Hello, everyone. Welcome, welcome. Thank you for joining. We’re going to give folks just another minute to join on before we get started. Again, appreciate you joining today. We’ll get started shortly.

OK, hello, everyone. Welcome. Thank you so much for joining today. My name is Chelsea Parsons, and I am a consultant with Guidehouse supporting CDC’s OneLab Initiative.

A couple of notes about the webinar before we dive in. If you have any technical issues throughout, please feel free to email our inbox at OneLab@CDC.gov. That’s OneLab@CDC.gov. We’ll have someone monitoring that throughout the session in case any technical issues come up. You can also feel free to email that email address if you have any questions following the session.

As questions arrive throughout the session, you’ll notice in the bottom pane of your Zoom chat that you have a Q&A function down there. So click open that Q&A function, put in any questions you have throughout the presentation for our presenter or for anything related to OneLab, and we will do a Q&A session at the end of the presentation. Try to get to as many of those questions as we can. If you do have any questions that arise after the session or that we don’t get to today, we’ll try our very best to respond to you via our OneLab email.

All right. Note that I’ve posted a link to live captions in the chat. If you need to use those today, you’re more than welcome. Open up that link, but just keep this Zoom link open as well, and you can follow along on both.

So let’s get into our agenda for today’s session. We’re going to pass it over to Alicia Branch, the OneLab network lead. She’s going to talk to you guys about a couple of resources and introduce today’s presenter.

We’re very lucky to have Miss Marranda Scott of the Division of Laboratory Systems here today for our session. We’ll go through the main presentation, and then we’ll have that Q&A, like I mentioned at the end, and then we’ll let you know what our next event is coming up next month in April. So I will go ahead and turn it over to our OneLab Network lead, Alicia Branch.

Thanks, Chelsea. Before we begin the main presentation, I would like to take a moment to share a helpful resource. It’s the OneLab Rapid Education and Capacity-building Hub or REACH.

It’s a targeted and customized learning management system for laboratory professionals. We consider this a laboratory professional’s one stop shop for all relevant laboratory resources in various formats, including videos, downloadable and printable job aids, and courses for PACE credit, including the Introduction to Clinical Laboratory Improvement Amendments of 1988 course related to today’s network event. Next slide, please.

CDC, our planners, and presenters wish to disclose that we have no financial interest or other relationships with manufacturers of commercial products, suppliers of commercial services, and supporters. And I’m excited today to introduce our speaker, Miss Marranda Scott. Marranda is a skilled clinical laboratory scientist in the Division of Laboratory Systems at the CDC, with an impressive 15 years of experience in laboratory testing, quality, and safety.

She is pivotal in enhancing laboratory practices, policies, and regulations. As a former CMS, CLIA surveyor, and CDC select agent inspector, Marranda has demonstrated her laboratory compliance and regulations expertise. Her extensive knowledge of laboratory procedures and safety standards has enabled her to provide invaluable guidance to laboratory staff across various settings.

Her commitment to excellence in laboratory science is matched only by her passion for serving her community and advancing public health. Our OneLab Network presenter for today, Miss Marranda Scott.

Thank you, Alicia. Good afternoon, everyone and thank you all for joining the OneLab Network event. As Alicia said, I’m Marranda Scott, clinical laboratory sciences with the Division of Laboratory Systems. Today, I’ll be presenting the survey process, what you need to know for your CLIA survey.

The mission of DLS is to improve public health, patient outcomes, and health equity by advancing laboratory systems. Just a brief overview of my background. As Alicia stated, I was a former select agent program inspector. I then moved on to CMS to be a CMS CLIA surveyor in the CMS Atlanta office, and then I returned back to CDC in 2022 as a clinical laboratory scientist with the Division of Laboratory Systems.

Today during my presentation, I will discuss the survey process, which will include getting ready for a CLIA survey. What surveyers expect when they arrive on site, the outcome of the survey, and what that means, and then provide you with resources that are available to everyone.

This presentation will be given from a point of view of a recertification survey as being done for a laboratory that has a certificate of compliance. However, if you are a lab that has a certificate of accreditation, you will find some of this information valuable.

So let’s jump right into it, getting ready for the survey process. In this section, I’m going to go over how surveyors get ready, what the laboratory needs to do to prepare, and then who is responsible.

