

An Introduction to Voluntary Standards and Their Role in Enhancing the Quality of Scientific Research



NanoEHS Webinar Series
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>> Treye Thomas: Thank you all for joining us today. My name is Treye Thomas, and on behalf of the NEHI Working Group I would like to welcome you to the webinar. The NEHI Working Group is composed of a number of representatives from Federal agencies, and focuses on the support of the responsible development of nanotechnology. So it's really important for us to reach out to our stakeholders and provide useful information on a number of topics supporting nano[technology-related] environmental, health, and safety [issues]. We're very pleased to have this webinar and pleased that you could join us, and since we have a very short amount of time, I would like to turn it over to Dr. Ajit Jillavenkatesa who will serve as our host for the webinar today. Thank you and I will turn it over to Ajit.

>> Ajit Jillavenkatesa: Thank you very much for that introduction and certainly my thanks to the participants who are taking time out of their schedule to join the conversation. So [for] those of us participating in the panel, it's pretty clear we like standards. We really like standards. That's why we're in the midst of it, but we also appreciate our participants joining in. Good morning to everyone, and good afternoon particularly to our international colleagues who are also joining from different parts of the world.

Speakers



Shaun Clancy
Evonik Corp.



Stacey Harper
Oregon State University



Anil Patri
Food and Drug Administration

>> Ajit Jillavenkatesa: So this is a great opportunity to start talking about some fundamental aspects around standards, and particularly exploring aspects of standards with regards to NanoEHS and why they're important.

We have a great panel representing three different perspectives. Dr. Shaun Clancy is a director of product stewardship at Evonik Corporation. Shaun is very active in a range of international, multilateral activities, and will provide industry perspectives. Following Shaun we have Dr. Stacey Harper, an associate professor at Oregon State University. Stacey is also the chair of [ASTM] Committee E56 [on Nanotechnology], and brings a lot of good perspectives.

And the last speaker this morning is Dr. Anil Patri, who is with the U.S. Food and Drug Administration. Prior to joining the FDA, Dr. Patri was a staff member and a leader at the National Cancer Institute's Nanotechnology Characterization Laboratory. So he brings really unique perspectives both from a practitioner's side and also from a standards development side, and now particularly from a U.S. Federal Government agency that has an important role in the regulatory context.

Standards – same word, different meaning

Standards – multiple meanings (physical standards, documentary standards, measurement protocols, specifications, guidelines, best practices, etc.)

Focus on documentary standards for this discussion

ISO/IEC definition (*emphasis added*): document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

[Ref: ISO/IEC Guide 2:2004, definition 3.2]



>> Ajit Jillavenkatesa: So without much ado, what I wanted to do is very quickly is to talk a little bit about some baseline issues. First and foremost is the concept of what is a standard? Colloquially, we use this to mean different things. It can be a protocol. It's often used to describe a kind of a very generally agreed-upon measurement method, because it's been used many times and fairly often, but it can also refer in this context or in an NPL [National Physical Laboratory of England] English context to a physical standard, the basis or the base units for measurement.

As many of you are familiar, standards also refer to well-characterized materials, but for the purposes of our discussion and the conversation here, what we're talking about is a documentary standard. This is also known as voluntary standard, consensus standard. These are products, which are typically defined or developed by a range of experts who represent different perspectives. They could be representing their individual perspectives or their organizations, coming together in a very well-run moderated forum, and through a very transparent and predictable and iterative process, they develop an agreed-upon way of doing things, which often represents the state of the art

Yes, standards do matter



>> Ajit Jillavenkatesa: A light-hearted look at why standards matter. I think all of us know standards are important, they matter. But the reason why also, from our perspective, standards really matter is [that] standards do a bunch of things.

Why standards matter

Common language for communication

Enable protection of health, safety and environment

Reflect state of technology

Foundation for technological innovation

Enable economies of scale



>> Ajit Jillavenkatesa: First of all, they actually enable us to develop a shared vocabulary. When I use a particular phrase or a word, how do I have assurance that what I'm trying to convey is exactly the same that you will understand, you will think of? Where this becomes particularly important is certainly in sharing of information, but also often in aspects of trade or in aspects of commerce, where words can have significant implications.

As many of you are aware, and certainly of big interest for you, is the fact that standards enable the protection of health, safety, and [the] environment. But also because standards and the standards development processes bring together a range of experts from a range of different industries, from a range of different academic institutions, bodies. And these are people who are experts in that particular area, in that field. It reflects the state of technology, the state of art.

Why standards matter

Common language for communication

Enable protection of health, safety and environment

Reflect state of technology

Foundation for technological innovation

Enable economies of scale



>> Ajit Jillavenkatesa: There is always a push for developing consensus, and in that manner, what standards do is they embody, really broad agreement about ways of doing things. By doing that, it creates the foundation for technological innovation. What this really means is that companies can use a standard as the basis for developing their product, their service, their system, which actually helps them save money, because of this foundation upon which they can build. And in areas like manufacturing, what standards enable us to do is develop economies of scale. We're not having to develop different products or different markets or different approaches for different markets. We can use the same standards as the basis for then developing differentiated or value-added products.

Nanotechnology standardization

Development of international standards started around 2004-2005

Activities underway in a range of bodies – developers of international standards, regional standards organizations and national standards bodies

Different trajectories for standardization in different bodies

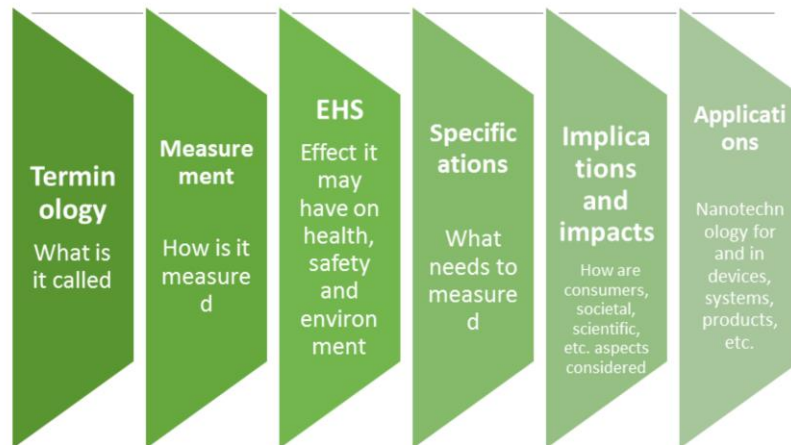
International standards efforts have some common features:

- Strong industry participation
- Standards to enable trade and growth of nanotechnology
- Development of tools and techniques to address many fundamental questions
- Extensive international participation

>> Ajit Jilavenkatesa: In the context of nanotechnology standardization, the formal international standards development activities in bodies such as ASTM, ISO, and the IEC [International Electrotechnical Commission] started right around the 2004-2005 time frame. So we're almost approaching -- just past about the ten-year point. And what we're starting to see is a certain maturity and certain maturation of the standards development process.

