Electromagnetic Compatibility (EMC) of In Vitro Diagnostic Devices
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Moderator: CDR Kim Piermatteo

CDR Kim Piermatteo: Hello and welcome to today's CDRH webinar. Thank you for joining us today. This is Commander Kim Piermatteo of the United States Public Health Service. And I serve as the Education Program Administrator in the Division of Industry and Consumer Education in CDRH's Office of Communication and Education. I'll be your moderator for today's webinar.

Our topic today is the final guidance titled Electromagnetic Compatibility, or EMC, of Medical Devices and its applicability to In Vitro Diagnostic, or IVD, devices.

This final guidance was issued on June 6, 2022 and provides the FDA's recommendations on testing to assess the EMC of medical devices and information to include in the labeling. This guidance applies to medical devices, including IVDs and accessories that are electrically powered or have functions or sensors that are implemented using electrical or electronic circuitry. The recommendations in the final guidance are intended to promote consistency and facilitate efficient review of EMC and medical device submissions.

We are holding this webinar to clarify FDA's recommendations for EMC information to include in an IVD premarket submission, as well as help manufacturers and FDA staff use the FDA-recognized standards and partially recognized standards for the evaluation of EMC for IVDs.

It's my pleasure, now, to introduce you to our presenters for today's webinar. Seth Seidman, EMC Program Advisor in the Division of Biomedical Physics in the Office of Science and Engineering Laboratories within CDRH, and Alberto Buenaventura, Scientific Reviewer in the Division of Chemistry and Toxicology Devices in the Office of In Vitro Diagnostics, which is also referred to as the Office of Health Technology number 7 within CDRH's Office of Product Evaluation and Quality, or OPEQ.

We'll begin with a presentation from Seth and Alberto and then field your questions about this topic. As a friendly reminder, for those of you participating live in today's CDRH webinar, please be sure you have joined us via the Zoom app and not through a web browser to avoid any technical issues.

Thank you all again for joining us. I'd now like to turn it over to Seth to start today's presentation. Seth...

Seth Seidman: Thanks, Kim. So why are we here today? We're here to discuss this final Electromagnetic Compatibility of Medical Devices guidance, which was issued June 6 of last year, and, specifically, to provide more clarity on the impact of this guidance for IVDs, based upon feedback received from the IVD industry.

Specifically, we'll be going over the following three learning objectives. Describe the purpose and scope of the final guidance. Describe the recommended EMC information for premarket submissions, specifically for IVDs. And also, to describe an example of how to apply EMC recommendations for an IVD submission.

First, we'll talk about the purpose and scope. The scope of the final guidance applies to medical devices, including IVD products and accessories that are either electrically powered or have functions or sensors that are implemented using electrical or electronic circuitry.

On the left, you'll see a blood glucose monitor, which is an example of an electrically powered device, generally either by AC mains or battery. The example on the right is what we mean by a device that, while isn't electrically powered, has functions or sensors that are implemented using electrical or electronic circuitry. This is an example of an implantable neurostimulator, which has no power supply, but is powered inductively through an external emitter.

There are several implementation dates to be aware of for the final EMC guidance. On August 5 of last year, for all device types except IVDs, we implemented this guidance 60 days after its publication. On June 6 of this year, we will implement it for IVDs. We had a one-year implementation period because we recognized and anticipated that both the agency and industry might need that time to perform activities to operationalize the policies within the guidance for IVDs.

For those that are familiar with the 2016 EMC guidance, I've included a high-level summary of changes. We have added more substance and clarity, including for IVDs. It's been organized to follow eSTAR and SMART, making it simpler for submissions and for review staff to review EMC information.

We specified gaps in recognized standards. IEC 60601-1-2 is a safety standard and has no performance or effectiveness requirements. We recommend testing in both mains and battery modes of operation when applicable. And we've also specified recommendations for common electromagnetic emitters not addressed in standards.

Prior to getting into the specific expectations for IVDs, I'll give a quick primer on what EMC information to include for premarket submissions.

We expect the sponsor to submit EMC-related device characteristics and intended use environments, including a device overview of the functions and modes, cables, and accessories used; a description of their power supply, whether it's mains-powered, meaning AC or wall-powered, or whether it's internally powered, for example, using a battery; to describe its intended use environments-- professional health care facility environment, the home health care environment, or a special environment-- and if there's any wireless technology being used.

The only appendix of the guidance includes many examples of typical medical device locations and how they can be categorized into these three separate environments. While I'm not going to read to you each example, I'd like to point out that the professional health care facility environment not only includes hospitals, physician offices, and outpatient facilities, but also laboratories, where many IVDs are used. Additionally, the home health care environment is not limited to the home, but includes most environments that are not specified as special or professional.

Assessment of medical device risks. We ask the sponsor to provide a summary description of the risks associated with malfunction, disruption, or degradation of the performance of the subject medical device due to EM disturbances. This summary should categorize the severity of each harm into one of the following three levels-- deaths and serious injuries, non-serious adverse events, or no reported or potential harm.

