

FDA Webinar: Final Guidance on Medical Device Reporting for Manufacturers

Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time all lines are in a listen only mode until the question and answer session. At that time if you would like to ask a question you may do so by pressing Start then 1 and recording your first and last name? Today's call is being recorded. If you have any objections you may disconnect at this time. I would now like to introduce your host for today's call. Ms. Irene Aihie you may begin.

Irene Aihie: Thank you. Hello and welcome to today's FDA webinar. I am Irene Aihie of CDIH's office of communication and education. On November 7, 2016 the FDA issued the final guidance document on medical device reporting for manufacturers. This guidance document is intended to assist medical device manufacturers in meeting applicable reporting and record keeping requirements for certain device related adverse events and malfunctions. The focus of today's webinar is to share information and answer questions about the final guidance document.

Today's presenter is Dr. Isaac Chang Director of the Division of Post Market Surveillance in the Office of Surveillance and Biometrics here in CDRH.

Following the presentation we will open the line for your questions related to topics in the final guidance only. Now, I give you Isaac.

Isaac Chang: Good afternoon. I'm going to start today's presentation with a brief overview of the MDR requirements. After that I'll focus on the discussion on a few areas that have been updated since the 1997 version of this document. The MDR guidance document describes and explains the aspects of the FDA's medical device reporting regulation applicable to manufacturers of medical devices. The MDR regulation sets forth reporting and record keeping requirements for certain device related adverse events. This regulation can be found at title 21 of the Code of Federal Regulations part 803. And it implements section 519 of the Federal Food, Drug, and Cosmetics Act. The regulation itself establishes the reporting requirements for device user's facilities, manufacturers, and importers.

The MDR regulation provides a mechanism that allows FDA as well as device manufacturers to identify and monitor adverse events. Specifically deaths, serious injuries, and malfunctions involving medical devices. The goal is to detect and correct problems in a timely matter. So what types of events must be reported to FDA. Events where a manufacturer suspects that one of their medical devices may have caused or contributed to a death or serious injury. Manufacturers are also required to report certain malfunctions even if that - if the event does not involve a patient. These requirements are described in great detail in section 2 of the guidance.

Aside from reporting adverse events other additional requirements are discussed in section 3 of the guidance. Manufacturers must conduct a complete investigation of each event or complaint they receive. They are required to report all information in their possession that is relevant to the adverse event. They must have and must have implemented written

procedures. They need to establish and maintain MDR event files, and manufacturers must ensure that there - there is a system in place to provide access to information that facility - that facilitates timely follow up and inspection by FDA.

I want to focus for a moment on the highlighted words on the previous slide. As it's important to realize that it's not necessary to establish causality. A manufacturer's medical device may not have cause but may have contributed to the death or serious injury of a patient. The word may is important as it implies discretionary judgement on the part of a manufacturer to consider how their device may have been a factor in a death or serious injury. For example a failure or a malfunction of the device may not directly injure the patient but may inhibit treatment of a patient. A critical component of a device may not be robustly designed in - and may be prone to breaking. Or may - it may the imperfections in the manufacturing process contribute to poor performance of the device.

Labeling issues and inadequate or even ambiguous instructions may contribute to improper usage of the device. Deaths, serious injuries and malfunctions are reportable events. Of the three, the one that is often the most difficult to discern is the serious injury. According to the MDR regulation a reportable serious injury is defined as an injury or illness that is life-threatening or results in permanent impairment or damage to a body function or structure. Or -- and this is crucial -- requires medical or surgical intervention to preclude permanent impairment or damage to a body function or structure. The first two conditions are a little bit more intuitive than the third condition. But it's worth clarifying a few points.

Life threatening does not have to be a permanent condition. A life threatening event -- even if it is a temporary threat -- is still a reportable event. For the

second condition - permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage. This does not automatically rule out all cosmetic damage. As not all cosmetic damage is considered to be trivial. Also of note is that it is not just damage to a body structure but also body function. This definition would include -- for example -- some instances of chronic pain. Where the chronic pain does - is a result of a device used that impairs a - impairs a body function.

The last - that's actually traceable to the - to the procedure that - that caused it. The last condition is one that is often forgotten. An illness or injury or illness that requires medical or surgical intervention to preclude permanent impairment or damage to a body function or structure. If you have an injury in which you must perform a medical procedure so that a permanent impairment does occur - it is a reportable event. So say supposing I have a medical device that I use in or near my mouth. And the device fails in a way that a piece of the device breaks off and enters my mouth and cracks a tooth. Is this a serious injury? Yes. Because it resulted in a permanent impairment or damage to a body function or structure.

Suppose the piece of the device lodged itself in the back of my throat and obstructed my airway and I needed the Heimlich maneuver to dislodge it? Is that a serious injury? Absolutely. It doesn't matter if the life threatening part was temporary it's still reportable. What if I can't - what if I couldn't get the - get the piece out on my own but I was still able to breath? I'm reminded of ball point pen caps several years ago that were specifically redesigned to allow breathing even if they couldn't be dislodged from a child's mouth. Is that a serious injury? Yes. It will require a surgical intervention to preclude permanent impairment or damage to a body function or structure.

Let's switch gears and talk about malfunction reports. Please note the 'and' condition. Previous slides said or, this one says and. The device fails to meet its performance specifications or otherwise perform as intended is the definition of a malfunction. The second part -- the device is likely to cause or contribute to a death or serious injury if the malfunction were to occur -- is what makes it a reportable event. So when is something likely to cause or contribute? This is discussed in detail in sections 2.14 and 2.15 of the guidance document. There is a presumption that a malfunction is likely to cause or contribute to a death or serious injury if the malfunction has already caused or contributed to a death or serious injury. There are additional conditions listed in section 2.14 that describe specific situations where device fails in a catastrophic way or maybe substantially - may substantially impact the devices ability to function as a life supporting or life sustaining device.

I now want to spend a few minutes talking about who reports adverse events. While this guidance document addresses manufacturer specific MDR reporting requirements. A reportable death, serious injury, or malfunction is based on information the manufacturer receives or otherwise becomes aware of from any source. Therefore it is important to understand what the reporting time frames are. Not only for manufacturers but for each potential reporting entity. This chart summarizes the timing for mandatory reporting based on 21 CFR part 803. Manufacturers are required to report deaths, serious injury, and malfunctions within 30 days of becoming aware. They are further required to report events that require remedial action to prevent an unreasonable risk of substantial harm within five days of becoming aware that the event requires remedial action.

