Meeting Report: Measuring the Impact of Voluntary Consensus Standards on Human Health and Safety

A Virtual Workshop via Zoom

Thursday, October 28, 2021
11:00am – 4:00pm Eastern

Hosted by the American National Standards Institute (ANSI)
in partnership with Underwriters Laboratories Inc. (UL) and the U.S. Consumer Product Safety Commission (CPSC)

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Executive Summary

The American National Standards Institute (ANSI), in partnership with Underwriters Laboratories (UL) and the U.S. Consumer Product Safety Commission (CPSC), brought the standardization community together to share best practices and methodologies related to measuring the impact of voluntary consensus standards on human health and safety. The goal was to initiate a dialogue, build upon existing work, and fuel future collaboration to develop common measurement methodologies.

ANSI president and CEO, Joe Bhatia, opened the workshop. He noted that much has been written about the economic impact of standards but there's less data on how to empirically measure the benefits that standards bring to health and safety. The discussions begun today will lead to more responsive standards development, by

providing objective evidence to support the public-private partnership that drives the adoption and use of voluntary standards and benefits the consumer.

Laurie E. Locascio, Ph.D., vice president for research, University of Maryland, and President Biden's nominee to be the next director of the National Institute of Standards and Technology (NIST), provided a keynote address. She provided numerous examples of the ways in which standards bring health, safety, and environmental benefits to our everyday lives, how they facilitate trade, and accelerate innovation.

Session one set the stage for the day's discussions with presentations on the use of data; the economic and business cases for measuring standards' impact on health and safety; a case study on the safety, performance, and effectiveness of medical electrical equipment standards; and case studies on occupational health and safety management systems standards and the use of leading indicators in standards. Key points included:

- UL Standards launched an initiative in March 2021 to identify effective ways to measure the impact of UL and UL of Canada (ULC) standards. UL found there is limited comprehensiveness in available injury data on consumer product incidents in the United States. Incident rates that are tied to the number of products in the marketplace are a better measure than raw incident counts. Data limitations make it difficult to establish a cause and effect relationship between the publication of a standard and injury reduction. UL Standards has some ideas for how to overcome these data limitations and will be continuing this study into 2022.

- The U.S. Environmental Protection Agency (EPA) does benefit-cost analysis (BCA) for its environmental health and safety regulations and policies. It uses two valuation methods: willingness to pay (WTP) and cost of illness (COI). EPA tends to think about human health improvements in terms of mortality risk reductions and morbidity risk reductions. Economists estimate the values that people place upon reducing risk of certain adverse health outcomes, and what people are willing to pay to reduce their risk of these outcomes.

- In May 2021, the CSA Group initiated a standards utilization and impact project to obtain repeatable, measurable data on how CSA standards promote social good, enhance the lives of Canadians, and benefit the world around us. They are currently focused on 321 CSA standards in the gas and healthcare sectors. After looking at who uses its standards in government and the private sector, and how they're being used, CSA plans to measure the impact of the standards on health, safety, and the environment, as well as the economic impacts. The project continues into 2022 and CSA hopes to develop trend data over time and expand the project to other sectors and to all CSA standards.

- The Association for the Advancement of Medical Instrumentation (AAMI) supports the development of the IEC 60601 series of standards which provide general and particular requirements for the basic safety and essential performance of medical electrical equipment. Assessing conformity to IEC 60601 is an important element of establishing the claim of safety and effectiveness in medical electrical device premarket review by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). FDA CDRH total standards lifecycle management promotes the use of voluntary consensus standards in the regulatory process through standards development participation, standards recognition, and standards conformity assessment.

- The American Society of Safety Professionals (ASSP) has issued a peer-reviewed report on the value of implementing occupational health and safety management systems (OHSMS) standards, in particular the ISO 45001 and ASSP Z10 standards. ASSP compiled the information via a literature review, data search, and member interviews, and believes it makes a solid case for OHSMS. In addition, ASSP's Z16 committee is working to create leading indicators, (safety and health metrics and performance measures) which can be used to prevent injuries before they happen, reduce costs, and improve occupational safety and health (OSH) performance and worker participation in OSH initiatives.

Session two further developed the themes raised during the morning with a moderated panel discussion featuring representatives of government, standards developing organizations (SDOs), the workplace, consumers, and manufacturers. Key points from organizations not represented in the morning session included:

- The Association of Home Appliance Manufacturers (AHAM) uses a special engineering flowchart to tailor standards proposals on technical aspects that went wrong (lagging indicators such as recalls, incidents) or could go wrong. It looks at new technology entering the marketplace and having multiple paths for compliance. In one example, CPSC found that incidents dropped significantly after AHAM worked with UL to introduce fire containment requirements in a UL standard for electric clothes dryers.

- Compliance Program Services, LLC, supports using incident data to improve consumer product designs and standards and to help prevent injuries and incidents. Types of data include: customer service call center data, product safety claims data, and retail returns data.

- The International Safety Equipment Association (ISEA) works to ensure that performance standards for safety equipment products are adopted by reference into regulation. ISEA also has attempted to quantify the economic impact of the safety equipment industry by measuring the number of jobs created. In addition, ISEA has measured the total number of employees in the U.S. workforce who are protected by standardized safety equipment. ISEA now has data at the U.S. federal, state, and local level by broad sector. It plans to replicate this data year after year with the goal of producing trend lines as new safety standards are promulgated or adopted into regulation to see how adoption of safety equipment changes over time.

Questions raised during the ensuing panel discussion included:

- Why it is important to measure the impact of voluntary standards on health and safety?
- How will information about the impact of voluntary standards be used?
- How do we scope/define this problem?
- What data would you like to use, but you don't have access to?
- What are some sources of international data?
- What are some leading indicators or progress markers?
- How can we use utilization and impact data to improve the quality of consensus standards?
- What are some first steps after the meeting that we can take?

A session with questions from the audience rounded out the day. The possibility of doing a follow-up event in a year's time was raised.

The meeting brought together a diverse group of speakers representing trade associations and professional societies, standards developing organizations, government regulators, and consumers. There was consensus that this is a complex and extremely important topic that needs to be addressed going forward. Whatever the result of a specific impact study, we need to be careful about how we use that information because we are in an environment of miscommunication and disinformation. We need to make sure that we have the right kind of impact story or data for the right audience. There are different kinds of standards: test methods, product standards, process standards, management system standards, etc. There are also a wide variety of effects, from injuries to chronic health outcomes. All of this complicates the overall landscape and how to approach this subject. We need to scope this into one or a few efforts that will allow us to take some concrete steps forward. In addition to this report, that might include some additional deliverables. A survey has been sent to audience members to see who might be willing to participate in follow-up meetings and activities.

Meeting Materials

Throughout this meeting report, speaker remarks are abbreviated and summarized to highlight key points. The meeting was recorded for those who wish to hear comments in full.
- Access the meeting recording.
- Access the master slide deck and complete set of meeting presentations. Individual presentation links also appear in this report alongside the name of the speaker.
- Access the meeting agenda and speaker biographies.

Welcome

- Joe Bhatia, President and CEO, American National Standards Institute (ANSI)

Mr. Bhatia welcomed participants. For more than a century, ANSI has been bringing diverse stakeholders together to address complex issues that cross multiple industries. ANSI's role as coordinator of the U.S. standards and conformity assessment system has provided it with unique perspectives into the business case of standards-setting. Much has been written about the economic impact of standards but there's much less data about how to empirically measure those aspects that help our families, friends, neighbors and colleagues live healthier, safer, and better lives. Today's workshop launches an important exploration on how to best quantify the health and safety impacts of voluntary consensus standards (VCS). Having the tools to measure impact will help us clearly see the effects of our efforts, so that we can reinforce what is working and change what is not.

The idea for today's event originated during a conversation between representatives of CPSC and UL. Both organizations were devoting time and resources to evaluate how and why the health and safety aspects of standardization are important. They knew that the standards developing organizations (SDOs) were considering the topic, and that other federal agencies, besides CPSC, are also interested in the results. To broaden participation, ANSI agreed to hold a forum that would bring together all the interested stakeholders. Representatives from SDOs, federal agencies, consumers, and manufacturers will share their perspectives during this morning's presentations and this afternoon's panel discussion. The open dialogue will be enhanced by active information sharing and participation. The work we do together will lead to more responsive standards development, by providing objective evidence to support the public-private partnership that drives the adoption and use of voluntary standards and benefits the consumer.

Mr. Bhatia introduced the keynote speaker, Dr. Laurie Locascio, vice president of research at the University of Maryland who has been nominated by President Biden to serve as the next director of the National Institute of Standards and Technology (NIST). Dr. Locascio previously spent three decades at NIST, most recently as acting principal deputy director and associate director responsible for leading the internal scientific research and laboratory programs across two campuses in Gaithersburg, Maryland, and Boulder, Colorado.

Keynote Address

- Laurie E. Locascio, Ph.D., Vice President for Research, University of Maryland

Dr. Locascio thanked ANSI, UL, and CPSC for putting together a meeting on this important topic of voluntary consensus standards related to human health and safety. She looks forward to hearing the presentations regarding the metrics to measure the impact of standards on our health and safety, and the panel discussion with leaders representing government, SDOs, industry, and consumers to hear their perspectives on this issue. She has had the opportunity to work with many in the community in her previous roles at NIST, and she welcomes the opportunity

to do so again if confirmed as the next NIST director. If confirmed by the Senate, she will be following in the footsteps of some wonderful people who she admires greatly: Willie May, Pat Gallagher, Arati Prabhakar, Bill Jeffrey, and Hratch Semerjian. Many of them are well known within the ANSI community. Today, she will speak from her personal perspective as a consumer, but also from her experience at NIST in the voluntary standards arena.

Every day we benefit from standards that have been developed through voluntary consensus processes, without ever hearing the word standard. Our small electronics and large appliances, the features in our cars that make driving less of a chore, our children's toys, and our grandparents' medical equipment, are all made better because of consensus standards. Yet the young mother, the teen with the cell phone, the person in the nursing home, none of them realize that there are sometimes hundreds of world-renowned experts behind the development of that new recommendation or new legal requirement that makes a valued product or feature reliable, safe, or interoperable.