Consensus standards. We recommend use of appropriate FDA-recognized consensus standards when applicable. If a standard is not FDA-recognized, provide justification regarding how the EMC testing performed adequately addresses EMC. If no consensus standards exist for a certain medical device type, we recommend specific EMC testing be performed, based on the foreseeable EM disturbances and the intended use environments.

There are several standards specific to IVDs. IEC 61326-1 and 61326-2-6, the 2012 versions, are in the FDA Non-Recognized Standards Database. If you click the first link in this slide, it will summarize the specific reasons for their non-recognition. FDA partially recognizes the 2020 versions of those standards.

For those unaware, when you search the FDA Recognized Standards Database, all recognized or partially recognized standards will have a link in the title of the standard pointing you to the supplementary information sheet, or SIS. The SIS sheets for the 2020 versions of 61326-1 and 61326-2-6 are linked here and clarify that they are only partially recognized because the immunity requirements for these standards are not adequate.

So what do you do for these partially recognized standards? For IVDs, FDA currently recommends using these recognized parts or test methods from the partially recognized IEC 61326 standards and using acceptance criteria specific to the device's functions and intended use, using test levels specified by IEC 60601-1-2. If the next editions of IEC 61326 become fully recognized by FDA, then FDA will recommend their use, avoiding this confusion of using test levels and acceptance criteria specified elsewhere.

As mentioned, IVDs should use acceptance criteria specific to the device's functions and intended use. One way of accomplishing this is by specifying the device's essential performance. Essential performance is most easily understood by considering whether its absence or degradation would result in unacceptable risk.

Pass/fail criteria can be different for transient versus continuous phenomena. For example, the transient nature of ESD, or electrostatic discharge, might allow for a device to reset without operator intervention, as long as the device returns to a predetermined safe state. However, this would not be an acceptable degradation for continuous phenomena, such as an RF immunity test mimicking an AM radio broadcast.

IEC 60601-1-2 is limited to safety. It does not necessarily test that the device is effective or performs as intended. So if the immunity pass/fail criteria for 60601-1-2 does not include effectiveness or performance, we recommend using 60601-4-2 to assess this.

Medical device configuration and functions tested. Test the device as a system. The device should be tested as a system, with all medical device accessories, components, and subsystems connected and functioning as intended.

If non-medical equipment is used in a medical system and could affect the ability of the medical device to meet the immunity pass/fail criteria, the non-medical equipment should also be tested as part of the medical device system. And yes, non-medical equipment can include phones, tablets, and computers. If this equipment can affect the ability of the medical device to meet its immunity pass/fail criteria, then it should be included and tested as part of the system.

Continuing on with our discussion of the medical device configuration, it is important to test in the device's intended use. This means all settings and modes should be configured as such. For example, medical device that can operate in battery power and in mains power mode should be tested in both modes.

Additionally, batteries with embedded electronic circuitry-- that is, smart batteries-- that are intended to be handled by the user should be removed from the medical device and tested separately for immunity to electrostatic discharge due to the potential of ESD damaging the circuitry of the battery. And if there's wireless technology, it should be on and communicating while being tested.

An important piece of the EMC guidance is clarifying expectations on how to address common emitters that are not adequately addressed by FDA-recognized standards. These include but are not limited to RFID, electronic security systems-- for example, metal detectors, electronic article surveillance-- near-field communication systems, wireless power transfer, cellular 5G, as well as unique medical emitters, such as electrocautery, MRI, electrosurgical units, and diathermy equipment.

If, during your assessment of the medical device risks, you fell into the "deaths and serious injuries" or "non-serious adverse events" categories, then testing against these emitters is recommended. If you fell into the "no reported or potential harm" category, then labeling is generally an acceptable mitigation.

Speaking of labeling, I've highlighted the most critical EMC labeling expectations. This includes the recommended separation distances and appropriate environments of use for which the device is suitable, the performance of the device that was determined to be essential performance, compliance for each emissions and immunity standard, any deviations or allowances used, and specifications required in any standards to which the device claims conformity.

I'd now like to pass it over to Alberto Buenaventura to discuss a hypothetical IVD example.

Alberto Buenaventura: Thank you, Seth, for providing us information on the impact of the new EMC guidelines to IVDs. Now, in this part of our presentation, I will be discussing a hypothetical example of a change in an FDA-cleared device, which required EMC testing based on the newly issued EMC guidance documents.

In this example, an IVD manufacturer of a handheld portable blood analyzer is changing a chip component, which is the microcontroller unit, MCU, of their FDA-cleared device. Now, the reason for the change is because the manufacturer switched to a different integrated circuit, IC, supplier for their chips.

Now, this hardware and software modification may have a significant impact on the overall safety and effectiveness of the IVD, as well as on the device's performance and risk profile. And it may also cause compatibility issues between the IVD itself and its parts and/or accessories. Because of the modification to the device, EMC testing based on the newly issued guidance document is recommended to determine that the IVD is safe and performs as intended.

