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Centers for Medicare & Medicaid Services
IQCP for CLIA Laboratory Nonwaived Testing: Workbook Tool—Webcast
MLN Connects National Provider Call
Moderator: Nicole Cooney
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Contents

Operator: At this time, I would like to welcome everyone to today's MLN Connects® event. All lines will remain in a listen-only mode until the question-and-answer session. This event is being recorded and transcribed. If anyone has any objections, you may disconnect at this time.

You can ask text questions — click the green Q&A icon on the lower left-hand corner of your screen. Type your question in the open area, and click Ask to submit. We will also be taking questions via the phone line, and instructions on how to do so will be given at the appropriate time.

If you would like to view the presentation in a full-screen view, click the Full Screen button in the lower right-hand corner of your screen. Press the Escape key on your keyboard to return to your original view. For optimal viewing and participation, please disable your popup blockers. And finally, should you need technical assistance, as a best practice, we suggest you first refresh your browser. If that does not resolve the issue, please click on the Support option in the upper right-hand corner of your screen for online troubleshooting.

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

Announcements and Introduction

Nicole Cooney: Thank you, I'm Nicole Cooney from the Provider Communications Group here at CMS. And as today's moderator, I'd like to welcome everyone to this MLN Connects event on IQCP for CLIA Laboratory Nonwaived Testing: A Workbook Tool.

MLN Connects is part of the Medicare Learning Network®. During this event, CMS subject matter experts introduce participants to "Developing an IQCP, A Step-By-Step Guide," a new workbook developed by CMS and the Centers for Disease Control and Prevention.

Before we get started, there are a few items I'd like to quickly cover. Today's event uses webcast technology. We recommend streaming the audio live through your computer speakers. All registrants should have received a link to the slide presentation for today's event in a reminder email.

Those of you participating via webcast may download a copy of today's slide presentation by clicking the Content icon at the bottom of your screen. You may also download a copy of the full workbook file by clicking the Content icon.

Please note that this event is being recorded and transcribed. The audio file and transcript of this event will be posted to the Event Detail page in approximately 7 business days. You can find the Event Detail page by going to www.cms.hhs.gov/npc.

Click on the Calls and Events link on the left navigation bar, and then look for the date of today's event in the list.

At this time, I'd like to turn the call over to Cindy Flacks.

Presentation

Cindy Flacks: Thank you Nicole. Good morning and good afternoon everyone. Thank you for joining our webcast today. The purpose of this webcast is to familiarize you with the IQCP educational material. By using the example scenario and forms within the IQCP workbook, you should be able to recognize the parts of an IQCP and be able to create a complete and customizable IQCP for your laboratory.

Next slide, please. On August 16th, 2013, CMS released a survey and certification letter, 13-54-CLIA, titled "Individualized Quality Control Plan, a New Quality Control Option." Attachment 1 of this letter provides laboratories with interpretive guidelines to meet CLIA's equivalent control procedures when the manufacturer's instructions for frequency of testing quality control is less stringent than the CLIA regulations.

This letter also announced an education and transition period, which began on January 1st, 2014, and will conclude on December 31st, 2015. There are several other attachments to this letter, but the primary focus is attachment 1, the interpretive guidelines.

The education and transition period allows you, the laboratory, time to learn about IQCP and decide if you want to transition your current QC practices. Keep in mind, after December 31st, 2015, EQC, or Equivalent Quality Control, will no longer be a QC option to meet CLIA regulatory requirements. There will be no grandfathering of any test system. You will need to look at your current practices concerning QC and determine whether IQCP is an option for your test system.

Beginning January 1st, 2016, there will be two options to meet CLIA QC requirements — you can follow the CLIA QC requirements or implement an IQCP. Throughout the planning, our rollout, and education and transition period, we here at CMS received requests for a how-to for IQCP. Our response was to develop the CLIA brochures and the workbook.

CLIA Educational Materials

Next slide, please. If you're following along just with the PowerPoint in front of you, we're on slide 7. Slide 7 provides a comprehensive list of educational material that's currently available on our CLIA website. We have an extensive list of frequently asked questions related to IQCP. We developed three new CLIA brochures — 11, and 12, 13, which are specific about IQCP. And finally, the last piece, the IQCP workbook.

Next slide. Brochure 11 is the first in the new series of IQCP brochures, and it provides a high-level overview about IQCP, including some frequently asked questions we received while we were in the planning stages.

Next slide. The next two IQCP brochures were actually worked on and released simultaneously. Brochure 12 contains questions and answers to help you, the laboratory, decide if IQCP is right for you. It also provides an example scenario to help with the decision making process, as well as a helpful flowchart that depicts each scenario.

Next slide. And finally, brochure 13. It provides more detail about IQCP and the three required parts, which are the risk assessment, the quality control plan, and of course, quality assessment. This brochure also goes into more narrative for each of the three required parts.

And finally, the most recent release of the CLIA IQCP educational materials is why we're all here on this webcast today, is the IQCP workbook. Using a detailed example scenario, this workbook is a step-by-step guide that consists — that can assist a lab in developing an IQCP.

I would now like to turn the presentation over to Sonya Strider from CDC. She will be navigating you through the workbook. Sonya?

Navigating the CLIA Workbook

Sonya Strider: Hello everyone, my name is Sonya Strider, and I work at the Centers for Disease Control, and I'm one of the collaborators on the development of this workbook.

If you're following along, not on the webcast, just with the slides, we are on slide 12. We wanted to go through the details of the workbook and give you a little guidance on navigating through it. The intent of the workbook is to provide you with a tool to assist you in determining if IQCP is right for your laboratory. If you decide to implement an IQCP, this workbook — this workbook will help you develop it. If you follow through the workbook and complete it as designed, at the end of the workbook, you will have a completed IQCP for the test system you were evaluating.

In this segment, we will be referring to pages of the workbook. So, hopefully, you have a copy of the workbook at your disposal. Let's begin.

Steps for Developing an IQCP

Slide 13, please. There are three steps, three phases, and five risk assessment components to developing an IQCP. We will walk you through the three steps of developing an IQCP, the first being the risk assessment. This is where you will take a

closer look at your processes and evaluate the potentials for error in what you are already doing.

The second step is the quality control plan. This is a way of documenting your quality control procedures to ensure that you are performing quality control as mandated by CLIA. Now if you already have an established quality control plan, performing the risk assessment merely allows you to determine if your current QC practices are sufficient to mitigate your potential risk. If you don't already have an established QCP, this workbook will walk you through developing a quality control plan sufficient for your testing environment. The same thing is true for the quality assessment section. We will look at each of those sections separately.

When thinking about your test systems and the potentials for errors, it is necessary to consider all phases of testing:

- The preanalytic phase. These are the things that can go wrong before you test.
- The analytic phase. These are the things that can go wrong during testing.
- And the postanalytic phase, which are those errors that can occur after testing has been completed, for instance, reporting or interpretation errors.

You will make these considerations for all five risk assessment components — the specimen, the test system, the reagents, the environment, and the testing personnel.

The Risk Assessment

Right now we will focus on how to use the risk assessment portion of the workbook. So if you have a workbook, please open it to page 9.

Next slide, please. The first step in performing the risk assessment is to gather all of your resource — all of your resources. On page 9 you will see a list of potential resources or supporting data. Review this list for ideas of the kinds of data that will be helpful in this process. Once you have gathered all the items that you think you need, you are ready to assess your test — your test system risks. You should look at what you are already doing and see if you can find areas for improvement in order to reduce potential sources of error in the future.

You should use the spaces provided to make notes, jot down your current practices, or identify the resources that you will need. In order to identify your potential sources of error, we have provided you with some example questions to ask yourself about your test system and test processes. We have provided these sample questions for each of the five risk assessment components. As we walk through the workbook, we will take a closer look at some of the example questions.