The standards developed by voluntary consensus standards organizations are responsive to the events in our lives every day. As an emerging virus became the COVID-19 global pandemic, the Association of Home Appliance Manufacturers (AHAM) developed much needed methods to clean face masks. And the International Organization for Standardization (ISO) quickly drafted through online meetings a new standard to support the rapid development of new lung ventilators. ASTM international (ASTM) convened experts to draft its standards for face coverings. And, just as importantly, the community has stepped up to make these standards accessible to those who need them the most. Many methods and standards developed in these and other groups have guided us through the pandemic as safely as possible.

A maturing technology, artificial intelligence (AI), is everywhere in our everyday lives. It is a dominant technology solution and the topic of conversation across the business landscape. And standards organizations like the Association for the Advancement of Medical Instrumentation (AAMI) are keeping up with this changing world by developing guidance documents and standards for artificial intelligence and machine learning, so that they can improve medical technology, while keeping it safe and secure. Similarly, UL is developing standards for the evaluation of autonomous products. And U.S. contributions to, and efforts in, ISO and the International Electrotechnical Commission (IEC) are helping to develop horizontal standards for AI.

The intense fires, storms, and floods of 2021 have painfully demonstrated the tremendous health and safety impacts of climate change. The U.S. Environmental Protection Agency (EPA) is working to develop standards and guidance to help us address this enormous challenge. And a no less impactful challenge on safe sleeping for newborns and infants was recently adopted as guidance for the CPSC. The Institute of Electrical and Electronics Engineers (IEEE), UL, and IEC are developing standards for the safety of batteries that power all of our home electronics while we work remotely.

Dr. Locascio explained that her professional roles have included scientist and engineer with a background in biomedical engineering and toxicology. At NIST, she had the opportunity to lead some of the earliest programs in bioscience and helped to permanently place that area of research, and related standards, in the NIST portfolio. While at NIST, she participated in and lead several standards committees and working groups related to public health and safety. In the aftermath of the anthrax attacks in Washington in the early 2000s, she was invited to be part of the group of government agencies, public health, and forensic science stakeholders to develop standards through ASTM for collecting suspected biological agents. She also had the opportunity to be U.S. chair and then international convener of the ISO/TC 229 nanotechnologies working group on the health, safety, and environmental impact of nanotechnologies. These opportunities gave her an inside look into the intricate development process that is behind both national and international standards.

Dr. Locascio observed that everyone here is aware that the standards process in the United States is not centralized but consensus-based, market-driven, led by the private sector, flexible, and adaptive. It's a living example of the strength of public-private partnerships where industry, government, academic experts, and users,

all come to the table equally to share knowledge and build out the best guidance based on the most advanced understanding of the applicable science and the field's technical capabilities and challenges. Standards developed in this way, by a sector's practitioners, are extremely effective in that they can be quickly adopted by those same practitioners. Direct experience with standards bodies has given Dr. Locascio a great deal of insight into international standards engagement and strategy, and the potential impact of all standards on our industries and on our economy.

When standards are adopted, they represent broad agreement on solutions. Broad adoption of a standard across an industry can translate into billions, even trillions, of dollars in trade across boundaries. It's important for us to be mindful of the significant negative impact when standards become technical barriers to trade. Standards can accelerate innovation because inventors and entrepreneurs can more quickly enter a manufacturing ecosystem, where the performance and safety expectations behind the product are clear because they have been defined by standards.

As economic competition around the globe heats up, more and more people are becoming more deeply aware of the foundational role of standards and the potential impact on industries, on communities, and on lives. As we contend with market and supply chain disruptions, it's important to stay focused on the goal of developing the best standards possible to support a thriving and robust economy. Our decentralized approach, our invitation to participation by all experts representing both the public and private sectors, is relatively unique compared with a top down approach used by many other countries. But this approach has also directly contributed to America's technological leadership during the past century.

Dr. Locascio remarked that in the group of international volunteers that she had the pleasure to convene, it was clear that some countries wanted to drive health and safety standards for their own national policies and politics. But, in that forum, with representation from across the globe, that approach did not win out. Through sound debate, despite the differing approaches to policy among those attending from around the world, sound science and technical merit won out.

Dr. Locascio noted that those gathered here today believe in the power of standards to propel society forward, address its greatest challenges, and protect us from harm. They do not have to be convinced of the importance of standards for preserving health and safety. Those who lead or participate in standards activities know that it's our responsibility to make sure that the best scientific and technical experts that the U.S. has to offer, which are often the best in the world, are at the table. And that perspectives from government, businesses large and small, as well as academic researchers, are heard. The international partnerships and technical and cultural understanding formed in the development of voluntary consensus standards helps to ensure the success of those very standards. In what may seem now an especially chaotic world, with new and ever bigger challenges and threats to our health and safety, involvement in the standards development process brings order and asserts direction where and when it is needed most.

Dr. Locascio thanked participants for their dedication to this vital work.

Session 1: Presentations

Session one set the stage for the day's discussions with presentations on the use of data; the economic and business cases for measuring standards' impact on health and safety; a case study on the safety, performance, and effectiveness of medical electrical equipment standards; and case studies on occupational health and safety management systems standards and the use of leading indicators in standards.

Moderator

- Scott Ayers, Voluntary Standards Specialist, U.S. Consumer Product Safety Commission (CPSC)

Scott Ayers explained that the purpose of today's meeting is to start a discussion on the impact of voluntary standards. The meeting has been divided into three parts. First, there are five short prepared presentations. Next these presentations will feed into a panel discussion. Finally, participants will answer questions from the audience. Mr. Ayers invited audience members to enter their questions into the chat at any time. Some questions may be answered during the first two parts of the meeting; others may be answered in a third part. Hopefully, today's meeting will interest participants in continuing this discussion in the future.

Mr. Ayers then introduced the speakers, invited each to deliver their presentation, and asked follow-up questions from the audience.

Presenters

- USE OF DATA **Presentation Link**
  Casey Granata, Senior Project Manager, Underwriters Laboratories Inc. (UL Inc.)

Casey Granata provided background on UL's standards development activity. In March of 2021 UL Standards launched an initiative to identify effective ways to measure the impact of UL and UL of Canada (ULC) standards, and other published content focused on prevention of injuries and deaths. During 2021, the initiative focused on three specific standards:

- ANSI/CAN/UL 325, ANSI/CAN/UL Standard for Door, Drapery, Gate, Louver, and Window Operators and Systems
- ANSI/UL 859, Standard for Household Electric Personal Grooming Appliances
- ANSI/CAN/UL 2272, Standard for Electrical Systems for Personal E-Mobility Devices ("hover boards")

UL Standards followed a case study approach utilizing data from CPSC's Clearinghouse and National Electronic Injury Surveillance System (NEISS).

UL found three limitations with the available outcome data:

1. **Limited coverage of adverse incidents.** This relates to the limited comprehensiveness of injury data on consumer product incidents impacting health and safety that are available in the United States through CPSC and NEISS. NEISS provides a nationally representative probability sample from hospital emergency department (ER) visits associated with consumer product injuries. This does not cover immediate care for injuries arising from consumer product incidents, including primary care physicians, urgent care facilities, independent medical clinics, and hospitalizations, unless the patient started in the ER before being admitted. Minor injuries are not captured in NEISS. The CPSC national injury information Clearinghouse also includes death certificates and medical examiner reports involving consumer products provided by CPSC.
2. **Limited usefulness of incident counts**. Raw counts can often be deceiving. Counts of incidents without an understanding of the number of products in the marketplace makes reliance on changes to these counts questionable at best for understanding the safety and health impacts of a voluntary product safety standard. Incident rates (i.e., number of incidents per number of products in the market) are a far superior measure for determining the risk of injury from a consumer product. As a hypothetical example, let's say product x experiences a doubling in the number of incidents in a single year. It may appear that product x is offering up a greater risk. However, let's say that product x has a great sales year and the number of units of product x in the market has quadrupled. The incident rate has actually dropped by 50% indicating a reduction in the risk injury. From a raw count, we would never see the incident rate.
3. **Weaknesses in inferring effects**. UL was unable to demonstrate cause and effect. With no data to illuminate the process by which a voluntary standard affects the occurrence of injuries and a consumer product, it often becomes difficult to make a credible conclusion of the cause and effect relationship

between the publication of a standard and any reduction of injuries from effective products that may subsequently occur.

Mr. Granata explained that these three major limitations made it more difficult to make a confident assessment of the impact of these three standards. He went on to describe how UL overcame these limitations and what further information could also be helpful if it was readily available.

1. **Limited coverage of adverse incidents**. Use all available incident data including "non- injury" incidents as reported through the Clearinghouse. UL is in search of more adverse data that could be readily available from additional sources. NEISS has a purpose, but it's not broad enough to provide the data needed for the case study.
2. **Limited usefulness of incident counts**. Include proportion of incidents statistics. Seek industry participation in the future to get market data on the number of products sold. Without really knowing how many products are out there, the raw data can be misleading.
3. **Weaknesses in inferring cause and effect**. Include additional formative assessment measures designed to shed light on the process by which standards eventually affect the design and construction of products in the market. Currently, UL has no data that catches the process by which a revision of a standard affects performance of products on the market.

UL Standards will be continuing this case study into 2022, and will be focused on overcoming these data limitations. This is a multi-year journey to find more efficient ways to measure the impact of published content.

Q&A:

What data would you like to use but you don't have access to?
We would love to know the number of products on the market, so that we can measure based on incidents that occur rather than the raw counts of data. We would like to get involved with industry in various ways to be able to readily obtain this kind of data.

What about data that you don't know how to gather?
If we don't know how to gather it, it's really hard to measure the actual impact of the data. For example, if we want to look at the incident counts. We would love to get involved with different associations that track that kind of data. From what we found, it is not easily available to identify the number of products that are on the market. That makes our case study approach a lot more difficult for us.