Now in this slide the response provided by the sponsor for this example was to perform the EMC testing using the FDA partially recognized standard IEC 61326-1:2020. However, based on the information in the

recognized standard database provided earlier in the presentation in slide number 14, Clause 6, which is titled Immunity Requirements from IEC 61326-1:2020 is not recognized by FDA per the supplementary information sheet, SIS, for IEC 61326-1:2020.

The EMC report provided by the sponsor was found to be deficient because of the use of the unrecognized immunity requirements-- performance criteria A, B, and C-- from IEC 61326-1:2020, instead of using essential performance or device-specific pass/fail criteria, as mentioned in slide number 16.

Now, based on the new EMC guidance document, the recommended approach for this example are the following. First, use EMC test levels from IEC 60601-1-2:2020, which is recognized by the FDA. Two, use test methods from partially recognized IEC 61326-1:2020 and IEC 61326-2-6:2020, but with an acceptance criteria that is specific to the device's function and intended use and test levels specified by IEC 60601-1-2.

And three, providing device-specific pass/fail criteria that are, one, quantitative, two, specific to the medical device and functions, and three, observable. Of course, these criterias should be determined based on the medical device's functions, modes, indications for use, intended use, and essential performance, if applicable.

Now, this table provided in this slide is an example of the EMC testing test levels that are from 60601-1-2, which shows immunity testing for power frequency magnetic fields and voltage dips using test levels from the FDA-recognized standard.

Now, this slide provides the additional considerations that should be noted. First, these recommendations from the new EMC issued guidance document should be followed if the IVD submission is submitted after June 6, 2023. And second, EMC testing of an IVD, when applicable, should include, also, the following, as mentioned in previous slides.

First, a detailed description of the medical device undergoing testing, including the configuration, functions, modes, and settings that were tested, as mentioned in slide number 17 and 18. Two, testing for both mains and battery modes of operation, as mentioned in slide number 18. And lastly, common EM emitters not addressed in the standards, as mentioned in slide number 19.

Now, as stated in this slide, the recommendations in this new EMC guidance document apply to any new submission for IVDs. EMC guidance recommendations should be considered in conjunction with other applicable guidances. Now, the other relevant guidances where EMC guidance recommendations should be considered are the following.

One, to determine whether a new 510(k) is required for a modification that may or may not affect EMC. Please refer to the FDA guidance document titled Deciding When to Submit a 510(k) for a Change to an Existing Device, which was issued on October 25, 2017. Two, to determine whether a modification to one's own device that may or may not affect EMC is appropriate for a review as a Special 510(k), please refer to the FDA guidance document titled The Special 510(k) Program, which was issued on September 13, 2019.

And lastly, for additional information on reagent changes on already FDA-cleared instrument or assay, please refer to the FDA guidance document titled Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices, which was issued last year, on August 17, 2022.

Now, as a reminder to subject matter experts, or SMEs, these guidances should be used in conjunction with the final EMC guidance to determine whether new EMC testing is needed or a new 510(k) is needed due to a change with the IVD's EMC.

So before we conclude this presentation, we would like to summarize the important points of the presentation. First, the new EMC guidance implementation date for IVDs is June 6, 2023.

We have provided clarification of EMC expectations for IVDs in this presentation, which is IEC 61326-1:2020 and IEC 61326-2-6:2020 are both partially recognized, and the immunity requirements from these standards are not FDA recognized, and to use IEC 61326 for test methods and IEC 60601-1-2 for test levels.

Now, the gaps in recognized standards were specified in this presentation. For example, IEC 60601-1-2 is a safety standard, and it has no performance or effectiveness requirements. Please test IVDs in both mains and battery modes of operation and the expectations for common EM emitters that are not addressed in the standards.

Lastly, standards that are fully or partially recognized may be used to evaluate the EMC of an IVD device. Please read carefully the Supplementary Information Sheet, or SIS, for the selected consensus standard for its scope and extent of recognition, as provided in the FDA Recognized Database. Thank you.

CDR Kim Piermatteo: Thank you, Seth and Alberto for that presentation. I'd now like to introduce our additional panelist who will be joining Seth and Alberto for the live question and answer segment of today's webinar. And that is Yasaman Ardeshirpour. She is an EMC Program Advisor in the Division of Biomedical Physics in the Office of Science and Engineering Laboratories within CDRH. So welcome, Yasaman.

Before we begin, I'd like to go over a few reminders and tips for our live question and answer segment. Foremost, to ask a question, please select the Raise Hand icon, which will appear on the bottom of your Zoom screen. I'll announce your name and give you permission to talk. When prompted, please select the blue button to unmute your line, and then ask your question.

After you ask your question, please lower your hand. And if you have another question, please raise your hand again to get back into the queue, and I'll call on you as time permits. Please remember to limit yourself to asking one question only and try to keep it as short as possible.

