

Eliminating Routine FDA Re-Review of Third Party 510(k) Reviews

Center for Devices and Radiological Health

510(k) Third Party Review Program



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Eliminating Routine FDA Re-Review of Third Party 510(k) Reviews

Introduction

Eliminating Routine FDA Re-review of Third Party 510(k) Reviews describes how FDA is updating its 510(k) Third Party (3P) Review Program to avoid the routine re-review of 510(k) submissions already reviewed by a 3P Review Organization (3PRO). Under this plan, FDA is setting a goal that by the end of FY 2021 at least 85% of 3P submissions will not require substantive re-review by FDA. FDA will achieve this objective by taking the following new, additional actions:



Ensuring the device types eligible for the 3P Review Program are appropriate.



Giving 3PRO reviewers the tools they need to succeed.



Providing a way for 3PRO's to demonstrate that they can successfully apply FDA's criteria for reviewing a 510(k) submission.

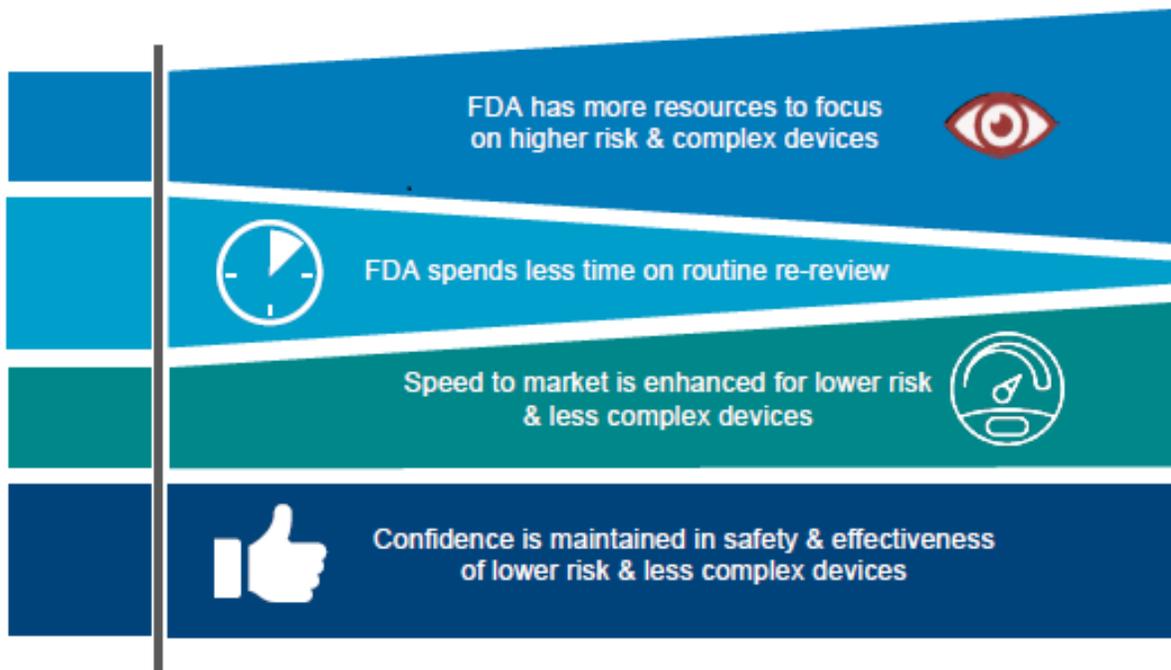


Implementing a comprehensive framework for FDA processing of 3PRO 510(k) submission packages.



Using program measures to monitor the 3P Review Program, adjusting as necessary to ensure goals are met, and using continuous process improvement activities to identify and implement improvements where appropriate.

Eliminating Routine Re-Review Improves Public Health



Implementing the Plan to Eliminate Routine Re-Review of Third Party 510(k) Reviews

→
time

Background

Highlight

The intent of the Third Party Review Program:

- 3PROs perform FDA-equivalent reviews of low-to-moderate risk and less complex devices
- FDA reviewers infrequently re-review 510(k) submissions from 3PROs

Highlight

This Plan addresses common reasons for FDA re-review by ensuring that appropriate devices are eligible for the Third Party Review Program and by giving 3PROs the tools they need to succeed.