Different bodies have taken slightly different approaches, and not surprisingly, while initially there's a slight shake-out period as different groups are trying to identify their scope of activities, we're now at the stage where international standards activities for nanotechnology have really started to develop some very good aspects. There is incredibly strong industry participation. It's very international in its nature. We're starting to see uptake of many of these standards, the nanotechnology standards, certainly amongst industry, but also amongst many regulators who are actually trying to reach out to really broad regulated communities. And these standards are starting to address some very fundamental questions around measurements, around EHS aspects. So this is really setting the stage for a solid body of work.

Areas of interest in nanotech standardization



>> Ajit Jillavenkatesa: Over this ten-year period what they're starting to see is a broad grouping of how standardization is starting to come together. This focus on developing terminology or nomenclature (what do you call something); how do you measure it (which is the measurement of the characterization aspect); the EHS aspects (what effect it may have on health, safety, and the environment); how do we categorize, how do we classify materials; often on specifications (this is a recognition of the fact that nanotechnology also is reaching a certain maturity in commercialization, and so as it enters into mainstream commerce, how should materials be specified in a supply chain or in a value chain?).

We're starting to address the question of impacts and implications through societal issues, through consumer and sustainability aspects, and increasingly as we're starting to see, again, from a commercialization perspective, both nanotechnology-enabled and nanotechnology-enhanced products, we're now starting to see a desire for standardization that helps address some fundamental questions around devices or around systems. So we're going past just the materials characterization, but that is not to say there isn't strong interest in further exploring issues around materials characterization, like there is a lot of interest around graphene standardization.

Trends in nanotech standardization

Continued focus on addressing technical issues

Increasing interest in related issues that have non-technical impacts:

- Consumer and societal considerations
- Policy implications
- Range of issues many of which standards organizations are not equipped to address

Increased participation of non-technical experts

- Common understanding of standards development process
- Shared end goal
- Alignment of priorities

>> Ajit Jillavenkatesa: So I think certainly one of the things that we see as a broad trend, is a focus not only on addressing technical issues, but also on broader issues, which go beyond just the technical issues. And I think this is a really good sign that standardization is not just applicable only to a few select experts working within technical companies, but is also really resonating with people at large.

Issues to be explored today:

Value proposition for organizations to engage in nanotechnology consensus standards development.

Organizations' use of resulting standards

Examples of nanotechnology standards development successes

Opportunities and gaps in nanotechnology standards

>> Ajit Jillavenkatesa: So some of the issues that we want to explore with our speakers today are: what is the value proposition that their organizations see to participating in nanotechnology consensus standards development? How are their organizations using these standards, or where do they see the use for these standards? And do they have any examples of successes that they've had in using these standards and developing these standards? And perhaps kind of bringing all those pieces together but also identifying opportunities and gaps, looking down the road and seeing what is coming down.

So with that introduction, what I would like to do is turn it over to our first speaker, Dr. Shaun Clancy.

What is the Value for Industry to Participate in Voluntary Standards Development?



Shaun F. Clancy, Ph.D.
Evonik Corporation

May 24, 2017



>> Shaun Clancy: Thank you, Ajit, thanks to Ajit and Treye for the introductory comments, and thanks to the NNCO for the invitation. And thank you in advance for your attention to my comments today.

So I'm going to try to present an industry perspective as to why industry generally participates in voluntary standards.

Before we begin...

This perspective is my personal point of view. It is informed by:

- I have used standards for many years
- I have participated in standards development for many years
- I have learned perspectives from other stakeholders including those who work for other companies and other stakeholder groups
- I have observed how standards have been used.

I hope that my perspective is representative of others in industry but we are a diverse group!

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>> Shaun Clancy: So first, a little about me. My comments today are really my own. But I hope they are well-informed by my participation in standards development in industry, and I've learned a lot from the people I work with, not just within the industry but all the other sectors that Ajit referred to a moment ago. I have had a chance to see how standards are developed; I see how standards are used. And I see, what Ajit was referring to, see where we have opportunities to improve standards, and I was fortunate to be involved in the process.

As you hear my comments today, I hope you keep in mind, they still are my personal comments, but I hope that you also will be hearing comments that are representative of industry, while recognizing that no sector is a monolith; we're a very diverse group.

We participate to help develop consistent practices

- **Not everything should be standardized**
- Standards need to provide a benefit
- **Often the benefit is the facilitation of commerce. Example – a material or device specification**
- Sometimes the benefit is that adhering to a standard is a recognized indication of quality – ISO 9000 series (Quality), ISO 14000 series (EHS)
- Sometimes the benefit is improving the language used within a field. Example – ISO 80000 series (metric units), ISO 80004 series (nano terminology)
- Standards are often developed to meet a need of a market/sector
ISO/IEC JTC 001 (IT) has published almost 3000 standards since 1987

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>> Shaun Clancy: I'll start off by making a comment that I don't think will be too surprising. Not everything should be standardized. I think that's a fairly obvious statement, but the purpose of stating it that way is, going to the next bullet, standards need to provide a benefit to those in industry. Companies are paying us to do things and companies are interested in things that bring in revenue. So we need to see a benefit. And Ajit also alluded to the benefit of commercialization. Standards oftentimes facilitate commerce. Examples that I hear most are how one defines a material or a device based on the specification. And specifications are oftentimes based on some sort of characterization based on the standard.

I've listed here some examples of standard classes that you might be familiar with, including quality and EHS and terminology, but these are areas that are clear benefits to industry participation. So when we think about our participation in the standards development process, it does have benefits to us as industry in mind.

We participate to ensure that standards are of good quality

- Standards can define consistent practices
- A consistent practice is not necessarily a good practice
- **Companies will participate in standards development not only to develop a practice but to ensure the standard is good and useful**
- Some standards may be used to support regulation so high quality can have special importance

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>> Shaun Clancy: More than just having the opportunity to be involved with the development and practices, we also look as to whether or not our investment in time and resources will ultimately end up with a good practice. Of course, having a practice doesn't necessarily mean it's good. It takes effort to develop a good practice, but that's one of the things we look at carefully.