The important thing to remember is that these are merely a few possibilities of the many that may present opportunities for error that could be identified in your laboratory. We encourage you to really look at your process and come up with questions of your own to identify potential sources of error that best fit your process and test system.

Next slide, please. We're now on slide 15. So if you have a workbook, let's turn to page 10 of the workbook and take a look at the scenario there. All of the examples in this workbook are based on this overarching scenario, where a laboratory director decides that she wants to consider implementing an IQCP for her laboratory in order to meet CLIA QC requirements. The laboratory director has asked the laboratory supervisor to lead the process, beginning with the risk assessment.

You will see that the laboratory supervisor has gathered her supporting data — the things she feels she will need to consider to evaluate her test system. She has gathered her package inserts, her PT performance reports, her test performance specification verification studies, and all logs and records for each of the five risk assessment components to include refrigerator and freezer logs, specimen receipt logs, instrument maintenance logs, and training records, just to name a few. She has recorded this information in the spaces provided in the workbook. They're indicated by a pencil, and you'll see one here at the bottom of this slide.

Next slide, please. So let's turn to page 12 if you have a workbook to see how the laboratory supervisor has used the information she has gathered to assess the specimen risk. Let's review the scenario here.

Kim reviewed the specimen receipt logs for the past 2 years and noted that, according to the laboratory's policy, not all personnel have properly documented requests for recollection of specimens. Additionally, Kim noted some specimens remained unprocessed for more than 60 minutes without being properly stored. A review of the refrigerator and freezer logs for the past year showed a few recorded temperatures outside of the acceptable range; however, they had been investigated and appropriate corrective actions were taken.

Kim identified the possible sources of error and recorded her findings in the risk assessment worksheet located on page 13, and you'll see a sample of that on this slide. If we flip to page 13 in the workbook, we will see how Kim completed the risk assessment worksheet.

In column 2, she recorded the things that could go wrong and basically what the manufacturer's instructions and other resources gathered tell you that should be happening. For instance, you should be documenting specimen recollection and use no serum separator tube.

In column 3, you will decide if your identified sources of error can be reduced. And in column 4 is where you decide what kinds of activities could reduce the source of error. In this example, retraining testing personnel on the recollection policy and proper test collection tube identification was noted as ways of — as ways of reducing the errors identified.

This example shows us how the laboratory moved from identifying their potential sources of error to determining solutions to reduce those sources of error. They indicated that not documenting specimen recollections was a potential source of error. Potentially, collection personnel could be recollecting specimens because they are improperly collected or storing them. Personnel could use more training. Possibly there has been personnel changes, facility conditions could change, maybe the collection personnel are feeling rushed and not be as careful as they could be in their collection technique. There are many reasons for this. So when thinking about this possible source of error, be sure to record all your findings.

Let's take a look at one more scenario. Let's look at the scenario for assessing the test system risk. It's located on page 16 of the workbook. Kim reviewed external QC logs for the last 2 years. Although she identified a couple of outliers, corrective actions were performed and QC results following the corrective actions were acceptable.

Her review suggests that the test system is stable. She also noted that the test system performs an internal control with each reagent disk; however, an unacceptable internal control does not prevent a patient result from being reported. The manufacturer has built-in safeguards to help reduce the likelihood of test system errors, including the detection of sampling errors. Again, Kim will complete the risk assessment worksheet for the risk — for the test system risk.

Now we have not gone over how you can use the example questions and questions that you create for yourself in order to identify and assess the risk. So let's take a look at that sample question — the sample questions that are located on page 14 of the workbook before we can review the completed risk assessment worksheet.

So when you think about your laboratory and the entire testing process, you should consider the potential for error if certain conditions are not followed or met. For instance, in this example, we ask, Do you see a potential risk of producing incorrect test results if:

- Maintenance procedures are not consistent with the manufacturer's instructions?

- The test is performed outside of its intended use as described in the manufacturer's instructions?

- The limitations to the test system are ignored; for example, do lipemia or medications interfere with the test system performance?

- Built-in monitors do not exist for the test system, example, the ability to detect inadequate specimen volume?

- The laboratory information system, or LIS, isn't transmitting results or other information accurately?

- The test system doesn't have a means to ensure positive patient identification, such as functioning barcode readers?

- There's no mechanism such as an operator lockout to ensure only trained personnel use the test system?

If you answer Yes to any of these questions, then you should record those sources of error in column 2 of the risk assessment worksheet and the mitigating activity in column 4 of the risk assessment worksheet.

Always remember, these are merely examples. You should evaluate your process and identify all potential sources of error. For the risk component, the laboratory director noted a potential source of error because the test system does not prevent patient results from being reported if the QC is unacceptable. So this is what they — this is what they recorded in column 2. In column 4, her mitigating actions are to assure that testing personnel review each QC result at the completion of the test run, document QC results in the QC log, and only report patient results if the QC is acceptable.

Slide 17, please. Now that you have seen how this laboratory has completed their risk assessment worksheet based on the information that they gathered, you will be able to complete the risk assessment worksheet for your laboratory by following these three steps: One, identify the possible sources of error — what could go wrong? Two, determining if there are steps that you can take to reduce the chances or occurrences of the identified sources of errors happening — can we correct it? Three, identify activities to reduce your identified sources of error — what can we do?

This worksheet will help you update your QCP and QA activity. There is one worksheet for each of the five risk components. However, you can download or photocopy as many as you will need. There are no right or wrong answers to complete these worksheets. What is included in your plan will be specific for your laboratory testing process. Each of the five risk assessment components that you will evaluate has its own section that shows you how to evaluate that risk component based on the overarching scenario presented on page 10. Use that as a guide to develop and perform your own risk assessment.

Slide 18, please. In closing, here are a few things that are important to remember. The risk assessment is a good way to identify gaps in your testing process and will allow you to identify potential sources of error that can affect your test results. The risk assessment can be done at any time, for any reason.

You may perform risk assessments anytime your testing process or test systems change. The more you write down, the more likely you are to identify your gaps and sources of error.

Thank you. I will now turn it over to my colleague Theresia Snelling to review the QC and QA portions of the workbook.

The Quality Control Plan

Theresia Snelling: Hello, my name Theresia Snelling, and I work with the CDC, and I am also one of the collaborators on the workbook.

Slide 19, please. After performing the risk assessment, the information gathered and assessed is used to determine whether the quality control you are now performing is sufficient to reduce or eliminate potential errors.

What is quality control, or what is a quality control plan?

Your QCP is activities that reduce the likelihood of failures and errors, identified by your risk assessment. Your QCP should describe practices, procedures, and resources needed by your laboratory to ensure the quality of a testing process. Perform a risk assessment, then look at your quality control process you're already doing, and see if there are any adjustments that need to be made.

What should be included in a QCP? Your QCP should include measures to assure the accuracy and reliability of test results. It also should include quality of testing to make sure that it is accurate or adequate for the patient. Your QCP must provide for immediate detection of errors. It must also monitor the accuracy and precision of the test. At a minimum, your quality control plan must include the number, the type, and the frequency of testing control materials, as well as criteria for acceptable quality control.

You can incorporate data from known sources to complete your QCP. You'll see this at the bottom of this slide, where it says, "Electronic controls, equipment maintenance, internal controls, personnel training and competency assessment, equipment calibrations, and other specified quality control activities."

Take, for example, the scenario on page 37 in the workbook. Kim notes that there are fluctuations in the room temperature. Your solution to this problem may be to take temperatures more than once per day if you are working on an 8-hour shift. You may

decide to take temperatures every 8 hours in a facility that's open 24 hours a day. This is why you've heard many times that some tests may require more QC, while some tests will be accurate and reliable with less QC. Your IQCP is a process by which you will do the right QC for your facility.

