

FTS-CDC-EPO

November 16, 2005
12:00 p.m. CST

Coordinator Welcome and thank you for standing by. At this time, all participants are in a listen-only mode. Today's conference is being recorded. If anyone has any objections, you may disconnect your line at this time. I would now like to turn the conference over to Channing Sheet. Thank you, you may begin.

C. Sheet Thank you. Good day. Welcome to our teleconference, the Food Emergency Response Network, FERN. My name is Channing Sheet, California Laboratory Training Coordinator at the California Department of Health Services, Richmond, California campus.

Before we begin, I have a few program notes for everyone. The Centers for Disease Control and Prevention, our planners and our presenters wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services,

or commercial supporters. Presentations will not include any discussion of the unlabeled use of a product or product under investigational use.

After the program, each participant needs to register and complete an evaluation form. Documenting your participation helps us to continue to bring you high quality programs in a variety of formats. To do this, you go to the address www.cdc.gov/phtnonline. The password is in caps and it is FERN. When you have completed the registration and evaluation form, you will be able to print your CEU certificate. You have until December 16th to complete this process.

These instructions are also in your original confirmation letter and general handout. They were also e-mailed to each site representative this morning.

There will be a question and answer period in the middle of the program, and you are on a listen-only line, which means we cannot hear you; you can only hear us. If you experience any problems with the line during the conference, please press *0. This will signal the attendant that you are having a problem.

Once again, I want to welcome you and thank you for joining us. We have over 70 sites across the United States listening to our teleconference, and today's speaker is Mr. Tom Sidebottom.

Tom earned his BS degree in entomology from the University of Maryland in 1987. Tom began his government career in 1987 at the Los Angeles District Laboratory as an entomologist. In 1994, he transferred to the San Francisco District Laboratory, where he served as the Deputy Laboratory Director, and had responsibility for research, quality management systems, and safety program. In 1999, he transferred to the Pacific Regional Office as a Special Assistant for Science.

Tom has coauthored journal publications on disease-carrying flies and food, and is the associate editor of a text book on microanalytical entomology. Currently serving as a Special Assistant for Science to the Regional Food and Drug Director in the Pacific Regional Office of the United States Food and Drug Administration located in Oakland, California, he coordinates the Pacific Region Quality Management System and Food Emergency Response Network Pacific Regional Coordination Center. Tom received an FDA outstanding achievement award for

exemplary coordination of the Pacific Region Quality programs, Quest for the ISO accreditation and the National FERN project.

Without further ado, I present to you Mr. Tom Sidebottom.

T. Sidebottom

Thank you, Channing. Good morning or good afternoon, everyone. I appreciate this opportunity to come and share the Food Emergency Response Network with you, known as FERN. We'll go ahead and we'll start the next slide.

The Food Emergency Response Network is a national network put together in 2003, to be able to respond to food event, food emergency events, networking federal, state, and local government laboratories across the United States. As you can see from the second slide, the regions of FDA as well as the regions of FERN are broken into five, and the five regional coordination centers mirror this organization and breakout. I am responsible for the Pacific region, which are the nine western states and Pacific islands.

The mission of FERN is to integrate, as I said, the nation's food testing laboratories, the ability to detect and identify threat agents in food, along with biological, chemical and radiological agents.

In 2004, Presidential Directive Number Nine came out to the Secretaries of the Interior Ag, Health and Human Services, and EPA about expanding and building their monitoring and surveillance systems. Particularly, in the second bullet, was the focus on coordinating surveillance and monitoring systems, including international information, specifically identifying food. We know that the Lab Response Network, the National Animal Health Alert Network, and the Plant Diagnostic Networks were functioning networks that were working, had been working for a period of time, and this particular directive focused on food and really put the emphasis on making sure that those networks come together. We'll talk a little bit more about the coordination of networks in the ICLN at the end of the presentation.

As we put together the networks and we're focusing on food, we need to have systems that track commodities and food, the analytes that we're finding. The FERN Network is using eLEXNET, and we'll talk a little bit more about that today. Also, to be able to put together a consortium of

laboratory networks, the presidential directive looked at integrating all these different networks and systems across the country, and trying to use standardized protocols and procedures on that. As I mentioned, we will talk about the ICLN this morning.

FERN has had four primary focus points. The two that have been the most prominent in the last two years has been the response and recovery efforts. As FERN started off, we needed to be able to identify laboratories that do routine food testing, be able to look at what kind of search capacity and capability that we have amongst those laboratories. We were also looking for making sure that we had those laboratories that would start the connection, because we know that there will be a day we will get that phone call that we need to respond, and we want to be able to provide the response to an event and also to recovery. How do we apprise the assurance to the consumers, to the public, that the food they eat is safe to eat? Those have been the two primary objectives over the last two years.

In 2004/2005, both FDA and USDA received funding to further the network, to be able to develop and start putting into play prevention and preparedness programs. I will be talking about a number of those today.

This slide has a lot of nice graphics on it, but I particularly like it because it ties together the food emergency response activities into normal, routine activities that go on in the public health arena already. The laboratories that are part of FERN come from all walks of life. There are environmental labs, diagnostic labs, agricultural labs, clinical labs, federal, state, county, university laboratories that are part of the network.

These are laboratories that do food testing on a regular basis. Food programs need to integrate with existing efforts that we do. We already have routine compliance and routine surveillance activities happening in Food and Drug, USDA, and other regulatory agencies. We do outbreak investigations when we are responding to illnesses and outbreaks related to food-borne events.

As we look at those programs, how does FERN then complement and work in those programs? We do that through a number of things. We tie in with the emergency response, our CT surveillance that are termed food defense and food security surveillance programs, where we may be looking at routine screening of food products, but now we're going to go in specifically and look for a number of select agents. We also tie in with our consumer complaint, other emergency response.

We have two programs specifically for FERN. How do we know when all these laboratories or members are all getting the same answer, they're using the same methods, and those types of things? We have a standardized proficiency test program, and we have a method validation process and standardization of our methods for FERN member laboratories to use across the board, very much similar to the LRN and other networks that are using standard SOPs and methods.

This is just a very plain organizational chart for FERN. FERN is made up primarily of managers from the Food and Drug Administration as well as the USDA's FSIS. Those two agencies really provide the key infrastructure at the National Program Office. That's at the center of your slide. From the National Program Office we have support programs. Some of them I've touched on. The surveillance programs, training, proficiency test programs, method validation, method development are all part of the support network.

Below the National Program Office, we have five regional coordination centers: Pacific, the southwest region, the central region, the southeast region, and the northeast region. I'm the regional manager for the Pacific

region. Again, these are made up of folks from FDA and USDA, and I do have contact slides at the end of this presentation for you.

At the steering committee level of FERN, that is a group that is composed of representatives from state, federal, and county agencies, Public Health, Agriculture, Animal Health, that provide oversight and are working with the National Program Office on policies, how FERN is to work, and also they are the interface with the Homeland Security, the Congress, the White House, related to the mission of FERN.

As you can see on the next slide, here are some of the members. This is not all-inclusive members of the steering committee, but you can see across the federal agencies and state agencies the membership.

As I mentioned, the National Program Office is really the core nation center for running the day-to-day activities of FERN. They coordinate with all the coordination centers. I participate in weekly phone calls with the National Program Office to stay up on emerging issues, as well we develop programs and are rolling those out to the regions, to help with that facilitation and get those programs out to our member laboratories. They

will also play a role in emergency response, when we are responding to an event.

The coordination center simply mirrors a lot of that activity with their region. From the Pacific, I have responsibility of interacting with the nine western states and the membership of those laboratories. As we work forward, that's in coordination training, in proficiency testing, cooperative agreements, and I'll talk a little bit more about those in my presentation, but also to identify needs and issues that may be on a region or sub-region level.

If you are in Hawaii, for example, you have issues that states that are part of the contiguous 48 states don't have. Where is the next laboratory? Where is their backup support, when their laboratory's infrastructure has been tapped to its limit?

If you are in Alaska, again, you have issues there that are not common elsewhere. But even in the cases of some locations across the county, your closest lab may be going east instead of west, because of the mountain range, the weather conditions, etc. So these are issues that the regional coordination center needs to help and make sure those issues get

moved forward to the National Program Office, as they put together programs and build the network.

As I mentioned, the FERN support programs help with the outreach to laboratories, method development, method validation. How do we get new methods to the table? As you know, food matrices pose a huge and complex analytical problem and challenge related to trying to retrieve the analytes and the agents you're looking for.

How do we get new methods? How do we quick assays, rapid screens to the table quickly, and to be made available to our laboratories? This is the main responsibility for the support programs. Training comes through them, proficiency test programs, surveillance assignments, and then the electronic communications, which predominately come through eLEXNET.

Laboratory outreach: Over the last two to three years, FERN has been reaching out to laboratories to participate. This has been based on the laboratories' willingness as well as need to participate. Currently, we have 122 laboratories across all 50 states in FERN.

The primary sign-up for those laboratories was to fill out a qualification checklist, which basically agreed that they would adhere to the Patriot Act. They had a quality assurance, quality control or accreditation program in their laboratory. They had safety and security protocols in place, as well as they were willing to participate, understanding that funding as it stood when they signed up was when it came through, but that there was the overarching requirement that if something happened and we needed to respond they were willing to.

Initially, a number of states and laboratories joined, and that's grown now to 122. You can see the breakout of affiliations across federal laboratories: 27 federal partners, 86 state partners, nine local, and also a couple of university laboratories are involved. You can see the breakout of disciplines across chemistry, microbiology, and radiological laboratory participation.

Those laboratories don't represent individual laboratories. In some cases, state laboratories joined as a laboratory system, where they have one or more laboratories as part of their organization, but they have joined as one organization.

This graphic here gives you a breakout of the current membership of those 122 laboratories across the five regions. As you can see, quite a number of laboratories have joined and, as I said, we have one in at least each of our 50 states. Again, we're continuing to develop and build those relationships. That's not all-inclusive of all laboratories, but this is where FERN is currently today.

In 2004/2005, we put on a number of regional coordination meetings. As I said, FERN started off as a concept. It came together. It received funding that we were able to start moving forward and hire positions and staff these positions. We've had five regional coordination center meetings, where we've brought in member laboratories to sit down, do the introductions, to really start building the relationship that we were doing distantly through meetings and other things in 2004.

Those meetings have been completed in the northeast region in 2004, the southwest region in 2004, as well as the southeast region. In August of this year, we were able to hold two meetings in the central region and the Pacific region, again, to bring in the member laboratories.

The method validation/method development piece of FERN is critical.

There are a lot of methods out there. We want to make sure that as a network we're using the same methods, that we're bringing assays to the table quickly. We have a collaborative effort set up with New Mexico State University that we have an opportunity to be able to get methods validated quickly through New Mexico State University.

We're still in development on that, but we do have a number of draft protocols in place that we're putting together on how to get methods quickly through the system. Also, in eLEXNET we have a methods module, where we can house these methods, so all the member laboratories can access the food testing methods that we're using.

Where possible, we're collaborating with other networks. For example, for the LRN, in methods that we can be used in common, so that member laboratories are using the same method for the same types of analyte to matrix that they would across one network to the other, where we can do that, and we continue to develop that with the other networks that we're working with closely. Currently, we have 31 FERN methods that are posted in eLEXNET, and we'll talk a little bit more about eLEXNET.

Training is a key part. There's a lot of effort that needs to go into this that continues to go on. We have done training across the country on a Web-based face-to-face format, as well as wet laboratory training. I do have a second presentation this morning, that I will talk a little bit more about FDA-specific training, but in the FERN side we've put on a number of courses in the micro area, in the chemistry area, and in the radiological area to help laboratories with our methods, to make sure that we are using the same methodology, and to deal with any issues and problems as we develop these methods and test them out, to make sure that those are covered.

We've had over 200 participants from FERN member laboratories since 2003, and we continue to do training. We currently have some training and some instrumentation on Pathatrix that is going on this week back in Maryland with a number of laboratories.

As with other networks and with FERN, we have our proficiency test program, really to make sure we have the assurance that the methods that we're using will work in those laboratories. We've done a number of these proficiency test programs in 2004 and 2005. We're actually starting on our second wave.

The nice thing about these proficiency tests is it helps us to identify any problems or challenges the laboratory is having early on, rather than when we get to an event and we have to respond and we're finding we're having problems. You can see from this slide on proficiency testing that a lot of emphasis has been put in this past year on the chemistry side using LCMS, GCMS and ICPMS platforms.

In 2004 and 2005, we have a number of surveillance assignments, food defense assignments – I'll refer to them; food security assignments is another name – where we are building into these assignments and using FERN member laboratories to specifically look for certain agents. I'm not at liberty to discuss which agents we're looking for today, but I can share with you that as we put our routine surveillance programs in, we're doing some screening again to have food defense strategies in place, to look and start on the prevention and detection mode with the network. Those assignments continue on. We have others that are going to be going on into 2005 and 2006.

The nice thing about the surveillance assignments, again, is it helps us to test our new network. We're a toddler in the network world. We're still

working out through some of the communications and protocols that we need to have, getting samples to laboratories, getting those samples analyzed, getting the results back in through eLEXNET, and these surveillance help us to really strengthen our response and our connections with our participating laboratories.

I'd like to now talk a little bit about the electronic communications that FERN is using. eLEXNET is the network we're using. That's Electronic Laboratory Exchange Network. I have a contact slide there for you, should you need more information or would like to learn more about eLEXNET. You can go to www.elexnet.com. Also, you can contact Ellen Olson. Her phone number is on the eLEXNET Web page, and there's a connection point there on how to join eLEXNET.

eLEXNET is open to anybody in government agencies that have an interest in food safety or food security. eLEXNET was a database put together using food safety initiative money under the last administration.

It allows us to centrally collect food testing results from a number of testing laboratories across the country. Some of these are FERN; some of these are not FERN laboratories. This is routine testing on chemistry,

microbial, and radiological analytes across all different types of food matrices. That includes also domestic food testing, as well as import food testing.

eLEXNET, as I said, was put together using food safety initiative money, and it also became a natural platform as FERN was developing as a place to put in the food testing results from FERN testing laboratories, and that's what we've done. We've been able to put together some modification.

We use eLEXNET because it provides us two things. One is a centralized place that's outside the FDA/USDA firewall that people can get to. However, it has built-in security features that we can limit access to our FERN laboratories. It allows us to post methods, as I mentioned. It allows us to report information into it. It also allows us to house our contact and emergency contact communications centrally across the country. Again, it's outside our firewall, so people that have access to the Internet have access to eLEXNET.

It also allows us to do data sharing. eLEXNET is built on a common platform using HL7 language. So we are now able to communicate with other networks that use similar platforms. This is key when we start to

share information and put together information that's coming in from other networks, whether it be the LRN's network, whether it be the National Animal Health Alert Network, to look at response and trending.

eLEXNET utilizes GIS reporting functions. This is just a screenshot of eLEXNET, but if I was to click on this slide, I could click on a state and start to tunnel down and come down to a county level or a city level in the map.

As you can see from this slide, this is salmonella results from cheese that was collected in 2002. The green triangles are non-detected samples. The little red dots are samples where salmonella was detected. Again, if I could click on the dot, I can then zoom in and find out information on this particular sample. If the specific location of this sample was entered in through the reporting organization, then I would be able to see where the sample was collected from. I at least will be able to identify who analyzed the sample and the findings that are associated with it.

As I mentioned, eLEXNET allows us to have a methods module that we developed. It was a feature that was in eLEXNET from food safety, but this is really an opportunity in a module that allows us to enter new

methods in. Member laboratories can enter those new assays into the eLEXNET and house them. They are available to all members. If you need to find a method, it's a quick place to go to see what methods are available from a number of different analytes and matrix levels.

As I mention at the top of my slide, the Presidential Directive Number Nine wanted the networks to coordinate. How do we have a coordinated approach? The ICLN integrated consortium of laboratory networks – you may or may not have heard about this – is housed and Homeland Security has the responsibility for bringing this network together.

They have put together a network coordination group that is looking at mirror issues, similar to the program issues that are identified. So when we talk about surveillance programs, we talk about methods, we talk about training, we talk about surveillance programs. They are looking at that across networks. What kinds of strategies do we want to have going out nationally? This organization is coming together and developing those, specifically in the training.

I know that the training entities from the different networks have met, so they can start sharing the training that is currently going on. They can

look at where can we streamline, where can we share, where are our gaps, and those types of issues the network coordination group is looking at.

Our IT side of things, information technology, our communications, how are we doing that? Again, they are looking nationally at how we can bring these things together, and what kind of prioritization and scenarios in terms of exercises is going on. They have that responsibility as well.

As I mentioned, their purpose really is to look at the relationships across the different networks, and bring those together and try to optimize our networks. Resources are limited. FERN, just like other networks, through FDA, through USDA, through the Congress is competing for resources. Homeland Security is getting resources.

The ICLN is going to look to optimize those resources, so that we're not just putting little pots of money into different networks, but when we want to focus and strengthen on a response capability, we can then enforce that through maybe one network or across multiple networks, and they can provide guidance and oversight on that.

This is a short list of the laboratory networks that are part of the ICLN, the Food Emergency Response Network, the LRN, the National Animal Health Laboratory Network, the National Plant Diagnostic Network, and the Environmental Network.

Before I go to question and answer, one of the things that's really important for FERN, one of the things that I've really come to appreciate on the West Coast as I interact with other networks and with our membership, is that these relationships are key to bringing new ideas, bringing in problem solving techniques and approaches that those networks, those member laboratories have already encountered part of why FERN has been able to move so quickly as a network over the last two years is because we've been able to learn from those networks. So those relationships are critical to FERN, not only on a national level, but on a regional level as we start to put together our strategies and approaches, work on exercises, and work on activities, so that when we do get that phone call that we need to kick in and move and provide the support, we're ready to do so.

FERN is really contacted either directly from the National Program Office, through Emergency Ops in FDA or USDA, as well as through the

membership laboratories and the State Emergency Response Services throughout. Those networks are already very well established and connected with FDA, USDA, and other federal agencies. So FERN really hasn't created a new contact point. We'll continue to work closely with those organizations, and make sure that they are aware of FERN, and when is the right time to call FERN, maybe as a primary, maybe as a secondary responder to a food event.

The slide you're looking at now is the FERN contacts for the National Program Office. Doug Abbott with USDA's FSIS, as well as Carl Sciacchitano with the FDA in Maryland are our two National Program Office contacts. You can see there's an e-mail address for the National Program Office.

FERN regional coordination centers across the country, the five regions, you have the southeast region, Tom Beacorn and Wayne Ziemer, the central region, Don Burr and Kevin Vaught, and the northeast region is Terry McConnell. You can see by their e-mail addresses some are FDA, some are USDA. It's one FERN organization. For the Pacifica and the southwest it's Karen Kreuzer and myself, Tom Sidebottom.

With that, I think I will end the presentation and we will go to questions and answers.

Coordinator I'm showing no audio questions at this time, sir.

T. Sidebottom Thank you. Channing, should we go into the training presentation?

C. Sheet I would like to say, if anyone does have any questions, and there were no audio questions, if your question was not answered, because we don't have any, please e-mail the NLTN office at neoffice@nltn.org, and the speaker will answer your questions by e-mail.

Coordinator We do have an audio question. Would you like to take it at this time?

C. Sheet Yes.

Coordinator Mike from Connecticut, your line is open.

Mike I have a couple of questions, if I can ask them both. What I'd like to start with is as the methods are developed and the protocols are put together, will there be a body that will oversee whether or not they overlap with the

LRN protocols in terms of reagents, the concern being that we will continue to build our stockpile of RNA and DNA kits, as well as the enzymes used in the process?

T. Sidebottom Mike, the answer to your question is yes. One of the primary responsibilities that the program support group has at the National Program level is, as those methods are being developed and put together they are looking at those types of issues going forward. So they should have been addressed as we go into this. However, if there are methods that come out and you see where there is some duplication or differences, then by all means I encourage you to raise those to the National Program Office. And your second question?

Coordinator He might have disconnected, sir. He dropped from the question queue. I'm showing no other questions at this time.

C. Sheet Again, if you do have questions, you can e-mail them to the NLTN Office at neoffice@nltn.org. Now Tom is going to continue with his training presentation.

T. Sidebottom

As part of the presentation today, I was asked to provide a brief presentation on FDA lab training that's available. Our Division of Human Resource Development has a number of training courses that are available not only to laboratorians, but to investigators, to compliance officers, to state, federal, and local tribal government folks, as well as to the private. These are offered through ORA University, through the Division of Human Resource Development. They are done in conjunction with our Division of Federal-State Relations.

What I would like to do at this time with this presentation of about 30 slides, is go through it fairly quickly and just give you an overview of the Division of Human Resource Development, the types of courses that they provide, the types of training that are available. I have a couple slides on specific laboratory training that's available to organizations. Then we'll come back, if we have time, with additional questions and answers on that presentation.

Please bear with me. I will go through these fairly quickly and will not cover all the information in detail. I really wanted you to have this presentation today as a resource, so that if you have training needs from

your laboratory or your organization, you have the contact and know how FDA sets up its training and how to contact them.

The Division of Human Resource Development provides training, as I said, to state, local, and tribal regulators. They have a state training team. They have a regulatory and science team, which is for internal FDA courses. They have a distant learning team that they provide overview and insight for, satellite Web training, as well as a certification team and a resource group that are part of this entity, and we'll talk a little bit about each of these as we go through the next slide, and you have the Web site there to contact for more information.

As you can see from their model, the training is like other training programs that you are familiar with. We have certification programs that are part of that. We have certification maintenance. We have all the records that are associated with it. The Division of Human Resource Development maintains a centralized national database on those records that are generated from training courses, whether they be face-to-face or online, as well as remedial training that goes on as part of improvement when we identify problems or areas where we need to improve on that training.

The training offered by DHRD and ORA University provide continuing education units for those attendees that require that. You can see the organization IACET, who helps us provide that, and the types of applications and where those CEUs come into play. Again, I'm not going to go into the objectives of the CEU application. You do have the slides there, but it does provide an aspect of the training to attendees that require CEUs.

Training needs, how do we identify those? We work through FDA's field offices, our district and regional offices throughout the country. We work with our Division of Federal-State Relations, and work directly with our state and local tribal governments to identify the training needs that they have to protect the public health. If there is a course that we don't have and we need to do that, then this group is available and we have a process of which you can develop specific training to your organization that you need in protecting the public health.

Training needs, succession planning, just basic skills: These are the types of courses that we look at putting together, uniformity, updates, making sure we're on the cutting edge, we're using the latest technology, the latest

tools, not only in the training, but in the case of analytical training, how do we get real-time PCR out to all our laboratories quickly.

How can we keep the cost down? As you know, training is a big cost. So this group is looking at strategies that we can optimize our training costs, be able to leverage our resources, and tap into other training. I know there are efforts going on with other training networks. Even out on the West Coast, looking at tying together training from FDA, working with the local National Lab Training Network for the West Coast and how can we partner. If we're bringing in folks for one training course, can we connect up and provide training to other folks as part of that? The right training the right time, the people is critical there.

This slide here is just in terms of making sure we have – why do we have the right training? We want to make sure that the food, that the food, the cosmetics, the regulated industry, the food items that we have to protect, that the folks that have to go out and enforce those regulations on our behalf have the right training to do that.

This is just a basic blended learning step, starting off with Web and satellite training, discussions, exercises, on the job, classroom, and in

audit. Depending on the type of training we're talking about, we provide certification to state investigators, who are credentialed and go out on behalf of FDA to conduct inspections in programs. We have to make sure that they have the credentials and the certification, and the DHRD unit provides that. We also have partnerships and other liaisons, where we help provide the training and the assets to those state folks in a cooperative program, to help them as they build the public health strategies and approaches into their state organization.

Curriculum and certification, I'll go through these fairly quickly. We have these programs for internal investigators and analysts in the organization. In the last two years we've really looked at standardizing our investigators across the country. So when we have a person go out and do an inspection or do a laboratory analysis in one of our locations, that's the same type of inspection and laboratory analysis you would get in another part across the country.

We do that through this level one certification program for new hires, as well as senior analysts and investigators. We really put a lot of emphasis into this program, when we had to do a lot of quick hire after 2001 with our counterterrorism hires as we were ramping up quickly. So these

programs really helped us to get standardization in quickly to our new inspectors.

We also have a level two certification process that gets into specific programs and devices, drugs, biological areas, seafood, and cooperative programs such as retail food, shellfish and milk programs.

We've run a number of our own folks through the training, both in the investigational laboratory side of health. There are more continuing – this slide is a little dated – and those programs continue on each year.

We have voluntary curriculums and certification to state, local and tribal on the retail food, shellfish and milk, as well as manufacturing foods, LACF, juice HACCP and other HACCP programs, as well as seed control. These are just groupings. You can get more information and contact information from those contacts I provided to you, if you have interest or know of other organizations in your state that would be interested in this that may not be aware of it.

This next slide is kind of a complicated house structure that was put together really to illustrate how the pieces work. I'm not going to spend a

lot of time going through here, but it provides, in the center part, a level one certification, the basic training requirements, the OJT efforts that go on that build into that level one certification. Then that in turn is followed up with on the roof structure, the level two certification, so after an individual has gone through and provided the basic requirements, whether that's through on the job training for our senior inspectors and senior analysts, or whether that's part of new hire, and then they also have a recertification and continuing education element that goes on with that.

Currently, to my knowledge, this is an internal level one/level two certification program. I believe there are efforts to take this beyond that, but you would have to contact the Division of Human Resource Development to get more information.

As I mentioned, courses in the catalog are available, but there are times when we come in and we need to put together new courses, and we have an approach through a cooperative research and development agreement, better known as CRADA. This is run through the Division of Federal-State Relations. It helps us to develop new courses with engineering, who is our partner in this, and it also helps us provide free access to federal, state, local and tribal regulators. For industries and others, they do have

opportunities to participate and take these courses, but there is a cost and you have to contact ORAU through the engineering organization. Their Web site is on this slide.

There are over 110 online courses currently available. There are 80-plus in the queue, and you can see some of the types of courses that are coming online and being developed.

Continuing education online: This slide just provides you a list of the courses with the catalog numbers. These are courses that our investigators and analysts would take. These are also available to others to take as they need, depending on the job and the public health requirements that they have in their state organization.

This is a slide on continuing education on the Web, trace-back investigations, food and drug law. Again, they are very specific courses that are available from DHRD.

Web courses: There are a number of Web modules. These have been run through internally. Almost all the folks in the field organization that carry out the operational activities have a basic requirement to go through their

supervisor. Make sure that they run through the basic training requirements and captures that in a centralized database is part of what we do.

We've completed over 80,000 Web modules since coming online, particularly in the last 12 months. That's a lot of Web modules. It goes a long way, when we are looking at equivalency of our organization, both nationally and internationally. You can see that there has been over 8,000-plus working with state, local, and tribal regulators.

There are classroom courses available, wet lab courses that are available. This is just a list of some of the types of courses that are put together. These are courses that if you have attended FDA courses in the past, before we had all this technology with the Web and the new training facility that's located in Rockwell, Maryland, these were course where we would take them out and offer them in our state locations. The Division of Federal-State Relations in conjunction with the Division of Human Resource Development also takes these courses on the road, and we work with our state partners, who have training facilities to provide those training locally or in their region. Again, this is a slide of the catalog of the number of courses that are available.

We have a process where we can develop new courses. We can customize the courses to the particular audience in need. We have done that in the past and will continue to do that through ORA University. I encourage you, if you have ideas and thoughts, whether it's FERN or for your own organization, to contact DHRD directly.

This is a slide, again, of the types of administration and activities that DHRD provides when we do these collaborative classroom courses. They are designed to be set up to where they are off-the-shelf ready-to-go. We can put them on through, as I said, onsite using video conferencing, using Web conferencing, and can get information and get things to. They bring all the materials, set up, and coordinate all those activities as normal training entities do throughout, as well as provide the attendance list, the tracking, the feedback, much the same way that NLTN is doing this Web conferencing today.

For today's call, I particularly wanted to provide you a list of laboratory training, face-to-face or wet lab training that is available currently from DHRD. You can see the courses that are listed there. They are broken out by chemistry courses, radiological courses and microbiology courses.

Some of those courses would be restricted to FERN member entities, but you can see the other courses that are available to them.

One course you see there, mobile lab training, FDA after 2001 purchased a number of mobile laboratories and put together specific training for those mobile labs to get them set up. In the case of the chemistry mobile labs, we were able to use those laboratories in part of the hurricane response in Louisiana and Alabama. Again, this training that we had helped us to rapidly get those mobile labs up and running, and deployed after the event down there.

On the next slide you can see the microbiological courses that are available to you, as well as there are some specialty areas for laboratorians. In the cases of inspections in pharmaceutical laboratories and sensory analysis, those are specific programs that our laboratorians are involved in, but again, they are available to those outside from DHRD.

The next slide provides you a list of laboratory online training. Some of these are common laboratory courses from basic laboratory safety, method selection, GLPs, laboratory orientation. They are targeted towards our

own laboratorians, but they provide a good fundamental overview of laboratory operations and are available online.

How to access the Web courses: To get a user ID, you need to contact ORAU directly at the e-mail address that's provided at orau@ora.fda.gov. If you want to take a sample of a course and see more about it, you can go to the engineering Web site. It's provided in this presentation. You can also, at the www.fda.gov Web site find ORAU and connect up and see more information about what I've presented to you today in this presentation.

When you contact them, this slide is the slide you would see from the Web, from the www.fda.gov Web site for ORAU. When you've contacted them, they will set you up with an account. This slide provides you the information and an overview of ORAU.

Then they'll set you up with an account, and the next series of two or three slides will run us through the registration process. This helps them then to start the database and identify the student in the system, and then keep track of the training that you take from ORAU.

If you have a basic Internet connection and login screen, you can connect to ORAU from any Internet site. You don't have to come in to a special computer. You just have to be able to have Internet access, and then you login to the account this way.

This is a quick snapshot of my catalog. As a student you can go in. You can search on the courses that are available, bring them into your training box, your catalog, and then go through. The different icons that you see next to these courses that are listed – I don't know how good the quality of the slide is on your presentation today – but if it's a little icon for a computer it's a Web online course. Maybe there's reading information that has to be done, but then you can click on these and it tracks your progress. Also then you're able to access your transcript to see what you have completed, and then you can print out any certificates, once you've achieved and completed the training.

With that, I will end that really quick presentation on the training and ORAU through DHRD and we'll take questions at this time.

Coordinator

I'm showing no audio questions at this time.

C. Sheet Give them just a moment.

Coordinator I'm showing no questions at this time, sir.

C. Sheet Thank you. I do want to remind everyone that the NLTN office is available to take questions via e-mail by e-mailing them at neoffice@nltn.org. I want to thank Tom again.

I would like to remind all the participants listening in our program to register and complete an evaluation form by December 16th. The directions are on your letter of confirmation or in the general handout. You can find them there. They were also e-mailed to each site representative this morning.

Coordinator Excuse me; we do have a question. Jason from Arizona, your line is open.

Jason I was just curious about the free access for the ORAU courses. Does that also apply towards FERN laboratories, or would we contact EDU Nearing?

T. Sidebottom You would go ahead and contact ORA University directly. If you're interested in specific FERN courses, then we need to go through the FERN National Program Office, but if you're interested in the other courses and signing up for those courses that ORAU offers, you may contact the Division of Human Resource Development.

Jason I had one other question, if I may. When you mentioned earlier in the program about a collaborative effort with New Mexico State University to provide effective means to evaluate essential FERN methods, was that the Chemistry department, the Ag department at NMSU?

T. Sidebottom I don't believe it's either one. It's both of those entities. The New Mexico State University connection is a pre-existing Department of Defense contract that we were able to partner with and connect in through. I don't have a lot of information on that, because our folks from our National Program Office are the ones that work with it, but if you would like to send me an e-mail with that question, I will forward it on and get more information for you.

Jason Thank you, sir.

T. Sidebottom Thank you, Jason. Are there any other questions?

Coordinator I'll give that one moment. At this time, there are no other questions, sir.

C. Sheet Once again, thanks to Tom, and a reminder to look on the Web and register and complete your evaluation by December 16th. The directions are in your confirmation letter or in your general handout, and they were also sent to each site representative this morning. Documenting your participation helps us to continue to bring you high quality education programs in a variety of formats. When completed, the registration and evaluation, you will be able to print out CEU certificate.

This concludes our program today. Our next teleconference will be December 14th, and the topic is "What's New in Tuberculosis?"

The cosponsors of today's program would like to thank our speaker, Tom Sidebottom. Thank you for joining us. I hope all of you consider joining us for future programs that will help to make the NLTN, National Laboratory Training Network your choice for laboratory training. From the California Department of Health Service Richmond, California Campus, this is Channing Sheet. Have a great day.