So first thing, a CMS surveyer. I know there’s a misconception that all the CMS surveyer does is survey laboratories, but there is a lot of people don’t know that happens behind the scenes, so I’m just going to give a brief 101 just to get us started in the presentation.

Now, CMS surveyors have to overlook the state agency. Each state has a CLIA office which has state surveyors, and those surveyors have to be trained by the CMS surveyors. They have to go in and make sure that they’re up to code.

They also have to perform state agency performance review. A lot of criteria is sent down. Any of the applications that are received, the CMS-116, the state offices have to enter those into a database. And so the CMS surveyor has to ensure that all that criteria, all the data is correct, and then they have to send that information back up to CMS Baltimore.

They perform complaint investigation. Those complaints can come in by a person, they can come in through the state agency, they can come in by their accrediting organization. But CMS surveyors do have to perform state complaint investigation.

And then there are the enforcement actions. And what I mean by enforcement actions is when a laboratory has to be sanctioned for noncompliance. And an example of that would be if PT referral happens, but today, we’re going to focus on surveys.

So how does a surveyer prepare? The first thing that they have to do, they have to make sure that the fees have been paid for a survey. They have to ensure that the laboratory CLIA certificate does not expire.

And so in the background before they even arrived on site, they’re checking the information that’s in the database. Did the laboratory pay their survey fee? Let me pull the information from the last survey, the CMS-116. The 209, did they have a 2567 that had deficiencies? If they did, let me review the plan of correction to make sure that those issues were addressed.

Were there any recommendations from the last survey that a surveyor actually wrote down to keep to remind themselves when we’re on site next time? I need to look at those recommendations.

What was the last test value of the survey? How many specialties does this laboratory have? And then they’re going to pull the proficiency test report and see, has the laboratory had any issues performing PT? Does the laboratory have any open enforcement cases? And so they’re gathering this information before they even contact the labs that they’re coming on site to do a survey.

Now, I want to answer a poll question. Would your laboratory be ready for survey if it was conducted one year before the CLIA certificate expired? And I think we’re going to actually do a poll.

So I didn’t see the poll pop up, but I think– oh, there it is. Give you a second just to answer. The majority of you said, yes, you’ll be ready, which is good.
OK, so most of you all say, yes, you’ll be ready for a survey if it was to take place a year before your CLIA certificate expires, which is good. And the reason why I bring that up is because in the song, which is Chapter 6, which is entitled “Special Procedures for Laboratory,” it states that a recertification survey can occur at least six months prior to the expiration date of the laboratory’s current certificate but no earlier than 12 months.

And so preparing for a survey doesn’t start when you get the email or the phone call that the surveyors want to come on site. It is a daily process of preparing, and you have to stay ready so when that time comes, you’re not just rushing around trying to get ready.

Now, the CMS-116. You’ve got an email, a phone call from the surveyor, they set the date. What are the things that the laboratory needs to do to start the process of preparing? Get your CMS-116 in order with the most current and accurate information.

This is the laboratory director’s name, email address, telephone number, address, test volume, specialty, analytes, the manufacturer. All of that information is put on the CMS-116. When you complete this, send it back to the master surveyor because this helps them in the preparation process to see if anything has changed since the last survey.

And if it has, they can go ahead and start making a mental note of what they need to do if they need to bring in more surveyors because your test bottom volume went up. Do they have to stay an extra day? If they did three days last time, do we have to do five now because they have a larger test volume, more specialty? So get that information to them as soon as possible. This information is also entered into the database, so we want to be very current and accurate.

Next is your CMS-209. And usually when they contact you, they’re sending you the link or a PDF of the 116 and the CMS-209. When you get that, go ahead and fill it out. Fill out your 209 with the personnel that are performing tests in the laboratory. And it’s not just tests. This is all the personnel that are the laboratory director, the clinical consultant, the technical supervisor, the general supervisor, the testing personnel. They have to be listed on the CMS-209.

Now one tip or one suggestion would be to separate your 209 out based on your specialties or subspecialty. What that does, it will allow the surveyor when they come on site and they have to qualify and they have to review competency and training for your personnel, they’re able to go through it a little quicker because it’s organized by the specialty.

And most surveyors are not surveying the entire laboratory. They might be surveying one section. I might come on site with four other surveyors, and I’m responsible for surveying virology. So if you have a slow night with just those individuals who are working in virology, it will allow me to go faster and more organized when it comes to reviewing training competency for your personnel.