If we're going to be involved, the result of the work needs to be good and useful. We want to have something we can take back home, whether it's individual companies or industry sectors or stakeholders more broadly. We want something that we're going to use. So we are looking ahead again as to why we should participate in things that are really voluntary. We look for the benefit and we look for the utility.

How standards are supporting Communication and Education

Terminology – TC229 Joint Working Group 1

- **Having commonly understood terms facilitates information exchange**
- This may allow more rapid development of new ideas
- Example: Engineered nanomaterial vs Manufactured nanomaterial vs Incidental nanomaterial vs Nanostructured nanomaterial

Education – ASTM E56 Standards for Workforce Education Programs

- **Guides & Practices for H&S, Synthesis & Processing, Characterization, etc.**

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>> Shaun Clancy: I would like to feature some of the elements in the nanotechnology standards committees that I participate [in] or am aware of that you might find interesting as to better understanding, again, why industry wants to participate in these things. Terminology, of course, is fundamental. When I first got involved with nanotechnology many years ago, more years ago than many would care to admit, just the definition of a nanomaterial was something that was widely variable. For some people, it was a particle that we might describe today as a primary particle, all the way up to collections of particles that exceeded a micron.

Now certainly the term nanomaterial can correctly apply to all these different forms, but the variability in those forms, and the narrowness of the term, oftentimes caused confusion. So it's taken us some time to develop terminology that allows us to communicate more effectively with each other. And to me, this is very fundamental, and something the industry really wanted to play a role in. First of all, we thought we had information we could offer, but we also wanted to make sure the community understood our perspectives, how terminology would be used, not just to develop materials but also to facilitate commerce, and then also help us to support the responsible development of nanomaterials and nanotechnology.

How standards are supporting Communication and Education

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>> Shaun Clancy: I'll talk more about it in a minute, but again, we want to be involved with these things because the development of the words we use is really important to us.

Consistent with that is also educational practices. ASTM E56 has been the leading group in this area in my opinion, and I hear they have already developed a number of guides and practices for health and safety, synthesis and processing, and characterization, among others.

And so as the field is maturing. I wouldn't say we're mature yet, although I think we've come a long way. Something [that] has lagged a bit is having a workforce, which is also familiar with the same things many of us know from our involvement over years. And turning these things into educational programs: as institutions train the workers of the future, and for that matter, workers of the present, they have consistent knowledge, fundamental knowledge, which allows them to be productive more quickly. So those are two areas where the industry community has really wanted to be involved.

How standards are supporting Product Quality

Metrology – TC229 Joint Working Group 2

Materials Specifications - Working Group 4

- Many methods have been used to measure the dimensions of nanomaterials
- The sizes measured by different methods may not agree and may be very different
- **Having standardized methods makes the results of measurements more meaningful and can explain differences**
- **Having product specifications can define quality & facilitate commerce**

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>> Shaun Clancy: Product quality, of course, is really important to us [in] industry because we're making materials we want people to purchase, and have confidence that the materials they are buying are of value. And standards oftentimes play a fundamental role there. In the case of metrology, it has to do oftentimes with characterization. If we say something has a certain particle size or certain particle area, we want our customers to have confidence that we've done a good job providing that information, generally numerical information, and that oftentimes means telling them what method we used.

Those of us familiar with a size know there's methods ranging from things like electron microscopy, which looks at particles at very small levels, up to things like aerodynamic diameter, which looks at larger scale things. Very different measurements; very different sorts of results. So having standard methods [that] define how those methods are practiced but explain the differences between them, it's fundamental to what we do. It's helpful to design [a] product specification, and that can also be then used to define quality and facilitate commerce.

How standards are supporting Responsible Development and Use

EHS – TC229 Working Group 3

- ISO Technical Committee 229 not only develops standards but also develops guidance documents
- Working Group 3 has developed guidance documents that remind researchers about how to consider topics that may be “nano-specific”
- Examples include: Safety Data Sheets, Control Banding, Screening testing for tox/ecotox, Confounding factors to consider in tox/ecotox testing
- **High quality tests can support responsible development of nanotechnology**

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>> Shaun Clancy: Responsible development of any technology is so important. It always has been, but we have even a closer look at this than we ever had today. And so as we're looking at developing new materials and the way materials, whether they be new or legacy materials, are used; we want to ensure that things are done well. Within ISO/TC 229, ISO's Technical Committee 229 on Nanotechnologies, Working Group 3 is focused on environment health and safety practices, because we want ... those people who use our products and those people who use their products, and so on and so on, to have confidence that they can be used safely.

Some examples of work that Working Group 3 has done [are] the development of guidance documents and standards pertaining to things like safety data sheets, control banding to do risk assessment and risk management, screening tests to quickly assess materials for toxicological effects or ecotoxicological effects. These are things that the community is hopefully finding great value in. And again, we in industry want to be involved because, first of all we're going to be users of these things, but we're also aware of some of the confounding factors that need to be considered in their development. We're able to offer input so the results of the work that people are involved with, among the stakeholders that are involved with standards development, are well-informed and are leading to things that are practical and useful.

Final Comments & Summary

There is value for industry to participate in developing standards:

- That are of high quality
- That support effective communication and open information exchange
- That promote the responsible development of new products and applications

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>> Shaun Clancy: I'm looking forward to discussion later on, but just to sum up with final comments: Industry gets involved with stuff like this because it provides value to us. It provides value in a number of ways ranging from responsible development to product quality, to an improved ability to communicate. All those things are important to us and they're really drivers for our participation. We want to participate in processes generally that support effective communication and open information exchange. One of the great things about being involved with the community is the opportunity to engage with so many different stakeholders from many different sectors, whether it be government, governmental organizations, academia, and others.

And we learn from each other and that results in better work products. Ultimately from an EHS perspective we're interested in responsible development of new products and applications because that's what is going to really benefit our companies and help us make some money.

Question? Comments?

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>> Shaun Clancy: So with that, I think the next slide is my contact information, which can be shared with the participants today.



>> Shaun Clancy: and then I'm ready conclude and turn things over to the next speaker

An Academic's Perspective



Stacey Harper

Associate Professor School of Chemical, Biological and Environmental Engineering & Environmental and Molecular Toxicology, Oregon State University



>> Stacey Harper: I would like to first start by thanking you and Treye for putting this together. I think it's a unique opportunity for us to engage in these conversations.

