STANDARDIZATION: JOURNAL OF RESEARCH AND INNOVATION

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Guiding Principles and Vision Development

By Alexis Shoemaker

Change is the only constant. As such, change leadership, or leading through change, is a significant facet of leadership. To "ensure broad and successive generations of management will also adhere to new ways of doing things,"[1] the literature suggests "establishing a sense of urgency, creating guiding principles, developing a vision and strategy, empowering broad-based action, generating short-term wins, consolidating gains and producing more change, and anchoring new approaches in culture."[2]

In this article, I will address developing guiding principles and a vision to equip leaders with the tools to kick-start meaningful and lasting change.

GUIDING PRINCIPLES

Leadership requires taking time off the metaphorical treadmill to take stock of past achievements, current conditions, and future goals. At its core, developing guiding principles and a vision is a creative process by which leaders develop roadmaps and bring the team together. As John Kotter states, "Guiding principles develop a picture of the future that is relatively easy to communicate and appeals to customers, stockholders, and employees."[3]

Developing guiding principles directly affects the ease with which larger decisions can be made. In other words, when it comes time to make decisions, a leader can refer to the guiding principles and determine how they may direct the desired outcome. Guiding principles can also function to "encourage team members to work outside the normal hierarchy."[4]

Developing guiding principles results in a grounded and focused leadership style. To this end, using "data tools to impact decisions, processes, and programming"[5] is immensely powerful. Importantly, though, guiding principles are not meant to remain static, and leaders should not hold fast to these pillars. Instead, guiding principles are intended to be a flexible framework, to be revised as necessary.

VISIONING

Taking root in the guiding principles, a vision "always goes beyond the numbers that are typically found in five-year plans," Kotter writes. "A vision says something that helps clarify the direction in which an organization needs to move."[6]

Developing a shared vision can pose a challenge; creating "a strong captivating vision [that] serves as a magnet to attract people to participate and helps create the highly functioning team's foundation"[7] is far easier said than done. Visions can be interpreted differently across the team depending on team members' "roles and responsibilities or their stage of career development."[8] As such,

essential to the vision is not that it be prescriptive by nature; instead, as Michelle Bennett states, "what is most important is that each person understands the overall vision and goals and how they contribute to the collective effort."[9]

Following vision creation is strategy development—that is, specific steps to achieve the vision. This can be done first, unbounded by resources, then further developed to work within the bounds of the resources at hand. This process can help define resources that may be needed and can serve as a rationale for the request.

CONCLUSION

By embodying the vision and intentionally incorporating the guiding principles into everyday activities, leaders empower others to act on their vision and fold their vision into the cultural vernacular. Turning a vision and guiding principles into action involves removing obstacles for team members so the act of incorporating the vision is the path of least resistance. To this end, systems and structures that undermine the vision should be removed.

Developing guiding principles and a vision is not intended to be a solitary job. In fact, part of communicating the vision involves empowering and encouraging employees to approach obstacles creatively, "trying new approaches, developing new ideas, and providing leadership"[10] to others.

Importantly, leaders should involve team members in the development process, allowing the team to build the nuance of the day-to-day experience into the guiding principles and vision. As simple as it may seem, the act of allowing team members to take ownership of the guiding principles and vision and the new procedures that fall out of them brings a sense of purpose and pride that isn't necessarily possible when procedures are handed down from the top.

The next column in this series will discuss effective and impactful communication techniques for ingraining a new direction into the fabric and daily activity of your team.

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Alexis Shoemaker is a senior specialist of technology and standards at the Consumer Technology Association (CTA). She holds a bachelor's degree in anthropology and a master's in research administration. She is the author of *Leadership in Research Insights and Business Intelligence: A Conceptual Framework and Guide*, published in 2022.

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Case Study: Engaging the Next Generation in Standards Development

By Laura Brumsey

In recent years, a common thread of conversation has been pervasive in the standards community: how to engage the next generation of industry professionals in standards development work. Many of our organizations are grappling with the retirement of subject matter experts who have long supported our standards development programs.

The Compressed Gas Association, Inc. (CGA) has studied this issue in our own membership for more than a decade. In 2019, we launched a Young & Emerging Professionals Committee, which has since played a significant role in shaping our priorities and programs. The lessons from our experience were presented at the 2022 SES Annual Conference and are summarized below.

