UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

+ + + + +

NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION

+ + + + +

SUBCOMMITTEE NUMBER 1
USING RISK TO DIRECT IN-PLANT PROCESSING
AND OFF-LINE SLAUGHTER INSPECTION ACTIVITIES

+ + + + +

October 12, 2006
2:30 p.m.

USDA South Building Cafeteria
1400 Independence Avenue, S.W.
Washington, D.C.

CHAIR: DR. DAVID CARPENTER
Southern Illinois University
School of Medicine

SUBCOMMITTEE MEMBERS:

DR. GLADYS S. BAYSE
MR. MICHAEL W. GOVRO
DR. ANDREA GRONDAHL
MR. MICHAEL E. KOWALCYK
MR. MARK P. SCHAD

FSIS:

DR. BARBARA MASTERS
MR. DON ANDERSON
MR. ROBERT McKEE
MR. BOBBY PALESANO

ALSO PARTICIPATING:

MS. FELICIA NESTOR
MS. JENNY SCOTT
MS. KATHY GRANT
MS. ANN RASOR
MS. KIM RICE

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

(2:20 p.m.)

MR. SCHAD: I'm Mark Schad. I own and operate Schad Meats in Cincinnati, and I've been on the Committee for four years.

MR. KOWALCYK: Michael Kowalcyk from Safe Tables Our Priority. I've been on the Committee for four years. In my professional work, I work in the area of database marketing and marketing research.

MS. NESTOR: I'm Felicia Nestor. I'm with Food and Water Watch and I'm not on the Committee.

MS. SCOTT: I'm Jenny Scott. I'm with the Food Products Association, and I'm the Vice President of the Food Safety Program and I'm on the Sister Committee, National Advisory Committee of Microbiological Criteria for Foods.

DR. GRONDAHL: I'm Andrea Grondahl, and I'm the Director of the North Dakota State Meat Inspection Program with -- which is with the North Dakota Department of Agriculture, and I've been on the Committee for two years now.

MR. GOVRO: I'm Mike Govro, Assistant

Administrator of the Food Safety Division, Oregon Department of Agriculture, and I've -- this is my last meeting with the Committee. I've been here six years.

MS. GRANT: Kathy Grant, Senior Mediator with RESOLVE.

MR. ANDERSON: Don Anderson, FSIS.

MS. RASOR: Ann Rasor with the North American Meat Processors Association.

MR. McKEE: Hi, I'm Bob McKee. I'm a frontline supervisor with FSIS.

MS. RICE: I'm Kim Rice with Crider, Incorporated, and I'm the VP of Quality Assurance and Regulatory Affairs.

MR. PALESANO: Bobby Palesano with Food Safety Inspection Service.

DR. CARPENTER: And Dr. Masters. Thank you.

You should have -- outlined by a member of FSIS, Bobby Palesano, and I think you can refer to what was discussed today, and if you can't hear, but you all have copies, Using Risk to Direct In-Plant Processing and Off-line Slaughter Inspection Activities, and he referenced three questions and

those are in the last three slides. What information should we use to support the optimal levels of inspection? What are the essential inspection activities for Level 1 inspection? And, what other inspection activities do you consider appropriate to perform in risk-based inspection above Level 1?

There was some discussion about algorithms, and how there might be different algorithms for different processes, which we should consider that. Bobby mentioned that PBIS stays. He talked about the PBIS scheduler perhaps being stopped in certain activities in certain plants, but the overall activity would continue. Am I talking loud enough?

DR. MASTERS: May I interrupt for just a second. Non-members --

DR. CARPENTER: Okay. Coming on. Is this any better now? It's working. Okay.

COURT REPORTER: Thank you.

DR. CARPENTER: You're welcome. So we should hold off until copies are in everybody's hands. No. Keep going.

Okay. Here's the way -- I think I'd just

like to paint a picture for us to start with. Taking what Bobby said, if you think about the nine pocket grid that he went through, which derives five levels, and they are essentially as outlined in -- is it the seventh slide, Bobby? Eighth slide. The second one. Is that what you guys all have? But he did throw it up on the board, and so if you look at it, if we can at least for a starting point of discussion, go with the five levels.

So he's got at the lower left-hand corner is Level 1, a really good plant, consistent in what it does and the product -- the inherent risk in the product that it deals with is pretty low. And then if you can look at that chart, going from the lower left corner to the upper right, you can see that Level 2 is a diagonal line, Level 3 is a diagonal line, 4 is diagonal line and at the very upper right-hand corner we have Level 5 which is a plant that needs a lot of babysitting. Just something to throw out for you.

One of the members of our Committee who is in Subcommittee 2, Joe Harris said, if we're going to implement something like this in the plants, why don't

we just go along in the first go around and say everyone's a Level 3. That's what we're going to start with. And then we're going to do the inspection based on predictive values and you either go minus 1, minus 2, plus 1, plus 2 or 0. For a starter? I don't know. Might it work that way? That's one option.

But as we consider all of the data that are needed, we've heard the predictive indicators, I think that was the right word. Is that the word that came up? Now, you know, in my mind, a predictive indicator is -- one example was the construction, you know, in a facility. Another one was what Mark related to me yesterday. As he considers product that he processes in his plant, don't let bad product in your plant. If you never get it in, you're going to pretty much assure that your product, in the overall processing of that product will keep you at Level 1.

So that's just another example in my mind at least of what is a component that contributes to an outstanding level.

Something else that comes to mind that I need I think FSIS to make input, I think Felicia made

some reference to it, and we've talked about it at other meetings, what are the best practices? I mean which inspectors feel, Bobby can probably address this for us, are there inspectors who feel, you know, I look at half a dozen plants in the course of a day, and I know which ones are best, and if I were to be slapped with a Level 1, 2, 3, 4, 5 system, I know who would go to 1, and I think I know who would go to 5. Maybe in between a little fuzzy. Do or does an evaluation or do inputs from the inspectors render this whole process a little easier. I mean I think that's something that we might consider as a recommendation. Maybe not.

So those are just my ideas. If I had a flipchart up here, you know, I would be drawing a three part grid and the other part -- I want to do a flipchart. The first one is the grid.

The second one is the effort of FSIS, and correct me if I'm wrong, Bobby, you can speak up, is that regardless of what level you're at, considering inherent product risk, or processing risk, we don't want to have a whole lot of Level 5 plants staying at

Level 5. Because we want to work them down to Level 1 because I think, I think what the members of FSIS want to say eventually is, we gave it all of our effort over the course of all of our deliberations to generate products from all of our 5600 plants that are close to or heading for a Level 1 and that the output of those plants represented an equivalent, an equivalent risk to public health which is very low.

I mean does that make sense? I mean if we consider the inherent risk in the product, if we consider the processing risks and appropriately address them or have FSIS and its employees address them, could we not get every plant and product closer to a Level 1 so that the threat to public health for any product out of any plant would be very low and hopefully close to nil to eliminate those 14 deaths. Is it 14, Michael, a day that occur? And 25,000 hospitalizations. Felicia.

MS. NESTOR: Felicia Nestor. I thought we can only get them to Level 3 because of the inherent risk. Are you saying there's a way to modify the product so that even the products don't have --

DR. CARPENTER: Go ahead. Good question. I'm just throwing out my impression, and you can tell me bad, not the right pathway, but I think, I think we can all agree that when you look at the varieties, and Bob could address it I bet, look at the variety of product that's processed and the different processing that's done, there are different types of interventions, interventions that can be initiated so that 8, 10 years from now, all of our plants are in a position to produce product that has the same level of threat, if I can use that term, to public health, and it's pretty low. Some plants are going to need a lot of work. Some plants not a whole lot.

So how do we go about helping the Agency to get all of those factors in place, so that 8 to 10 years from now, that's another fuzzy number, you know, we can finally be there. Those are the kind of impressions I have.

So from that point, how do we go about it?

MR. GOVRO: I had a question for Bobby regarding question 1. I think I understand what it says but please allow me to rephrase it and you tell

me if I've done it correctly, and then I'll know if I understand the question.

If I said what criteria should we use to accurately determine the correct level of inspection for a plant, is that what we're after there?

MR. PALESANO: I believe what we're after in question number 1 relates back to a comment that was made at the public meeting yesterday. We were talking about the chart and the chart, whatever, how many ever numbers you put in the chart, you know, whether it's 5 levels of inspection or 12 levels of inspection, what we're really trying to get at in the first question is what information should we use to make that determination for the appropriate levels of inspection. Did that help?

MR. GOVRO: Yes.

DR. CARPENTER: Okay. Are you okay, Mike, or do you have another question?

MR. GOVRO: Okay. And then maybe to kind of take it where you were going, David, obviously there's a lot of information that should be collected daily from the inspections that are done by FSIS employees

and that is going to give us particularly, if those are ranked with regard to criticality, that's going to give you a pretty good indication of how that plant is doing relative to the requirements. What I -- let me throw something out as an idea that might be used in risk.

Obviously temperature control times, temperature relationship are important in the production of any food product. So I would, I would say that maybe it would be useful to look at the plant's heating and cooling capacities relative to the volumes that they produce and their ability to heat and cool quickly and properly. If a plant was constantly at the edge of the capacity, I would consider them to be a high risk, than a plant which had adequate or more than adequate capacity to heat and cool. Am I on the right track there?

MR. PALESANO: This is Bobby Palesano. Again, I think you're looking at the establishment level. What we're really looking at is -- the comment was made yesterday that when I put the chart up or after I put the chart up, that there were five levels

of inspection on that chart. The question was asked of me how did we determine those five levels.

So what we are looking for more broadly is the process that we use to determine those levels and how we would support the levels that we selected. And in our example chart, Mike, there were five levels. What information do we need to support that five levels of inspection is the correct number. Okay. Does that help?

MR. GOVRO: Yes.

DR. CARPENTER: Mike Kowalcyk.

MR. KOWALCYK: Thank you. Michael addressed the one question I had about the first question. I think question 2 and, David, you talked about the essential activities for a Level 1, and I would caution against getting caught up in levels, just to Bobby's point as well as we don't know how many levels there are going to be essentially, and if you think about it, I think about what I taught in graduate school, you have classes where these levels are always going to be changing. If you're looking at a system that's constantly using data to provide some type

of -- I look at this as some type of score card based on plant attributes as well as the product that the plant is making at that given time. It's possible for a plant to go across multiple levels during a year. I mean the types of data we're looking at bringing into this process, it's not unrealistic.

Now we don't know what attributes are going to be most indicative. We saw some evidence on the NR analysis that kind of points us in one direction, but I think the question here is if the statutory requirements aren't necessary on the table, then wouldn't the least risky -- the least risky would always be Level 1, because that would be you're A+ students in the class. And as the system, if the system is successful, the average test score is going to go up. So everybody on average is going to lower its risk. Even if the bottom, they're not as risky, they're still your riskiest. So you should still pay attention to that because you always want to force that to drop.

So the essential inspection activities for me for the least risky, shouldn't that default to the

minimum as required by the statutes? I don't see if there's -- to me it seems clear to provide no changes in the rules and regulations, why would you go, why would you go beyond that or below that level of inspection? That's just a question that I have out there related to this because it seems like the least risky group.

Now within that group there's going to be some variance because you're going to have, I don't know, maybe it's got 100 plants, the number 1 plant and number 99th plant, they have different levels of risk. So what do you do with that? So again it gets to, how many levels do you have? So that's just a concern I have going into this.

DR. CARPENTER: So let me get it clear so Rob can capture it. I mean you're saying that a Level 1 plant, if we arbitrarily say the best, you're going to apply or you're suggesting that we apply the minimum statutorily required inspection for that plant. Is that what you're saying? So at the Level 5, we ought to be putting five times the effort into?

MR. KOWALCYK: Well, I don't know how many

times the effort is because a Level 5 might be 100 times more risky. We don't know. So a Level 1, you need to have some minimum threshold of inspection system, like what are you doing today, and what would you not do if you found the plant was less risky, and maybe that goes into we're looking at implementing some type of process that would use this data.

You say I have, I don't know, Carpenter's Meat Processing Plant, okay. This is how we are inspecting them today. You have a stellar record and you would be classified as a Level 1. Now what does that mean? Does that mean we cut back on inspection? Well, I would argue that you certainly would not want to cut back inspection because there is a possibility that if inspection became lax, you could move into a Level 2 or a Level 3.

DR. CARPENTER: Uh-huh.

MR. KOWALCYK: Because there could be things in there that are helping you manage your business and that's part of your process. So that's why I have that concern that if you reduced inspection, that would go below statutory requirements and that

involves changing the rules and I think that's outside of the realm of this question.

DR. CARPENTER: You know, I've always felt that minimum statutory requirements is subject to interpretation, and I may be wrong. Dr. Masters could probably correct me, but I think if FSIS is not intent on backing away from statutory minimum requirements, but I think you're asking us to help them apply resources in a way that is conducive to giving greater attention where greater attention is needed. I don't know if I said that well, but if you go from Level 1 to Level 5 plants, and 1 is consistently good, I, you know, Mark, maybe you could answer that. If you're a Level 1 plant and you're good and you get five marks of inspection all the time, and -- are you going to want to do things that make you drift off to 2 or 3?

MR. SCHAD: To answer your question, no. I was thinking about what Mike said, and I don't think Mike is too far off as far as the answer to question 2 because I was thinking, what if say you had a Level 1 plant and the inspector was -- he was going to come in every day to meet that requirement, the daily

inspection, but what would he do on a Level 1 plant, or the safest plant there is, and he would make his -- come in every day. He would make sure that the HACCP plan or the food safety system is being implemented, the SSOPs are being met and, you know, he would do that by inspecting records, SSOPs, you know, do a sanitation pre-op, and I think that's what he would do on the Level 1 plant, that that would be -- my understanding is that that would be meeting the statutory requirements.

