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National Provider Call - Transcript

Centers for Medicare & Medicaid Services
Individualized Quality Control Plan for CLIA Laboratory Non-Waived Testing
MLN Connects National Provider Call
Moderator: Nicole Cooney
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2 p.m. ET

Contents

Operator: At this time, I would like to welcome everyone to today's MLN Connects National Provider Call. All lines will remain in a listen-only mode until the question-and-answer session.

This call is being recorded and transcribed. If anyone has any objections, you may disconnect at this time.

I will now turn the call over to Nicole Cooney. Thank you, you may begin.

Announcements and Introduction

Nicole Cooney: Thank you. Hello everyone, I'm Nicole Cooney from the Provider Communications Group here at CMS, and I'll be your moderator today. I'd like to welcome you to this MLN Connects National Provider Call on the Individualized Quality Control Plan for CLIA laboratory non-waived testing. MLN Connects Calls are part of the Medicare Learning Network.

During today's call, CMS subject matter experts will provide information on Individualized Quality Control – on the Individualized Quality Control Plan for CLIA laboratory non-waived testing. The presentation will include information on IQCP, the new quality control option for Clinical Laboratory Improvement Amendments, or CLIA, laboratories performing non-waived testing. IQCP will provide laboratories the flexibility in customizing quality control policies and procedures based on the testing systems in use and the unique aspects of each laboratory. A question-and-answer session will follow the presentation.

Before we get started, I have a few announcements.

You should have received a link to the slide presentation for today's call in previous registration emails. If you have not already done so, please view or download the presentation from the following URL: www.cms.gov/npc. Again, that URL is www.cms.gov/npc. At the left side of the webpage, select National Provider Calls and Events, then select the data of today's call from the list.

Second, this call is being recorded and transcribed. An audio recording and written transcript will be posted to the MLN Connects Call website. An announcement will be placed in the MLN Connects Provider eNews when these are available.

At this time, I'd like to turn the call over to Judith Yost, director of the Division of Laboratory Services here at CMS.

Presentation

Judith Yost: Thank you very much, Nicole. Good afternoon or good morning everyone, and thank you very much for joining us today. We'd like to briefly provide you with some updates and some insights on the status of IQCP implementation. We are hoping

that you will find IQCP to be a great and exciting step forward from the previous quality control policy just as much as we do.

But before I begin, I'd also like to thank the members of the planning team and the work group for all of their hard work on IQCP now and ongoing, as well as the MLN for supporting this effort.

If you go to slide 3, you'll see that it is the standard disclaimer that only regulations represent official policy.

Moving along to the agenda on side 4. The topics today are basically a series of questions to help bring you forward from the historical perspective of quality control to the present. Most importantly, we, the IQCP team, are here to answer your questions this afternoon.

The Individual Quality Control Plan (IQCP)

Moving to slide 5. The first question is, What is IQCP? And I am going to read this one: A voluntary, flexible alternative quality control protocol with added value that, if followed, grants compliance with CLIA quality control regulations and provides equivalent quality. So that means that we have an optional program for non-waived laboratories that represents the total testing process. It is customizable. It is enforceable even though it is in the IGs because it is – it emanates from a regulatory provision.

Your quality control under IQCP may be greater than or less than what you're currently doing for quality control compliance. But it does consider all of your quality control activities. It is the best option for your patients. And remember, you can't do no QC under this option. You must do some QC at some frequency and amount and then document it.

Moving to slide 6. What is IQCP? And continuing with that slide, there are three parts to IQCP—the Risk Assessment, the Quality Control Plan, as well as Quality Assessment. What this does is it collects and organizes and formalizes all of your existing intellectual and documented quality activities. There are no regulations changing for us to implement IQCP.

Let's use an example because the term risk assessment is, perhaps, something you're not as familiar with. The others you do already for CLIA compliance in some fashion. Let's use an example like new instrument selection.

So you look at the manufacturers' instructions and all their manuals and materials with regard to accuracy, precision, and other specifications. You're going to think about the patient population that your laboratory serves. You're going to look at the cost – as always, we have to do that – the turnaround time, the usability of the test system or device, the throughput, and a lot of other factors. And, then, you take all that data and you make a decision with regard to your selection.

And so, you're doing this process already essentially using information available to you or, perhaps, you may have to do some additional studies. But the same process that you walk through in order to select a new instrument is very similar to the type of assessment you would be doing with risk assessment and making sure that you include all phases of testing and all the components of the testing process.

Moving to slide 7. We're still continuing on the – on the definition of what is IQCP. Again, it does include the entire testing process, all the phases of testing. It includes all the quality activities, systems, and processes. And again, because it's including all these activities, not just the liquid quality control that you may add during the analytical phase, it is no longer your grandmother's quality control.

So why are we moving to IQCP? I'm sure you're curious what impetus there was. Well, there's a lot of things happening, in case you haven't noticed, in the healthcare environment. We have testing moving to point-of-care. A lot of it is moving in that direction because the devices are more accurate and more robust and portable.

Payment rules have changed. The Affordable Care Act is in – is in play now. There is, certainly, an improvement in the accuracy and reliability of the testing systems now. The – and faster and faster turnaround time is necessary both for physician needs as well as patient convenience, so that the testing can be done at a local site rather than in a central laboratory. Again, the technology is more robust, more automated.

And so, alternative QC is really the way to go here. If you recall, back in 2004 we implemented Equivalent Quality Control. And that was really the first step of a toe in the water for alternative quality control. And it works OK. But it only covers a very limited number of tests. And so – and it is very, very, very rigid. So, we knew that we had to move on for something that we could use now for quality control, as well as to plan for the future and something that was better than that initial step.

Moving to slide 9. So, "OK," you say, "This does cover everything I'm already doing. Why should I – why should I use IQCP?" Well, because it is customizable and it would be unique to your laboratory. But it – but you're thinking, "Oh my goodness. It does look like a whole lot of work." But, this is really the best that you can be for your patients, as well as for future technology. So the next time that something – there are advances in technology, you won't have to be changing your quality control again and we won't be having to have this talk.

So again, we're including information and activities that you currently do for CLIA compliance. And if you use quality system principles, then this fits perfectly into them.

Implementing IQCP

Again, let's move on to slide 10 about when do I implement IQCP? So the education and transition period to implement IQCP began on January 1st and will end at the end of 2015. The education and transition period is now under way. And if you recall, we used key concepts from Evaluation Protocol Number 23 – EP-23 – a CLSI consensus

document. The use of this document is not necessary for CLIA compliance. However, it is a good resource, so you may consider using it. But you don't need it in order to meet the CLIA principles and protocol for IQCP.