UNDERSTANDING OUR COMMITTEE POPULATION

In 2010, CGA initiated a data collection effort aimed at understanding participation trends and succession probabilities across our 25+ technical committees. Our goal was to better understand which committees were at risk for mass turnover due to retirement and to aid our member companies in conducting more advanced planning for committee transitions.

We asked our committee members to provide their birth year range, which was presented in five-year segments (e.g., 1970 – 1974) to avoid the collection of specific birth dates. That information was examined in conjunction with meeting and event participation data and cross-company participation to create an overview of overall participation and preparedness for succession.

The key indicators identified by our data analysis included the following:

- a committee member median age of 60 or higher;
- 50% or more of voting committee members were age 60 or older; and
- the absence of an incoming participant engaged in committee activities when the current member was approaching retirement.

While the initial data set identified several areas of industry practice that needed attention, a predictive forecast added in 2014 highlighted an alarming trend: retirement rates on our committees were forecasted to reach to be as high as 70% across many high-priority topic areas over the next 10 years.

COMMUNICATING THE NEED FOR CHANGE

As our understanding of CGA's committee demographics grew, communicating with our member companies about this topic became an immediate priority. Committee

participation trends became a regular reporting item on our Board of Directors agenda, and strategic conversations about the future of our organization often centered on how to engage new people in our work efforts.

The communications around this issue faced two significant challenges: (1) how to encourage the development of a transition plan without violating our volunteers' trust related to sharing their birth year range information, and (2) how to encourage the continued participation of experienced committee volunteers who held critical institutional knowledge. Creating a shift in our committee demographics was important for CGA's organizational survival, but we also needed to maintain participation from subject matter experts to maintain the credibility of our standards and create opportunities for knowledge transfer.

Ultimately, we developed broad-based communications identifying area in CGA's communities of practice that needed new volunteers and laying out best practices for planned transitions of committee volunteers. This approach avoided sharing personal information about individuals while allowing us to highlight specific areas that needed an influx of new participants. We reached out to industry leaders to reinforce the value of continuing participation by long-time members while simultaneously developing programs and creating policy changes that allowed us to focus more on capturing important lessons learned for the future. By request, we also worked with individual member companies to evaluate their committee representation and create succession plans for the future.

UNDERSTANDING NEEDS AND CHALLENGES

As CGA's communications program progressed, we experienced success in addressing acute committee challenges but were not seeing widespread engagement of new participants. Working with member companies, we set out to connect with young and emerging professionals in our industry. In doing so, we developed a new understanding of their needs, preferences, and willingness to engage in CGA work.

In 2019, CGA distributed a survey to young and emerging professionals. Since we were trying to connect with a new audience, we needed to cooperate with our member companies to get the survey to contacts outside of our existing reach. Many responded positively to our request for assistance and shared the survey with their internal networks, encouraging their colleagues to respond. The survey garnered a response from representatives of more than 40% of CGA member companies, and many of the respondents did not have a previous connection with CGA.

Some of the most valuable feedback we gathered from the survey pertained to what was stopping young professionals from getting engaged with CGA. There were several common threads among the responses:

- I don't know how to get started.
- I don't have enough technical expertise to contribute in a meaningful way.
- The committee work process is hard to understand, and meetings are long and dry.
- Getting involved alone is intimidating and challenging.
- I don't have company support to get actively involved.
- The value of participation is unclear.
- Nobody has asked me to get involved.

When asked what they would like to get out of engagement with CGA, the young professionals responding to the survey had four clear themes in their responses: they wanted (1) meaningful interaction with industry experts, (2) opportunities to network with experienced industry members and their peers, (3) access to training and educational programs, and (4) chances for leadership development. Many also identified a desire for access to industry mentors and indicated that CGA's highest priority for the future should be supporting knowledge transfer.

The survey results also generated some surprises. Contrary to the generalizations from workplace demographic experts indicating that young professionals prefer virtual events, more than 80% of the respondents expressed a desire for in-person events so they could interact with industry experts and peers in their field. The desire for more personal interaction was also evident in the communication preferences section of our survey, where 84% of young professionals selected direct email as a preferred communication method.

The survey painted a clear picture of participants who wanted to get involved in our organization but didn't know where to start. We decided to start a Young & Emerging Professionals Committee to create a defined point of entry into our committee system.