DR. CARPENTER: Okay. So -- I mean it would be difficult -- unfavorable to put yourself in a position to go from a 2 to a 3 or a 3 to a 4.

MR. SCHAD: You know, personal opinion, I would not want to, you know, move out of that.

DR. CARPENTER: But Michael still has the concern that without inspection, you can't be sure of that. Jenny, I'm sorry. Go ahead. Fire away. You've got some input.

MS. SCOTT: And sort of to play on what Michael was saying, which takes us back to the first question, as I interpret Bobby's interpretation is

basically how do we decide how many levels you want.

Now given there's a statutory requirement for at least daily inspection, you have to start there, and then you have to say, well, within the district, there's a finite number of inspectors, inspection hours that you can distribute across the plants at these various levels, and so we want to focus more at the higher levels and less at the lower levels. And I will put it back on the Agency. How many levels could you really manage? Does it make any sense to have 10 different levels? Can you really distinguish different amounts of inspection based on that? And in my way of thinking, five is probably about the most that you could adjust the inspection resources and have any kind of significant differences between the levels and something that's meaningful.

DR. CARPENTER: And the Level 5, it's probably fluid at this point, you know, like Bobby said, you start off at 3 and they went to 5 and Dr. Raymond said, you know, why don't we make it 4 by 4 and that's 16 and I think the Agency is going to have to determine once you answer these questions. Bob, go

ahead.

MR. McKEE: Yeah, Mike hits on a real important point, and the point is that regulatory compliance is mandatory to our plants to operate. I mean that's the minimum standard. So if you've got a plant in category 1, in my mind, that's the plant that meets all of the minimum requirements but then goes beyond and has certain interventions and prerequisite programs that insure ongoing compliance with that regulatory requirement.

We're not going to change the number of visits. We're going to go there every day, but under RBI we may have the latitude to adjust our inspection intensity which is very important because it deals with the amount of time that we're going to need to spend at each location. So we may be able to satisfy our concern that the plant is complying in a Level 1 plant by doing a review of records, a spot check of their monitoring practices, whatever it might be on a particular day, where when we go into that Level 5 plant, we're going to kind of want to set up our stuff and spend maybe 3 or 4 hours looking at records,

justifying their monitoring activities. We're going to assure ourselves that this plant is going to comply now. We're going to be in a position to identify those failures, document them and either move them to a lower level or out of the system, and I think that's kind of the intent in my mind with RBI.

DR. CARPENTER: Okay. Good think. Kim. It is Kim, right?

MS. RICE: Yes, it is Kim. It's not Bobby. I just wanted to -- just more of the same I guess. Once product comes through anyone of these levels and bears the mark, it's all equal. The mark makes it all equal. It says it has met the statutory requirements, it is safe and it is wholesome, once the mark is on the product and it leaves the plant.

The level determines how much help I get from this gentleman and this gentleman every day, day in and day out, and like he said, whether they spread it out on the table and set up their computer and decide to spend the week, or whether they're there, take a walk through, look at a couple of pieces of paper, make sure we are monitoring according to how we

are supposed to monitor, you can get a general feel, anybody who has spent any time in plants, just by walking through, how things are going. So I would say that just keep in mind that once product comes out of one of these plants, regardless of the level, and there's the mark, it's all equal.

DR. CARPENTER: Bobby.

MR. PALESANO: Yeah, this is Bobby. Just more of a point of clarification to try to help the group so they will understand, that in order to meet the statutory requirements, we have to visit the establishments daily. So the frequency at this point in time is not optional.

What we do when we visit daily is something that question number 2 actually addresses. So now we've got an establishment in Level 1, what is it that we should do there that is of utmost importance for us, as far as the methods are concerned why we are there, keeping in mind that if we are looking beyond turning the scheduler off, we are no longer bound to the particular procedures that we may have in place today.

So if Mark has a plant and his plant is in Level 1, what would be the most important things that inspection personnel to focus on during their visit to a Level 1 establishment?

DR. CARPENTER: So -- go ahead. I'm sorry.

MR. SCHAD: I just wanted to follow up with what Bobby said, and this is just my viewpoint of it. A lot of this goes back to the food safety system design, and if the food safety system design is a good one, then the inspector comes in, and the CCP or CCPs are being met, then everything else should fall into place. That's my viewpoint on that. So if you're asking what an inspector would look at, I don't think you would call that an assumption up front, but if a FSA [Food Safety Assessment] has been done and the EAIO [Enforcement Analysis and Investigations Officer] says, you know, this is a good, this is a good design, this is a good plan and the CCPs are being met, then the end product should be safe and wholesome.

DR. CARPENTER: Another question, Bobby, or are you all done?

MR. PALESANO: Don.

DR. CARPENTER: Okay. Kim, I'm going to go back to your point, once it gets the mark of approval or inspection, going out the door, they're all the same. Is that what you said?

MS. RICE: Yes.

DR. CARPENTER: Okay. So that mark is a fix. When the inspector is in a very objective way satisfied with the controls of the process in the plant, okay, could it be that that mark of inspection would go on a product and the microbiological quality of the product coming in the door was less than fully acceptable and not known. How would you know going through the process that you had, that you had processed a, you know, sub-par product, raw product?

MS. RICE: And I think that goes back to Mark's point, that it is all based on the food safety system design, that you are part of your food safety system design, understanding whatever the criteria is for start to finish, and I believe that the regs read before, during and after the product leaves the establishment. And that's the standard we're held to. And if you use a real live example, and I've been out

of the ground beef side for a while, but it's my understanding that ground beef suppliers are required to take into account the testing programs of their suppliers, and also as part of their food safety system design determine and develop testing programs to insure the safety of a raw product leaving their facility, and all ties back into their food safety system design.

But it's the Agency's statutory charge, if you will, that once that mark is on the product, they have insured that it has met whatever the requirements are.

DR. CARPENTER: Okay. I asked that question, Kim, because the question specifically addresses what information should we use to support optimal levels of inspection. It's actually a complex question. What's the optimal levels of inspection? And what information do we need to use to support those inspections?

Okay. So going back to what Mark said, and Mark and I have had some conversations about, he knows who his suppliers are and comes up with the best or is

one supplier better than another. So is that information that every processor should embrace and make part of their SSOPs? You know, I want to know the microbial quality. I want to know the kind of SSOPs you have in your slaughter plant. Mark doesn't slaughter for instance, et cetera, et cetera, because I think Bobby's looking for that information.

MS. RICE: Well, I think that first question at least in my mind and I apologize, I'm not on the Committee, but I'm answering a lot of questions, is it goes back to the wheel, the data wheel with the six or five, if you take food defense out, those, those are the parameters or the input I believe as it was discussed yesterday that talked to determining the establishment risk or the X axis versus the inherent product risk which is the Y axis which in the diagram that they put forth with the five levels, or three, if that one was taken out, both of them though had the X and the Y axis with those inputs. So I think question 1 goes back to that. Are those the right pieces of information that should be used? At least that's my view of the world and maybe I'm wrong.

DR. CARPENTER: Okay. Michael.

MR. GOVRO: As I understood Bobby to answer the question, that's not the question. The question is how do we decide how many levels there should be and what information do we use to decide that as opposed to what I thought the question was in the beginning which was how do we -- what information do we use to appropriately place the firm in the right level. Did I get it right?

MR. PALESANO: You got it right, Mike. Actually what we were trying to get at with the first question, which was related to a comment that was made yesterday, and we only used those five levels again as an example. It could be 25 if that were the optimal levels of inspection. But the comment was made did you arbitrarily pick five levels or was there some basis for those five levels? And if there was a basis, what was it? So we're trying to put that back on the Subcommittee today to help us know what kind of information should we use to support whatever those levels are, whether it's 5 or 25.

DR. CARPENTER: That's pretty fluid. The

number of levels. I mean we know we'll have a Level 1 because that's the first one, because that's referred to in questions 2 and 3. We have one. Where we go from there -- the comment that Jenny made --

MS. SCOTT: I mean we have to think about what we're trying to achieve when dividing up these different levels, and that really is how many -- how much of the inspection resource should be devoted to each of these different levels, and again to be -- you can't infinitely divide that up and have any kind of meaningful difference. So, you know, maybe we ought to think a little bit about what different goals we would be focusing on at different levels, and that might help tell us then how many we would really need to achieve those different goals.

DR. CARPENTER: And maybe we ought not try to get ourselves bogged down right now, what's an optimal level. Once the Agency has got a whole ton of data, they can come back to us six months from now and say, it looks like 8's the perfect. I don't know. Andrea.

DR. GRONDAHL: I guess I'm having a really

hard time coming up with anything for question 1 because it is a very complex question, and it just seems to me that that seems like more of a last question that could be answered rather than one of the first questions, and that maybe it would be easier to look at what inspection activities are necessary for Level 1, and then question 3, what inspection activities do you consider necessary above Level 1, and those are both difficult questions, in my mind, too. How do you answer that and I guess the only thing I'm thinking is, you know, maybe you need to go back to looking at the expert elicitation or inspectors and say, okay, if you have, you know, what we're looking at as Level 1, a low risk product with good establishment risk control, you know, what's absolutely -- what's the minimum necessary to control the risk of that product as far as inspection activity, and then looking a the highest risk and doing the same thing. What inspection activities are necessary? I think, you know, in my mind I'm thinking about the various PBIS procedures and, well, what, you know, that's a really hard thing to answer. I think

it almost takes a focus group or expert elicitation or something to start looking at, you know, what product are we talking about. And if you have like an establishment control, you know, what inspection activities do we need to do, how much time is that going to take, and then how many levels are between that and Level 1. -- Okay. Mike Govro.

MR. GOVRO: I was going to suggest that perhaps we, for the sake of discussion, we start with five levels and then discuss more levels and fewer levels and list the pros and cons of having more or less and perhaps we could then come up with something that would point us in one direction or another. Does that make sense? I'm just throwing that out.

DR. CARPENTER: So do you think we would be in a position to list what are associated with each of the levels in terms of inherent product risk and risk associated with an establishment? Go ahead. Just elaborate.

MR. GOVRO: More or less. If we said let's say the number we've chosen arbitrarily is 5, let's talk about 6 or 9 levels, and what would be the

advantages of having more levels, and what would be the disadvantages and, you know, Jenny's already mentioned some possible disadvantages to having more levels. What would be the advantages and disadvantages to having three levels. I don't think you can go much lower than that, but -- and then see if we could -- see if anything shakes out as we make a laundry list of pros and cons.

DR. CARPENTER: Okay. It could work. Mike Kowalcyk.

MR. KOWALCYK: I would agree with that approach. I think what we need to keep in mind is, and this is related to the first question, too. What information should be used? Well, in looking at -- just looking at establishment risk and looking at the data wheel, around this data warehouse, we saw a good example on NRs and some good analysis that was put into that, to get an understanding as to what type of relationship there is with respect to certain types of NRs. Now similar methodologies can be undertaken to look at, I don't know, FSA outcomes. What are elements from those data sources that can be used in

some type of system? Pathogen control, in-commerce findings, public health data or attribution data that could be linked up at a facility level. And then to make it even more -- unfortunately more complicated, then you've got interactions across all these data sources. Because your pathogen control results are probably related -- there probably is a correlation with the number of NRs if the inspectors are seeing things that are causing contamination.

So -- I don't know if there's the research out there that shows any correlation yet. So using the information, there's a wide variety of data that comes into this, and then I mean I'm looking at it as the Agency looking at building a statistical model using regression techniques to develop a score. So then this gets into forming levels then. Let's say we've got a score and what is the score's range? I mean going back to the stats 101, you can look at distributions of data and some of them are very skinny, some of them are very wide, some of them are a normal bell curve, some of them are highly skewed.

So levels, I mean for the sake of our

discussion, sure, 1, 2, 3, 4, 5 is fine, but what is the spread of those levels? I mean how different is a Level 5 from a Level 4? It depends on the data that goes into it, and I mean you could have other confounding factors that Mark and I were discussing, such as plant size. Do you want a small plant like Mark's in the same distribution or the same -- should it be modeled the same way as a large ConAgra plant? Maybe, maybe not. I don't know. I don't know if anybody knows that at this point. So I think the -- looking at Level 5 is your most risky, how are they to be dealt with? Level 1, your least risky, and then in between. I mean it's -- I think it goes back to what data would we recommend the Agency to look at and to investigate and then to use that additional information to aid the allocation process and how the inspectors are allocated. You have a minimum requirement. So you need daily visits, and then even that daily visit can be components of, you know, you spend a small amount of time there but there's riskier parts of that plant's process that, okay, you don't have to spend four hours there, but in your hour, make

sure you look at this.

So there's even another risk assessment that's kind of at that level, and I think we want to make sure that the inspection force is trained well enough to -- and still have that latitude to make those decisions in the field. So I don't know if I helped answer any of your questions, but that's just in my mind what drives this whole thing, if it's to develop some type of score for each facility, that I hope would be dynamic. I mean even from a producer's side, if you come out and you've got a score that puts you in a Level 4, you would, you know, you would want to make efforts to move yourself up to a Level 2 or a Level 1 over time. So --

DR. CARPENTER: Mark, I'm going to ask you to talk -- I want you to address what Michael just said. You feel the same way when you go to a very small plant and you go to a ConAgra plant in assessing overall Level 1, 2, 3, 4, 5, being theoretical. Okay. Mark, go ahead.

