Hello. And welcome to today's CDRH Industry Basics workshop. I'm Joseph Tartal, the deputy director of the Division of Industry and Consumer Education at the center for devices and radiological health. And I'll serve as your moderator for the next two hours . Thank you for joining us. The CDRH Industry Basics workshop was launched in 2014 and serves as a way to interact with you on various topics of interest to you. At the Division of Industry and Consumer Education it's our core vision to provide you with the most accurate, up to date and useful information about medical devices in a format that best meets your learning needs.

It's our belief that knowledge fosters voluntary compliance. We've developed several educational products for you that we encourage you to use. If you learn most effectively by reading, then Device Advice is for you. Device Advice consists of hundreds of web pages of written information that cover a range of premarket and postmarket regulatory topics. It is truly comprehensive regulatory assistance. You can find Device Advice at www.FDA.gov/deviceadvice. If you prefer a multimedia format with audio and video, then check out CDRH Learn. This is a great catalog of videos, training modules and audio webinars covering a wide range of discussion topics as well as the latest in regulatory policy and hot topics. Past Industry Basics workshops can be found here. And of course, to get personalized feedback on specific questions about medical devices, there are two ways you can reach us. You can call us at the phone number listed here, or you can email us at DICE@FDA.HHS.gov. You can also check out our home page at dwut FDA.gov/DICE for more information.

Now let's switch gears and introduce today's CDRH Industry Basics workshop. The overall theme of today's program is the Quality System Regulation. Ensuring that all nonconformances and complaints are appropriately handled, properly investigated, and controlled effectively is important be to the functionality of your Quality System and the safety and efficacy of your device. So we are glad to address these topics for you today. We'll follow a schedule so you can join in for the topics that you want to learn about. Product failures and nonconformances can have an enormous impact on patients -- your customers, so it's fit that go our first topic is Nonconforming Product. Then at 2:00 p.m. we'll begin the second topic of the day, Complaint Files.

At any time throughout the program you may send in your questions about that topic. After each presentation we'll have an approximately 30 minutes for a Q&A session for answering your emails as well as your phone calls. So let's get started with our program and the first topic, Nonconforming Product. Your presenter is Vidya Gopal a former FDA compliance officer and currently a consumer safety officer in the postmarket and consumer branch in DICE. Now let's hear from Vidya.

Vidya Gopal: Hello. My name is Vidya Gopal and I'm a consumer safety officer in the Division of Industry and Consumer Education. I've worked in industry for many years, and I understand the pressures and difficulties associated with bringing and keeping a product on the market. I have done postmarket compliance work at the FDA , so I understand the agency's stance on safety and effectiveness. I hope to bring you a balanced perspective to my discussion on nonconformances and nonconforming product.

Nonconformances are a key part of the Quality System for medical device manufacturing. When you don't pay proper attention to nonconformances you may end up distributing Nonconforming Product. You will have to deal with the direct cost of Nonconforming Product and possible recalls, but you will also have to deal with the indirect cost of liability, brand image, and market share loss. These are expensive and cost the company both time and money. Conversely, when nonconformances are properly handled, and coupled with other corrective action systems, the result is a mechanism for continuous improvement. This can result in successful product longevity, increased market share, and consumers will ultimately benefit from a better, safer, and a more effective product.

Today, I will be focusing on the following learning objectives: First, we will understand the context of nonconformances within the overall Quality System and CAPA., or the CAPA subsystem. Then define Nonconforming Product. Next, we will go over the process flow and finally learn how Nonconforming Product disposition contributes to the quality and safety. These objectives will give you a firm start in understanding the role, function, and importance of nonconformances.

What is the CAPA subsystem? It is a key component off the Quality System, and it is itself comprised of three parts. This is articulated in the simplified and generalized table. Nonconforming Product which functions primarily during manufacturing, CAPA, which functions during both manufacturing and after distribution; and Complaint Files, which generally functions after distribution.

We are going to focus this talk on Nonconforming Product, the regulatory requirements for which can be found in 21 Code of Federal Regulation CFR 820.90 as highlighted in the table. We are going to start with some definitions. Just so that you know, all definitions pertaining to the Quality System are found in 21 CFR 820.3. Specification is any requirement that you set for proper functioning of the product during design controls . Products are components, manufacturing materials, in-process devices, finished devices , and returned devices. Nonconformity is the nonfulfillment of those specified requirement. Nonconforming Product is product that does not fulfill its specified requirements. Nonconformances can occur in both product and process. Nonconforming processes can lead to Nonconforming Product.

I will give you examples of this a little later under identification of nonconformances. The regulation 21 CFR 820 .90(a) requires manufacturer to establish and maintain procedures to control product that does not conform to specified requirements. And these procedures shall address the identification, documentation, evaluation, segregation, and disposition of Nonconforming Product. This means that you are responsible for your non conforming product and the control of it.

Now that we know you are responsible for your own nonconformances, let us try to figure out where it comes from and what you do with it. Now let's take a look at the process flow for nonconformances. Identification, documentation, evaluation, segregation, and disposition. We will go over in detail each one of these in the following slides. Nonconformances need to be identified to be processed. So this is our starting point in our process flow.

We will talk about some of the common sources of nonconformances. First, received components that fail incoming inspection. For example, you obtain a part from your vendor. Your specification for the length is 6 plus or minus one inch. But when you measure it during incoming inspection, it is 8 inches. It does not meet your specification, and therefore is Nonconforming Product . Second, products are components that fail to meet specification or inspection during manufacturing. An example of this is during a manufacturing process for thermal bonding, you set your process parameter to be 300 degrees plus or minus 10 degrees.

During inspection, it was noted that the machine was set to 280 degrees. This is a nonconforming process. Now you will have to evaluate the product to verify if you have product that is within specification. This is also an instance of nonconforming process that could lead to Nonconforming Product where the bond fails to hold. Lastly, product returned to manufacturer with defects. For example, if a catheter is supposed to fit inside a 6 French guide and it does not fit during procedure. The doctor or the facility decides to return the product to the manufacturer. This is then handled through the complaint handling, and is not in the scope of this presentation. When you become aware of a nonconformance or receive a nonconformance report, you have to evaluate it. One industry practice example is to assemble a group of experts to figure out what comes next. These convened groups are sometimes referred to as a material review board, or MRB, or material review committee, or MRC. Please note that these groups are not formed ad hoc, but through approved procedures.

Next in the process is documentation. An example for documentation is to have a form, such as a nonconformance report, that walks through the entire process from identification to disposition along with signatures. The forms are sometimes part of a larger standard operating procedure, or SOP, with a work instruction outlining how to use the form.

Next, let's talk about evaluation. Evaluation of non conformance product is addressed in 21 CFR 820.90(a). Manufacturers must evaluate the nonconformance to determine whether an investigation is necessary. If no investigation is pursued, the name of the responsible individual making that determination, as well as the reason , must be recorded. Also, you must notify the person or group responsible for the nonconformance. Investigations are not always required. The regulation provides you with the flexibility to decide if an investigation is necessary or not. For example, you may not need to investigate when a nonconformance is already known due to a similar issue .

Please note that while a similar issue may not require an investigation under Nonconforming Product, it may require a referral to the CAPA system due to recurrence and a CAPA investigation . I will discuss CAPA referrals later in this presentation. Next is segregation. The important point to note is that you have to segregate Nonconforming Product to make sure that it is not released. We always get questions on what this segregation means. Does it mean locked cages? Digital controls? Separate area ? It is whatever works for to you make sure that this is not inadvertently released. Again, the regulation provides you this flexibility. Next is disposition. Disposition is addressed in 21 CFR 820.90(b)(1). Each manufacturer shall establish and maintain procedures that define the

responsibility for review and the authority for the disposition of Nonconforming Product. Let's briefly discuss the typical types of dispositions. First, let's talk about scrap where you decide not to use the product and destroy it. Even though you are destroying the product, it is still important you understand what your scrap data is in order to benchmark if your processes are working in a particular norm. For example, this information would be important if one day you had a scrap rate of 5, and the next day it was 500. As that may be indicative that your process is moving all over the place and not in control. Second, return to the supplier.

For example, where you determine that the nonconformance is the supplier's mistake because they sent the wrong product. Depending upon the recurrence or severity of mistake, it may be referred to outside of the Nonconforming Product process and could touch upon both CAPA and purchasing controls. Please note that the requirements within the regulation are not intended to be duplicative, but to be complementary. Third, down grade. This is when you have upgraded a version of your device and there is a problem with the up graded version. So you decide to downgrade, which is still safe and effective until you figure out the issues with your latest version. Fourth, use as-is. An example of this is you receive product from your vendor and notice that there is a cosmetic defect that does not affect the safety and effectiveness of the product. You still open a nonconformance, and let your supplier know, but you end up using the product as you know that it does not hurt the product performance. And the regulation says disposition of nonconforming product shall be documented.