Another thing to keep in mind is CMS typically does not prescribe how to do IQCP. I know folks have asked, "Give us the template. Tell us what to do, and we'll do it." The reality is there are just too many – too many different circumstances, test systems, processes, devices, different types of patient population, and even environments where laboratories are performing testing. We couldn't possibly devise something that would fit all these circumstances.

Another thing, for those of you who are accredited to keep in mind is that we have been working continuously with the approved accrediting organization. It is optional for them to adopt IQCP, but they will have to have some quality control protocol that is equivalent at least. So we suggest that you just keep in touch with your own accreditation organization and follow their standards as written and approved.

The Transition Period

Moving to slide 11. So what happens during the education and transition period in which we're currently engaged? During the education and transition period, it is truly educational. There will be no quality control deficiencies cited for laboratories unless the laboratory is not doing quality control, unless there is risk of patient health and safety or immediate jeopardy.

We suggest that – you have 2 years, so – to go ahead and plan. Plan for your non-waived tests as to whether you wish to use IQCP or the default quality control regulations at (4931256D3). You can actually decide on a test-by-test basis if you wish to adopt IQCP for your test systems or maybe by a specialty basis. The only exception under IQCP is for pathology testing. CMS is continuing to work on additional educational materials and brochures as well as with the CDC on a workbook for laboratories so there will continue to be additional materials and tools available for laboratories to assist them with compliance and IQCP.

Now, what happens after – moving to slide 12 – the education and transition period? At that point IQCP – you must be in compliance with either IQCP or the CLIA regulations. It will no longer be educational. And if compliance is not achieved, then there will be deficiencies cited. Remember that time comes at the end of December in 2015. More than likely, we will probably convene another call just like this one to answer any final questions you might have prior to the conclusion of that process.

Moving to slide 13. And so, what other information should I keep in mind when planning for IQCP, should I decide to implement it? Again, if you look at the list that's on this slide, you'll see again that these are all materials and information that you already have with regard to CLIA compliance. And so that's what you want to consider when you are planning your Quality Control Plan and your risk assessment.

So this is really just a starter list. There are many, many other sources of information that I'm sure you can think of as well. You obviously want to follow the manufacturer's instructions in the package insert and other materials. You want to think about quality assurance data that you may already have with regard to a particular test system.

Remember for those of you that are already doing EQC successfully, that's a good thing because you can actually take that data and transfer it over into your risk assessment for IQCP. So it's not lost. It's actually just being moved over and utilized in a different fashion. So again, that's a good thing. Any historical data that you have on test performance is certainly usable towards your ability to define your Quality Control Plan under IQCP, and it will help with your justification as well.

Additional Resources

So moving on to – that concludes really the formal part of the presentation today. But we do have resources for you already that you can use. Most importantly, ongoing, your questions can be sent to the IQCP mailbox. And the link is at iqcp@cms.gov. Also, on the CMS CLIA website, there is additional information. The guidelines are there that – it contains the IQCP protocol, the letters to the state agencies, including all of the frequently asked questions, the brochures, and so forth are all on the CMS CLIA website, and it will be continually updated with new materials and information.

I'd like to thank you now for your time and attention today. We look forward to continuing to work with you on IQCP implementation and our mutual goal of quality testing. And we will be happy to entertain any questions that you might have and do our best to answer them.

Keypad Polling

Nicole Cooney: Thank you, Judith. At this time, we will pause for a few minutes to complete keypad polling so that CMS has an accurate count of the number of participants on the line with us today. Please note there will be a few moments of silence while we tabulate the results.

Victoria, we're ready to start the polling.

Operator: CMS appreciates that you minimize the government's teleconference expense by listening to these calls together using one phone line. At this time, please use your telephone keypad and enter the number of participants that are currently listening in. If you are the only person in the room, enter 1. If there are between two and eight of you listening in, enter the corresponding number. If there are nine or more of you in the room, enter 9.

Again, if you are the only person in the room, enter 1. If there are between two and eight of you listening in, enter the corresponding number. If there are nine or more of you in the room, enter 9.

Please hold while we complete the polling.

Please continue to hold while we complete the polling.

Thank you. I would now like to turn the call back over to Nicole Cooney.

Question-and-Answer Session

Nicole Cooney: Thank you. Our subject matter experts will now take your questions about IQCP. But before we begin, I'd like to remind everyone that this call is being recorded and transcribed. Before asking your question, please state your name and the name of your organization. In an effort to get to as many of your questions as possible, we ask that you limit your question to just one. If you'd like to ask a followup question or have more than one question, you may press star 1 to get back into the queue, and we will address additional questions as time permits.

Victoria, we're ready to take our first question.

Operator: To ask a question, press star followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the pound key. Remember to pick up your handset before asking your question to assure clarity. Please note your line will remain open during the time you are asking your question, so anything you say or any background noise will be heard into the conference.

Please hold while we compile the Q&A roster.

Your first question comes from Richard Robinson.

Richard Robinson: Hi, this is Richard Robinson from American Red Cross. On slide 7 you indicated that IQCP includes the entire testing process, including pre-analytical, analytical, and post-analytical. Does this mean then that we need to develop quality control practices for specimen accession and handling and test reporting?

Penny Meyers: Hello Richard, this is Penny Meyers. And that does not necessarily mean that quality control practices have to be developed for every aspect of the risk assessment. What it does mean is that the laboratory director needs to take into account all of these elements of the pre-analytic, analytic, and post-analytic system in order to develop and approve the Quality Control Plan.

Judith Yost: This is Judy Yost, too. And what you want to look for – places where you know there – where you have data or where you've had problems, where you can see test system failures or other errors that might have occurred in each of those phases of testing. And those are the things that you want to evaluate as to whether or not you want to mitigate that risk or whether or not it's something that what you're doing currently is already acceptable or it's not serious enough to even consider.

Richard Robinson: Thank you.

Operator: Your next question comes from the line of Dixie Marshall.

Dixie Marshall: Hello, this is Dixie Marshall with Memorial Hospital in Martinsville. I was reviewing the CMS memorandum that came out August 16th and it's S&C 13-54-CLIA. And it refers to the like – I guess – I think there's a D-tag. Where do we find those?

Judith Yost: This is Judy Yost, thank you for your question. The D-tags are actually included in the official interpretive guidelines. If you go to the CMS CLIA website that is included on the link in your PowerPoint information, you can go down the left-hand side, there's a menu of all the items that are available to you. And in that interpretive guideline document is the regulation, which will be written in bold, and the interpretive guidance, which is really just an interpretation of the regulation in plain English, and that's in italics.

Now, the IQCP is not yet included in that document. It is in the S&C letter. There's just a CMS internal process where it has to go out first in the letter in order to be made available to the laboratories and to the surveyors. And then it ultimately will end up in that interpretive guideline document that is on the website.