The 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 Act, and applies to specific medical device Product Codes. Under this program, a 510(k) submission for a device in an eligible Product Code may first be submitted to a 3P Review Organization (3PRO) rather than directly to FDA. The 3PRO uses FDA's criteria for reviewing the 510(k) submission and sends a 3P submission to FDA consisting of the original 510(k) submission, the 3PRO's review, and a recommendation of either "Substantially Equivalent" (SE) or "Not Substantially Equivalent" (NSE). FDA makes its final determination on the 510(k) submission based on the review and recommendation in the 3P submission. When necessary, FDA may also re-review all or part of the 510(k) submission. 510(k) submissions reviewed by 3PROs using the 3P Review Program must receive a final determination within 30 days of receipt by FDA.

510(k) submissions received through the 3P Review Program are accompanied by a review and recommendation that are intended to be equivalent to that which would have been provided by an FDA reviewer. An FDA-equivalent review and recommendation by the 3P reviewer reduces the time needed by FDA reviewers to make a determination on the 510(k) submission, and thus reduces the time needed for submitters to receive a determination once their submission is received by FDA. FDA reviewers are freed to focus on the review of higher-risk and more complex devices while maintaining a high degree of confidence in the review of low-to-moderate risk and less complex devices.

When FDA routinely re-reviews 3P submissions, it prevents FDA and sponsors from experiencing efficiencies the 3P Review Program is meant to achieve, including that reviewers do not have more time to focus on higher-risk and more complex devices. This Plan addresses common reasons for FDA re-review, such as by ensuring that appropriate devices are eligible for the 3P Review

Program and by giving 3PROs the tools they need to succeed – that is, to be able to produce FDA-equivalent recommendations and reviews. This Plan also describes a comprehensive framework that can help FDA reviewers decide when re-review of a 3P submission is needed and give 3PROs clear expectations of what is required to avoid re-review, including a way for 3PROs to demonstrate that they are capable of producing FDA-equivalent 510(k) review recommendations. Finally, the Plan provides for continual improvement by instituting 3P Review Program processes for monitoring program efficiency and effectiveness and adjusting the 3P Review Program as necessary to ensure that Program goals are met.

Ensuring Only Appropriate Device Types are Eligible



FDA will a list of low-to-moderate risk and less complex devices that are eligible for the Third Party Review Program. These devices will be less likely to need re-review.

Input from FDA review divisions indicates that 3P submissions/510(k) applications for simpler, lower-risk devices should not need re-review, while 3P submissions/510(k) applications for complex devices are more likely to require re-review. FDA intends to tailor the list of eligible devices, excluding those that are complex and require additional levels of FDA review. Before the FDA Reauthorization Act of 2017 (FDARA), the law did not allow FDA to tailor the list of eligible devices, which was defined by criteria set in statute. Thus, some complex devices that were ill-suited for the program were eligible for 3P review while some simple devices that would be good candidates for the program were ineligible for 3P review.

The FDA Reauthorization Act (FDARA) of 2017 provides FDA with the authority to tailor the list of eligible devices and directs FDA to provide guidance that states how a device type, or subset of a device type, is determined to be eligible for review by 3PROs. To comply with this direction, FDA issued *510(k) Third Party Review Program Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations* (3P Review Program Draft Guidance) on September 13, 2018. In general, devices are included in the 3P Review Program unless they are explicitly excluded. The 3P Review Program Draft Guidance details how FDA intends to consider the risk profile of a device type when determining whether it will be eligible for the program,

including whether the device type is implantable, life sustaining, life supporting, and well understood. Further, the 3P Review Program Draft Guidance notes that FDA will also consider the extent to which 3PRO's have access to the information needed to make a well-informed recommendation, the extent to which the review requires multifaceted interdisciplinary expertise, and the extent to which postmarket safety data should be considered. FDA will carefully consider all comments received by the close of the comment period when finalizing the Guidance.

FDA maintains a current list of eligible devices on the web page, "List of Devices for Third Party Review", <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm>. This list will be updated to reflect the final version of the guidance.

Giving Third Party Reviewers the Tools They Need to Succeed



FDA will...