- ECONOMIC CASE **Presentation Link**
  Chris Dockins, Senior Economist, U.S. Environmental Protection Agency (EPA)

Chris Dawkins explained that the National Center for Environmental Economics (NCEE) performs research and economic analysis for the rules, regulations, and policies of the EPA. He discussed the approaches used at EPA for benefit-cost analysis (BCA) for environmental health and safety regulations and policies. There are two types of valuation methods: willingness to pay (WTP) and cost of illness (COI). EPA tends to think about human health improvements in terms of mortality risk reductions and morbidity risk reductions. Economists estimate the values that people place upon reducing risk of certain adverse health outcomes, and what people are willing to pay to reduce their risk of these outcomes. There are four components of WTP: avoid medical expenses, avoid loss of productive time, avoid defensive expenditures (i.e., to protect oneself from whatever the risks are), and avoid pain, suffering, and discomfort. WTP is a comprehensive measure that economists seek to estimate for BCA. Premature mortality is usually expressed as the value of a statistical life (VSL). Morbidity is usually expressed as the value of a statistical case avoided.

In terms of where WTP values come from, economists can't turn to market prices directly for that. Instead, they look at related markets where people undertake some action that reveals their preference for risk reduction. For example, averting (defensive) behaviors such as goods that people buy in the marketplace that might have some

degree of risk reduction built into them. A major source for WTP values is hedonic wage (or wage-risk) studies. The idea is that wages or salary are driven by many factors, one of which is the risks faced in the workplace, e.g., the risk of fatal injury and the risk of non-fatal injury. This provides insight into people's willingness to accept compensation for certain higher risks and is widely used for VSL estimates by a lot of federal agencies. Another source is hypothetical markets where people's stated preference for risk reduction is captured via a survey.

WTP is what economists engaged in BCA really would like to focus on but it's not always possible to get WTP values through the methods described above. A more limited method is COI which is usually composed of two factors: medical expenses avoided from a given injury, and the value of lost time. The value of lost time would include absence or reduced productivity from work. In principle, it would also include the lost value of household production, e.g., taking care of your home, children, etc. Lost leisure time due to injury or illness also has value to people but is often not included as it's difficult to estimate. COI does not include pain, suffering, and discomfort, and people's willingness to pay to avoid that.

A lot of the estimates in published studies in economics journals and elsewhere often have to be adapted. The term benefit transfer refers to the need to adapt values systematically because they might differ from the population of interest in an analysis, the severity of the illness, timing differences, etc. For premature mortality, most agencies have clear guidance on what VSL to use (EPA's value is around $10 million). This is consistent with guidance from the Office of Management and Budget (OMB) that applies across federal agencies. For other illnesses, for the kinds of things that EPA addresses, relatively few use WTP estimates, in part because all illnesses are somewhat unique in duration and severity and the frequency of symptoms and their impact on health. It's expensive to estimate WTP for every single illness so frequently they use COI. WTP and COI may be additive under certain conditions. Costs and benefits from the EPA's Clean Air Act provides an example of this. It is very common in analyses for EPA that they are dominated by the value of reduced premature mortality. This makes sense as it is the most serious possible health risk and the VSL is a well-established figure used.

Q&A

The presentation seems grounded in the model of for-profit healthcare insurance. Have you given any thought to how you would modify this approach to evaluating risks in a universal "Medicare-for-All" healthcare system?
Some of the survey work done has been in collaboration with European researchers where there's a very different health insurance context in those countries. In the U.S., people are very often thinking about their well-being and the financial impact. The WTP values will often reflect that here in the U.S., and much less so elsewhere where you have public health insurance. If you elicited WTP in that context, it would not reflect the healthcare costs. You'd have to do it carefully but WTP would probably be additive to the savings in healthcare expenditures. Taken together, those might be a better estimate of the benefits.

How does the WTP and evaluating risk approach relate to the impact of voluntary consensus standards on human safety and health?
The approach that we're taking at EPA for BCA is directly applicable if we can overcome some of the data challenges that Casey pointed out. We can then say, given the adoption of this standard, here's the change in expected cases of injuries or premature mortality. The tools are directly applicable once we are able to project the expected implications of the standard for changes in health risks.

You mentioned that valuation estimates often need to be adapted for the BCA. Can you give an example?
Using the VSL, a lot of the values come from workplace studies where there are fatal accidents, immediate or within a year. A lot of the risks in EPA analyses are cancer risks where there can be latency time between exposure and when the cancer occurs. So, we have to account for timing differences.

- BUSINESS CASE **Presentation Link**
  Adi Iyer, Manager of Government Relations, CSA Group

Adi Iyer provided background on CSA Group and its standards development activity which is committed to social good, enhancing the lives of Canadians, and benefitting the world around us. CSA has undertaken a standards utilization and impact project to obtain repeatable, measurable data on how CSA standards are achieving these goals. They are currently focused on CSA standards in the gas and healthcare sectors. That amounts to about 321 standards or just over 10% of CSA's total standards repository. CSA is looking at who uses these standards in government and in the private sector – what drives use of the standards and are they being referenced in government documents (federal, provincial, territorial, municipal)? Once CSA knows who uses its standards and how they're being used, it will measure the impact of the standards on health, safety, and the environment, as well as the economic impacts. That will help answer the mission fulfillment question on enhancing the lives of Canadians. The very last step is to track data and how it trends over time. Once CSA completes this exercise for its gas and healthcare standards, it hopes to extend the project to other sectors and to all CSA standards.

CSA has a variety of stakeholders and so the impact of standards on them will vary. Questions that arise include: Are we making it easier to choose and compare products by increasing interoperability? Are we making products safer and more durable for consumers? Are we providing certainty in fields such as construction and manufacturing? Are we helping government legislators and regulators when they begin to think about mandatory requirements? How do our environmental standards help stakeholders reach their environmental stewardship goals? Do they help to reduce greenhouse gas emissions and pollutants? CSA is also interested in measuring standards' impact at the individual level. How does a safety standard affect my child when she goes to the playground?

From an organizational perspective, knowing where CSA standards are utilized and what impact they're having will help CSA allocate resources to increase utilization and calibrate the standards to make them even more impactful. One of the data points that CSA is seeking is the time lapse between the publication of a standard and the first use of that standard. If the time is reasonably short, that's fine. However, if it is a long period of time, that may warrant investigation into why that is and perhaps committing additional resources for advocacy and government relations. Maybe the standard needs adjustment to make it a bit more relevant. Knowing how CSA standards are used by internal stakeholders (members, Board, and staff) will help the organization to improve its processes, stakeholder engagement, and advocacy. The project will also help to recognize, re-focus, and re-energize the work of the individuals that serve the gas and healthcare sectors. More importantly, it will spell out the benefits that they're helping deliver to the world around them through standards. External stakeholder utilization and impact measurement provides evidence of the value of standards. This is important to CSA and should also be important to others who serve similar stakeholders. Ultimately, understanding standards' utilization and impact will help to guide CSA's legacy for the next century and beyond.

CSA is currently going through the results of the utilization phase (phase I) of the project which informs the later stages. At the end of the project, CSA is hoping to be able to make attributable statements. For example, since its first use in 1974 and its incorporation by reference into regulation, a standard on playground equipment and surfacing has helped to reduce playground injuries by a certain percentage. Phase II, measuring the impact, will start in November. By the end of March 2022, CSA hopes to have devised a method to track utilization and impact on an annual basis so that it can build a trend over time. After this limited look at the 321 standards in the gas and healthcare sectors, CSA will expand the project to its other standards. CSA looks forward to sharing the results of this work sometime in the future.

Q&A

Do you expect that knowing the impact of a standard will help CSA choose standard development priorities?

In a way, yes. If there is a standard that we worked on and it hasn't been used, if we've reached out to stakeholders and they don't see as much purpose for that standard anymore, if it isn't having the intended impacts, then we might take another look at the standard to see if it can perhaps be made more impactful.

How does CSA propose to collect so much detailed data from so many individual users?
For the utilization phase, we contracted out to a reputable consulting firm. The data points are vast and diverse and we know what we are looking for. As we look at impact, it will be a large sample size as well. We've scoured all the federal, provincial, and municipal government websites, as well as large utilities, industry associations, and nonprofits that may be using our standards. We've used artificial intelligence and traditional surveys.

Can you share your timeline for the overall project?
The project kicked off in May. We went through the RFP and scoping process. The consultant had eight to ten weeks to deliver the first phase of the project. The second phase we're hoping to complete by the end of January. And in February/March, we hope to devise a method to collect data from phase one and phase two on a continuous, annual basis. So, between now and the end of the fiscal year we hope to finish the project.

Will the study be extended to other sectors?
Yes. We wanted to test this out in a limited way with just gas and healthcare and then extend it out to other sectors if we are happy with our methodology and scope and if we are getting the data points that we hope to get.

- CASE STUDY: SAFETY, PERFORMANCE, AND EFFECTIVENESS OF MEDICAL ELECTRICAL EQUIPMENT STANDARDS **Presentation Link**
  Amanda Benedict, Vice President, Standards, Association for the Advancement of Medical Instrumentation (AAMI)
  Rui (Ray) Peng, General Engineer/Senior Standards Advisor, U.S. Food and Drug Administration (FDA)

The two-part presentation on *Getting from Basic Safety and Essential Performance to Safety and Effectiveness* was kicked off by Amanda Benedict of AAMI who gave an overview of the IEC 60601 series of standards on medical electrical equipment: what it is, how it came to be, who's responsible for developing and maintaining it, and why it is important to the medical electrical equipment industry and regulators.

The IEC 60601 standards provide general and particular requirements for the basic safety and essential performance of medical electrical equipment. In this context, medical electrical equipment are devices that are powered with a plug or a battery and come in contact with the patient, or are involved in the transfer of energy or detection to or from the patient. The intent of this series is to ensure that there is no single failure, whether it's mechanical, electrical, or functional in origin, that poses unacceptable risk to patients or the operators of the equipment. The foundational document is IEC 60601-1, general requirements, which was originally published in 1977 and has been continuously reviewed and updated over the years. The designation was changed to "dash one" in 1988 with the second edition, and the third edition which is the current edition was published in 2005. This edition represents a restructuring and strengthening of the risk management content requirements and the addition of the concept of essential performance.

The series also includes 7 collateral standards which are designated "dash one, dash x", and about 70 plus particular standards which are designated "dash two, dash x." There are some that are ventilator equipment which are ISO/IEC 80601-2-x. The collateral standards are horizontal standards as they apply across medical electrical equipment types. They address hazard concepts such as usability, electromagnetic compatibility, environmentally conscious design, etc. The particular standards modify/tailor the requirements of the collateral and general standards and apply to specific equipment types such as noninvasive blood pressure monitors, internal pacemakers with internal power sources and so on. Where there are applicable particular standards, their requirements take precedence over the general or collateral standards.