User facilities are required to report deaths to both FDA and the manufacturer within 10 working days of the adverse event. And they are required to report serious injuries to manufacturers within 10 working days. And to FDA if they

cannot identify the manufacturer. Importers report deaths and serious injuries to FDA and manufacturers within 30 days. But report malfunctions only to manufacturers. And of course voluntary reports can come from patients, physicians, and user facilities in the case of malfunction reports at any time. These are the basic requirements which are discussed in detail in section 2 and 3 of the guidance document. Section 4 covers specific issues and situations. Section 5 of the guidance talks about the logistics of how to file a report including specific references for how to submit reports electronically to FDA.

So what's new in this guidance? I wanted to highlight a few topics. When a firm becomes aware that an MDR reportable event has occurred the rules for submitting adverse event information involving marketed devices under an IDE. Foreign events, exemption request processes, clarifications for five day reports and remedial actions, and clarification of the 2 year presumption for reportable malfunctions.

Becoming aware. If any of your employees become aware of information that reasonably suggests that an event is required to be reported in a 30 day report or any five day report that we have required from you. Notice that it says reasonably suggests. It does not say you have definitively determined that the adverse event is a reasonable - or is a reportable event. If the information you have reasonably suggests you become aware. Also you become aware if any of your employees with management or supervisor responsibilities over persons with regulatory scientific or technical responsibilities -- including consultants or contractors -- or whose duties relate to the collection and reporting of adverse events. So -- I highlighted including consultants or contractors -- specifically to draw your attention to situations in which a manufacturer uses third party consultants and or contractors who perform complaint handling or MDR reporting functions.

For purposes of MDR reporting FDA considers the consultants and contractors to be agents of the manufacturer and hence the manufacturer becomes aware when these agents become aware. On the issue of MDR's for investigational device situations. If a device is legally marketed in the US and is also under an investigational device exemption. Any adverse event that involves the investigational use of the marketed device are subject to reporting under both the IDE and the MDR regulation. The note that this applies to the non-investigational device is there to remind everyone that we're not talking about the investigational device. That's actually bullet number two. Investigational devices should be reported under the IDE as per 21 CFR part 812.

Going back to the first bullet. The phrase investigational use of the marketed device are subject to reporting under both the IDE regulation and the MDR regulation requires a little clarification. The key lies in the manner in which the device is used in the investigational study. If the device is used in a manner that's consistent with its marketed indication for use then its MDR reportable. However, there are situations -- IE in bullet number three -- where the marketed device is used as the investigational device itself with new indications for use. Since the investigational use is not a marketed indication for use, and the study itself may not lead to a market indication. Adverse events of a marketed device used as an investigational device consistent with a new indications for use should be reported under the IDE. Marketed devices used as an investigational device under the labeled marketed use of the device need to be reported as MDR's.

This slide summarizes the requirements for foreign adverse event reports. These are addressed more fully in section 4.11 of the guidance document. This too can be confusing, complicated situations. If the firm that makes the device is a US firm and the device is marketed for export only. Foreign adverse

events are required in situations where there is a device concern. And FDA need's information regarding these foreign events. If the firm makes and markets the device in the US and an adverse event occurs outside the US. Adverse events occurring outside the US are required to be reported. If a foreign firm markets the device in the US. Then reportable adverse events that occur outside the US must also be reported.

If the device is not marketed in the US regardless of whether it is being studied under an IDE there is no requirement to report MDR's unless a similar device that you market in the US would be likely to cause or contribute to a death or serious injury. The MDR regulation defines the manufacturer to include any firm that initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating this specification. A contract manufacturer is a second - is the second party who manufactures the device on behalf of the specifications developer. This guidance clarifies that if the contract manufacturer does not distribute or market the devices that it makes it would not have MDR reporting obligations.

No exemptions are needed in this situation. If the contract manufacturer decides to also market the devices they make then both the contract manufacturer and the specifications developer have MDR reporting obligations. Because both of them are marketing the product. If either the contract manufacturer or specifications developer wants to report on behalf of the other then an exemption is needed as one firm would be representing the other firm. A five day report is a report that must be submitted to FDA within five work days after the day you become aware of an MDR reportable event that necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. They're also required when FDA requests them but let's put that aside for the moment.

The five day's start when an employee with management or supervisor responsibilities becomes aware of the event. That is that you have become aware that a reportable event necessitates a remedial action to prevent an unreasonable risk of substantial harm to the public health. It is important to understand that this may not necessarily correspond to five days after you have become aware of the adverse event report itself. If during your investigation of the adverse event you discover that substantial harm may result to public health if you do not intervene you are required to report this within five days of this determination. For example. If 6 days after you become aware of an adverse event you determine that it is - that it is a reportable event that requires remedial action to prevent substantial harm to public health. You have until day 11 to file this report.

The spirit here is that FDA cannot wait until day 30 to hear about this event. Certainly it's in everyone's interest to make sure that an issue that requires remedial action be addressed as early as possible. Remedial action isn't any action other than routine maintenance or service of a device necessary to prevent recurrence of an MDR reportable event. Recurrence is a key word. A correction that applies only to a single device is not considered to be a remedial action. Not all MDR reportable events that require remedial actions need to be reported as five day reports. Just the ones that require remedial action to prevent an unreasonable risk of substantial harm. If there are a series of events. The initial report is reported as a five day report. All subsequent reports associated with that specific remedial action should be submitted as 30 day reports instead of five day reports. Unless otherwise instructed by FDA.

The last area that I wanted to highlight today is the discussion of the two year presumption for likely to events. The MDR guidance for manufacturers issued in 1997 stated that once a malfunction has caused or contributed to a death or serious injury a presumption that the malfunction is likely to cause or

contribute to a death or serious injury has been established. This presumption will continue until either the malfunction has caused or contributed to no further deaths or serious injuries for two years. Or the manufacturer can show through valid data that the likelihood of another death or serious injury -- as a result of a malfunction -- is remote.

In the 2013 draft guidance, FDA indicated that manufacturers could request an exemption sooner than 2 years with data. FDA's primary concern is making sure that the manufacturers that have the potential -- malfunctions that have the potential to introduce patient harm -- be addressed. However, it was not always clear after two years whether the discontinuation of reporting was because the malfunction was fixed or that no other serious injury and deaths were reported. In this final guidance document FDA has addressed this concern by recommending manufacturers submit a notification to FDA with a summary of the data and the rationale for any decision to cease reporting at the end of two years. Alternatively a manufacturer may make an argument under an exemption request to discontinue reporting sooner than two years if they have evidence that demonstrates that the malfunctions cannot recur. In this situation the manufacturer should continue to report until FDA has rendered its decision on the exemption request.

