

**FDA Webinar: 510(k) Third Party Review Program: Final Guidance**

**Moderator: Irene Aihie**  
**April 16, 2020**  
**1:00 p.m. ET**

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. During our Q&A session you may press star one on your touchstone phone if you would like to ask a question.

Today's conference is being recorded. If you have any objections you may disconnect at this time. Now I'd like to turn the meeting to Miss Irene Aihie. Aihie, you may begin.

(Irene Aihie): Thank you. Hello, and welcome to today's FDA webinar. I am Irene Aihie, of CDRH's Office of Communication and Education. On March 12, 2020, the FDA issued the final guidance, 510(k) Third Party Review Program.

This final guidance described the factors the FDA uses to determine device type eligibility for review by Third Party Review Organizations, outlining the FDA's process for recognition, re-recognition, suspension, and withdrawal of recognition for 3P510K review organizations, and ensures consistent quality of work among 3P510K review organizations through the Medical Device User Fee Amendments IV.

Today, Allen Hill, Policy Analyst in the Office of In Vitro Diagnostics in Radiological Health here in CDRH will present an overview of the guidance document.

Following the presentation, we will open the line for your questions related to information provided during the presentation. Additionally, there are other center subject matter experts here with us to discuss and assist with the Q&A portion of our webinar. Now, I give you Allen.

(Allen Hill): Thank you, Irene. As Irene said, I'm Allen Hill, a member of the 510(k) Third Party Review Program team, and on behalf of the team, thank you for your interest in this guidance and this webinar.

The program that's currently led from within OHT7, the Office of In Vitro Diagnostics and Radiological Health, within the Office of Program Evaluation and Quality, or OPEQ. But the program covers products reviewed in all the offices of health technologies within OPEQ. Next slide, please?

The agenda for today: Our discussion today will focus on key areas of the guidance that have enhanced the program. Our focus is aimed at what 510(k) submitters, and Third Party Review Organizations, should do to achieve success under this guidance.

While our discussion today will focus on a few key areas, when we get to the question and answer portion, you're welcome to ask questions about areas we do not touch in detail. Next slide, please?

Objectives: We want 510(k) submitters, Third Party Review Organizations, and

the public to understand how this program works. We want stakeholders to understand how we identified which devices should be eligible to make the program successful.

The Third Party Review Organization's two key takeaways are: How to perform an FDA equivalent review, and, since the guidance is published on March 12, you have until September 12, 2020, to submit your application for recognition. I'll have more to say on this later. Next slide, please?

Publishing this final guidance delivered on MDUFA IV commitments, and statutory requirements, is part of revitalizing the program. We've consolidated two previous guidance into this one guidance, hopefully simplifying for all stakeholders. Those two previous third party guidances have now been withdrawn.

One of those, the "Implementation of Third Party Programs Under the FDA Modernization Act of 1997," that was issued on February 2, 2001, and the other was "Guidance for Third Parties and FDA Staff," issued on September 28, 2004.

The guidances provided - this guidance provides additional background on its history for those who are interested. Next slide please?

Now, how the program works: The Third Party - the 510(k) Third Party Review Program is a voluntary alternative 510(k) Review Process, whereby the Third Party interacts with the submitter of FDA's behalf. The major steps which would occur with every Third Party 510(k) submission are:

First, the submitter identifies an appropriate Third Party to review their 510(k).

Second, the submitter sends the eligible 510(k) to the Third Party.

Third, the Third Party reviews the 510(k), resolves any differences they find, documents their review, and sends their recommendation to FDA.

Then, FDA does a supervisory-level review to make the final decision. If a re-review is deemed necessary, FDA may find deficiencies that it sends back to the Third Party, who will work with the submitter to resolve them.

It's important to note the interactive nature of the process. Everyone can be part of the conversation and talk with each other. The Third Party is the primary contact point.

The submitter can ask questions of the FDA, and should do so through the Third Party unless there are unusual extenuating circumstances. There can be a three-way call if that's what's needed. It's important that lessons learned be passed along as appropriate.

If, for example, if a Third Party review organization learns something from FDA relevant to the submitter, they should pass that along. We might also provide feedback to the Third Party review organization specific to how they structure their own memos, and that's the kind of thing they wouldn't need to pass along to the submitter. Next slide, please?