- Deliver web-based training and resources to 3PRO reviewers
- Provide a review template to 3PRO reviewers to help guide their review and ensure their review contains all required information
- Make it easier for 3PRO reviewers to ask questions to FDA and receive swift responses during their review
- Establish an Updates Channel so 3PRO can stay current as technology evolves

FDA reviewers have access to resources that 3P Review Organizations do not. For example, FDA reviewers can access proprietary databases that provide devices' background and history, allowing reviewers to focus on areas that previously had an impact on safety and effectiveness. FDA reviewers participate in FDA's internal Reviewer Certification Program (RCP), a set of courses intended to provide a complete foundation for performing premarket reviews. FDA reviewers submit their reviews using tailored templates that guide them to include the appropriate information for specific device types. Finally, new FDA reviewers receive significant mentoring from experienced reviewers, and have informal channels for resolving questions.

FDA cannot make proprietary information available to 3PROs. However, FDA is developing training, resources, and support programs that will allow 3P reviewers to make recommendations that are equivalent to those of FDA reviewers. Specifically, FDA will enhance its existing general and device-specific training and resources, provide a guided tailored template to ensure that review memos contain all information required for specific device types, and establish an Early Interaction process that allows 3PRO reviewers to

ask questions of FDA at any stage in their reviewing process. FDA is also establishing an Updates Channel, a way to help 3P reviewers know when they need to update their approach to accommodate events such as changing regulations or the issuing of new guidances.

Highlight

FDA will...

- Identify gaps in current publicly available training and internal FDA reviewer training
- Enhance available web-based training accordingly
- Inform 3PROs of new material through the Update Channel

General Training and Resources

To address industry’s need for training, FDA currently provides Center for Devices and Radiological Health (CDRH) Learn, known as CDRH Learn. CDRH Learn is an educational tool that consists of a set of learning modules provided in various formats, including videos, audio recordings, and slide presentations. CDRH Learn modules describe many aspects of medical device and radiation emitting product regulations, both premarket and postmarket – and many CDRH modules are directly applicable to 3P reviewers.

FDA’s internal Reviewer Certification Program (RCP) is intended to provide the basic knowledge and skills necessary to evaluate pre-market medical device submissions. The RCP covers all types of medical device submissions, and a subset of RCP courses provide instructions on activities relevant to 3PRO reviewers. FDA will compare existing CDRH Learn modules to the courses provided in the RCP and identify topics that should be enhanced or added, and FDA will identify the most efficient and effective way to provide training on those topics. For example, topics of truly general interest might be posted on CDRH Learn, while topics more specifically applicable to 3PROs might be posted to the *Third Party Review Program* site; the latter site would provide weblinks to applicable training on CDRH Learn. FDA will maintain an index of relevant training and resources for 3PROs and will keep 3PROs informed of new material through the Update Channel described below.

Highlight

FDA Subject Matter Experts will develop and teach device specific training. This training will be posted to the *Third Party Review Program* site.

Device Specific Training and Resources

In addition to general training, FDA recognizes that device-specific training can also help 3P reviewers produce FDA-equivalent review results. For device types that are often the subject of 3P submissions, the 3P Review Program will

develop training to provide 3P reviewers with device-specific information relevant to the production of FDA-equivalent reviews.

Training for specific devices will be developed and taught by FDA Subject Matter Experts (SME) with experience reviewing those devices. As training modules are completed, they will be published on CDRH Learn for easy access by all 3PROs. At the time of this Plan’s publication, a pilot is underway in which an SME is using the Training Development Toolkit to develop device-specific training focusing on radiography devices. The results of the pilot will be reviewed, and the Training Toolkit will be updated as needed.

As well as providing device-specific training, FDA is increasing access to Agency review memos written for common device types. Although FDA cannot share proprietary information, FDA will create a library of redacted memos for selected devices with a high volume of 3P reviews and provide instructions for accessing that library on the 3PRO web site.

Tailored Review Memo Templates

One of FDA’s goals is to use least burdensome approaches in its internal reviews. To support this goal, FDA has developed “smart” review memo templates—templates that are designed to prompt only for needed information and are tailored to the type of device being reviewed. For example, questions about sterilization would only be presented for device types for which sterilization must be evaluated. FDA intends to create a version of the smart template for 3PRO’s which facilitates a tailored, formatted review memo based on the submission’s device type.

Highlight

FDA intends to create a template for 3PROs which facilitates a tailored, formatted review memo based on the submission’s device type.

“Ask the FDA Expert”

The 3P Review Program Draft Guidance outlines situations where 3PROs should contact FDA before initiating a review, and FDA encourages open communication between 3PROs and FDA experts. “Ask the FDA Expert” is a way for FDA to provide 3PRO reviewers with an “on-demand” way to get answers to questions they may have about current FDA

processes and policies, and FDA’s thinking on specific regulatory questions.