In this presentation I have highlighted the major challenges - the changes between this final guidance and the previous version. There are several sections of this guidance that we were not able to cover in great detail. I would strongly encourage you to look at section 4 of the guidance document which covers specific issues and situations. For further information on how to report MDRs to FDA electronically. And the definitions of the data elements on the FDA 3500 A - please see section 5. Thank you so much for your attention I'd be happy to take questions at this time.

Coordinator: At this time I would like to begin the formal question and answer session of the call. If you'd like to ask a question please press Star then 1 and record your first and last name. To withdraw your question you may press Star then 2. Again to ask a question please press Star then 1 and record your first and last name. One moment for the first question please.

Irene Aihie: Please hold for our first question. Operator are you there?

Coordinator: Our first question comes from (Keith Worgood) for Berger Dutronics. Your line is open.

(Keith Worgood): Yes my question is - is electronic reporting of MDRs mandatory or are companies still allowed to submit MDRs in a paper based system?

Isaac Chang: So electronic reporting of MDRs is mandatory for manufacturers at this time. This went into effect in August of 2015. And remains - remains so.

(Keith Worgood): Okay thank you.

Coordinator: Next question comes from (Wendy Kavenough). Your line is open.

(Wendy Kavenough): Hi. I just wanted clarification on medical intervention. I've had some associates I've worked with that a Band-Aid on a small cut is a medical intervention and does need to be reported. Where others say something more serious needs to be reported. How is that looked at?

Isaac Chang: So medical intervention here. There are - there are a lot of different situations. So it's - it's - there isn't going to be a one set of rules for everything. I think one of the things that we, you know, are not going for is every time somebody takes an aspirin that's a medical intervention. I think one of the things that we

are looking to do is - either - especially in the - in the frame of making a determination that something is a serious injury. We really want to look at procedures that potentially impact the health of a - the health of a patient. So you can really think about it in terms of, you know, what kind of risk is the patient going to be, you know, if you, you know, do not do that intervention? So in the example that you have of a Band-Aid. It does - it really doesn't put the patient in per se at additional risk.

Which is one of the - which is one of the reasons that, you know, we are looking -- we do want to consider -- I think the example I gave as doing the Heimlich maneuver to actually, you know, unclog an airway. In that example, you know, if for some reason you didn't do the procedure - you're exposing the person to additional risk and potentially life-threatening situation right? So - so while I understand, you know, there's something of a discretionary call that you need to make. One of the - one of the, you know, concerns - and I hear the concern because I think the concern that you're bringing is one of. Well if, you know, if I don't report and I did a medical intervention like a Band-Aid is this - is this going to be problematic from a compliance point of view?

And I think the - the short answer to that is you need to document the rational. You know, I think if your saying that, you know, this -- a minor procedure like putting - applying a band aid -- isn't really going to really going to add to the risk of the patient or has no, you know, tangible impact like that. That's sufficient for, you know, for - for not - as a rational for not reporting that.

(Wendy Kavenough): Okay thank you.

Coordinator: Next question comes from (Anderson Dirazo). Your line is open.

(Anderson Dirazo): Hello how are you? I have a question. As an importer if you are notified of an event that requires an MDR be filed. How much of an investigation are you expected to perform? And to elaborate on that -- as an importer -- you don't have probably enough knowledge of the design. For instance you don't have the engineers who designed it and stuff. So how much of an investigation do you have to perform? And my second question. Are you expected to be the one making the decision if a recall is necessary? Or is that only the manufacturer?

Isaac Chang: So the MDR regulation itself has a section for importers. And we didn't specifically cover that on this call and I would refer you back to the section in the - in 803 that specifically addressed what the importers are to do. In brief, you know, importers - its true importers do not always have all the information they need to make - make a decision. But whatever information that they do have is helpful to both FDA and to the - and to the manufacturer. And so what we are asking in the regulation is for importers to provide whatever information that they actually have.

(Anderson Dirazo): Okay thank you. Oh I'm sorry. And how bout in the case of a recall? Are we expected to make that decision or only the manufacturer can do that?

Bill Maloney: I think that would be something for Division of Industry and Consumer Education. Recalls are kind of beyond the scope of this discussion today.

(Anderson Dirazo): All right no problem. That's it. Thank you very much.

Bill Maloney: Oh I'm sorry guys my name is Bill Maloney.

(Anderson Dirazo): Thank you sir.

Irene Aihie: We'll take our next question.

Coordinator: Next question comes from (Robin Strosinger). Your line is open.

(Robin Strosinger): Yes. Hi. Thank you. I have a question regarding a statement on page 12 of the guidance document. With regards to similar devices. My company distributes tissue adhesive that is manufactured and the legal manufacturer is in Europe. And in Europe they have additional intended uses. So some of those intended uses include internal surgical uses. In the US we have a 510k cleared just for external use of the tissue glue. So when we have - when we're notified by our -- our corporate partners -- regarding an adverse event that may have occurred with the same product that we sell in the US. However, it is not approved here in the US for that - that particular use. And has a different instructions for use. Are we reported - are we required to report that as an MDR? Hopefully that made sense.

Isaac Chang: Okay so. Let me run that back. So you are - you have a device that is - you have a device that is manufactured outside the US correct?

(Robin Strosinger): Correct.

Isaac Chang: Let me just - let me just actually get back to slide 12 so that it's - so that it's easy to see. You're talking about this right?

(Robin Strosinger): Well we're not the legal manufacturer. We're the importer and distributor for our parent company.

Isaac Chang: I see.

(Robin Strosinger): Yes.

Isaac Chang: Okay. And so you're an importer of a device.

(Robin Strosinger): Mhmm.

Isaac Chang: And - I'm sorry can you run that through again?

(Robin Strosinger): So the device in the US is cleared for an external use - it's a tissue glue. In Europe the device is approved to be used to different internal surgical uses as well. In the US that's considered a class three use of the device and would need a PMA. So in the US we - we sell the product with an instruction for use to only be used topically. And that's how we market it. However, because it is a similar device when there is an adverse event outside the US that occurs for an intended use that we don't have approved here in the US. We have -- on those occasions -- submitted an MDR and it has seemed to cause confusion.

We have had follow up questions from FDA about this. But the fact of the matter is we don't have the approval for that particular indication or intended use. So in - on page 12 when it says that FDA generally considers the device to be similar to another device if the device has the basic design and performance characteristics intended use and function. So in this particular case it's the same exact product however, it doesn't have the same intended use.