Different stakeholders see different benefits in the program. For manufacturers, they can see a quicker time to marketing clearance. For FDA and the public, the primary benefits are a better allocation of FDA resources.

Recognized Third Party Review Organizations conduct the initial review of

lower risk and less complex 510(k) submissions. So, FDA only needs to conduct a supervisory review, allowing FDA resources to focus on review of more complex and higher risk 510(k) submissions, while maintaining confidence in the safety and effectiveness of the devices reviewed by the Third Party Review Organizations.

A submitter and Third Party Review Organization contracts for the review. While a 510(k), submitted directly to FDA has due dates based on MDUFA goals, the submitter and the Third Party are free to come to agreement on more aggressive dates.

By having the Third Party conduct the initial review, with FDA conducting a supervisory review, the goal is to allow FDA to focus reviewer resources on more complex and higher risk devices while maintaining confidence in the review of all these eligible devices. Next slide, please?

In 2018, we published a plan to eliminate routine FDA re-review of Third Party 510(k) submissions. This guidance is another key step in implementing that plan. When FDA receives a quality review from a Third Party Review Organization, an FDA-equivalent review, FDA can make a final decision through a supervisory review.

That uses fewer resources than if FDA had to do re-review. This allows FDA to reach a final decision through interactive review, reducing total time to decision while maintaining the standards of the 510(k) program. That's the quality goal of Third Party review.

In the guidance, we've updated or clarified many aspects of the program. But here are the key quality takeaways from today. Quality is enhanced:

First, because we have the right devices eligible for the program, devices Third Party Organizations can be successful in reviewing.

Second, because we receive quality reviews that FDA can verify through supervisory review, Third Party Review Organizations know what an FDA equivalent review should be.

Third, because we ensure only quality Third Party Review Organizations remain in the program. Next slide, please?

FDA wants to be sure that the right devices are eligible. Product-code eligibility should support successful, FDA-equivalent reviews. This slide illustrates some of the factors we took into account in deciding that.

First, lower risk: That includes that there's less need for multi-faceted or interdisciplinary expertise.

Well-understood: That includes having publicly available information that the Third Party Review Organization needs to conduct a quality review.

And, lack of post-market safety signals. One conclusion here is that the Third Party Program is not a novel devices program. Next slide, please?

We can ask, then, how tightly drawn is that center circle with the thumbs up? Even with these boundaries for defining what devices should be eligible, half of all 510(k)s submitted to CDRH are eligible for Third Party review. We don't receive that many Third Party 510(k)s, so there's tremendous potential for this program. Next slide, please?

So, we expect FDA-equivalent reviews. The first check by a Third Party Review Organization should be that the device is eligible. This is done through the product code database on our public website, and I put a references slide later in this deck that has that link. The submitter should also check eligibility.

Second, the Third Party Review Organization should assign a reviewer who is qualified to review this device type.

Third, proper use of guidances and standards for a given device type are key to FDA-equivalent reviews.

Fourth, if a Third Party is not sure of the appropriate guidances or how to apply a standard to a particular device, early interaction with FDA is available so the Third Party Review Organization can make the most effective and efficient review.

As stated in the guidance, we recommend early interaction if a Third Party has not reviewed the device of that type in the last six months. Early interaction is also available if there's a question specific to that submission.

Fifth, third parties resolve deficiencies prior to sending a file to FDA. The review files should be well-documented and well-organized.

As one key example, changes from the predicate should be thoroughly reviewed. Are the IFUs the same? Are any differences thoroughly accessed? Is there a history of modifications that were not previously submitted?

Do any of these raise concerns that should be discussed with the submitter and

documented? Are there technical changes that raise new questions of safety and effectiveness? Next slide, please.

I should also note for you that you'll see at the bottom that each of these slides - there's some grey text that tells you where in the guidance to get more detail on any particular topic that's in one of these slides.

A quality Third Party Review Organization's memo describes why you came to a particular recommendation on that submission, and by "you", I'm referring to the Third Party Review Organization. You should provide an evaluation rather than restatement of the submission.

This includes assessing how to submit or comply with the standard or follow the guidance. How the submitter responded to deficiencies, and the sufficiency of those responses. Organize your review to support your recommendation.