MR. SCHAD: Yes, very quickly. I agree with Mike Govro. I believe we need to pick a spot here

because we're bouncing all over the place. So let's pick a number and start with that.

DR. CARPENTER: What if I said let's put all the data in and then pick a level?

MR. SCHAD: Well, let me just say to that, I'm glad we have a frontline supervisor here, not that I'm going to put you on the spot right now, Bob, but I think another think we have to think about this, is the workability of it on a daily basis, the different levels. I mean we can sit here and make this big fancy picture and everything, on how many levels on a piece of paper, but a frontline supervisor, they'll end up directing these activities, so many hours for this plant, so many hours to that plant, baby-sit this plant, baby-sit that plant, you know, but from a frontline supervisor's point of view, I'd be -- I think it would be good input on workability on a number of levels on a daily basis.

DR. CARPENTER: Robert's back here, we've got these questions, we've got to get answers to them. He's going to tap me on the answer pretty much and say Dr. Masters says you're fired unless you start getting

some answers here, and he's here being a wonderful scribe. So help us out, Bob.

MR. McKEE: I'd like to just make a blanket statement and say that I'm very comfortable with five levels, but I know Michael will challenge me statistically, so I don't want to do that. But in my mind, without getting real deep into it, I can see where we could operate on five levels and certainly if a plant were running between two and four, we would have a fairly good level of competence, and then 2 would certainly start to -- I'm sorry. Four would raise the flag for us. We would start to become very interested, more interested in what was going on and certainly with 5, so we'd be spending a lot of time.

Given that the 1s, 2s and 3s are all generally in compliance, meeting all of the requirements, at least the way it's laid out, I would feel comfortable with that. But then as we start to edge up into Level 4 and 5, I think we need some more latitude to be able to really focus there.

So I think what we need to be careful of is setting up the parameters for each level, and for

movement between those levels.

DR. CARPENTER: Bob, share with us, if you approach a very small plant and if you approach a ConAgra plant, I mean do you based on previous data, do you -- about those plants, would you be in a position to slot them at a certain level or would you look at a really big operation very differently, when you look at all the aspects of their operation? Or can you be objective regardless of size?

MR. McKEE: We really have interest and concern in the food safety systems, whether it be a ConAgra or a very small plant. If that food safety system is all-inclusive, and it's written properly, implemented properly, there's not a great variation in what we're going to find. Usually when we get into problems, it's in a plant where the design is not what it should be or the implementation doesn't match the design. So if you've got a good foundation in food safety plans, you can pretty well expect that you're going to have success if they're implemented properly.

DR. CARPENTER: Good. Thank you. Gladys.

DR. BAYSE: I don't know if this is

subliminal, but as a teacher, the five really sticks. We call it A, B, C, D and F, and in the course, I'm wondering if we all sort of weren't thinking about that. We also have pass/fail courses. And, in fact, we have B-, B+ and so forth. So I think it seems to -- but it's very -- it's more than apples and oranges. It might be like herding cats. I've heard that expression. I think it's really difficult and that's why we're struggling with all these things, but I like five.

DR. CARPENTER: Felicia.

MS. NESTOR: I just wanted to remark on something that Bob said. You were saying something about plants 1, 2 and 3, are in compliance, but my understanding of the chart is that a plant 3 could be one of the least compliant plants if it's making a low risk product, right? Am I right about the chart?

Okay. So we can't assume that a plant 3 is following the regs.

UNIDENTIFIED SPEAKER: Well, and Kim says if they're not meeting the minimum standard which is the regulatory requirement, the product is not going to

ship. The HACCP plant or the SSOP has to be met. If they're not meeting critical limits, the product would not be eligible to be shipped.

MS. NESTOR: Yeah, but the presumption of this whole thing is that all plants, 1 through 5, are shipping. All of these plants are in business and shipping, even though they may be making a high risk product and have a number of NRs. I mean I think it's, you know, it sounds good to say that a product that bears -- that has the seal meets the requirements, but I don't think in actuality that is a factual determination. A lot of times it's the result of the fact that, for instance, an inspector might not have gotten to that plant that day, but it still bears the seal. I don't know why you're shaking. Some plants, inspectors don't get to them every day and they still produce product with the seal. I don't understand how that could be theoretically wrong.

DR. CARPENTER: Kim.

MS. RICE: Kim Rice. My understanding of the regulations and the statutory meaning of -- legal meaning of the mark, if the product bears the mark,

and it has been made available for inspection, then they've met the minimum requirement legally. Now if the Agency has taken action whether it's in plant, a regulatory control action in the plant, and retained the product or detained the product, retained the product at the plant, and the plant ships it, yeah, then we're in a whole different realm, and it's not -- it falls completely outside this little diagram.

Now it may move them from, you know, over here on the 3 -- down here on the 3 up to the 5 because they've done that once, but still once the product is in the marketplace and bears the mark, they theoretically met the minimum requirements -- statutory and regulatory requirements.

MS. NESTOR: Theoretically, but it can still kill somebody.

MR. McKEE: We could be dealing with a high risk product like ground poultry or ground beef, and that may automatically put that plan into a risk 3 which doesn't mean they've violated anything. It just simply tells us that they're dealing with a higher risk product, and certainly we would deem that plant

to be in compliance and then expect that they would continue to ship product. So I'm not sure if that helps you out or --

MS. NESTOR: Well, I know --

DR. CARPENTER: Felicia, please.

MS. NESTOR: I know that on the chart there's a plant Level 3 that is in compliance and it's one of the best compliant plans, but has a high risk product, but there is also another Level 3 which is a very low risk product that is a non-compliant plan, or one of the least compliant plans.

DR. CARPENTER: So the point being made is you could be a wonderful plant, a great operation, fantastic control of the process but always dealing with a high risk product, you'll never get better than a 3. Is that true?

MS. NESTOR: That's my understanding of the chart as presented by FSIS.

DR. CARPENTER: So maybe that argues for -- oh, we did get a flipchart. Thank you, Michael.

MR. McKEE: And we do have an enforcement system in place --

DR. CARPENTER: Bob McKee.

MR. McKEE: -- and if we have plants that are dealing with low risk products that are gravitating to an area where we can demonstrate non-compliance, we will take enforcement actions. A plant may not necessarily have to go to a Level 5 to fall into an enforcement action, and again that's going to be based on our knowledge at the circuit level of that plant, the inspector's judgment and supervisory input. So there are ways to encourage those people to come back toward the left-hand side of the box.

DR. CARPENTER: Dr. Masters.

DR. MASTERS: I've seen Mike has taken over what I was going to suggest, even though we had come up with three questions we thought would be helpful, I really like the suggestion of going through pros and cons on different levels because I think this is an area that would be very helpful feedback to the Agency, the pros and cons of different levels of inspection. Because until we get some decision around the number of inspection levels, it becomes much more difficult for us to make some more affirmative

decisions as to what those inspection levels could do. So I think this would be a very helpful exercise. Although it's not one of the questions, I need to say as the Committee we took over the Agency and marked out one of their questions and gave us a new one and I think that would be a fabulous approach. So we would greatly appreciate it. I think this is very useful feedback.

MR. GOVRO: I'll be the scribe and let's just -- do you want to start with 5 or --

DR. CARPENTER: Jenny, please.

MS. SCOTT: Jenny Scott, and before we go into doing this, I think this is a really good idea. I want to make sure that we're not thinking of a Level 1 box, we'll just spend this much time in a Level 1 plant. I'd like Gladys' analogy of the grades with the A+ and B+ because if you think about a Level 1 plant, and you know, this is low risk product and generally in control, you're still going to have very small plants and large plants, and you're going to have to do more in the large plants because there's more to oversee even though they're low risk.

Likewise, in a Level 3 plant, I see a difference in a low risk plant that's highly variable in their controls, and a high-risk product that you have very good control. You would still have a different level of intensity in what you do in there. So it comes down to what things we would want to do with respect to those and there's going to have to be some judgment call in this. That being said, we can go to the pros and cons of the different levels.

DR. CARPENTER: So before we get -- Michael, do you want to make an input before we get to the chart?

MR. KOWALCYK: Yeah, I want to clarify the statement I made earlier. I don't know if it caused confusion. I think the reason why I said that, you know, there may be more than five levels, we don't -- I think FSIS wants to use this as a management tool. I don't think this is, while the goal is to push everybody into a Level 1 because, you know, the grade example, if you're teaching a class and the grade distribution goes down, the lowest score is an 80, that's still the lowest score. Okay. And maybe the

push is to get everybody's risk scores lower. Now it depends on how that score is assigned really matters in ranking everybody and how you segment that. That's up for debate, and I guess that's a management question is, you know, what is workable for the Agency.

Thinking about my job, when I allocate work to analysts in my team, I'm not going to give one analyst let's say three Level 5 projects, okay. I'll give that person a Level 5 project, maybe a Level 2 and two Level 1s. And it's about allocating inspection resources, i.e., inspection intensity, then maybe that -- maybe five levels is fine. Maybe three levels is fine. That's for the Agency to consider but again, it's how, within each level, what's the disparity and risk. And, you know, that -- I don't know what that is until I see what goes into creating that score. Mark Schad's establishment gets, I don't know, a very favorable risk score of like 5. Well, what does 5 mean? What's the range of scores? So 5 levels for practical purposes, probably a reasonable place to start. So I'm not opposed to that, but I

just want it to be considered that within score ranges, there's going to be differences like the example like A+, A-, or that. So five levels is a place to start for practical reasons, yeah, fine.

DR. CARPENTER: All right, Michael. Thank you.

Michael's got up for discussion, pros and cons of five levels or pros and cons of six levels?

MR. GOVRO: The first one I wanted to capture because it's already been thrown out is what Gladys said which is people can relate to five steps, to the grading system. I'm trying to think how to write that down briefly.

DR. MASTERS: I would say familiarity which something that people do relate to when you're going through a significant change. I think it's a well-known factor that you would try to have something that people can relate to, that's familiar to them.

DR. CARPENTER: So familiarity grading.

MR. GOVRO: I would suggest that it provides a reasonable level of differentiation between the top and the bottom, and another thing I wanted to bring

up, this is kind of a side note, but I'm a little bit concerned that as we rate these 1 through 5, we really have two different things that we're talking about, you know, the X and the Y axis, and it might be more useful or less a source of confusion if we used a two number grading system, a 1/1, 1/2, 1/3. My concern is that we would look at one that was a Level 3 and you look down that diagonal access and you would be saying that a plant that was a low risk product with poor controls was -- had an equivalent risk to a product -- a plant that had just the opposite, a high risk product but was run very well, and I know that to some degree industry is concerned with the public perception of their number, and I think it's important -- and I just throw that out as a suggestion that we could do a two number system. So I'm going to write down differentiation. You're free to disagree with me if you'd like.

DR. CARPENTER: Go ahead. Jenny. While Michael's writing.

MS. SCOTT: Jenny Scott. I just heard a con on this, that you have plants that are the same level

but that level doesn't reflect necessarily the same thing because the level incorporates both the inherent risk and the establishment risk control.

DR. CARPENTER: Andrea.

MS. SCOTT: I'm not sure we would want two numbers but maybe you would want numbers and letters. Letters on one access, numbers on the other.

DR. CARPENTER: Okay. And so for all of us numbers and letters product and establishment process. Help me out. Is that what we're looking at Michael?

MR. GOVRO: Yeah, didn't we say the same thing pretty much. Yeah, that the risk would not necessarily be equal between two firms that were at a Level 3.

DR. CARPENTER: Okay. Andrea.

DR. GRONDAHL: I think it's already been said but I was just going to add a little to what Mike and Jenny both said, just because right now the way the sample chart is, if you have someone producing a high risk product but good establishment risk control, they're already policing themselves. They're not going to need the same amount of inspection activity

that a plant producing a low risk product but doesn't have good as controls needs. So I think you need to differentiate that and I think that's a con of the current five level system.

DR. CARPENTER: Andrea. Thanks. Felicia.

MS. NESTOR: I'm really struggling on here, but just based on everything that everybody's saying, someone was just mentioning a 1/1, a 1/2. What is going to be the distinguishing feature between levels and inspection. I mean is it going to be tasks that get performed or is it going to be amount of time, because like Jenny was saying, if you've got a very small plant at a 2, it's going to take less time than a very small -- a very large plant at a 2. So I don't know, I mean how helpful is that going to be to the Agency. Is the Agency then going to have to deal with, well, this is a 2 at a large plant or this is at a large plant that makes 40 different products or this is a 2 at a large plant that makes one product? I mean it seems like there's so many different factors that could factor into what the activities are plus how much time one inspector has to spend in doing it.

So I don't know how, I don't know how that's going to be helpful to the Agency.

MR. GOVRO: Okay. You guys can correct me if I'm wrong on this. I would have to say that that's probably a question for another day. The Agency's asked us just to come up with a rating system. I think we should focus on that today, but you're right. It's going to be problematic and difficult and I'm sure they're up to it.

DR. CARPENTER: Jenny, did you want to add something else?

MS. SCOTT: Jenny Scott. I was just saying that it's going to be a combination of the amount of time and the type of tasks that are performed that are going to be different at these different levels, and clearly that is something that is going to take some in depth discussion.

DR. CARPENTER: Okay. Thanks. Michael.