Bill Maloney: This is - this is Bill Maloney. If the device is being used outside the United States for a different intended use and the malfunction or death or serious injury are related to that different use - not to the same use that it would be used in the United States - then that would not be reportable. But if it is being used under the same conditions and indications in the US then it would be reportable.

(Robin Strosinger): Okay. That's exactly what I was looking for. Thank you.

Bill Maloney: Sure.

Coordinator: If you could please limit your questions to one question per person. If you do have additional questions you may re-queue. Again that was one question per person. If you do have additional questions you may re-queue thank you. Our next question comes from (Sheryl McCarthy). Your line is open.

(Sheryl McCarthy): Hi thank you. I have a question about -- on this very chart -- the difference between marketed in the US and registered in the US. And our question is are we required to report MDRs on products that are manufactured outside the US, currently sold outside the US, but not yet sold and marketed in the - not yet placed in the US but registered for sale in the US.

Isaac Chang: The answer to that is yes. Because the registration is -- the device -- if your registering in the US you could potentially market it here.

(Sheryl McCarthy): Okay thank you.

Coordinator: Our next question comes from (Sherry Wang). Your line is open.

Irene Aihie: Caller are you there? Operator we'll take our next question.

Coordinator: Our next question comes from (Donna Smith). Your line is open.

(Donna Smith): Hi. I had a question regarding the reporting requirements for distributors of medical devices.

Isaac Chang: Okay.

(Donna Smith): Is - is a distributor also required to report an adverse event or are they supposed to report it to the manufacturer and have the manufacturer report it?

Isaac Chang: So let me - let me take you back to this chart for a second. According to this chart importers - importers have a reporting obligation. But as a distributor specifically - a distributor does not.

(Donna Smith): Okay. Will it - so do we have any - would it be an obligation to report it to the manufacturer or not at all?

Isaac Chang: So it would be - it would be a good thing to probably report to the manufacturer but there is not specific...

(Donna Smith): Okay.

Isaac Chang: ...the part 803 is silent on that.

(Donna Smith): Okay. Okay. All right. Thank you.

Coordinator: Our next question comes from (Brian Vogul). Your line is open.

(Brian Vogul): Yes hi. On the new draft guidance final on page 1 it talks about device related adverse events and certain malfunctions. Can you clarify your definition of an adverse event? Is this specifically considered a serious injury or death? Or is it also considered a malfunction as well?

Isaac Chang: We consider adverse events to be death, serious injury, and some malfunctions. So, you know, as we talked through the presentation we - we're

interested in hearing about all of them. Part of the reason we're interested also in the malfunctions is because - as we talked through the presentation -- in the presentation -- the reportable malfunctions are malfunctions that, you know, are situation where, you know, the malfunction may have caused or contributed to a death or serious injury eventually to occur. That kind of implies that there are a class of malfunctions that you have that may present some risk. And I think that's, you know, that's sort of - I agree it does look a little strange to say malfunctions is an adverse event. But that's the reason why we include it under the definition for purposes of the guidance.

(Brian Vogul): In the journal articles or medical review. They state new in the final draft that an adverse event -- if it happened at multiple times at different dates of time -- to remain those as separate MDRs. I was just trying to clarify that an adverse event at that point was a serious injury or a malfunction.

Isaac Chang: It can be - again it could be either one. So if you have malfunctions that are associated in a chain of events. Those can also be considered to be reportable events on their own.

(Brian Vogul): Okay thank you.

Isaac Chang: And would need to be - and would need to be reported separately.

(Brian Vogul): Okay. Thank you.

Coordinator: Our next question comes from (Denis Regin). Your line is open.

(Denis Regin): Hi. My question may be somewhat related to the last one. Back to slide 11. The indication there for that chart was for adverse events. And so I guess the clarification was whether this applied to malfunctions as well.

Isaac Chang: Yes. And for the reasons that the last caller just had. Adverse events - the way we're using the term adverse event here - is in the broader definition of adverse events being death, serious injury, and malfunction reports. And for the reason that the malfunction reports. They're reportable malfunction reports because they may cause or contribute to a death or serious injury if they should occur.

(Denis Regin): Thank you.

Coordinator: Our next question comes from (Mike Rencurry). Your line is open.

(Mike Rencurry): Hello. I had a question. We import acupuncture units and needles, and we use them on animals. What would he have to do for reporting for that? Sometimes the owners will use this method as a last resort. So the dog may be old or sick and then sometimes something may occur. What should we do for that case?

Isaac Chang: So -- I just wanted to get a clarification -- so they - the usage of the acupuncture is on animals and not humans right?

(Mike Rencurry): Yes exactly.

Isaac Chang: Okay. So that kind of goes a little bit beyond the jurisdictional bounds of the MDRs. The MDRs is really talking about human patients. Not animal patients.

(Mike Rencurry): Okay great. Thank you.

Coordinator: Next question comes from (Trisha Koffman). Your line is open.

(Trisha Koffman): Hi thank you. I had a question about the two year presumption and the clarification that's now provided in the new guidance. For discontinuing reporting after two years with notification of FDA with data and rationale for discontinuation. In what circumstance could you expect FDA to come to respond to that? To respond to your notification.

Isaac Chang: Well we - the guidance does say that we could come back. I guess one of the prevailing thoughts is. You know, from FDA's point of view, you know, if you think about how this is set in motion. A malfunction occurred, we found that there are also presumably a death or serious injury. Which made the malfunction into a reportable event. And if the malfunction is continuing to occur after two years. You know, we're concerned of why that is. And if we - I mean regardless of any notifications. If a malfunction is - that was a repairable malfunction is continuing to happen two years out - that's concerning to us. And so we wanted to understand the rationale. We didn't want to just have folks stop reporting after two years with the - with the assumption that the problem has been resolved. You know, if you're one day short of two years and you're still having issues we want to understand why that - that's happening.

And so in the rationale that you provide to us. If you're providing it of the indication that, you know, sort of explains what we - we've seen the drop off on the issue, we've done these corrective actions, you know, here's how we know that this has actually been effective. That provides a much more enriched means for us to evaluate, you know, from a patient safety point of view. Now if you're asking a situation an "oh what situations would we" I think your question is what situations would we, you know, come back to you for additional information. Well if what you provided us is, you know, simply saying. Well it's been two years and we haven't seen any other events - we may probe a little deeper just to figure out, you know, why - why that is.

Because, you know, it would be unclear to us that the problem itself hasn't resolved. That make sense?

(Trisha Koffman): Yes. Mhmm. Thank you.

Coordinator: Next question comes from (Miraj Patel). Your line is open.