Slide 20. We've added questions on page 40 in the workbook that you may ask yourself when considering potential sources of error. It will be helpful to form groups from cross-sections of your staff to see what other potential sources of error need to be addressed. We included blank forms, like the one shown here on page 41, to help with the process. These forms are just one way to accomplish this task.

In the workbook, we have given you two examples of a QCP, one using the chart, which you will see on page 38, and one that's typed out in sentence form that you will see on page 39. You can decide which format you like the best. You may start out using the chart form. That will help you to brainstorm, and then you may switch over to the sentence form to place it in your procedure manual.

If you look at the scenario on page 38 and you see how we document it in the chart form, you'll see where we've given you a temperature, we've told you how often we're going to take temperatures, and we've given you the acceptable range for those temperatures. There's a pattern that you see established. It's what type of control will be done, the frequency we will do those controls, and the acceptable limits for those controls. You may choose to switch over to the standard format to document all of your QCP in your procedure manuals. The main point to remember here is there is no one way or one format that is acceptable.

Slide 21. When you have completed your QCP, review it to make sure it contains the five things listed here on the slide:

- Does your QCP provide for immediate detection of errors for each phase of the testing process?
- Does your QCP specify the number, type, and frequency of testing?
- Does your QCP contain criteria to determine acceptable QC results?
- Does your QCP require the laboratory perform QC as specified by the manufacturer's instructions?
- And does your QCP show that the laboratory director has reviewed, signed, and dated the document?

If it does not include all of this, you need to find out what is missing and add it.

Quality Assessment

Slide 22, please. After performing the risk assessment and creating your quality control plan, you should now be able to determine if you have put enough corrective actions in place to control and/or eliminate risk. We're going to look at quality assessment.

Quality assessment is a multilayered function:

- You monitor and evaluate the process you have put in place,
- You review the effectiveness of your process, and
- You make corrective actions where needed.

Let's look at the differences between quality control and quality assessment, OK?

Examples of QC activities include recording the room temperature and putting that temperature on the temperature log, running your controls and recording those controls in your control log, or training new employees or doing competency assessment on your established employees and documenting that you've done this training in your employee files. Those are all examples of quality control.

Examples of quality assessment would be when you take that temperature log sheet and you review it at whatever given point you've established — weekly, monthly, quarterly — and you review that temperature log for fluctuations. And if you see something that's out, you look to see if corrective actions were taken.

Another QA activity would be reviewing the control logs to see if there are any outliers, see if there's any shifts in trends, and see if there's documentation that someone took action to correct whatever went wrong. When you review your personnel records for completion of required trainings and competency assessments, making sure that all your employees have taken their training, even on those tests that may only come in once or twice a year. Those are examples of quality assessment, OK?

If during your review process, you find something has not been addressed, you will need to modify your QCP. There is a difference between troubleshooting a problem and fixing the visible issue on the surface and finding the root cause and fixing the underlying, systemic problem. And what the IQCP should do is help you look for the root cause and eliminate it so that the error does not occur again.

Slide 23. Let's take a look at the scenario on page 47 of the workbook. As a result of the QA reviews, some discoveries are made, correction — corrective actions are implemented, and potential errors are mitigated. We find that the staff was not following the written SOPs and that what we've put in place is a review of the instrument printout logs.

We're not going to just look at the logs where people have documented what has been done. We're going to look at the printout from the instrument to make sure that the SOPs are being followed. We're going to do periodic remedial training of staff if needed, and the lab director will review and sign and date all QCPs.

Page 48 demonstrates how to document your findings. In the chart, these examples show one way to evaluate what is going on in your laboratory to determine the areas of most concern. So review of your quality assessment will help you determine if your quality controls are working. Again, we've added a section where you can write down questions and/or your ideas — that should help motivate you to think of situations and circumstances where you might consider potential sources of error. And just a reminder, it may be helpful to form work groups from cross-sections of your staff.

Slide 24, please. When you complete each section of this workbook — risk assessment, quality control plan, and quality assessment — you should have a complete IQCP. Continuously review your plan. Take a look at the diagram here on this slide. We started at the very top of the diagram, where it says "Review Quality Activities."

What do we already know? We already have some data to start with. Your review should include all phases of the testing process — preanalytical, analytical, and postanalytical. Your review should include specimen, test system, reagents, environment, and personnel. Your risk assessment should focus on determining what risks are possible and eliminating all risks.

Your quality control plan should provide for immediate detection and elimination of errors. Your quality assessment should indicate if your quality control plan is working. Review your plan and update it periodically and/or when changes occur. These changes could be manufacturer's update or anything that might happen in your facility — renovations, remodeling, moving, new staff, etc. And don't forget to document, document, and document. I'm turning it over to the next presenter.

The CLIA Survey Process

Keith Scott: Next slide, please. Hi, I'm Keith Scott, and I'm a CMS Federal CLIA surveyor. And I'm here today to discuss the CMS survey process for certificate of compliance laboratories in regards to the IQCP workbook.

What does the IQCP workbook change for the survey process? Nothing. The routine outcome-oriented survey process remains the same. If your lab uses IQCP, the surveyor will expect to see the required IQCP documentation for each test system using IQCP. All of these requirements are included in the workbook.

The specific documentation will depend on the test system and the laboratory. IQCP documentation will vary from lab to lab, and that's OK. CMS is not being prescriptive about how you document IQCP, as long as all of the essential elements are

documented. Accredited laboratories with a certificate of accreditation will need to contact your AO concerning IQCP requirements.

Next slide, please. The IQCP workbook is just another tool in your laboratory's toolbox of information that can be helpful with the IQCP process.

Next slide. When a lab has used the workbook to document their IQCP, the surveyor will not critique your use of the workbook, but rather assess whether your IQCP is complete and if it's working through the outcome-oriented survey process.

And what does complete mean? Well, the RA has addressed all phases of testing and all five components. The quality control plan states number, type, and frequency of quality control. It's reviewed, signed, and dated by the lab director, and the quality assessment monitors have been identified. Use of this workbook is not mandatory. Labs may use the workbook, they may utilize other products on the market, or they can come up with their own approach. No matter how labs decide to approach the creation of their IQCP, the survey process will remain the same.

Next slide. And now, I'll turn it back over to Cindy Flacks.

Resources

Cindy Flacks: Thank you Keith. The slide before you, if you're following along, is the list of resources and links that are available. As mentioned earlier, I believe from slide 7, we have IQC— IQCP brochures 11 through 13 and the FAQs on our CLIA website. We also have the IQCP workbook, which can be downloaded at the addresses listed from the CDC website as well as the CMS CLIA website.

Free hard copies are available by request from CDC by emailing the email address on your slide. And if you have any further questions after the webcast today, feel free to submit any questions to the IQCP mailbox, and again that address is on the slide.

Thank you. Nicole?

Question-and-Answer Session

Nicole Cooney: OK. Our subject matter experts will now take your questions about today's subject. As I mentioned when we started, we've been collecting questions from webcast participants during today's presentation. Please continue to submit any content-related questions that you may have.

I'd like to make a special note that our subject matter experts will be happy to answer general questions about IQCP requirements, but they will not be able to answer questions about QC for specific manufacturer's test instruments.

During today's Q&A, we also have a few polling questions for our webcast participants. Please remember to disable your popup blockers and take a minute to respond.

We'll begin our Q&A session by fielding a few questions that we've received from webcast participants, and we'll then alternate to a question from the phone. We will also address some of the questions asked during registration.

Kalia, could you please prompt the telephone users and begin to compile that Q&A roster?