Highlight

FDA is enhancing “Ask the FDA Expert” which encourages open communication between 3PROs and FDA experts. This open communication helps 3PRO reviewers produce FDA-equivalent reviews and recommendations, making routine re-review unnecessary.

FDA is enhancing “Ask the FDA Expert” in response to feedback from 3PROs and FDA reviewers on how interactions between 3PROs and FDA are currently handled. Specifically, stakeholders recommended that the process:

- Be tracked
- Have consistent timelines
- Have consistent contacts within FDA

The proposed revisions to the process are described in the 3P Review Program Draft Guidance and address every aspect of an interaction. First, example questions are provided, specifically designed to walk a 3P reviewer through the creation of a detailed review that follows the approach FDA would take to review that same submission. Second, timelines are provided - for example, FDA will acknowledge each interaction consultation request within two (2) business days. Third, the FDA contact will remain the same throughout the interaction wherever possible, to ensure that communications are timely and consistent. A pilot of the revised process began in July 2018. The pilot includes training for both FDA staff and 3PROs and will provide a way for both groups to submit feedback. At the end of the pilot, all feedback will be considered and incorporated into the process as appropriate, and the final process will be posted on www.fda.gov.

These improvements are intended to provide 3P reviewers with “just in time” access to information about FDA’s most recent review practices. Answers obtained through the process will help 3P reviewers produce FDA-equivalent reviews and recommendations, making routine re-review unnecessary.

Highlight

FDA is establishing an Update Channel to notify 3PROs of adjustments in FDA review practices as technology changes.

Updates

Medical device technology is constantly changing, and these changes often lead to adjustments in FDA review practices. In order to continue to produce FDA-equivalent reviews, 3P reviewers need to be aware of these adjustments.

The 3P Review Program will address this need by establishing an Update Channel on its Third Party Home page; 3PROs will subscribe to that Channel to be notified when an update is posted. The 3P Review Program may supplement Update Channel postings given the complexity of the topic. For example, for more complex topics, FDA may post modules on the Third Party Review Program site, or FDA may meet with 3PROs.

Demonstrating 3PRO Capability: Recognition



FDA will...

- Communicate a comprehensive approach to Recognition of 3PROs in guidance
- Audit recognized 3PROs to verify they continue to operate according to their procedures, qualifications and certifications in their application and the FD&C Act
- Audit 3P submissions and provide feedback to 3PROs

The 3P Review Program Draft Guidance includes a comprehensive approach to the Recognition of 3PROs. Recognition is the process by which a company becomes a 3PRO and retains its ability to submit 3P submissions to FDA. Recognition is a key way in which 3PROs demonstrate that their 3P submissions should not need re-review. Recognition must be renewed every 3 years. To obtain and maintain recognition, a 3PRO will demonstrate technical competencies specified in the 3P Review Program Draft Guidance (when final); for 3PROs who have already been recognized, FDA will also take into account past premarket review performance and audit results. Poorly performing 3PROs may be denied Recognition or may receive tailored training based on audit results.

Recognition eligibility criteria especially relevant to the elimination of routine re-review include:

- The 3PROs and their personnel should demonstrate knowledge and experience with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Public Health Service Act (42 U.S.C. 201 et seq.), as applicable, and regulations in the Code of Federal Regulations implementing these statutes, particularly 21 CFR Parts 800 through 1299.
- The 3PROs should establish and execute organizational policies and procedures that ensure 510(k)s are reviewed by qualified personnel.
- The 3PROs should employ personnel who are qualified in all the scientific disciplines addressed by the 510(k)s they accept for review.

- The 3PROs should identify individuals responsible for providing supervision over 510(k) reviews who have sufficient authority and competence to assess the quality and acceptability of these reviews.

FDA will periodically audit recognized 3PROs throughout their three-year recognition period. These assessments may be routine or “for cause,” and are intended to verify that 3PROs continue to operate according to the procedures, qualifications, and certifications specified by their application and the FD&C Act.

FDA will also periodically audit 3P submissions and provide feedback to 3PROs.

FDA is authorized to suspend or withdraw any 3PRO's Recognition if the 3PRO is not substantially 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 consistent with the purposes of section 523 of the FD&C Act, after providing notice and an opportunity for an informal hearing.