And lastly, because device-specific modifications have additional considerations, these types of questions are outside the scope of our webinar today. If you have such questions, we recommend you submit a Q-Submission to discuss with the appropriate Office of Health Technology and review staff.

I'd like to start off this segment by asking a few questions to our additional panelist and presenters that we've received regarding this topic. So for our first question, I'll be directing that to you, Yasaman. And that question is-- well, it's two parts. So what would constitute a device change or modification affecting

EMC? And what is FDA's recommendation on how a sponsor should determine when to submit new EMC testing for such a change?

Yasaman Ardeshirpour: Thank you, Kim. Many types of modification can alter a medical device EM disturbance and susceptibility, including hardware, software, firmware, and even cosmetic changes-- for example, if you're changing the labeling place of the device from metal to non-conductive material.

If you're replacing components with almost exact equivalence, you wouldn't need to retest, as long as the scientific rationale for their equivalence is provided. But if you're changing the circuit boards or cable routing, then EMC should be retested, as they could change the EM immunity or emission of the device.

Software and firmware changes can also affect the EMC of the device. As you know, software controls the hardware and also runs by hardware. Software modification may change the current paths and current consumption. Or it may activate different parts of the device hardware, which could affect the EMC results of the device.

When you submit a new 510(k) based on the FDA guidance on Deciding How to Submit a 510(k) for a Change to Existing Device that was issued on October 25, 2017, in your submission, we recommend that you provide the following items. Identify and summarize all modifications or changes from the previously tested medical device, and include any changes in the medical device indications, intended use, and intended use environments.

Also, provide an analysis of whether each modification could affect EMC of the medical device. And also, assess whether the consensus standard used for the prior EMC testing has been superseded or replaced by a revised version.

New EMC testing should be performed if any of the analysis of the device modifications indicate that the prior testing might not support the EMC of the updated medical device model or version or the current device intended use environment. Recommend the sponsors contact the agency through the Q-Submission Program if they have doubt as to whether new EMC testing is needed for their submission.

CDR Kim Piermatteo: Thank you, Yasaman. Alright, I see a few raised hands, but I'm going to go to Seth real quick for a longer question. But Seth, I want to ask you this question that we previously received. So the question is, the EMC guidance document goes into effect for IVDs one year from the date of publication of the guidance, which would mean effective June 6th of 2023 for IVDs.

It is our understanding that this date was selected with the belief that the fourth edition of IEC 61326-2-6 would be published by that effective date. Since the guidance was issued, extensive work has been done by both FDA and industry, and a committee draft, or CD, for a fourth edition of 61326-2-6 has been released.

That being said, the fourth edition will not be published by the time the guidance goes into effect for IVDs. Moreover, the CD includes some new testing, proximity field testing, that could require substantial redesign.

Given these changed circumstances, there are two questions that I'll read to you, Seth. I'll read the first one. Then, I'll allow you to answer. And then, I'll read the second one. So the first question is, what would FDA recommend for those sponsors for whom the guidance does apply and are preparing original submissions for new IVDs?

Seth Seidman: Yeah, the one-year transition date that are speaking about was chosen to give time to both the agency and manufacturers to implement any necessary changes. It wasn't based upon any time expectations of consensus standards, which are ultimately outside of the agency's control.

So the final guidance and its recommendations will go into effect one year after the publication, which is June 6th of this year. And as we stated both in the guidance and the webinar, we recommend using the test methods from those 2020 partially recognized both 61326-1 and 61326-2-6 versions, using acceptance criteria that's specific to the device's functions and intended use, and using the test levels specified by IEC 60601-1-2.

CDR Kim Piermatteo: Great. Thanks, Seth. And then, the second part to that question is, will FDA advise such IVD sponsors to follow the CD? Or would FDA consider extending the effective date?

Seth Seidman: Yeah, I mean, I think-- advise sponsors-- so I mean, if a published EMC standard in the future receives full recognition, then we'll recommend its use over this sort of piecemeal approach. But currently, you should follow the guidance recommendations, as previously stated.

CDR Kim Piermatteo: Alright. Thanks so much, Seth. Alright, we're going to go ahead and call on Leo. Leo, I have given you permission to talk. Please unmute yourself and ask your question.

Leo Eisner: Thank you. So I'm Leo Eisner, with Eisner Safety Consultants. So I was actually on the committee for the CD. And I understand that Naomi Schwartz, from FDA, has retired. So I was wondering who from FDA would be the co-convener for the group, for the 61326-2-6. And I assume Seth might know.

CDR Kim Piermatteo: Thank you, Leo, for that question. Seth, do you have a response?

Seth Seidman: Yeah, I mean, I am the FDA primary liaison for that standard currently. And we are looking for an alternate. However, I do not believe that I will be the co-convener. I think we'll just leave one convener now.

Leo Eisner: Thank you.

Seth Seidman: Yep.

CDR Kim Piermatteo: Thank you, Leo, for that question. And thank you, Seth, for that response. Alright, our next question is coming from Bill. Bill, I have unmuted your line. Please unmute yourself and ask your question.