But the D-tags itself are just little snippets of the regulation that surveyors use to cite deficiencies. That's really all they are. And so for laboratories, they have no real meaning unless you get cited on a deficiency statement and you have to respond to it. So it sometimes will be pieces of a regulatory statement or a standard rather than the entire requirement because it may have several different components involved in one – in one regulation. And that's why – that's why they're broken down even further than just the regulatory citation.

Dixie Marshall: Thank you.

Operator: Your next question comes from the line of Jerry Waupoose.

Jerry Waupoose: Hi, my question is regarding IQCP. How does this affect us when we have the site visits by CLIA surveyors? Are they going to be – do we say that we're implementing this system? And will this affect us any differently when they do their surveys?

Judith Yost: Well, during the education and transition period that we're currently undergoing, the surveyors will look to see what you're currently doing for quality control. If you're beginning to start to implement IQCP, they will provide some education and assistance to get you on the way and look and see whether or not what you have already is in compliance.

Because it's an educational phase-in and, perhaps, if you have initiated your IQCP but haven't gotten it quite right, instead of a citation, you will get a letter from us just explaining that and that – and let you know that by the end of the education period you will have to be in compliance with whatever option you choose for quality control compliance.

So, again, it's fully educational for the next 2 years. Following those 2 years then, obviously, you will need to decide on a test-by-test basis which choice you prefer.

Operator: Your next question comes from the line of Randee Lunn.

Randee Lunn: Hi, my name is Randee Lunn. I'm calling from South Shore Lab Consultants in Scituate, Massachusetts. And I'm a consultant for clinical labs here in this state and most of mine are high complexity genetic testing labs. So I'm wondering what experience you have with those types of laboratories and the IQCP. Have you had any conversations with any of those or any – just some information on that and how that's working for them, for those labs?

Judith Yost: This is Judy Yost. We're going to let our molecular expert respond to that question for you. Maybe that would be more helpful.

Randee Lunn: OK, thanks.

Penny Keller: Hi, Randee, this is Penny Keller. We haven't gotten any specific inquiries from genetic testing labs. But genetic testing labs are all high-complexity tests and all high-complexity tests have to comply with high-complexity test requirements. And for molecular under controls, it's – they usually apply as far as extraction requirements, the amplification step, electrophoresis – any of those things that are currently required, you can either choose to follow that or now you have the lovely option of considering IQCP. So you can use the IQC process to evaluate the test system and generate the data and the evidence to support your IQCP.

Randee Lunn: OK, so I've read the brochure and the memo as well – the documents that have come out over the last 6 months or so. So basically, for the genetic testing labs, it would allow them to perform QC that meets their instruments' instructions for QC but less stringent than CLIA QC. That's the idea if they do an IQCP?

Penny Keller: If you do an IQCP? Yes, if you – the CLIA – the minimum CLIA requirement is that you have to – you can't be less stringent than what the manufacturer tells you that you need to do for QC.

Randee Lunn: Right.

Penny Keller: But, if it's less stringent than the CLIA requirements, you can now use the IQC process to actually use – to be less stringent as far as your QCP.

Judith Yost: As long as you have the data document.

Randee Lunn: Yes, right. Because a lot of these – a lot of these instruments for genetic testing don't have specific – well, they don't have two levels – certainly not two levels of QC always. But CLIA regulations require.

Penny Keller: Penny Keller: Yes, I understand that. And that's where the IQCP comes in. It's that whatever you are doing is adequate based on your risk assessment for your Quality Control Plan. As long as you have the supporting data and evidence, you now actually have the ability to what I call substantiate whatever quality control means that you're going to use for your test system.

Now, I know we're limited in time. So if you want to forward me your specific question, I will definitely get back to you. I usually return emails within 48 hours if I'm in the office. So it's Penny.keller or – but, you can also – as Ms. Yost said – had mentioned, all IQCP inquiries can go to the IQCP mailbox, and they'll be forwarded to the appropriate subject matter experts and they will return your – you know, return to you with whatever answers they can answer.

Randee Lunn: OK. So, I'd just send it to iqcp@cms.gov and then just write your name? And that…

Penny Keller: Yes, that would be fine.

Randee Lunn: Penny Keller. OK, thank you.

Penny Keller: You're welcome.

Operator: Your next question comes from the line of Max Williams.

Max Williams: Hi, this is Max Williams at Bio-Rad Laboratories. A question for the team: Judy, when you mentioned that during this education period, there would be no citations for QC issues – I think was the word in that phase, I just wanted to square that up with the other statements, one about manufacturer's instructions and some other things.

So, could a laboratory sort of say, "I'm going to reduce my QC now for the next year and a half because, you know, I'm in the educational phase. I'm trying to figure this out." One I guess, could they go below manufacturer's instructions and, also, would they need to declare that they're – they're working on their IQCP? What would be the things that you'd be looking for in that? For example, could a laboratory just say, "Well, I'm going to reduce down to once a week as I evaluate my risk?"

Judith Yost: Hi Max, this is Judy. I'll start and anybody else can jump in. The laboratory cannot do less than the manufacturer's instructions ever. That's kind of the first and foremost requirement for quality control. So with that said, that would be something that would be actually cited if the laboratory is performing less than what the manufacturer instructs.

In the meantime again, because this is educational, the surveyors will work with the laboratories. But I think, what – most of what the laboratories – the surveyor is going to be looking for in each laboratory that is initiating the IQCP process will be to see, for

example, under the risk assessment, are all three phases of testing considered? Are the five components of risk assessment – the sample, the reagents, the test system, the environment, and the testing personnel – are they addressed appropriately?

And then from that, the surveyor will look at the Quality Control Plan that is to be considered. As the interpretive guideline say, it is a – it is a procedure. So, it would have to be signed and dated by the laboratory director and then, followed by the laboratory as written. And then, just as they do now, the laboratory would have to have a quality assessment program for – to monitor on an ongoing basis the effectiveness of that plan.

Max Williams: Great, thank you.

Operator: Your next question comes from the line of Janet Graff.

Rama Tyagi: Hello, my name is Rama Tyagi. I actually work with Janet and we – calling from the Response Genetics. And most of my question is being, I think, already addressed because one of our listeners from – asked already. We are molecular genetics. And I didn't see the list of the name of molecular genetics in the specialty or subspecialty list. So, that was my first question – was coming – was like, we just had the quality plan for IQCP we developed according to the high complexity and since it is –no regulation apply, we just go by the risk base. That was my question going to be.

Penny Keller: This is Penny Keller again. We don't actually have a specialty category for molecular genetics. We have the clinical cytogenetics. We basically advise the laboratory to pick an appropriate specialty based on what your test is detecting for or identifying for…(inaudible)). So, molecular genetic tests tend to fall in many of the CLIA specialties that's listed – chemistry, immunology, histopathology, cytology – depending on what your test system is identifying. So, that's number one. That's for question number one.