MR. KOWALCYK: Michael Kowalcyk. Looking at the level assignment using the values of the cell. So you've got low risk, consistent establishment risk control, they're a 1/1. Okay. I'm an inspector. I'm

assigned at a Level 3 level of inspection, okay, for an establishment that has the highest risk product category, consistent control. So you would be a 3/1. I'm also assigned to Level 3 that has more variable establishment control, but a low risk product. They're both ranked as a Level 3, but the reason they're a Level 3 is because for different reasons. So my focus obviously with that upper left-hand side should be product related. Is it more microbial testing? Because I know this plant. They're doing the best job they can process-wise. I mean they're following their plan. Their NR records are good. But then you're focus -- so maybe having that level of granularity is a management tool rather than just a Level 3 might be more useful because then it -- and then it also begs a question, is it appropriate to weight product risk and establishment risk at the same level? That's a question for another meeting I think but --

MR. GOVRO: I think that's what we're getting to here with a two digit designation, is that a 1/3, the Agency would not necessarily have to look

at that in terms of assigning time and intensity as a 3/1.

DR. MASTERS: I want to ask Michael a clarifying question.

DR. CARPENTER: Dr. Masters.

DR. MASTERS: It gets to -- Barb Masters -- gets to question 3 but asking it in a different way. We were asking what inspection activities you would consider appropriate to perform above a Level 1, and I think now is really doesn't matter what level you're at with the approach you all are considering, and as I understand what you're suggesting, Michael, is that you're considering that since we in this five square analogy that -- or five levels that we came up with, that if the level is higher because you're high on the inherent risk category, compared to the establishment risk control category, you think the inspection activities ought to be related to the product as opposed to the establishment risk control. And so you're, and I think, if I understood you correctly, I'm hearing the answer a little bit to question 3, that depending on where they land on this chart, might

drive something as far as what their inspection activities are.

MR. KOWALCYK: Yeah, I would say that's accurate. I mean it's a simple example but I think it makes sense that there's a reason why that facility is at a Level 3 or Level 4 or Level 2, and what are the driving factors. Is it because the product's so risky? Is it because the process, there's a lot of holes in it, and that would help. If the true goal is to efficiently allocate resources, that may help get you there. So I think that should be considered as the decision making process.

DR. CARPENTER: Mark.

MR. SCHAD: Yeah. I'm just going to put my two cents worth in as a small plant owner. I think that's an excellent -- I agree with Mike. I think that's an excellent way of doing it. That's definitely a pro in my opinion, of the two digit.

MR. GOVRO: Okay. Do I need to capture anything you've said, Michael, that's not already here? Have we --

MR. KOWALCYK: I just think rather than just

the five levels capturing the detail as to what rank they are with respect to product as well as to establishment should be accounted for, how they're categorized. Yeah, I would think that basically a dual matrix approach where you're cell 1/1, 1/2. Again, you know, we can go out to whatever number it is, but for practical reasons, this might be sufficient. At least it's a place to start, and I think it helps drive the efforts, the inspection efforts towards the issues that needs to be looked at more so than just treating all Level 3s the same way.

DR. CARPENTER: Don Anderson.

MR. ANDERSON: Don Anderson. Just as a point of clarification, in all the discussions that I've ever had with the staff around the Agency, we have never -- I don't think we've ever considered that we would just give inspection force Level 1 or Level 3 or Level 5 without any additional information. We've always known that we have to give them some deeper information as to what gave rise to that number because it may influence how they do inspections. That's about all I could say about it. I don't know

all the details but that's always been an assumption.

MR. GOVRO: At the moment, I'm not seeing any other hands. On the five levels or what we've come up with, the dual 1, 2, 3, 3, 2, 1 system. Shall we go to more and less and take a couple of comments on those, so we've got something on the record?

DR. CARPENTER: Michael.

MR. KOWALCYK: I guess the answer I would have is I don't know if that would be appropriate or not, if we even have enough information. I think Mr. Anderson raised a point that as far as, and then it goes back to question 1, maybe I should table it for later but providing that detailed level of information to the inspection force, I mean I'm going back to this, and I don't know what methodology the Agency is going to ultimately use to generate this ranking but you have all these data elements in here, even where the plant's located, if this data would be summarized in such a way wherein in the morning, you can go do your inspection and say, here, this plant's on your list today, they're in this level and here is the information that's behind why they're in this level,

and say it's updated weekly or monthly, based on the most recent data, this is why this plant is classified here, and here's the things that you could probably look at.

But I don't know where that fits in with these questions but when you made that recommendation, it seems like managing resources, I would hope that your management, middle level management would be directing them in that way and using this information. Again, I don't know whether it would fit at level -- more than five levels, I don't know. Again, it goes to how wide is that distribution score. It depends on what the disparity is.

DR. CARPENTER: Kim.

MS. RICE: Yeah, this is for me, not Bobby, and -- Kim Rice. We're sharing a name tag here. I guess I'm kind of a simple, visual person. If we're going to use an X and a Y axis, then four in my, you know, the least number I could get is four, and you're still on the same situation. So I don't think where five gets you anything. I mean you get the same detail but you're in the same position. So you have

less familiarity with four. You don't have the grade association, et cetera. So I don't think less than four is going to get -- or less than five, excuse me, is going to get you much of anything else. If you come off the inherent product risk and the establishment risk, then it's all open season again, and I think we start over where we did Tuesday, and I'm not sure any of us want to do that again.

DR. CARPENTER: You know, I have to expand on Gladys' academic analogy, just thinking about the wheel, you know, ever -- when you start a class every year, you give students a syllabus. Thirty percent of your grade is your final, 25 percent is your midterm, 30 percent is your presentations and 10 percent is your class participation. Do you do that for every plant? Come up with a grade, A, B, C, D, E -- no, A, B, C, D, F, you know what I mean.

(Laughter.)

DR. CARPENTER: Gladys.

DR. BAYSE: I know you don't want to go there, but you know there's always the question, is an A the same at Harvard as at Southern Illinois. So I

know we don't want to go there.

(Laughter.)

DR. CARPENTER: Good point. The pros about less than five levels? I mean -- Mark.

MR. SCHAD: Yeah, this is Mark Schad. I'm probably repeating the same thing but just looking at the number of these potential factors that we're putting into this thing, and not knowing what the algorithm is going to look like, really specifically, I just don't see how anything less than five is going to work. You're going to come up with a number and I don't know whether you're going to be rounding off, you know, rounding up or rounding down. I just don't see enough -- less than five where you're going to be able to make enough distinction among different plants.

DR. CARPENTER: Okay. Thanks, Mark. Jenny, please.

MS. SCOTT: And I was just going to offer words that says that less than five is not discriminatory enough.

DR. CARPENTER: That's another con. Okay.

We're into this about an hour. Bobby, back to you. We've got questions 1, 2, 3. How are we doing? Are you getting what you need?

MR. PALESANO: I'm not here to give you an A, B, C, D, or F grade.

DR. CARPENTER: So we're not -- are we getting there or are we just rearranging the questions with new verbiage? Greater than five. Pros. Well, Jenny will say that is definitely more discriminatory. Go ahead, Jenny.

MS. SCOTT: So the pro could be it would be more discriminatory but the con would be you have to divide up your resources to meet those different levels, and it may be more difficult to appropriately segregate tasks that distinguish between those levels.

DR. CARPENTER: Good point. Michael, please.

MR. KOWALCYK: I think to follow up with Jenny's comment, I think she's right. Allow for more granularity and the breakout. It does bring in the logistic issue and managing, but you might find that the range across product inherent risk, you might --

your table might look more like a rectangle, depending on the spread of the data. So that may be something that should be on the table based on what further analysis would tell us.

Another thing to put out there is would the Agency entertain, I guess stratifying the population of plants, into -- I mean right now we have large, small and very small. That turns into three tables, maybe still have five levels, but, you know, 5A, 5B, 5C, but it's based on plant size, because you might not -- again, it goes back to the comment made earlier, you might not want, you know, a plant the size of Mark's in the same mix as a large ConAgra plant, so to speak. I don't know. Maybe that will allow for further discrimination.

DR. CARPENTER: Don, please.

MR. ANDERSON: What I've been trying to do is just keep track between these three notes and go directly to the question of what information, what information should we use to support the optimal number levels of inspection, and things that we keep hearing over and over are differentiability or

granularity, whatever words you want to capture how many levels do you need, given the distribution of plants. So that's one, is kind of granularity. The second that we keep -- that we've heard at least once is familiarity. Familiarity is a totally different concept. The third we've heard about which is going to be a pro or a con is manageability. How, you know, what is the manageability of the number of levels? So we've got granularity or differentiability, we've got manageability, we familiarity. The only one I haven't hear, maybe it's a subset or part of manageability are training issues, that it may be that the more levels of inspection that you have, the more challenging your training is. I don't know if that's an issue or not, but that's something that I would just put out as a question.

DR. CARPENTER: Okay. Thanks, Don. Mark.

MR. SCHAD: Yeah, I'm just going to address what Michael said here, and I think it's, I think it's a good thought because I think we just need to be very careful what that idea, and I learned this from working in a food defense focus groups, because we're

trying to get out guidelines to different size plants, and really it's the small plants, that there's such a wide range there, you know, if we differentiated the plants from that standpoint, we would be doing from 10 to whatever that number is, there's such a wide range there, and there's also some plants that have a very few number of employees that put out a lot of poundage and vice versa. So I'm not saying it's a bad idea. We just have to be very careful how we differentiate that.

DR. CARPENTER: Okay. Good point. Kim, go ahead.

MS. RICE: Well, I have a comment to make to Don or to support what he was saying, related to training. I don't have the number of employees that the Agency has but I have had responsibility for up to 10 plants at one time with anywhere from 1,000 employees to 500 plus employees in each facility, and the more complicated you make whatever, anything from a HR policy to how they're going to pick up their paychecks, the more difficult implementation becomes. And I think we can all, those of us involved in HACCP

implementation, as simple as we tried to keep that, that was still overwhelming at times, and still can be challenging even how many years later it is. I try not to think about how long we've been doing that. So that's -- as simple as we can keep it is how we need to keep it.

But then my second question is, I'm sitting here trying to do the two number thing, and just a point of clarification for myself is when we go back to that five level, is the intent to keep five levels. If you look at the picture, the nine blocks, with the 1, 2, 3, 4, and 5, the way it's done, the second set of numbers that you're assigning, is it going to be 3 or is it going to be 5, or is it going to be letters? Is it going to be -- because you really are getting to be more than five levels. It actually becomes nine levels.

MR. GOVRO: It becomes nine levels, yes.

MS. RICE: Right.

MR. GOVRO: You're correct.

MS. RICE: So the answer to greater than five is we're already there, if we all agree, and I

think we all do agree that the two -- assigning two numbers is an easy way to -- easier way to communicate that it's either inherent risk product or control of the establishment that puts it in one block or the other, excuse me, the combination of the two. So we may want to go back and relook at what we've done so far. Or rewrite what we've done.

MR. GOVRO: Yeah, actually I would maybe just success that now these titles are simply wrong. Okay. Do we have consensus? Do we like the two designations for each axis rather than one single number?

DR. CARPENTER: Bob, do you agree with that? Do you see yourself five years from now having to do this on a day-to-day basis and is it practicable, reasonable?

MR. McKEE: The double digit designation may actually be very helpful to us.

DR. CARPENTER: Okay. Good. Thanks. Jenny, go ahead, please.

MS. SCOTT: Just personally I would find the double digits confusing and would rather see a digit

and a letter than the double digit. I have enough trouble with the way they reverse the dates in Europe. But it doesn't matter. I can certainly live with it.

DR. CARPENTER: Okay. Thanks. Kim, did you have something else?

MS. RICE: No.

DR. CARPENTER: Do we then agree or do we need to revise that the original five -- the five levels that we've got from three in each axis is still appropriate even though it's giving us nine boxes? Do we want to go with four on each axis or five on each axis? Personally, I'm comfortable with three and three.

So we can all embrace the fact that there's nine levels now in a way, like Jenny said, with a letter and a number. Okay. Michael.

MR. KOWALCYK: This is Michael Kowalcyk. I would just want to make sure that we put in our recommendation that as a starting point, this seems to be a good place to start. Again, we don't know what the tool's going to give us. So -- and, you know, the Agency might want to manage it very, you know, very

specifically. You don't know what the data's going to tell you. So it's a starting point though. It's probably sufficient, high, medium, low for establishment, high, medium low for product, have a three by three matrix.

DR. CARPENTER: Okay.

MR. GOVRO: I just added one here on the pros at this, to digit or letter, digit with the three levels on each axis, not too complex. It was a thought of mine as well as someone else's, the complexity of going to too many levels. So I added that.

DR. CARPENTER: All right. So I mean we agree, looking at question one, we write looked at the issue of optimal levels. There's still the other part of that question about information, and I'd like to go back to what Bob said about 20 minutes ago, you know, when I go into a plant and there's all these things I look at, are they in total compliance with the SSOPs and do they have -- I mean could you generate a list of appropriate information, you know, give it to Robert and he'd wrap them up and -- oh, we can't turn

to my slide right there now. Do you know what I'm getting at, the information issue that's outlined here in question 1? That, that came to mind, the things you were saying Bob when you go into a plant and you know, those are kind of the issues that I thought were related to information that was referred to in this question 1.

MS. RICE: That's what I thought, too, and was told I was wrong. Because that's what's on the date wheel, the information that he was talking about, right? SSOPs and HACCP.

MR. McKEE: Primarily we're going to focus on the SSOP and the HACCP when we go in.

DR. CARPENTER: Okay. I guess I wasn't listening real well then. Go ahead, Bobby.

MR. PALESANO: Yeah, I just want to make a comment that when we had someone volunteer to take over the flipchart, I thought it was decided that we were going to go down the road to changing what the initial charge was on the first question, to help us determine what the appropriate optimal levels of inspection were. So the group decided that we were

going to change that question, and this is the work of this wonderful working group that we have, this Subcommittee.