Operator: You can ask text questions. Click the green Q&A icon on the lower left-hand corner of your screen. Type your question in the open area and click Ask to submit.

For those of you participating via telephone only, to ask a question, please press star followed by the number 1 on you touchtone phone. To remove yourself from the queue, press the pound key. Remember to pick up your handset before asking your question to assure clarity. Please know your lines will remain open during the time you are asking a question, so anything you say or any background noise will be heard in the conference.

Please hold while we compile the Q&A roster.

Nicole Cooney: And before we begin, I'd like to remind everyone that today's call is being recorded and transcribed.

Our first question comes from an online participant. Which accreditation organizations are allowing IQCP?

Cindy Flacks: At this time, three accreditation organizations have received CMS approval for their IQCP programs — CAP, COLA, and the Joint Commission. In addition, the two States with CLIA exemptions —New York and Washington — have received CMS approval for their IQCP programs. We strongly suggest contacting your accreditation organization or exempt State to obtain its own specific IQCP requirements, which may be equal to or more stringent than CLIA.

Nicole Cooney: Our next question. Several participants inquired at registration — oh, I'm sorry, several participants inquired at registration about specific accreditation organization requirements for IQCP as well as any State requirements. Can you address this topic?

Cindy Flacks: Sure. Several accreditation organizations are allowing IQCP for their laboratories. Again, you should contact your accreditation organization to inquire about its specific IQCP requirements. In addition, if you are located in a State that has laboratory regulations, you should contact your State for its requirements.

Nicole Cooney: OK. Our next question comes from Stewart Jordan. Is it true that a lab can decide to do QC on each nonwaived test every day of patient testing and not have to develop an IQ – I think it should be IQCP, correct? Yes, IQ — yes, I think it should be IQCP.

Cindy Flacks: Yes, yes. Sorry, a laboratory may follow the CLIA QC regulations or develop and implement an IQCP. Keep in mind, a laboratory doesn't have to develop an IQCP for every test system that they have. They may do a mix — follow the QC regulations for some tests or test systems and implement IQCP for others.

Thank you for your question.

Nicole Cooney: OK. And here's a question that we received from registration. Does a change in sample types used on any instrument require a separate IQCP?

Cindy Flacks: That's a good question. If more than one sample type can be run on an instrument, this does not necessarily mean that a separate IQCP needs to be developed for each sample type. However, the risk assessment should address each sample type to identify any risks that are unique to each type of sample.

Nicole Cooney: Here's another question from registration. If a lab chooses to go with IQCP, must it be implemented by the deadline of January 1st, 2016?

Cindy Flacks: Another great question. After December 31st, 2015, laboratories will have two options for compliance — that is, either implement IQCP or follow the CLIA QC regulations as written. If a laboratory initially chooses to follow the CLIA regulations as written, they may decide to implement IQCP at a later date.

Nicole Cooney: Is it possible to implement some parts but not all?

Cindy Flacks: This question can be interpreted in two ways. If this questioner is asking if they can implement just a part of IQCP, for example the QCP, then the answer is No. Laboratories that choose to implement IQCP for CLIA compliance must follow all of the requirements laid out for IQCP. On the other hand, if the questioner is asking if the laboratory can implement IQCP for some of its testing but not all, then the answer is Yes. Laboratories may choose to implement IQCP for none, some, or all of its testing.

Nicole Cooney: OK. Give me just 1 second.

OK, our next question comes from a webcast participant. We are a high-complexity lab; however, we use various waived kits such as Flu A, B, and Rapid Strep. For these, we can just follow manufacturer instructions. If the kits require external QC each kit lot shipment, new operator, and every 30 days, since this is less stringent than the CLIA requirements — oh boy, of two — hold on, I'm scrolling — of two external QC each

day, do we have to do IQCP or follow CLIA for waived test and manufacturer instructions?

Cindy Flacks: IQCP does not apply to waived testing. IQCP is intended for nonwaived testing. So if you are in a laboratory that is performing only waived testing, you may follow the manufacturer's requirements. With that said, if you are under an accreditation organization or exempt State or in a State that has specific laboratory requirements, I would firmly suggest that you contact your AO or State.

Nicole Cooney: OK, our next question comes from Linda Green. Do we show inspectors risk assessment or just for lab use in creating IQCPs?

Cindy Flacks: Keith, would you like to answer that question?

Keith Scott: The risk assessment should be a part of what you show the laboratory inspector. It's part of the IQCP documentation.

Nicole Cooney: Thanks Keith. OK, our next question comes from registration. Do all labs need an IQCP, even if they follow manufacturer directions? If QC requirements are part of the SOP, is that sufficient?

Cindy Flacks: If manufacturer's instructions are less stringent than the CLIA QC regulations, a laboratory must choose to do an IQCP or follow the CLIA regulations.

Nicole Cooney: If the test manufacturer does not specify a QC frequency, can IQCP be used?

Cindy Flacks: Yes, IQCP can be used or the lab can choose to follow the CLIA QC regulations.

Nicole Cooney: The salesman for one of our test systems supplied us with a step-by-step template for implementing IQCP. How can we find out if the template has been approved by CMS? Are we allowed to use the template instead of the workbook?

Cindy Flacks: We at CMS are aware that the laboratory industry is developing various IQCP products for the marketplace. These products might include templates, forms, IQCP guidance for specific test systems, and even computer programs. They are being developed by test system manufacturers, accreditation organizations, consultants, as many others.

Laboratories are allowed to use these products. CMS, however, does not require any specific format for IQCP documentation and does not have the legal authority to review

and approve these products. It is strictly up to the laboratory director to determine if they are adequate and whether or not to use them.

Nicole Cooney: OK. If we are already following the CAP guidelines to the letter, aren't we already completing this whole process?

Cindy Flacks: Again, I would highly suggest that you contact CAP. As I mentioned in an earlier question, they have been approved for their IQCP policies and procedures.

Nicole Cooney: If a lab chooses not to implement IQCP, what is the alternative?

Cindy Flacks: Follow the QC, the – excuse me, the CLIA QC regulations.

Nicole Cooney: OK, our next question comes from registration. If there are three coag instruments in cardiac Cath department in three different rooms, does that mean three separate IQCPs?

Cindy Flacks: That's a great question that we get asked a lot. If the laboratories have multiple identical devices, the IQCP may be developed for the test system, taking into consideration the unique environment, testing personnel, as well as any other factors while doing the risk assessment. However, if those devices are dispersed throughout a healthcare facility, the QCP must be developed for the devices at the different locations. Each device must be monitored in some way.

Nicole Cooney: To the best of my ability, I have written IQCPs for all systems impacted by this CMS option. When I am inspected, will surveyors cite minor differences in opinion? What constitutes a citation? My medical director has signed off on all IQCPs that we have implemented.

Keith Scott: I can answer that one. A surveyor will be using the outcome-oriented survey process to conduct the survey. That has not and will not change. They will be looking to make sure the IQCP has all three parts — the risk assessment, the quality control plan, and the quality assessment piece, and meets the individual requirements of the risk assessment and the quality control plan.

Nicole Cooney: Is there a preferred format that will be acceptable to CLIA surveyors?

Keith Scott: Sounds one like — sounds like one for me also. The lab director chooses to implement IQCP. He's responsible to ensure that all IQCP requirements are followed, regardless of the type of documentation that's used. Laboratories can use the forms in the workbook, materials obtained from other sources, or an in-house developed format. CLIA surveyors will use the outcome-oriented survey process to ensure that IQCP has been implemented according to the requirements, regardless of the documentation format.

Nicole Cooney: OK. Our next question comes from Lynn Cruz. We are acquiring a pain management practice and we have a physician-owned lab with CLIA. Does this apply to us?