Establishing an FDA Framework to Help Determine When Re-Review is Not Needed



FDA's framework will...

- Help FDA reviewers decide when re-review of a 3P submission is needed
- Give 3PROs clear expectations of what is required to avoid re-review, including a way for 3PROs to demonstrate that they are capable of producing FDA-equivalent 510(k) reviews

As part of this plan, FDA is establishing a framework to help reviewers determine whether the re-review of a 3PRO's 510(k) is needed. The first version of the framework will consist of areas to be considered. FDA intends to enhance and refine the framework over time as we gain experience. FDA will use 3P510k@fda.hhs.gov to gather feedback from 3PROs and others related to non-routine situations that merit re-review.

Areas to consider:

1. **Ongoing 3PRO organizational capability:** Has the 3PRO demonstrated ongoing organizational capacity for following the steps needed to submit a 3PRO submission that makes the same recommendation that would be made by FDA staff?

Highlight

“After a predetermined number of re-reviews show that the 3P reviewer is producing FDA-equivalent recommendations, FDA would accept some predetermined number of reviews from the 3P reviewer before performing a post-decision audit of a submission a 3P reviewer has reviewed.”

The above section, *Demonstrating 3PRO Capability: Recognition*, describes the 3P Review Program’s approach to ensuring that 3PRO’s are capable of reviewing 510(k) submissions without the need for re-review. The Recognition process includes consideration of 3PRO’s past premarket review performance and regular assessments of its ongoing review performance. A record of good historical and ongoing review performance may indicate that submissions from the 3PRO may not need re-review. In contrast, if FDA regularly identifies deficiencies with a 3PRO’s review memos, this may indicate that the 3PRO is not capable of producing FDA-equivalent recommendations and reviews. In these cases, FDA may re-review submissions until the 3PRO can be removed from the program.

2. **Ongoing 3PRO reviewer capability:** Has the specific reviewer handled similar device types; if so, were they handled successfully?

If a 3P reviewer is working on device types for which they have shown acceptable results, the 3P submission is less likely to need for re-review. FDA plans to adapt the concept of a “skip lot” or “cumulative results” plan to determine whether a 3P reviewer’s submission should be re-reviewed. In such a plan, FDA would begin by re-reviewing all initial submissions from a 3P reviewer. After a predetermined number of re-reviews show that the 3P reviewer is producing FDA-equivalent recommendations, FDA would accept some predetermined number of reviews from the 3P reviewer before performing a post-decision audit of a submission a 3P reviewer has reviewed. The number of 3P submissions accepted by FDA between audits would increase as the 3P reviewer demonstrates their capability to comply with 3P Program requirements. However, if a 3P reviewer’s submission was found to be out of compliance with 3P Program requirements, submissions from that 3P reviewer could again be re-reviewed until the 3P reviewer shows that they are capable of producing

compliant submissions or until the 3P reviewer is removed from the program.

3. **The type of device being reviewed:** Are there special complexities?

Even eligible devices types may have special complexities. Device types that are better understood and have lower complexity are less likely to need re-review. In the event of emerging postmarket safety or effectiveness information, FDA may temporarily re-review 3P submissions for a device type while considering whether to remove the device type from the program.

4. **The specific device being reviewed:** Are there special complexities?

Even though a device type does not have special complexities, a specific device may have features that would affect the need for re-review. In some cases, FDA may re-review a small portion of the submission if a technological characteristic of the device necessitates unusual testing or consideration.

5. **The manufacturer of the device being reviewed:** Are there special circumstances?

There may be special circumstances related to the manufacturer of the device that might increase the need for re-review. Conversely, an application from a manufacturer with a history of developing and producing high-quality devices would be less likely to need re-review.

Monitoring and Continuous Improvement



FDA will publicly report summary results of audits of 3PRO submission efficiency and consistency. Another important component of the Plan to Eliminate Routine Re-review is FDA's use of quantitative measures to monitor and continuously improve the 3P Review Program. FDA has defined efficiency and consistency measures for both FDA and 3PROs, and FDA publicly publishes these measures in

FDA will...