I come from an academic perspective. I'm an associate professor of nanotoxicology at Oregon State University, and I have a joint position between the department of environmental and molecular toxicology and the school of chemical biological and environmental engineering. That is because my research focuses on nanotechnology and environmental health and safety as well as nanotoxicology. We do a lot of research in the lab, leveraging rapid assays that use full organisms and communities of organisms to evaluate the biological activity and toxic potential of vast array of nanomaterials. In testing all these materials, it was important to me to make this data publicly available, so I put together the nanomaterial biological interactions knowledge base [<http://nbi.oregonstate.edu/>], in which I put all of the primary data from our testing to share more broadly with the global community; people who are doing modeling and can utilize the data in ways that I either don't have the time nor the inspiration to do.

An Academic's Perspective



Stacey Harper

Associate Professor School of Chemical,
Biological and Environmental
Engineering & Environmental and
Molecular Toxicology, Oregon State
University

>> Stacey Harper: Being an academic, we don't get a lot of credit for engaging in standards work, so I wanted to explain a little how I got into standards. I saw a presentation back in 2006 or 2007 by Clayton Teague, when he was director of the National Nanotechnology Coordination Office, and he stressed the importance of standards and in particular for nanoscience and nanotechnology, and knowing that ultimately I wanted to gain a deeper understanding of which nanomaterial physical/chemical features kind of drive their environmental fate and biological interactions. I realized that there was an overarching need to have standard descriptors and standardized assays and standardized reporting to really enable data sharing among nanoscience databases.

So I became engaged with standards bodies, both ISO and ASTM, and also a pre-standards working group that I'll share a little bit of our work today.

An Academic's Perspective



Stacey Harper

Associate Professor School of Chemical,
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>> Stacey Harper: So I joined and continue to serve as a member on ISO/TC 229, and primarily focused on Working group 3, which is health and safety and the environment. And Shaun covered some of the ongoing efforts there, so I'm not going to expand upon that.

I also serve as the chair of the ASTM International E56 Committee on Nanotechnologies, and the scope of this group includes the development of standards and guidance documents for nanotechnology and nanomaterials as well as the coordination of existing ASTM standards that are related to what we need in nanotechnology and nanoscience. Standards include test methods, specifications, guidance documents, terminology. Thus far, we've put together 18 standards; several of those have now been adopted by regulatory agencies.

An Academic's Perspective



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>> Stacey Harper: Some of the unique or growing areas where we're developing new standards are in the fields of consumer and medical products; I am thinking of drugs and drug delivery systems and devices. We also focus a lot in ASTM on education and workforce development; and in fact, ASTM education standards that are coming out of this group are now being used by numerous undergraduate institutions, particularly the two-year colleges, so that we're providing the skills really needed for workers in future nanotechnology industry.

We also work on informatics and ontologies, and being interested in the nanoinformatics area, this is a logical place for me to have some efforts. And then just regular stuff like physicochemical characterization, documentation, and stuff like that.

An Academic's Perspective



Stacey Harper

Associate Professor School of Chemical,
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Molecular Toxicology, Oregon State
University

>> Stacey Harper: So those are my formal investments in standards development, but I also co-lead the National Cancer Informatics Program's Nanotechnology Working Group. I co-lead that with Christine Hendren of Duke University, and this is really a voluntary community that is kind of grassroots, coalesced around some very common interest in nanoinformatics and ultimately data sharing, where we can share information, data, and resources among the nanoscience community.

This working group is open to all, and we have weekly teleconferences and presentations, and we have a website that posts all of our presentations that we've had over the last several years.

An Academic's Perspective



Stacey Harper

Associate Professor School of Chemical,
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University

>> Stacey Harper: The goal of this working group is really to demonstrate the scientific potential of federating nanotechnology databases through pilot projects that are really aimed at integrating semantic search and retrieval of, in particular nanomedicine, but nanotoxicology as well, and now we're moving a little bit into some of the environmental considerations. But being able to merge, share, and understand that, you know, you're comparing an apple to an apple, was highly important. So you can imagine within this group that standardizing ways of collecting, of managing, describing, and reporting or even storing and sharing the data are very highly valued by this group.

So I wanted to share with you a couple of examples that kind of illustrate the value of pre-standards development because a lot of what we do is pulling together groups of people and experts in a less formal way than the standards process, and trying to gain consensus among the community, and then take that information or that work product and move that towards standards development. It takes much of the time burden out of the formal system when groups of people have already coalesced around, yes, this is a workable standard.

An Academic's Perspective



Stacey Harper

Associate Professor School of Chemical,
Biological and Environmental
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Molecular Toxicology, Oregon State
University

>> Stacey Harper: And so one good example of this was, the Nanotechnology Working Group worked collaboratively on the development of a nanoparticle ontology for cancer and nanotechnology research. This was led by Nathan Baker, Dennis Thomas, and Rohit Pappu, and this has now moved forward and they developed this ontology back in 2009, and it's now being moved to ASTM to be vetted as a standard.

An Academic's Perspective



Stacey Harper

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>> Stacey Harper: And another success story that we have is the development of ISA-TAB-Nano. This project was launched in response really to the lack of common reporting standards and non-uniformity of information, which really posed significant barriers to data sharing and data reuse, and that was one of our major goals. So from 2009 to 2012 our group really worked on establishing a standardized file format where we could use this or supply it to the community for submission and exchange of data on nanomaterials and their characteristics, including the metadata that needs to be tracked with them.

We didn't start this from anew. We actually leveraged a tab-delimited file structure developed by the European Bioinformatics Institute called ISA-Tab; ISA meaning Investigation Study Assay, and tab meaning that it is a tab-delimited file structure. And what we basically did was add an extension to this that was specifically to capture the nanomaterial characteristics. So we called it the materials file and it captures what we felt were the more important characteristics of the nanomaterials so that we could know we were talking about an apple or an orange.

An Academic's Perspective



Stacey Harper

Associate Professor School of Chemical,
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Molecular Toxicology, Oregon State
University

>> Stacey Harper: We ensured, when we were doing this, we also wanted to make sure there was support in place to use proper ontologies. So we put in fields to capture ontologies, not to specify a particular ontology, but to document what ontology you're referencing, which was, I think, a critical aspect of developing that.

And then after years of developing and vetting over test cases, we had, you know, groups of researchers trying to utilize it, and we worked through the bugs and so it was submitted to ASTM and became a standard in 2013, which was great.

And we're actually now reassessing that, and trying to add some additional value to that by adding some functional assays and templates for research that we already know is going on.