MAKING SPACE FOR THE NEXT GENERATION

In September 2019, CGA's Board of Directors agreed to support the launch of our Young & Emerging Professionals Committee for participants who were age 45 and younger or new to their role in the industry. We immediately initiated a communications campaign that included a description of the committee and the topics that would be prioritized for work: technical education, leadership and professional development, networking, and new member onboarding. The campaign featured a letter to member company leaders, shareable graphics with brief descriptors of the committee, and an infographic with an invitation to join the committee. We worked closely with member company representatives to share these internally so that the information would reach new contacts who weren't aware of CGA.

The committee invitation received a tremendous response. We held our first Young & Emerging Professionals Committee meeting in December 2019 with more than 40 virtual attendees, which is quite large in comparison to CGA's technical committees. There was clear enthusiasm for the committee's mission, and attendees brought many new ideas to the table in that first session. From the start, it was clear that this group would bring significant changes to our organization.

The initial priorities that the committee agreed to address were creating a process and materials for onboarding new committee members, developing educational programming, and helping young and emerging professionals communicate about the value of participation in CGA within their companies. They formed task forces to address these issues and, with staff support, quickly progressed on several major initiatives.

SHAPING THE FUTURE

CGA's Young & Emerging Professionals Committee continues to be one of our fastest growing bodies and currently has more than 145 participants. They have been instrumental in creating several groundbreaking events, including an annual Young & Emerging Professionals Summit, which features several weeks of technical webinars and panel discussions with our industry's subject matter experts and has drawn more than 3,000 participants in the past three years. They also worked to create content that would appeal to all facets of our membership, including leadership webinars with industry executives, communications workshops, committee showcases, and more.

Beyond creating educational programs, this committee has prompted us to rethink our approach to many facets of our standards development and committee work processes. They identified significant gaps with our approach to onboarding new participants and worked with us to develop a comprehensive onboarding guide and new member welcome process.

The committee also took on an initiative to get more young and emerging professionals engaged in our technical committees and has been successful in substantially growing participation. As they've become more engaged in technical committees, they have pushed us to re-examine our work processes and

make them more efficient, to communicate more effectively about the important work that our committees are doing, and to consider how to add value to our meetings and work efforts for participants. In 2022, the committee adopted a strategic plan that defines their leadership structure, short- and long-term goals, and key indicators of success.

LESSONS TO SHARE

As we look back on a decade of work related to bringing new participants into our committees, there are a few lessons that stand out.

Go straight to the source

Although insights from generational experts and industry leaders were helpful as we initially formed a strategy around this program, getting feedback directly from potential participants in our Young & Emerging Professionals Committee was by far the most valuable. There were a lot of assumptions about this demographic that didn't hold true in practice.

Clearly define the problems you are trying to solve

Initially we began creating programs, events, and content just to connect with younger members of our industry, without a clear understanding of the problems we were trying to solve. While those early programs had strong participation, it became difficult to communicate success to key leaders and stakeholders. With defined issues that our committee is working to address and related metrics, we are now in a much stronger position to maintain support for this program.

Be prepared to meet potential participants where they are

Many participants in next-generation programs might not have much exposure to standards development or association participation. Beyond needing to think about how to orient them to your organization and work processes, it's important to consider that they might not know how to make a business case to build support for their participation. They also might not get support to participate in traditional events, so think about how to make those programs more accessible for your new audience.

Understand that technical standards development might not be the place to start

New participants might not feel comfortable contributing in the traditional spaces in your standards process, as many are intimidated by the full technical committees. Have a plan for how you can encourage people to get involved in those spaces and also in other areas where they might be able to contribute to your organization if those technical spaces aren't the right fit.

Don't underestimate the staff commitment

Starting our Young & Emerging Professionals Committee took a significant staff lift. While they had a fantastic amount of energy and ideas, much of the leg work was done by staff for the first several years as our participants gained an understanding of our work processes, how to organize events, etc. Now that we are three years into working with this committee, we have a core leadership group that is able to take a more direct role in supporting committee initiatives.

We are excited to see where our program goes as it continues to evolve to meet the needs of the next generation of subject matter experts in our industry. I hope that your organization will consider making space at the table for the next generation by creating intentional programs and spaces for young and emerging professionals. If I can provide any additional information about our program and our experiences with this population, please feel free to contact me at LBrumsey@cganet.com.