- Monitor efficiency and consistency measures of 3PROs
- Use measures to track goals and identify improvement opportunities

the *Third Party Review Organization Performance Report* (3PRO Performance Report), posted every quarter on the *Third Party Performance Metrics* web page. By analyzing these measures, FDA can gain insight into both individual 3PRO performance and the performance of the 3P Review Program as a whole. More details about these measures may be found in 3P Program measures on page **Error! Bookmark not defined.** below. FDA will monitor these measures and use them with other material generated by the 3PRO program to determine how well the Program is achieving its goals and to identify areas for improvement. FDA is evaluating options for collecting FDA reviewer reported outcomes data on 3P review quality, potentially including data on the practice of re-review, and will update the program accordingly, as appropriate.

3P Program Measures

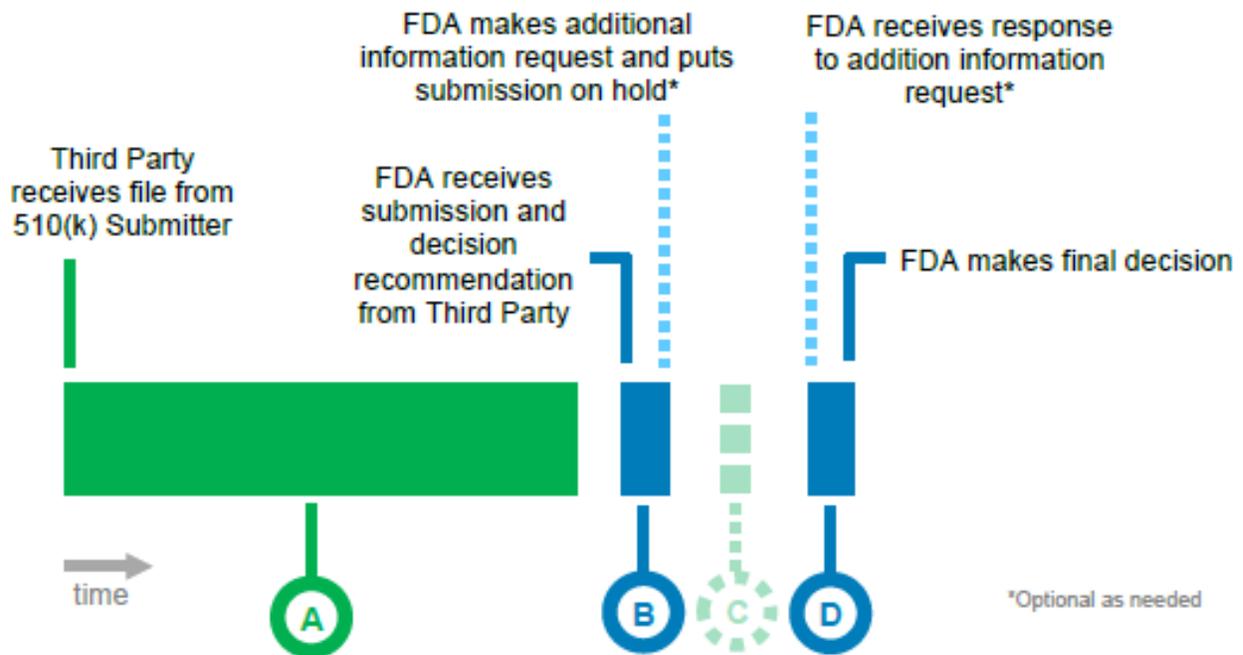
To provide a comprehensive view of 3P Review Program efficiency, the 3P Review Program has defined measures that cover the entire 3P Review lifecycle. As illustrated in the *Third Party Review Organization Report, FY18, Q2*, the lifecycle has four Stages:

Stage A: The Third Party receives file from 510(k) Submitter

Stage B: FDA receives submission and decision recommendation from Third Party

Stage C (Optional): As needed, FDA requests additional information and puts the submission on hold until it receives a complete response to the request.

Stage D: FDA reviews all needed information and makes a final decision.



3P Review Program measures give insight into all four stages (see the 3PRO Performance Report for details):

Highlight

Under this Plan, an Additional Information Request and Stage C in the lifecycle should be rare which will shorten the overall length of the lifecycle.

1. Initial Third Party Review Time: Time in Stage A - Time taken by the 3PRO to review the 510(k) Submitter's file and determine its decision recommendation.
2. Third Party Hold Time: Time in Stage C - Time taken by the 3PRO to respond to a request for additional information from FDA.
3. Total Third Party Review Time: Time in Stages A and C - Time taken by the 3PRO to review the 510(k) submission and respond to any requests for information from FDA
4. Total FDA Review Time: Time in Stages B and D - Time taken by FDA from the receipt of the 3PRO Submission Package to a decision on that Submission Package, not including Third Party Hold time.
5. Total Time to Decision from FDA Receipt: Time in Stages B, C, and D - Time taken by FDA from the receipt of the 3PRO Submission Package to a

decision on that Submission Package, including Third Party Hold time.