This series of standards is developed and maintained under IEC Technical Committee (TC) 62 which is electrical equipment in medical practice. This TC has four subcommittees (SCs). SC 62A is responsible for the horizontal standards, so the general and collateral standards. SC 62B-D are responsible for the particular standards. The structure and scope of the TC and SCs is left deliberately flexible to accommodate future evolutions of medical electrical equipment. AAMI administers the Secretariat for SCs 62A and B and the U.S. TAG to TC 62 and SCs 62 A and D. Hae Choe and Ladan Bulookbashi at AAMI serve as secretary for these two SCs, respectively.

The IEC 60601 series of standards is recognized around the world. They're not only crucial resources for industry for the design and development of medical electrical equipment, but they're also necessary for regulatory compliance in many markets around the world.

Ray Peng represents FDA's Center for Devices and Radiological Health (CDRH) in various standards committees including the U.S. TAG for IEC/TC 62. He reviewed how the 60601 series fits into FDA premarket review of medical device safety and effectiveness. The 60601 series is a large and complex body of work, often not well understood by many stakeholders in the medical device sector.

When clinicians think about safety and effectiveness, they focus on patient outcomes, positive and negative, and the result of intended use of the device. These principles are the basis of IEC 60601. CDRH as an institution is known worldwide for its ability to weigh and balance these issues. There are a great many engineering aspects of the typical medical device design that bear on safety and performance. These need to be examined during premarket review. A manufacturer must provide evidence obtained through testing that a device achieves the performance necessary to fulfill the intended use. Nonclinical bench testing is done to confirm all relevant aspects of engineering performance. There is usually also some clinical testing performed in the real world, or simulated use conditions. Assessing conformity to IEC 60601 is an important element of establishing the claim of safety and effectiveness in premarket review. Dr. Peng provided an example of a recent premarket submission for an airway pressure monitor where FDA's review resulted in the manufacturer revisiting its risk analysis and doing a significant redesign.

FDA CDRH uses consensus standards for its regulatory needs. Its standards program has three major pillars: standards development participation, standards recognition, and standards conformity assessment. FDA liaisons bring a regulatory perspective into the standards development phase early on. A lot of the standards published as a result of this level of participation can move into recognition discussion. Specialty Task Groups (STGs)—a key component of FDA's standards participation—include subject matter experts in regulatory policies and technical aspects from different offices across the Center.

Once standards are recognized, sponsors have the option to submit declaration of conformity to them, which may reduce testing data required in submission. Currently, FDA recognizes about 1400 standards. Through the promotion of conformity assessment, FDA is trying to enhance the use of declaration of conformity in device submissions. The FDA's Accreditation Scheme for Conformity Assessment (ASCA) pilot is intended to help with this initiative. Through this pilot, FDA wants to enhance the confidence in medical device testing and promote consistency and predictability in premarket review. It also wants to encourage effective use of resources and support international harmonization.

Use of voluntary standards in CDRH covers the total product lifecycle. On the premarket side, standards have been cited in all types of submissions. The use of standards is voluntary unless incorporated by reference into FDA regulations and then it becomes part of the mandatory requirement. Standards can be used with a declaration of conformity (only for recognized standards), for general use (for any type of standard, recognized or not), or both. In terms of post-market, FDA has seen standards being used for root cause analysis for medical device reporting (MDRs) and for risk mitigation.

In summary, the IEC 60601 series provides a good evaluation protocol for medical electric devices' basic safety and essential performance. Regulators benefit from the use of standards to review devices' safety and effectiveness. And FDA and CDRH total standards lifecycle management promotes the use of voluntary consensus standards in the regulatory process.

Q&A

IEC 60601 is a huge and complex series of standards. What resources exist to help manufacturers and regulators identify and use the applicable parts?

(Amanda) From an industry perspective, Ray mentioned that there's the AAMI consensus report CR500 which was a basic introduction to the IEC 60601 series that's intended to explain the importance of the series and clarify how to navigate and implement the parts of the series. There's also guidance documents or technical reports that have been developed under IEC/SC 62A that help with interpreting and applying the requirements of the series. Those are designated IEC TR 60601-4-x. These are geared more towards industry.

(Ray) FDA started the ASCA pilot and has published several final guidance documents on conformity assessment, one being on basic safety and essential performance that was published in September of last year. It's mainly for the ASCA program utilization, for testing labs, and the sponsors who are willing to participate.

Can you clarify how the FDA gathers data on standards recognition, assessments, and clinical performance?

(Ray) For the standards recognition, FDA is pretty open. We have several pathways for this information to be fed back. One is our liaisons who are sitting in the SDO working groups and developing new standards projects. A lot of times the relevance and importance to the Center is already justified because these were already prioritized. These newer standards can be brought back by the standards liaisons for recognition. Internal reviewers provide another means when they see the submissions. We also have an official recognition request pathway where anyone in the standards community can send in a request. By law we must respond to those within 60 days whether we will recognize the standard or not. As for the utilization of data, we had done data mining to see which standards are being used and which are cited most frequently.

How do you appropriately use declaration of conformity when using recognized standards?

(Ray) When you look at the 2018 appropriate use of consensus standards guidance that FDA published, we identify several scenarios for declaration of conformity use. It varies depending on the types of standards being used. For the standards that contain a very clear testing method and clear acceptance criteria, you can do a one-page declaration of conformity and you don't necessarily need supporting documentation. But the supporting documentation increases when the standards have fewer details. We want sponsors to understand that use of voluntary standards only fulfills part of the premarket requirement. We encourage them to look at the relevant guidance and regulations and also reach out to the corresponding review divisions for any additional regulatory requirements.

- CASE STUDY: OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEMS STANDARDS AND THE USE OF LEADING INDICATORS IN STANDARDS **Presentation Link**
  Tim Fisher, Director of Standards and Technical Services, American Society of Safety Professionals (ASSP)

Tim Fisher described studies that ASSP has done on the use of management systems standards and on leading and lagging indicators. ASSP hears a lot from stakeholders and occupational safety and health (OSH) professionals who ask: What's the point of standards? Can you prove they have value? Why should we use consensus standards when we have government regulations? This is something that ASSP has spent a lot of time on over the last three years in response to hundreds of inquiries from OSH professionals, engineers, and higher levels of management.

The first case study deals with occupational health and safety management systems (OHSMS) standards, in particular ISO 45001 standard and ASSP Z10. ASSP did an extensive report *The Return on Investment for Safety, Health, and Environmental (OSH) Management Programs*. Mr. Fisher invited people to contact him directly for a

copy of the report. He noted that ASSP wanted to show there are demonstrated, solid reasons to implement these systems. The report is a combination of anecdotal information and data that makes a good case. Around 10,000 copies of it have been given out. That was in response to some 500 objections to the standard. He noted that after the report was circulated not one organization said you didn't make the case. The response has been positive.

ASSP is working on another study now related to the return on investment. The U.S. Department of Labor (DOL) is doing a study on the value of standards for OHSMS including Z10 and ISO 45001. Hopefully, that will result in additional data and material that can be used. In September, the U.S. Mine Safety and Health Administration (MSHA) published a proposed rule on mobile equipment that cited the Z10 and ISO 45001 standards, and ASSP's report. They specifically said that ASSP was able to make the case that OHSMS standards and specifically Z10 and ISO 45001 make a difference. This is a good indicator of cooperation and collaboration between the private and the public sectors. ASSP would like to see more future public and private sector implementation of the standards to provide implementation data. The report has also been used at the global level where ASSP serves as the U.S. TAG administrator to ISO/TC 283 on occupational health and safety management which is responsible for ISO 45001. In general, health and safety management standards are continuing to grow and that's one of the reasons ASSP wants to show the value. The other big issue they are seeing is the measurement and definition of risk.

The second case study described by Mr. Fisher had to do with the use of leading indicators in standards. The ASSP Z16 committee, with about 60 organizations, is working to create leading indicators which can be used to improve OSH. Historically, the U.S. government regulatory framework is based on lagging indicators, e.g., the number of people injured. ASSP is working with its stakeholders to prevent these from happening. The Occupational Safety and Health Administration (OSHA) recognizes the value of leading indicators and the value of preventing safety incidents before they happen. Z16 is working to write standards and technical reports addressing safety and health metrics and performance measures. Key takeaways from ASSP's work with Z16 and leading indicators are: 1) prevent injuries and illnesses at companies and organizations, 2) reduce costs (both direct and indirect) associated with adverse events, 3) improve safety and health performance, and 4) increase worker participation in OSH initiatives. Getting the whole organization behind standards and standards development promotes better organizational performance and safety.

Q&A

Could you expand upon ASSP's methodology for gathering data on Z10, ISO 45001, and Z16?
We did three things: a literature search and a data search to see what data existed including in our own journal. We also did interviews with our members and looked at other sources. We compiled all that information into our report which was then peer reviewed by about 100 professionals, a lot of them from government and academia. Say what you want but that was our methodology and we think in produced a pretty solid paper.

In your paper, you have a lot of good anecdotal evidence-based information. But are you sure you've proven your case via the data? Are there more steps you can take to better back your contentions with the data?
It's a fair question. We make a very good anecdotal and evidence-based argument for the use of standards for OHSMS. Is our data completely adequate? No. What we're hoping is that we'll see more definitive data coming out of the Department of Labor effort. We are looking at doing some additional studies through our foundation perhaps down the road. There has been some good stuff done globally that doesn't necessarily equate to the U.S. There's still work to be done.

Session 2: Panel Discussion

Session two further developed the themes raised during the morning with a moderated panel discussion featuring representatives of government, standards developing organizations, the workplace, consumers, and manufacturers.

Moderator
David Wroth, Director, Data Science, Underwriters Laboratories Inc. (UL Inc.)

David Wroth welcomed participants to the afternoon session. He noted that the afternoon is intended to build on the morning presentations which provided a wide variety of points of view on how to measure the impact of voluntary standards and why this topic is important. The afternoon continues this conversation. Mr. Wroth then introduced the panelists.