Laura Brumsey is Vice President of Operations and Administration for the Compressed Gas Association, Inc. She works with the President & CEO, Vice President of Technical and Regulatory Affairs, and the CGA Board of Directors to provide executive oversight and leadership for the association. Laura is a passionate advocate for the engagement of young and emerging professionals in standards activities and for the continuous improvement of CGA's member services and work processes.

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Consensus Standards: A Framework for the Future of Science, Health, and Technology

By Samuel B. Lum

To a great extent, consensus standards are documents that form the foundation of science, health, and technology in society.[1] They have ensured that everything from infrastructure to consumer products works together in a safe, reliable manner. Standards are used and adopted around the world by governments, corporations, and non-governmental organizations.[2]

The language and requirements within standards are unequivocally part of frameworks that have been agreed upon through a fair and balanced consensus process. This transparent, open consensus process is what makes standards particularly unique. For the Food and Drug Administration's Center for Devices and Radiological Health (CDRH), which is responsible for regulating medical devices in the United States, FDA-recognized standards include product specifications, test methods, guidelines, and performance criteria. These standards are tools that contribute to the center's regulatory capabilities to oversee the total product life cycle of devices and support the FDA's mission to protect the public health of the United States.

Back when I was a mechanical engineering student at the Rochester Institute of Technology, I was constantly bombarded by standards. It seemed there was a standard for everything, complete with a never-ending list of confusing designations. How was I to remember all of these editions, revisions, and standards developing organizations?

My classmates and I always saw standards as a way to add legitimacy to the learning process and as a tool that took our projects from ideas to the test bench. What was not apparent to us was that standards could be viewed from a standards management perspective. Standards could be found across multiple industries and were woven into the very fabric of the American economy, touching on manufacturing, trade, technology and innovation, and intellectual property. They also were an integral part of our competitive strategy. You can imagine how an engineer, having only taken three non-technical classes, might be completely unaware of these other affected areas.

Today, the complex aspects of standards designations still have not changed, but I have become enamored of the regulatory ecosystem of standards since joining the FDA Standards and Conformity Assessment Program (S-CAP) less than two years out of university. One of the things I love most about working in a government agency like the FDA is our mission to protect and promote public health.[3] I believe it is in the public interest to have standards behind technology development in order to prioritize the safety and effectiveness

of medical devices across the total product life cycle.

Standards, when properly utilized to support regulatory decisions, benefit manufacturers, suppliers, and firms economically. They can streamline product development, ensure quality, promote trade, and improve supply chains. Standards are increasingly seen as a tool for neutral cooperation and as a means of effecting beneficial systemic solutions in modern society.

Moreover, standards have been important for carrying out the Sustainable Development Goals of the United Nation (UN), providing a way for nations to define, implement, and measure systems and technologies. Notably, with respect to the field of global development, two international standards- developing organizations, the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), jointly released guidance on gender- responsive standards that seeks to advise developers on assessing diversity, physical differences, and gender roles. The guidance is intended to ensure that standards support safety and efficacy for both men and women, thus acknowledging that there are still significant gaps in the effort to achieve gender balance.[4]

One of the things I appreciate is that S-CAP's role in standards and conformity assessment is promulgated under Section 514 (c-d) of the Federal Food, Drugs and Cosmetic Act (21 U.S.C. § 360d).[5] The level of integrity needed to conform with Section 514 must necessarily be high; consequently, S-CAP must work to recognize standards and ensure they are fit for their intended regulatory purpose, whether it is to allow manufacturers to declare conformity to performance standards or develop conformity assessment tools. For these reasons, the FDA has recognized more than 1,450 consensus standards to date and supports 400-plus staff serving as liaisons to national and international standards committees. These liaisons continually work to engage with stakeholders and revise standards to become "regulatory ready" such that they can be readily used by FDA to support the total product lifecycle, from pre-market review to post-market surveillance activities.

At S-CAP, one of my duties is to promote and manage standards development within the material sciences and tissue engineered products specialty task groups (STGs), a set of device areas developed by S-CAP that divide medical device standards into nineteen different specialties.[6] Most recently, I co-led the launch of the CDRH Emerging Standards Professionals community, setting forth a pipeline to support new and experienced scientific and regulatory staff to become standards professionals within the center. Through it all, many of the skills and personality traits I've had to hone include being resourceful, charismatic, and socially and emotionally intelligent. Putting these skills to work to form communities and drive scientific consensus is critical to becoming a leader in standards.