Cindy Flacks: Thanks for your question Lynn. If your laboratory is performing nonwaived testing, then IQCP can apply to you.

Nicole Cooney: OK, our next question comes from Cynthia Ryan. We have laboratory medical directors who are not our CLIA director. Can the signature on QC plan be delegated to those medical directors?

Cindy Flacks: Another great question. The signature for the QCP has to be from the laboratory director. This is something that cannot be delegated.

Nicole Cooney: OK. Our next question comes from registration, and this question relates to microbiology. How does the removal of CLSI microbiology standards from the CLIA interpretive guidelines affect ID and MIC panels in microbiology?

Cindy Flacks: Well, that's a great question. As a result of this removal, you have two QC options. Number one, you can follow the CLIA regulatory quality requirements in Subpart K or implement IQCP. Laboratories may use the data collected while following CLSI microbiology standards as information for their risk assessment. But the CLSI microbiology standards in and of themselves do not meet all elements required for a complete IQCP.

Nicole Cooney: For microbiology laboratories, how does the development of an IQCP apply to instruments, cultures, organism IDs, AST?

Cindy Flacks: There is no specified way in which the laboratory must organize the risk assessment information for IQCP. For example, some are organized by instrument and within each instrument, the specimen sources are each considered. For media, some laboratories have chosen to create a single IQCP that addresses all media used, while others might develop individual ones for each media type.

Nicole Cooney: And here's another question from registration. Are there more specific guidelines from microbiology and serology tests?

Cindy Flacks: If a laboratory chooses to implement IQCP, the IQCP requirements for microbiology and serology are the same as — excuse me, are the same as for tests in any other CLIA specialty or subspecialty.

Nicole Cooney: Do we need to do IQCP for catalase, oxidase, and individual biochemicals?

Cindy Flacks: Another great question. IQCP is strictly voluntary. We can't stress that enough. Laboratories may choose to use IQCP or follow the CLIA QC regulations.

For catalase, oxidase, reagents used with biochemical tests, and Cefinase, the CLIA requirement at 493.1256E1 is to check each batch, lot, and shipment when prepared or opened for positive and negative reactivity. For beta-lactamase methods other than Cefinase, the CLIA requirement at 493.1261A1 is to check for positive and negative reactivity each day of use. Laboratories that perform less QC than the regulations require must develop an IQCP that supports their QC frequency.

Nicole Cooney: Does IQCP change the requirements for gram staining?

Cindy Flacks: No. Again, another important point to remember, no CLIA regulations have changed with IQCP. To that end, no CLIA regulations have been changed with the implementation of IQCP, including those for gram stain. IQCP is intended to offer laboratories another option for CLIA compliance.

Nicole Cooney: For microbiology laboratories, how does the risk assessment differ when the test is performed on an organism colony instead of a patient's sample?

Cindy Flacks: Well, there isn't anything the lab must do differently. The risk assessment must still incorporate all five components in all three phases of the testing process.

Nicole Cooney: OK. We are a microbiology laboratory, evaluating whether or not we meet CLIA regulations for QC. For example, gram stain requirements are once per week for positive and negative reactivity. The requirement for antisera is to check with a positive and negative control each batch, shipment, and lot, and once every 6 months thereafter. If we are doing that, can we say we meet CLIA or do we need to do an IQCP to continue this QC schedule?

Cindy Flacks: The procedures that you have outlined here meet the current CLIA regulations; therefore, you do not do — excuse me, you do not need to do an IQCP in order to be in compliance.

Nicole Cooney: Must we implement IQCP for antimicrobial susceptibility testing platforms?

Cindy Flacks: Again, if your lab is performing quality control that is less stringent than the CLIA QC regulations, your lab must develop an IQCP that supports your QC frequency.

Nicole Cooney: OK. And here we have a question from Marina Dowdy. According to the Individualized Quality Control Plan Step-by-Step Guide, it says that the IQCP is voluntary. Is that correct?

Cindy Flacks: That's correct, Maureen — oh Marina, I'm sorry.

Nicole Cooney: OK, our next question. I have a blood culture instrument. The manufacturer does not require any QC. Do I need IQCP?

Cindy Flacks: Again, you can follow the CLIA QC regulations or implement an IQCP.

Nicole Cooney: If you follow CAP guidelines and CLSI guidelines, do you have to do an IQCP?

Cindy Flacks: Well that depends. If your — again, if your laboratory is CAP accredited, I would strongly suggest you contact CAP for their IQCP requirement. Keep in mind, they can be equal to or more stringent than the CLIA IQCP guidelines.

Nicole Cooney: Here's another question from registration. If we have been using equivalent QC, known as EQC, for a test, and now wish to perform an IQCP, can we use the data from the past in our risk assessment?

Cindy Flacks: Yes, absolutely. The data can and should be used in performing the risk assessment. Keep in mind that the data in and of itself is not enough to fully meet all the requirements for a risk assessment.

Nicole Cooney: Here's a followup to a previous question. Is IQCP mandatory or not?

Cindy Flacks: Again, here at CMS, we cannot emphasize this enough. IQCP is voluntary, but if a lab intends to perform QC that is less than what is required by the CLIA QC regulations, the lab will be expected to do an IQCP that supports its QC frequency.

Nicole Cooney: I would like CMS to address validation of replacement instruments when IQCP is being used.

Cindy Flacks: This is another great question, and we get asked this a lot.

IQCP doesn't change the process for a replacement or learner instrument. The laboratory still needs to do validation prior to use. When a temporary replacement or loaner instrument is received which is identical to the instrument being replaced — in other words, the same make and model, the laboratory must verify performance specifications prior to reporting patient results.

Nicole Cooney: Does CLIA require that QC be performed more frequently than manufacturer's recommendations?

Cindy Flacks: Well, it is possible that a lab's IQCP may require more frequent QC than the manufacturer's instructions. The minimum labs must do is either follow the CLIA QC regulatory requirements or, if doing less than these requirements, implement an IQCP. An IQCP cannot be less stringent than the manufacturer's instructions.

Nicole Cooney: Here's another question from registration. This seems like a huge amount of work in addition to what we already do for test verification and QC. Why is this necessary now?

Cindy Flacks: Well, again, IQCP is strictly voluntary. Due to the advancements in technology, CMS is offering IQCP as an alternative to the one-size-fits-all QC requirements that are currently in the CLIA regulations. IQCP provides laboratories with an opportunity to develop a customized QC program for some or all of its testing. Laboratories will continue to have the option of following the CLIA regulations as written, and in that case, IQCP is not necessary.

Nicole Cooney: Here is a question from Judith Bridges. All other IQCP webinars and symposiums I have attended indicate that the risk assessment includes what is the frequency of occurrence and severity of harm matrix for each possible error. There is no mention of this in the workbook.

Cindy Flacks: That's a great question Judith, thank you. CMS does not have any such requirements.

Nicole Cooney: OK, our next question comes from Bradley. It is require — is it required to have a numeric overall value for the risk assessment with a range that evaluates low to high risk assessment?

Cindy Flacks: Hey Bradley, thanks for your question. This actually relates to the one that was just asked, and, no, there aren't — there aren't any requirements.

Nicole Cooney: OK, and the next question comes from Kerie Erickson. Do I need to take into account how the reagents are transported to my facility in my IQCP plan, especially since that is out of my control?

Cindy Flacks: That's a great question Kerie, thank you. That is entirely up to the laboratory director. If he or she thinks that is a risk that they can mitigate, then absolutely, I would include it.

Nicole Cooney: For a waived test, will I need to run QC every 8 hours?

Cindy Flacks: Again, IQCP does not apply to waived testing. For waived testing, you are required to follow the manufacturer's instructions.

Nicole Cooney: We are a POL serving greater than 100 physician multispecialty practice with multiple satellite labs over an approximate 50-mile radius. How do we set up IQCP?