A table of contents is incredibly useful. At our end, we often see submissions that have, say, 13 files from the original submitter and 13 files from the Third Party Review Organization. So it's very helpful for us to have a table of contents to know what goes where.

If the FDA does send deficiencies, please update your review memo with your evaluation of those responses. Next slide, please?

510(k) submitters using the Third Party route, and Third Party Review Organizations, both have the same dispute resolution rights as regular 510(k) submitters.

We encourage anyone who has a concern to first seek clarification with the

review team to see if there's a less burdensome approach to resolving their concern. If seeking clarifications does not resolve the concern, then the formal appeals process is available—the links here point to those.

If a submitter has a complaint about a review organization, they can send a complaint to FDA, using the Third Party 510(k) inbox, listed here. Next slide, please.

In today's global, interconnected economy, leveraging global standards provides a common and thereby least burdensome expectation for Third Party Review Organization. CDRH has been working with the regulatory bodies of other nations through the International Medical Device Regulators Forum, IMDRF.

That effort has produced the Medical Device Single Audit Program, MDSAP. MDSAP has been well-received by regulators and industry. This guidance makes use of MDSAP's N3 document, in the context of organizational behaviors, so that CDRH's expectations are placed into a globally consistent set of expectations.

Good Regulatory Review Practices or GRRP are another product of IMDRF. This guidance draws on GRRP's N40 document for good regulatory review practices.

Some important aspects of those documents are common to quality organizations, from process control, which is having good processes in place and documented compliance with those processes, to having processes for qualifying reviewers and avoiding conflicts of interest, which are essential to the integrity of the 510(k) Third Party Review Program. These are important to

the discussion of section VII of the guidance which we'll turn to next. Next slide, please.

Section VII of the guidance focuses on conduct of Third Party Review Organizations to support recognition and re-recognition. The letters in this slide refer to lettered subsections in the guidance.

While section VI discussed the process of a 510(k) review, this focuses on the integrity of the process. Integrity is important to provide an FDA-equivalent review. We want our expectations to be clear to Third Party Review Organizations. You should read this section in detail as we will not review every point.

A few highlights:

Maintain impartiality. For example, do not participate in the preparation of 510(k) submissions. Giving feedback is okay, just as FDA gives feedback, if you're not one of the preparers or consultants.

Do not advertise or promise any guarantees for FDA clearance.

Have knowledgeable trained personnel who are free from conflicts of interest. These apply equally to external expertise you may acquire via contracts.

Maintain confidentiality.

Handle complaints, including documenting those complaints.

Keep good records of what you do. Next slide, please?

We also clarify suspension and withdrawal of recognition.

The act provides exact language in 301(y)(1) for prohibited acts.

We expect Third Party 510(k) Review Organizations to demonstrate technical competency.

We will assess and audit Third Party 510(k) Review Organizations periodically as necessary.

If needed, we will suspend or withdraw recognition after providing notice and an opportunity for an informal hearing. Next slide, please?

This is good business practices: Core requirements are to document your processes and to have the records that show you followed those processes. The statutes prohibits false or misleading statements, disclosing trade secrets of submitters, and taking bribes or other corrupt acts. We also expect that you will maintain good quality reviews. Next slide, please?

So, here's a key takeaway: Per guidance, every current Third Party Review Organization should submit an application to be recognized within six months of the guidance being final. So, by September 12, 2020. This includes those who were recognized prior to the guidance being finalized.

For the first six months, currently recognized Third Parties can continue to review Third Party 510(k)s.

For recognition, the guidance lays out what we are looking for. You should

work proactively to pull that together. Proactively in the sense of don't wait for us to come knocking on your door. Submit your application as soon as practical, so you have time to resolve any issues that FDA raises.

FDA will review applications within 60 days of receipt. If we need additional information, you should hear from us within those 60 days.

Per statute, any recognition or re-recognition will expire in three years, so you will need to do this every three years going forward. Next slide, please?

As discussed in section VIII, FDA recommends that any organization seeking recognition, including those recognized prior to this guidance being final, include the following information in this section in their application. The numbers on this slide correspond to numbers in subsection A, titled 'Recognition.'

Note that the administrative info should include the device types you are seeking recognition to review. This should be supported by the personnel qualifications that will be discussed in sub-section (3). I.e., the people should be, in subsection three, should be qualified to review the items that you list in subsection 1 as things you want to have in your purview.