Next, a test directory. Have your test directory current, ready to go. So early indicate what test was added since the last survey. Include the instrument, the kit name. Having this information up front and before a survey allows the surveyor to know how many validations they will have to be reviewed, and then it helps them to plan what section they might need to go to first because it’s going to take a little more time in that area if a new test has been brought on since the last survey.

Now, here’s the critical piece. Your procedures, your policy, and your documents. And hopefully I put the high point, but there’s probably a lot of procedures, policies, and documents that you have to have, but these are most of the high points.

All 10 essays and examination, including package inserts, dated, signed, IQCP procedures, textbooks if you adopt those, reference laboratory, client services manuals, records of tests referred to other laboratories. Have those documents ready, organized in folders, in binders ready to go.

Then the personnel record. Any board certifications for your laboratory director, any certifications for any of your personnel that you have listed on the CMS-209, diplomas, degrees, and transcripts. A lot of individuals forget the transcript portion, and that will help a surveyor out. If a degree only says Bachelor of Science, then Bachelor of Science of what? That’s why a transcript is needed. So go ahead and get that already together before the surveyors arrive. Training records, competency assessment.

Then proficiency testing. This test runs with PT results printouts, signed attestation sheets. The surveyer is going to want to see where there has been review of unsatisfactory results. Even the results that have 100, you still need to review. And then any twice a year verification, and that’s when there’s no PT available for any other nonwaived tests that are listed in Subpart I, then you do a twice a year verification.

Moving on to your quality control records, calibration, calibration verification records, any of the beginning chart, remedial action information, instrument maintenance and function checks. Have those documents ready. Procedures, policies, anything regarding quality control should be prepped and ready to go.

The quality assessing is policies and procedures to monitor, assess, and correct problems. And then documentation is the ongoing assessment of those activities. So for Sub-Part K of the regulations, and that’s the General Laboratory Systems Pre-analytic, Analytic, and Post-analytic, you have to have a QA plan and documents for each of those sections. Have that ready to go and ready to review.

And then patient test records. That’s requisition, any of the direct printouts, and then your test reports. You should have that ready to go. And then, if a two year, within two years, or once in the last survey cycle, all those documents should be prepped and ready to go before the surveyors come on site.

Now, I’m sorry. Who is responsible when it comes to preparing for a survey? And it’s really all hands on deck. And the reason I say that is because everybody plays a critical piece in preparing for a survey. It’s not just your laboratory personnel that are listed on the CMS 209. It’s also the individuals who do shipping and receiving, the IT individuals, and then anybody in human resources.

You say, why shipping and receiving? They’re receiving in the specimens, if you’re getting specimens shipped in. Surveyors are going to go to that area to see and ask questions, to make sure that those individuals have been trained correctly. Even though they’re not listed on the CMS 209 as a testing personnel, they still touch that specimen. There are still procedures that they have to follow.

When it comes to IT, they’re going to want to ask questions about the laboratory information system. How are you ensuring that your test reports are going across correctly? And then with human resources, they’re probably keeping most of your documents as far as personnel, whether it’s the degrees, the transcripts, and things like that. And so you don’t want the surveyors to get on site and now all of a sudden you can’t get your hands on any of those documents, because the human resources individual is out on vacation. You want to make sure you keep an open line of communication with all these individuals when you’re preparing for a survey, because they’re going to be also a part of the process.

Now we’re going to move to the survey, as I keep. You’ve gone through, you’ve gotten all your documentation together, the surveyors are arriving, it’s survey day. In this section, we’re going to go over the opening meeting, the tour, and the review. But first, I have another poll question for you. How frequently does your laboratory conduct internal assessments to evaluate the effectiveness of your quality management system? Quarterly, semi-annually, annually, and we do not conduct internal assessments.

At D. It’s either between quarterly or annually. Just a few that say they don’t conduct internal assessments. Give you a few more minutes. OK, so right, between quarterly and annually are where we have.

The reason I ask this question is because I’ve gone to a lot of laboratories that might not even conduct an internal assessment. But it’s a good process to go ahead and have in your laboratory. You want to know what’s going on in your laboratory before the surveyors arrive. And that’s one thing that surveyors do look at. Have they gone in and done their own internal survey?

When our survey is on site and you’re shocked that, oh, I didn’t know that competency testing wasn’t done. How did you miss it? You should have done your own internal assessment. So if you don’t have that implemented in your procedures right now, I think that’s a good idea to go ahead and implement internal assessments.