Cindy Flacks: Ah, another good question that, believe it or not, we get asked a lot. The IQCP applies to the one specific laboratory, hence, Individualized Quality Control Plan. Therefore, each CLIA laboratory, in other words, each CLIA certificate, must have its own IQCP. CMS does not — oh, excuse me, CMS does recognize that it is becoming more common for large multisite systems to standardize processes where feasible to achieve efficient operations. It would be acceptable if laboratories in a multisite system collaborated on the common elements that could be used throughout their system. For example, the process and format for developing IQCP.

For devices used throughout the system, the laboratories may also collaborate on those portions that are common to all, for example, the manufacturer's QC instructions. However, the end product must include an evaluation of the risks associated with each individual location, and each QCP must be approved by the laboratory director for that laboratory. Also, each CLIA laboratory must produce its own supporting data for its QCP. Each device must also be monitored in some way.

Nicole Cooney: What information can customers expect to get from manufacturers in regard to IQCP for individual tests?

Cindy Flacks: Well, it depends on the manufacturer, but CMS does recommend that labs contact the manufacturer for information that can help them with their risk assessment.

Nicole Cooney: Does the IQCP pertain to high-complexity testing, example, CBC and/or chemistry analyzers?

Cindy Flacks: Yes, IQCP does apply to high-complexity nonwaived testing.

Nicole Cooney: The next question comes from Lynn. If I have a test implemented in a new location and do not have 2 years of QC data from my IQCP plan, can I still implement IQCP?

Cindy Flacks: Yes, you can still implement IQCP. You just have to ensure it covers all three phases of testing — it covers all three parts, which is the risk assessment, the QCP, and the QA.

Nicole Cooney: If we decide to bring in new tests into the test system, do we have to use IQCP?

Cindy Flacks: No, not necessarily. Again, if the test that you decide to bring in that is new, is a nonwaived test, you may either follow the CLIA QC regulations as written or implement an IQCP.

Nicole Cooney: It is stated that IQCP is optional and voluntary, but must labs currently using EQC change to something else such as manufacturer requirements?

Cindy Flacks: That's a great question. A lot of EQC users have contacted us asking this question. As I stated earlier in the presentation, EQC will no longer be an option to meet CLIA QC requirements effective January 1st, 2016. The lab must either implement IQCP or default back to the CLIA QC regulations.

Nicole Cooney: If a blood-gas analyzer uses an equivalent QC process that checks every part of the analyzer at least every 8 hours, is an IQCP necessary?

Cindy Flacks: Well, again, if you're using equivalent QC for the blood-gas analyzer, starting January 1st, 2016, you must either default back to the CLIA QC regulations or implement an IQCP.

Nicole Cooney: If you have different analyzers that require an IQCP plan, do we have to develop an IQCP for each analyzer?

Cindy Flacks: Yes, IQCP is not required for any specific analyzer. And the second question, I'm sorry?

Nicole Cooney: Do we have to develop an IQCP for each analyzer?

Cindy Flacks: Yes, if you want to implement IQCP, you have to have a separate IQCP for each analyzer.

Nicole Cooney: OK. I have my CLIA survey in August. What will the surveyor be looking for next month?

Cindy Flacks: Oh Keith, would you like to answer this question?

Keith Scott: Well, IQCP is not required until January 1st, 2016, so they're going to be looking just like they have in past years. If you've actually started an IQCP, you can show it to them and they can have a look at it and see how you're doing, but it's not actually required until 2016.

Nicole Cooney: Thanks Keith. Our next question, do I understand a system approach to IQC must take into account the environment of each affiliate lab, so each lab must have their own plan?

Cindy Flacks: Yes, that's correct.

Nicole Cooney: The next question, are risk assessments required, even if the lab chooses to adhere to CLIA requirements rather than perform IQCP?

Cindy Flacks: No, a risk assessment currently isn't required if you're following the CLIA QC regulations. The risk assessment is only required if you decide to implement IQCP.

Nicole Cooney: OK, give me 1 second. Are any accrediting agencies — CAP, COLA, TJC, etc. — making IQCP mandatory?

Sorry, sorry. Can you start over Cindy, I'm sorry?

Cindy Flacks: Oh sure.

Nicole Cooney: Oh, the question, I'm sorry, the question. Are any accrediting agencies — CAP, COLA, the joint commission, etc. — making IQCP mandatory?

Cindy Flacks: Again, with the accrediting organizations, if your laboratory is accredited by one of the seven CMS-approved accrediting organizations, we suggest that you contact your specific AO for guidance.

Nicole Cooney: OK, the next question comes from Nancy Lowdermilk. If QC is performed daily for a test, are we required to have an IQCP?

Cindy Flacks: Well, it depends what the QC requirement is for — is it a CLIA QC requirement that you're currently following? Then, no, you would not need to implement an IQCP.

Nicole Cooney: The next question comes from Mary Hathaway. If the nonwaived testing is being performed in the laboratory by lab personnel, does there still need to be an IQCP? Is the current SOP enough?

Cindy Flacks: If you're following current CLIA QC regulations, you don't need to implement an IQCP.

Nicole Cooney: Give us 1 second. The next question comes from Marissa Kane. If you follow CLIA QC requirements, are you required to perform a risk assessment?

Cindy Flacks: That's a good question Melissa. If you're following current CLIA QC requirements, there is no need to perform a risk assessment. Again, you only need to perform the risk assessment if your laboratory is deciding to implement IQCP.

Nicole Cooney: Your next question comes from Susan Brian. Is it all or nothing for all of the nonwaived testing that is performed in your lab? Can you do IQCP for nonwaived POCT and CLIA guidelines for the big analyzers?

Cindy Flacks: Sure Susan, that's a great question. Again, IQCP isn't all or nothing. You can continue to do CLIA or follow the CLIA QC requirements for some tests or test systems and implement IQCP on other test systems.

Nicole Cooney: Please explain how PPM labs are required to comply with IQCP.

Cindy Flacks: For laboratories performing provider-performed microscopy — otherwise known as PPM procedures — they must continue to follow the CLIA regulatory requirements for PPM and moderate complexity testing. While IQCP may not be practical for PPM laboratories due to the nature of PPM testing, IQCP is available for those laboratories that would choose to implement it.

Nicole Cooney: My next question comes from Deborah Wells. Does IQCP apply to laboratory-developed tests?

Cindy Flacks: Yes, a laboratory-developed test is considered a high-complexity test. It is nonwaived; therefore, you may — you may implement IQCP or follow the default CLIA QC regulations, either/or.

Nicole Cooney: OK, give us 1 second. For those of you on the webcast, again, if you have a content-related question to ask, please click the Q&A button on your screen. As of right now, we've addressed the questions that have come in. Anything that's left in our queue is duplicative or, you know, has already been answered. So we'll give you all a few minutes to bring in some additional questions for us.

Our next question, for LBTs where CLIA does not provide guidance, are IQCPs required?

Cindy Flacks: No, IQCPs are not required.

Nicole Cooney: Give us 1 second.

Our next question comes from Holly Shields. Keith, we think this one's for you. Is it reasonable to assume that following the IQCP process for a test currently using an EQC plan will provide supporting documentation that continuing to use the already established EQC plan is an acceptable QC practice for that assay? Keith?

Keith Scott: Well, if you've been following an EQC that you've documented in the past, you can use that data as part of your risk assessment. But when you actually go through and do a complete risk assessment and a complete IQCP, you may find that what you've been doing in the past is really not the best way to go for quality control. But if your risk assessment that you perform shows that what you've been doing as part of an EQC plan is adequate, then that would be fine.

Nicole Cooney: Thanks Keith. Give us 1 second.