It is critical to avoid actual conflicts of interest and the appearance of conflicts of interest. We will review your policies and procedures that present these.

We will also review your personnel qualifications. Note that this includes statements on the structure of your organization and qualifications of supervisors who concur on reviews.

For example, do those supervisors have the authority and expertise to challenge reviewer's recommendations when appropriate?

For example, if you use external technical experts, how do you manage them?

Note that if the most responsible party signs off on the review, we do not require that person have a supervisor. We know that there are some small organizations out there, so we're not insisting on a supervisory structure when the person that is our responsible party signs off on the review.

We will look at your statements certifying compliance or intent in a variety of areas, from accurately reflecting data reviewed, through promptly responding to complaints to protect against conflicts of interest. Next slide, please?

We've talked about recognition, which is the first step. As noted in the guidance, you must complete FDA training prior to conducting reviews. Shortly after receiving your recognition you will receive FDA's recommendations for FDA training.

Once a Third Party certifies that it has completed training, it can begin reviewing eligible 510(k). Note that several training modules for the 510(k) Third Party Review Program are available currently through CDRH Learn—see the link on the resources slide.

As Third Party 510(k)s are closed out—as in, meaning that we've made a final decision on them—the team will review and assess the quality of the Third Party 510(k) review organization based on FDA review team's feedback and note any particular feedback for the Third Party to improve future performance.

Regularly, based on volume of 510(k)s reviewed, FDA will provide feedback to each Third Party on how it's doing, and solicit feedback from them. We'll also periodically audit Third Party Review Organizations to maintain high-quality reviews. Next slide, please?

So this is the dense page of printer-friendly links and resources for you. Next slide, please? So that concludes the presentation. And shortly, I think, we will begin to have a Q&A session. Thank you for your attention.

(Irene Aihie): Thank you, Allen. Operator, we'll now open the line for questions.

Coordinator: Okay. If you would like to ask a question on the phone line, please unmute your phone, press star one, and record your name when prompted. Once again, that's unmute your phone, star one, and record your name. One moment for our first question.

(Greg Pishko): Allen, great presentation. This is Greg Pishko with the 510(k) Third Party team. We're getting started with that popular question we hear a lot: what product codes are eligible for participation in this program?

(Allen Hill): So, this is Allen. The product code database was updated when the guidance went final back in - on March 12. So if you go to the product code database, you can do a search there. There's a drop-down on the search page so that you can only see things that are Third Party eligible.

Or if you want to just look up a code, you'll see sort of towards - about 3/4 of the way down the page - whether it's Third Party-eligible and what are the Third Party Review Organizations that are qualified to review that product code. So that's - the product code database already reflects this guidance.

Coordinator: Once again, if you would like to ask a question on the phone line, please press star one and record your name when prompted. Once again, it's star one and record your name. Thank you.

(Irene Aihie): Allen and team, while the operating is looking to see if we have any questions in the queue, are there any other final thoughts that you would like to share with participants?

(Allen Hill): While we're waiting, this is Allen, I'll say that the - as we pointed out in the presentation, there's a tremendous potential for this program and I gave a talk not that long ago to a dental group where it was - it's just an excellent alternative for devices that do fit the parameters we discussed here for devices where the program can be most successful.

And something that I would encourage manufacturers to consider when they think about submissions to - 510(k) submissions to (CDRH).

(Irene Aihie): Thanks, Allen. Operator, do we have any other questions?

Coordinator: No, we do not have any questions at this time.

(Irene Aihie): Okay, thank you. Well thank you. This is (Irene Aihie), and we do appreciate your participation today. Today's presentation and transcripts will be available on CDRH Learn Web Page, at [www.fda.gov/training/cdrhlearn](http://www.fda.gov/training/cdrhlearn) by Friday, April 24.

If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation, and as always

we do appreciate your feedback. Following the conclusion of today's webinar, please complete a short 13 question survey about your FDA, CDRH webinar experience.

We'll start making these found at [www.fda.gov/cdrhwebinar](http://www.fda.gov/cdrhwebinar) immediately following the conclusion of today's live webinar. Again, thank you all so much for participating. This concludes today's webinar.

Coordinator: This concludes our conference. And you may disconnect. Once again your conference has ended and you may disconnect. Thank you for joining.