Bill: Sure. So I'm Bill. And I actually work with Leo Eisner for Eisner Safety, as well, not that we are hogging the line. But in any case, 61326-2-6 does not have, in any version, the equivalent of table 9 or

table 11 from 60601-1-2, which is wireless immunity frequencies and RFID approximate field-- RFID is another word for the approximate field.

And so, is there going to be a requirement that table 9 and table 11 be met, in the short term, for IVD devices from 60601-1-2? And are you going to push, in the 61326-2-6 committee to add the equivalent of table 9 and table 11?

CDR Kim Piermatteo: Thanks, Bill. You kind of got a little muffled there. But I believe that Seth is going to provide a response based on your question about table 9. So Seth, do you need him to repeat anything?

Seth Seidman: No, I think I understood. And Yasaman or Alberto can chime in if they also want to. So there's no requirement to do table 9-- and I think it was 8.11, maybe, I heard you say-- for IVDs because we're recommending the test methods from 61326-2-6, and, like you said, they're not in there.

However, I would point you to take a look at the EMC guidance-- I think it's section J, is on common RF emitters. And it talks about the potential risk of the device you're submitting and whether you need to address those emitters. And if your device does line up in one of the categories where you should address those emitters by testing, obviously, using other recognized standards, such as the ones you mentioned, would be the recommended way to do that.

CDR Kim Piermatteo: Great. Thank you for that response. We're going to go ahead and move on to the next question. The next question is coming from Torsten Backer. I have unmuted your line. Please unmute yourself and ask your question.

Torsten Backer: Thank you. My question may be somewhat technical in nature. Your guidance asks us to assess relevant emitters. Now, relevant emitters may be different depending on the environment of our device. But I think a 5G mobile radio seems to be applicable for almost every medical device due to the widespread use. However, there is no standard yet for this test. Can you share some insight for testing against 5G or any recommendations how to do this?

CDR Kim Piermatteo: Thank you Torsten for that question. Alberto, would you like to provide a response?

Seth Seidman: I can give a start.

CDR Kim Piermatteo: That's OK.

Seth Seidman: There is no recognized standard. So I think we would be pretty lenient in the type of testing that we're going to be reviewing. However, you could do something like ad hoc testing. Or you could do a 61000-4-3 radiated test with 5G-type signals. But understanding that there is no recognized test method for 5G, we understand that and are going to be as flexible as possible when we're reviewing that.

CDR Kim Piermatteo: Thank you Torsten for that question. And thank you, Seth, for that response.

Torsten Backer: Thank--

CDR Kim Piermatteo: Oh, sorry. I cut you off. Alright, I am going to go back to Alberto. Alberto, I want to ask you a question that we previously received, as well.

So that question is, if a new 510(k) submission is only for the addition of a new agent to a previously cleared instrument, and it does not require any change to the instrument itself or its environment of use-- for example, no additional hardware, firmware, or software is required-- should the sponsor submit new EMC testing for the device in the new 510(k) submission?

Alberto Buenaventura: Thanks, Kim. Now, the risk-based assessment of the cleared instrument and any modifications to it, like the addition of a new agent, as mentioned in this question-- that will determine if a new 510(k) or EMC testing should be completed and submitted. For example, if there is low risk to the modification in the EMC testing previously done to the instrument, and that is representative of today's environment, then maybe leveraging previous testing may be accepted.

Additionally, from a technical standpoint, the EMC standards previously used in the EMC testing are old, and the EM disturbances or interferences use in these testings aren't representative of today's environment. Then, the instrument should be retested.

Now, we also recommend referring to the FDA final guidance of Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices, issued August 17, 2022, for any reagent changes to FDA-cleared instrument or assay, and the Electromagnetic Compatibility of EMC of Medical Devices, issued June 6, 2022, for more information if the addition of reagents to the cleared instrument requires changes or modifications to the FDA-cleared instrument itself.

Now, sponsors can also contact the agency through a Pre-Submission if they have any doubt as to whether a new EMC testing is needed for their submission. So in summary, if the addition of a new agent-- example, a reagent-- to declared instrument changes, one, the risk profile of the IVD, two, analytical and clinical performance, three, indications for use, and four, any other factors that may affect the risk profile of that IVD instrument, then it needs a new 510(k). Kim.

CDR Kim Piermatteo: Thank you, Alberto. Alright, our next question is coming from Victory Yin. I have unmuted your line. Please unmute yourself and ask your question.

Victory Yin: Thank you. Thank you. I saw this webinar is majorly focused on the IVD. So are we going to have another session for the drug delivery device or not?

CDR Kim Piermatteo: So your question is about whether or not there'll be another webinar on the final guidance?

Victory Yin: No. That's about the [INAUDIBLE] drug delivery device. So are we going to have a different session for webinar for the drug delivery device, I mean.

Seth Seidman: Oh, for drug delivery devices. I'm sorry. I'm having a hard time hearing you. No, there is no webinar currently planned at this time.