So, if your QC – current QCP plan is following the high-complexity requirements for the various components, extraction phase, amplification phase, electrophoresis phase et cetera, that's fine and you can continue to do that. And that – but the IQCP is then another option in case you want to have a – what I call an alternative control plan that fits your test system, that's more appropriate.

Rama Tyagi: Thank you, I appreciate that.

Penny Keller: You're welcome.

Operator: Your next question comes from the line of Dave Kicker.

Dave Kicker: Hi, yeah, this is Dave Kicker with Crisp Regional Hospital of Quill, Georgia. So, I'm an administrative type guy and I don't understand a lot of what has been discussed today – I guess, the two things I'm trying to understand – if you have a budget kit test or non-waived type testing , IQCP does not apply. I guess, this is the way I've read some of this. And then I guess, the second piece would be to have an assessment of

what non-waived testing that you do have that would come under this IQCP and to develop your protocols around that.

Judith Yost: Hi, this is Judy Yost. I'll go ahead and start to try and respond to your question.

Actually, any non-test – non-waived test except for pathology is eligible for IQCP. But the laboratory itself and that – you know, with the staff and the – and the technical folks and the director can decide on a test-by-test basis which test they actually wish to use IQCP for or which test, you know, they choose to default to the CLIA regulations for quality control, the two – the two levels per day of testing, and the specialty requirement, so that you have a choice for each non-waived test.

Dave Kicker: All right, thank you.

Judith Yost: You bet.

Operator: Your next question comes from the line of Margaret Yew

Margaret Yew: Hello, this is Margaret Yew of VA Roseburg. I think my question was already answered – was already asked by somebody else. I got the answer. Thank you.

Judith Yost: You bet, thank you.

Operator: Your next question comes from the line of Lisa Calabria.

Lisa Calabria: Hi, this is Lisa Calabria at Internist Associates in Syracuse, New York. I know that you said each lab would be different. But I was wondering if there's somewhere to go to see an example of how to make an IQCP plan. I mean, I think we have a very good quality control program. But this risk assessment part – I don't really understand all the parts of it. Is there some place to go to see some kind of example?

Judith Yost: I think that you can probably go to, to like consensus documents, they have examples. We are working with the CDC on a workbook that will have – it will take a test and walk it through the entire process. And that will have examples. That will probably not be out 'til later this year though, I think at the earliest. But, that will be available. I also suspect that some of the manufacturers will also be providing some ideas for you for your particular test systems as well. So, there'll be sources out there. You know every time we do something different or new, there's a new cottage industry that rises up out of the depth. So they'll be something forthcoming I'm sure.

Lisa Calabria: OK, thank you.

Operator: Your next question comes from the line of Debra Wilhelm.

Debra Wilhelm: Hi, this is Debra Wilhelm with Quality Healthcare in Hillsboro, Oregon. I have a question about current acceptable manufacturers that recommend or that have electronic QC available. So for activated clotting time they have meters that will do electronic QC every 8 hours. Will that still be acceptable under this new system?

Judith Yost: It should be if it's in the manufacturer's instructions.

Debra Wilhelm: So, there's nothing that's going to stipulate that the electronic QC isn't acceptable anymore.

Penny Keller: Can you clarify? Are you asking if the electronic – if it has electronic control, that they would have – you have to perform IQCP? Is that the question?

Debra Wilhelm: Yes, because electronic QCs are still going to be acceptable, aren't they, for – if the manufacturer has them available and it's in the instructions?

Penny Keller: You can use them, but in order to use them, you will have to do – you will have to perform the IQC process.

Debra Wilhelm: Even though there is a recommended manufacturer's recommendation?

Penny Keller: Yes, but they're not – they're electronic controls and they're not what we interpret as the quality controls – external liquid type of – or external type of control that's required by the regs. So internal controls, electronic controls, alternative forms of controls – the IQCP process allows you to now actually use them as long as you can justify it by having the evidence and the data.

Debra Wilhelm: OK, thank you.

Operator: Your next question comes from the line of Janice Wayrynen.

Janice Wayrynen: Hi, my name is Jan Wayrynen and I'm from Family Medicine Associates in Beverly, Massachusetts. My question is, would you have – post the questions and answers that are put to you in the IQCP mailbox?

Penny Keller: Do we post them? We haven't yet – we're – we – I guess, because we had the frequently asked questions in August attached to the S&C letter. And then the education and transition phase just started in January. So we are planning – we are gathering – we are planning to do another set. But we haven't gotten to the point where we've accumulated enough to put out another letter with the frequently asked questions. But yes, there will be another posting of the most common questions.

Janice Wayrynen: Thank you.

Operator: Your next question comes from the line of Lisa Ball.

Lynn Solick Hello, this is an associate of Lisa Ball, Lynn Solick, Black Hills Pediatrics in Rapid City, South Dakota. And my question concerns testing personnel. Who is qualified to write up the risk assessment? Who is – and I know the director will evaluate and sign it, but are – I was just wondering who is qualified.

Penny Meyers: OK, that's a great question. This is Penny Meyers. And we encourage all laboratory staff who have information and knowledge about how the test system works to participate in providing information and helping to perform the risk assessment. Now that being said, the implementation of a Quality Control Plan is ultimately the responsibility of the technical director or technical supervisor according to the CLIA regulations. And the laboratory director must ultimately approve the Quality Control Plan that is based on the risk assessment.

But we think that performing the risk assessment by receiving information from all laboratory staff – and let's face it – those who perform the test are often the ones who are most knowledgeable about where the weak points are in a test system, and they can be involved in gathering data and helping to perform the risk assessment. Ultimately though, it goes back to the technical director or supervisor and the laboratory director, who are ultimately responsible for making sure that the Quality Control Plan is based on the risk assessment, and they approve that.

Lynn Solick: Thank you.

Operator: Your next question comes from the line of Karen Sanderson.

Tammy Hartley: Yes, this is Tammy Hartley at North Carolina State Lab. I hate to be dense, but what I'm trying to understand exactly what IQCP is. Is it like if we have – if current CLIA regulation says, do quality control daily and – on a particular test, and perhaps the manufacturer says, you know, by lot number, we perform a risk assessment, present data, approve – have it approved, and just do it weekly or by lot number or something like that, is that essentially IQCP?

Judith Yost: That's really what you're doing, is, you are – this is Judy Yost. You are making an assessment of where you might have problems or errors with the test system. That's your risk assessment using the five components and all phases of testing and then analyzing that data in total to develop your Quality Control Plan.

And so yes, you possibly could be able to reduce your quality control down to the level that the manufacturer indicates. That would be the minimum that you could do. But on an ongoing basis, remember you need to really look at the effectiveness to ensure that there are not testing errors or QC failures with your Quality Control Plan because if so, you may have to go back and reevaluate and readjust a little bit.