Now for the opening meeting, you set the tone, you know, be polite, be cordial, professional, approachable. Get ready for your surveyors to get there. Invite your laboratory staff. It doesn’t have to be everybody, but you want your key players, the director, the technical supervisors, general supervisors, your quality manager.

Let them come to the opening and then prepare to give update, any facility changes since the last survey, any added specialties or new tests. Do you have a new TS or a GS, that’s the technical supervisor or the general supervisor? Are those individuals new?

Let all that information come out during the opening meeting. And then allow surveyors to discuss the survey flow. How long will the survey be? Do they want to do an in-depth tour before they get started?

Or do they want to just go each individual and do a tour of only the areas that they’ll be surveying? And then they’re going to tell you what records they want to review. And then they might already have an idea of who they want to interview when they start that interview process.

Now the tour, so it’s tour time. Surveyors normally like to do a facility tour all together, right after the opening meeting. You don’t need everybody in the laboratory following the surveyors around. You can just appoint key people to take the surveyors to different areas.

This is the observation and information gathering part or parts of the survey. And they’re going to really want to start from how the specimens come in, specimen collection and processing. Then they’re going to go to the prep areas and the storage areas, and then testing and reporting areas. When it comes to the facility tour, have people in the laboratory.

A lot of times labs think, let me clear everybody out. Don’t want anybody working. No, have people available in those areas. Surveyors want to see people working. They want to engage with your laboratory personnel when they’re doing their walk-through.

Now I’m going to insert a quick little story-time. I was on a survey, and I haven’t surveyed since 2019, when I was a CMS surveyor. And I’m walking through a laboratory to do just the walk-through. And I’m engaging with the individual as I’m talking to them. I do a quick interview, and I have other surveyors with me.

I get back into the room to do a record review. And the lawyer comes in. And they’re just like, you can’t talk to anybody else. If you want to talk to somebody, you need to tell us the name and then we’ll approve if you can speak to that person. That’s not how surveys go.

It’s not that you tell the surveyor who they can speak to. If the surveyor can say, this is who I want to speak to, if they’re available. So do not block surveyors from having that interview with personnel. That’s a very important piece in the information gathering on the survey.

So next is the review process. You’ve done all the prep work. You’ve gotten all those documents that we talked about from, I think it was a few of the earlier slides, slide 13 and 14, where we talked about the quality control, quality assessment, efficiency testing. You’ve had all that information together.

That information should be ready to go when the surveyors are done with that facility tour. Surveyors want to walk in and see where there are binders, there’s information, there are folders, ready to go. If you’re thinking I’m just going to wait until they ask for it, don’t let the surveyor wait.

They’re on a time limit. They have a lot of things to review. Get those documents together and all ready in a room for them when they arrive on site. So you have your PT. That’s still Part H. They’re going to review the test runs and the PT results and the printouts.

All the signed attestation sheet, remedial actions, and twice a year verification. Have it all laid out, organized, labelled. If they get in a room and they’re going through binders and they can’t find things, then they’re going to be calling you saying, where’s this, help me locate this.

And you don’t want that, because now the surveyor’s thinking, if I can’t find it, and they’re having a hard time finding it, then there’s probably going to be some issues. They probably don’t have all their checks and balances in place. So take that time before a survey starts to get all your documents organized. That’s very important.

It helps the flow of the survey go much smoother. Facility, they’re going to be walking through. When they do that walk-through, they’re looking at the space. They’re looking at safety. They’re looking at ventilation.

They’re going to look at those documents, too, contamination procedures, retention. Are you keeping your records for two years? Can they say, bring me this document from two years ago, and you’re able to put your hands on it?

And then the quality system was just Sub-Part K. That’s the General Laboratory Systems, to bring any legacy systems, analytic systems, post-analytic, then the quality assessment piece. Now, on that same survey where I was blocked from doing an interview, I had another issue to arise, and it was me trying to get documents.

I was going through the tour. I said, can I see this binder. It was four hours before that binder actually made it to me. And I’m sitting in the room and I’m just waiting and waiting and waiting. Where is the binder that I pointed out when I was walking through the tour?

They had taken the binder to go and do their own review before they bring it to me, to make sure that they had all the documents that they were supposed to have. And that’s holding up your surveyor. All of that should have been done prior to the surveyors arriving on site.