(Miraj Patel): My question has to do with like medical diagnosis. When there are injuries going on - and of there are diagnoses that occurred. Like for example a knee meniscus injury, a twisted ankle, back pain, a broken foot - for example. Why is it taking the government four years to recognize these medical injuries when there's ample evidence? And frankly taking four years to even certify these medical injuries.

Irene Aihie: Thank you so much for your question. Unfortunately that question is outside the scope...

(Miraj Patel): No you can answer my question.

Irene Aihie: ...of this webinar. Hello?

(Miraj Patel): Yes.

Irene Aihie: Yes that question is out of the scope of today's webinar so please send that question to the...

(Miraj Patel): Why is that out of the scope if there are medical devices involved in relation to any serious injuries...

Irene Aihie: Thank you so much for your question. Yes please send that question to DICE@FDA.HHS.GOV. Thank you. Next question please.

Coordinator: Again if you have a question please press Star then 1 and record your first and last name. One moment for the first question please.

Irene Aihie: One second as we get callers back on the line for questions.

Coordinator: Next question comes from (Sheryl McCarthy). Your line is open.

(Sheryl McCarthy): Hi. So I have a question regarding the off label use of medical device. If customer use our device off label. And if they have a complaint on it should we file an MDR?

Isaac Chang: They can always submit a voluntary MDR to the FDA. They can do that through the Med Watch portal. Or they can go online and - the best place to go is to go to Med Watch. I think we have a link.

(Sheryl McCarthy): Okay. So - so should manufacture file MDR?

Isaac Chang: So manufacturers if they're aware of adverse event report with their own product or with - is it some other product?

(Sheryl McCarthy): Even if customer use off label. We also have to file MDR?

Isaac Chang: Yes. Because the requirements to report the MDR has to do with, you know, for manufacturers. It has to do with your products.

Bill Maloney: This is Bill Maloney. If there is a death or serious injury - even if the device is being used off label. And even if there is a user or use error with the device.

Then because the device caused or contributed to a death or serious injury it would have to be reported as an MDR.

((Crosstalk))

Coordinator: Next question comes from (Evelyn Henry). Your line is open.

(Evelyn Henry): Hi. My question is in reference to filing the MDR electronically? If I have a component -- we already established that it is an adverse event -- and it had five different components. Could I file one - all the parts on - under one MDR submission? Or do I have to file five - file five -- or however many components -- separately?

Isaac Chang: So the answer to that is yes. You have to file them all separately. MDR - EMDR - in the MDR regulation where there's a link in section five. It specifies there that one report -- each MDR report -- should reflect one MDR device and one event.

(Evelyn Henry): Tell me again about - where is section five at? I'm sorry.

Isaac Chang: Section five - I'm sorry - section five of the actual MDR reporting for our manufacturers.

(Evelyn Henry): I got you. Thank you.

Isaac Chang: Yes if you go to the main document and it's - its section five.

(Evelyn Henry): I understand. Thank you.

Coordinator: Next question comes from (Caroline Seer). Your line is open.

(Caroline Seer): Hello. Thank you. I would like to know whether a US agent for foreign manufacturers could file an MDR report on behalf of the foreign manufacturer.

Isaac Chang: So is your question can a domestic manufacturer file on behalf of a foreign manufacturer? The answer is yes, if they - if they have an exemption with us. Because - and the reason why you need an exemption in that case is because one party is representing another party. Both of which have reporting obligations.

Bill Maloney: This is Bill Maloney. This - that's called a single reporter exemption. And if -- for instance -- an importer and a foreign manufacturer wish to only submit one report. They can apply for an exemption. And if you want additional information you can send an email to that mdrpolicy@FDA.HHS.GOV email address if you want additional information on how to submit a single reporter exemption.

(Caroline Seer): Okay. Thanks a lot.

Coordinator: Next question comes from (Kristine). Your line is open.

(Kristine): I guess you're talking about me? My question is regarding the - the use - our instruments are used for - in future diagnostics. And they're used in combination with lab developed test methods. And one of the things that we run into sometimes - the lab developed test method may actually be the cause of - not necessarily a serious injury but it may appear to be a device malfunction. So when we get that information and they say we've reported incorrect results of our testing - they immediately jump to it being the device malfunctioning. It takes us a while to determine what actually caused it. Are

we required to report from the day that they tell us that, you know, our device may have malfunctioned? Or once we've actually determined no it may not be our device that caused it. Your method is the problem? We're having a lot of grey areas with this.

Bill Maloney: This is Bill Maloney. When you receive that information. Once it reasonably suggests that your device has caused or contributed to the malfunction then it would be reportable. Now if at some point in the future you receive additional information that indicates the device -- that your device did not cause the contribute -- then you can submit a supplement and indicate that in the supplement. But there's a presumption of reportability once -- and the phrasing that's used in the regulation -- is reasonably suggests. So if you don't have enough information to preclude your device from being considered as causing or contributing to a - to a death or serious injury, or to a malfunction then it would be reportable.

(Kristine): So - in the event that - the problem is it takes a while to actually determine what the cause was. Some of these things can takes months to determine what actually caused it. Generally it has not been the instance that we've seen that our instrument was actually the cause. It will be the grade of a reagent that someone used. But it takes a while to do that investigation. Should we err on the side of caution and report and then follow back up and then say no it actually wasn't the instrument?

Bill Maloney: Yes. Once you -- once you determine -- once again the wording is reasonably suggest. So if you have very strong evidence that your device was not -- initially if you have very strong evidence that your device was not part of the malfunction -- then there wouldn't be a need to report. But once it reaches the level of reasonably suggesting then you would be required to report. And then as you said possibly weeks or even months later when you receive additional

information. That indicates your device did not malfunction - then you can submit that as a supplement. So yes. Err on the side of caution and submit that.

(Kristine): Okay. And hang on we have one more follow up. Sorry, go ahead.

(Julia Aker): My names Julia Aker. I have a question about non-medical devices. We - we manufacture general laboratory equipment that are not registered and listed as medical devices. They're not labeled as invetro diagnostics. Sometimes customers use them for invetro diagnostics off label. My understanding is they would not be subject to the reporting requirements? Because they're not medical devices. Is that - is that correct?

Bill Maloney: If they're not labeled in any way as a medical device and there's been no premarket submission or approval for a 510k or a PMA and someone just incidentally uses it as a medical device that would be correct. They would need no MDR required.

Isaac Chang: However, it's -- this is Isaac -- if it's in the process of trying to do that evaluation. You have causes or concerns and you wanted to reach out to us you can always contact us at our MDR Policy desk for further clarification on how to treat those cases.

(Julia Aker): Yes you might be seeing those from us. Okay thank you.