Documentation shall include the justification for use of the Nonconforming Product and the signature of the individual authorizing the use . If you end up using Nonconforming Product, then you must document a justification, and the signature of the individual authorizing the use. The Preamble to the Quality System states that justification should be based on scientific evidence. Concessions should be closely monitored and not become an accepted practice. And this is one of the connection points to CAPA. You will analyze your concessions and will refer it to the CAPA system based on your thresholds. In the example of the cosmetic defect, let's say that you start to see the same defect in every lot that the supplier provides. Then you may need to refer this nonconformance to the CAPA system based on the criteria set in your procedures. And finally, make one additional point regarding "use as is " in that it lay lead to another concern. For example, if there is a trend of use as is for the same issue over and over, you may want to relook at your specification and determine if they are appropriate. The last type of disposition is rework. For example , your quality group notices that the inner pouches are not sealed when they are performing the final acceptance testing for sterilized product. You open a Nonconforming Report, or NCR, and then decide the correction is to r resterilize the product after sealing the pouch. When the product was retested, it was noted that the burst strength of the balloon did not meet the acceptance criteria.

The regulation states that you must have procedures for rework, and the reworked product is retested and must meet the original approved specification. Basically, this is making sure that you do not have a special set of specifications for reworked product.

So, in the above example, the balloon burst strength did not meet the original specification. Rework and reevaluation activities must be documented in the DHR, or the Device History Record. When should nonconformance be handled under 21 CFR 8 20.90, and when should they be referred to corrective and preventive action 21 CFR 820.100 ?

Corrections may be handled locally under Nonconforming Product, 21 CFR 820.90, here are some examples of the general criteria for handling a correction under Nonconforming Product. If it is an easy or specific correction, an isolated incident, a minor issue, not a design issue, and not a manufacturing issue. In some cases, nonconformances may be referred to the CAPA system, 21 CFR 820.100.

Here are some examples for when you should refer nonconformances to CAPA: There is no easy or specific correction; it is recurring, based on a valid analytical method of determining; it is a severe issue; a design issue; or a manufacturing issue . Please note these are not all -inclusive lists, and where and how you handle nonconformances should be defined in your procedures. In deciding on which system to handle nonconformances, balance is key . Too many nonconformances handled under 21 CFR 820.90 may fail to address systemic issues. Generally, nonconformance issues should be simple , specific, and contained. Conversely, too many nonconformances referrals to CAPA will overwhelm that system.

Generally, CAPA handles for complex, ambiguous, and systemic issues. Additional information on the Quality System, its Preamble, and the FDA Inspection Guide, can be found at the links on this slide.

In concluding this presentation, I now ask you to take on the following call to action: Use your nonconformance system to learn from mistakes. They can impact everything from quality to design to manufacturing. Know that nonconformances are a gateway mechanism for CAPA, and leveraging a robust nonconformance system to avoid repeating mistakes can allow you to improve quality and safety of your product.

We encourage you to use other industry education resources we've developed especially for you, as shown on this slide. Of note, for comprehensive regulatory information, please contact CDRH's Division of Industry and Consumer Education. We look forward to helping you. Thanks for watching this program.

Joseph Tartal: Welcome back, and thanks for viewing the presentation on Nonconforming Product. I hope you found it informative. Once again, I'm Joseph Tartal, deputy director of the Division of Industry and Consumer Education in CDRH's Office of Communication and Education. I'm joined by Vidya Gopal, who just gave the presentation on Nonconforming Product. Thank you, Vidya. Completing our expert FDA panel is Tonya Wilbon from the Division of Industry and Consumer Education, as well as Eric Horowitz from CDRH's Office of Compliance. Let's now proceed with the Q&A segment of our session. You can email us your questions by clicking the "Ask a Question" icon, which looks like a small thought bubble at the bottom of your screen. Or, if you'd like to ask your question live, you can call us at 1-800-527-1401 . Our next session on Complaint Files will begin promptly at 2:00 p.m., so we'll try to get as many of your questions on Nonconforming Product before then.

Now let's get started with some of your email questions that have already come in. So the first question I have, and I'll address it to Tonya, is when do controls for addressing Nonconforming Product primarily apply? Tonya Wilbon: So controls for addressing Nonconforming Product apply when product has been identified to not meet the predefined specification, and this can occur during in processing activities, it can also occur during receiving of those products, as well as during final acceptance activities with those particular products.

Joseph Tartal: Okay, thank you. And we have another question that has come in. Who is responsible for handling nonconformances? And this goes a little bit farther than just a Nonconforming Product question to nonconformances in general. Eric, if you wouldn't mind taking this one.

Eric Horowitz: So in terms of the actual responsibility for handling it, it falls on whomever is aware of that nonconformance. So anyone within your organization can bear the responsibility for ensuring that not only products that are nonconforming but also any kind of product that's gone through a nonconforming process, anything along those lines, that gets handled in accordance with those nonconforming process procedures, that really it's put on to everyone in the company to ensure that that product is handled properly. And so there isn't necessarily one specific entity that is always going to be responsible for handling non conforming product. It really falls on whoever can.

Joseph Tartal: Okay, so it sounds like you're talking about a team , company-wide approach with regard to dealing with nonconformances. And I'd agree that dealing with nonconformances, it may be the product or it may be the process itself where you're finding these

nonconformances. Vidya Gopal: Mainly it's whatever is outlined in your procedure for handling of nonconformances. So if it is some kind of review team that looks through all of those, and says what the disposition is, and segregation policy is, that's addressed in your procedure.

Joseph Tartal: So do all manufacturing or Nonconforming Product need to be elevated to a CAPA, to a corrective or preventive action ?

Vidya Gopal: Not necessarily. As I was mentioning in the presentation, it just depends on the severity, or if you can like address it locally, you would address it locally. But if this is a thing that would affect multiple projects or products, then you would try to elevate it to a CAPA.

Tonya Wilbon: And I would add that you would want to make sure that your procedures dictate how those particular nonconformances will be handled and will be processed. So you want to make sure that you are actually following your procedures, and your procedures provide you with those instructions that clarify in which system you will actually handle and address those nonconformances.

Joseph Tartal: Correct, because I can see -- go ahead, Eric.

Eric Horowitz: In addition to really understanding that it's good to also ensure that your procedures have actual methods in place for how your CAPA system views nonconformances, that certain risk levels may trigger CAPA, and that nonconformances are really evaluated using the statistical methods that you have identified in your CAPA procedure to ensure the CAPAs are being initiated when it's really warranted –

but also keeping in mind that there are going to be plenty of nonconformances that happen that in and of themselves that should just be handled through the Nonconforming Product procedure.

Joseph Tartal: Correct, and that's a good point to make. Because if you put everything through to CAPA you're going to overwhelm that it takes away the main purpose, which is like you said , something that's either being trended out as a continual recurring problem, or something that you've defined in your thresholds as being higher risk. And that's a really important point to make. And that ties into the next question that I have. Please give some examples of scenarios when I should revise my thresholds for nonconformances, and escalation into CAPA. So this kind of ties into that question with regards to, okay, what I'm seeing with regards to an example of something that would be a nonconformance versus something that would go into CAPA.

Tonya Wilbon: So one example perhaps could be in the event you have identified a certain amount or percent of your product that you, based on testing and some statistical methodologies, you've determined there's a certain amount of failures that may occur with the products that you manufacture. And so if you have -- or if you become aware and determine that the amount of nonconformances that you are encountering exceed that level, then you perhaps want to escalate that to do some further and some more in depth investigation into your CAPA, your corrective and preventive action subsystem, to really get a better understanding of why these additional nonconformances are occurring. So one example again, would be in situations where you're exceeding your initial expectation of failures.

Joseph Tartal: Okay.

Eric Horowitz: Another example might be if you have different data analysis methods that you're using. One of them is more of an acute threshold referring to how many nonconformances you have within a given month. Another might look at it more long-term, looking at how the progression of the rate of nonconformances changes over the course of a year or multiple years. And what you may find through doing things that way is that you see a concerning trend over the course of a long period of time that makes you think, well, even though we haven't met that threshold so far, maybe we need to make that threshold a little stricter, because we're seeing that there's a problem that could be occurring that maybe we just haven't identified because of the methods we're using . And so it can be very beneficial to look at that long-term approach, and then pull that back in to look at whether your short-term data makes sense.

Joseph Tartal: So it means it sounds like using statistical methodology as well as looking at duration of time and frequency of the different things that are feeding that data into your system, as to then using it to change your thresholds as needed.

Vidya Gopal: The other example I had was if you have a process that is similar across like multiple product lines, or multiple manufacturing lines, then you might want to think about escalating it to the CAPA system, because it not only affects the product where that nonconformance was found, it could affect many other products.

Joseph Tartal: That's a good point Vidya is saying because you're now talking about the individual nonconforming products into how that looks with all your product lines, and if there are similar processes or products, that failure may be somewhere else. What I would add to that too, is looking at the threshold with your risk profiles. So if you identify a risk that you previously are seeing, that could be something that now we know about this risk, it may change the threshold that we feed into our Corrective and Preventive Action symptom. So I think it was a good question to go around. The next question I have online is - during manufacturing, a component is affected by the process and does not meet the requirement for the next manufacturing step. Is a component considered nonconforming invoking the entire documented process, or can it be thrown away as manufacturing waste?