Panelists
- Casey Granata, Senior Project Manager, Underwriters Laboratories Inc. (UL Inc.)
- Elise Owen, Standards Executive, U.S. Environmental Protection Agency (EPA)
- Doug Morton, Vice President, Government Relations, CSA Group
- Amanda Benedict, Vice President, Standards, Association for the Advancement of Medical Instrumentation (AAMI)
- Tim Fisher, Director of Standards and Technical Services, American Society of Safety Professionals (ASSP)
- Don Huber, Principal, Compliance Program Services LLC
- Randy Cooper, Vice President of Technical Operations & Standards, Association of Home Appliance Manufacturers (AHAM)
- Charles Johnson, President and CEO, International Safety Equipment Association (ISEA)

Mr. Wroth invited those speakers whose organizations were not represented in the morning session to make brief opening remarks.

- Randy Cooper, Vice President of Technical Operations & Standards, Association of Home Appliance Manufacturers (AHAM) **Presentation Link**

Randy Cooper provided a brief overview of AHAM, a trade association that is accredited as an SDO by ANSI for its performance standards of which there are 21 published. AHAM submits safety standards proposals to UL and CSA depending on the product, and it has submitted over 100 to date. Before it submits proposals to these other SDOs, AHAM uses a special engineering flowchart to focus on technical aspects of what went wrong or could go wrong that will help drive a consensus standard. For example, it looks at aspects that maybe had driven a recall or a field incident. It also looks at new technology that's entering the marketplace. AHAM focuses on having multiple paths for compliance including product requirements and test out clauses that help to drive innovation. It also reaches out to suppliers and other experts during development of a proposal. Mr. Cooper provided an example where AHAM worked with UL to propose fire containment requirements for electric clothes dryers. CPSC examined the number of fires in machines built before and after the fire containment requirements were put in place. It found that the number of incidents dropped from 2.5 incidents per year to .5 per year after the introduction of the fire containment requirements. This is a lagging indicator. AHAM has submitted additional proposals for dryers and is waiting for things to appear in the latest data. But at this point it really hasn't been able to find anything other than lagging indicators.

- Don Huber, Principal, Compliance Program Services LLC **Presentation Link**

Mr. Huber explained that his background includes 40 plus years in industry, consulting, and publishing that has primarily focused on product safety and quality. He started with Kenner Products back in 1980 and was with that organization, which later became part of Hasbro, for about 20 years. After that, he went to work for Evenflo, a baby products company, and was there for about 12 years. He then spent some time as a consultant with Deloitte and most recently he was director of product safety for Consumer Reports. He is now in business for himself and providing advice to clients around product safety and compliance. Today, he wants to talk about using incident data to inform standards development to improve the standards and to help prevent injuries and incidents. There are different types of data such as customer service call center data, product safety claims data, and retail returns

data. Companies can leverage this information to improve product designs, while SDOs can use this information to cause product designs to improve by strengthening the standards.

- Charles Johnson, President and CEO, International Safety Equipment Association (ISEA) **Presentation Link**

Chuck Johnson provided background information about ISEA, a trade association for safety equipment manufacturers, distributors, and testing laboratories. In addition to policy advocacy, ISEA is an ANSI-accredited standards developer and works to ensure that performance standards for safety products are adopted by reference in regulation. ISEA also provides a voice for the safety equipment industry in other SDOs that develop standards for or that utilize its products. Standards for test methods and predictive performance standards for safety equipment products are building blocks for safety management system standards and for regulation. Measuring the impact of these is important. Without predictive performance, there is a huge decrease in adoption of safety equipment in the field, in regulation, and in safety management systems. Providing minimum performance standards for safety equipment is a bedrock for the vocabulary of safety. ISEA measures the impact of safety equipment products to mitigate injury and illness. It also may measure the uptake of safety equipment into regulation or the number of workers protected. Mr. Johnson noted a number of standards that ISEA has developed for personal protective equipment (PPE) and body safety equipment. Recently, ISEA undertook an effort to quantify the economic impact of the safety equipment industry using the number of jobs created as a measure. However, ISEA's leadership felt that the economic impact of the industry was secondary to its impact on protection. So, ISEA also measured the total number of employees in the U.S. workforce who are protected by standardized safety equipment. ISEA now has data at the U.S. federal, state, and local level by broad sector. It plans to replicate this data year after year with the goal of producing trend lines as new safety standards are promulgated or adopted into regulation to see how adoption of safety equipment changes over time.

David Wroth noted that the intent of the panel discussion is to have an open dialogue on the topic of measuring the impact of voluntary standards. He invited the panelists to ask questions of each other and to challenge some of the viewpoints that might be put forward. He acknowledged some of the earlier comments that this is a difficult topic and then kicked off the conversation.

Why is it important to your organization to measure the impact of voluntary standards on health and safety?
(Doug) As my colleague, Adi, mentioned this morning, there's a variety of reasons that we're trying to measure the impact of standards in a fairly quantitative way. The importance of that project was reinforced by some of the other presentations. Casey talked about vulnerabilities in terms of where the data is coming from and how reliable it is, and Chris talked about the vagaries of data. I'd be interested in talking to Tim or having him comment on some of the things he mentioned this morning about leading and lagging indicators. I'm a big believer in those but even they have to be measured so that we can have effective metrics. So, I'd be interested to know from Tim how they plan to actually put metrics on those leading and lagging indicators. I can see from Chuck's presentation that he has a number of metrics and I'd also like to understand where those came from. One of the objectives coming out of this session is where do we go from here. Whether we represent SDOs, industry associations, or government, we all have a vested interest in standards that impact the lives of everyday people, whether they're consumers, manufacturers, hospital workers, etc. CSA would be happy to coordinate and work with other organizations to help advance how we view the impact of standards. We're all in this together. It's complicated, and the more people that get involved, the better.

(Amanda) AAMI was founded as a standards developing organization. We have a legacy that's more than half a century long supporting our stakeholder community by bringing groups together to develop standards for the safe and effective use of health technology. Standards are central to our mission and knowing the impact of the standards that we support, whether it's a qualitative or quantitative measure, helps us to assess how well we're delivering on our mission and what our members expect of us. And, if we're not, then what do we need to do to get there. I suspect that other SDOs that are also membership associations might have a very similar view.

(Tim) ASSP's been around for over 100 years, so it's kind of steeped in safety. The number one question we get from our members is what difference do standards make, what's the impact. Safety is heavily regulated in a lot of areas. If you have a federal standard for confined spaces, then why do you also need to have a consensus standard for confined spaces? We have to make that case. We created a committee to do a literature search on leading indicators to see what work had been done. We followed a consensus process and produced a good, solid document that has to be revised, reaffirmed, or withdrawn every five years. This is a start.

(Elise) From my perspective, one of the most important benefits is that this kind of methodology can help inform decision-making. There are several agencies like FDA, CPSC, EPA that are charged with protecting human health and safety. It's a big mission and we need to use our resources wisely. Having data to help us make those decisions about where we're going to get involved and what we can spend would make a profound difference. With this data, you will probably see a lot more participation from government agencies as well as consumer and environmental protection groups which is really important to having credible standing.

(Chuck) Ditto to what everyone else has said. There are long-standing questions and evidence that our industry needs to drive the use of standards forward. I'd like to raise a new issue arising from the COVID-19 pandemic which is that our industry is looking at new tools and pathways for communicating because of hesitance, skepticism, and disinformation. We're engaging with the communications community about how to deal specifically with misinformation around safety equipment that has been introduced from the pandemic. We believe that this body of data and work like this can help us combat what has become a very recent, new environment and landscape for the use of these products.

(Casey) It's important as a standards development organization to see how our work changes out in the real world. When we look to evaluate impact, we want to know what works and what's not working. We want to persuade others about the importance of what we're doing. Ultimately, we want to manage more successfully, better prioritize, identify better programs, and make course corrections if needed.

(Randy) I'm going to try to link a couple things that I've heard with our philosophy at AHAM. We believe you get what you honor. If I'm going to honor something, I need to understand what's good or bad which leads you down to that metric. Looking at what's the mission from an appliance standpoint, we believe the product should be as safe as it is functional. So that informs what we want to measure. We start with the lagging metrics.

(Don) Most of my experience has been in the consumer products industry. I participated in ASTM International and was chair of subcommittees dealing with handheld infant carriers and stationary activity centers. I did it for many years and it was very rewarding. I participated because these were products that were produced by one of the companies that I worked for. Standards participation is important if you're working for a company that's producing a consumer product. That way you're always on top of what's going on as the standards are worked on and improved by the subcommittee. It is a way to easily stay current so that you can affect the designs of your products in a positive way to make them better. I've seen across all of the different juvenile products and the toy standard itself where people and companies are participating and understanding that incident data and things like that have great impact. It allows them to go back and improve the designs of their products to make them safer. It's also a huge savings in the long run, not having to deal with incidents that are associated with children or any consumers being injured by a product. So, I'm a true believer in the process. I have seen it work and used in developing our internal standards when I was in industry.

(Doug) I'd like to pick up on what Chuck was saying. I'm aware of disinformation around the pandemic from a political point of view but with respect to disinformation about safety equipment and standards, I want to check if Chuck can maybe expand on that a bit?

(Chuck) At our annual business meeting later this month we're bringing in a speaker to discuss disinformation that's deliberately promulgated during the political cycle. We have some specific examples from our industry. Some of the information that was circulated during the pandemic about oxygen deprivation during the use of

facemasks and some other information along those lines is what we're looking at specifically. There also have been a few measurements of personal protective use, and whether or not polarization on that particular subject led to a decreased utilization of face coverings and respirators. Finally, there's some specific discussion happening around polarization of the subject in the medical community. All of these things are issues that our industry is worried about. We want to make sure that good decisions are made as we move forward as an industry. Some research in the communications field shows that responding to this fear-based disinformation with data and facts can re-entrench skeptics. Different communications strategies have to be pursued in order to combat this. We're at the beginning stages of this work but we feel like the industry needs to be prepared for what comes next because we do feel like there's a new normal out there.

(Tim) At ASSP, we have the Z9 ventilation standards. I did see a lot of misinformation during COVID-19 which is still ongoing. What I saw was more misreporting of the impact of industrial ventilation on worksites, how many cubic feet per minute has to move, that type of thing. Evaluations of facilities was the thing that I saw with ventilation. That was an example that I saw and it was fairly common.