And so now you have surveyors sitting in a room for four hours without documents. And they’re on a time limit. So when I finally get the binder, now I see what’s the real issue is because they haven’t really mitigated things. It was the binder for their near misses. They were just writing it down.

So now I’m asking questions. And this was a certificate of accreditation. So if you’re allowed to have a COA, don’t think that CMS surveyor cannot be on site. Complaint investigations happen all the time. And they can show up unannounced.

And so I’m going through the binder and now I’m asking questions. This was a blood bank. I see where blood has been picked up for transfusion. It goes up to the operating room. And when the nurse is getting ready to hang it to do the transfer, she realized that this is not the correct patient. OK, She brings it back down to the laboratory.

Well, how does this happen? What are your checks and balances? Were your procedures not followed? And everyone’s looking at me as though why is she asking these questions. And this is information I need to know, because you have a quality assessment plan.

Did you go back and say, now that we see that blood can be issued to the wrong patient, now we need to go back and address our procedure for issuing blood? No, none of that had been done. And then I see where it happens again.

So now I’m asking more questions. Let me see your procedure manual. Was this not followed? What did you do in the process? What have you changed? And nothing had been done.

And they’re giving me answers like, well, we didn’t have a quality manager at the time. And we didn’t have this, and where there was nobody in the laboratory to issue blood and so the nurse just picked up the cooler through the window. All these questions, you’re not following your procedure.

So I’m making a mental check of this is going to have to end up being a citation. I finally say, OK, where’s your QA plan? What changed? Nothing had changed. The quality manager was new.

She was like, oh, I wrote up something. It hasn’t been approved by the laboratory director. At this point, this happened eight months ago. And you’re still telling me that you haven’t made any changes?

Well, the regulations say that you have to review the effectiveness of your corrective actions. You haven’t put any corrective action in your procedure. Like you haven’t done anything. So now it’s going to be a citation.

So you have to think about all of it. Have your documents already reviewed. You need to go through them before the surveyors do, because they’re going to start asking questions. And you can’t wait until they’re on site.

You have to do that before. And then for your personnel, training record, competency, any of the reason to have that information already ready to go. You don’t want surveyors just sitting in a room waiting for you to bring them documents, because that is not a good look on the laboratory.

So now survey is over. They’re ready to do the close-out. So, our last poll question, do you attend closeout meetings for your survey? OK, yes. I’m seeing yes. I’m seeing yes. Good. OK.

So the close-out, the surveyors have gone through all the documents. They’ve asked a lot of questions to gather their information. Now it is an outcome-oriented survey process. So they’re not looking at every piece of paper, but they’re gauging and getting a good idea of what has been going on within the last two years, or when the last survey happened.

Most of the time laboratory directors or the technical supervisors will say, can you tell me the findings before we do the closeout meeting, because they don’t want to be alarmed. They don’t want to be shocked. And that’s OK to ask a surveyor to do that, because they will.

They will go over through, go over what their findings are. Now they might not tell you verbatim, what D-tag, what citation it will be. A lot of times that takes place on the back-end when they return back to their homesite. And they’re going through all the documents again before they start writing the report, what they’re actually going to cite, if there are citations.

But I highly encourage laboratory to let everyone be involved in that closeout process. Let the testing personnel come. Let the shipping and receiving individuals come. They need to understand why that survey process is so important.

I was a bench tech for several, several years before I even became a CMS surveyor. And I always heard surveyors are coming, inspectors are coming, we’ve got to get ready. We’ve got to get ready, but was never actually involved in that getting ready process.

When I became a CMS surveyor, it changed the way I really looked at the work that I was doing on the bench. It gave me a better understanding of why these documents had to be a certain way, why I was initialling here and making sure I didn’t do this. It’s very important, get all your testing personnel involved.

I think CLIA is not taught when you’re in med tech school. And I’m showing my age, because I was a med tech. But clinical laboratory scientists, that information is not taught. And so getting them involved in that process and letting them see what the surveyors are really there doing is not just making sure that the countertops are clean, that you’re wearing your lab coat, and your gloves, because most of the time they’re kind of looking over that.

It’s the quality piece. It’s the documentation that’s very, very important. And just letting them be sitting in on that closeout meeting, I think is a very good idea for any laboratory, whenever you’re doing a closeout meeting. And once we get to the closeout meeting, you know, listen to the findings. Don’t be argumentative.