Victory Yin: OK. Thank you.

CDR Kim Piermatteo: Uh-huh. Alright, our next question is coming from Pere Marin. I have unmuted your line. Please unmute yourself and ask your question.

Pere Marin: Hello. Thank you. This is Pere Marin from [INAUDIBLE]. I just have, probably, a silly question. But I have seen in many of the slides you presented that it's talking about you may, or the sponsor or the manufacturer may, or are recommended. There's no must or required. What does that mean? And it's not this the direction we need to go? I wanted to see if there's some qualification to be given on that.

CDR Kim Piermatteo: OK. Thank you, Pere, for your question. I had a hard time hearing you. But I think you're asking about the recommendations that are provided in the guidance. Is that correct?

Pere Marin: So yeah, the term used-- you may, or we recommend, but not you must, or it's required, and in the case of a submission because, obviously, if you have a device that you are changing, and you think it's going to impact, you obviously need turn to another EMC testing and, maybe, to resubmit. So it's why the term that you use is "may" or "we recommend" and not "must" or "required."

CDR Kim Piermatteo: I got you. OK. Thank you for clarifying. Seth, do you want to provide a response?

Seth Seidman: Sure I think what you're asking is why there's, maybe, just shoulds and mays and not shalls. And this isn't a standard. So these are just our recommendations and the agency's current thinking on this subject. So they are not fast requirements. And they are our recommendations. I don't think I can say too much more than that.

I mean, if you have an alternate proposal than something that's in the current guidance, then you can always submit that, and it will be reviewed as such by our review staff. But obviously, we recommend-- following the guidance would be the easiest way towards approval.

Pere Marin: OK.

Seth Seidman: Does anybody else-- I mean, I don't know if anyone else, Yasaman or Alberto, have anything to add that I didn't cover.

CDR Kim Piermatteo: No. I think that was good, Seth, I think. Just to clarify, Pere, these are guidance. These are recommendations. So assessing-- unless there's something that's in the regulations or there's a special control, alternative proposals can be provided. But I think, if you have questions about that, definitely consider a Q-Submission to discuss with the subject matter experts directly or the review team.

Pere Marin: Mm-hmm. Alright. Thank you.

CDR Kim Piermatteo: Thanks. Alright, our next question is coming from Sheila. Sheila, I have unmuted your line. Please unmute yourself and ask your question.

Sheila Ramerman: Thank you. Yes, my question is kind of specific about the description on slide 12, I think it was. So in a submission, does FDA expect a separate text description, say, to introduce the EMC

testing? Or is the description of the unit under test in the test report likely to be sufficient? Or is it a "that depends" kind of answer? Thank you.

CDR Kim Piermatteo: Thank you, Sheila. I'm going to turn it over to Seth to provide you a response.

Seth Seidman: Yeah, so I mean, I think what would be helpful for review staff is that, yes, you have a separate EMC section. Now, I don't want that to mean you just copy and paste all the information over into that section. While you're in your response, you can certainly reference the device description section. And you can point to different areas in your submission so it's not just a huge copy and paste because we know that can be problematic.

So I think a separate section talking about the EMC information would be helpful. But it doesn't have to be specifically in that section. You can point to other places.

CDR Kim Piermatteo: Thank you, Sheila, for that question. And thank you, Seth, for that response. Alright, I'm going to circle back to Alberto for a question that we have previously received that I think would be beneficial. So the question, Alberto, is, if an IVD device uses other manufacturers or off-the-shelf instruments, should they be included in the EMC testing?

Alberto Buenaventura: So the answer to that question, Kim, is yes. The final marketing device should be tested as a system, with all medical device accessories, components, and subsystems connected and functioning as intended. Now, if there are non-medical equipment used in the medical device system, and these could affect the ability of the medical device to meet the immunity pass/fail criteria, the non-medical equipment should also be tested as part of the medical device system.

Manufacturers who use off-the-shelf instruments in collaboration with their IVD device are basically creating a medical device system that comprises of the IVD device itself and its off-the-shelf instruments. Now, these off-the-shelf instruments may consist of electrically powered components that could be vulnerable to electrical and safety risks in the device's intended use environment.

And these electrical and safety risks could adversely impact the safety and performance of that IVD device. Therefore, the manufacturers are accountable for the safety and effectiveness of the hardware with respect to the proposed intended use of that hardware, including EMC.

CDR Kim Piermatteo: Thank you, Alberto.

Alberto Buenaventura: Mm-hmm.

CDR Kim Piermatteo: Alright, our next question is coming from Oliver. Oliver, I have unmuted your line. Please unmute yourself and ask your question.

Oliver: Thank you. Oliver McEwen here from Siemens Healthcare. My question is, is there an explanatory document on why the FDA decided to use the limits in 60601 standard instead of the existing limits in the 61326-2-6 standard?

CDR Kim Piermatteo: Thank you Oliver for that question. For standards, Seth, would you like to provide a response?