Eric Horowitz: So a component or a part or any type of material used throughout the manufacturing process, that is nonconforming, is nonconforming product. It should be handled in accordance with your nonconforming product procedures. You may have procedures that specify exactly how you would handle different types of nonconforming products, so there may be a different method for how you handle that given component than it would be for if you had nonconforming finished devices. But it still needs to be handled in accordance with your Nonconforming Product procedures and controls through a very well-documented method . It's not adequate to simply throw it away.

Tonya Wilbon: Yes, and you may address that process in clarifying and determining the disposition of your Nonconforming Product.

Joseph Tartal: We have a caller from North Carolina. Caller, you have a question?

Caller: Yes, I was going to ask what level of investigation is typically required for a nonconforming –

Joseph Tartal: I'm sorry, I'm not hearing you through the system. Please ask your question again .

Caller: Yeah, we're trying to figure out what level of investigation is required for a nonconformance versus a CAPA.

Joseph Tartal: The question, is if I understood it right, what level of investigation is required for a nonconformance versus an investigation for a corrective action and preventive action?

Caller: Correct.

Tonya Wilbon: So here again, it depends upon the risk of the device that you actually have in question that you considered as a nonconforming product as to the level of investigation. Your Corrective and Preventive Action system is going to require more in-depth level of investigation than you would have for your nonconforming products. And here again, remember that you can always refer that Nonconforming Product into your Corrective and Preventive Action subsystem for further investigation. So what you would have is a less involved nonconformance that you are addressing, and you may handle that with a less involved investigation. Whereas within your Corrective and Preventive Action subsystem you may have -- may be involved with a more detailed investigation because you want to provide that assurance that there is not some systemic issue. As

we've indicated previously, there may be times when your nonconformance may also address and affect other products as well as other processes within your facility, and in your Corrective and Preventive Action subsystem your investigation should address those options.

Joseph Tartal: And also remember, when you're entering something into Nonconforming Product, you're generally looking at something that's going to be a correction. Whereas if you're putting something through your corrective action system, you're trying to stop its recurrence or you're dealing with something that is a higher risk. So remember the outcome, too, as to what you're trying to look for. And I've always looked at the CAPA system as being that wider net. So you're looking at it from a bigger, systematic standpoint, as Tonya pointed out. And remember, there are two different aspects of what you have to do in follow-up. With Nonconforming Product, you're probably just making a correction. With a corrective action, you're doing some action to prevent recurrence from continuing to happen . So any other –

Vidya Gopal: I think you addressed that.

Joseph Tartal: Okay, did that address your question , caller?

Caller: Yes, sir. We have it documented in our nonconformance process to I guess record the investigation , and oftentimes that recorded investigation step is kind of lackluster in response. From a quality perspective, we're always a little leery of approving getting the nonconformance through the audit pro process we're trying to get an understanding how much level of detail is expected, for the root analysis versus the CAPA and I think you addressed that pretty thoroughly.

Joseph Tartal: Thank you. Thank you for calling . With that I'm going to go back to another question that we received online. What would be considered the best practice for approving a downgrade disposition? So that's the first part. There are two parts to this question. The first part is - what would be considered the best practice for approving a downgrade disposition? And the second part - how would you capture the use of a specification that has been superseded by the current specification? So let's start with the first. What would be considered the best practice for approving a downgrade disposition. Eric?

Eric Horowitz: So there isn't a one size fits all practice when it comes to this type of determination. Generally speaking, if I'm understanding what's meant by a downgrade disposition, generally speaking, what's really going to drive this is the information that you have about that product, because the real expectation here is that if you're going to make that type of a disposition, that you've got objective evidence that you're basing that determination on. It's not something you're simply entering into because it sounds like the right thing to do. It's important that that kind of determination is made really with something behind it, that you're really making it knowingly, with a clear view of how you came to that conclusion.

Joseph Tartal: And I would agree, because when you start changing your specifications you then need to ask the question - why was that specification set to begin with? And if you now can downgrade, well, why did you set it at the level that it was initially set up?

And that kind of falls into the second question here - How would you capture the use of a specification that has been superseded by the

current specification? So I'm guessing you're talking about one specification, now you've downgraded, and now you're talking about the current specification, and how would you capture that change?

Vidya Gopal: I think the best thing I would say first of all, is to address the risk part of it. You upgraded it for a certain reason. Why did you upgrade it, was there a risk involved, and you addressed that risk by upgrading that version? And now you're going back, which means you have introduced that risk into the system because you have changed it. Because you said okay, this upgrade is going to address this risk, and now you're downgrading it, so you're back to having that risk in your system. So you would have to address it when you say you're going to go back to your downgraded version.

Joseph Tartal: Correct, and go back and see what was the reason for that specification - was it determined through risk, was it determined as design, part of your design input?

Tonya Wilbon: Sure I would add that when decisions are made to down grade it for perhaps a different use, such as you're downgrading it for researchers only . And remember, one of the purposes of the nonconformance system is to make sure you control that Nonconforming Product to ensure that it is not distributed . So if your decision is to downgrade use of that Nonconforming Product for different use, you just want to make sure that you have those controls in place that would ensure that that product, that you're no longer going to distribute it for its initial intended use, that it's now downgraded for let's say, research use or for teaching purposes, just to make sure that those products are not used as it was initially intended for human use. And not distributed.

Eric Horowitz: Now, the one caveat that I'll give to that is - if you are making a change where it's driven by truly making upgrades to a system, that it isn't driven by a risk. That it's not driven by some sort of reason that you're trying to correct something, such as you just have a new version that you want to put out. So long as you have documented reasons and documented rationale that the product that exists has nothing wrong with it, and so that you're perfectly -- that it's acceptable for it to be used, there is nothing wrong with using that product and really not considering it to be nonconforming. Because it still meets the specifications that you originally had it under.

Joseph Tartal: Correct, and that's going to the second part of this question - if you're going the opposite direction, you're upgrading to now you just have a newer specification, and that you're not trying to say, well, the previous one had to meet it, too. Well, guess what? The previous one was already made. You've just changed it at this time.

Eric Horowitz: Right.

Vidya Gopal: And one of the places where we see this very commonly is when they do software upgrades. And if something goes wrong, then they just say oh, we'll just go back to the original version, or the downgrade version of it. And that's when you know, as Eric said, that the downgraded version is still safe and effective. And you have that documented evidence, and then that's when that disposition is considered acceptable.

Joseph Tartal: And that's a pretty good example, through software updates. So with that, we'll go to the next question. Are there additional

or different requirements for nonconformances identified through an internal audit? Vidya, if you want to start...

Vidya Gopal: I don't think so. I think even if it's addressed during an internal audit, it's still a nonconformance. And it just might be that you deal with it with your internal audit procedure and it's documented there first, and then you decide to deal with it. But it's still a nonconformance, and you have to address it through your nonconformance procedures eventually.

Joseph Tartal: At some point or through CAPA, if it raises to the level of CAPA.

Vidya Gopal: Yes.

Tonya Wilbon: I would just agree with that. Definitely no difference, you would still have to identify it as a nonconformance and take it through your procedures for addressing Nonconforming Product, nonconformances.

Joseph Tartal: Because I think where a lot of people get hung up we don't necessarily look at internal audit findings and while we don't look at those internal audit findings, they should be going through the appropriate systems, and we do look at Nonconforming Product in CAPA. And actually, if your system is running appropriately the way it's supposed to work, we expect to see those things. Because that's telling me that you're doing your due diligence doing your internal audits.

Vidya Gopal: The point is to make sure you utilize the tools for the nonconformances in internal audits to identify problems, to make your product better.

Joseph Tartal: Correct.

Vidya Gopal: It's not to just have them segregated that you don't catch one or the other.

Joseph Tartal: Correct. Eric Horowitz: And along those lines, there's nothing that says that you have to have a Nonconforming Product procedure, that this is the only thing that we use for handling Nonconforming Product. If you have a procedure for your internal audits that has mechanisms in it that follow the same requirements that your Nonconforming Product procedure does, that's perfectly acceptable. I would caution that if you have those kinds of disparate systems, that you make sure that there's sufficient links, that when one is changed, the other is changed as well - that they're talking to each other, and you're using a Quality System that works together. But the really important thing, and the thing that we as the FDA truly care about, is that your Quality System is functioning, that you're handling these nonconforming products in the proper way, regardless of which system you're using to do that.

Joseph Tartal: Correct, and which system identifies, only just a matter that you're handling it, and that you're doing it appropriately. Okay. Does an investigation of a nonconformance and a nonconformance process involve getting to the root cause, or does that need to be done in the

CAPA process.? So this kind of goes off a little bit further from the caller's question, and getting to the root cause question.

Tonya Wilbon: So I would say or reiterate the fact that yes, you still want to make sure that, you know, you're handling, you're conducting an investigation, to identify the cause. It may be multiple causes for your nonconformances but you want to make sure that you have those controls in place that will certainly identify those, and to make sure that you're conducting an investigation that would lead you to actions to ensure that you either correct the immediate nonconformance, and that you also have controls in place to ensure that future nonconformances of similar or at some other quality type do not continue to happen or do not happen again. So yes, you can make sure that you reference both of those systems to talk to each other and have the procedures in place that dictate which system you're going to address the issue in.