If you know that there was documentation that the surveyor may just didn’t look at, you can bring that to them before they leave that building and say, hey, I heard you say that this was going to be maybe a citation. But we do have that documentation. That’s OK. You can do that.

And ask questions to get clarity. Now a lot of laboratories are in the thought process of the surveyors are going to come. They’re going to tell us what we did wrong. And then they’re going to tell us how to fix it.

But that’s not it. They’re going to come. They’re going to tell you what you did wrong. Now, when I write the report, you have to tell the surveyors how you’re going to fix it. I often would hear that, tell me, I just want you all to tell me what you want us to do.

And that’s not what a CMS surveyor does. They don’t tell you what to do. It’s up to your organization to sit down and make that decision of how you’re going to go about this process to get into compliance.

Now when it comes to citations, I just want to quickly show you two things. And both of these documents come from the interpretive guidelines. But they’re going to put a link in the chat later on and in the next section. There is a decision-making process that actually takes place when surveyors are trying to decide, are they going to cite, are they not going to cite.

And then there are some mandatory citations, that regardless, this has to be cited. And that comes from competency, well, qualifications of personnel. When those individuals are not qualified, CMS surveyors, they have to cite that on the CMS 2567. Then like I said, there’s a decision-making process.

So if they’re seeing oh, for two days you didn’t run QC, but you only ran five patients, 9 times out of 10 they’re not going to cite that on the report. Now, if for two weeks you didn’t run a quality control, and you’ve tested 500 patients, that’s probably going to be a citation. So if an outcome of survey process, not every little thing will be cited.

They have to look at the bigger picture of it. Does this have a big effect on the laboratory and the quality of testing? If it doesn’t, then they’re not going to cite it. They’re going to bring it to your attention, though, so you can be aware of it, and you can monitor those things going forward. And they’re going to give you recommendations.

And also PT referral, PT referral is a citation, no matter what, no matter if you’re saying, oh, I didn’t mean to. It was an accident. It has to be spotted, and you will be sanctioned for it. But that’s a whole other discussion.

Now you get the report, CMS 2567, some people have never seen it. Some people usually get it and it might say that they were in compliance with CLIA regulations. And then those are those moments where you get one and you have citations that you have to address.

When the surveyor gets back to their home office, they’re going to write the 2567, which is the report. And I just wanted to point out how it’s laid out. You have a D tag, which is– the D tag is on the far left in that column. It’s found in the IGs. That’s the Interpretive Guideline.

In the next column, you have your CFR or your Code of Federal Regulations, which is the regulatory language. This is what the regulations say. And then the surveyor is going to write the deficient practice statement. It explains why the laboratory was not in compliance.

So when you get the report, that’s how the breakdown is. And then you’re going to respond, depending on if you have condition level deficiencies or just standard level deficiencies. If it’s standard level deficiencies, it’s going to be your plan of correction. If it’s condition level deficiencies, it’s the allegation of compliance.

But here are the four questions or statements that you have to respond to. I had a friend not too long ago. She received her first 2567, she was just like, what do I do? I don’t even know how to respond to this.

And so I had to point her in the right direction. This is what you need. And it’s just not worth it. Also documentation that goes along with it, describing the corrective actions that have taken place. If you have to go back and show when you tested 500 patients, then you need to be sending that information along with your 2567 response.

All of that information needs to go along with it. So make sure that if you have a 2567 that you have to respond to, that these four points are addressed. And you don’t have to put it in that column on the side. You can do it as an attachment, and that’s OK. But that has to be addressed.

Now we’re going to go into resources. And this is where a lot of different websites and things and links that I think a lot of people don’t know about, they kind of have an idea. But I think it’s just very, very good to point out.

First thing is the CMS website. I didn’t know about the CMS website until I became a CMS surveyor. So I think it’s very poor, because you go on site and you notice that a lot of laboratories don’t know where to find that CLIA information. You’re going to go to CMS.gov, click on regulation and guidance, and then click on Clinical Laboratory Improvement, CLIA.

From there you’re going to get this screen. And it has a lot of information listed on the side– from, and I have two screens, so I’m starting looking this way too. CLIA brochures, you have your how to apply for CLIA certificate, on the laboratory registry, proficiency testing programs. You can find your state agency, CLIA operation contact.

All of that is listed on the CMS CLIA website. You got to know where this is and where the information is. One thing I wanted to point out was the CLIA brochures, CMS has written out brochures for PT, PT referral, verification and performance specifications, calibration, and LD responsibilities, competency, and so on.