DR. CARPENTER: Oh, yeah, as I look back at the slide, yeah, we did agree to that. Okay. Granularity, familiarity, manageability, training challenges.

MR. PALESANO: I just have one comment, and it will probably come into play as we, as we move forward with the other two questions, that for all intent and purposes, I do believe now that we have established that we have nine levels of inspection. Is that kind of true? Keeping in mind that we believe that, and we believe there is some differentiation between all nine of those levels, the next question I believe that we are to address, I think, if my senile memory will keep me on track, is what would be the inspection activity for a Level 1 establishment? That means that we will have eight more somewhere in the system to define. I just wanted for you all to keep that in mind as we move forward.

DR. CARPENTER: The way I look at it, Bobby,

going from 2 through 9, they may not be different but just additives perhaps, right?

MR. PALESANO: I didn't mean your charge was go to through all nine of those. What I mean is as an Agency, if we take this approach, someone in this room, that I know quite intimately, may have to go through that process of trying to come up with nine levels of inspection.

DR. CARPENTER: Don, do you have something to add?

MR. ANDERSON: I just wanted to -- I would rephrase -- I would suggest that we rephrase what Bobby said a little differently. I don't think that we've determined that we have nine levels of inspection. I think we have acknowledged that we have nine combinations of risk and risk control and what we're trying to figure out is given that, and give other types of information, how many different levels of inspection should we have? It could be less than nine. It could be more than nine.

DR. CARPENTER: Okay.

MR. SCHAD: Should we call that nine

categories instead of nine levels, if that helps out?

MR. GOVRO: Whatever you say.

DR. CARPENTER: Okay. Ann, did you have something to add?

MS. RASOR: I think that's what I was going to say, what Mark is saying, is the way we have it here, one is better than two, is better than three, like that, and if we have these nine, then it's not necessarily that one is better than, you know, seven is better than eight, but seven is different than eight. So that's a way to think about it a little differently I guess.

DR. CARPENTER: I think you're trying to wordsmith category, with whatever descriptive level or -- Kim.

MS. RICE: Well, I think in looking at question 2, if I understand question 2, which is up for debate, somebody said, and I don't remember who it was, that if, you know, with the two numbers, one would say, you look more towards product related issues, for example, inherent risk, you're up in that top row, that's supposedly the riskiest groups of

products. So if you're up in that top row, you know, the essential inspection activities should be related to -- something related to the product, and that's probably going to end up being CCP type stuff or system design stuff. If you're in the bottom or I guess the top row again -- excuse me -- if you were in the first column on risk or the last column on risk, if you're in the -- on the establishment risk where you're on that riskier end of the spectrum, then you're going to be -- you're going to want to focus on implementation type stuff, if you're in that, you know, your ability to implement whatever it is you've got going is probably in question --

DR. CARPENTER: Okay. Good point.

MS. RICE: -- and so you focus more on and, Bob, you may have been the one that said it, but you're going to focus more on one side of the coin rather than the other depending on what the -- was it you, Jenny?

MS. SCOTT: I believe Michael said that.

DR. CARPENTER: Michael, did you -- Michael -- I might be out of queue. Go ahead,

Michael.

MR. KOWALCYK: Yeah, I -- my fellow Committee members are going to love me for this but (laughter) but question one in the context of this dual -- this matrix with two numbers assigned to what cell you're in, 1/3, what does that mean, and what information should we use to support the optimal levels of inspection?

Optimization is a difficult thing to tackle. Optimal is the best, and that's a tough thing to come up with at this stage, but what information should we use, and I'm thinking back to work I've done in direct marketing, as a simplistic example, but if I have an algorithm that brings in data about a household, their spend with my company recently, what they bought, how many times they bought it. Okay. These are just simple factors that go into, their score is 10.

Now the information that you would use to -- then if I printed out that record of data about that household or about that plant, okay, this plant score is 10, and what does that mean. Well, that means they are in cell 3/2, which would be Level 4 inspection.

Now what information would we use to support optimal inspection. Well, if something -- the product inherent risk is high. Their establish risk control is in that variable range. Now what information from the data warehouse could we provide to the inspector so that they can make the optimal decision for that day or that week. Maybe that's what we should really be looking for is to say, you've got all this information and it could be -- there could be an outbreak in an area that this plant is shipping to. They could be a very good plant but the product is high risk. Ah ha. Do we need to do pathogen testing? Or something else because of the information we have. So it's almost like what information should we use. You have the data, take advantage of it. It's like leaving a, you know, I've got a power saw but I use my old hand saw that my dad gave me years ago. Well, that's dumb. I ought to use the power saw. So it's kind of the same thing. If you're armed with the data, and you're confident in that data, you use it so that you shouldn't -- the information that goes into creating that score be available because also if I was

an industry, if I was a producer, I would want to know. Why are you looking at me more intensely this month than you did last month? What's going on? You have evidence to show, well, you had three NRs last month or, you know, there's something else with your pathogen control testing that you've had these positives. So we've got these things more closely now. That can be a sticky issue but I mean to mean that would be the power of this tool is to say, you know, you have your procedures at a minimum but then what are the things you really focus on?

So maybe we should address that question of what information should we use to support optimal inspection? Well, you know what category the plant would be in at any given time and -- then you almost need -- you don't need just a score. You need the data behind the score. So I think we should recommend to the Agency that they have a means of communicating that information to the frontline.

DR. CARPENTER: And so what I think you're saying, Michael, is what Dr. Masters referred to earlier, we eliminating stovepipes of data, and it

will be in the warehouse and easily accessed by field personnel. So to implement what Michael said, it would be facilitated. That's what you're saying, right?

MR. KOWALCYK: Yes.

DR. CARPENTER: Okay. Good. Excellent. Mark.

MR. SCHAD: Yeah, I stand with you, Michael. I think it's a good idea and from a plant owner, I think that should be shared with the plant owner also. I think it would be frustrating for a plant owner, for the inspector to come in and say, well, you're in this category now or this level now, and I'm going to spend a lot more time here. As a plant owner, I would want to know why? You know, what happened or -- maybe I should know that already, maybe not, but I would want to know what data the inspector had, what data does the Agency have that put me there.

DR. CARPENTER: Okay. Now, you know, when NRs are in the hands -- I mean the data, but is there also associated CA that an inspector can get those data and find out if they implemented that?

MR. McKEE: That data is available daily to both inspection personnel and plant management. We have access to our laboratory information, through the -- system. We have NRs on file and they have access to PBIS database that they can go back and track trends through today. So if we get a plant that's flagged at a certain level, we would have an expectation that our people would go in and review the available data and utilize that as they go.

MR. GOVRO: I just wanted to ask, were you just adding that as a side note to question number 1 or -- has his comment just negated the need to write anything down with regard to what you said?

MR. KOWALCYK: Well, you know, I think we should consider in, you know, question one, the information that should be -- what information should be used to support optimizing inspection levels. It should be, you know, all relevant information that would be captured in this system, not just, okay, you're a Level 4, and your Level 4 becomes -- it's you're Level 4 because of this, and then the details of what's shared and how it's managed, you know,

that's another question but to me it would make sense that -- I'm just thinking if this is used as a management tool, you would want the inspectors to be aware of why I've got three plants to inspect today, and why plant C, my boss is asking me to spend three and a half hours at, okay, when I'm only spending an hour at the other two. Why is that? And what should I be looking for, because, you know, you don't just want to have an inspector there just for the sake of putting in more time, but that time should be more productive. So --

MR. McKEE: The large of majority the data that's going to drive those level of assignments is going to be generated at the location. So the inspector is going to be aware or at least have the ability to become aware in very short order of what the immediate history is. In fact, there's two years worth of history available there. So if a person is assigned to a Level 4/2 plant, we would have an expectation that they would go in and take a look at the history there, and that should inform them and bring them up to speed with things that are going on.

Certainly if you've got a plant that's traveling upscale, there's going to be a history that's available.

MR. KOWALCYK: Okay. Now is that, is that data at the plant itself?

MR. McKEE: That's correct.

MR. KOWALCYK: And is that PBIS?

MR. McKEE: Well, it would be hard copy. It would be NRs. They have the ability to access the PBIS data. They can getting into our -- system which tracks the pathogen sampling. So it's all readily available through the computers.

MR. KOWALCYK: So would it be necessary to have the -- the data that's housed in this, that would generate that classification of that plant, that would have to be synced up with what's at the plant or not necessarily so?

MR. McKEE: Well, we're going to input those systems that will make those determinations daily --

MR. KOWALCYK:

MR. McKEE: -- through synchronization of the computers and what not. Our people report

everything through the laptops. They synchronize at least once a day, and that's all going into the warehousing and stuff where it can be sorted.

MR. KOWALCYK: So it's --

MR. McKEE: It's real --

MR. GOVRO: I think I get your point in that we need to make this -- the determination transparent to the plant, and I've added the recommendation on the previous page that we make that information available to the plant owner. I'm sure it's probably all available there. At some point it's going to be melded into the algorithm that's going to create the category, and I think it's important that the plant be able to see that. So that again will be something for the Agency to work on.

So I would suggest that we maybe go to question 2, and I had a suggestion for perhaps changing this question as well a little bit. Since we've abandoned Levels 1 through 5, it seems to me the question you're asking there is what are the essential inspection activities for the lowest level. So should I put -- could I say base level inspection activities?

Will that be fine?

MR. TYNAN: I've been taking notes diligently. But did we abandon five levels?

MR. GOVRO: Yes.

MR. TYNAN: And we went to what?

MR. GOVRO: Well, we went to a two --

MR. TYNAN: Two tier.

MR. GOVRO: -- digit/letter system that ends up with nine categories.

MR. TYNAN: Okay. I see. I've got you.

MR. GOVRO: And I'm trying to convert question 2 so that it fits the system we've come up with.

Did you get most of that? He said we didn't -- to answer Robert's question, we -- yeah, we came up with a two digit or digit/letter system that ended up with nine categories. Now I'm trying to change question 2 so that's the system we're now on.

DR. CARPENTER: And the change would be to call it basic -- base level activities, base level inspection activities. Okay. Jenny, take the first crack at that. What do you want to put in here?

MS. SCOTT: Jenny Scott. First let me go back to the dual number system and tell you why I really don't like it. I spent half of the time that Mike was talking trying to figure out which box he was in when he talked about box 3/2, and it wasn't until he said certain things that it was, okay, he's in this box, not this box.

So just to get away from that, and back to something Kim said about the, you know, you're focusing more on the product when you're up here, and you're focusing more on the process down here, but -- and I know what she's getting at, but if you think about it, really the only place we can focus is on the process control because it's inherent risk. It's in the products you're producing, and you can't change that without changing the product. So really, we're coming back to what activities we're going to be doing, in these different boxes, whatever we call them, A through I, 1 through 9, letter number, double numbers, whatever, and starting out the low risk where you have consistent control, you're going to do certain things, and we can start out by describing it

in general terms, and Mark said -- gave us those initially but, you know, we would go in, we would look at HACCP critical control points and some SSOPs, and it's hard to get too far in depth on this because a lot of this is going to depend on the product and the process. We're not going to be taking any microbiological samples, I can guarantee, in a canning plant regardless of how well -- I mean pathogen testing samples in that plant, no matter what the control is. You might take some samples for the lab. So that one doesn't figure in. So we can't get into that kind of detail, but we could certainly talk in general terms about the types of verification activities that are most appropriate and what you would do more of certain activities in other plants, depending upon the level of control or the risk of the product.

DR. CARPENTER: So the very first step for inspection activity is to look at that plant, past performance in terms of the six spokes in the wheel, pathogens control, system design. Is that what I'm hearing? Bobby.

MR. PALESANO: Well, I guess I kind of would like to throw out just a little bit of a suggestion and maybe Mark can help us with this, and I think, you know, if Mark put himself in the base level as far as the inspection level is concerned, if he ends up in that low level, which is the desired level, because he has a low risk, low inherent risk and he also has great control, then he is at the base level.

I guess my thought would be, and the reason I'm saying this to Mark, and maybe the folks on my right can also play into this, what I would think that we would want to look at is we already know the risk of the product is fairly low, and we know they have good controls. So what is it that we really need to do when we go to that establishment because as Michael pointed out on more than one occasion, we're trying to use this as a management tool perhaps. So, you know, we don't want to use a lot of our resources in Mark's plant if, in fact, we don't have a lot of concerns. So what is it that we ought to do when we're there, right? And then so that we can actually put some management thoughts into our resource use, into some

of the other establishments in our charts.

DR. CARPENTER: Michael?

MR. KOWALCYK: Michael Kowalcyk. I have a comment that points back to question 1, but if we want to stay on this topic, that's fine. I'll hold it until later.

I think the comment I have was or question is that the process behind formulating that question for this Subcommittee, were you getting at this wheel diagram? Do you want guidance on what should be included in here? Is it a conclusion? Has a conclusion been made about what information is going to be used or is that still open for discussion because there are certain data elements that from a public health perspective I feel would be important to include in this. Dr. Goldman presented consumer complaint database. There is also public health data, the potential use of attribution data. Is that the essence of question 1? Are you looking for guidance with respect to that or is that going to come through this committee at another time or in some other form because I'm getting the sense that this is seen as

kind of a final product, and I hope it isn't. I hope it's still up for discussion.

DR. MASTERS: The --

DR. CARPENTER: Dr. Masters.

DR. MASTERS: Yes, this is Barb Masters. That document was handed out yesterday in response to question we were receiving. It is more applicable to the risk control document that Don Anderson presented at the workshop for RESOLVE. It's certainly appropriate to present comments to the Agency through our risk-based website in response to having it provided at the RESOLVE workshop. If we end early tomorrow and we have time, certainly we'd take them here, but it wasn't intended to be the driver behind this question.