Coordinator: Next question comes from (Tim Cribbs). Your line is open.

(Tim Cribbs): Yes my - my questions in regard to life support ventilators. We're currently reporting basically most any malfunction on a ventilator. Is it now - am I

understanding that we would only report on malfunctions that could potentially lead to death or injury?

Isaac Chang: So it - what we - we have in the guidance is you need to - you need to make an assessment. As a determination of whether or not the nature of the malfunction may cause or contribute to a death or a serious injury? You know, should that malfunction occur. And that - that may have a number of factors. It's not just one factor of determination. If you - if you do an assessment of this and you document your decision. That's - that's - you're probably in a good position that way.

(Tim Cribbs): So if we do an investigation and we decide this particular malfunction would not lead to a death or injury don't report it?

Isaac Chang: If you believe that you're - if you believe that your -- the nature of your malfunction -- is not - it does not cause or contribute to death or serious injury. You may not have to report it but you will certainly need to document that as part of your MDR - MDR event file. As your - as to your rationale for deciding that way.

(Tim Cribbs): Okay. Thank you.

Coordinator: Our next call is from (Doug Huntington). Your line is open.

Irene Aihie: We'll take our next caller.

Coordinator: Our next question comes from (John Beisley). Your line is open.

(John Beisley): Thank you very much. I wanted to go back to the single reporting exemption - and specifically on slide 12 -- where you talk about the contract

manufacturer markets the device. I understood that during the presentation markets the device means in the United States. And an earlier question related to a foreign manufacturer who has listed the device but has - but does not market it. And you said there's no - there's an assumption that if it's listed that it will be marketed. So reporting is required. But my question is -- or my statement is -- that all contract manufacturers are required to list the device. So does that mean that all contract manufacturers intend to market their device?

Isaac Chang: So the decision of whether or not you - the decision of whether or not you have reporting obligations - that's a lot with whether or not you are actually - whether you're marketing your device. Now if you're - if you're a domestic firm and - if you're a domestic firm then you have reporting obligations.

(John Beisley): Well yes. But what I'm talking about though is the specification developer in the United States has a contract manufacturer in say China. The contract manufacturer in China is required to list - to register and list the device. And so - but the contract manufacturer does not market the device under its own name or anything. But they - but they list that device. So I understood that. And so there would be no obligation for that contract manufacturer to report. But then a question was asked - it says I have a foreign manufacturer who lists the device but doesn't intend to market it. And the statement was if they list the device it says there's an understanding or an ability to market the device so therefore they had reporting requirements. So the information seems to be contradictory. So I'm looking for clarification.

Isaac Chang: My recollection of the question that we had -- and I don't have the exact question in front of me -- but my recollection is that was the case of a foreign manufacturer not necessarily a foreign contract manufacturer?

(John Beisley): Okay so that's the difference - would be - foreign manufacturer versus contract manufacturer.

Isaac Chang: Yes I mean if you're a foreign manufacturer of a product then you have reporting obligations. If you're a contract manufacturer then the rules on the slide actually apply.

(John Beisley): Okay then. All right. Then that clarifies it. Thank you so much.

Isaac Chang: Thank you.

Coordinator: Next question comes from (Connie Speck). Your line is open.

(Connie Speck): Thank you. I have a question regarding MDRs for IDE situations. What if the trial you're participating in is a blinded clinical trial? How should you handle it in terms of submitting MDRs for the control unit that would be approved in the United States? Because if you submit them they become public and then you - essentially have - are endanger of unblinding the trial?

Isaac Chang: So the - the way that - apologize. The - if you take a hypothetical situation - maybe this helps clarify, you know, that - the logic on this. Suppose you have an implant procedure and you have a patient whose hooked up to a ventilator. And the ventilator itself - the ventilator itself is the - it's the cause of the adverse event. That would definitely be reportable. If you actually have a - if you have a situation where you have an investigational device - the investigational device is always reported under the IDE - but you're talking in a situation where you have two devices - one that's market approved and then one that is - that is not market approved but is a comparator in a study correct?

(Connie Speck): Correct.

Isaac Chang: Okay. So in that particular case. The device that's actually marketed is actually -- the device that is marketed and you're using as a comparator -- is a device that's being used on label whether it's indication for you. And so if there is a - if there is an adverse event associated with that use - regardless of whether or not it's part of the study. If you have a marketed device that's actually being - that's being used on label with how it's marketed - and the adverse event is - you can attribute the adverse event to the use of that device then. Then it's a reportable as an MDR.

(Connie Speck): Despite the fact that by reporting it as an MDR you could be un-blinding the study. Because that device -- that marketed device -- is the control device that you're doing a comparison against.

Isaac Chang: Well - it's - certainly you would, you know, report that as part of the IDE. The MDR - the MDR guidance is basically saying to the extent. I mean you - okay let me play this right. You do have a - there is a reporting obligation to report that event. How you report it may not - there are ways that you could probably report that such that you don't actually un-blind the study.

Bill Maloney: This is - this is Bill Maloney. One of the items is of course - you haven't become aware if the - if you haven't heard about the event. But now assuming you heard that there was an event but you don't know which particular device it was - you can submit an MDR with limited information and indicate in the text field that due to this being under IDE and your blinded to which device it was you cannot identify the device. Does that answer your question?

(Connie Speck): Yes.

Bill Maloney: I mean there are two things. One is if you don't become aware at all you don't actually have to seek out information and un-blind the study just to submit an MDR. That would - that would be inappropriate.

Isaac Chang: Right.

Bill Maloney: No reason to un-blind the study.

Isaac Chang: Yes. Right. And that's sort of what I was getting at. You don't have to un-blind the study to acknowledge there was an - that there was an adverse event associated with it. And, you know, one might think - well okay but then how am I going to know if it's the marketed product that actually was involved. In some cases you may not know what it is because it's a blinded study.

Bill Maloney: And you - you can - this is Bill Maloney again - you can submit a limited information MDR. And then when the study is eventually un-blinded you can supplement it with additional information indicating either the MDR shouldn't have been submitted in the first place because it was possibly the investigational device. Or submit additional information that it was the comparator device and here is additional information. This MDR was appropriate.

Isaac Chang: Does that answer your question?

(Connie Speck): Yes it does.

((Crosstalk))

Coordinator: Next question comes from (Purity Anon).

(Purity Anon): Hi. I have a question regarding foreign reporting of MDRs. So if we have a product that's marketed as the device in the US (But it's actually marketed as a drug in the EU but it's for the same indication. Does that mean that any reportable events from the EU will be cross reported to the FDA as well?