They have brochures that will give you information on those different areas. So I just wanted to let you know where that information is. And I think they should have dropped the CMS website in the chat. Interpretive guideline, a lot of people don’t know this exists, but it does.

If you go to interpretive guidelines, on the left hand column, you’re going to get a page that looks like this, which is Appendix C. It’s that SOM 107 Appendix C Lab PDF. What that is is going to be the CLIA regulations, the D-tags, and there are a lot of probing and background information.

Now surveyors do not survey off of the interpretive guidelines. It’s just that, a guidance document for a laboratory of putting them in the right frame of mind, of what I need to have prepared, what the surveyor might possibly look at when they come by. And it is a great tool for all laboratories to use, whether it’s your COC or COA.

Next, the CDC CLIA page, and this page is actually operated by the Division of Laboratory Systems. And as Alicia pointed out, before we got started, there is a free online CLIA training listing. Have all of your laboratory and clinical staff to take this training.

This is the introduction to CLIA. It will give them the information, a lot of background information, and it should be a part of your training process, that when you hire on new staff, sit down and take this CLIA training. Think that will really help bridge a lot of gaps when it comes to that laboratory information.

Now, also found on that website, you have your CLIA regulations. You can get to them from the CMS website, but they’re also listed on the CDC CLIA website. Any of those CLIA document test complexities, if you’re trying to figure out what’s the test complexity of this new test that we’re going to have, if you click on the link, it’s going to link you to FDA.

FDA, that’s the agency that is responsible for doing test complexity. And then you can search any laboratory. You could search laboratories from the CMS website, and then they also have that information on the CDC CLIA site.

Another button that I want you to be aware of on this page is the email for CMS. If you click on it, it’s going to directly take you to email and the Lab Excellence mailbox. If you have any questions regarding CLIA, anything regarding this survey, you can email CMS. It goes to Lab Excellence, our Lab Excellence email. And individuals will respond to you.

That they want you, they want you to reach out. A lot of people don’t know that. Reach out to your CLIA surveyors is fine. And then a lot of people don’t know about CLIAC. In CLIAC, we have CLIAC the Laboratory Improvement Advisory Committee. They have meetings twice a year, in November and April. The next meeting is scheduled for April I think it’s 12th and 13th.

So, right, it’s coming up in a few weeks. If you want to join in and listen to the Advisory Committee as they go over different– and make recommendations as far as CLIA, you can do that. I highly encourage everyone to go ahead and listen in on the next call. There might be some topics that you might find important. So this is the CDC CLIA site.

And lastly is APA. A lot of people don’t know that the public health laboratories, they have so many resources when it comes to CLIA. Some of the things that I didn’t even know when I was a CLIA surveyor, but I found out once I transitioned over to CDC. And I think you will find it highly, highly helpful.

Two things I wanted to point out, they have a high complexity testing checklist. And it lists all the requirements. And then they also have the radio bio-assay and biomonitoring laboratory checklist for LRNs. So those are two resources that you can find on the website, which is APA dot org. And they should be dropping that also in the chat for that link.

And I just wanted to briefly show you that first document, which is the high complexity. It goes through all of the CLIA regulations. And they have it laid out so well. This document is fairly new. I think it was created 2021-2022, but it’s laid out from facilities and safety, this color coded, it has the D-tags, the regulations.

If you are new to surveying and laboratories, this is a great document to do your internal inspections for yourself. As you can see the color codes, clinical consultant is in red. You have your technical supervisor in orange, laboratory director was in purple. So great, great tool.

Lastly, this is the last slide, if you haven’t learned anything else, documentation is so important when it comes to a CLIA survey. But the one thing that you do need to equip yourself to have a successful survey is knowing the regulations and knowing where to find it, having those interpretive guidelines. That is very, very important.

When you have that and you have nowhere to refer to, you will do well when it comes to going through a CLIA survey. If you have any questions, I know we’re going to have a short question and answer session. But feel free to reach out to me directly. My email address is J-U-V JUV2@CDC.gov. I’ll be happy to help you.

If I don’t know the answer, I will point you into the right direction. And I thank you all so much for joining. I hope this was helpful, helpful information. So I’m going to turn it back over to Alicia

Thanks, Marranda. Let’s just take a few questions. There are quite a few questions about everything being electronic. Is it OK for laboratories to have everything electronic, or should they actually print things out?