MR. KOWALCYK: Okay.

DR. MASTERS: Just put it in front of this because recognizing these are all intimately tied together, but it became clear to me yesterday in our iterative Agenda, that we needed to give you enough information at that meeting so that you would have something to comment to. So we wanted to give you

something to work from.

MR. KOWALCYK: Okay.

DR. MASTERS: And it's not a done deal, it's not a finished document. I'll make that very clear.

DR. CARPENTER: Okay. Jenny, did you want to make a -- Jenny or Mark? Jenny first.

MS. SCOTT: Jenny Scott. Coming back to this question of the base level, and I was trying to put myself into an inspector's position going into a plant that has low level, low risk product, and it has a good level of control, and we want to make sure they stay there. So I would think that that inspector would have certain tasks that would be mandatory, you want to go in and you want to do some observation on the line, to see that people are following what they're supposed to be doing in the HACCP plan, and a review of records, probably centered around critical control points and maybe some clarification activities.

And then provide them with some flexibility to look at other areas of the operation because there are other regulatory requirements they have to meet

and certainly other things that are important as well, but the biggest focus would be on those areas that are critical to insure the safety of both -- of the product.

And so my suggestion is that for essential inspection activities at the base level, that there be some record review, some on site observation and focusing on critical control points in the plant.

DR. CARPENTER: Okay. Maybe I'm the one that's confused but base level to me means there's inspection activities that are going to be done always. No matter what level you go into, you've got to cover these bases. I mean do we agree? I mean it doesn't refer to five level, nine level, whatever, okay and then you just mention what they are. Okay. Is everyone -- is there consensus on that?

All right. Mark, go ahead.

MR. SCHAD: Well, maybe I don't need to add anything. I was just going to start off, you know, go with what you were saying, Bobby, and I think I've said it before, going in that the food safety system or the design has been, you know, determined to be a

good one, and I was talking about the CCPs being met every day, and SSOPs, are they being met?

And the other thing I didn't mention before is I think reviewing the pathogen records are being met because I think that's also proof that the food safety system is a good one and being implemented correctly. So that would be my input on what would be the base level of inspection activities.

DR. CARPENTER: So, Mark, are you saying two more items up here, pathogen review and SSOPs?

MR. SCHAD: Yeah. The review of the pathogen analysis, to review those records, whether it's, you know, from Agency samples and possibly the, you know, company or the plant might be doing its own sampling, and --

DR. CARPENTER: Great.

MR. SCHAD: -- I would think the plant, you know, would share that if they had it.

MR. GOVRO: So this is HACCP record review, on site observations related to CCP, laboratory review of laboratory results.

MR. SCHAD: Review of lab results, yes.

MR. GOVRO: Did you have one other? SSOPs.

MR. SCHAD: Yes, SSOPs. Maybe just say prerequisite programs.

MR. GOVRO: All right.

DR. CARPENTER: Don, please.

MR. ANDERSON: I just think that we maybe are going down the -- not the wrong path, but again a point of clarification. I think that we probably would agree that almost all of the tools that the Agency has at its disposal are appropriate to conduct at some frequency in a Level 1 plant. I don't think we're -- I mean I don't know. Are we saying that we would never sample a Level 1 plant or that we would never do a SSOP? I think that it's not what we do, it's what we do and how often we do it in different levels of inspection? Because that list you're putting up there, you're almost to an exhaustive list of the things that we can do in establishments. And to say that we should be doing all of those things in a Level 1 plant, does that mean every day or what does that mean?

MR. GOVRO: Well, my question, when I saw

question 2 was, could we possibly tell you anything about making an inspection that you don't already know and, and is that a question that might better be answered by the Agency and put out for discussion? I think it's going to be very difficult for this group of people, most of us not dealing with inspection on a regular -- on a daily basis, to provide you a list of things other than in general concept which we're doing.

DR. CARPENTER: So are you saying the Committee members could probably concur with the list you've got?

MR. GOVRO: Well, I guess maybe I'm asking, given the direction we're going with our answer, Bobby, could you clarify the question or steer us in another direction so that we could give you more useful information?

DR. MASTERS: This is Barb Masters. We had asked this Committee once before and tried to particularly get those such as Mark that work in a facility to answer. What are those things in your facility that you do each and every day that you feel

is essential to accomplishing public health activities, and tried to really hone down on those activities you believe if you left unaccomplished truly could lead to public health consequences. And that was somewhat what we were hoping to get out of this discussion.

DR. CARPENTER: Gladys, did you want to add something?

DR. BAYSE: Well, I guess it's sort of relevant to the other things you were saying, and we keep changing Bobby's questions and his words. The Level 1 inspection to me is bothersome because we've got 1/1, 1/2, a numeric system, and as Mike said, how can we possibly tell you anything from this group that you don't already know about inspection. And so I guess the issue really is do we expect any less in Mark Schad's establishment, and I don't know how we're supposed to handle that, you know, than we do ConAgra.

And I guess as Dr. Anderson said, you know, everyone needs to be at some interval inspected in every way because one might not stay a 1/1. So -- but anyone, Level 1, if will let us, might be another

term.

DR. CARPENTER: Okay. Committee members, Mark and Michael.

MR. SCHAD: I remember you asking the question, Barb. You asked me if there was one thing I had to do every day, what would I do? And really I told you two things, and I have a RTE [Ready-To-Eat] plant. I said I make sure the CCPs are met and sanitation.

DR. CARPENTER: Is a sanitation record something that an IIC [Inspector-In-Charge] would come in and look at or an inspector, sanitation records? Is that important or can you just see it by walking in?

MR. SCHAD: I guess you can see it by walking in.

DR. CARPENTER: Okay.

MR. SCHAD: The question was posed to me, what would you do, Mark? It wasn't like what would you have the inspector do? So that's the way I'm answering the question. If I did one thing every day, what would I do to insure the product was safe?

DR. CARPENTER: Okay. Michael.

MR. KOWALCYK: Yeah, I would just have to agree with Mike Govro about running a track to an exhaustive list, and I think one thing is the testing regimen that the Agency has, you wouldn't want to exclude Level 1 plants from that because they're a Level 1. You should get a look at across all spectrums of perceived risk levels. So, yeah, I mean it's a struggle here, and that's why earlier on I raised, you know, that that statutory requirement needs to be met. If that's on the table, then that's a whole other probably meeting and everything else. So I would have to agree with Mike. Maybe the Agency can provide some more guidance in what you're looking for.

MR. GOVRO: I'll let Felicia go first.

MS. NESTOR: This is Felicia Nestor. I just would hate to see the Agency limit itself to a review of a plant's CCPs because a plant can, plants do, and it has been recognized, plants do designate CCPs in order to limit Government inspections. So I think if the Government has information about something that

could be a problem which is not necessarily identified by the plant's HACCP plan, the inspector should have the authority to look further than the company's HACCP plan.

MR. PALESANO: I do have a thought or two and I want to go back to what Mark said. Mark said in his particular operation, there were two things that as a manager/owner/operator that he would not give us. In my opinion from an Agency perspective at least, Mark is not willing to give up those two items or those two situations because he would consider that if he did not do them, then he would have some questions about the safety of that product that was being produced.

Now that kind of ties in with what I feel like our verification activities might be in those particular operations, keeping in mind that I think that the in-plant inspection personnel should always have the flexibility to do -- to go above and beyond based on what they see on any given visit in that establishment.

DR. CARPENTER: Bob, please.

MR. McKEE: To tie in with what Bobby's talking about, generally we would expect our people to walk through the plant on each visit, regardless of how much or how little they're scheduled to do, and during that walkthrough, if there are issues that come up that demand attention, our expectation is that they will address those issues. So we won't ever I don't believe abandon that. That's kind of key and central to our being there.

It really kind of boils back to intensity. Don said it right. We've got procedure codes to address everything. I think it's a matter of frequency how often are we going to do them, and as you travel through the levels, I guess at the local level we need to make those determinations.

DR. CARPENTER: Okay. Felicia.

MS. NESTOR: They're doing away with the Procedure Codes as far as I know. So we'd have to -- aren't we trying to devise a system of guidance now that's sequential? I mean we're not using O1BO1 as far as I know anymore.

DR. CARPENTER: Bob.

MR. McKEE: I think we're only going to turn off the scheduler. We will still report our work under specific procedure codes.

MS. NESTOR: Oh, is that right?

MR. McKEE: That's my understanding.

DR. CARPENTER: Andrea.

DR. GRONDAHL: In an attempt to kind of summarize what everyone saying in answer to question 2, I would suggest that there's three inspection activities, CCP verification, sanitation verification, pathogen reduction verification. From what I've heard and what I see in our plants, those are the three basic inspection activities that need to be performed at Level 1 inspection.

MR. GOVRO: Is that captured in any of these four things that I've listed here or does it need to be put down separately? Maybe I should ask what you mean by -- what does pathogen reduction activities entail?

DR. GRONDAHL: I guess it would entail both verifying any lab results the plant is doing as well as Agency testing.

MR. GOVRO: Okay. So I started the first two that Mark mentioned, CCP verification and prerequisite programs which I use as a term for sanitation verification, that sanitation has been done. Should I also include this as a start or would you rather have it written down differently?

DR. GRONDAHL: I guess in my mind as far as inspection activities, you know, just to use those key words, CCP verification, sanitation verification, pathogen reduction verification. It's just a suggestion to narrow it down to three things. In my mind, that answers the question.

DR. CARPENTER: Andrea, are you saying that pathogen reduction verification is different than review of lab results?

DR. GRONDAHL: No, I'm just saying that's part of pathogen reduction. Review of lab results would be reviewing the testing that the plant is doing but it doesn't include the testing that the Agency would be doing. So I just used that term to include both review of lab results and Agency testing.

DR. CARPENTER: Okay.

MR. GOVRO: What was the term you used for the third one?

DR. GRONDAHL: Sanitation verification.

DR. CARPENTER: CCP verification, pathogen reduction verification, sanitation verification. Okay. Jenny, please.

MS. SCOTT: Jenny Scott. Given how Andrea described the pathogen reduction verification, I think we need to say where appropriate because not all establishments produce products where there would be any kind of microbiological testing. Canned foods is an example. I certainly wouldn't waste any time testing lard or things like that. There's quite a number of products that may not have that component. They will all have HACCP, CCP and SSOP or sanitation verification.

DR. CARPENTER: Add, where appropriate. Okay. Felicia.

MS. NESTOR: Felicia Nestor. I think we should explicitly say sanitation including pre-op. I don't think any plant should be, you know, let off of having pre-op occasionally, you know.

DR. CARPENTER: Explain that.

MS. NESTOR: Pre-op sanitation. There's operational sanitation and pre-operational sanitation and it's important that the plant periodically cleans top to bottom so you don't have residue from yesterday's product going into today's product.

DR. CARPENTER: So pre-op is going to be every day then.

MS. NESTOR: Well, they don't do it every day now. Pre-op inspectors do pre-op maybe twice a week now as far as I know. They used to do it every day. Now they only do it twice a week as far as I know.

DR. CARPENTER: Can you ding them on that, Bob? Can you ding a plant when they don't have -- get rid of all of today's stuff to start clean the next morning?

MR. McKEE: Well, certainly we perform procedures to verify the effectiveness of their sanitation systems, and when we find that they haven't been successful, we take appropriate action.

DR. CARPENTER: Got you. Ann.

MS. RASOR: First just to clarify, the plants do pre-op everyday. The inspectors aren't there to see their pre-op every day.

DR. CARPENTER: So it's a moot point. It's a moot point, right, Felicia?

MS. NESTOR: No.

DR. CARPENTER: No.

MS. NESTOR: No --

DR. CARPENTER: I apologize. Right. Okay.

MS. RASOR: I just wanted to say that when we first started talking about this, I was thinking about it, and when Bobby asked the question and you answered, it still made me think about it in that way, is what are the essential activities that they're performing on a daily basis? I assume that all the verification activities are going to be done on some basis but on a daily basis, the CCP and the sanitation are the two that need to get done, and then everything else, the pre-op and the lab reviews and all that, that's going to get done at some point, at some frequency, but it's not the two most important things that need to happen every day.

So I don't know if daily is part of that or not but maybe we should discuss that.

MR. GOVRO: It seems, since Felicia brought up the point, that they should have a periodic pre-op inspection, I think it would make sense to perhaps build in some level of periodic activities where there's weekly or monthly or whatever, that you wouldn't necessarily include. I mean you would -- as you said, you would want a plant to sometimes get a pre-op and basically this is a system where we're formalizing the assignment of work. So let's include that. That's my opinion.

DR. CARPENTER: Michael.

MR. KOWALCYK: Yeah, I think, just to follow up on that, I think in our answer back to the full Committee we should delineate between daily and then the periodic. I think that makes sense.

DR. CARPENTER: Okay. So it's the consensus of the Committee, that we should go with that. Okay. Ann, did you have something else?

MS. RASOR: No.

DR. CARPENTER: Okay. Question 3, have we

touched that in any way, shape or form? What other inspection activities do you consider appropriate to perform an RBI and we've eliminated the words above Level 1, right, Bobby? What other inspection activities do you consider appropriate to perform a RBI? You know, Mark, they're going to use your plant for a guinea pig. You know it's coming, huh?

(Laughter.)

DR. CARPENTER: Jenny, go ahead please.

MS. SCOTT: Jenny Scott. Well, we listed that CCP verification as a basic activity. Is that correct?

DR. CARPENTER: Yes.

