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Q & A

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DR. TEUTSCH: Are you happy to entertain questions?

DR. MAY: Sure.

MS. ASPINALL: First of all, a very impressive presentation. It was great to give us the history to get to where you are going now. How do you implement new standards? In brief, how does that process work? How do you get the communication and the time frame to do that?

DR. MAY: Right now we are developing a strategic plan. We are putting together the strategic plan. We have catalogued a number of workshops, conferences, and visits to stakeholder communities. We have captured conversations that we have had when we had official visits from stakeholder communities to NIST to try to develop some sort of coherent plan for NIST.

What we have done in the past is that individual divisions within NIST would conduct their own needs assessment. Lots of the standards that we have now were developed because of input most often from the American Association for Clinical Chemistry. So we would have workshops at AACC meetings often and try to interact with stakeholders and say, what are your top priorities. If you could give us priorities, what would the top five be, for example.

Basically, to answer your question very quickly, we get input from lots of sources. We distill that, try to look at the highest priorities, and then match that with the capabilities that we have. If there is something that is a high priority but we don't have the skill set to address that problem within the next two or three years, then we tend not to address that because it wouldn't do us any good to have an answer 10 years later when probably the priorities have changed.

MS. ASPINALL: Do you use those same societies to disseminate the information after you have created new standards?

DR. MAY: We disseminate information probably poorly. We have our website. The standards are in our standard reference materials catalogue. Right now, NIST has about 1,400 standard reference materials. About 1,000 of those have values assigned for chemical or biological analytes.

Our old customers know to go through that SRM catalogue to look for what they need. But what we have not done as effectively as we should is provide avenues for new customers and people who don't know about that. That is one of the reasons we are down here today.

DR. TEUTSCH: Julio and then Andrea.

DR. LICINIO: Wonderful presentation. I had a question on the cortisol and progesterone measurements that you had, which was, I think, a fantastic thing to do because it is true that you have the same sample and you get different measures. It can be very confusing.

One of the things we discussed here before is that one of the issues in the area is that genetic labs sometimes can get disparate results. Would you be willing to do the same type of thing with genetic companies and see what the divergence rate is?

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DR. MAY: I guess we could do that. Normally we look to the CAP and other accreditation bodies to do this. This was a comparison among national standards laboratories. These are the laboratories that are supposed to be providing traceability to the companies within their region.

Now, obviously, that is not a perfect thing because right now more than half of the standard reference materials that we sell at NIST are sold internationally, not within the United States. So people are free to get their reference materials from wherever they want.

But this basically is information to the national metrology institute as to how they stack up relative to others. You might ask, how do we know the true answer here? These are not spiked samples. We don't use spiked samples. We use naturally occurring samples. We have a lot of, let's say, intellectual debates, if you will. We have each of the participants go through their methodology. We shoot holes in it. Then we try to discern from those arguments which laboratories will be used to assign the reference value.

It is not just if you happen to luckily get an answer. We look at the material. For example, LGC's information wasn't used to define this. As it turns out, they were right on. But in their description of their methodology there were some issues. The same thing here. There were only three laboratories that we agreed to consensus had a sound approach.

So everybody develops the approach in their laboratories. This is not using one published method but methods of the highest metrological order as defined by that individual institution. Then we try to get from that to discern what we think the truth is. Then we compare things against that.

DR. FERREIRA-GONZALEZ: Part of my question has already been answered. But, you bring that information back to NIST and assign a value. Before you commercialize that, do you engage your end users again to see if that value has changed? Do you periodically send surveys out to some of these laboratories to recheck the values?

DR. MAY: It is within our system to do a stability check on all of our reference materials. Some of them might take a year or two years. We might make a measurement now and might make another set of measurements in our laboratories a year or a year and a half later to assure ourselves that the matrix is stable. So it is not until we have addressed all of the issues.

Every certification campaign is different because it depends on what the material is and how stable we think it is. Then we do other measurements to try to assure ourselves that in fact the values are correct and that the material is stable. We do all of that before the customer ever gets the material.

DR. FERREIRA-GONZALEZ: Different analytes for materials will have different times from conception to distribution. What is about a mean time from actual formal distribution of some of these?

DR. MAY: I guess, back when I did useful work in the laboratory I could give you that answer.

[Laughter.]

DR. MAY: It varies so much. For clinical material, I would probably say two years. For a genetic standard, how long would that be, John? A year? I would say a year minimum, probably a maximum of two to three years from the time that we actually began working on the project.

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Now, from the time we get input from the stakeholder community, that could be three to four years. Getting the input and deciding that this is going to be our priority, that might take a year's time, because we get lots and lots of input from lots and lots of people. Part of that is deciding internally if this is going to be one of our priorities and making sure that we have the resources to have a successful campaign for development of the reference material.

DR. TEUTSCH: Great. Thank you so much, Dr. May.