Isaac Chang: So as far as an indication for use that's already here in the US yes.

(Purity Anon): Okay so they will have to be.

Isaac Chang: Yes.

(Purity Anon): Okay. Thank you.

Coordinator: Next question comes from (Laura Harper). Your not - your line is open.

(Laura Harper): Yes. I'd like - can you hear me?

Irene Aihie: Yes we can hear you.

(Laura Harper): Okay. Okay great. Yes I wanted some clarification on the - when you have a malfunction that did not result in a death or serious injury and your trying to assess whether or not it would be likely too - should it recur. The wording in the guidance -- section 2.14 -- says that the chance of death or serious injury occurring as a result of the recurrence of the malfunction is not remote. And the word remote. We've had a lot of discussion about - that sounds to be a lot less probable to occur than likely to occur. Is there any clarification that you could give on what is meant by remote or not remote? When you're talking about the likelihood of - of causing a death or serious injury in the event of recurrence of the malfunction?

Isaac Chang: One of the issues with this is it's probably very dependent upon the kind of - the device that you're talking about. I think one of the - I think what the statement really is -- is hedging at -- is that you need to be able to justify, you know, why you believe that the - the recurrence of the malfunction is not likely to happen. Or is very remote right? So, you know, it - with any one of these, you know, regardless of whether it's a reportable MDR or it's not a reportable MDR. Every one of these adverse events - the manufacturer is investigating and documenting their findings. And so that should be part of your findings. So if you choose - if you choose not to report it to FDA because you believe it's remote. Then that documentation really needs to be part of your MDR file.

(Laura Harper): Okay. Is - but is there any further definition of what - what is meant by remote? We've had some discussion where some people have argued that for something to be likely it means it has to be more probable that it's going to happen than not happen. So likely means more than 50% probability that it - that if the malfunction occurs - there's more than a 50% probability that it would cause or contribute to a death or serious injury. That seems to be a lot higher than remote?

Isaac Chang: In the situation like this - I mean I think the specifics are going to be really important to help guide you further. My recommendation would be to submit that to the MDR policy branch. So you can send that to MDRPOLICY@FDA.HHS.GOV. And, you know, if you can give us a little bit more detail on the exact situation that you have - what kind of device you have. And the situation - it will be a lot easier to parse that out.

(Laura Harper): Okay. Thank you.

Coordinator: Next question comes from (April Croft). Your line is open.

(April Croft): Yes good afternoon. I have a question concerning slide 8 which kind of highlighted the what's new in the new guidance documents since the 1997 guidance document. Which is very helpful thank you for providing that. My question is - is there a means of still accessing the 1997 MDR guidance document simply for the purpose of just doing a thorough review and comparison as I'm sure everyone is interested in being sure that they're procedural updates are aligned with the new guidance document. And, you know, sometimes it's helpful to be able to do a comparison. I had noticed when I tried to do this that it - I kept - and maybe this was just a temporary issue but I - it kept telling me that what I was trying for wasn't available. And I kind of got the sense that, you know, the document was no longer available. So I wanted to just check on that.

Isaac Chang: I can say that by default when the - when a new guidance document -- or a new version of a guidance document posts -- the previous one is removed. Does that help?

(April Croft): So I guess kind of. It sounds like we just need to try to do a thorough review with the new document if it's no longer available. Yes I think that's helpful to know thank you.

Isaac Chang: Yes.

Irene Aihie: We'll take our next question.

Coordinator: Next question comes from (Harry Long). Your line is open.

(Harry Long): Hi. I'd like to go back to the last tenant of serious injury a little bit when it comes to IDE products. Specifically, you know, medical intervention or

surgical intervention that's needed to preclude or prevent. The question I have is - that seems to be more of a direct harm type of statement versus an indirect harm where you'd see with like a chemistry analyzer or something of that nature. That the actual act of having an incorrect result would not cause a serious injury but it would maybe cause a change in patient management. Is there any guidance that you can provide on the IVD side when it comes to indirect harm?

Bill Maloney: Yes this is Bill Maloney. Yes false positives and false negatives with diagnostic devices certainly can be reportable events depending on the consequences of what happens due to the, you know, what type of patient management results from the incorrect diagnosis. So in many cases absolutely that could be a reportable event. Does that answer your question?

(Harry Long): Yes and no. So if you had a medical intervention that really didn't cause anything, you know, any further harm. I mean would you still file it under the category of that third tenant of serious injury? So perhaps there was a change in medication or something of that nature. But follow up on that particular complaint indicates that there was no, you know, the medication may have been discontinued and there was no further adverse consequence to the patient?

Bill Maloney: The other thing you have to keep in mind. It may not be reportable as a serious injury but -- for instance like the last caller was saying -- that the malfunction of the device you have to take into account that if it recurs what could possibly be a medical intervention that would also occur due to that? And then therefore cause additional injury to a patient. And certainly possibly a serious injury. It seems to me of course you're the ones who have to document this in your - in your files. But it seems to me that if a malfunction can lead to a change in medication maybe with one patient it doesn't lead to a

serious injury but it certainly would have the potential and could be likely to in the future lead to a serious injury. But if you can document that this false diagnosis or, you know, false positive/false negative with the device would be, you know, unlikely to or as a remote possibility of leading to a death or serious or injury. Then, you know, document that internally in your files. But once again seems to me that that might be hard to document in many cases.

Isaac Chang: To add - I'd like to add even if it is not reportable to us as a serious injury. That malfunction may still be reportable as a reportable malfunction itself. For the reasons that, you know, it may cause injury if it recurred.

(Harry Long): Okay. Thank you, appreciate it.

Coordinator: Next question comes from Pam - (Pam Meadows). Your line is open.

(Pam Meadows): Hi. I don't - wanted to get clarifying information regarding the 2.6 in the guidance with regards to the user errors? It states that user error needs to be reported if its - if the use of the device has caused a reportable event. But then further down it states that if you determine that the event is solely the result of user error with no issue or device that leads to death or serious injury. Then you're not required to submit. So could you just clarify what is intended here a little bit?

Isaac Chang: So there are - there are situations where a device is actually used correctly - or the device itself did not malfunction but it simply just, you know, it simply just - a user who used the device may have improperly just - may have improperly used it. In which case, you know, does a manufacturer - will the manufacturer have to report in a situation where, you know, it's pretty clear that the - the user misused the device or - or did not use it correctly.

(Pam Meadows): So you're saying that if we can identify that the use of the device was based solely on -- failing to follow the IFU for example -- and there was no harm. Then we don't have to report it. But if they fail to follow the IFU and there was a harm do we have to report?