No, it’s actually OK for laboratories to have electronic documents. A lot of laboratories were moving that way before I left CMS. And sometimes it makes it just easier for the surveyor to just click and go through. So if your laboratory chooses to have electronic document, just make sure that they’re current and that those surveyors can access it to go through it.

OK, there’s another question about what type of procedures, policies, and documents does the CLIA want regarding IT LIMS system. They’re especially curious about security, the security documentation requirements.

OK, so when it comes to the LIMS system, you want to just have a procedure just to say if your LIMS goes down, if your LIMS systems go down, what happens? When your test reports are going over electronically, what’s the procedure to ensure that they have gotten to their destination correctly?

What do you have in your process? Do you go in every quarter just to do a review check, having the laboratories to send that information back to you to make sure that they have it correctly? Hopefully that answers it. If not, like I say, reach out to the lab. It’s my mailbox.

OK, let’s see. There’s a question about, are there any legal authorities requiring an interview or interviewing specific personnel, or is that just good practice?

Are there any legal–

Requirements.

No, nothing. No, they can just really talk to whoever, whoever is in the laboratory. That was my first experience of someone actually shutting me down from actually interviewing. And that’s simply because there was a certificate of accreditation.

So they probably weren’t used to the survey process of a CMS surveyor. Normally attorneys don’t get involved. That was my first experience of that, too. And so because there was so much pushback and because of what the complaint investigation, I knew what I was there looking for, I was going to find it anyway. I didn’t even have to talk to anybody.

Someone wants to know what level of involvement a safety manager or department should be in a CLIA lab.

Well, it just depends. Normally from a CLIA, let me see, normally from CLIA we really don’t get involved with the safety managers. We may ask a question or two, but, yeah, that might be also a question for a CMS.

If the inspection date is delayed, what should be done to have the compliance with the certificate end date?

Now if an inspection date delayed, CMS is going to take care of that. They’re going to make sure that your certificate does not expire. They cannot allow it to expire. I know a lot of you all probably experienced that when it came to the public health emergency. They’re going to make sure that it doesn’t expire.

OK, you don’t have to worry about it on your end. They’re going to take care of it on their end.

Let’s see. Someone wants to know if we get an unannounced CLIA inspection, are we allowed to ask the surveyors what the complaint was?

You can ask them. They probably won’t tell you. They probably won’t tell you. When I was on that complaint investigation, I didn’t let them know what the complaint was and who it came from. They just knew it was a complaint investigation.

And that one actually came in from the AO. So don’t think you’re safe because, oh, I’m CAP or I’m Joint Commission. They can submit complaints to CMS.

OK, and we’ll take one last one. One last question, we are a moderately complex cancer group with multiple sites that staff one to two medical assistants that rotate across sites. These sites have their own CLIA paths. But the procedures, training, competencies are identical.

Do training and competency need to be performed at each site? Will one site perform all paths, by one document?

If they had the different CLIA numbers, then they have to have training at each location.

Yeah, well, I’ll take this one last one, and then I’ll be done. Does bioinformatics simply treat it– OK, I guess they want to know if the bioinformatics personnel perform a high complexity test, be treated as personnel.

And I really think that’s an ongoing discussion, because it’s kind of hard to qualify them. So I don’t want to say yes. That may be a question also. And like I said, tune in to CLIAC. That might be a discussion on it when it comes to bioinformatics. But you might have some information.

And I think that’ll be all the questions we’ll take today. The remaining questions, we’ll actually try to provide them by email at a later date.

And like I said, please feel free to reach out to me directly, it’s J-U-V-2@CDC.gov. And I’ll be happy to assist anyone and point them in the right direction.

I’ll say thank you again, Marranda, for this helpful information. This truly would have been helpful for me when had my first clinical lab job. I literally had nightmares during the first survey. Well, I’d also like to let all the participants know that you’ll receive one PACE credit for this webinar today.

In order to receive the PACE credit, you need to go to the link in the chat and complete the evaluation within two weeks. As a reminder, the slides with the links will be posted to www.CDC4/OneLab within the next two weeks. And lastly I would like to briefly highlight the next One Lab event, which is identifying and recognizing select agents or toxins.

It will be held on April 26, 2023 at 1:00 PM. The registration link should be posted in the chat. And again, I would like to say thank you again, Marranda, and thank you for joining us. Have a great rest of your day.