Developing specific initiatives and agendas is important because technical experts and standards developers have limited time and resources to work on standards research and development. Beyond this, it is beneficial for an emerging professional to build technical expertise in a domain, not only to fully appreciate the requirements but also to grasp the social and regulatory challenges to using standards effectively and responsibly to promote a common good.

Finally, with respect to emerging professionals, my experience in the standards profession has been an unexpected journey, with a world full of knowledge and people to meet. Amusingly, I can also no longer describe my job in standards at a cocktail mixer in a succinct sentence. After two years of reading about the law, policies, and our research, I can say I've only scratched the surface of standards. The fact is that standards are a key element in the public-private partnership and have social, commercial, and technological consequences for how innovative health technologies are developed.

Disclaimer: The views expressed herein are solely the opinions of the author and do not

reflect the viewpoints of the Food and Drug Administration, U.S. Department of Health and Human Services, or their affiliates.

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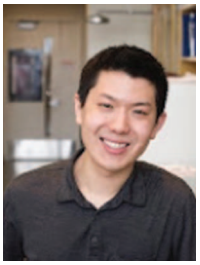

Samuel Lum is an engineer and standards advisor in the Standards and Conformity Assessment Program at the FDA Center for Devices and Radiological Health. In his growing role, Mr. Lum oversees materials science and tissue engineering standardization activities that affect medical devices. He co-leads the CDRH Emerging Standards Professionals Community and is Secretary of the USNC Young and Emerging Professionals committee. Mr. Lum is currently pursuing an M.Sc. in Global Technology Development from Arizona State University. Previously, Mr. Lum was a patent examiner in the U.S. Patent and Trademark Office.

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Energizing Emerging Areas of Research with Standardization

By Jia Mi

I began my career in a mature and well standardized field—the automotive industry. Dating back more than a century, the automotive industry was an emerging technology where a need for standards was identified. Over the past century, thousands of standards were established and enforced for different aspects of automotive operations, such as safety, emissions, and fuel economy. For example, the safety belt was invented in the 1880s, but researchers did not investigate the impact of the safety belt on injuries and deaths until the 1950s. After that, legislation approved by Congress mandated that specific safety standards be met by all automobile manufacturers.

Now, I'm working on marine renewable energy, which is an emerging area being targeted for a sustainable future. With the rapid development of this emerging area, standards are becoming more and more important.

IMPORTANCE OF STANDARDS FOR EMERGING RESEARCH

Due to their potential to revolutionize future society, emerging areas of research attract more and more people. As for a grid-connected marine renewable energy plant, it is essential that the quality of the converted power should meet the standards for grid connection; otherwise, the converted power cannot be transmitted via the grid and be used in homes.

In addition, a rigorous standardization system can be an important driving force to impel technology innovation. Another important role for standards is to improve emerging technologies' readiness level and facilitate technology maturity toward the realization of commercial-scale applications.

CHALLENGES FOR EMERGING PROFESSIONALS WORKING WITH STANDARDS

One challenge for emerging technologies is that the relevant standards haven't been widely accepted. Usually, the maturity of a standards system is an indication of the maturity of its related technologies. With emerging technologies, the standards system has a short history and hasn't been widely accepted yet. Some standards accreditation bodies still use standards from other relevant fields as references.

A second challenge for emerging technologies is the limited access to standards, especially for students and researchers in start-up companies. Typically, standards for emerging technologies are not available to the public for free. A third challenge for young

professionals working on emerging technologies is the lack of knowledge about how to use standards appropriately. Classroom training for students still focuses on fundamental knowledge and engineering skills, but standards-related trainings still haven't been widely adopted in the curriculum.

RECOMMENDATIONS TO YOUNG PROFESSIONALS FOR INCLUDING STANDARDS IN RESEARCH

It's critical for young professionals to acquire training on standards. Universities should offer more elective courses or certificate programs for students to learn standards-related knowledge. It would be great if relevant standards associations could provide trainings to students.

Working closely with industries governed by standards can help young professionals learn how to understand and use standards. Engineers working in industry usually have good access to relevant standards and have already gained rich experience with standards. In the past few years, I have worked on several industry-university collaboration projects and collaborated with experts in industry, which helped me a lot on standards implementation.