Eric Horowitz: Yes , and when it comes to the term root cause, which you will notice that root cause doesn't occur anywhere in the regulation. And the reason for that to some extent is that the depth of investigation that you're looking at really is what should be appropriate for the situation. Now, when it comes to the in-depth analysis that people usually think of when they hear root cause, that's typically something that would happen in your CAPA system. Typically, every nonconforming product, every nonconforming practice, in and of itself, doesn't necessarily require a root cause analysis. However, that doesn't mean that it doesn't require any kind of analysis of cause.

So it's an important thing to get that a lot of Nonconforming Product is going to require some kind of investigation as to why it was non

conforming. But that doesn't mean that every one of them is going to require an investigation as in depth as you would in your CAPA system, where you're going to be really trying to identify where you need to go in order to prevent this from happening.

Vidya Gopal: I think it also depends on the severity of the nonconformance. And if you think that this could affect the product more, and it's going to be -- get to a point where it's unusable, or it's going to create more nonconformances or things like that, then you would want to delve deep and investigate the cause for it, as opposed to just not investigating it. So I would say it just depends on what the nonconformance is.

Joseph Tartal: And I think this is where the Preamble comes in very handy as Eric was talking about, the severity and risk associated with it, that's where it's talked. So the Preamble talks about these are not all created the same, and that you're going to do different levels of investigations depending upon what system you're in. And you're going to make that call off of that severity. So the next question that I have online - can raw material not meeting the required specification, but not necessarily affecting the performance of final product, be accepted after authorization by a person from higher management without failing a nonconforming report? That's an interesting question. Who would like to take that first? Vidya?

Vidya Gopal: I would be very hesitant to do that. That would be my first like gut reaction. I think it's a very slippery slope here.

Like why would you not want to put it through your Nonconforming Product. Is there a reason for it? And the other aspect of it is, if you put it through the right processes, then you have documentation to provide to your vendor to say - hey look, this is happening, so can we figure out what's the cause for it? Especially if it is an outside vendor that is providing you that raw component.

Joseph Tartal: So you think it could lead to purchasing controls there? Tonya?

Tonya Wilbon: What I was going to add is regardless of your disposition and use of that raw material, if you have identified it as not meeting the specifications that you initially defined, you do have to document a report of that , and the disposition of that. So regardless of what decision, and someone who is in authority and has the knowledge and the expertise to make the decision to continue to utilize that raw material as part of the finished device, definitely has to document and sign and date when that decision was made, and provide the justification and rationale for using that raw material. So regardless, you still will have to document some type of report, regardless of if you call it a report, you have to document what was done and who made those decisions, and the justification for that.

Joseph Tartal: And the regulation is pretty clear and specific on that.

Vidya Gopal: I was going to say in the regulation, the definition of product calls for components in it, so it is part of your process.

Eric Horowitz: And part of why that's important is really because while you may be tempted to make gut decisions about whether or not a given nonconformance is acceptable or not, it's really important for you to be able to document the fact that that was nonconforming, it didn't meet our specifications, and here's exactly why we're going to accept it anyways. Otherwise, things slip through the cracks. You can end up with something that really shouldn't have been accepted at all, and you're making a call just based on your gut with no real good rationale for it. And you end up with problems down the road, because what appeared to be a situation where it's not going to affect the device, it's okay, but we don't have a real good justification for thinking that, ends up with not just nonconforming materials, but nonconforming finished devices and potentially adverse events.

Joseph Tartal: I agree that you're going down that slope, and you're now running afoul of the regulation as well as the procedures that you've established with regards to setting that specification, as well as the procedures that happen afterwards. So I think the second part that we talked about, with regards to you need to document it, you need to document why it was not meeting its specification and becoming nonconforming, and you need to document the justification for why you've now accepted it.

Vidya Gopal: And just to add to Eric's point, especially down the road if you end up at Nonconforming Product, now you don't have documentation to tell you why it became nonconforming in the first place. So now you have like -- you don't know what the root cause is.

You've kind of it slipped through the crack, you have no clue what happened.

Joseph Tartal: It's a snowball effect. You're building upon the initial problem, just going to become bigger and bigger and bigger, I'd agree. The next question online – with products or low risk devices are corrective actions required for each nonconformance, and if not, how much justification if any is needed to be documented? Tonya?

Tonya Wilbon: Sure. So with regards to product that you determined have a low risk, here again it depends on what risk you're willing to take with regards to accepting and distributing these products that are not meeting specifications or, if you don't have that full level of assurance that these products do meet the intended use. With regards to putting it or referring it to your CAPA subsystem to identify the causes that are going to assist you in identifying the actions, be it corrective actions or corrections, to ensure that the product will meet specifications, and that those are the only products you distribute, that would depend here again on the level of risk that you've determined to take for that particular finished device.

Eric Horowitz: One thing I would add to that is you should be careful about thinking of it purely as your device is low risk. Because you can have an inherently low risk device that has some high risk failure modes. So really, keep a thought process around the type of nonconformance that you're looking at, and what the risks of that nonconformance are, because it's not necessarily the overall risk of that device, such as the risk of that nonconformance, that you should be considering when you're looking at how to handle that Nonconforming Product, and whether or not a CAPA is necessary.

Joseph Tartal: Agreed. So with that, we're going to give Vidya her final thoughts on Nonconforming Product.

Vidya Gopal: Thank you, Joe. So basically, learn from your mistakes, and just be aware that if you are not using your Nonconforming Product process correctly, not only will you be dealing with the direct cost of the nonconformance and possible recalls, you'll also be dealing with the indirect cost of brand image, market share loss, liability, and things like that. So just be aware of that, and just make sure you use your Nonconforming Product system to learn from your mistakes and to improve your quality of the device.

Joseph Tartal: Thank you. And with that final thought, this concludes our session on Nonconforming Product. Thank you for sending in all of your great questions. Remember, if we didn't get to your question or if you have other questions in the future, please contact us at that time DICE. We've posted a survey on the workshop website where you accessed this program. We welcome your feedback, which helps us to improve programs like these, and gauge how well we serve your educational needs. We'd really like too hear from you. The survey will be available for several weeks, and will take just a few minutes to complete. Now let's get to our today 's secretary topic, Complaint Files. Your presenter for this topic will be Stanley Liu. At the conclusion of his presentation we'll bring back the panel for this interactive q question and answer session with you. So we'll see you in a little while. Thank you.

Stanley Liu: Hello, my name is Stanley Liu and I'm a consumer safety officer in the Division of Industry and Consumer Education. I worked in industry for many years, and know how difficult it is to compete and

manufacture medical devices in the United States. Working at FDA, I also understand the big picture regulatory framework that helps ensure quality. I hope to bring a balanced picture from both perspectives to my discussion today on Complaint Files. Complaint Files are a key but often neglected aspect of the Quality System for medical device manufacture. It's human nature to focus on getting a task accomplished. In this case, getting a device marketed and manufactured . But what comes afterwards is oftentimes neglected or forgotten. However, what occurs after a device is released for distribution can be just as important as pre market and manufacturing activities. When Complaint Files are properly handled and coupled with other corrective action systems, the result is a mechanism that can be used to learn from past mistakes. This can result in success ful product longevity, increased market share, and consumers will ultimately benefit from a better, safer, and more effective product. Today I will be focusing on the following three learning objectives: One, understand the context of Complaint Files within the overall Quality System and Corrective and Preventive Action, or CAPA, subsystem . Two, learn about the mechanisms of Complaint Files and their continual postmarket role. And three, understand the contribution of Complaint Files to quality and safety. These three key objectives will give you a firm start in understanding the role, function, and importance of Complaint Files. What is the CAPA subsystem? It's a key component of the Quality System , and is itself comprised of three parts . This is articulated in this simplified and generalized table. Nonconforming Product, which functions primarily during manufacturing ; CAPA, which functions during both manufacturing and after distribution; and Complaint Files, which generally functions after distribution. I'll be focusing today on Complaint Files, as highlighted in bold. Complaint Files, in turn, comprise 7 sections

labeled A through G, as listed here. However, you can think of them as being divided into procedural mechanisms, A through D; and record-keeping requirements, E through G . We will go through each of these groups in greater detail as I progress through my discussion.

Now that we've taken a brief look at how Complaint Files are laid out, let's explore the procedural mechanisms. We'll start with the formal definition of a Complaint. What is a Complaint? It is any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it's released for distribution. In other words, a Complaint is any communication alleging an issue with a device after it's been released for marketing and distribution. All complaints must be processed in a specific manner, as defined in the first Complaint Files subsection, General Requirements.

Manufacturers must establish and maintain procedures for receiving, reviewing and evaluating complaints by a formally designated unit. This unit must ensure processing of complaints in a uniform and timely manner; documentation of oral complaints upon receipt; and evaluation to determine if a failure investigation and/or a Medical Device Report, or MDR, is required. Some devices may require servicing after distribution. And during this servicing, complaints may arise. What do you do with servicing reports with potential complaints? Well, there are many different solutions, and I will describe two common ones.