An Academic's Perspective



Stacey Harper

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>> Stacey Harper: And then I wanted to share one other example that was kind of different. Our group had a focus workshop on zeta potential. This is something we had discussions about, that this was a problem in the field that we had identified. So we had this workshop and wanted to pull together people from life sciences all the way to environmental engineers, because we needed to understand, you know, within these different fields, the analytical techniques, data output, and the interpretation that they had.

And so this disparate community needed to come together with some suggestion of how to interpret zeta potential. We had discussions about likely misinterpretations, or over-interpretation, of what zeta potential measures actually represent, and that was a very interesting discussion, so from that workshop we put together a manuscript and published that late last year. That's Lowry et al. 2016 [<http://dx.doi.org/10.1039/C6EN00136J>].

An Academic's Perspective



Stacey Harper

Associate Professor School of Chemical,
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Engineering & Environmental and
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>> Stacey Harper: And so I guess I'll end by saying, as an academic, even though we don't get a lot of credit for doing this type of work, as far as promotion and tenure goes; but now that I've gotten tenure it doesn't matter so much, but I do it because I personally believe that the standards are one of the most important things that I do. And it's worth it to me because I feel like, by doing this, we can accelerate really our scientific understanding of which nanomaterial features can be tweaked to obtain both high performance and product safety. And so with that, I will end my remarks as well.

Collaborative Standards Development for Regulatory Science



Anil K. Patri, Ph.D.

Chair, Nanotechnology Task Force
Director, Nanotechnology Core Facility
National Center for Toxicological Research
U.S. Food and Drug Administration
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>> Anil Patri: I guess it's my turn. My name is Anil Patri from FDA. My thanks to Ajit and I appreciate NEHI's bringing the NanoEHS webinar series, and for organizing this webinar on nanotechnology standards.

The previous presenters really set the baseline for the standards from industry perspective, and standards agency perspective, and on the challenges from an academic perspective, because not a lot of standards are necessarily used in academia. But I would like to bring a regulatory perspective coming from FDA.

Standard disclaimers apply for my presentation. Any opinion expressed as part of this webinar are my own, and from my personal experience, and do not necessarily represent the official position or policy of FDA.

Collaborative Standards Development for Regulatory Science



Anil K. Patri, Ph.D.

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>> Anil Patri: As you all may know, FDA is a regulatory agency responsible for protecting and promoting public health by ensuring safe... and effective medical products, and safe foods for humans and animals. More recently FDA was given the authority to regulate tobacco products; there's a new center called the Center for Tobacco Products, CTP.

In meeting its mission of making science-based decisions for reviewing, approving, and monitoring the products it regulates, in this context standards are very important for FDA to facilitate the evaluation of products, streamline the pre-market evaluation and post-market surveillance, and for international harmonization. This is a reason why FDA has over 700 representatives participating in standards activities in over 1,000 committees from standard development organizations.

Collaborative Standards Development for Regulatory Science



Anil K. Patri, Ph.D.

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>> Anil Patri: Specifically for nanotechnology-related participation, FDA is active at ASTM, ISO, OECD, and [the] United States Pharmacopeia. Ajit suggested four main topics. and I will try to cover them briefly here.

In term of value proposition, to engage in the nanotechnology consensus standards: this is, again, very important to FDA. FDA has already [reviewed] more than 350 drug products and medical devices containing nanomaterials for human use. In recent years we have seen a gradual increase in submissions containing nanomaterials, combined with increased complexity of these products during investigational new drug submissions, called INDs. INDs are submitted with preclinical data before one gets into clinical trials.

And so the increased intricacy of these material syntheses, to assembly, to products, along with novel instrumentation that we see coming up every year, to measure the critical quantity attributes, to ensure reproducible manufacturing, safety, and efficacy of these products, makes assessment more challenging for us.

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>> Anil Patri: In this context, consensus standards developed through collaboration with industry and other stakeholders facilitate the regulatory review. The Center for Devices at FDA (CDRH) is mandated to recognize standards to facilitate industry's use of these standards.

Currently, there are four standards that have been recognized by CDRH on nanotechnology: two guides from ASTM--one on particle size measurement, and the other on handling unbound engineered nanoscale particles in occupational settings; two from ISO--one on the surface characterization of gold particles, and the second on vocabulary.

Additional standards are constantly in review. So FDA has, in addition to participating in these activities, we have internal nanotechnology core facilities, and they are well equipped with instrumentation to conduct research, understand new technologies, and actively participate in the interlab studies if those are organized by other agencies.

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>> Anil Patri: There are many gaps. Ajit asked us to talk about the gaps. And we see many gaps [in standards] that are not already there. ISO has developed many standards. But for medical products, we see certainly many of them are relevant, but new standards are needed, relevant to drugs, devices, and consumer products.

FDA has internal working groups and experts in different centers to comment on standards that are coming through for review. Based on the specific need, we may suggest new standards that need to be developed through these standards bodies, and we participate in the committee meetings. We coordinate the standards activities internally within FDA on nanotechnology, through the nanotechnology task force standards subcommittee. We also work closely with other agencies through the NNI, NSET, and NEHI Working Group to coordinate across the agencies, both the research activities as well as standards activities.

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>> Anil Patri: A few months ago we had a global summit on nanotechnology standards and applications at the NIH campus, with the global regulatory research and standards agencies, industry, and academic stakeholder participation, to ascertain the need for new standards. This group reviewed existing standards and came up with a list of much needed standards for drugs, devices, and consumer products containing nanomaterials.

The goal is to disseminate this information to the community, so that appropriate standards are developed that can benefit industry and global regulators. The report and publications are forthcoming on this activity.

So we look forward to the collaborative development of standards with other stakeholders. Again, I thank you, NEHI, and Ajit for the opportunity to be part of this panel and present the regulatory perspective. Thank you.

Q&A / Discussion

Question: Based on your experiences in participating in the development of nanotechnology standards, what do you see as the biggest challenge that you are confronting, you have faced either in the development of these standards or in their use?

>> Ajit Jillavenkatesa: Anil, thank you very much and thanks to Shaun and Stacey also for those perspectives. You know, we will now transition into the Q&A section, and I would invite our participants to... type in your questions, if you have any questions, into the question queue box that should be on your screen. While we're waiting for questions to come, I figured we could get the Q&A session started with a question for all the panelists. Based on your experiences in participating in the development of nanotechnology standards, what do you see as the biggest challenge that you are confronting, [that] you have faced, either in the development of these standards or in their use?

>> Shaun Clancy: Ajit, if you don't mind, I'll take a first shot at that.

>> Ajit Jillavenkatesa: Shaun, all yours.