Last but not least, it's important for young professionals to keep their eyes on standards updating, since relevant standards may change rapidly. For example, the latest "Strategic Business Plan" of the IEC/TC 114 Marine energy summarized strategic objectives for 3-5 years, with different target actions from months to years.

Jia Mi is the recipient of the HUGHES, J. AND H. Fellowship and Rackham Block Grant Fellowship. His research focuses on marine renewable energy and the blue economy. He received the SES Emerging Professional Award and SES Student Scholarship. He is awarded with the Rising Stars Award from the American Society of Mechanical Engineers (ASME). In addition, he received the Best Presentation Award from the 2022 UMERC & METS joint marine energy research conference. He serves as co-chair of the International Network on Offshore Renewable Energy (INORE) and on the Board of Directors of the University Marine Renewable Energy Community (UMERC). Meanwhile, he is the member of the USNC Young and Emerging Professional Committee. He earned an M.S. in mechanical engineering from Virginia Tech and a B.S. in automotive engineering from Wuhan University of Technology. He is seeking his doctoral degree at the University of Michigan.

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WORLD STANDARDS DAY WINNING PAPER

The Next Generation of Industry Standards: A Proposed Solution for Digital Transformation

By Andrew Bank; Rupert Hopkins; Bob Solomon

(NOTE: This is the winning paper in the 2022 World Standards Day Paper Competition.)

Abstract

Organizations of all kinds, in nearly every industry, are making huge investments in digital transformation. It would be difficult to pick one industry that is not affected. But there is one area across all these industries that has lagged behind.

In our experience, engineering documents—industry standards included—have been neglected in digital transformation. Most of these documents and the data contained within are still "locked up" in dead-text PDF or Word format, making them difficult to use in engineering workflow, the very process that companies are working to modernize with digital transformation. Most product design data containing geometric dimensions and tolerances (GD&T) were transformed into "digital model" artifacts (like CAD files) starting in the 1990s. Around the same time, engineering documents went from paper to PDF and have remained there ever since. PDF was never meant to be an engineering information tool and it produces more problems than it solves.

Manufacturing companies are hit the hardest by this challenge. For American manufacturers to continue thriving and to remain competitive at home and abroad, the American public-private partnership of standards developers must address these challenges with a new solution. Taking swift and thoughtful action to develop a "SpecX" system – the next generation of industry standards – will help organizations gain the full benefit from their digital transformation investments, contribute to the continued leadership of the American standards system, and ensure interoperability with commercial end-users and international standards developers.

THE DIGITAL TRANSFORMATION BANDWAGON IS MISSING A PASSENGER

Digital transformation (DX) is underway in a big way. "The process by which companies embed new technologies across their businesses to drive fundamental change"[1] has permeated nearly every industry, and all signs point to acceleration. Organizations of all sizes are making long-term DX investments to create—or modify existing—business processes, culture, and customer experiences to adapt to evolving needs of customers and markets. With the advent of industry 4.0, the manufacturing industry has witnessed a spike in demand for automation technologies including machinery,

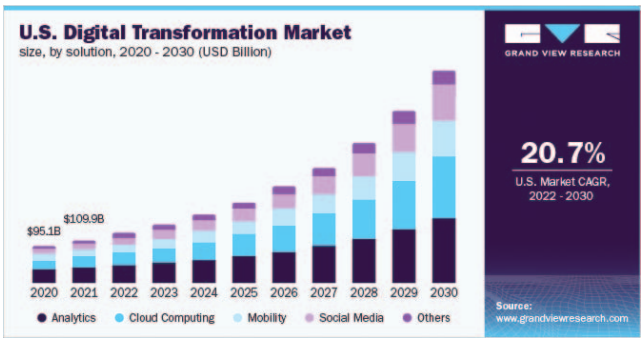

Figure 1. *The US digital transformation market is expected to grow at a compound annual growth rate (CAGR) of more than 20% from 2022 to 2030.*

robots, software, controls, and IoT. Global investment in DX is forecast to increase from $600 billion in 2022 to nearly 1.6 trillion in 2027 (Figure 1).[2]

The U.S. public-private sector partnerships that develop standards have played an important role in this transformation effort by identifying areas of innovation and providing consensus-based market-driven standards. ASTM developed important standards for additive manufacturing.[3] ICC now provides an open API into its building code content.[4] IEEE is developing standards on ethical design of AI.[5] ASME recently published a report on the potential benefits of big data in oil and gas workflows.[6] These standards and related products will undoubtedly help U.S. companies keep pace with technology and maintain a competitive edge.