First, manufacturers may train servicing personnel to identify possible complaints and flag them for the formally designated unit to subsequently review. Second, manufacturers may have the formally designated unit

itself review all servicing reports and records for possible complaints. Each solution has its advantages and disadvantages. Manufacturers have the freedom to find a solution that meets both regulatory requirements as well as their own needs. Please note that these examples focus solely on servicing as they relate to Complaint Files, and we won't be discussing servicing beyond this limited scope.

Once an alleged complaint has been received, manufacturers must review and evaluate complaints to determine if an investigation is necessary. If you determine that an investigation isn't required, then accountability information such as the reason and responsible individual must be documented. Any alleged complaint involving the possible failure of a device and/or its labeling and packaging to meet specifications must be reviewed, evaluated and investigated. The exception to this would be when an investigation has already been formed on a similar complaint.

Please note, though, that a similar complaint may not require an investigation under Complaint Files, but it may require a corrective and preventive action investigation due to recurrence. I'll discuss CAPA referrals later in this presentation. Let's briefly discuss a specialized form of complaint known as a Medical Device Report, or MDR. All MDRs are a form of complaint; however, not all complaints are MDRs. Our discussion will focus strictly on MDRs within the context of Complaint Files.

When MDRs are received, they must be promptly reviewed, evaluated, and investigated by designated individuals, just like complaints. However, MDRs must also be maintained in a separate part of the Complaint Files or be otherwise clearly identified. Additionally, investigation records must be kept indicating whether the device failed specifications; any use in

treatment/diagnosis, and the relationship of the device to the reported incident. Additional information on MDRs can be found in 21 CFR 803.

Now let's look at a very basic, simplified diagram of how the three CAPA subsystems function, focusing on after distribution mechanisms on the right. Corrective and Preventive Action is in the middle, spanning both manufacturing and after distribution. Complaint Files and Medical Device Reporting are in the lower and upper right respectively, within after distribution. Complaints enter from the lower right. Note that complaints initially go to the Complaint Files. From this point, they may be handled locally, or referred to CAPA. MDR complaints are fed into the MDR system, which can also potentially lead to CAPA.

With a basic understanding of how a Complaint Files System is established and maintained to review, evaluate, and investigate failures and MDRs, I'll now turn my focus to two common questions that are asked of the FDA. The first is - why are investigations necessary? Isn't it enough to simply catalog and note complaints and failures? The answer is, no. Based on statistical probability, the likelihood that a product line will eventually have a failure or MDR increases as time passes. Such a failure can conceivably impact everything from manufacturing to design.

A robust investigative system ensures responses/ reactions are accurate, appropriate, and timely. Complaints are captured, reviewed, evaluated, investigated, and corrections made. The end result is a better, safer and more effective product. The second common question is - why are there specifics on how to conduct an investigation? On first glance, the regulation does not appear to be that complicated or specific. There are a multitude of variables and reasons for this. These include the

heterogeneous nature of devices and complaints; risks involved; severity of issues; frequency of complaints; and many other factors, including conditions and context. Therefore, a set of prescriptive requirements governing all possible variables and situations is simply not feasible. Consequently, the regulation is flexible . The FDA recognizes that it cannot foresee every potential situation or contingency. As a result, the regulation is not vague; rather, FDA has given manufacturers the freedom to define their own circumstances.

Manufacturers must understand their product, associated risks, the conditions, and context for use, and apply the regulatory rirmghs to make their own Complaint File System work. The result is that manufacturers must decide upon their own details. Manufacturers are responsible for the details of their own Complaint File System. These would include : Definitions, actions, and investigation thresholds. For definitions, this means defining failures of devices and labeling/packaging MDR and is other non-complaint communications. For actions, the manufacturer must establish criteria for what constitutes an investigation, as well as what happens with other activities such as non-complaints, and similar complaints . Finally, there needs to be a provision for investigation thresholds.

Specifically, when should complaints be handled locally under Complaint Files or referred to CAPA? This last topic, thresholds, is now something we'll examine in more detail. Corrections should be handled locally under Complaint Files if they meet the following general criteria: easy, specific correction; isolated incident; minor issue, not a design issue and not a

manufacturing issue. I've provided illustrative examples in the next five slides.

Easy specific correction. A device was mishandled during shipping and is dented or scratched. Isolated incident, a minor malfunction occurred when it was used once outside the intended indicated uses in an unanticipated way. Minor issue, a part became loose or unattached, but was not damaged. Not a design issue. The plastic casing cracked when accidentally dropped. Not a manufacturing issue. The instruction manual got lost during unpacking. Complaints should be referred to CAPA if they meet the following general criteria: No easy specific correction; Recurring problem, severe issue; A design issue; And a manufacturing issue.

Again, I have provided illustrative examples in the next five slides. No easy/specific correction: Complaints of short battery life. Recurring problem: A large amount of product frequently dented or scratched during shipping over time. Severe issue: A device caught on fire or exploded. Design issue: Reports of frequent, specific malfunctions in a high E.M. area. Manufacturing issue: Mold was found inside the packaging. In deciding on specific threshold parameters, balance is key. Too many failures handled under complaints may fail the address systemic issues.

Generally, complaint file issues should be simple, specific and contained. Conversely, too many complaints referred to CAPA will overwhelm that system. Generally, CAPA handles more complex, ambiguous, and systemic issues. I hope my previous examples helped to illustrate the general typo line that needs to be drawn.

Now let's view a final assembled diagram of how complaint file investigations worked. Note that this is again simplified for illustrative purposes. Complaint Files are in the center, while Corrective and Preventive Action and Medical Device Reports are in the upper and lower right side, respectively. Complaints enter from the left side. An initial complaint is received, reviewed, and evaluated. If it is not a complaint, then it is either closed or dealt with in another manner. If the complaint requires further investigation, as in the case of device failures, then it proceeds to the investigation phase. MDRs are identified or separated and dealt with separately, which may include forwarding to CAPA. Failure investigations are examined to determine whether they are to be handled within the Complaint Files System or referred to CAPA for further investigation.

Now that we've examined the basic procedural mechanism for the Complaint File System, let's switch gears to focus on the second part of the regulation regarding complaint files, recordkeeping for actions that we've discussed. Complaint file records must be maintained to capture the device name; date the complaint was received; unique device identifiers; complainant contact information; nature or details of the complaint; results and dates of the investigation; corrective action taken; and the response to the complainant.

In cases where a designated complaint unit is located offsite and/or outside of the U.S., records must be reasonably accessible to the manufacturer and the FDA at either the U.S. location where the records are regularly maintained, or with the initial distributor or importer. Such records must comply with all other Quality System requirements as per 21

CFR 820 Subpart M. Additional information on the Quality System, its Preamble, and the FDA Inspection Guide can be found at the links on this slide.

In concluding this presentation, I now ask you to take on the following call to action: Use your Complaint File System to learn from mistakes. They can impact everything from quality to design to manufacturing. Know that Complaint Files are a gateway mechanism for CAPA and postmarket activities. And leveraging a robust Complaint File System to avoid repeating mistakes can allow you to improve the quality and safety of your product. We encourage you to use other industry education resources we've developed especially for you, as shown on this slide. Of note, for comprehensive regulatory information, please contact CDRH's Division of Industry and Consumer Education. We look forward to helping you.

Joseph Tartal: Thanks for viewing the presentation on Complaint Files. Once again, I'm Joseph Tartal, and we're joined by your presenter, Stanley Liu. Thank you, Stanley, for your comprehensive overview presentation. Completing our expert FDA panel is, once again, Tonya Wilbon from CDRH's Office of Communication and Education. And Eric Horowitz, from CDRH's Office of Compliance .

Now let's proceed with the Q&A segment of your session, and you can email us your questions by clicking the "Ask a Question" icon, which looks like a small thought bubble, at the bottom of your screen. Or if you'd like to ask your question live, you can call us at 1-8 00-527-1401 . This session will go all the way to 3 p.m., so we'd love to answer as many of your questions about Complaint Files before then.

Let's get started with some of your email questions that have already come in. So the first question I'd like to ask Eric , which has come in, which is: Can a third party be contracted to handle Complaint Files?

Eric Horowitz: It's a good question, and to put it simply, yes. You can have a third party handle your Complaint Files. However, there are certain things that you need to keep in mind when you are contracting the handling of your Complaint Files. First of all, whoever you're contracting to do it is a supplier, and should be handled in accordance with your supplier control requirements. In addition to that, you should have in your agreements with that supplier, with that contractor, exactly how that handling something is going to occur, what is going to be forwarded to you as the manufacturer, how the links are there between complaint handling and the CAPA system and other systems, so that everything is still functioning in terms of a well-oiled quality system. However, it is perfectly acceptable for you to have a third party handle your Complaint Files themselves.

Joseph Tartal: Okay, so it sounds like yes, you can contract out the duty, but the responsibility is still on you, you've got to qualify them under 820.50.

Your purchase controls, and you've got to make sure that they're meeting whatever your requirements are to feed into CAPA or I guess your MDR requirements under 803, so you've got to make sure that all those things work in conjunction with one another . Good answer.