Seth Seidman: Yeah. There's no documents that's explaining the rationale, I think. There was a lot of technical expertise that went into the recommendations for 60601-1-2. And we thought that the work that went into that best represented the environments of use of today, rather than the work that went into publishing 61326-2-6 when it was published.

Oliver: Right, because it is putting a lot of extra work on IVD manufacturers. And we don't mind having to gear up to comply once we understand the rationale for the differences.

So I, for one, would expect to see a written explanation on why the different limits are deemed to be appropriate instead of the existing limits that have sufficed since the EMC standard was originally issued back in the late '80s, I guess, yeah? So is it possible to get an explanation written up so that we can get our heads around this?

Seth Seidman: I would have to talk to others here at CDRH. I mean, I do not believe that this is, essentially, a lot more work. I know it may look like that at first glance because the levels are higher.

Oliver: Right.

Seth Seidman: Also, you have to take a look at the pass/fail criteria being different and being very much risk-based, meaning that some things that were failures in the past with the ABC criteria may not be failures when you're talking about a risk-based approach like essential performance.

And usually-- I'm trying to think about a rationale. I think, as we move forward in the CD for 61326-2-6, that's something that I will bring to the group and, if there are changes in that standard, to make sure the rationale explain why the levels and the pass/fail criteria are changed.

Oliver: Great. That would be good because that vote, the panels in each country-- yeah, would need to see that explanation at that point, if they're default for the update to the fourth edition, yeah. So that would be good.

Seth Seidman: Great.

Oliver: Great. OK, thank you.

CDR Kim Piermatteo: Thank you, Oliver. Thank you, Seth. Alright, our next question is coming from Bhaskar. Bhaskar I've unmuted your line. Please unmute yourself and ask your question.

Bhaskar: Thank you. So this is Bhaskar calling from Intelligent Ultrasound Limited. My question is-- so using the device change flowchart, if we determine that the change that we're making to the software is not substantial, and it doesn't require a new 510(k), and we can just make a note to file, do we still need to justify the EMC, that the EMC is not required?

CDR Kim Piermatteo: So Alberto, I think he's talking about the 510(k) modification guidance. Is that correct, Bhaskar?

Bhaskar: Yes, that's correct. Yeah.

CDR Kim Piermatteo: Yeah.

Alberto Buenaventura: OK. Well, it really depends on your risk-based assessment of the changes or modifications to your device, Bhaskar. That's what I'm going to point to. I mean, I know that there's a flowchart there. But I mean, for us to get a complete understanding of the changes that are happening in your analyzer that was cleared, we really need to see that risk-based assessment to determine if any changes to the risk-safety benefit profile of the instrument was changed, Bhaskar.

Bhaskar: Thank you. I mean, once we have internally determined that it's a non-substantial change, and we decided that we don't need a 510(k), how do we still check-- are you suggesting that we have to make a 510(k) submission anyway?

Alberto Buenaventura: Mmm. As far as-- my understanding is that you shouldn't have to do that, Bhaskar, as long as all your internal documentation are in place about that changes to the device because, when you do come in for any future submission, any future modification, that's something that we would-- may ask from you.

Bhaskar: Sure. Thank you.

Alberto Buenaventura: You're welcome.

CDR Kim Piermatteo: Thank you Alberto and Bhaskar for that question. Seth, I'm going to circle back to you to ask you another question that we received previously, as well.

And Seth, that question is, you stated that, for IVDs, FDA currently recommends using the recognized parts or test methods from the partially recognized IEC 61326-1 and IEC 61326-2-6 standards and recommends using test levels specified by IEC 60601-1-2 for acceptance criteria specific to the device's functions and intended use. Is it, then, acceptable if a sponsor uses the test methods of FDA-recognized standard 60601-1-2 instead of 61326-1 or 61326-2-6?

Seth Seidman: Yeah. Thanks, Kim. Yeah, that would be acceptable. Essentially, the test methods from 61326-2-6 are very similar to 60601-1-2. So they reference most of the same basic standards. And so that's certainly an acceptable alternative.

CDR Kim Piermatteo: Great. Thanks, Seth. Alright, our next question is coming from Jamie. Jamie, I have unmuted your line. Please unmute yourself and ask your question.

Jamie Wolszon: Thank you. Thanks, everyone, for this webinar. I think you know that, for industry, it's been really important to have clarity. And we're continuing to seek clarified expectations going forward. So thank you, again, for this webinar.

I just had a question based on-- a follow-up based on what I thought I heard. So in the event that you have a modification that the sponsor determines will indeed require a new submission, but the risk-benefit assessment indicates that change will not-- it might require a new submission, but it will not-- and that's the risk-based assessment-- will require-- that it won't impact the EMC, right, that you've

looked at the risk-based assessment, and it will not impact the EMC. Is it the view that new EMC testing would not be required under those circumstances?

CDR Kim Piermatteo: Thank you, Jamie, for that question. Yasaman or Seth, would you like to provide a response?