Tammy Hartley: Thank you.

Operator: You have a followup question from the line of Dixie Marshall.

Dixie Marshall: This is Dixie with Memorial Hospital in Martinsville. I tried to email your question, and I got a return that the email was not available.

Nicole Cooney: Hi. Yes, this is Nicole Cooney. I will send some clarification out this afternoon. That would be iqcp@cms.hhs.gov. So, you need to add hhs in there for the email address.

Dixie Marshall: OK, thank you.

Nicole Cooney: Yes.

Operator: Your next question comes from the line of Dale Gibson.

Dale Gibson: Yes, I just want to see if there was going to be replay on this. I've got some clinics that really need to listen to this.

Nicole Cooney: I'm sorry, could you repeat the question?

Dale Gibson: Yes, is there – is there going to be a replay or a – you know, a – the call being put out there where you can pull it up and replay it?

Nicole Cooney: Sure, sure. This is Nicole Cooney again. We will be posting an audio recording and written transcript of the call. We are required to post both of those items together. So usually it's posted between 7 and 9 business days after the call. But it will be accessible on our Call Detail page on www.cms.gov/npc under the date of today's call. So, you will be able to go back and listen to the call as well as read the transcript.

Dale Gibson: Thank you, ma'am.

Nicole Cooney: Thank you.

Operator: Again, to ask an audio question, press star 1 on your telephone keypad.

Your next question comes from Travis Williams.

Travis Williams: Hi, this is Travis William from Numale Medical Center. My question is, in the situation where we are overseeing multiple clinics and we're still opening up new clinics, if one of those new labs does not pass, if they fail some portion of the IQCP, does that affect the overall rating of the – you know, the clinic, the brand, the name itself as a whole?

Penny Meyers: This is Penny Meyers. And if a laboratory receives a CLIA citation for a deficiency, regardless of its related to IQCP or QC or anything else, it affects the laboratory that operates under that CLIA number.

Travis Williams: OK, so all of our laboratories would have the same CLIA number, right?

Penny Meyers: Right. Then they're generally treated as a single laboratory as far as CLIA goes. The way we look at it is one CLIA number means one lab.

Travis Williams: OK, thank you.

Operator: Your next question comes from the line of Janet Hugg.

Janet Hugg: Yes. Hello, my name is Janet Hugg with Mercy Harvard Hospital in Harvard, Illinois. I have a question regarding the direction to always follow manufacturer's instructions. And perhaps this is sort of a question of semantics, but we've found several of our analyzer procedures have what they call a manufacturer's recommendation. And this would be, for instance, for frequency of calibration. Is that – a manufacturer's recommendation – does that carry the same weight as a direct instruction? Or can that be interpreted through your process under IQCP?

Judith Yost: This is Judy Yost. Any information that is included in the manufacturer's instructions is there because it's intended that it is to be done. We've had multiple conversations with the FDA who approves those manufacturers' package inserts, and they indicate that they – that they will – you know, whatever is in that insert is – should be done by the laboratory and followed.

Janet Hugg: Thank you.

Operator: Your next question comes from the line of Maureen Wolfenden.

Maureen Wolfenden: Hi, this is Maureen Wolfenden from the Orthopedic Surgery Center in Peabody, Mass. How do you submit an IQCP plan?

Penny Meyers: This is Penny Meyers. The IQCP plans are not actually submitted to us ahead of time. They'll be reviewed by your CLIA surveyor at the time of your routine recertification survey.

Maureen Wolfenden: Great, thanks very much.

Operator: Your next question comes from the line of Kathy Yates.

Kathy Yates: Hi, this is Kathy Yates from United Memorial Medical Center in Batavia, New York. My question is, am I doing IQCP per analyzer? Per test? Per panel? Or am I doing it, like, per sample if I'm doing it for chemistry? Am I doing it for all of my plasma tests? For all my serum? Or how would I break it down that way?

Judith Yost: Hi, thank you for your question. Actually it's a test-by-test basis. And then, depending if you have multiple analyzers throughout your facility, then you would do it –

you would do it for the test system. However, your Quality Control Plan has to be by location. So there is a distinction. Your evaluation needs to be on a test-by-test basis. But if you do have the same analyzer in various locations, your plan – you can evaluate the test system – all at once. But the Quality Control Plan has to be per location because there may be variations in perhaps, the testing personnel, or the environment, or even the way the test is being used in different sites.

Now if you have a device that has multiple analytes on a single platform, many times those are the same test procedures. And so you can probably end up, even though there are different analytes on the same – on the same platform, you can do your risk assessment. More than likely if there are no distinctions between those tests and the test processes, you can probably just do one risk assessment and one Quality Control Plan would be acceptable. So there is where your savings are. It's kind of comparable to how you do competency assessment. It's the same kind of concept. Multiple analytes on a single platform can be done together.

Does that answer your question?

Kathy Yates: Yes.

Judith Yost: Great, thanks.

Operator: Your next question comes from the line of Tamara Toney.

Tamara Toney: Hi. This is Tammy Toney at Reid Hospital in Richmond, Indiana. Actually, I have two questions, I hope that's all right. The first one is, if I understand this correctly, the IQCP is only if we differ from the – if the manufacturer states that we need to do two QC levels for 24 hours, which is what the CLIA regs. are – and that's what we're doing, we do need to do nothing. It's only if it differs from the plan, say their previous information was from a Hemochron or the ACP testing, that does not have you do two controls per se every day of patient testing. Is this correct?

Penny Meyers: For each test system, the laboratory has a choice, and the laboratory may choose to either perform an IQCP or follow the regulations as written. That's for every case. In neither case can it be less than what the manufacturer instructs.

So if you have a test system whose manufacturer's instructions are less than what the CLIA regulations require, you have a choice. You can either perform an IQCP and put into place a QC system that provides equivalent quality or you can choose to follow the CLIA regs. as written.

Tamara Toney: OK. My second question is – goes back to the ACT testing. I didn't think that CLIA actually defined – which, I could be wrong, which I probably am – that they actually defined what quality control is, if it has to be a liquid quality control or a quality control of some measure. Is this true because the ACT does do quality control every day – every 8 hours? It's just not liquid quality control.

Judith Yost: I think, as Penny Keller explained earlier, if, if you wish to meet the regulations, you would have to do the external quality control to meet the regulations. However, if you choose to do IQCP, then you can do your risk assessment and then, based on that analysis of that information, the data, and the – and the – and the material and information you gather, then you can determine what your quality control would be. But at a minimum, you still must meet the manufacturer's instructions.

Tamara Toney: OK.

Penny Keller: And this is Penny Keller. Our interpretive guidelines for an example of compliance does actually go into external controls. And that's how we've always interpreted the QC requirement.