Tonya Wilbon: And I would add, if I may, you want to make sure that you have access to those files, as well.

Joseph Tartal: Absolutely, because I think that's an important aspect, that those are your complaints.

Tonya Wilbon: Yes.

Joseph Tartal: So our next question that's come in online is: Do offsite complaint handling units need to register and enlist?

Stanley Liu: Do offsite complaint handlers need to register and enlist? Yes, they do. Anyone engaged in the proper handling of Complaint Files beyond just forwarding them needs to register, list, and pay the annual fee as a third party complaint handler.

Joseph Tartal: Correct, so it sounds like the facility registration piece, if you're doing some function under 820, as part of quality systems, then more than likely you're registered and listing. So if you're doing something like an 820.98, even though you're doing that same function even though it's still a function underneath the Quality Systems - Yes.

Joseph Tartal: With that we'll get to the next on line question. What is FDA's definition of a customer complaint?

And then there's a second part to this question - what's the difference between a customer service request and a customer complaint?

Tonya Wilbon: So I'll take that one, Joe, thank you. Actually, FDA has not defined, per se, a customer complaint. But FDA has defined what a Complaint is, under 820.3, and I believe the actual citation is under 820.3(b) , so Complaint is defined as any allegation that your product does not meet its specification. And that's during receiving , or after the

product has been released for distribution and is not meeting its specification as intended. With regards to I believe your second part of the question was the difference between servicing versus a complaint. Servicing is part of the design of your finished medical device, so those requirements for servicing of your product, which would be intended to make sure that your product still continues to meet its pre-defined specification, then would differ from what's considered a complaint.

A complaint would occur after the product has been released for distribution, and it would go beyond what your specifications, or you've determined that the device currently does not meet its specifications. So servicing is part of the specification, and you would have determined or documented that those requirements may not be met, let's say, within six months or a year, and you want to service it within that time frame to ensure that it does, or to make sure that it continues to meet the intended use, or the specifications of that device. So the major difference is that servicing is part of your design of your device, so it's predefined when the servicing will take place. If your device does not meet specifications after that defined servicing period, then it would be considered a complaint.

Joseph Tartal: Okay. Eric?

Eric Horowitz: One just quick reminder is the fact that even if something falls under your definition of what a servicing request would be, if the situation involved would be MDR reportable, it still must be handled as a complaint.

Joseph Tartal: Correct, and I think in Stanley 's presentation it talks about the fact that all MDRs are considered Complaints and that's the way it's looked at because you're looking at a serious injury or death. And to go further into that servicing aspect is - what are the expectations that you've built into the intent and design of the device? Is this something we knew we were going to do servicing at three months or is it something that meets that Complaint definition with regards to a deficiency being found or made outside of what the expectation was? But I would agree that MDRs are a whole different risk level, which moves it into a Complaint scenario.

So with that, we have another question. Which complaint handling procedures are required for an initial distributor within the U.S., where the design and manufacturing process is done by a supplier outside the U.S.? So Eric, if you wouldn't mind handling this. It talks first about complaint handling procedures for an initial distributor within the U.S., where the design and manufacturing is done by a supplier outside.

Eric Horowitz: So one of the requirements of all initial distributors is that complaint handling aspect. And the bare minimum requirement there is that you have the processes and procedures in place to ensure that all the complaints that you receive are forwarded to that manufacturer somewhere outside the United States. However, if there are other activities that you perform, as that initial distributor, you may be responsible for additional parts of the Quality System Regulation. Simply put, as an initial distributor, you have those bare minimum requirements of complaint handling through forwarding it to the manufacturer, but if

there are other activities you're performing, you are on the hook for performing them in accordance with the regulation.

Joseph Tartal: Correct, so it really depends on how you've defined yourself as an initial distributor. Are you a subsidiary of the original equipment manufacturer, or are you just an initial distributor that goes okay, I take these complaints, forward them, versus take these complaints and actually process them through 820.98? Tonya, you had a question?

Tonya Wilbon: No, I agree.

Joseph Tartal: So with that, we'll go to the next question. Should our procedure specifically state that all voluntary reports submitted to MAUD be considered to be a source of complaints? So this gets into really an MDR question. Should our procedures specifically state that all voluntary reports submitted to MAUD be considered a source of complaints? Stanley, if you want to touch on that a little bit?

Stanley Liu: Okay. MDRs are all complaints. But not all complaints are MDRs. So basically, for the system that they have in place, they need to carefully define according to what the regulations already have as a basis, what is a complaint, and what is an MDR. Specifically –

Joseph Tartal: Reportable event.

Stanley Liu: Yes, so that they have a separation of the two in the case an eject happens. And there's always the possibility that something, an incident may come along that may be very close to the gray line between one or the other, but more thoroughly, they define their system from the outset to specifically shunt, in essence, the incident one way, towards

Complaint Files, or the other way, towards the specialized Medical Device Report. The more careful they are creating that system, the less likely they will have any type of trouble. But with regards to whether an MDR should automatically be sent through the Complaint Files System, that is up to them. But if you look at the regulations, and my earlier presentation, if you go through that mechanism, then basically the initial complaint goes through the system for Complaint Files, and then if it's determined to be an MDR, then it goes one way. And then if it's still a complaint, with a potential for a failure, then it stays in the system and goes another way.

Joseph Tartal: Correct, and I think where this gets a little interesting is when they talk about voluntary reports. And the aspect, when you're talking about a complaint, a complaint is just an allegation. So I would say voluntary or mandatory reporting, you're still dealing with a complaint, because you're dealing with an allegation.

Eric Horowitz: Well, the one place that I've seen this get a little bit more questionable is in the instance of if, for whatever reason, a voluntary report was to be filed by a user facility, and they don't let the manufacturer know about it.

Generally speaking, it's very important for manufacturers to understand what is out there in terms of the things that are being said about their product. And honestly, if their voluntary report is being submitted to the MAUD database, it's very important that you are considering those, and that they are handled in accordance with your procedures. Honestly, it would be best if whatever user facility was submitting that voluntary report was also submitting information to you . But if for some reason a

voluntary report was issued where nothing was sent to the manufacturer, the manufacturer really should be looking at that and considering how that fits into their own processes.

Joseph Tartal: Correct, because this gets back to the definition part of Complaint, which is any written, electronic or oral communication, but you're finding it through MAUD. But I would say that once you have found it through MAUD, you're now aware of it. So I think as you pointed out really nicely, is you should be looking at MAUD because you're talking about things that are being put in about your product. And it's something that should be important to you about what type of reports are being put into your product. Okay, here's one that's a little more of a software based question. If I use cloud computing systems such as salesforce or other CRM systems to document and file customer complaints, are there any additional requirements for onsite versus cloud data backup? Is having access to our online system sufficient ? Do you want to take this Tonya?

Tonya Wilbon: So certainly. What I would say to that is definitely, yes, you will have to meet the requirements for validation of that software.

And oftentimes, we get follow up questions from manufacturers with regards to concerns about that. The regulation requires that you validate that software for its intended use -- not necessarily validating the legality, logistics or specifications of that software, but the intended use for that software as it pertains to its function in your Quality System. And so those requirements will be found under 820.70(i). So yes, there are additional requirements under Quality System Regulation that you would have to ensure that you're meeting when you determined or decided to use

software or some other type of electronic system within your Quality System.

Eric Horowitz: The other thing I would point out is you may also have some requirements, depending on how your system is set up, based on Part 11 and in terms of the accessibility of the system, and how different data is used. But I would encourage you to look at the Part 11 guidance documents in terms of how we view that type of situation.

Joseph Tartal: Especially when you're dealing with backups, because I think you're still on the hook with both accessibility and backup that you just can't say - oh, well, we lost our system, therefore we don't have our complaints. And that's going to be an issue with regards to not just the agency, but yourselves, with that data is very important to you. So, good answer. Is it considered a nonconformance when a part software's normal wear tears and breaks and then does that then become a complaint? I think this is another question tying a little bit to the service aspect of this.

Eric Horowitz: So first of all, the definition of complaint says that it's a complaint if you become aware of it after distribution of the device.

So yes, after release into distribution of the device. So keep that in mind in terms of whether something is required to be handled through your complaint system. If you have nonconformances that happen while something is still under your control, that's not necessarily a complaint. You can choose to handle it that way, but it's not a regulatory requirement. Once it has been released into distribution, any kind of nonconformances that you become aware of, either through your distributors or through user facilities or through end users, any of those

sources then become complaints. It's not a matter of complaints that are just something you receive from a hospital, or just something that you receive from a patient. It's really any of those sources. Once it's been released for distribution, it then becomes a complaint.

Joseph Tartal: Once it's outside of your control, it can be these other sources, it doesn't have to be the end user, it can be other sources as well . That's a good point to make. That will come to our next question. When investigating a complaint, does the reply/response to the complaint need to be written, or does oral communication suffice if the document -- if it is documented properly, and what would the FDA expect to see if oral communication is used? So a complaint comes in, and there is a requirement to respond to the complaint. And is it okay to do that through an oral method? Basically, I receive a complaint, I find out the issues with the complaint, and I'm calling the person back. Is that acceptable, if that is being done?