>> Shaun Clancy: The biggest challenge I see is a recognition in the community how important it is for them to be involved in this. There are a fair number of people involved and they're great, but we can always benefit from more. So as I talk to people about getting involved, they don't oftentimes recognize the benefit of their involvement, whether [to] them personally or to the process. I would say that would be one thing I would describe as a very big challenge.

Q&A / Discussion

Question: Based on your experiences in participating in the development of nanotechnology standards, what do you see as the biggest challenge that you are confronting, you have faced either in the development of these standards or in their use?

>> Anil Patri: If I can comment, I think Stacey mentioned this. Within nanotechnology, the research is almost very new and, you know, new products have been developed that come through the regulatory agencies, but expertise for [the] most part lies with academia, a lot of people doing excellent research in academia. But when it comes to participating in standards activities, we see very few of them participate. I guess, you know, ... Stacey mentioned about this, mainly because it's not really part of the review process for either promotions, tenure, and they don't really get a whole lot of publications from that, which is a challenge. So I think that is one major area, that we certainly need more participation from academics in the standards development activities.

>> Ajit Jilavenkatesa: And Stacey, from your perspective?

>> Stacey Harper: I think one of the biggest challenges is when you have created... the standard and gotten everybody engaged on it, if it requires additional effort or a change of practices, it's very hard; the sales pitch has to be very strong and the industry has to buy into the process, like Shaun was saying, that there is added value by utilizing the standards that are developed.

Q&A / Discussion

Do you have any perspectives, from the context of NanoEHS studies about what are the friction points around nanotechnology standards use and the use of these standards enabling greater confidence in data for NanoEHS-related studies

>> Ajit Jillavenkatesa: Thank you. You know, I think that also begs yet another question, right? So this is a question where, if we take this issue, not so much from the development side, and I'll come back to the question on the development side in just a few minutes, but particularly on the use side, in the abstract, very specifically, the nanoEHS, I think a concern that we hear is when we are trying to understand or compare data, particularly in the context of EHS-related studies, we have a really hard time in comparing this data because really we don't know if the data is being generated in a similar manner, whether there are variables that are being introduced.

So do you have any perspectives from the context of nanoEHS studies about what are the friction points around nanotechnology standards use, and the use of these standards enabling greater confidence in data for nanoEHS-related studies? Go ahead. This is a question for any of the panelists.

Q&A / Discussion

Do you have any perspectives, from the context of NanoEHS studies about what are the friction points around nanotechnology standards use and the use of these standards enabling greater confidence in data for NanoEHS-related studies

>> Stacey Harper: ... Ajit, what do you mean by "friction points"?

>> Ajit Jillavenkatesa: What I mean is, from your perspective, is it a lack of awareness of the types of standards that are out there for people to be able to use? Is it that the standards are often too complex or the instruments that are needed for implementing the standards are not easily available? **Are the protocols not clear enough?** How can we actually enable, there are two aspects: one is the awareness of standards, and the other is the use of standards. How can we actually increase uptake of the use of standards in the nanoEHS community?

>> Stacey Harper: I think awareness of standards is being doing things like this, having a webinar and broadly announcing that there are these standards out there, and trying to engage the rest of the community. I think as standards come out, there's not a prestigious roll-out for them, if you will. So those who have been working on them are well aware of them. Those who haven't rarely hear about them. So I think a campaign to make people more aware of it would be very helpful.

Q&A / Discussion

Do you have any perspectives, from the context of NanoEHS studies about what are the friction points around nanotechnology standards use and the use of these standards enabling greater confidence in data for NanoEHS-related studies

>> Stacey Harper: Also, engaging the nanoEHS community on needs, like the FDA just did. So I think that we're moving there. I think, you know, oftentimes, if it requires extra work, right, if you think about developing a standard way of describing size..., we all know that size matters, right? But when we describe size, when we report it in the literature, when we store it in databases, we have a mean and a standard error or standard deviation. And that's insufficient probably, but how do we engage people to say, it makes it more difficult for them to capture, you know, an entire histogram of the size distribution and how that might shift over time? And all of those additional considerations. So it's really a matter of, I think, more the complexity around it as far as having the standards developed.

Using them, I think, is about the campaign. I think that we have to make the sales pitch to academics as well as industry partners to utilize these. I think the more weight that regulatory agencies put on them, that will also help the situation.

Q&A / Discussion

Do you have any perspectives, from the context of NanoEHS studies about what are the friction points around nanotechnology standards use and the use of these standards enabling greater confidence in data for NanoEHS-related studies

>> Ajit Jillavenkatesa: Shaun, I think you were going to add something also?

>> Shaun Clancy: Yeah, I can actually build off what Stacey just commented. Awareness is certainly a pretty important thing. [If] people don't know the standards exist, it's going to be challenging for them to know to use them. But her last comment about regulatory driver[s]: Certainly, as industry, when we are aware of standards, we can use them internally and you never know about them. We use them to make our internal decisions, inform us internally, but we're also really interested in what the needs of the community are, especially the regulatory community. So if any of the regulatory bodies have interest in collecting information according to a certain method, we want to know about that method.

If they need information but they don't have a method, standards work needs to be done; we're interested in participating with them so that we can work together on giving them the tools to collect the information they need. So just to summarize, one element is awareness of what is already out there and another is awareness of what the needs are among the stakeholder community.

Q&A / Discussion

Do you have any perspectives from the context of NanoEHS studies about what are the friction points around nanotechnology standards use and the use of these standards enabling greater confidence in data for NanoEHS-related studies

>> Stacey Harper: Shaun, did you want to mention the nanotechnology standards database, for combining ASTM and ISO, and other standards and guidance documents into one place?

>> Shaun Clancy: Sure. You pretty much summed it up right there, but just to put a few more words around it, ANSI coordinates the nanotechnology standards panel, which Ajit and myself are the co-chairs of. One of the work products of that group, which is actually done by ANSI, is they created a repository for standards and related documents that is available to the community. I do not know the URL off the top of my head, but if you do a search on ANSI and nanotechnology standards or nanotechnology standards panel, I'm sure you'll find the link [https://www.ansi.org/standards_activities/standards_boards_panels/nsp/overview]. But it is a good source for a lot of what is already out there. And for those that have documents that you would like to have the community know about that they may not already, it's a great place to load them up.