Seth Seidman: Yeah, I think this was addressed, partially, in a prior question. But essentially, I think it also-- I mean, I think it's important that that risk-based approach looks at when prior testing was done and whether that prior testing is still representative of today's EM environments because, just because the change might not affect EMC, if this testing was done 10 years ago, and the test levels and the environment of use have changed dramatically since then, that may necessitate looking at future tests.

Jamie Wolszon: So I'm not sure if I need to-- I want to follow the rules. But I do have a follow-up. Do I need to lower my hand and come back?

CDR Kim Piermatteo: If it's a quick question, Jamie, you can go ahead and ask it.

Jamie Wolszon: Yeah, I think it'll be, hopefully, relatively quick, which is-- so if they can consider, as part of the risk-based analysis, how old the testing is, and they still determine that there'll be no impact to EMC, would it be the view that no new testing is required?

Seth Seidman: I believe so. I mean, if you've taken a risk-based approach, and the device change does not necessitate new testing, and the testing that you're previously leveraging also is still representative of today's EM environments, I see no reason why you would need to retest that.

Jamie Wolszon: Thank you.

CDR Kim Piermatteo: Alright. Thank you, Jamie. Thank you, Seth. We have time for one more question today. Therefore, I'm going to call on Bhudeep. Bhudeep I have unmuted your line. Please unmute yourself and ask your question.

Bhudeep Patnaik: Yes, hello. I have a simple question. Is this EMC testing can be done in-house? Or it has to be done by the third-party FDA-recognized centers? Can you hear?

CDR Kim Piermatteo: Yep. Thank you, Bhudeep. Seth, I'm going to come back to you.

Seth Seidman: Yeah, I mean, no, there's no requirement to use a third party. In-house testing is certainly acceptable. And many manufacturers choose to go that route.

Bhudeep Patnaik: OK. Thank you.

CDR Kim Piermatteo: Thank you, Bhudeep. Alright, since that was a quick one, I'm going to try to get in one more question. I'm going to call on Gary. Gary, I have unmuted your line. Please unmute yourself and ask your question.

Gary Bell: Alright. Can you hear me?

CDR Kim Piermatteo: Yes, we can.

Gary Bell: Yeah, so a simple question-- may have been covered in the beginning. But was wondering if you're going to be sending out-- I notice this is being recorded. Are you going to send out a recording of this that would be available?

CDR Kim Piermatteo: Yes. Gary, we'll get to that next slide. But we will post a recording with the presentation, as well as a transcript, within a few weeks after the webinar.

Gary Bell: OK. Great.

CDR Kim Piermatteo: Yeah.

Gary Bell: Thank you.

CDR Kim Piermatteo: Great. Alright, so thank you all for a very interactive question and answer segment. At this time, I'm going to go ahead and turn it back over to Seth for some final thoughts for today. Seth.

Seth Seidman: Yeah, I hope that this webinar has been informative on how our published EMC guidance will apply to IVDs after the implementation date of June 6th of this year. We highlighted that IVDs should be designed, tested, and verified to meet the recommendations discussed in this guidance and that they should be labeled with the appropriate information related to their EMC performance.

Specifically, we explained our expectations that sponsors use the 2020 versions of 61326-1 and 61326-2-6, with the acceptance criteria specific to the device's functions and intended use, and using the test level specified by 60601-1-2. We went over an example of changes to a handheld portable blood analyzer and how those changes can impact EMC, along with recommendations on how to address those in a premarket submission.

I thought we had some good discussion in the Q&A webinar, centered around what changes necessitated the EMC recommendations of this guidance. We hope this information was helpful and clear, with the understanding that, if you have any device-specific considerations and questions, that we recommend you submit a Q-Submission to discuss with the appropriate Office of Health Technology and review staff.

So to conclude, this EMC guidance provides important information for manufacturers and others in the IVD industry on the EMC recommendations for these devices. It highlights the importance of ensuring the safe and effective performance of IVDs and provides the agency's recommendations regarding appropriate testing and labeling for EMC. We hope it's been helpful to manufacturers and others in the IVD industry. And I'd personally like to thank everybody for joining.

CDR Kim Piermatteo: Great. Thank you, Seth, for those final thoughts. And again, thank you to Seth and Alberto for their presentations today. And also, thank you to Yasaman for her participation.

So as we just mentioned, printable slides of today's presentation are currently available on CDRH Learn at the link provided on this slide under the section titled In Vitro Diagnostics, and that recording of

today's webinar and a transcript will be posted to CDRH Learn under the same section in the next few weeks. And I've provided a screenshot of where you can find those webinar materials on this slide.

If you have additional questions about today's webinar, please feel free to email us at DICE@fda.hhs.gov. And we also encourage you to attend a future CDRH webinar. And a listing of all of our upcoming webinars is available at www.fda.gov/CDRHWebinar.

This concludes today's CDRH webinar. And thank you all again for joining us. Have a nice day.

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