How are we going to use this information about the impact of our voluntary standards? What is the ultimate goal? What are the ways we can use the results of these impact studies?
(Chuck) We can't just post it. The days are over when you can post a 30-page white paper to your website and expect pretty much anybody to read it. There are professionals in the safety industry who are absolutely swayed by good science, and in-depth reporting of that science, but that is one audience, and there are many more audiences now. I showed you some of the data that we're using within our industry and the data can be very persuasive to an informed community. But we have to figure out how to reach less informed communities including the skeptics who are being inundated with information.

(Randy) Chuck, as you're looking at these different groups, is there anything in common?

(Chuck) I am by no means an expert and certainly don't want to focus this discussion on just one item. The common denominator is that a lot of deliberate disinformation and some organic misinformation that is available to the public is driven by fear. For example, fear-based disinformation on the internet that wearing facemasks for respiratory protection causes oxygen deprivation. How do we combat that? We have engaged with a community of communicators who have been dealing with this. The GMO industry is an industry that's had to deal with this for quite some time and we're learning a lot from them.

(Amanda) I agree it's not enough to just post a document. Some of the impact data might point to ways that we might improve standards but it might also suggest that there's more work to be done to operationalize standards and make them more usable. So, things like derivative tools and calculators based on the standards, or even educational resources.

(David) Great point, Amanda. The idea that it's not just a standard but maybe a standards solution that surrounds the standard with other products and deliverables would be a good way to use some of this information.

(Doug) My role is in CSA government relations so our task is to connect what we're doing in terms of standards development, research, or education with the needs of government. To the question about how we plan to use the data, as was pointed out this morning, we want to use it to make sure our standards are being utilized and they're effective and, if they're not, we need to update them. There may be new areas that we need to be exploring and hopefully that information will help determine those directions. But one of the things we are trying to do from a government relations perspective is tie what we do to key public policy initiatives. To show how standards, education, and research can support public policy objectives. For example, we're talking to the local government in Ontario who wants to double if not triple the number of referenced standards in regulation in order to reduce red tape. They have challenged us by asking, if we're going to use your standards, how will they impact the public

policy objective and Ontarians. So that's a challenge that we have and it's another motivation for the exercise that we're going through.

(Elise) I work in an agency where it's full of people who would read the 30-page document but I take the point that executive level communication is also really important. If I could create the perfect scenario here, it would be a voluntary consensus standard for measuring the impact of voluntary consensus standards. That would make it easier for federal agencies to use the outputs of this discussion. Add to that case studies that have credible data as part of a short, interesting story about how this can benefit public health and safety.

(Don) With respect to regulatory agencies, the one I've dealt with most over time is the Consumer Product Safety Commission. I note the importance of CPSC being part of the standard development process – for me it was primarily through ASTM – and having their input because of the depths to which they go in assessing incidents that are occurring in the field. That data is very important for the subcommittees or committees to have within SDOs in order to strengthen the standards and make products safer for those who are using the products. Whatever industry you're in, it helps to develop a working relationship with the regulatory organization. When I worked for a baby products company, we developed a relationship with the CPSC staff and commissioners. We learned a lot from them and could adjust our own internal standards based on those discussions.

(Tim) Working with government has been extremely beneficial. OSHA and NIOSH/CDC have contributed very much to our programs and our standards. We rely on them for a lot of the data that proves the value of what we're trying to do. A lot of the fall protection testing methodologies came from the Air Force many years ago. The U.S. Army Corps of Engineers EM-385 manual for construction and demolition safety is another good example of how the public and private sectors can work together on the measurement of value.

What are your thoughts on how we scope/define this problem in order to make progress?
(Doug) We're focusing in this initial stage of our exercise on gas standards and healthcare. Looking at some of the preliminary information that we've received from the consulting company that we're working with, this is a complicated issue. There are lots of URLs that have to be checked to make sure that we're gathering the right information and that it isn't out of date. We will certainly have a better idea of where our standards are being utilized in the healthcare sector after this exercise and what some of the challenges might be in extracting and dealing with that information. Occupational health and safety is another complicated subset of standards. As Adi mentioned this morning, we will probably be looking at other areas of standards once we have a model that works for gas and healthcare, but the magnitude of healthcare and occupational health and safety are very significant. It'll be interesting to see just how challenging or easy it is to extract some of this information.

(Randy) It depends whether it's health or safety. It's going to come down to the individual association, manufacturer, group and whatever it is that matters to them. From our standpoint, we start where the recalls happen, so at safety. But now we're also into indoor air quality and health aspects. It's all about setting the metric and continuous improvement.

(Tim) If we're talking about health, it's measured in a different way. You have latent effects, indirect, and all that. If you're talking safety, a lot of times it's direct like a fall from heights, an immediate type thing. In some ways, we have two different models that may not have as many synergies as you'd think. We should consult the epidemiologists. But to me it's a different methodology and different results.

(Casey) In our case study approach, we really focused on the principles that safety is dealing with acute injuries and health is focused on measuring the chronic. The impact on public safety can be a direct contribution to health. Health includes injury prevention and safety, part of UL's mission.

(Elise) There are a lot of definitions for health. It might be useful to find out what resources are available that can help with this and then work around an existing framework. Tim mentioned epidemiology. Another source of

expertise at least within government is risk assessment. Building our definition at least initially around that might be a way to make some progress.

(Don) I have a question for the whole panel and it has to do with organizations that are not governmental organizations or SDOs, but organizations such as the International Consumer Product Health and Safety Organization (ICPHSO). I would love to hear more about organizations like that because ICPHSO has a big impact on consumer products companies learning from each other to develop stronger safety programs and sharing information. I find it to be very beneficial in that area. I served on the board of directors of ICPHSO for a while and truly believe in that organization, but I'd like to hear from the rest of the panel about organizations similar to that.

(Amanda) I was going to say that the definition of health and safety are evolving. In the medical device field, traditionally safety related to the patient or to the operator. But now, with interoperability issues for medical devices, safety also applies to systems and networks if you've got connected devices. It's not just the risk of adverse events to the individual patient but also to an entire network. I would also add that safety is evolving to refer to different ways of delivering care. So, for example, with remote control enabled devices to more safely deliver care. Maybe part of it is an issue of whether we need to define impact, so we have a better basis for comparison.

(David) That's a great point. We need to make sure that we have a common understanding of what is impact.

(Chuck) In response to the question that Don threw out about other organizations that may be active in this space, we operate within a broad ecosystem for safety. You can bucket it many different ways. Very often we bucket it as the standards community, the producing or professional community, and then the end users who are sometimes the employers and sometimes the users, but that's just one way to do it. You can do it in a thousand different ways. For this particular project, we can slow ourselves down just trying to organize the entire ecosystem around these questions. So being fully inclusive may not be the goal. However, reaching out to some of those groups to ask what questions they would like incorporated here might be very useful. I can give at least one example. When we are contacted by user groups about safety equipment standards, the question asked is not did the standard work; it's about conformity assessment and product differentiation. So, it's a different frame to look at the effect of the standard. Today we're talking about whether a standard impacts injury and illness or a couple of other metrics. But the end user may be less interested in that and may be interested in another basket of questions. So, yes, there is a broad universe of groups out there. We work with many of them, e.g., the American Conference of Governmental Industrial Hygienists (ACGIH) but I think they would have a completely different view. We run afoul of that in some SDOs. For example, chasing the standard's effectiveness and regressing to zero is something the industry worries about because you can drive up costs and drive down implementation instead of reaching a broad audience. But some SDOs are chasing those nth degree impacts, which is not wrong. Yes, there are groups out there and we should ask them questions. I'm just not sure the answers should be central to the endeavor.

(Tim) The standards we write primarily are process-based standards, e.g., how do you enter a confined space, how do you test copper tube piping on a construction demolition site. We don't write too many product-based standards. Some of our fall protection standards might be under there but generally our standards are not sold to end users like that. They are generally sold to the companies that use them on sites. Labor unions are very active in our work. No question that we should do more outreach to consumer groups. We find that they ask if we manufacture products which we don't. They are very interested in the ISO 45001 standard for the global health and safety management standard because of sustainability in the supply chain and the like.

(Elise) ICPHSO is special and Don should be proud to have served on their board. I really like the idea of consulting international organizations early on, with the goal of aligning views, seeing where they may not be aligned, and identifying other resources that we may not have thought of. I agree with Chuck that trying to make this a global initiative is probably unmanageable. But early consultation would be good. In our space, the WHO, UN Environmental Programme, OECD, could help with linkages.

(David) As we move forward, we'll want to ask who's not at the table now that needs to be going forward. Some of those other organizations may be critical to us making progress.

What data would you like to use, but you don't have access to?
(Casey) We would love to know more about the number of products out there on the market so that we can measure the incidents rather than the raw counts of data. If we can get associations on board and manufacturers, that would really help tremendously to measure the impact of our published content. Our focus would be partnering with individuals on this panel in any associations that we need to get plugged into, but then also getting accurate incident data from those trade associations and manufacturers.

(Chuck) There's a broad set of data that you can cut several ways but it amounts to the delta between incidents before and after standardized equipment has been adopted. There's some Bureau of Labor Statistics (BLS) data about the adoption of new safety regulations but it's pretty haphazard. OSHA acknowledges it has to be updated. Getting new and up to date data about pre- and post-regulation and pre- and post-promulgation of broadly used management system standards would be helpful. We're looking at many of those and would like to see that data.

(Doug) It's cumbersome to look at government regulations from one province to another. We're using AI technology to scan some of these resources. It will be interesting to see how much information we get and how many questions that may raise in turn.

(Randy) There's a need to understand what's changed after you've implemented a standard or a change to the standard. So, again, lagging data. Being able to come up and model that. Being confident in the correlation of the modeling. We deal with consumer products so we look at ratings from places like Amazon. A lot of initial things show up in somebody's comment about a product that they bought. So maybe work from there. Mine the data and then get it correlated and look at the differences. There's a whole opportunity here of better data. I love the NEISS database and what CPSC has put in place, but a lot of that takes too long to get to the information.