Q&A / Discussion

Do you have any perspectives from the context of NanoEHS studies about what are the friction points around nanotechnology standards use and the use of these standards enabling greater confidence in data for NanoEHS-related studies

>> Ajit Jilavenkatesa: And, Shaun, if I may also add that the database is pretty much a self or individual contribution-driven database, it's not specific to any one organization. It's also not specific to documentary standards. We certainly have references to reference materials. We also have actually links to regulations or rules that may involve standards-related aspects. So the idea is to kind of keep it as a slightly expansive clearinghouse for lack of a better term. And there are also similar databases around the world, which try to capture different aspects. Anil, do you have any perspectives around how we increase or how do we raise awareness and also the update of these nanotechnology standards, particularly for nanoEHS-related applications?

>> Anil Patri: Thanks, Ajit, again. I reflect on the points that were raised earlier. When we develop standards, the question is, okay, who is going to use them? And industry certainly uses them if there's a regulatory need or regulatory agencies are recognizing the standards that the industry can use. And that's where certainly FDA is participating in these activities. And so this database that you mention, I think it's an excellent tool, excellent idea where all the standards are in one place, where people can go and see what standards are out there.

Q&A / Discussion

Do you have any perspectives from the context of NanoEHS studies about what are the friction points around nanotechnology standards use and the use of these standards enabling greater confidence in data for NanoEHS-related studies

>> Anil Patri: Certainly I think it's only an informational database. One has to go to the specific standards development organization to request for the standards and then pay per standard. That's where I think if you were to increase the use of these standards, they have to be more readily available. So I don't know if there can be an effort to talk to the standards development organizations where they can make them available. They make part of their money through the subscriptions, or selling these standards. Somehow making them more freely available would enable the use of these standards apart from the knowledge of what standards are available out there.

>> Stacey Harper: And, you know, something simple that could be done, for example, for the nanomaterials standards database, is just putting a link from the National Nanotechnology Coordination Office on the front page or something that links to standards within the field. You know, that's kind of low-hanging fruit but could make an impact and give people a place to launch into the standards database.

Q&A / Discussion

So often people believe, rightly or otherwise, that standards development is -- it's a very painful process. Spend a lot of money on travel, takes too long and labor intensive and when you get the end product because it's a consensus document it doesn't necessarily meet all your needs. From your perspectives of participating in different standards bodies, what do you think? Has this been your experience? Do you have a different perspective?

>> Ajit Jillavenkatesa: Great. Thank you. I think we have a couple of questions coming in, and Kristin is typing those in. I want to ask the panelists another question. And this kind of gets to the issue of participation in development of standards.

Often people believe, rightly or otherwise, that standards development is, it's a very painful process. Spend a lot of money on travel, takes too long, it's labor intensive, and when you finally get the end product, because it's a consensus document it doesn't necessarily meet all your needs. From your perspectives of participating in different standards bodies, what do you think? Has this been your experience? Do you have a different perspective? This is a question for any of the panelists.

>>Anil Patri: I'll briefly take that up. It does take time, it does take effort, at least a couple of years for a guide or a test method to become a standard through the consensus process. And I think we can expedite that, if you have a proper expertise within the companies that work with the standards. Even with expertise, we all differ in our opinions and that's why a consensus standard has a lot of value.

Q&A / Discussion

So often people believe, rightly or otherwise, that standards development is -- it's a very painful process. Spend a lot of money on travel, takes too long and labor intensive and when you get the end product because it's a consensus document it doesn't necessarily meet all your needs. From your perspectives of participating in different standards bodies, what do you think? Has this been your experience? Do you have a different perspective?

>> Anil Patri: You develop this consensus from a completely different perspective from industry or research. So, yes, it does take time, but having the inter-lab studies and things like that beyond a test method, for example, to come up with the precision and bias in a measurement, they certainly help, especially the nanotechnology area where you have, let's say, a polydispersed material, and to define the polydispersity and surface coating appropriately would help, because those subtle changes in the size of surface properties have significant influence on the biological outcome, both in terms of safety and efficacy. So, yes, it does take time, but I think we have to put in the resources needed to develop the standards.

Q&A / Discussion

So often people believe, rightly or otherwise, that standards development is -- it's a very painful process. Spend a lot of money on travel, takes too long and labor intensive and when you get the end product because it's a consensus document it doesn't necessarily meet all your needs. From your perspectives of participating in different standards bodies, what do you think? Has this been your experience? Do you have a different perspective?

>> Ajit Jillavenkatesa: Thank you, Anil. Shaun, **any perspectives over there in industry and, Stacey, from your interactions with nanotechnology standards?**

>> Stacey Harper: I guess I have to agree that sometimes it is painful, but the group of people that I work with through ASTM, through the pre-standards development, through our nano working group, and collaborators at ISO, are amazing people. If you have a fun group it can also be a lot of fun.

>> Shaun Clancy: I agree with the comments of Anil and Stacey. I wouldn't use the word "painful" myself, but it requires effort. As Stacey noted, the people involved in these things are fun to deal with generally. With respect to things like travel, all the groups I'm aware of go to great length to make participation easy by using phone, web tools, *et cetera*, in order to minimize those sort of things. So it encourages participation without having to have people get on an airplane. But there is a real benefit to face-to-face meetings too. We haven't found a way to rule them out yet.

>> Ajit Jillavenkatesa: So the message over here is, get engaged, and get engaged often and early?

>> Shaun Clancy: Yes.

Q&A / Discussion

Are any approved food applications of products of nanotechnology to date?

>> Ajit Jillavenkatesa: We have a couple of questions that have come in from our webinar participants and I don't think these are standards-specific, but I'll still go ahead and pose those questions. We'll let Anil start because they seem more FDA-specific. First whether there are any approved food applications of products of nanotechnology to date. I'm reading the question here.

>> Anil Patri: Again, this is very specific. Certainly there are products, I cannot name them. I don't know whether we have a list that is publicly available, and there is, we know that food material uses nanoscale materials. But in terms of the drugs, there is public information; there is a review that just came out. We spent maybe two years within FDA to look at what products, drug products, contained nanomaterials in the last 40 years. We are using the word "nanotechnology/nanomaterial" for only 20, 22 years, but there are many products that have been approved in the last 20 years for human use. If you go to Nature Nanotechnology [<http://dx.doi.org/10.1038/nnano.2017.67>] and type in "Katherine Tyner". She has a review that came out a few weeks ago that describes all the drug products approved and the trends in the submission of the drug products, the INDs, the NDAs, and what kind of instrumentation is used in measuring these kinds of nanomaterials, and then also what kind of nanomaterials are submitted to FDA.

Q&A / Discussion

Are any approved food applications of products of nanotechnology to date?