Tamara Toney: Right

Judith Yost: That is not a change. That is not.

Penny Keller: That has not been a – that's not a new change.

Tamara Tony: OK. Thank you very much.

Operator: Your next question comes from the line of Victoria Mallon.

Victoria Mallon: Hi, this is Victoria Mallon. I'm a senior lab manager at Hologic, and we make a test for fetal fibronectin, which is a small benchtop analyzer and it's QC for both a liquid and an internal control. And so it's a candidate for IQCP. And I just wanted to let everyone know that we put together guidance for implementing the IQCP for our instruments. But it's a sample, so it could also be used for other analyzers, and it's been posted on the CLS by Quality Management Systems Community online. So I think it's a pretty good example of what you need to do in order to figure out the risk for your individual laboratory. So it might be a useful template for some people.

Nicole Cooney: Thank you very much.

Operator: Your next question comes from the line of Raphael Franquiz.

Raphael Franquiz: Hello, hi, my question is, after December 15, we're going to be able to have a hybrid QC, which mean we're going to be able to use IQCP plus the regular quality control that we're using?

Penny Meyers: Yes, the answer to that is yes. You may choose to use either IQCP of the default quality control as described in the regs. You can use some for once – or use IQCP for some tests and the regulatory quality control for other tests. That's up to the lab director.

Raphael Franquiz: Perfect, thank you.

Operator: Your next question comes from the line of Leo Moons.

Leo Moons: Hello, this is Leo Moons from Long Beach Veteran's Affairs Medical Center in California. And my question is regarding using IQCP for the required competency assessment methods. Can we use IQCP to change the required six elements that are needed to be performed every year for each test system if we find the risk assessment?

Judith Yost: I'm sorry, those two are not – this is Judith Yost. Those two are not interchangeable. You need to use all six elements and competency assessment for every test.

Leo Moons: OK, thank you very much.

Penny Meyers: And if I could add – this is Penny Meyers – there is a table in the IQCP CLIA survey insert letter 1354 that outlines exactly which regulations are eligible for IQCP. And any regulation that is not in that list must continue to be followed as written.

Leo Moons: OK, thank you very much.

Operator: Your next question comes from the line of Joseph Loscalzo.

Joseph Loscalzo: Hi, this is Joseph Loscalzo from Kaiser Regional Laboratory in Honolulu, Hawaii. If a laboratory decides to perform more QC than is required in the manufacturer's instructions, does that fall under the IQCP protocol?

Judith Yost: You also have to be able to meet the regulation then. If you're doing more QC and it's more than the regulation requires, then you don't have to do anything.

Joseph Loscalzo: Thank you.

Operator: Your next question comes from the line of Julia Sommers.

Julia Sommers: Hi, this is Julia Sommers. I am from Patient First in Lancaster, Pennsylvania, and we have a combination of moderate- and waives- complexity testing in our laboratory. So my understanding is that the IQCP that we need to develop will only be reviewed for our non-waived testing and that our waived testing will continue to move forward as manufacturers' guidelines.

Judith Yost: That's correct.

Julia Sommers: Thank you.

Operator: Your next question comes from Maria Grana.

Maria Grana: Yes, hi, good afternoon. It's Maria Grana from Baptist Hospital of Miami, Florida. And I just had a question, just actually a clarification on the manufacturers' instructions. So if the manufacturer deems that their QC – that doing QC for their instrument is less than they have currently have, they would have to send us documentation that it is less, you know, that we can do less. And then we will have to do the risk assessment to make sure to match it, correct?

Penny Meyers: If the manufacturer changes their QC instructions then ...

Maria Grana: Yes.

Penny Meyers: … then the manufacturer needs to go through whatever process they do to get that approved. But as far as the laboratory goes, if you receive manufacturer's instructions that are different than what you have had before and the QC requirement is less than what you've been doing and you wish to reduce your QC to that less frequent requirement, then you would need to include in your IQCP risk assessment data and evidence to support the fact that this reduced QC provides equivalent quality.

Maria Grana: OK, thank you so much.

Operator: Your next question comes from Melissa Sealie.

Melissa Sealie: Hi, it's Melissa Sealie from Temple University Hospital. When they were first talking about IQCP, EQC or Equivalent Quality Control – what is going to be gotten rid of and it wasn't going to be able to be grandfathered in. So I was just wondering, is that still going to be in place? It's not going to be able to be grandfathered in? And would that be acceptable if hospitals decided to do like a stability study with internal and external QC? Would that be an acceptable part of an IQCP plan?

Judith Yost: OK, this is JudyYost. We'll start with the EQC part of the question and kind of go from there. EQC, you are correct. At the end of the education and transition period, at the end of December in 2015, EQC will, as it – as it stands alone, will no longer be acceptable to meet CLIA quality control requirements. In the interim, during the education period, you can continue to use EQC if you're doing it correctly. So there is no problem there.

The other thing that you need – you can keep in mind – is that the historical data that you've compiled from using EQC over the period of time that you've been using it can be used towards developing – towards your risk assessment and towards developing your Quality Control Plan.

Melissa Sealie: Thank you.

Judith Yost: Sure.

Operator: Your next question comes from the line of Billy Heeper. Billy, your line is open. If you're on mute, please unmute your line.

Nicole Cooney: Next question, please, Victoria.

Operator: Yes. Your next question – you do have a followup from the line of Dixie Marshall.

Dixie Marshall: Yes, this is Dixie Marshall with Memorial Hospital. If we are – as we go through this process and we think we've got the plan really we're ready to implement. So we can implement the IQC plan before December 2015?

Judith Yost: Yes, you can. Yeah, you can start now.

Dixie Marshall: OK, thank you.

Operator: Your next question comes from the line of Diane Mullen. Diane, your line is open. If you're on mute, please unmute your line.

Gina Hearn: Hi, this is Gina Hearn from Boston Medical Center. I work with Dianne Mullen, who's right here listening as well. Just wondering – there was a person who spoke from Hologic who said she already had a template. Wondering if somehow we can get that online to use as a guide for now?

Penny Keller: I think you need you need to Google for that – for the Holistic contact and email it to them because we don't have any direct contact with the manufacturers that way.

Judith Yost: And one thing to keep in mind is you still have to do your own assessment. You have to compile your data and do your own analysis and assessment and determination about that information that you're ultimately going to use as your Quality Control Plan. The manufacturer can assist you and provide some guidance, but the actual work needs to be done by the testing personnel and the technical supervisor in the laboratory.

Gina Hearn: Of course.

Penny Keller: The manufacturer was Hologic. Excuse me if I got it wrong.

Gina Hearn: Thank you.

Operator: Your next question comes from the line of Shirley Heber.