How Will We Use Measures?

- Determine individual 3PRO performance by analyzing review times of individual 3PROs
- Determine performance of the program by analyzing measures averaged across 3PROs
- Determine trends in performance
- Identify activities to improve when we detect a decrease in performance

Two of these efficiency measures, Total FDA Review Time and Total Time to Decision from FDA Receipt, are correlated with 3P review quality because both incorporate Hold Time—that is, the amount of time needed by FDA to obtain missing required information from the 3PRO - and the amount of time needed by FDA to make its recommendation. When all required information is supplied by the 3PRO in their initial submission and FDA is able to process that submission quickly, Hold Time approaches zero and Total FDA Review Time and Total Time to Decision from FDA Receipt are shorter. Thus, submissions with shorter Total FDA Review Times and Total Time to Decision from FDA Receipt have a higher likelihood of being a quality review. All measures are calculated for individual 3PROs and averaged across all 3PROs. Thus, the measures can be used to analyze both individual 3PRO performance and the performance of the Program as a whole.

Measures calculated for individual 3PROs allow 3PROs to demonstrate their efficiency. For example, Total Third Party Review Time, when calculated for an individual 3PRO, shows the amount of time that 3PRO has taken to process each submission.

Measures averaged across 3PROs are monitored by the 3P Review Program to understand how well the Program is meeting its goals, and whether there are areas for improvement. For example, a decrease in the average Third Party Review Time across all 3PROs may indicate that training programs are successful, while an increase in average Third Party Review Time may indicate that training programs need to be enhanced.

FDA will review all the phases of the Program periodically to identify areas for improvement and will update the program accordingly as needed. For example, in FY18, FDA is analyzing deficiencies found by FDA reviewers in 3PRO submissions and performing Pareto Analyses to determine the most frequently identified deficiencies as well as those deficiencies that would be most likely to cause the 3PRO to come to a recommendation different from that of FDA. Depending on the results of the analysis, FDA may decide to adjust or expand training modules, or FDA may explore

whether it should enhance additional reviewer helps such as the Smart template. As available resources improve and 3PROs gain access to the tools and information they need to succeed, FDA will act to remove 3PROs from the program if deficiencies are indicative of unacceptable performance.

Conclusion

Highlight

“Strengthening the 3P Review Program will make the 3P Review process what it was meant to be: a means of streamlining the regulatory process while maximizing patient benefit.”

FDA’s re-review of 3P reviewed submissions has been routine for many types of devices. Both the practice of routine re-review and the issues that led to it have prevented the 3P program from fulfilling its purpose and potential. This plan describes how FDA is strengthening the 3P Review Program to eliminate routine re-review:

1. Remove the types of devices that consistently require FDA re-review from the 3P process.
2. Provide 3P reviewers the tools they need to succeed, including expanded general training opportunities, expanded device-specific training, the provision of tailored review memo templates, an updated Early Interaction Process, and an Updates Channel.
3. Enhance the Recognition process to give 3PROs the opportunity to demonstrate their capability to perform FDA-equivalent reviews, including the creation of standards for recognizing, re-recognizing, auditing, and suspending 3PROs
4. Establish a Framework to help FDA reviewers determine whether re-review is necessary.
5. Use publicly-available metrics to monitor both individual 3PRO performance and the performance of the 3P Review Program as a whole; periodically perform continual improvement analyses to identify possible areas for improvement and to adjust the program accordingly, as necessary.

FDA believes that these steps will make it easier for developers of lower-risk devices to get their products to market swiftly, obtaining FDA-equivalent review results while reducing the amount of time FDA spends re-reviewing applications that have already been reviewed by a 3PRO. This will free FDA resources to focus on those higher-risk

devices that require more rigorous review. Strengthening the 3P Review Program will make the 3P Review process what it was meant to be: a means of streamlining the regulatory process while maximizing patient benefit. FDA believes this approach will lessen burden on 510(k) applicants and FDA reviewers while ensuring that medical devices continue to meet high standards for safety and effectiveness.