MS. SCOTT: We've specifically written in CCP verification in there --

MR. GOVRO: Yeah, we did. CCP verification, pathogen reduction verification where appropriate and sanitation verification, including period pre-op.

MS. SCOTT: Other HACCP related activities would -- the plant does verification which includes calibration, direct observations of monitoring and corrective actions as well as record reviews. So the

inspector would want to verify that those verification activities were occurring.

DR. CARPENTER: Do you want Jenny to repeat those, Michael?

MR. GOVRO: I believe so.

MS. SCOTT: It's verification of plant's verification activities is the shortcut.

DR. CARPENTER: Verification of plant's verification activities. Do you have another one, Jenny? That's one, right?

MS. SCOTT: No, that --

DR. CARPENTER: That's it. Okay.

MS. SCOTT: That covers multiple activities there. If anyone asks you, it relates to their calibration activities, their direct observations, and their records review.

MR. GOVRO: He's taking much more thorough notes than I am.

MS. SCOTT: Do you want it again? It's their calibration activities, their direct observation activities and their records review activities. Those are just three examples. There may be other

verification activities as well, but those are three required ones.

DR. CARPENTER: What's the third on Robert says?

MS. SCOTT: The first one is calibration, the second one is direct observation of monitoring activities, and the third is records review.

DR. CARPENTER: Records review. Got it? Andrea, it's getting more into her program. Go ahead.

DR. GRONDAHL: I was just going to say I think we could come up with a really long list of inspection activities that are ready and within the PBIS inspection procedures, and so I don't know, maybe a way to answer the question would be a simply all current inspection activities.

DR. CARPENTER: All current that are well known by inspectors and that are part of PBIS now.

DR. GRONDAHL: Right.

DR. CARPENTER: Okay. Does everyone concur with that? Bobby?

MR. PALESANO: I would just like to throw something out to the group to consider because what I

hear you all saying, even though you may not realize what you have done (laughter) is that you have, in fact, separated some of our verification activities from our current procedure codes. So presently, today, when our inspectors do a HACCP procedure, verification procedure, they would look at certain regulatory requirements. One of them would be verification and the other one might be monitoring, et cetera.

So I guess my question to you all is are you recommending, when you separate out verification, of the establishment's verification activities, are you suggesting that now we separate out, or we change the methodology that is present described in some of our Agency issuances? That's only a question to the group. It's not a suggestion.

MR. McKEE: Let me build in that a little bit before we try to answer. Every plant has a list of procedures that is to be followed in that plant that are relative to what goes on in there, whether it's net weights, labeling concerns. So there's a whole inventory of procedures that are already in the

computer for that plan to undergo, and again, I hate to keep repeating myself, but in my mind, I just see this more as a matter of frequency than procedures. Questions 2 and 3 in my mind run together because the procedures that should be performed at any point are already listed. So, you know, I don't want to short circuit the process here.

MR. PALESANO: I don't think you're short circuiting the process, and I think I said this during my presentation, and I would like to reiterate it if I overlooked saying it, if we are going to look at designing a truly risk-based inspection system, I think we need to examine are we doing the right things to give us the data that we need to use Michael's works to manage our resources effectively. So, if in fact, in some of our examples, you know, we say CCP verification, if we're going to do that as we presently do that because we believe that is the right thing to do, then we can move forward with that and play with the frequency as to how frequently we would do that versus how frequently we would do something else, you know, and make that work.

I just want to be sure that everyone understands that we are asking you openly to provide input as to whether what we are presently doing fits into the risk based environment correctly.

DR. CARPENTER: So we modified that statement to say as applicable within current provisions and guidelines. Is that something --

MR. PALESANO: I'm very sorry I created confusion. I just wanted you to know that if we continue to do HACCP verification procedures, we would be doing verification of the establishment's verification at some frequency when we perform those procedures and if I confused the issue, I apologize.

MR. GOVRO: At a Level 1. So what you're saying is it's not currently considered something that's optional, that would be optional in a Level 1/1 plant. And you're not suggesting that we change it. You're just making us aware that we have separated it and --

MR. PALESANO: I'm only creating confusion because I was not sure that you understood how we presently do inspection procedures. I wanted you to

know that our inspectors have been trained to verify all regulatory requirements using the existing procedures that we have.

MR. GOVRO: And speaking for myself, I wasn't aware of that we had differentiated.

DR. CARPENTER: Who's next here? Mark.

MR. SCHAD: I guess I'll start out with a question. Bobby, you used the term methodology. Did you mean frequency when you were asking the question?

DR. CARPENTER: Bobby, do you want to answer it?

MR. PALESANO: I'd be happy to attempt. I guess what I'm suggesting is that presently when we do a HACCP procedure code, we have trained our inspection personnel to randomly select one or more of the regulatory requirements which are monitoring verification blah, blah, blah. Okay. They will verify whether or not the establishment is meeting those regulatory requirements that they selected. Methodology to me might mean there are specific things within the establishment rather than verifying a monitoring requirement. We may decide that now there

are some other things that we believe are more important to look at. So we might need to change how a procedure is done, and it may not even be called a procedure, and I'm not -- again, I'm not suggesting that we do that. I'm just letting you know that we're here seeking input for a system that gives us the best results for designing a risk based inspection system.

DR. CARPENTER: Are you okay with that, Mark? Michael.

MR. KOWALCYK: I think I'm seeing where you're going with this, where right now currently they're randomly selecting what they want to verify based on information and this is probably why it's useful looking at where that plant is in the vertical and horizontal axis because that should guide -- take the randomness out of it and say this plant is in this cell because of these factors. So you verify this. Maybe still randomly verify something else, but again rather than spinning your wheels testing something that really isn't the cause of that plant being in that risk level. So is that what you're looking for?

DR. CARPENTER: Bobby.

MR. PALESANO: Keep in mind, I'm not trying to design the system. I'm seeking input, but I think at least what I thought we might get is some suggestions similar to that where there is a reason why we would look at something, and that does not prevent inspection personnel from looking elsewhere as well.

DR. CARPENTER: Okay. Michael.

MR. GOVRO: Then would it be appropriate for me to mark down here to link the frequency and methodology of inspection activities to the reason why they've attained a certain risk category?

MR. KOWALCYK: Yeah, it should be -- I guess it would be relative to the risk level with respect to product and the establishment. It would have to account for both if it's just a two dimensional.

DR. CARPENTER: Michael's going to wordsmith that please.

MS. NESTOR: Felicia Nestor. I think as Bobby was saying, they instruct inspectors to randomly do certain tasks but they -- but the inspectors do not record what specific tasks they do or what specific

CCPs they verify. It's my understanding that the plant could have -- let's say they have three CCPs. The inspector goes in, he can check one CCP. He doesn't make a note to himself or to the night inspector or to anybody else, I checked CCP 1. He just makes a note, I checked CCP.

So I mean in order to insure coverage of all the important aspects, I think the inspectors should use their computer and make little notes like that.

DR. CARPENTER: To assure comprehensive monitoring --

MS. NESTOR: Exactly. To make sure everything's getting covered. You know, because if some CCP is in the back of the plant or at some inconvenient location, you know, you don't want the inspectors going to the easiest one all the time.

DR. CARPENTER: So Michael's writing, should link intensity and frequency of inspection activities to reason firm is in a particular risk category. Basically assuring that all critical elements are evaluated each month or each week or --

MR. GOVRO: Can you summarize it?

MS. NESTOR: The inspectors should record the particular things that they monitor in a plant. They shouldn't just record I monitored sanitation. They should say I monitored sanitation at X spot or I monitored CCP 1 as opposed to I monitored a CCP.

DR. MASTERS: They should be more explicit in their documentation of their requirements in the HACCP O1 procedure.

MR. GOVRO: -- procedure verified or --

DR. MASTERS: The regulatory requirement verified as well as the CCP verified on a HACCP O1 procedure.

MS. NESTOR: Maybe they should do that with sanitation, too. Maybe not just with HACCP O1. And so what would it be in sanitation?

DR. CARPENTER: Bobby.

MR. PALESANO: This is Bobby. I think they could probably do that, if that is a suggestion and a consensus of the Subcommittee, by using some method of recording what regulatory requirements they verified. You know, presently they only record a procedure as being performed if, in fact, it is incompliant. So

what you're suggesting I believe is a record to show what they verified when it is in compliance. That could be done similarly I believe.

MR. GOVRO: Do I need to expand on this? I'm not sure I'm --

MR. PALESANO: You might just put HACCP/SSOP or sanitation requirements, so we have them both covered.

MR. GOVRO: SSOP requirements.

MR. PALESANO: Yeah, just put /SPS and you'll have all of them.

DR. CARPENTER: Mark, go ahead. I'm sorry.

MR. SCHAD: I keep on running through my mind that this is HACCP and it's industry's responsibility to prove safe product, and so I'm going to pick up Bobby's term, methodology. So say a plant comes up with -- has been doing well but comes up with this positive pathogen on the sample, and so maybe some of the methodology of an inspection would be like, okay, the inspector goes to the plant owner and says, well, we've got this positive on this sample, and sometimes the plant owner might say, okay, well,

this is -- I've investigated it, and I found something happened here in the process and I've corrected it. So that would be one method of looking at it.

Say he went to a plant owner, another plant owner had the same situation but the plant owner says, well, you know, I don't know what happened, and I'm going to get to it next week. Well, I think that guy needs -- the inspector might want to spend some time with that plant owner and operator.

So maybe -- I'm trying to think how to put this in a concise way, but that's when I start thinking in terms of what type of different inspection activities might be going on in a plant that was not a Level 1 plant.

MR. PALESANO: Yeah, I think what you're getting at a little bit is how an establishment might react to a positive result, whether or not they met the regulatory -- the corrective action regulatory requirements or not. Obviously you indicated you are an RTE facility and if, in fact, the Agency got a positive result, you know, we might do some testing in conjunction with a FSA as well. You know, those are

additional activities that will be factored in obviously when -- on an as needed basis, and our sampling direction that we're taking now it trying to go with risk-based sampling anyway. So we kind of have not factored sampling in only from the standpoint that we're already building in a risk-based sampling system. So obviously that is a very important point that you're bringing up.

MR. GOVRO: Shall I add sampling to the list?

DR. CARPENTER: Mike, you've had additional time to formulate this into words that go right up on here, other activities?

MR. GOVRO: Just a clarification for my own edification. Does this item here that we've listed, document regulatory requirements, verified SSOP/SPS, does that fall under this heading of something to do in addition above base level or does it belong in all inspections?

MR. PALESANO: I think what Felicia is suggesting is that we put in a system of some sort to capture the inspector would be documenting what

regulatory requirement they verified even when it is in compliance so that another inspection personnel that came in would have that information and know what they looked at and what the status of it was when they verified it.

MR. GOVRO: I understand that, but I've written this down under the category of other inspection activities that would take place above Level 1.

MS. NESTOR: No, it should go everywhere. Level 1, too.

MR. GOVRO: Okay.

MR. PALESANO: That would be --

MR. GOVRO: I'll put it off of this page and put it somewhere else. Okay.

DR. CARPENTER: It stays there or moves to another page?

MR. GOVRO: It really --

DR. CARPENTER: Okay. I mean, Mark, did you have a concise thought that you wanted to put up here regarding an inspector comes in the plant, ought to be spending more time with this guy. I mean do you know

how to say that? I know what you're saying --

MR. SCHAD: --

DR. CARPENTER: Hit the button. Oh, you're not ready yet. Okay. We can go over here to Jenny. Okay, Jenny, go ahead.

MS. SCOTT: Jenny Scott. In thinking about this, it seems to me that you're going to be doing a lot of the same types of activities at the base level, but you'll be doing more of them. You're going to look at more of the records. If there are multiple products, you will look at more of the critical control plans for more products. For example, the Level 1 plant may have five different products, but you may feel they have enough control that on one visit you'll look at one product and another visit you'll look at another product and rotate through there whereas at a Level 5 plant, you may go in and look at every one of those products. So more of what you would do at a base level. The higher up you go in this -- in terms of risk product, in terms of loss or limited control.

DR. CARPENTER: So the inspection

activities, what you want to capture is the intensity of the inspection activity should be commensurate with the volume of the plant and/or product inherent risk. Can someone else say that differently?

MS. SCOTT: It should be --

DR. CARPENTER: Have you got your button out? Yeah. Go ahead.

MS. SCOTT: -- based on the lower the establishment risk control, and I'm not talking about numbers, I'm -- the less in control the establishment is, the more frequent the --

DR. CARPENTER: More extensive.

MS. SCOTT: -- more extensive, more intensive, whatever term you want to use, there will be more of them with lower control.

DR. CARPENTER: How should we -- Don, do you have some input on this?

MR. ANDERSON: Yeah, I think I can maybe help clarify. Don Anderson. We've got either two dimensions -- we've either got two axes or three axes. If production volume is part of inherent risk as originally shown here, then you have two dimensions.

If instead volume breaks out to be a third dimension, the Z axis so to speak, then you've got three dimensions, but perhaps what you're saying is that the intensity of inspection should increase, not necessarily proportionally, but should increases with greater inherent risk, that the intensity of inspection should decrease with the effectiveness of the risk control and should increase, again maybe not proportionally, but should increase with the production volume of the establishment. Those are the relationships I think I hear people saying.

DR. CARPENTER: So Michael wrote what you said succinctly as link inspection intensity to degree of control exercised by plant.

MR. ANDERSON: That is one of the three factors. There is two others. There is volume and there is inherent risk. I'm having a little trouble reading what's up there. My eyes aren't that good.

MR. GOVRO: What I got from Jenny was that she was specifically interested in focusing on the controls as opposed to inherent risks which are related to volume and product. Am I correct on that?