Shirley Heber: Hi, this is Shirley Heber from Avera McKennan Hospital in Sioux Falls, South Dakota. My question is just in reference to the statement that was made a couple of questions ago about a list of analytes that went out in a letter of some type. And I don't

think – I don't remember seeing that letter. But if I did, then I apologize. Where is that document that we can pull up?

Penny Meyers: This is Penny Meyers. And were you – what you were referring to was the list of regulations. That's the only list I can recall us speaking about here. It was a part of the question, the response to the question about competency.

Shirley Heber: OK, I may have misunderstood you – you were addressing not specific analytes that would be eligible for this program. This was about regulation …

Penny Meyers: That's exactly right, that's exactly right. The table lists these specialties and sub-specialties that are eligible for IQCP, as well as those each –within each specialty and sub-specialty, those CLIA regulations that are eligible for the IQCP process. All other CLIA regulations continue to be fully enforced, regardless of whether the lab chooses IQCP or following the regulatory requirements as written.

Shirley Heber: And where is that list available did you say?

Penny Meyers: That's in the survey insert letter of CLIA 13-54. And the – you'll find it by going on the link that's in your handout.

Shirley Heber: OK.

Judith Yost: And this is – it's dated August 16th, 2013, just to give you a timeframe.

Shirley Heber: All right. Thank you, Judy.

Operator: Your next question comes from the line of Raphael Franquiz.

Raphael Franquiz: What would be the acceptable frequency to review the IQCP?

Penny Meyers: The – this is Penny Meyers. And the IQCP must be reviewed in accordance with the laboratory's quality assurance policies and procedures that are put in place by the laboratory director.

Raphael Franquiz: That means it will depend on each lab?

Penny Meyers: Yes.

Raphael Franquiz: Each lab director will decide the frequency. And the inspector, when they come to inspect the lab, will agree with whatever was written on that plan, correct?
Penny Meyers: Our inspectors use the outcome-oriented survey process and they look at the laboratory's overall compliance. So they would look at that in context with what's going on in the laboratory. If it were to turn out, for example, that there were a lot of mistakes and problems in the lab that weren't being seen and corrected in a timely manner, then the surveyor may make comment about the frequency of the QA review.

But in general, as long as the QA program is working, then the surveyor would not question the laboratory director's determination of how frequently it needs to be done.

Raphael Franquiz: Perfect. Thank you.

Operator: Your next question comes from the line of Kate Bauerle.

Kate Bauerle: Hi. When I'm looking at the risk-assessment section, I'm wondering, is there any kind of pointers or things that we should be looking at when we're assessing the pre- and post-analytical phase, specifically about the environment? What exactly are you questioning with the environment? What exactly are you questioning with the specimen after everything's done? How do we work in those components in the risk assessment?

Judith Yost: This is Judy Yost. As far as the environment, you're going to be looking to see whether or not for the – the easiest example for environment is temperature. Many of the test systems may have reagents or components of the test system themselves that may be temperature- sensitive. And in some cases, manufacturers will put into the – for example, a reagent, an indicator of sorts that if the temperature is out of range, you know, you'll get a reaction or a flag or some kind of indicator that the temperature is out.

In other cases the reagent still may be temperature-sensitive but the laboratory will have to then monitor its own temperature. So that's an easy example of something. But you would look first in the manufacturer's instructions to find out if, in fact, there were any problems with that. There are some test kits, for example, where the quality control is stored at a different temperature than the reagents are. So again, you'd have to be monitoring to ensure that those are met as well according to the manufacturer's instructions. So you're looking environmentally at temperature, humidity, dust even sometimes. Some things are sensitive to light.

So whatever the manufacturer indicates is what you'd be looking at. With regard to the sample, we're talking the process all the way from collection until you place it on the test system for analysis and – you'd – would look at – because in many cases in laboratories that process is manual, there are opportunities for errors. So where you know in your laboratory there are specimen-processing errors, you would have to be able to put in place activities in order to monitor those problems and then evaluate them on a regular basis to ensure that they're not happening.

Kate Bauerle: So, like if we already have something in place where we're already monitoring the temperature, humidity, and all the ...

Judith Yost: You're good to go.
Kate Bauerle: ... in the lab, we have to – like for each individual test, do we have to document that? Is that – I just – I just – I'm kind of confused about how to show all five of these things in all three of these phases and not have your document for IQCP be 25 pages long for each analyte.

Judith Yost: As long as you have that information, you could put it in the plan, but the data you can probably keep just as you've been maintaining it now.

Kate Bauerle: OK. I guess that'll ...

Judith Yost: You don't have to put it all together. But you have – you have to formalize the process and write it down to show what your plan – what your risk assessment was and document it and then what's your plan is and how you're monitoring it to ensure its effectiveness. But perhaps the supporting data and stuff that you're already doing – you can keep it just as you're currently keeping it just so that is available when the surveyor would ask for it, just as they do now.

Kate Bauerle: OK. And, then, are you going to – I know – I came into this call late because I'm also working as tech today. For the risk assessment, is there any other like supplemental documentation for you – for us labs to start developing or doing these risk assessments on the tests? Is there any examples or anything besides just listing certain things we have to do like templates or any kind of helpful user-friendly things for us to use or find for CLIA to make sure that our risk assessment is sufficient?

Judith Yost: We do not typically prescribe just because of the huge variety of different situations that might occur in laboratories. So we will not prescribe. What we do say is that it has to cover all three phases of the testing process as well as the five components – the sample, the environment, the reagent, the testing personnel, and the analysis.

I can say that probably some of the consensus documents that are available, they have information. Manufacturers, I know, are – many of them will be providing, I'm sure, some information to help you through that part of the process as well.

Kate Bauerle: OK, thank you.

Operator: Again, if you would like to ask an audio question, press star 1 on your telephone keypad.

Your next question comes from the line of Jennifer Paretta.

Jennifer Paretta: Hi, this is Jennifer Paretta from Bostwick Laboratories.

My question is, on slide 13 you list everything that we should be doing, reach out – we're a molecular genetics lab. We're doing everything that's listed there. Is there anything else that needs to be done other than this – what's listed on slide 13?

Judith Yost: This is Judy Yost. I'll start to answer the question. That's not everything, that's just some examples of things that you might want to consider. But certainly you may have – when you do your own risk assessment, there may be other data, something like, you know, beyond what is listed here. You probably have historical quality control data that you may want to evaluate as part of this process.

These were just ideas of places that you can start with. But it depends on, again, your laboratory and the types of errors that you have already seen or where you have a potential for a failure, a test system failure based on, perhaps, some of the manufacturer's information that you get with your test system. Those are the kinds of information that you may want to consider at the outset as part of your evaluation for risk assessment and developing your QCP.

You have – did you have a second part to that?