Stanley Liu: That's a good question. I would say that the regulations are broad and flexible on that. Basically, you have to record that you have responded , and then what the response is.

The details of that are left to the manufacturer. And it's also dependent on many factors, including the nature of the complaint. How serious was the complaint? If there was an oral response via phone or something like that, or Skype or something like that, if the response is then subsequently recorded with the specific details of what the response was, then that written response would be likely sufficient. I'm saying likely, because I don't know what the details would specifically be in this particular case. But if the response that is recorded, which is the thing that will basically

ultimately last, and what the FDA will ultimately see if it were to inspect the system, if it reconstructs sufficiently to a level of detail where we can follow what the response was, then that would be sufficient.

Joseph Tartal: And I would agree because sometimes those complaint responses become important from the standpoint that you want to have that more personal touch. And the regular legislation is not specific in how you're going to do it, just that you need to do this.

Eric Horowitz: And the one thing I would say in addition is, make sure that you're following your procedures.

Joseph Tartal: Yes.

Eric Horowitz: If your procedures say we need to respond in writing, you need to respond in writing.

Joseph Tartal: That's a great point.

Eric Horowitz: However, if your procedures allow for responding verbally, that is absolutely something that you can do.

Joseph Tartal: Correct. You're in charge of establishing your procedures, and then once they're established, you need to follow what you've established. That's a great point. My next question online -- does the FDA expect that all complaints be investigated, whether product is returned or not? So Tonya…

Tonya Wilbon: Sure, so the regulation does specifically indicate that each and every complaint is required to be evaluated to make a determination

as to whether or not an investigation is required or not. And when, in those cases when you've determined that an investigation is not required, you have to document that. And the regulation goes further, to provide an example of when such a case would be such - for example, if you're already conducting an investigation for a similar case. And what the regulation doesn't specify is whether or not that's based on returned product or not. So to address that question specifically, no, it's not based on whether or not you have returned product or not. But you have to evaluate whether or not an investigation is required, and when it's not required, provide that justification for not conducting one, and the authorization of the person who provided that.

Joseph Tartal: Because just not getting product back is not justification by itself.

Tonya Wilbon: Yes.

Eric Horowitz: There are plenty of methods by which you can investigate a complaint that aren't necessarily returned product. There's communication with the complainant, there's evaluation of your own existing data from your own Quality System.

The fact that you don't have returned product isn't in and of itself a reason not to investigate.

Joseph Tartal: Correct, because you may have -- and there's no requirement, but you may have held stability samples or other samples of that same product, same product numbers, like you said your device history records are, you know, a gold mine if you don't get it back you can

go back and review the device history records to look for information, as well.

Stanley Liu: And that may also depend on the nature of the device itself. If, for instance, you have an x-ray machine. Returning an x-ray machine would be a lot more problematic than returning something like a power toothbrush. So it depends on the device, lots of time it depends on the circumstances, and that's why the regulations were written to be more flexible to the manufacturer. You can also investigate by, nowadays, you can send a phone picture or something like that. So that is yet another way to examine a particular burn or some sort of a mark on a particular device can be seen by photograph without actually sending it back to the manufacturer.

Joseph Tartal: Correct, and you may be dealing with a single use device, in which case the device has been used, there's no way that you can do anything with that returned device.

I'll take another question online, and this one is actually an interesting one. Are negative reviews on Amazon considered complaints? Do you want to take this Tonya?

Tonya Wilbon: Certainly. So what I would say to that is, the complaint is meeting the definition that says any written, graphic, oral allegation that your device is not meeting its specification. So if you become aware, as a manufacturer, of that information, then it is incumbent on you to follow that through and channel it through as a complaint, until you deemed otherwise.

Joseph Tartal: Correct. So if it meets that definition as a complaint as you pointed out in 820.3(b), if it meets that definition just because it's on Amazon, guess what, it's still a complaint. We're probably going to see more of that as time goes on.

Tonya Wilbon: Probably social media.

Joseph Tartal: And like the database manufacturers are looking all the different places their devices are being talked about.

Stanley Liu: That's probably why they have the formally designated unit.

Joseph Tartal: My next question online is - if there's no device labeled lifetime, at what time is a wear or tear considered a complaint? There's no expiration date and they're talking about an expected device, when is it considered not a complaint anymore?

Eric Horowitz: So generally speaking, anytime you have an allegation that your device is not meeting its specifications and you're not in a predetermined servicing situation where you know that the device is going to have some certain amount of wear and tear, and you're expecting to follow a specific procedure about how you handle that, it is a complaint.

There isn't a point at which a device with no expiration date simply because it's gotten old enough, no longer receives complaints.

Joseph Tartal: Because it's still being used. And if it's still being used, and it meets that definition of a complaint, it's still a complaint.

Tonya Wilbon: And there are also requirements in the Quality System with regards to records that are required, and complaint is a set of those records that are required in the Quality System Regulation. So with regards to keeping documents and record retention, the requirement is if there is no life, then the expectation is you keep that, retain that information, which means collecting it as well, for at least two years from the date of manufacturing of that particular device. So if you have a device which there are not a lot of them that do not have an expiration date, then it would be at least the minimum of two years from the date of which that device was manufactured.

Joseph Tartal: Correct, and generally expected life is much longer than that. Again, it becomes that gold mine of data, because it could be something that you didn't expect your device to last for much longer, and that becomes something for you to be able to look at and deal with.

Tonya Wilbon: Exactly.

Stanley Liu: At the same time, the regulations do have a mechanism in place to ameliorate issues where, for instance, you have a device that is 25 years old, and you have one type of complaint. Then later on, you have another device that's similarly aged, has the same complaint.

Then the regulations specifically state that if you have a complaint that is similar to one that has previously been investigated , then you don't have to investigate that particular one, because you've seen something already like that. Now then, of course, if you start seeing five or six of these, then that may be referred to CAPA. In which case, it may be a possible issue where you might have to actually assign an expiration date in the next

design revision of the device . Perhaps the life span may only be 15 years, or 10 years or something like that.

Joseph Tartal: Correct, because I do think there is a feedback loop with regards to your complaint handling into the rest of your system. We've been talking about the whole aspect of these things are not siloed, that these things talk to one another. Good , okay. My next question online -is there a specific time period for closure of a complaint, and what is the acceptable maximum time period for responding, investigating , communicating, on its closure? So do you want to take this one, Eric?

Eric Horowitz: Sure. So there isn't a specified time period. Now, to get at the first part of the question, the closing a complaint, the regulation actually doesn't talk about the concept of closing a complaint. In fact, there isn't necessarily a requirement that you ever close a complaint. However, if that's the mechanism that your procedures use for documenting when you reach a certain point in how you handle the complaints, you need to follow what your procedures say. What it does say in the regulation is that complaints need to be handled in a uniform and timely manner. And generally speaking , what this means is that complaints need to be handled fast enough so that you would reasonably be able to draw conclusions that are necessary in a time that is -- that allows you to make the decisions that you need to make. It's not a perfectly defined, exact period of time. However, it's something that you really should be determining - what that time period should be based on the information that you know about your device, know about your Quality System, and should have built into your procedures - how you're going to view that. Not every complaint needs to be handled at the same

speed as every other complaint. However, your procedures should have mechanisms in place for how you determine what that time period is, and how you are actually defining it so that you are getting this done in a timely manner.

Joseph Tartal: Correct.

Tonya Wilbon: And I'll add also with regards to the requirement for timely manner, is it meeting those requirements under part 803, in your complaint handling requirements under 820.198, it requires the manufacturer to evaluate that complaint, to determine whether or not that event is to be reported under 803. So there are certain specific time frames under 803 in which you are required to submit that information to the agency. So some of those requirements under the complaint handling requirements for making or having timely actions and activities completed, is so that you can meet other regulatory requirements as well.

Joseph Tartal: It's tied to your Medical Device Reporting, and there's a 5 day and 30 day requirement with regards depending on that report. So you have to do an evaluation , and if you deem it –

Tonya Wilbon: Within that time frame yes.

Joseph Tartal: You have a time frame under 803, very good point. I think too with regards to the complaints from a nonregulatory requirements standpoint, these are your customers that are putting in these complaints. You have a vested interest to respond and get back to those customers outside of just that regulatory requirement. And then on top of that -- and this is something that we see with regards to our division, Division of

Industry and Consumer Education - in seeing that consumer when your complaints are not being handled by you, they do come to FDA and that's not where you want to be, because then you have the complaints coming to the agency.

With that we'll move on to another question. If there's a Post-it note on the device regarding a malfunction, is that considered a complaint? So the question is, and you can answer this, if they find a Post-it note on the device, I'm assuming that the device is being found during servicing or is part of returned goods. Is it considered a complaint?

Stanley Liu: That's a good question again. It goes back to the definition of what a Complaint actually is. And it's written , electronic, oral, et cetera. And so if there is a Post-it note, it's an unorthodox complaint, but it is a complaint.