Bill Maloney: This is Bill Maloney. Yes. The last sentence in 2.6 is referring to malfunctions. It's referring to when there is a use error or a user error but there is no other performance issue and there is no device related death or serious injury. So if the device malfunctions due to a use error with the device and there's no death or serious injury that would not be reportable due to the fact that if the physician -- or whoever's using the device -- is mishandling the device it would be unlikely to occur again. You know, it's hard to - it's hard to envision the device malfunctioning in the same way twice due to the same user error.

Isaac Chang: But if - going - going back to, you know, sort of the previous part of what Bill was saying. This is for - this last sentence specifically is for malfunctions. If - if a user missused the device and that resulted in a death or serious injury that's still reportable to us. Because that's associated with the device. But if, you know, specifically for malfunctions if there is - if you can clearly parse out that it was -- it was the user and not the device -- and there's no death or serious injury impact then - then it may not be reportable.

(Pam Meadows): Okay.

Isaac Chang: Provided that it's - provided that it's not a problem that would be there if it - if it were to ever recur again.

(Pam Meadows): Okay thank you.

Coordinator: Next question comes from (Racheal Scott). This line is open.

(Racheal Scott): Hi just a question about the two year reporting. And we're just wondering - we have multiple devices with our company. And we just want to know -- going back -- is it starting with this new guideline - we should look at anything reported in the last two years and keep that as a running list going forward? As we - are we starting from today and we just move from here? Generally our practice is to -- whenever any complaint comes in -- look back for a full two years, see if there was anything reportable, but - should we maintain a master list basically to start of anything reportable to get off of this list that is being kept?

Isaac Chang: Well so - again, I mean, the - I think most of the time when we talk about -- or the two year presumption comes up in conversation -- it's usually the - it's usually within reference of, you know, when can we - when can we stop reporting on an issue. I think your situation you're describing is more, you know, do I have an obligation to go back and look for events from two years ago and - I don't. I mean - your - your current practices are your current practices. And I think one of the things that, you know, we - what we're looking to do is if you do happen to have a malfunction and - and you've tried to resolve this. You do have a malfunction that has been associated with serious injury and deaths in the past. And you - you're working to resolve this. And two years later you're still having issues.

You know, we certainly want to - we certainly want to understand why you're having issues with that. And if you present - if you have sufficient information to show that this issue has been corrected or this issue isn't a problem anymore because you have relevant data that demonstrates that. Then that's - then that's really what is resolving the two year presumption.

(Racheal Scott): Okay so this is more for a device that has - that is being watched more carefully. This isn't for all devices that would be reported?

Isaac Chang: No. The two year presumption really has - really specifically has to do with malfunctions. Because in the malfunction report really talks - the malfunction and requirements - say, you know, that, you know, it's likely to cause or contribute to a death or serious injury if it should occur. And so the question then becomes well what do you mean by likely to? How do you know it's likely to? It's likely to because it's already happened before. You already had a death or serious injury in the last two years.

(Racheal Scott): Right. So any time there is a malfunction we look up that device and look back for two years. And if it has had any kind of malfunction like that and we've reported it we report again?

Isaac Chang: Yes.

(Racheal Scott): We don't need to get off any lists is what I'm saying for those types of a matter. Okay

Isaac Chang: No. But I think the cautionary -- the cautionary note though is -- most people will look back in their - most people will look back into the data they have and they'll say "well do I have any serious injuries and deaths in the last two years?" and use that as the benchmark. Because what kicks off the two years is that you had a death or serious injury related to the product. Okay but - but, you know, so most folks I think will look at that and say well do I have a death or serious injury in the last few years? If I don't I'm fine. I don't think that's what we're saying. I think that what we're saying is if you continue to have this malfunction going on for two years - we're concerned about that too. Right? And so we want to understand what's happening with, you know, if

you have a likely to situation and that malfunction is still happening two years later. We - we kind of want to understand why that's happening.

(Racheal Scott): Right. Okay.

Coordinator: Next question comes from (Kim Goss). Your line is open.

(Kim Goss): Hello. I have a question. I'm working in a company manufacturing medical devices. And so I would like to ask for getting requirements for an event where no deaths or serious injury and normal function appear. For instance we had this situation with a patient pulled from a bed and did not sustain any injury. The malfunction has a (unintelligible) and we would like to know if that event would be reportable only based on the fact that the device was used at that time of the event occurring?

Isaac Chang: I think your question goes to whether, you know, if there is no injury associated with the device -- if there's no serious adverse event -- if there's essentially - I think the question that you're really asking is whether it's even reportable right?

(Kim Goss): Yes. Correct. Because we know that in some instances the folks in the bed may end up with a serious injury or death.

((Crosstalk))

Isaac Chang: Yes. And so the best advice that we can give you is that you need to make that determination. And if you decide that - if you make a determination that your device is connected with the adverse event then it's a reportable event. If from whatever reason, you know, you're able to - to determine that your device did not cause or contribute to the death or serious injury of the patient then you

need to document that information in your MDR file. So if - even if you don't - even if you don't still wind up submitting an MDR report to us - you do have to have a clear documentation that you - that you investigated the adverse event that happened and made the determination that your device is not involved.

(Kim Goss): Okay. Thank you.

Coordinator: Next question comes from (Jackie Arshnor). Your lines open.

(Jackie Arshnor): Hi thank you for taking my question. This is about exemptions and your slide 12 which talks about exemption request for contract manufacturers. We're an OEM manufacturer and we sell to distributors, customers. We are in many cases quality agreements with them that say that they will do any reporting that is required. This has always worked whenever our inspections have happened. We've pointed to quality agreements. FDA's been fine with that - the office of compliance. Is that still going to be the case or do we have to have this single reporting exemption with each of our customers whether there is a quality agreement in place that says that they'll do that reporting?

Bill Maloney: If you've been inspected by the FDA and the investigator indicated that the quality agreement was acceptable I'm not sure if there's any - any additional information that we can give you than that they've indicated that that's acceptable to them.

(Jackie Arshnor): Okay. Thank you.

Coordinator: This concludes the question and answer portion of this call. I would now like to turn it back over to Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questioning. If you were unable - to ask a question today please use the email address at the end of the slide presentation. Today's presentation and transcript will be made available on the CDRH learn webpage. At www.fda.gov/training/CDRHLEARN, by Thursday December 8. If you have additional questions about the guidance documents, please use the contact information provided at the end of the presentation. As always we do appreciate your feedback. Again thank you for participating and this concludes today's webinar.

Coordinator: This concludes today's call. You may disconnect at this time.

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