(David) We had a question come in from the audience for Chuck. How do you measure the number of workers protected? I think it was one of the statistics you had in your slides.
(Chuck) It's a lot of work. There's a complex methodology and I won't go into a lot of detail but the consultant that we used for the foundation of that work is a group called Dunhill and Associates. Their established methodology is a Department of Labor methodology that takes employment data across the country at a very granular level that's been produced by the DOL. They can go through that data and peel out your industry, which is an intensive process. We took that employment data and our own membership went through it, something like 3700 job types. We identified the job types that use personal protective equipment, and we identified the types of PPE that are used as a matter of regulation. It's not exhaustive. It doesn't capture for instance all work that is done for which the PPE is provided through retail sources. But it's a great start. It's a beginning of the work, essentially a non-exhaustive identification process that went through the BLS data, identified those job types, counted them, and differentiated them. As you can imagine, there were hundreds of issues with double counting and there are limitations to the data set in that regard that we have to be careful of. But our intention was to make sure that whatever we did was defensible and that's why we used a third party that is broadly recognized for doing quality work for the DOL.

Another question came in regarding data. What are some sources of international data that we might look at?
(Tim) When ISO 45001 was proposed by the British Standards Institution (BSI), they did a masterful job compiling all the data and background that justified the creation of that standard. The ISO proposals for new standards are pretty extensive. The International Labour Organization (ILO) has some very good data. The United Nations has some data but it's tough to find. If you're looking for good OSH data, take a look at the ILO and ISO.

(Randy) On the consumer side, we have the IEC international safety standards. A lot of different countries are bringing in information while we're working on improvements to the standards, whether that's RAPEX out of Europe, London Fire Brigade, Australia, etc. Connecting those dots around the world is kind of the first task. But there's a lot of common information and, in some cases, a product may have been launched in Asia before it was launched in the U.S., so their data is ahead of ours, even though it's still lagging data. So, it's important to look at that and connect with those sources.

What are some leading indicators or progress markers to make sure we're on the right track to impact?
(Doug) The pandemic was mentioned earlier. We're very much involved in looking here in Ontario and across the country at the long-term care sector where there's significant issues around PPE, infection prevention, and control. I guess the lagging indicator would be are we improving the situation, reducing infections, etc. But leading indicators could be how many people, say in a long-term care facility, have been trained on infection prevention and control, what systems have been introduced to deal with infection, etc. Some of those elements will lead you to the end result in terms of the lagging indicators. I'm a big believer in leading and lagging indicators because if you wait until the end, it's too late. You have to be measuring step by step to make sure you're making progress but that largely depends on the topic you're dealing with.

(Elise) There's two things that regulatory agencies do that could be helpful. The first is the benefit-cost analysis (BCA). In general, when an agency produces a regulation, there's a BCA that goes with that. There's a methodology for doing that. It's done by many agencies across the federal government to project how that regulation will impact things. The other is risk assessment. We run risk assessment on substances and look at the research on possible impacts. Those two disciplines could help inform what is the intended impact of a standard, as opposed to looking at what actually happens. And the public can provide comments.

(Don) One of the most valuable sources of information for a consumer products company and for consumer product standards development organizations is listening to the consumers who have had issues with the products, especially from call center complaints. When someone's gotten hurt or a consumer has other complaints around quality, that kind of data is really important. SDOs should find a way to get more of that kind of data directly from consumers, not just from the governing regulatory body.

(David) That reminds me but the saferproducts.gov website takes some of that feedback from consumers and that data set is publicly available. Nowadays, consumers are also able to review products online. Mining some of those sites for product reviews might be useful approach.

(Chuck) To your original question about leading indicators, we have a host of them. The first is Trust: Does the standard affect trust, that you are being protected? Adoption: Did the standard affect the widespread use of the safety intervention or product? Compliance and education: Is the product being used more effectively or properly? Behavior in general: Has the safety culture improved through standardization of the product? Differentiation: Did the standard lead to consumer choices across the spectrum of quality? And, finally, Employer Adoption, not just in the use of a safety product but in general. Those are all metrics that we have looked at to measure over time.

(Tim) We did a webinar the other day on risk assessment to 750 people so lots of interest. One of the big questions was: How do you tie leading indicators, specifically survey data for OSH, and then use that with remediation efforts and ongoing improvement? Here's another example of a lagging and leading indicator: You're installing a power press from a European country. What's the first thing you're going to do besides looking for directions? You're going to look at any incidents or history on the thing as far as installation and use, and then tailor your engineering and safety programs to address that. In effect, you're going to use a lagging indicator now, and a leading application.

(Amanda) To the point raised earlier that leading indicators can become lagging indicators if left unaddressed, there have been times where we've had process-related standards and shortly after the standard has been published, we brought the group back together to look at what's new that has happened. What else needs to be

considered in the time since the standard was released? Are there reports of adverse events that we need to mine for additional data? Are there news reports? What's been the impact on public perception and patient confidence? Is there any new guidance from regulatory agencies or government agencies? What new research has been issued? What changes have happened in the technology? What changes have happened in the profession? In some cases, we've had compulsory certifications come down the line and those need to be taken into consideration. There have been times where we have decided not to wait for the usual five-year review cycle and to move much sooner to incorporate the changes in the landscape that have happened so that we don't get to the point where a standard is obsolete, or it's not serving the group that it's intended to serve.

The goal of this workshop is really to get people interested in the topic and to identify a coalition of the willing to help us solve this problem. What are some first steps after this meeting that you think we need to take in order to make progress on this topic? What would you like to see happen in the next week, month, maybe six months, coming out of this meeting?
(Elise) This meeting has really opened my eyes to how much is out there. Measuring the impact of EPA's use and participation in standards has been a bucket list topic that I've hoped we can get to, so this is really exciting. The first step is to take stock of what resources and methodologies exist. Running a gap analysis to figure out what's missing would need to be one of our next steps.

(Doug) This has been an excellent event and I've learned a lot. This is a complicated subject. We need to narrow it down to what are the key components that we're really trying to address. If we take a shotgun approach, we may hit a lot of things but not deal with anything effectively. We have to look at what's important from a safety and health perspective, and what we can reasonably tackle. Then, figure out how to do it.

(Casey) Here at UL we have some good ideas for our case study approach and we're looking forward to filling in those details. Going forward, we hit on earlier about partnerships and learning best practices. No matter what additional outcome data we can get, we need to move away from just measuring outcomes and also expand our portfolio. We need to know more about the process and what happens before manufacturers are producing the products in conformance with the standard.

(Tim) I've heard stuff today that I had no idea was going on, some really solid information. One thing I hope that comes out of this is that we figure out a way to open up the channels of communication so we're talking to other organizations that doing good work as far as showing the value of their programs.

(Don) We need to do this more often, maybe annually or more often than that and get more people involved. I thought the program was excellent. The more we can share this kind of information will be hugely helpful to industry and to safety.

(Randy) I'm thinking that my problems are not other people's problems. What I'm going to have to do to fix mine is probably different from others. But it was really good to have this discussion because what Chuck and Tim are doing is quite different than my product specific standards yet there are still things that I learned about how they look at things. There's ICPHSO for consumer products Maybe this panel can kind of become that for knowledge sharing across different industries and how to look at standards and drive improvements. But each one of us probably has a different plan.

(Chuck) There were a lot of great ideas. We'd like it if someone can distill this into a report and identify if there were any common questions across all of the participants. Our organization would be interested in a further discussion about how to address any question that came out of this process. Certainly, if someone wants to propose a project that solves all of our problems, that would be ideal. But, short of that, there may be a question that we can pick up as a group. I didn't hear a piece of this where I feel like our organization would take the lead but I heard several places where we would certainly participate if a further project comes out of this.

(David) The team from UL, CPSC, and ANSI will produce a report from today and a recording will be posted after the event.

There is one more question from the audience. How can we use this utilization and impact data to improve the quality of our consensus standards?
(Chuck) Regarding utilization, there are some good standards that lie fallow after they are produced. Utilization and impact data can help us understand why that is the case. That's first order for our association and I think for any standards development organization. We need data that steers the effort, because writing standards is a lot of effort. Becoming more effective and efficient is something that we would like to do with this data.

(Elise) There are a lot of ways that this data can be used but outreach is a really important one. This would be valuable to us and to any organization that might have a lot of standards professionals who are retiring and where a new crop is coming up that might be more skeptical, that might approach standards by running a cost-benefit analysis to make sure it's worth their time. People who might ask is this going to advance our mission and is it a good use of resources. I think that's true of government agencies and companies. This data helps to answer those questions and helps to get the new crop of standards professionals involved in using the standards.

(Doug) We have to look at the exercise we're doing as part of a continuum. When proponents are advocating a particular change to our major safety codes, like our electrical code or gas code, we ask them to describe why they're recommending the change, what they believe the impact of that change is going to be. If we make those changes to a code, it's incumbent upon us to measure the impact afterwards. Did it have its intended consequence and, if not, why not? Understanding where our standards are being used, and what kind of impact they're having or not, is part of a feedback loop for continuous improvement in the standards we develop.

(Tim) When we have that data, we use it because it shows the value and ensures the integrity of what we're doing. The best way to raise recognition of standards, sell standards, have them implemented, is to show the value of them and how they are being used in the workplace. If you can do that, that's nine tenths of the battle.

* * *

(David) Thank you to all our panelists today. We had a very diverse panel from manufacturers and associations, folks who have worked in the consumer space, as well as SDOs. It has been very valuable gathering those different perspectives. A couple things that I heard: First, there is consensus that this is an extremely important topic that needs to continue to be addressed and advanced as we go forward from this meeting. Second, whatever the result of a specific impact study, we need to be careful about how we use that information because we are in an environment of miscommunication and disinformation. We need to make sure that we have the right kind of impact story or data for the right audience. Third, we talked about how broad this situation is with a lot of different kinds of standards, ranging from test methods to systems standards to management standards. We're looking across a wide variety of effects, from injuries to chronic health outcomes. All of this complicates our overall landscape and how we go about doing this. We need to scope this into one or a few efforts that will allow us to take some concrete steps forward. We heard that the panelists have learned a lot. We hope the audience has too. We all remain committed to advancing this dialogue after the workshop today.

Open Dialogue with Audience Q&A

- Moderators Scott Ayers and David Wroth

Mr. Wroth reiterated that the goal of today's meeting is to begin the process of developing a methodology or methodologies for assessing the impact of standards on health and safety. Audience members were invited to raise any additional questions that they had for speakers who were still in attendance.