Joseph Tartal: Correct, and now you need to do some further evaluation as to - okay, who put this Post-it note there? Where did it come from? And I think it depends, going down that route of okay, was this a service device, where the servicer went in and found this Post-it note? Was it something that was returned, usually within your own return procedures you're aware of the returns, but if you were to receive something in the mail, now you have to do some good faith effort of doing some evaluation work.

Eric Horowitz: Yeah I think the overarching concept here, is it doesn't matter what mechanism you receive a complaint in. It could be a Post-it note, it could be posted online in some way. Any type of documentation

or verbal or really any way that you become aware of an allegation, that is a Complaint. Regardless of what medium you received it in.

Joseph Tartal: Correct. And I think -- it's an interesting question and it actually leads a little bit into our next question, which is -- and it's a follow up to the Amazon posting. If a posting about a complaint and the response time or there's postings that are not germane to the actual product, such as that it's not about the specification, it's not an allegation, but it's saying things to the effect of we'd really like to have this new feature, or you know, this product is not very good because it doesn't include this feature, would that still be considered a Complaint? And my clarifying aspect of that, if it doesn't meet the Complaint definition then it's not a Complaint. So if somebody is commenting on Amazon, hey, I got my device and the device is blue, and I really like red, that's not really a Complaint because it's not an allegation to a deficiency meeting the definition regarded to 820.3(b).

Eric Horowitz: Now, what I will say is, while it doesn't meet the definition in a regulatory standpoint of a Complaint and you're under no obligation to use your complaint handling system for those types of information, I would encourage manufacturers to leverage the systems they already have in place to handle these kinds of situations so that's still good information.

Joseph Tartal: Absolutely.

Eric Horowitz: You're gaining information about user needs that you may not have had before, and why not use the systems you have in place to document those things. However, it's not a regulatory requirement.

Joseph Tartal: Correct, and I would agree with you, it's a great source of information to feed into your design process, because now you're talking about user needs that maybe if you start adding those, you may have more of a customer base. But I would agree. Okay, so I'm going to move to another question, and this, we're getting a lot of these service questions. Is replacing a part during servicing considered to be a Complaint?

Tonya Wilbon: So I'll take that. Certainly if your servicing procedures dictate that you are to replace a certain or specified component of that particular finished device within a certain time period, and that is what you are performing, then no, that is not considered a Complaint. It's considered servicing as part of the design of your full finished device. So that would not be considered a Complaint.

Eric Horowitz: The one thing that I would say on top of that is, if on the other hand you went out there to do servicing and you're replacing this part when you didn't expect to, where it's not part of your servicing procedures, it's not something that is part of routine servicing, you're replacing this part because you noticed there was something else wrong. That absolutely can be considered a Complaint, and may potentially be considered a recall.

Joseph Tartal: Correct, it depends on the situation with the complaint. So it all comes back to the expectation. So if I'm going out to service part A, and as I'm doing part servicing of A, I notice oh, part B is looking really bad, and there's no expectation that B should be wearing out at this time, that then becomes a different ball game. Good.

Another question on complaint closures. Should a complaint be closed if a related CAPA is open, or the complaint should remain open if a related CAPA is open? So now we're talking about how complaints feed into CAPA and how we set up those systems. And you talked a little bit earlier about complaint closure, so…

Eric Horowitz: So similarly to what I said before about complaints not having a regulatory requirement to be closed, the same is actually true of CAPAs. There is no regulatory requirement that you close a CAPA, per se. And so what's important is that the systems work off of each other properly. So if you have systems in place where closure is your mechanism for understanding certain things about your complaints or about your CAPA, then you should be using those systems the way that your procedures lay it out . But the important thing really is that you're maintaining that information in a way that is useful for both systems. So if you have a complaint that requires additional investigation, and that information is being fed into an investigation that's being done under the CAPA system, you should be knowingly closing that investigation of that complaint with the understanding of how that affects the CAPA that has its own investigation, that is looking at really the causes and how to prevent recurrence . So it's not a question necessarily of there's a certain time when you should close one or the other, or both.

It's really important that whatever system you're using, it's what works for your Quality System, and what really enables that proper feeding into each of the systems.

Joseph Tartal: Correct, and I think that's where I've seen firms get into trouble, is they either put in their procedure all complaints will be closed

by X amount of time, and they don't really understand well why does that X amount of time have a meaning. Or they'll do something where everything is open ended and you go okay, it's been six months and nothing has been said on this complaint or this CAPA, what's going on with it.

Tonya Wilbon: Right. I would like to add, as Eric has indicated, that's perfectly acceptable to handle or to address your investigative activities that way. But when you do that, you want to make sure that you reference that CAPA into which you will be performing that investigation. Otherwise, the documentation for your complaint- handling requirements will be incomplete. Because you won't know which CAPA investigation also addressed that complaint. So you want to make sure that you reference the CAPA on which the more in-depth investigation is being done.

Joseph Tartal: Correct. I think where I've seen that happen, we've talked earlier about similar investigations. Where you'll have something that will start the complaint handling system, you'll see trends, you'll see reference to CAPA. But now you need to make sure that those particular complaints are being referred to a specific CAPA so you can trace all of those things together.

Tonya Wilbon: Yes.

Joseph Tartal: That's where I've seen it come up - like I said, the similar ones where okay we've already done an investigation we know this is the issue, but this needs to be further investigated outside of CAPA.

Eric Horowitz: And the other aspect of that is also understanding where the differences lie in your systems for investigation between the different systems, because your complaint handling system may have specific requirements about things you should be looking for in terms of the event that was involved, that may be questions that your CAPA system assumes you already asked. And so, I would be wary of closing that complaint investigation assuming that the CAPA investigation will cover the same information.

Joseph Tartal: Correct.

Stanley Liu: Yes, there needs to be traceability above all so that when you have any transfer between Complaint Files and CAPA, that you know exactly what happened to this complaint file, and where it ended up, whether it ended up finished or in CAPA. Additionally, there's always the possibility that a closed complaint may be opened again, because there is another issue that came in, another one of those types of issues, in which case, then you have recurrence. Then instead of just a complaint being handled, you may now need to take that as a new incident and refer it to CAPA due to recurrence.

Joseph Tartal: Okay, so we have time for at least one more question that I've received online.

When customers do not respond after a complaint is given, how many times do we have to follow up with a customer before we can again, using that term, close the complaint? So do you want to answer this, Stan?

Stanley Liu: There is no regulatory driver for that type of closure. Basically, what you have to do is give a good faith accounting for that particular closure - if you try, for instance, three times or something like that, and you can't get through. Or if you got through and then you left a message but they never called you back , but you don't try another time -- it depends on the situation. But as long as it's really a good faith effort to contact the original complainant then the FDA would have considered the fact that you have done that, and that it is a notification .

Joseph Tartal: Ccorrect, and I would add to that, what have you defined in your established procedures, like what have you defined as to how many times you're going to reach back out, how are you going to reach back out? And as long as you're meeting those needs, then you're probably going to be okay with regard to having shown or given objective evidence of making that good faith effort.

Eric Horowitz: Yeah , and the one thing I would caution about is how you reached out, because a good faith effort means that you actually made an attempt and were actually trying to get in contact with them, as opposed to if you made a very minimal effort and kind of pinged areas where you thought they might be without a lot of real effort to try to actually get information from them. It might be viewed differently than if you truly made an attempt to contact them.

Joseph Tartal: Correct. And document those attempts, too, that you have it documented.

Tonya Wilbon: I'll just add that the Preamble to the Quality System Regulation includes FDA's response to a comment that is very similar to

that. And an example FDA provided was be mindful that you know just one telephone call to your complaint is not considered by the agency as good faith effort. So to obtain some additional information, you can review the Preamble to the Quality System Regulation, which does include FDA's response to comments received to that regulation.

Joseph Tartal: And helps you understand the expectation of what the agency is thinking.

Tonya Wilbon: Yes.

Joseph Tartal: With that, we'll have Stanley give his last thoughts on Complaint Files.

Stanley Liu: I think that Complaint Files are an often neglected part of the Quality System. It's mandatory, and yet people don't always take it that seriously. But if properly leveraged, the Complaint File System can be used to learn from mistakes. And when you do that, not only will you increase the product safety and effectiveness, but you'll also increase the product longevity, conceivably, as well as market share. And market share is very important to every manufacturer. So thank you.

Joseph Tartal: Thank you. So this now concludes the session on Complaint Files and today 's Industry Basics program.

If we didn't get to your question today or if you have any new questions in the future, please reach out to us at DICE. You can find our contact information at www. FDA.gov/DICE. Please take a few minutes to fill out the survey about today's program. The survey is listed on our website, and your feedback is very important to us. Today's program, both the

presentations as well as the question and answer segment, will be posted to CDRH Learn in about a week's time. I'd like to thank the entire FDA team who put this program together, especially our expert panelists, Vidya , Stanley, Tonya and Eric. And our FDA studio team who put on this production. And to the DICE team members who fielded your questions behind the scenes. Most importantly, I'd like to thank you, our audience, for joining us today. DICE is here to help you navigate the complex medical device regulatory landscape, so we look forward to helping you in the future. Remember, we're just a phone call or email away. Thank you for joining us today, and we'll see you next time.

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