Operator: For those of you participating via telephone only, to ask question, please press the star followed by the number 1 on your touchtone phone. To remove yourself from the queue, press the pound key. Remember to pick up your handset before asking your question to assure clarity. Please know your line will remain open during the time you are asking a question so anything you say or any background noise will be heard in the conference. Please hold while we compile the Q&A roster.

Nicole Cooney: Did we have any questions on the phone?

Operator: We do. We have a question on the line of Jessica Bradley.

Nicole Cooney: Hi Jessica.

Jessica Bradley: Hi, ma'am, how are you? I have a question about implementing the actual IQCP. I was wondering if there are, like, subject matter experts that would do site visits or teleconference to help implement it?

Nicole Cooney: Give us 1 second.

Jessica Bradley: Um-hum.

Cindy Flacks: Hi Jessica, this is Cindy. Unfortunately, we don't provide that. However, I would strongly suggest that you contact your manufacturer, try to get as much information as you can. Again, we have our CLIA brochures and this wonderful workbook that we just presented today that can help you walk through that, and professional organizations as well.

Jessica Bradley: Thank you very much.

Cindy Flacks: Sure, you're welcome.

Nicole Cooney: Thank you. Next question.

Operator: Your next question comes from the line of Cynthia Bauman.

Cynthia Bauman: Hi, I had difficulty connecting to the website for the presentation and I was wondering, will the recorded session be available online somewhere that I can watch it kind of late? I listened to everything and I went through the workbook with you, but I really wanted to see the slides.

Nicole Cooney: I apologize for your technical difficulty. Yes, we will have the audio recording, the transcript, and the slide presentation — it's all currently on the Event Detail page for the event. We will be sending a link out that will include — we'll be

sending an email to all the registrants that will include the link of where to find all of those materials after this call.

Cynthia Bauman: Thank you very much.

Nicole Cooney: You're welcome. Next question, please.

Operator: Your next question comes from the line of Connie Weston.

Nicole Cooney: Hi Connie.

Operator: Connie, if you're on speakerphone, please pick up your handset. If you're on mute, unmute your line.

Connie Weston: Hi, this is Connie.

Nicole Cooney: Hi, did you have a question for us?

Unidentified Female: Yes we do.

Connie Weston: So my question is about molecular testing. We do extraction for RNA and DNA on the patient samples and we set up assays that have all the controls that are needed in each assay, but the controls don't go through the extraction process. And my question is, is an IQCP necessary?

Nicole Cooney: Just give us 1 second.

Cindy Flacks: Hi Connie, this is Cindy. Thanks for your question. Again, you can continue to follow the CLIA QC regulations or implement an IQCP, either one of those are acceptable. Thank you.

Connie Weston: Oh, we have another question.

Nicole Cooney: OK.

Unidentified Female: I have a question for microbiology-exempt media. I know you have to probably perform an IQCP because that CLSI guideline is no longer pertinent. My question is, how do you prove that from an IQC standpoint that – because it — you cannot possibly QC that exempt media every day. If you just QC it by lot, then write up a QC — IQCP, or how does that go for the exempt media?

Cindy Flacks: Hi Keith, can I ask you to answer that question?

Keith Scott: My understanding is for laboratories that have been doing this for years, you can use the data that you have about the acceptability of what you're doing and use that in your risk assessment as part of your IQCP instead of having to do it from scratch. Use your historical data of how you've been — of how you've been receiving and using this medium.

Unidentified female: So the only thing you do for exempt media currently is just, you know, it looks like it's filled properly, no cracks, etc. There's, per se, no organisms cultured on that, so is that all we have to prove is that we visually looked at it for the last 2 years and we find that acceptable and can keep going that way?

Keith Scott: You can use your event logs, your, you know, your QA logs, if anything has ever been — had a problem and how you resolved it. Or if you've been doing it for years, the way you're doing it and had no problems, use that as your proof — your data in your risk assessment.

Unidentified female: Would that go the same for blood culture bottles that are on automated system. Those now become exempt as well? How do you know if you haven't had a problem?

Keith Scott: I throw that back to CO.

Nicole Cooney: Give us 1 second.

Cindy Flacks: Thanks — thanks while we gathered here. For the blood culture, you still have to follow the CLIA QC requirements.

Unidentified female: And what is that?

Unidentified female: Two QCs daily.

Unidentified female: Two QCs daily that — for blood culture media, that really won't make much sense because you have inoculated a blood culture bottle each day. It could take more than a day. What are the CLIA guidelines for blood culture media?

Nicole Cooney: I just need to jump in here. This is the last question we're going to be able to address, and then we need to move on to some other questions that we have. Cindy, I think you have the response.

Cindy Flacks: Hi, yes, thanks Nicole. Yes, you need to — you need to look at the CLIA QC regulations or contact your accrediting organization or exempt State if that's what you are governed by. Thank you.

Connie Weston and unidentified female: Thank you.

Nicole Cooney: Next question, please.

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

Bill Dickinson: Yes, hi, my name is Bill Dickinson from Cogdell Hospital in Snyder, Texas. The question specifically relates to, what is the tipping scale point? I know it's a pretty vague question in a sense of, we write this risk assessment, we determine our — our information. Normally people have statistical data that determines whether 50 percent of the time or 25 percent of time or, say, 5 percent of time we'll say yes or no, this control or that control. Is there some more defined guidelines instead of just this written — this written workbook that has, like, you think for a moment and just write. Think, have your documentation of the past? It just seems so — not so scientific, you know? So I just need — I guess I'm thinking this too hard. Anyway, I don't know if it's a question or comment, but anyway, thank you for listening.

Nicole Cooney: Give us. OK. Give us 1 second.

Bill Dickinson: OK.

Cindy Flacks: Hi, thanks for your question. The bottom line is to follow your own SOP. It's not a requirement. I understand what you're saying as far as, I liked your term tipping point — is it 15 percent, 20, 25, 50 percent — that's something that the lab has to, you know, analyze in their risk assessment.

Bill Dickinson: OK, so the onus will be on laboratory directors as far as what percentage they put?

Cindy Flacks: That is, if you want to label it with a percentage, yes, that's entirely up to the laboratory. CMS is not requiring that.

Bill Dickinson: OK, well thank you for your time and you all have a good day.

Cindy Flacks: Thank you, you too, thank you.

Nicole Cooney: You, too. Our next question comes from Stacy. If you are doing IQCP and identify a QC failure, do you have to default back to the CLIA regs for QC or can you continue to use your IQCP while doing your investigation?

Cindy Flacks: That's a good question. If your laboratory SOP states that you have to go back, then that's what you must follow.

Nicole Cooney: Our next question comes from Ivy Douglas. Please clarify, can different locations within the same CLIA number be under one IQCP but just under the RA location-specific issues addressed, is that correct?

Cindy Flacks: Yes, that's correct.

Nicole Cooney: Our next question comes from Deborah Levy. I work in a blood bank and we do daily QC for most reagents. Is IQCP required for antibody identifications such as panels?

Cindy Flacks: No, IQCP isn't required.

Nicole Cooney: OK, our next question comes from Gary. Which CLSI guidelines, if any, will no longer apply if an IQCP is utilized?

Give us 1 second.

Cindy Flacks: Hi, thanks for your question. CLSI documents can be used as part of a laboratory's risk assessment; however, CMS is not requiring the use of CLSI guidelines. But that doesn't mean they can't be used, but they cannot stand on their own. The laboratory still must look at their own environment, testing personnel, etc. Thank you.

Nicole Cooney: Our next question comes from Cynthia Long. If the three steps in the IQCP process are followed in the guide, are you to assume that this meets all requirements, or is there someone to verify that what you have created is acceptable?