MR. ANDERSON: Well, it depends again. By one definition of inherent risk, inherent risk is -- includes volume, but if there is this third axis, then inherent risk is not related to volume. If inherent risk is just product process, then that's one definition. If inherent risk includes volume, then that's another definition.

MR. GOVRO: Okay. What I'm specifically trying to get at, I think Jenny made a point earlier that she was really more concerned about controls than those which were related to other factors. So -- but I can certainly put them down. Also consider volume and inherent risk.

MR. ANDERSON: Well, those are the three factors or the three dimensions in that three dimensional world, talking about volume, inherent product process risk and risk control.

MR. GOVRO: I've been putting words in your mouth, Jenny. Do you want to speak up?

MS. SCOTT: No, I think that Don is right, that if you envision this three dimensional surface as you go up in risk, as you go up in lack of control, as

you go up in volume, there's an increase in your inspection intensity, and as Don says, it's not necessarily proportional. I think a lot of it comes back to exactly why that plant is where it is on that, what data as Michael talked about, back when we started a long time ago, that you need some information about why the plant is at the position they are in, and use that to factor in what you're going to be doing.

DR. CARPENTER: So it's been captured with link inspection intensity to degree of control, exercised by plant, volume, inherent risk, not necessarily proportional. Don. Jenny. Okay.

MR. GOVRO: I'm just the flipchart keeper. So Robert's surely getting the notes here.

DR. CARPENTER: Felicia, were you next or Michael? Go ahead, Felicia.

MS. NESTOR: Felicia Nestor. I think some plants, especially those that are the ones over to the very non-compliant side, I think they need an inspector there sometimes just to hang out and watch production. I mean if you have a very small plant,

the inspector can go in and verify that they've done all of their CCPs in no time flat, but I think that, you know, you may need the inspector to stay there and watch how they're producing because you can have -- and I read NRs where, you know, product is piling up on the floor and people are, you know, picking it up and they're stepping on it with their boots and climbing up on the conveyor belt to get something, you know. I mean sometimes they just have to be watched how they produce.

DR. CARPENTER: Okay. Michael, Mark, Bobby, who's next? Michael. Okay. Please, thanks.

MR. KOWALCYK: I would be in agreement with linking the intensity to the degree of control exercised, volume, inherent risk, and you don't know how -- what's going to have more weight. I think we also need to look at targeted based on what weight those elements draw. So I think we get to it earlier on in our discussion about it's not random anymore. It's verify something that's relative to why that plant is scored as a higher risk plant for whatever reason. So maybe it's linking intensity but also

direction of that additional inspection as well. So maybe we want to add something in there as far as targeting those inspection efforts. Maybe we need to be more specific.

MR. PALESANO: By modifying what?

MR. KOWALCYK: Or do we already have that?

MR. GOVRO: I've got this down.

MR. KOWALCYK: Yeah, I think that gets to the essence of what I -- the point I'm trying to make is that you can increase intensity but if you're looking -- if you just inspect more than one area of the plant, where that's really not the problem, you're not doing the right thing. So it should be relative to the reasons why.

MR. TYNAN: Robert, the recorder. Could I make a suggestion? I've taken an awful lot of notes. Would it be helpful to print them out, get a couple of copies and then look and see where you are? Because you have you have just about an hour left. So that would give you enough time to mull it over and maybe make a few more comments and be done for the day. And you could reconvene in the morning to discuss it

further if you want, but --

DR. CARPENTER: Unless somebody has a real point they'd like to make. Mark, do you want to say something? Bobby or not? Mark and Bobby.

MR. SCHAD: I was just looking at on the next page there. I was just looking at that statement there. It seemed like a broad statement. I was just wondering where we were at on that, you know, link inspection intensity to degree of control, you know. What are we saying that's not new?

MR. GOVRO: This is --

MR. SCHAD: Yeah, okay. All right.

MR. PALESANO: And my comment was on that same -- Bobby -- statement because I thought I had heard Jenny say that many of the verification activities that were going to be performed would be repetitive in some of the higher inspection level facilities. So, you know, depending on the process category, and I was wondering if, in fact, what was put on the flipchart actually captured what Jenny was saying because somehow I got lost in what went up on the flowchart, and I was just trying to understand if,

in fact, that was captured correctly to get her comment.

DR. CARPENTER: Jenny.

MS. SCOTT: Jenny Scott. So this is that link inspection intensity --

MR. GOVRO: Link inspection to the degree of control exercised by plant -- volume and inherent risk, not necessarily proportionally, and so I don't know if this watered down the statement you were trying to make or I didn't fully capture what you were trying to -- the point you were trying to make?

MS. SCOTT: Or does it come back to what do we mean by intensity. I mean to me what I was trying to reflect is that we're doing similar types of activities. We're just doing more of them, and --

MR. GOVRO: And frankly I chose to leave that just intensity --

MS. SCOTT: Right.

MR. GOVRO: -- to cover frequency, depth of, you know, depth of the look you give it. It's sort of a catchall word --

MS. SCOTT: Yeah.

MR. GOVRO: -- but if you want to use some other word in place of that, I'd be --

MS. SCOTT: I would certainly say frequency and you might spend more time analyzing what's there than. So I don't have any objection to intensity.

DR. CARPENTER: But should we -- I mean after the word intensity, should we add something like frequency parenthetically, frequency and time?

MS. SCOTT: Yeah. Yeah. Did you hear me say something different, Bobby?

MR. PALESANO: I really again was not trying to create confusion. I thought I heard you say something different than what was put up, and I wanted to be sure that what was put up there captures your comment because I thought we were talking about, you know, doing HACCP verification, sanitation verification and as we went from one level of inspection to another, you indicated based on the process categories, et cetera, we would be doing similar type activities more frequently, and I somehow got some language in there that I didn't understand where it came from.

DR. CARPENTER: Are you okay, Jenny? Or no, go ahead. Clarify.

MS. SCOTT: So inspection intensity, instead of saying HACCP verification activities but I guess maybe that's what we're talking about here. We might be a little more clear about when we say inspection intensity.

DR. CARPENTER: Well, what Michael has modified intensity to say is frequency in time.

MS. SCOTT: And we're not capturing that it's HACCP and SSOP types of verification activities. So we might have to --

MR. PALESANO: I'm okay if you're okay.

MS. SCOTT: I'm okay.

DR. CARPENTER: You're okay with that, Bobby. Consensus? Have we -- okay. We have one, two, three. The answer's two. We'll look at them. One more comment that Robert should catch before he prints out. Okay. Felicia's got another --

MS. NESTOR: Well, I just want to make sure that my previous comment got in there because it didn't get up on the -- where I'm saying that -- no,

not pre-op. That sometimes depending on the level of compliance in the plant, that the inspectors have to be there just to watch production, and that's not a HACCP verification activity. So it's a different type of inspection activity. So it doesn't get caught when you say inspection intensity because -- as I understand it, we mean by inspection intensity, we mean inspection intensity of HACCP and SSOP verification activities as opposed to just monitoring production.

MR. PALESANO: I think I might try to rephrase that a little bit in a couple of words or a phrase. I think what she is suggesting is, it is necessary for inspection presence to be there.

DR. CARPENTER: So we should modify that statement to capture that?

MS. NESTOR: No, add.

DR. CARPENTER: Excuse me.

MS. NESTOR: Add.

DR. CARPENTER: Add. It's necessary for inspection presence. What else did you say, Bobby? Necessary to be there. Presence kind of says that.

MS. NESTOR: It means something though in terms of FSIS terminology. I mean --

DR. MASTERS: The --

MS. NESTOR: And not necessarily specific activities but just to be there, to monitor. To baby-sit.

DR. CARPENTER: Wait a minute. He's getting frustrated because you're not using the microphone. You're talking --

DR. MASTERS: The inspection process is in the more variable plants on the right side of the chart and inspection presence, as FSIS lingo, the inspection presence is based on their knowledge and ability of the plant environment and they then have the flexibility not tied in to do these specific activities but they're there, providing oversight and based on what they observe at the time, then they make their own inherent decisions on what inspection activities to do. So there really is that flexibility and latitude to do what they need based on what Felicia was talking about earlier. We can't take away the inspector's ability to do what they see needs to

be done at the time, and an inspector's presence gives them that ability to do that.

DR. CARPENTER: So due to plant variability, inspection presence is necessary when appropriate.

DR. MASTERS: Right. We're focusing primarily on the more variable plants and the more variable plants, we would look at a higher inspector presence.

DR. CARPENTER: Plants exercise more variable control should be subjected to increased inspection presence. That's what's going up on the board, gang. Are we okay? Don, are you fanning yourself or --

MR. ANDERSON: This is maybe almost philosophical but I would like to think that rather than saying that we want to put -- that we want more presence in a plant, I would say that we would want them doing more inspection activity in a plant which would naturally mean that they would have a greater inspection in the plant. I don't think we want to be in the business -- I really don't like the word babysitting. We're not babysitting the establishments

it seems to me. We are performing inspection activities, and if we have a lot of inspection activities to perform in a plant, we will have to spend quite a bit more time there I suppose.

MS. NESTOR: But you may not have a lot of inspection activity, and the inspector may feel like he needs to stay there past the point of doing the verifications. I mean he could get through with the verifications in short order, but he happens to know that this plant, you know, when he leaves the plant, runs up their line speed and the product piles up on the floor.

DR. CARPENTER: Don, do you want to rebuttal quickly?

MR. ANDERSON: Don Anderson. I think if that's been -- I would hope that we would see more NRs written in that establishment. I would not like to think that happens but --

MS. NESTOR: I would think you would get more NRs written in the plant if the inspector was there to see it, but if he's not there to see it, he can't write it.

DR. CARPENTER: Mark.

MR. SCHAD: Well, I'm -- I don't use the FSIS lingo every day but I think I see what Don is saying. I agree more with Don. I mean presence to me like he's in the front door. That's what presence means to me and I would think -- I understand Don's point. You want the inspector to be performing some type of activities other than just maybe in the front door.

DR. CARPENTER: Bob McKee.

MR. McKEE: I just want to make sure that everybody understands that we do unscheduled activities. The purpose of inspector presence, and I'm just trying to shorten what Felicia was saying, she was saying that sometimes those establishments need FSIS oversight and so if they are there, they would not be standing inside the front door. They would be doing some kind of inspection activity, whether there was anything specifically assigned for them to do or not. If they are there, they will be doing some verification.

DR. CARPENTER: So before we go onto the

next -- I mean are we all done adding to question 3. I mean does anybody else want to make any additions? Bob, you clarified it. Is there consensus? Robert wants to print this out. So is Robert ready to hit print? Ann, did you want to add to this?

MS. RAZOR: No.

DR. CARPENTER: Okay. Mark, you're still -- you're good. Okay. Felicia and Jenny.

MS. NESTOR: I'm good.

DR. CARPENTER: You're good. Okay. We're going to get a printout of all of our deliberations to consider. Tonight, what is the consensus of the group? Committee members, we get the printout from Robert, look at it now or look at it tomorrow morning? And then hack through it because Robert's going to make me stand up here and give your thoughts tomorrow morning. So I want to make sure there is thorough consensus.

UNIDENTIFIED SPEAKER: --

DR. CARPENTER: Really, and one of them's not me? Andrea, that's right. She said she wanted to finish off.

DR. BAYSE: How many pages is it going to be?

DR. CARPENTER: How many pages, sir?

MR. TYNAN: It looks like four.

DR. CARPENTER: Dr. Bayse, it looks like four.

MR. GOVRO: I just wanted to get to Felicia's last point because I sense that maybe there wasn't a consensus on the need for inspection personnel to just be there to simply watch the plant work, to prevent them from doing something that they might do if you weren't there. Am I correct on that? And that the focus would be on inspection activities, assigning more inspection activities, and I got from you that that wasn't exactly what you wanted to say.

MS. NESTOR: Well, Jenny explained to me that there's actually -- that is actually an inspection activity.

MR. GOVRO: Okay. So we're trying to get this sentence to read -- it's necessary for inspection presence to be there for simply monitoring, and I don't think that's -- monitoring and making decisions

on activities to be performed by inspectors using their knowledge and skills.

MS. NESTOR: They also said increased oversight. How about increased oversight?

MR. GOVRO: That would be a good catchall.

UNIDENTIFIED SPEAKER: The --

DR. CARPENTER: Okay. Felicia, we're going to reread the sentence. It's necessary for inspection presence to be there for increased oversight and to perform unscheduled inspection activities. This is more critical in plants with variable controls. Okay. All right. Don.

MR. ANDERSON: I'm sorry. I wanted to -- it was my understanding that eventually under RBI there will be no such thing as a scheduled activity. So I would assume there would be no such thing as an unscheduled activity. What would that mean?

DR. CARPENTER: Yes.

MR. PALESANO: Well, you're right, Don. There won't be any scheduled procedures if we turn the scheduler off. What I heard from this group, however, is that they are suggesting, I believe, that we

continue with present inspection verification procedures. So what I thought we were putting up there is with the increased oversight time, we would be doing extra unscheduled verification activities.

DR. CARPENTER: So what I think you said is extra previously unscheduled inspection -- no.

I think we can tell our recorder, you're officially -- you captured everything.

(Whereupon, at 5:22 p.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

SUBCOMMITTEE NUMBER 1

USING RISK TO DIRECT IN-PLANT PROCESSING

AND OFF-LINE SLAUGHTER INSPECTION ACTIVITIES

Washington, D.C.

October 12, 2006

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

_____

TIMOTHY BOND, Reporter

FREE STATE REPORTING, INC.