Are there any risk or downsides to measuring the impact of standards and, if so, what are they?
(Casey) When we started our case study approach, that was something that we looked at. We understood that as we pulled data on safety and number of injuries from CPSC's saferproducts.gov page and NEISS, that doesn't mean it would necessarily be positive in our favor with revisions to our documents. It could be a negative impact rather than a positive impact.

Lagging indicators are outcome measured and are easily identified. How do you know an appropriate leading indicator when you see one?
(Tim) We're writing a standard for leading indicators. The indicators should be applicable to your organization, be implementable and measurable, and they should have a positive impact. If you're talking lagging indicators and safety, a lot of those are required by the government to be reported.

(Elise) Not to sound like a broken record, but risk assessment and benefit-cost analysis are great tools. How do we know that those are good? Because they're based on science, they're published, they're public and transparent. Often, they are peer reviewed. Those are disciplines that are important when you're looking at leading indicators. If there is interest in going the voluntary consensus standards route to measure the impact, in our agency and maybe others voluntary consensus standards do meet our requirements for peer review.

There's a follow up question about risks to the SDOs. We talked earlier about the state of disinformation and, in some cases, respected organizations have lost credibility. How can we address the credibility or bias issue if the SDO assesses the impact of its own standards? Is there what might appear to some people to be a conflict of interest there?
(Doug) This illustrates the importance of using outside sources to validate the impact of your standards. In addition to the project that we described this morning, we're undertaking another initiative, from a marketing perspective, looking at how our stakeholders—governments, industry, consumers—view us as an organization. How do they view our standards and their value to them? In the model that we're going to be using, we're not evaluating ourselves; instead, those using our products will be evaluating us.

(Tim) It's very important within the committee that you're using. ASSP doesn't dictate to our committees what to do. It's a give and take, 50/50 proposition. What that does is it maintains the integrity of the standards development process. I wouldn't disagree that there's some value in having an outside group look at it. But to me it's the value of the committee, how they're making their decisions, and can you defend the process that was used to create the standard. That's what's going to give it its credibility.

What are specific next steps and long-term goals? Developing a voluntary consensus standard was mentioned but that might be further down the road than more immediate things.
(David) The team that put the workshop together over the last six months culminating in today is going to take all the information that we heard from our presenters, panelists, and audience member questions and condense that down into a report and some additional deliverables, maybe more bite size than a report, that will summarize the activities that we heard about today. The next thing we're going to do is to survey the audience to see who might be willing to participate in follow-on activities. At the close of the meeting today, there will be a survey link that is provided where you can express your interest in joining this coalition of the willing. We'll take that information and begin to scope out a set of preliminary meetings to talk about how do we move forward from here, and assess whether it is one group or some teams.

(Scott) That makes a lot of sense to me. It's been pointed out earlier that what affects one organization is not necessarily the same stuff that affects another, but the problems are pretty similar. It makes sense to look at that and see how to divide it up within a group of interested parties. We could certainly talk with ANSI about revisiting this next year to cover what's happened between now and a year from now. If this is something that people felt was worthwhile, maybe we do a continuation of this at World Standards Week next year.

Do the panelists have any questions for David or Scott? Joe Bhatia has a comment.
(Joe Bhatia) I just wanted to say you did a great job—congratulations! I also intervened to reinforce your thoughts about being able to work on this again next year. It would be wonderful if we could have the same team with CPSC and UL, supporting the effort together. It's worked out very well.

(Scott) I would be on board for participating next year. This has been a very worthwhile experience.

(Doug) My question for Joe is: Did this day achieve the objectives that you had established for your organization?

(Joe Bhatia) It was a great discussion. I don't think you have achieved your goals yet but you're on your way. We encourage you to continue. You've done a great job. The theme is very complex and there are a lot of difficulties as you talked about that we need to work on. But the motivation is there in all organizations: SDOs, certification bodies, industry, users, and ourselves. As ANSI's role is along these lines, we're very happy to continue to work with you.

(Scott) I can answer what my desired outcome was which is really going to be the follow-up. Are we going to get people who want to continue this dialogue, after today? If we indeed get that, then I think it's been successful meeting.

(David) I would add that one of the goals for today was to share best practices in various disciplines. We heard from an economist, we talked about information that might come out of epidemiological studies, that kind of thing—various approaches that are potentially applicable to the problem that we're trying to get to. A number of people have mentioned that it has expanded their view of what might be possible, as well as what the problem is. I think we did a good job of getting that kind of broader perspective on the problem out there which is a necessary step to solving the problem.

(Tim) I'd be really interested to see the feedback that comes back on this. My guess is we're going to get some really good ideas from participants. You both put a tremendous amount of time into this, so thank you very much.

(Scott) David and I were just the ones who volunteered to go on screen. I would like to also thank David's colleague at UL, Andrew Kapp, as well as Jim McCabe at ANSI, who have helped organize the event.

(David) I echo that.

(Elise) I have a question for ANSI, UL, and CPSC. Today's discussion was excellent—thank you for leading this. What is it going to take to keep you in that leading position to move this initiative forward?

(David) Our leadership has been very clear with us, that we want to understand the impact of our standards. Our team is up for the continued engagement in whatever path we go. We'd certainly love to do this again as part of World Standards Week next year.

(Scott) I'll speak for myself individually—I'm certain that my organization loves my participation. To keep me interested I want people to get something out of this. I get a lot out of going to meetings and talking with other people and trying to move concepts forward, whether it's trying to develop a consensus safety standard or to solve something else. I get a lot of enjoyment over getting to work with a variety of people, so hopefully there are people who want to work with us, and that's all I'm looking forward to.

It makes sense for the standards utilization and impact data to drive the opportunity to improve our stakeholder audience and outreach, in getting the right people at the table. Suggestions for setting the mindset and accomplishing this? Basically, how are we going to convince people to come talk, and how are we going to keep them engaged in the conversation?

(Scott) The goal here is the message that you're telling your potential participants. You want to share with them what they're going to get out of it. When we set up these presentations, we were very deliberate in trying to do that. CSA was kind enough to talk about what they were working on, because it really gets down to the overall business case. If you're able to get some organization to understand the benefit in real dollars and cents that their participation is going to have, you're more likely to get their participation in the process. CPSC is not an SDO but this all started because we wanted to try to gauge the overall benefit that we provide to the American people by our participation in standards. When you look at other organizations, whether they be manufacturers, safety professionals, or even consumers, the goal is to convey the message that they can benefit from participating and we can measure that benefit. That's how I think you get them there and keep them there. In any sort of consensus group, it comes down to the leadership and keeping conversations moving forward. If we can find the right people and the right chair, we will put ourselves in position for success.

(David) One of the things that UL Standards recently did was to ask our technical committee members why did they participate in our standards process. One of the most common responses was that they felt that they were doing a good thing for society. That mission of undertaking standards development for security, sustainability, safety, is something that they personally got a lot of gratification from. The other thing that will bring people to the table is to be able to measure and report back to those volunteers that it is leading to that better outcome for society. Having that very specific outcome, that there is a measurable benefit to it, will keep those folks engaged, and they'll pass that on to the next generation that we want involved in our standards development activities. So, being motivated by the mission and then being able to back that up with specific metrics, will help people to get involved, stay involved, and bring their best to the table.

(Joe Bhatia) If I may add a comment, there are other elements that may be part of the solution. Many countries in the world, especially developed economies, analyze what the commercial value is of engaging in standardization activities and compliance. As an example, the UK recently hosted the ISO General Assembly meeting and they developed a results-oriented report, basically saying that participation in standardization activities has created revenue growth. Other countries like Germany and France have done that also. So financial gain to the economy, uplifting of the commercial activities, benefits if you will various constituencies. Not just health and safety, but these other elements of “benefits” could be looked at as potential areas to measure, for which measurements could be easier to get. If we go through a process next year, one could start by looking at what are the best practices that exist around this type of activity, and how do we better capture the data, financial numbers, and other benefits of all types that are tabulated by many countries in different ways. Then pick and choose the ones that are applicable here, that might be resonating with our community who may be more interested in learning about those. It's just a thought. I'm not an expert in this area but just listening to you talk made me realize that there are a lot more benefits that accrue out of what we do. Last year, we had even talked about going to Congress to find out if there would be a way for a credit to be given for investment in standards, because standards produce a lot of benefits to society, the country, the economy, commercial and otherwise. It got distracted because of COVID and other issues but there was a lot of passion for that among industry so that they can continue to support and more robustly participate in the process that we all embrace.

(Doug) Just to add to what Joe said, one of the things that we're doing here in Canada is looking at inter-provincial trade barriers and, of course, standards allow you to overcome those barriers. Standards help with alignment across policy issues. We're seeing that with boilers and pressure vessels, occupational health and safety, first aid kits, etc. To Joe's point, standards can help remove inter-provincial trade barriers and allow free movement of people and expertise across the country, so there's an economic side of this as well as safety and health.

There’s one other question that I would pose to Scott and those who have participated today. Is there a short-term deliverable that you think we should be focused on beyond the report from today? A voluntary consensus standard for measurement is a long way off but is there something that we could get to in six months to a year that would be a good intermediate step along the way?

(Scott) I'll share really quickly my thoughts. The biggest challenge we have is data. Maybe the first step would be to put out a guidance document about sources of data, using data, mining of data. Can we get that done in six months to a year? I'm not sure. But that's probably the first step in any sort of work that we do collaboratively.

(Casey) I totally agree. If we can identify additional sources of data, e.g., international sources, that would be a huge step that would help our case study approach. To get some credible data, identify what kind of data we want to receive, tap those sources, and get those individuals on board—that would be a positive step, and I agree with that direction.

Wrap-Up & Next Steps

- Moderators Scott Ayers and David Wroth

Thanks to the tech team behind today's meeting: Jana Zabinski and Stephanie Carroll of ANSI, and Stacy Leistner of The TAGS Group. Without them, the meeting would not have been as well-organized and well-run as it has been today.

A link to the post-event survey is on the screen and in the chat and will be sent out via email. The idea again is to see who is interested in being part of the group to discuss next steps to move this effort forward.

Participants who want to have further dialogue are also invited to reach out to Scott Ayers, David Wroth, Andrew Kapp, or Jim McCabe (emails provided) for any further conversations.

Thanks to the presenters, panelists and participants for their engagement.