Cindy Flacks: And that will be surveyed at the time you have your onsite survey.

Nicole Cooney: I believe that we have one more question on the phone. Kalia, we'll take that at this time.

Operator: Your next question comes from the line of Raul Ruiz.

Raul Ruiz: Hi, good afternoon, this is Raul from Westchester General Hospital. I got a question particularly to — respect to arterial blood gases with internal QC cartridges. Basically, we have a model made it, and they do quality controls every 8 hours internally. Anyways, we are electing not to do IQCP. Now on top of that, if — and I'm asking to see if I'm correct, I am to do external quality controls to meet the CLIA guidelines twice a day at least minimum, correct?

Cindy Flacks: Yes, if you want to meet the CLIA QC regulations, two external QC per day of patient testing.

Keith Scott: Right.
Raul Ruiz: But I can continue to use the internal AQC as the primary mechanism to monitor my quality controls and the efficacy of the blood gas results that I'm providing to the patients, correct?

Nicole Cooney: Could you repeat that last bit for us? Sorry.

Raul Ruiz: I'm so sorry. OK, basically what I'm — I just don't know. Everybody out there with an arterial blood gas instrument that has internal quality controls — what, you know, basically we either have a choice to continue to use the internal quality controls and add the external QC, which is the CLIA recommended. But what I guess I'm trying to figure out the validity or the — what weight are we going to give the internal quality controls if we're just now going to go back to external QC?

Nicole Cooney: Give us 1 second.

Cindy Flacks: Hi Raul, thanks for repeating your question. You can either implement an IQCP, or you can follow the CLIA QC regulations.

Raul Ruiz: No, I get that. I understand that. So basically, I can continue to use my quality controls and just do external QC once a day? All right.

Nicole Cooney: Give us 1 second Raul.

Raul Ruiz: Yeah, yeah I know, I know, I got it, sorry.

Cindy Flacks: So Raul, if your — if your IQCP supports the external QC frequency that you are performing, then, yes, you're in compliance.

Nicole Cooney: Thank you for your question.

Raul Ruiz: Thank you.

Nicole Cooney: Our next question comes from Christina Horn. If you have two different tests, one is waived and the other nonwaived, but use the same equipment, do you do IQCP on all tests or just the nonwaived?

Cindy Flacks: IQCP only applies to the nonwaived testing.

Nicole Cooney: Our next question comes from Stacy. When doing your QA activity and you identify a QC failure that was not identified at the time it occurred, do you need to suspend your IQCP and default to performing QC as CLIA requires while you determine if you need to make changes to your RA and QCP?

Give us 1 second.
Cindy Flacks: Thanks Stacy. There is no requirement. And the bottom line is, the lab must be following its SOP.

Nicole Cooney: Our next question, is IQCP required? If not developed, what are the consequences?

Cindy Flacks: Again, we can't stress enough, IQCP is not required. A laboratory has two QC options beginning January 1st, 2016 — that is to either follow the CLIA QC regulations or implement an IQCP.

Nicole Cooney: Our next question comes from Latisha Hardy. What is the recommendation to new customers for the type of data they need to generate to make a decision about the frequency of QC?

Cindy Flacks: Hi Latisha, that's a good question, and ultimately the lab director is going to have to make that decision.

Nicole Cooney: OK, give us 1 second. Again, if you have a question — if you have a question, please type it in on the Q&A button. We're seeing that a lot of the questions that are coming in are repeats of previously asked questions or sometimes we get some casework type of questions that really — this isn't the appropriate forum to address. So again, let us know.

Looks like we have one from Diane Mullen. This is a point-of-care testing question. We have about 11 Signature Elite instruments in several locations across campus. They are used to measure ACT in our procedural areas such as the OR, Cath labs, interventional radiology, and more. Is it true that we would need to do a separate risk assessment for all of the 11 instruments?

Give us 1 second.

Cindy Flacks: That's a good question. If labs have multiple identical devices, the IQCP may be developed for the test system, taking into consideration unique environments and testing personnel and any other factor. But, if your device is dispersed throughout a healthcare facility, the QCP must be developed for the devices at the different locations. And keep in mind, each device must be monitored in some way. Thank you.

Nicole Cooney: Our next question comes from Tim. Why implement an IQCP program when we are already following CLIA QC regulations as written? What would the benefits be?

Cindy Flacks: Keith, would you like to answer that question as a surveyor?

Keith Scott: Sure. Even though you're following CLIA QC guidelines or CLIA QC regs, you're in compliance, but it's always good laboratory practice to perform risk assessments on any process that you have to make sure that you're doing what's

appropriate for your – for your laboratory situation and doing your — the best possible job that you can.

Nicole Cooney: Thanks Keith. Our next question comes from Tracy Adams. How do you determine which test should have IQCP done?

Give us 1 second.

Cindy Flacks: Hi. Again, it's up to the laboratory director to make that decision, but ultimately, if an IQCP is decided that that's the route the lab director wants to go, it cannot be less — the QC type and frequency cannot be less than what's specified in the manufacturer's instructions.

Nicole Cooney: OK, give us 1 minute. We're pausing for a few seconds to allow some more questions to come in.

Our next question comes from Kathryn. Will the CLSI-exempt media QC guidelines now fall under IQCP?

Cindy Flacks: Well, a laboratory may, again, continue to use CLS guidelines as part of their risk assessment in order to help the laboratory determine its QC type and frequency.

Nicole Cooney: OK. Pausing just for a few more minutes to allow some more questions to come in.

Our next question comes from Angela. How would you recommend approaching a test that does not have commercial tests available — manual differential post vas semen analysis, etc.?

Cindy Flacks: I'm wondering, Angela, if you meant commercial controls available? In that case, you can follow 1256H or implement IQCP.

Nicole Cooney: Our next question comes from Michael. What States have elected not to allow IQCP?

Give us a minute.

Cindy Flacks: Thanks for your question. Again, contact your State agency directly.

Nicole Cooney: The next question comes from Rob Wright. For a corporation that has multiple facilities with the same QC and QA processes, can one IQCP be established for the involved labs if signed by their individual medical director?

Give us 1 second.

Cindy Flacks: Thanks for your question. The IQCP applies to the one specific laboratory, hence, Individualized Quality Control Plans. Therefore, each CLIA laboratory, in other words, each CLIA certificate, must have its own IQCP.

CMS does recognize that it is becoming more common for large, multisite systems to standardize processes where feasible to achieve efficient operations. It would be acceptable if laboratories in a multisite system collaborated on the common elements that could be used throughout their systems, for example, the process and format for developing IQCP.

For devices used throughout the system, the laboratories may also collaborate on those portions that are common to all. For example, the manufacturer's QC instructions. However, the end product must include an evaluation of the risks associated with each individual location, and each QCP must be approved by the laboratory director for that laboratory. Also, each CLIA laboratory must produce its own supporting data for its QCP. Each device must be monitored in some way.

Nicole Cooney: Give us 1 second.

OK, Karen Hastings has our last question of the day. If we change our specimen type from a nonwaived specimen to an acceptable waived specimen type, we do not — we do not have to implement IQCP, correct?

Cindy Flacks: That's correct Karen. IQCP does not apply to waived testing.

Additional Information

Nicole Cooney: OK. That's all the time that we have today. On slide 30, you'll find information on how to evaluate your experience with today's call. We'll also push out the link to the evaluation to our webcast participants right now. Remember to disable your popup blockers in order to view the evaluation.

Evaluations are anonymous, confidential, and voluntary. But we hope you'll take a few minutes to evaluate your experience with today's event. I'd like to thank our subject matter experts and all participants who joined us for today's MLN Connects event. Have a great day everyone.

Operator: Thank you. That concludes today's conference call. You may now disconnect.

-END-


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