of interest;

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

a. Will demonstrate conformity while recognized by FDA with the requirements of section 523 of the FD&C Act;

b. Will maintain records in a manner consistent with Section VII.G of this guidance;

c. Will comply with the eCopy requirements[83] for premarket submissions as described in the guidance document titled, "eCopy Program for Medical Device Submissions," as discussed in Section VI.I of this guidance;

d. Commits that their most responsible person or designee(s) will have completed FDA training prior to performing any reviews by the 3P Review Organization, and agrees that their most responsible person or designee(s) will attend such training when offered and applicable;

e. Will contact FDA for early interaction consults before reviewing any subset of device type (by respective product code) that they have not reviewed as encouraged in Section VI.D of this guidance; and

f. Will commit to only accepting reviews where the 510(k) Submitters certified that any relevant prior communications with FDA are disclosed.

B. Rerecognition

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

In accordance with section 523(b)(2)(D) of the FD&C Act, a 3P Review Organization's recognition by FDA will sunset 3 years from the date the recognition was granted under section 523 of the FD&C Act. To continue conducting 3P 510(k) reviews beyond 3 years from the date of the last recognition or rerecognition, the 3P 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 VIII.A of this guidance. For rerecognition, FDA may also consider the past premarket review performance of the 3P Review Organization and any information that comes to FDA's attention about the status of the 3P Review Organization's recognition, including information from an audit.[84]

FDA recommends that 3P Review Organizations apply for rerecognition a minimum of 60 calendar days before their recognition status expires to prevent any lapse in recognition. A 3P Review Organization may request a rerecognition earlier if it so chooses.

C. Recognition or Rerecognition Denial

A 3P 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 titled "Center for Devices and Radiological Health Appeals Processes".[85] A written appeal should be submitted to the CDRH Ombudsman at:

CDRH Ombudsman
Center for Devices and Radiological Health
Food and Drug Administration
WO32 Room 4282
10903 New Hampshire Avenue
Silver Spring, Maryland 20993 USA

IX. Suspension or Recognition Withdrawal

Section 523(b)(2)(B) of the FD&C Act authorizes FDA to suspend or withdraw recognition of any 3P Review Organization, after providing notice and an opportunity for an informal hearing, when the 3P 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.

[84] See section 523(b)(2)(C)
[85] Information on the appeals process for CDRH is available on FDA's website at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM352254.pdf and https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm284670.pdf .

Under section 301(y)(1) of the FD&C Act, the following actions are prohibited by a 3P Review Organization:

(1) Submission of a report or recommendation that is false or misleading in any material respect;

(2) Disclosure of confidential information or any trade secrets without the express written consent of the person who submitted such information or secrets to the 3P Review Organization; and

(3) Receipt of a bribe in any form or doing any corrupt act associated with a responsibility delegated to the 3P Review Organization under the FD&C Act.

FDA will perform an assessment of each 3P Review Organization on a periodic or "for cause" basis as part of its auditing to ensure 3P Review Organizations continue to meet the standards of recognition (see section 523(b)(2)(C) of the FD&C Act). Generally, assessments will involve inspecting a 3P Review Organization's facility and/or records to ensure that the 3P Review Organization is operating in accordance with the procedures, qualifications, and certifications specified in the 3P 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 3P Review Program and will provide feedback to Product Specialists and the Final Reviewer of 3P Review Organizations following its audits.

3P Review Organizations should continue to demonstrate technical competency to maintain recognition. If monitoring of a 3P 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 recognition of the 3P Review Organization, after providing notice and an opportunity for an informal hearing. See section 523(b)(2)(B) of the FD&C Act.

IX. Leveraging the International Medical Device Regulators Forum's (IMDRF's) requirements for the Medical Device Single Audit Program (MDSAP)

In February 2011, the IMDRF was convened 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 collaborate 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 convergence.

The IMDRF developed the Medical Device Single Audit Program (MDSAP). Program details are outlined in a collection of documents finalized from 2013 through 2015 and available on the

IMDRF website.[86] These documents provide the fundamental building blocks of a 3P auditing program by providing criteria for the recognition and monitoring of entities that perform regulatory audits and other related functions.

There are many shared elements in FDA's statutory and regulatory criteria for 3P Review Organizations and IMDRF MDSAP WG/N3 FINAL: 2013– "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition"[87] and IMDRF MDSAP WG/N4 FINAL: 2013 – "Competence and Training Requirements for Auditing Organizations."[88] 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.

Due to these similarities, FDA believes that potential 3P Review Organizations in compliance with the MDSAP program are to be likely in compliance with most FDA 3P Review Organization requirements and meet FDA's recommendations outlined in this guidance document. Such organizations do not necessarily need to generate new documentation for FDA, but rather can leverage existing documents in their applications to FDA and for ongoing recordkeeping. As there are some differences between terms used by various international organizations, Table 1 below provides an explanation of how terms used in the IMDRF MSDAP documents should be interpreted in relation to FDA personnel and 3P Review Organizations for purposes of the 3P Review Program.

Table 1. Relationship of different terms used in the IMDRF documents, by 3P Review Organizations, and by FDA.

IMDRF MDSAP Equivalent	3P Review Organization Equivalent	FDA Equivalent
Auditor	Product Specialist	Lead Reviewer
Regulatory Authority	FDA Representatives	FDA Representatives to the 3P Review Program
Audit	Review	Review
Final Reviewer	Final Reviewer	Branch Chief or equivalent
Technical Expert	Technical Expert	FDA Internal Consultant (e.g., statistician)

[86] As of the publication of this draft guidance document, the IMDRF has published five documents related to MDSAP. All the IMDRF MDSAP documents are available on the IMDRF website at:http://imdrf.org/documents/documents.asp.

[87] IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf

[88] IMDRF MDSAP Working Group N4: Competance and Training Requirements for Auditing Organizations can be found at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf