NWX-HHS FDA ORA (US)

Moderator: Angela Kohls
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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen only mode. After the presentation we will conduct a question and answer session.

To ask a question please press star one. Today's conference is being recorded. If you have any objections you may disconnect at this time.

Now I will turn over the meeting to Mr. (Tim Weiner). Sir you may begin.

(Tim Weiner): All right. Thank you (Kelly) and happy holidays to all. And welcome to today's office of partnership Manufacture Food and Regulatory Program Standards Broadcast.

We have a lot that we're going to cover in a very short time period. And so I'm going to ask (Angela) just kind of go through the slides quickly.

So (Angela) if you want to go to slide two. And so by looking at the agenda today we have a lot that we are going to be covering. The primary focus is going to be strengthening the relationship between a member of state

programs with their counterparts that are involved with the ISO lab accreditation program.

As you can see from the slide, there's a lot of information. A lot of good examples that we can be providing you from one of our (unintelligible) of states. And a lot of resources to share.

So (Angela) if you could go to slide three. As you can see from this slide, there's a lot of folks that are also going to be talking on this program today. They include (Guy Daletas) who will be serving as our host from the office of partnership Standards implementation staff.

(Chareece Shay) from the Association of Public Health Laboratories. (Wendy Campbell) from our Office of Partnerships Contracts, and Grants staff. (Tim McGrath with the FDA's Office Regulatory Science.

And several representatives from the New York Department of Ag and Marcus to include (John Luker), (Dan Rice), and (Karen Stephanie). Each will be sharing their knowledge and the perspective on the sampling programs to support the charges of the ISO accreditation grant. As well as that grant supporting the manufacturing and food program standards.

As with past broadcasts, there are just a few housekeeping rules want to remind everybody about. Today's meeting is going to be recorded and it's being broadcasted via (Food Shield). And this will allow for future access.

So if you have staff that want to come back and view this broadcast and listen to the key messages later on in the future, they can do that by accessing (Food Shield) through the (Mythbrips) portal. The first portion of the call will be

closed to allow for presentation of all materials. Then we'll open up the call to hear your questions and your dialogue.

It's important that we also listen to hear some of the challenges that you all face. And maybe suggestions on how the strength in the program capacity building. For the general participant, you should either use your telephone calling number or the listen in only mode via your computer speakers.

But try to avoid using both. Because it will result in feedback. All material for today's meeting, to include the transcripts and recording will be available in the next week.

And we will also send out all of the attachments to the participants. We recognize that there are several participants on today's call that aren't enrolled in the (Mythbrips) portal. But they're participants in the (Lab) program. We want to make sure that you receive everything also.

If you look on your screen, you will see a chat box located in the lower left portion of your screen. You may use this to submit end comments. If you have problems with the visuals or audio difficulties, we have somebody that's going to be monitoring that and will be responding to it quickly.

You may also use this chat box to present questions during the presentation and we'll address them towards the end. If one or more of - if you have more than one person at your location who's viewing today's broadcast from that computer location, just go ahead and enter that information in the chat box. Noting what agency is listening in and how many folks you have at that one particular site. We try to keep track of who's our attended audience.

And if you don't see any particular portion of the screen or meeting materials, please try clicking on the full screen button on the bottom left hand side of your screen. Okay. Next slide.

So there's a lot other under this objectives, and I'm not going to spend a lot of time this because the speakers are going to be going through each one of these. But the goal is to build on how do we bring together the laboratory accreditation program. How do we bring together the (unintelligible) program?

And how do we get them to work collaborately (sic) together? And to help develop a sampling program or sampling plan that is being as part of the ISO accreditation program. So (Guy) I'm going to go ahead and turn it over to you.

(Guy Daletas): Thank you (Tim). And (Angela) if you can go to slide five, it looks like you're there. Which is perfect.

And good afternoon everyone. We're talking today about ISO, MFRPS sampling and how laboratories food safety programs all work together in unison and in corporation and proactively. And both ISO and MFRPS and sampling agreements propels state food laboratory programs forward by supporting public health missions in response frameworks.

Harmonizing the direction of an integrated food safety system. Sampling agreements requires and enhances communications among state food and laboratory agencies for improved state and federal routine in emergency food safety response and actions. And basically these agreements that we're going to talk about today encourages the dialogue and communications up front before an event happens.

And certainly this will - what we want to promote is a dialogue of communication between laboratories. Certainly in food programs upfront and ahead of times so that things work smoothly when there is an event. And certainly communications and planning are keys to success. And (Angela) next slide.

ISO in particular, sampling has a direct impact on the manufactured foods regulatory program standards. Obviously the ISO standards relates to directly with standard three. In the MFRPS standard three which deals with collecting adequate evidence.

And in this case we're talking about samples and documentation to support inspection observations that are done in the field. It relates directly with standard four because that is a quality assurance auditing segment and standard. And it actually has a segment in there about sampling reports and auditing those reports.

It also relates directly with standard five. Because it's the laboratory support for investigating freeborn illness. And how that relates to both laboratories and MFRPS programs.

Standard eight works directly in there because standard eight talks about the resources that state programs need whether it's laboratories and or food programs. They need the proper resources to do the sampling. Which would consist of funding, stamping, and equipment, etcetera.

And the last standard, standard ten deals with overall laboratory support to the program. So sampling is way strongly intertwined in the MFRPS program as well as the ISO program. And it has a true impact in the overall state, local, federal, integrated food safety system. (Angela) next slide.

So coordination is needed and that's what we're after here. So as we move forward you are going to see successful programs are going to exhibit integrated planning. And enhanced routine communications between laboratory and between the food programs regarding sampling.

A robust ISO sampling program is needed to advance the MFRPS program as it is a strong manufactured foods regulatory program standards program needed to advance the ISO program and sampling. So as you can see, sampling MRPS, ISO they all go hand in hand together. With that foundation I want to be able to go to next slide (Angela).

I would like to introduce Ms. (Wendy Campbell). (Wendy)'s with the Food and Drug Administration's Office of Partnerships Contracts and Grants Wing. And (Wendy) we'd love to have you. Thank you.

(Wendy Campbell): Sure. Thank you (Guy). Well just going to briefly reiterate some of the information that we discussed in our conference call earlier. And really why we felt the sampling agreement was so important for us to be able to meet the goals and objectives of the ISO Cooperative Agreement.

You know, we see that the sampling agreement supports the laboratory in obtaining or expanding the scope of ISO accreditation. As well as (Guy) was mentioning it supports the main manufacturing food program and achieve and conformance with the manufactured food and regulatory program standard.

Also as we were developing a request for applications for this corporative agreement program, here's a list of goals and outputs that we want to see was laboratories analyzing surveillance and emergency response samples. And overall to be able to increase our National Laboratory capacity. And quite - to

be able to advance our efforts to protect public health and the overall food supply.

We also want to see greater sharing of lab results within a web net. And just really again want to commend everyone's commitment to entering all the lab results into (Lex Net). We've seen a great improvement in the amount of data that's being input. And just appreciate everyone's help with that.

Next slide please. Some of the feedback that we gotten after the call earlier was that there was some concern with meeting the time requirements to submit the sampling agreement. And we so we are pushing the deadline back to April 1st. So we're providing you with additional month in order to submit your sampling agreement.

You're midyear report will still be due at the end of January. However the sampling agreement can be submitted either then or you can wait until April 1st to submit that.

And we wanted to give you the time to be able to collaborate for the labs and the manufactured food programs. They'll work more closely together to develop a sampling agreement that would benefit both agencies. Also to allow laboratories an opportunity to tend to the manufactured food laboratory food alliance meeting.

And we will be discussing that a little bit later. But that's going to be coming up in March. And there's going to be also laboratory workshop as part of that.

Also we need sometime in order for us to be able to review the sampling agreements and be able to work with the laboratories if any revisions are needed. And then give finally the laboratories and the manufactured food

programs time to finalize the plans. And be able to implement the sampling agreement before the start of the third year of this cooperative agreement which will be September 1st. And that is everything I have.

(Guy Daletas): Well (Wendy) thank you so much. And I know you will be available a little bit later on in the call. If we have any questions. So thank you. Thank you for joining us and (Angela) I think we're ready for the next slide.

As (Angela) is getting ready to upload our next document these protocols that we are looking at right now help us outline the parameters other types of samples that should be and should not be collected under this initiative. So what we're going to look at now is the ISO sampling initiative protocols. And I'll run through these fairly rapidly because we will have these documents available for everyone after the call in feature.

Regarding the MFRPS ISO sampling agreement plan, the following items are acceptable. For inclusion into the state sampling agreements and plans. So these items are acceptable to be put in as part of your sampling agreement.

Manufactured foods are under the privy of FDA. Manufactured foods under the privy of state inspection if also under FDA jurisdiction. Environmental samples of manufactured food production, storage, and transport facilities. Routine manufactured food samples obviously.

Sea food samples, processed shell fish samples, bottled water samples, I know we're not looking for municipal water samples but we are looking for bottle water as being appropriate for some analysis. Non-routine manufactured food samples plan for and collected during a latest illness investigations and complaints.

Produce if it's washed and processed such as cut, sliced, cored, or manipulated in any manner from its fresh state is acceptable for use under this agreement. Fresh produce may also be included in this initiative. If it's sampled for pesticides or if it's collected in conjunction with an FDA sampling assignment or if it's associated with a foodborne illness outbreak.

Okay now we are going to move into the areas that are not quite suitable under this sampling agreement. Those items would be typically your grade A dairy products, milk. Grade A products are covered under the Grade A Pasteurized Milk Ordinance. The PMO program.

Food produced in retail settings. Again this is manufactured foods initiative so foods produced in retails settings are not really what we're looking for. Unless it's part of a national sampling assignment or in conjunction with a foodborne illness outbreak.

Environmental samples from retail settings should be discouraged again unless their associated with an illness or a complaint. May include manufactured food. Again municipal water we touched on is not one of the items we're looking to head sample.

USDA regulated products are not proper here. Or are foods intended for animals. We would discourage those samples here.

Raw shellfish such as oysters, clams, mussels, scallops covered under the National Shellfish Sanitation Program the NSSP would be not included here. However, processed shellfish products such as breaded oysters, oysters in soup, or heat treated which fall more into the realm of manufactured food products now and no longer under the umbrella of the National Shellfish Program would be acceptable. So the key here is manufactured food products

are included way as products covered under the NSSP program are not covered under the initiative.

So that's a thumbnail sketch of some opportunities for items to fall within the parameters of these agreements and plans. And some of the types of samples for analysis to be acceptable under the MFRPS ISO but not limited to items such as chemical analysis, pesticides, biological analysis, physical tests such as foreign matter and filth allergens, metals, toxins, contaminants. Items such as species substitutions or confirmations as well as confirmation of product identities would be acceptable as well.

So this thumbnail is for you hopefully will be able to provide this information a little bit later. And exceptions to these guidelines may be requested by the state programs. Certainly the lab and the food program jointly request and exception. And that will be reviewed by FDA.

So we hope that's going to be of help to you as we move forward. And as we're getting ready to go to the next slide for (Angela) I would like to introduce our next speaker who is Ms. (Sherry Shay). Ms. (Shay) is the Director of Food Safety for the Association of Public Health Laboratories. So Ms. (Shay) welcome.

(Sherry Shay): Great. And hello everyone and thanks (Guy) for the invitation to this call. I'm (Sherry Shay) with the Association of Public Health Laboratories in Silver Spring, Maryland. For those of you not familiar with APHL we are the member organization representing state and local governmental laboratories that perform testing of public health significance.

So our members are public health labs, environmental labs, agriculture labs, and state chemist labs across the country. As well as individuals in the public

health field and select corporate entities. We support our members in areas such as work force development, laboratory systems improvement, technology development and implementation, leadership planning, informatics and electronic result messaging. And public policy.

Over the past five to ten years our members have been actively engaged in building an integrated food safety system through cross discipline efforts such as the partnership for food protection, the council of association presidents, and the (FISMA) implementation groups. As well as the council to improve foodborne outbreak response. APHL is totally supportive of efforts to implement the MFRPS including the standard ten.

We believe that laboratories and program personal working in partnership with solid lines of communication is a foundational element of - for the ISFF. We're excited by calls such as this that bring together laboratory and food program leaders to openly discuss improvements that will make our food supply even safer. We also believe that accreditation of food and feed testing laboratories to the ISO 17025 standard is a key component in building and integrating food safety system.

Accreditation will insure that food and feed testing results from state and local laboratories are acceptable for regulatory and compliance purposes. Under a cooperative agreement with FDA's office of regulatory and science and office of partnerships APHL is collaborating with (AFTO) and (AFCO) to help prepare food and feed laboratories that wish to seek, maintain, or enhance accreditations of ISO 17025 standard. Including but not limited to the 3100 laboratories invited to this call.

Along those lines if anybody - any laboratory on this call needs help accessing our resources and tools, or perhaps would like to request a creation of

additional resources, please feel free to contact me directly. You can ask (Reaching) or any of your FD assessors how to reach me. Or reach APHL.

The three associations are committed to ensuring that the number of accredited governmental laboratories will significantly increase within five years. And all of this has been an expensive and time consuming process. We believe it will advance to public health initiatives and improve the safety of the US food supply.

As we work with our member laboratories and other food and feed testing labs across the country we will continue to encourage interactions between laboratory and food program personnel. Good things can happen from the integrations of efforts within the state or jurisdiction. And we commend the FDA for organizing this call.

I look forward to the presentation from (New York Ag and Markets). And I appreciate this opportunity to learn more about the benefits of sampling plans and sampling agreements. Thank you.

(Guy Daletas): Thank you (Sherry) so much for your insight and dedication to food safety. Thank you for being on the call with us. And (Angela) as you are moving to the next slide I want to introduce our next speaker which is Mr. (Tim McGrath).

And Mr. (McGrath) is the Deputy Director of the Office or Regulatory Science with FDA's office of ORA. And Mr. (McGrath) we welcome you to the podium. Thank you.

(Tim McGrath): Thank you very much. So I'm here to talk a little bit about some - a subject I brought up on the last call, where we talked about this. And that is some of the

FDA off (unintelligible) assignments on kind of a national surveillance level. That's what I love here is those larger scale multi-state surveillance type assignments are still under development.

We really want to roll them out later in the calendar year. Say spring of next year. That's when there's going to be a lot more information to follow.

I was very excited to be involved in this because to me it's a great way to begin to pull all of these elements together. All of these funding elements. The (Mervniphoraous) ISO accreditation, pull all that together. Bring in the elements of the integrated food C safety system.

The partnership of food and protection. Bring all that in and show a dramatic impact on - for the FDA, for senior leadership. Especially as, you know, we come into some of these times of limited funding. So we're so excited about that.

We're still trying to roll that out. It's just going to take a little bit longer. Unfortunately we're walking it back just a little bit for a couple or reasons. As I said we're not really quite ready.

Bur also two the actual an analytical testing is not scheduled to begin until somewhere in like fiscal year '15. So I think we've got a little bit of time to evolve it and do it correctly. And that's going to be our intended goal.

But also too as I kind of further conversations and discussions with office partnerships and where these the deliverables of these particular grants are going, we really see that the emphasis is on the development of sampling plan, learning what's involved there, and pulling that together to meet the (mifrips)

and the ISO deliverables. To figure out, you know, exactly as what was said what suitable samples are.

And essentially to work to enhance the communication as you develop these sampling plans and the coordination that's required. So that's kind of this point the key take home here. Essentially the sampling plans that are going to be developed will eventually result in sample analysis. That's where I'll come back and get excited again.

Because I really think there could be some Federal, State surveillance assignments that could be involved in that if y'all want to play later. That we can bring forward and as I say kind of really show the impact that these programs can make and the impact this funding creates both at the state but all particularly at FDA level.

So we'll look at the next slide. Just a little bit of information here. I think really those of you that are kind of familiar with some of these things we've done in the past with State, we've seen some very common threats here. Some potential assignment.

For instance we're currently developing a large scale surveillance assignment working with the sample foods trying to get some good statistics on contaminants in the food supply. So as an example, one of the things we're rolling out is later in the year we're going to be collecting about 1600 avocado samples and be testing those for various pathogens. Which will essentially give a great statistical base line for the status of avocados in the food system.

The center has developed about 20 fruits they want to do this with through the course of the next few years. I think a great way to be involved in a National Large Scale Assignment would be if we could put together assignments that

would involve some of these. Like perhaps the next one is, I'll make this up, cilantro. And we - you all could be involved in these large scale assignments.

Not doing all 1600 samples but in fact doing whatever number you work out with us that we could put forward. That would provide a lot of good baseline data for the FDA and the States to move forward and look at the food supply.

Next on the list here I think a lot of you that participated in USDA NDP program aware that no longer that in effect. That's really a lot of data that has been lost. And once it certainly envision a larger assignment that would put together that would begin to try and replace some of their lost data on some of the produce that were looked at.

And there if you're familiar with that you know that the collection schedules were set up ahead of time. You knew what you were going to get. You knew when you were going to get it. You knew how it was going to be tested.

That could be a fairly painless large scale assignment that the States could plug into if they wish to next year. And of course some of you participate in National Event Surveillance Testing. Typically organized around (unintelligible) conventions. Things like that where FDA directs assignments that look at the particular foods of the area and we do various testing's on that. We've done that in the past. That was an easy program to bring forward and I think that that's a - it's always set up so that the laboratory's participate at the level that they were supposed to participate at.

So I guess to kind of sum up, I think that's my last slide. We're still looking forward to putting together these larger scale assignments. They can involve multiple states.

We hope that we can convince a lot of you to participate in those. We're going to be producing information on that as soon as we can. But I think the key take home here is that the development of that sampling plan as we've seen in slides past is really the critical emphasis at this point.

And that helps you also meet the manufactured foods and the ISO deliverables and I think that's the key feature here. I think that's all I got so I'll end there.

(Guy Daletas): Mr. (McGrath) thank you so much for insight and wisdom into the operations of laboratories. And just stay with us, we may have some questions as we move into the later part of our call. Thank you so much.

We're very excited to have a wonderful state program on the line with us. So I would like to introduce our next speakers now which are going to be Mr. (John Luker) is the Assistant Director for Food Safety and Inspection Division with the New York State Department of Agriculture and Markets. And while we're getting ready to introduce him, following him is going to be Mr. (Dan Rice) laboratory director with the New York State Food and Laboratory. Again with the New York State Department of Agriculture and Markets.

And then assisting him is going to be (Karen Stephanie) Quality Assurance Manager with the New York State and Food Laboratory dealing with the New York State Department of Agriculture and Markets. I think as (Angela) is bringing up our first uploaded attachment for you Mr. (Luker) you have the floor.

(John Luker): Okay. Thank you very much and good afternoon or good morning depending on where you are in the country. I want to thank you for allowing us the opportunity for us to highlight our sampling program here in New York State.

In the interest of full disclosure though, I also want to let everyone know that we are also at this point working on a sampling agreement.

We do not have one in place here in New York State. But we are putting that together for the Manufactured Food Standards. In New York State both the Food lab and Food Safety Inspections are both divisions of the Department of Agriculture and Markets.

And I always kind of went back to the mission statements of both divisions to look at in terms of the agreement per say. Quotations for the sampling. The Food Safety Inspection Mission helps ensure safe and proper labeled food supply. And to contribute to the orderly marketing of food and farm products in New York State.

And the farm - the food labs mission statement that provide expert state of the art analytical testing and support of food safety and security programs in consumer agriculture interest in New York State. So basically if you look at those two together they obviously fit together very well.

The first slide I have up here is actually our sample report and the instructions for filling it out. And what I've submitted here is actually our instructions that we've sent out to the field on a couple different slides here. We identify our sample report as an FL report.

And we can kind of go through the first slide pretty quick here. Because it's really just a step by step instruction. And you'll see when you get to the last part of this slide. Each page is just another piece of instructions for filling out the form that's at the back of this packet.

So we can go on to the next slide. Step by step numbered, you'll see on the final form where the numbers are correspond to where the information needs to go. You can scroll right through this to page five, which is the next page.

I just wanted to take a minute and highlight page five where we have the different commodity codes. The different commodities that we are sampling on any given day routinely. This information is important because this is fed into computer tables and we're able to query information based on any of these commodities sampled in New York State at any given time.

So pretty much anything that we are sampling fits into these categories in one way or another. Next slide. The next couple charts here, one is the salesman codes.

And this is an indication of pretty much all the locations that we are inspecting, licensing and also collecting samples. For the most part, many of the samples are manufactured food samples. We have always maintained that even though we are picking up an intact sample in a grocery store which is the bulk of what we're inspecting, that particular product is a manufactured food. It's manufactured somewhere.

If you could scroll down just a little bit further you'll see the different test codes that we test our products for. The samples we collect. And this is the lab I don't want to steal (Dan)'s thunder or (Karen)'s thunder but the lab is broken up into a back piece side and a chemistry side. And obviously the test codes are dependent - it depends on which part of the lab that information is going to.

Next slide. So this is the actual form. And it is still a hard copy paper form filled out by the inspectors. As I said the corresponding numbers -- I guess

everybody will have a copy of this -- the corresponding numbers indicate where and what they need to fill in those areas. We are working diligently to try and come up with a way to automate this using self-technology. So hopefully that will happen sooner rather than later. Because this form is filled out for every sample that's collected. It we're in a store and we collect five samples this form is filled out five times for each sample so.

There's a few samples that if we want to run multiple tests it's all in the back T lab or the chem lab we can send it on one sample or one form. But for the most part there's one of these forms associated with each sample. And at the top of this form, we've already gone past it, there's a number. An SL number and that's what we, you know, anytime we're referencing a sample we go by that SL number. You see it right in the middle there. SL 306400. Okay we can go to the next slide now.

Next slide. Next slide - next one down. So what I wanted to talk about was our scheduled sampling program. And I wanted to give a little bit of information, a little bit of background.

Our schedule sampling program has been in place for years. And what it was for many years was basically identifying the product, assigning it to an inspector, having them going out. Collect a sample.

Send it into the lab for analysis. From 2008 through to the present we've - our staffing we've had some issues with staffing so our inspections numbers have dropped a little bit. And in turn our sampling dropped off a little bit too.

What we did in 2010 myself, (Steve Stitcher). Director (Erin Sawyer). Our Director Field Operations, as well as the lab, folks from the lab, (Dan) form the lab. We took a look at the scheduled sampling program and what we

wanted to do was we wanted to make sure that all of our inspectors were participating. That all of our zones and just so you know, we have 15 zones here in New York State where we have inspectors covering the different areas geographically in New York State.

So we essentially said we wanted four scheduled samples per month, per zone. Two of them should be micro-biology samples, the other should be chemistry samples. And we kind of at that point left it up to the expertise and analysis of our inspectors.

We do have a lot of veteran inspectors and supervisors. And rather than telling them what to pick up, we basically just gave them a list of some of the concerns that we've had over the years or have come up in other parts of the country. And basically left it up to them to make the selection of the scheduled sample.

Supervisors can have input into this selection as well. As you can see by the second bullet point. It's worked out very well for us.

Previously, we were doing a lot more samples and a lot less recalls where once we implemented this program, our recall numbers have gone back up to the level they were at when we were at the full staff level. And the other thing is I want to make sure that everybody is aware is scheduled samples really represent about half maybe actually less than half of the samples we're collecting. We're also collecting samples of products that are picked up in the course of a routine inspection or investigation.

So that's one of the bullets there is the scheduled sampling. In addition to any inspections or compliance sampling.

If you scroll down a little bit at the bottom of this form you'll see some of the areas where we offered the inspectors to focus their selections on. For chemistry sampling, antibiotics and honey. Standard of identity for products, imported honey, and I'm sure you're all aware of these products. Lead in Mexican candy is something that we do fairly often.

Olive oil alteration that is something New York State adopted. Olive Oil Statue here within the last couple of years. And we continue to find olive oil that's - extra-virgin olive oil that's basically not extra virgin olive oil. Okay you can scroll down to the next section.

Some other items. Toxic elements in juice. I don't know we've done a lot of sampling recently then we have in the past.

Colors in imported foods. Colors is probably our number one recall. And obviously here in New York State we have a huge amount of recall - imported foods.

I've always - we've always considered imported foods to be manufactured foods as well. Obviously they're coming into the country, they're manufactured. Ground beef or species and then on micro side, obviously pathogens and many different products.

We do have a program in place where any facilities that are growing and packaging sprouts we're in those facilities typically three times a year and we're sampling product at least one of those times. Same situation with vacuum packed smoked fish which is very prevalent down in New York City area. We're in those facilities three times a year and we're also sampling and that would be considered an inspection sample, that's not a scheduled sample.

Salmonella and spices, pathogens and Spanish style soft cheeses, these are just some of the areas where the inspectors have a little bit of discretion as to what they're collecting and what they're sending it in for. And as I say as we go to - well we can scroll down a little bit here for the summarize.

But four samples per zone per month. I said we have 15 zones. So we have 60 samples coming into the food lab every month, scheduled samples.

And then we also have at least as many coming in under inspection samples. Next slide and what I kind of wanted to end my part with is the actually it's the next - yes okay.

This is some information over the last three years for New York State. Egg in markets food safety inspection as well as working with the food lab. And the number of samples actually if we could look back even further the number of samples have dropped off.

You can see that the - from January to September of this year we're down from where we were obviously last year. The number of recalls though is actually been increasing. And that's a good thing. We're actually getting more recalls on less samples.

As opposed to more samples and less recalls. We do break them out class one, two, and three. Obviously class two our biggest recalls but the - we're averaging anywhere from, you know, 275 to 350 recalls a year. And I'm going back on years and so but the...

So that's pretty much what I had. It's an offer on the Food Safety and Inspection side, the field side. I'll turn it over now to (Dan) and (Karen).

(Dan Rice): All right. Again I want to thank everyone for the opportunity to share our program here in New York with everyone on the call. And hopefully they'll be some questions if you'd like to answer any after we get through here.

So I'd like to stress that, you know, in New York as (John) said we're the lab and the food and safety inspection division are all part of one department. So we have the opportunity for excellent communication and collaboration in our programs. And we meet regularly with food (unintelligible) inspection to talk about sampling issues and testing issues.

We have a quarterly meeting that is sort of a standing meeting and then on a weekly basis I think we are communicating almost daily with staff from food (unintelligible) and inspections. So I would say that communication is really important. Feedback on the types of samples that are coming in.

Any sorts of quality issues with the samples, if that's for some reason you're seeing a lot of rejected samples because the integrity of the sample has been compromised, that kind of stuff, you know, really needs to be fed back to the inspection division so that they can address those kinds of issues. Because the goal is to - in the lab is to, you know, test every sample that comes in with the test they request. And we really don't like to reject samples.

But so in our laboratory to meet the sample agreement, we're really just going to be capturing the type of samples that we're already doing. And as (John) indicated we really don't have a scheduled sampling approach. We do get manufactured food into the lab and looking back at 2012 we had about 306 coming directly form food manufacturers and distributors. And then an additional over 1000 samples that are manufactured foods. But those are mainly coming from retail grocery stores. So, you know, to me the sampling agreement I think is really pretty straight forward in New York because we

are already doing a lot of food testing. What we're not really capturing right now is the types of samples were getting and what we're testing these for. And so we'll be, you know, working to get an agreement in place. Next slide. So as it is said, FDA provided a nice template for us to work off of. I think that we'll meet the sampling requirement and we'll be working at doing that as well. And getting one in place that would kind of outline a little bit more specifically what we do here in New York and then allow us to report on an annual basis the types of samples we received the previous year.

And so we'll be tracking these a little more carefully by the types of foods that are being tested and what we're testing for. And then obviously the results of our testing. And I think I'll offer our Q and A manager (Karen) if she has any comments.

(Karen Stephanie): Not really. If anybody has any questions later about how to meet the standards in relation to all this I'll certainly have the answer. But I think you got it covered.

(Dan Rice): All right. We'll turn it back over to the host for the call.

(Guy Daletas): Thanks guys.

Man: Hey (Guy) are you on mute?

(Guy Daletas): Yes I am on mute. Sorry about that. (John), (Dan), and (Karen) thank you all so much for your insight and we can tell that you're very expansive program is very robust.

And you have a wonderful system in place so you're developing your agreement as we speak. And only good things are going to come from that.

And already we can tell the key to your all success so far has been the communication between your laboratory and your food safety program.

So that shows the success of what you're doing. (Angela) is in the process of, I think, pulling up our sampling agreement example. And what we're going to look at here real quickly is just an example of a template that could be used. And this is going to be part of the information that we'll send out to everybody.

So no need to write anything down. But this is an example of a template agreement that you could have the State Laboratory and the State Food program listed. It would show that there's an agreement between the two and is developed to ensure sound plain regarding sampling of food products for protecting the public health.

The sampling agreement would support the cooperative agreement criteria in pursuit of or maintain nice little accreditation for State laboratories and State MFRPS programs to make advancements and maintain confronts with the MFRPS standards. And then there's a couple of quick questions that you would answer to let us know if this is a new program that you're putting together or if this one that has been in place for a long time.

And then moving on to the next page I think there's a little bit of information about the information you would want to have in your agreement. Which is a minimum number of samples to be collected, the types of analysis to be performed, frequency of testing.

You would want to outline your collection methods or your methodology. Outline how these sample proposals are risk based and support the food safety priorities of FDA. And certainly you would want to attach the proper

documentation to show that. And then have signatures on there for your food safety office and your laboratory office.

And that would kind of round out your agreement. Now there's another page on the backend of this which is like an addendum. That shows a little bit more deeper information in the weeds about some things that you would want to include in your sampling agreement. So on the efforts of time that's basically what we wanted to show you. And we'll have this document available for everyone to look at as we come out the backend of this.

The next document that we want to show real quickly is our sampling resource document. It's a document that (Priscilla Arnez) has put together initially and we've expanded a lot on that. It actually has a lot of links to sampling plans and it goes to everything from FDA to States to ISO. And again it's several pages about really good information about sampling resources. It has FDA (Bayum) in there and it's got some information in there that (Tim Weiner) is going to talk about here in a minute. The best practices manual for the PFT group and just a lot of information. So again in efforts of time we want to move on through this slide.

Thank you (Angela) and real quickly we want to show our next slide. It's talking about our MFRPS national meeting. Which is coming up on March 10 -13 in 2014. This is going to be in Fort Worth, Texas. And it's going to specialized regarding sampling workshops on March the 10. This is open to and invited for MFRPS enrollees and State Lea sons and ISO lab grantees. You're certainly encourage to attend. You can use your MFRPS funding and your ISO grant funding to attend. Please refer to your NGA for the specialized criteria. Just wanted to get that on everyone's radar screen that that's coming up. And with that I would like to turn it over and (Kelly) I think you can open our line for questions and answers. Because this is an important part because

we want to be able to let folks call in an let us know of any questions that you may had. And we'll get those to the right people to get those answered. So (Kelly) thank you.

Coordinator: You're welcome. Thank you. If you would like to ask a question please press star then one.

(Guy Daletas): Then we'll hold the line for some questions and answers while their coming in. We do have a question that came in that deals with environmental sampling. The question was can a state include environmental sampling in this protocol?

And I'll think I'll pass that over to Ms. (Wendy Campbell) to answer that dealing with environmental sampling. Wendy

(Wendy Campbell): Sure. Yes definitely environmental samples can be included as part of the sampling agreement. And most likely there's going to be some manufactured food products that are going to be included. But environmental samples could certainly be a component of the sampling agreement.

(Guy Daletas): Great. Thank you (Wendy). (Kelly) is there any questions incoming?

Coordinator: No questions at this time.

(Guy Daletas): Okay. Well as we're waiting for questions to come in I have another one that was sent in. The question is dealing with sampling retail deli equipment. Is it acceptable to use samples collected from retail deli establishments for use in this particular sampling imitative? And (Wendy) I'm going to put - pass this one back to you as well.

(Wendy Campbell): Sure. And again, you know, we'll be glad to review the proposals and suggestions. But in general I do not think that type of sampling would be allowed. The sampling agreement is really just to support the manufactured foods regulatory program standards. And it sounds like that type of sampling would be more relevant to the retail food program instead.

(Guy Daletas): Okay. Great. Thank you (Wendy).

Coordinator: Tim we do have some questions now did you want to take them?

(Tim Wiener): Yes Ma'am.

Coordinator: Thank you. (Arnez Juline) your line is open.

(Arnez Juline): Hi - hello. I saw on your slide that you couldn't pick up foods that were manufactured at retail. But what about manufactured food sold at retail?

(Guy Daletas): (Arnez) this is (Guy). Real quickly I think that's going to be acceptable. Because the foods are would typically be considered manufactured foods. Their locations just happens to be at a retail outlet. I think the focus overall is for foods to be picked up and secured through and from manufacture firms. But certainly if it is in a retail firm I think that may be appropriate. (Wendy) any thoughts on that?

(Wendy Campbell): I would agree. I think that would be appropriate.

(Guy Daletas): Great questions.

Coordinator: Next question is from (Virginia). Your line is open.

(Guy Daletas): Yes (Virginia).

Coordinator: Please check your mute button (Virginia) your line is open.

(Virginia): Hi. Can you hear me?

(Guy Daletas): Yes.

(Virginia): Okay. We just had a question regarding bottled water sampling. If they would count from a municipal source? It's bottled but it's coming from municipality.

(Guy Daletas): I believe it would. But we may need some further guidance on that. If it's not out of the tap and it's going through a bottling process through a manufacturer even though it's starting from a municipal source. I think that would fall under the parameters of being acceptable. But certainly normal municipal water from a tap would not be.

(Virginia): And what about whole and uncut but packaged produce?

(Guy Daletas): (Tim McGrath) are you on the line? I think that would be acceptable if we're looking at pesticides or if we're for or if it's a part of a foodborne illness outbreak. Or an FDA sampling initiative I think that would be acceptable.

(Tim McGrath): Yes this is (Tim). I agree.

(Virginia): And okay and then just last question, if we have state statute that requires us to submit our samples to different laboratories would - is that counting as a sampling agreement or do we need something more specific? An actual plan like that was discussed?

(Tim Weiner): Well certainly we may need to look at your proposal individually because that's a really good question. It may be something as simple as having an agreement with some signatures on it kind of outline what you've already - what you're already doing. So it may be very easy to get there. Very good question.

(Virginia): Okay. Thank you.

(Tim Wiener): Yes.

(Guy Daletas): Any questions in line?

Coordinator: Yes the next question is from (Megan). Your line is open.

(Guy Daletas): Hello (Megan).

(Mike Moore): No it's not (Megan) it's (Mike Moore).

(Guy Daletas): Oh hello (Michael Moore).

(Mike Moore): Yes. Thank you. (Megan) called in. I actually have two questions about your request I guess.

First if Massachusetts would be interest in talking with some states, I know New York and some other states have a sampling protocol in place. And we've been back and writing that in from the FDA guidelines. Don't know many states out there who themselves are developing a sample plan from scratch between the two programs. So I think I've talked to Minnesota already but if there others out there I would like to talk to them.

Second I'd also be interested that kindly have a sampling plan that you're sampling and how they're using the results in the enforcement action. I'm not just talking about initiating recalls. In fact I do not want the other information to be used in different states tracing back from a form and taking enforcement actions under their laws.

And finally a request from Rhode Island is developing a sampling plan that test manufactured food in retail. As request for a need that he not include manufactured foods from Massachusetts. New York is fine. Thank you.

(Guy Daletas): Thank you. Those are very good thoughts and as we're developing the process to move forward we'll be addressing those questions about who may have these in place. And especially about the enforcement action. So very good thoughts.

I see unfortunately that we are at the top of the hour which is unbelievable but I wanted to turn this over to (Tim Wiener) to determine to rather we have an opportunity to go forth with any questions or rather we need to wrap it up.

(Tim Wiener): I would say we could take a few more questions. But we did start a few minutes late. I do know that was a question that came in would we be able to kind of provide guidance on the number of samples that we're expecting per month in our plans?

(Guy Daletas): Yes. Great question. And I think that there's not a set limit. And I want to go to (Wendy) for her thoughts.

But I think there's flexibility built in for large states as well as small states to be able to meet the need for the sampling agreement. I don't think there's a specific number that we're looking for. But (Wendy) fill us in on that.

(Wendy Campbell): You're absolutely correct (Guy). We did not specify a number of samples that would have to be analyzed or, you know, even the type of analysis that would have to be performed because we wanted the sampling agreement to be able again to meet the needs of the laboratory and the State program. Understanding the sizes of the laboratories and the capabilities really do vary.

And so once we get your sampling agreement we will review it. We may come back to your laboratory and ask for additional information. And we might be able to work together to modify the sampling agreement.

But we did not set any minimum number of samples that would have to be analyzed. We do plan to work with each laboratory individually. And as we approve the sampling agreement and make sure that it's a successful collaborating going forward in your three.

(Guy Daletas): Great answer (Wendy). Looks like we...

(Priscilla): This is (Priscilla) I just had a quick question. How do you expect the district to be working with the state? Do you because I thought it would be important to have the State key districts in the loop and let them know.

Will that be done through their existing protocols or will it be done through Office of Regulatory Science in terms of follow up on positives and enforce everything else?

(Guy Daletas): Very good question. And obviously we would all lean towards more communication versus less. And I wanted to let (Tim McGrath) have an opportunity to address from the Office of Regulatory Science perspective for sure.

(Tim McGrath): I think that's something we still need to figure out. Exactly how things will be handled. But certainly I think that if there's a follow up that needs to be done we can work through both OP and OR as to accomplish that.

(Guy Daletas): Yes. That sounds good. Kelly any questions on line.

Coordinator: No further questions at this time.

(Tim Weiner): Okay. (Guy) I would say this would be a good time to go to the next slide and I guess bring this call to a close.

(Guy Daletas): I think you're exactly right. Take it away.

(Tim Weiner): All right. As their transitioning one of the things that in talk about signing This week at the beginning of the week the PFP was able to release from the laboratory work group was one of the ten work groups that the PFP had in the past.

The PFP released a Food P Testing Laboratories Best Practicing Manual. And this is a draft manual but it is released out there as a resource. And it's on the public domain website. If you go to www.FDA.gov.

You can use their search engine and look for it under their partnership for food protection. Or under the title of this document. We will also be including this with the distribution of all of the attachments we covered today. But a wealth of information in this document. It covers a lot of information that was covered today. It's probably one of the most important aspects of this is at the end of this document there is a list of the stakeholders that were on the workgroups.

And 41% of the programs that were receiving funding under the ISO accreditation were involved as group members. So this is a document that was put together by the key players that are talking today.

Put together with the vision of where we want to really take this program. And we'll designed and it has a wealth of resource listing included in this to include definition of the different types of samples and what to do with them. Such as if you're going to have to regulatory compliance action and who to network. So just be please be aware of it is out there now. It's in the public domain website and one the additional tools to include.

Can we go ahead and go to the next slide. So as a reminder that (Guy) had mentioned in a previous slide go ahead and mark your calendar for the week of March 10 through the 12. Will be their annual member alliance.

The first day of that is actually going to be a workshop on laboratory program support for accreditation and to support the (Myrifs). This will be one of the multiple events that's occurring really to show the emphasis that we really want to make this program successful and build on it. It is also one of the requirements that's under the (FISMA).

So go ahead and please mark your calendar for that. As in the past if you have any questions reach out for the (Mymphas) program that are on the call reach out to your standards implementation staff for guidance. Or feel free to reach back to (Wendy Campbell) if you have questions regarding your cooperative agreement.

We also have a laboratories support folks form the States and from Academia at the Sate labs. Please feel free to reach back to your (ORA F) supporting

official that is providing support for accreditation. We want to make sure that there's a lot of networking occurring here.

If you have any additional questions you can reach us by through the Office or Partnership on our main telephone line. Or visit our website and keep an eye on that website. We periodically post new information.

I would like to thank all of our presenters today for sharing their insights on this important topic. And then on behalf of (Barbara Cassen) the active Director for the Office or Partnership, and the staff of the Standards of Implementation Staff, the Contracts and Grant Staff, and the Office of Regulatory Science I would like to thank you all for your participation today and wish you the happiest holidays. And a successful and safe New Year's. Thank you all.

Coordinator: Thank you for participating in today's conference call. You may now disconnect.

END