>> Anil Patri: So we have seen one-fourth are liposomes and another one-fourth are vitamin supplements, and the rest of the 50% include emulsions, metals, metal oxides, polymeric nanoparticles, and dendrimers. Also the tools, we see maybe 50% of those using nanomaterials use dynamic light scattering as a size measurement, but there is an extensive analysis, so one should look at that publication.

Q&A / Discussion

Could you also speak a little bit to FDA's approach or FDA's list of, you know, what is called the FDA recognized standards. And speak a little bit about how many of nanotechnology specific standards are on the list and how do standards actually get on to the list and perhaps what is the value of having standards on a regulated recognized list of standards

>> Ajit Jilavenkatesa: Great. Thank you very much. If I could follow up on particularly FDA's use of standards. I think this is a really, very excellent, and telling, example of a regulatory agency looking to use standards. Could you also speak a little bit to FDA's approach, or FDA's list of, you know, what is called the FDA recognized standards. And speak a little bit about how many of nanotechnology-specific standards are on the list and how do standards actually get on to the list, and perhaps what is the value of having standards on a regulatory-recognized list of standards?

>> Anil Patri: Thanks, Ajit. That's a very good question. I briefly mentioned about the Center for Devices is mandated by Congress to look at the standards available. We have the standards committee within the CDRH that actively participates in many of these activities, ISO, ASTM, and others. So they go through the standards, whenever a standard comes through. Because they're members of these committees, they get to comment on the standard, but at the same time they also go through internally. There is a defined review process for how this happens, which is extensive, and takes a lot of time. And sometimes we approve a complete standard. Sometimes we approve a standard with some comments or only a partial standard from the CDRH perspective.

Q&A / Discussion

Could you also speak a little bit to FDA's approach or FDA's list of, you know, what is called the FDA recognized standards. And speak a little bit about how many of nanotechnology specific standards are on the list and how do standards actually get on to the list and perhaps what is the value of having standards on a regulated recognized list of standards

>> Anil Patri: So they're all approved standards, and then there are two from ASTM and two from ISO. But we constantly review and then approve more standards. So if CDRH approves a standard or recognizes, I'm sorry, not approving a standard, recognizes a standard, then industry can use that standard, and then come with an application. That process becomes much faster and easier because they used a recognized standard that they already went through.

But FDA is a very complex agency, as you know, and each center has a different perspective on standards. For example, the Center for Drugs works very closely with the United States Pharmacopoeia, and they have monographs and standards that CDER uses, for example, generic drug applications and approvals. So there is a pathway as to how those standards are used for drug-related admission. At the same time, other centers also actively participate and then, if there are standards that are recognized and it is easier both for us because we understand what was done or what test method was used by industry to come up with a submission and approve a submission.

Closing comments



Shaun Clancy
Evonik Corp.



Stacey Harper
Oregon State University



Anil Patri
Food and Drug Administration

>>Ajit Jillavenkatesa: Thank you very much. Also, recognizing that we're almost about 8 minutes after noon here on the East Coast of the United States, and we were planning this as a one-hour workshop or webinar, I would like to try to wrap things together. And I was wondering, as a last round amongst our panelists, if you had any closing observations or thoughts. So whoever wants to get started.

>> Stacey Harper: I'll go ahead and start. I think a standards campaign, you know, going and touring the country and promoting standards, is probably a really worthwhile effort, and we have enough people engaged in standards that it could be a very distributed effort, but high-impact if we get people engaged. With that, I also wanted to see if we're able, Rhema [NNCO contract staff] if I can send you some contact information for anybody who is on the call or who signed up for the webinar to join ASTM or ISO or the Nanotechnology Working Group. If I send that information to you, can you send that out to the workshop participants or the participants today?

Closing comments



Shaun Clancy
Evonik Corp.



Stacey Harper
Oregon State University



Anil Patri
Food and Drug Administration

>> Ajit Jillavenkatesa: Yes, Stacey, we can always send that information to Rhema, and that's a good reminder also that people should not consider the questions closed. If anyone has follow-up questions, they should actually reach out to any of the NNCO staff through www.nano.gov, and they'll be sure to make sure questions get to us and we'll post answers to the questions. Shaun, any closing thoughts?

>> Shaun Clancy: I'll just reiterate -- like early comments about participation--more the merrier.

Closing comments



Shaun Clancy
Evonik Corp.



Stacey Harper
Oregon State University



Anil Patri
Food and Drug Administration

>> Ajit Jillavenkatesa: And Anil, the last word.

>> Anil Patri: Participation is very important. We encourage people with expertise to participate in these activities.
Thank you.

>> Ajit Jillavenkatesa: Folks, once again my thanks to our panelists, to our colleagues over at the National Nanotechnology Coordination Office for pulling together the logistics, and perhaps most importantly thank to all of you, the webinar participants, for joining us in this conversation. As you would have seen, there is a lot of enthusiasm for standards development, and as Stacey noted, it's really a very satisfying and fun group of people. So the more the merrier and we look forward to having some new participants. And please do not hesitate to let us know if you have any follow-up questions, we'll do our best to get back to you with answers.

Thank you again and I'll turn the microphone back to either Treye or our colleagues over at the National Nanotechnology Coordination Office.

Closing comments



Shaun Clancy
Evonik Corp.



Stacey Harper
Oregon State University



Anil Patri
Food and Drug Administration

>>Treye Thomas: Ajit, this is Treye. I just also want to thank all of our panelists, Shaun, Anil, and Stacey. Thank you for providing us with a really great, I think, and diverse, perspective on voluntary standards, hearing, again, the benefits, improving data quality, and some of the challenges, how to increase awareness of the available standards, the needs, and the availability of standards to our stakeholders.

Also, I want to thank the NNCO contract staff Rhema and Kristin, for your help and support, and to you, Ajit, and Dave at NIST, thank you. This has been very timely. And hopefully an important topic. Again, I just want to reiterate, Ajit, what you said. For those who are participating in the webinar, please feel free to reach out to us through www.nano.gov to provide feedback on this webinar, and if you have other ideas, if there's more information, perhaps we can have a follow-up on this area of voluntary standards. Again, it's such an important area, and there's still a wide range of issues that can be covered. So please let us know if you would like to learn more about that, or if there are additional webinar topics. As I mentioned earlier, this is our opportunity to engage with stakeholders. So we certainly would like to hear from you. With that, NNCO, do you have any last-minute comments?

>>Rhema Bjorkland [NNCO contract staff]: Thank you all very much for joining. Thanks to the panel. Have a wonderful day.