Jennifer Paretta: Yeah, like we just opened up, so our QC, all of our PC, all of our risk assessment – we had to do that to provide to New York State. So, we're not seeing – I mean, we have our internal controls, we have our PT that we do, we have all of our documentation set – so, I'm just trying to think what is additional is this going to require when we have our risk assessment? We have our competencies, we have our PC, we have all of our logs that we logged the world. But, will that change anything we do – that we document? So, I'm just trying to get a handle on what possibly else we should be doing because we're not seeing – we're not seeing anything. We just opened. But, you know where I'm coming from, I mean we had to provide everything to New York State to get opened for our – all of our validation – you know, do everything.

Penny Keller: Jennifer, this is Penny Keller. Are you – are you in New York State, your facility?

Jennifer Paretta: Yes.

Penny Keller: So, you are required by New York to follow whatever New York standards has as far as their QC?

Jennifer Paretta: Oh yeah. And we do to the letter of the law – they come in, we've done it.

Penny Keller: Then you're – then that's – you should be following whatever New York is going to require for their interpretation of IQC – their equivalent of IQCP if you are a New York State lab.

Jennifer Paretta: OK, and we're doing that. So, there is nothing additional that we need to be doing other than what we're currently doing?

Penny Keller: If you need to, they'll let you know, I'm sure.

Jennifer Paretta: Oh, I'm sure – I am sure they will.

Penny Keller: Thank you.

Jennifer Paretta: OK, thank you.

Operator: Your next question comes from the line of Mary Lay.

Mary Lay: This is Mary Lay from St. Luke's Health System in Western Idaho. My question for you is, how do you envision IQCP as it would pertain after 2016 to new instrument validation?

Penny Meyers: This is Penny Meyers. And IQCP for new instrument validation, of course, is going to, I guess, look a little different than IQCP for a test system that you've had in place for a long time. Because you're just bringing something new into your laboratory, you're not going to have the wealth of historical data that you've produced right there in order to – in order to perform your risk assessment and create your QCP.

So in that case, you'll really have to take a look at the performance specifications that you establish or verify when you set up your test system as well as any other testing that the laboratory director and technical supervisor choose to do in order to set the QC frequency. When you bring a new instrument or test system into the lab, at the beginning, especially those that you don't have much experience with, it's probably also a good idea to keep really an even closer eye on your QA to be sure that as you're starting to run the test system, that your Quality Control Plan is really doing everything that you think it should be because there may be some adjustments that are needed until you have a little bit more experience with the test system.

Mary Lay: OK, thank you. I did want to just add if I might, the EP23 was a very good and valuable situation so that we could rely when we switched over to only doing liquid QC periodically. That EQC study was awfully – it made us feel good that we had already done some studies.

Penny Meyers: OK, good. Thank you.

Operator: Your next question comes from the line of Bill Donohue.

Bill Donohue: Hey everybody, Bill Donohue with CarePoint Solutions in Boston. Judy and company, the recent – well, my request is this. When you look at the interpretive guidelines, there's a statement about the Quality Control Plan. And it says that QCP must provide for the immediate detection of errors that occur due to the test system failure, adverse environmental conditions, and operator performance.

It sort of sets the standard that not even risk mitigation. It's risk elimination almost. And it's set a very high standard. And I'm just curious, you know, if you could elaborate on that statement because it just seems like a very onerous and high degree of scrutiny that you're holding everybody to, but at the same time, you know, there are very few practices and clinical labs that could ensure absolute error detection every – with every patient sample.

Judith Yost: Thank you for your question. It's a good question. That language about the immediate detection of errors and so forth is actually right out of the CLIA regulations

for quality control. But with that said, really we're still, perhaps, defaulting back to the original idea of the risk assessment. That's up to the laboratory director then to decide. You know, we realize that no – number one, we all know that no test is perfect, and number two, we know that you'll never, ever be able to eliminate all the errors.

And that's clearly not the intent of IQCP. It's to identify those errors or potential test failures in your laboratory that you feel are serious enough that some action needs to be taken to mitigate those problems. So, it's up to you, the – and the laboratory director to determine which ones, in fact, you would choose to mitigate and which ones the manufacturer already has taken care of, and those that you feel are not serious or frequent enough to take any action for. So that process is already built into IQCP.

Bill Donohue: Great, that's very helpful. Thanks.

Male: Sure.

Operator: You can have a followup from Raphael Franquiz.

Nicole Cooney: Did you have a followup question for us?

Raphael Franquiz: Oh yes, sorry, I apologize, Raphael Franquiz from Miami. Are we going to be able to use EP23 as a guideline to do our IQCP?

Penny Meyers: This is Penny Meyers. If when – for CLIA purposes, you are required to follow, if you choose, the guidelines in IQCP that are put out by CMS. Now, that being said, if you would like to use EP23 or any other reference material that's available to you to assist you in meeting the IQCP requirements, we certainly don't discourage you from doing that. But the CLIA requirements will be surveyed against the IQCP that has been published by CMS.

Raphael Franquiz: OK. Because I went to a workshop in November 2013, and CMS was there when CLSI put out EP23. And it was supposed to be taken from EP23 in order for us to do the IQCP. We started in my lab doing since last year IQCP following the guidelines of EP23. Are CMS guidelines similar to EP23?

Penny Meyers: CMS guidelines are based on the general principles found in EP23. So I'd suggest what you should do is take a look at the CMS IQCP guidelines and ensure that your laboratory is following them, that its risk management or laboratory QC based on risk management.

Raphael Franquiz: Perfect.

Penny Meyers: So, you should take a look at those. And you're correct; the IQCP was based on principles contained in EP23, but the two are not 100 percent identical.

Raphael Franquiz: OK, thank you.

Nicole Cooney: Victoria, we have time for one final question.

Operator: And there are currently no further questions at this time. If you would like to ask an audio question, press star 1.

And you do have a followup question from Bill Donohue.

Bill Donohue: Hey, just again. I wonder how many participants were in the call today.

Nicole Cooney: I don't have that information at this time. Sorry, this is Nicole.

Bill Donohue: OK, thanks Nicole.

Additional Information

Nicole Cooney: OK. Thanks everyone for all your great questions today. And, once again, just to clarify, if you do have a question that you would like to send to the IQCP resource box, that address is iqcp@cms.hhs.gov. Again, that's iqcp@cms.hhs.gov.

An audio recording and written transcript of today's call will be posted to the MLN Connects Call website. We will release an announcement in the MLN Connects Provider eNews when these are available.

On slide 16 of today's presentation, you'll find information and a URL to evaluate your experience with today's call. Evaluations are anonymous, confidential, and voluntary. We hope you'll take a few moments to evaluate your MLN Connects Call experience.

Again, my name's Nicole Cooney, and I'd like to thank our presenters and, also, thank you for participating in today's MLN Connects Call. Have a wonderful day.

Operator: This concludes today's call. Presenters, please hold.

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