However, the method by which standards are written, published, and delivered to end-users—plain-text documents delivered as PDF files—has not kept pace with technology and has already begun to cause more problems than it intended to solve. One of the biggest obstacles to efficient and productive DX is having to deal with analog artifacts in digital engineering workflow. This challenge represents a giant industry opportunity hiding in plain sight: developing a solution can be a powerful force multiplier for the very standards and drivers of DX itself.

For companies to fully leverage the benefits of DX, they must be able to consume and integrate the standards and specifications into their modern engineering workflow. This does not mean developing standards for integration or engineering; it means writing and delivering standards information in such a way that the individual data elements—text, tables, equations, graphs, images, and more—are described and tagged with their meaning, their place in a standardized ontology, and their contextual relationship to other pieces of data. It means that the information contained in standards must be interoperable with common enterprise applications (e.g., PLM, MES, ERP), and maintained in a master repository that permits access to the data with proper licensing and authentication. Furthermore, DX depends to a large extent on automating as much as possible; therefore, standards of the future must be written for humans but also for machines.

This sounds complex and perhaps a bit like fairy dust, but there are powerful reasons behind these requirements and powerful forces driving them. This paper will recall the events that led us to this moment, describe some of the difficulties in using static PDF files in digital engineering workflow, and then propose a set of principles to govern the future development, publishing, and delivery of "SpecX standards," the standards of the future.

IT'S ALL ABOUT CHANGE—AND WHAT HAS NOT CHANGED

The *MIT Sloan Management Review* says, "Digital transformation is better thought of as continual adaptation to a constantly changing environment."[7] Today's process of DX takes transformation to a whole new level primarily because it's all about change, and change is happening more rapidly now than ever before.

Applying new technologies to business with the goal of improving products, culture, and customer experience is not new. In the 1990s, there was a paradigm shift in which engineering and industrial companies migrated their paper documents, drawings,

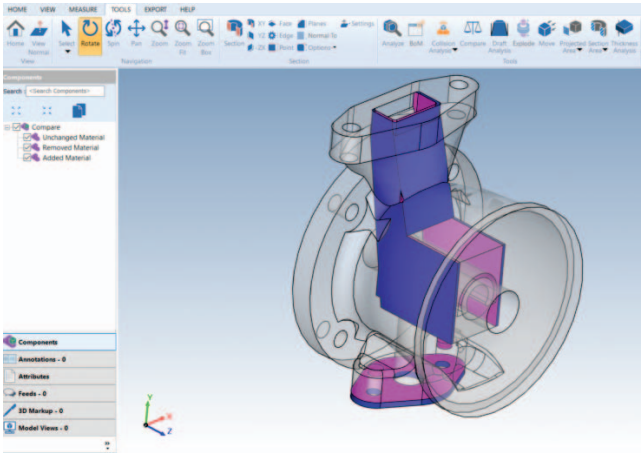

Figure 2. *In the 1990s, physical parts moved from paper to virtual 3D CAD models. Engineering documents never made the same transition.*

and blueprints to electronic format. With the growing adoption of model-based engineering (MBE), product designs—those with geometric dimensions and tolerances, or GD&T data—were "freed" from 2D versions and placed directly into 3D models, ostensibly making the 3D CAD (computer aided design) model a single source of design information (See Figure 2).

At the same time, the underlying engineering documentation—non-GD&T information such as industry specs and standards, as well as internal corporate standards—moved from paper to PDF. At the time, it was a revolution that increased productivity and speed, enabled simple sharing, and reduced human error.

Amazingly though, not much has changed with engineering documents or industry standards formats since the mid-1990s. All the text, graphs, tables, equations, images, and references that comprise manufacturing notes, materials and finishing requirements, test methods, work instructions, supplier instructions, customer requirements, and more are often trapped in legacy paper, static PDF, PowerPoint, or Word files. Manufacturing engineers, procurement professionals, estimators, factory-floor workers, testing labs, and others struggle to find the precise information they need, extract the relevant requirements for the task at hand, and feel confident they are using the right versions and references in a sea of disconnected, static documents.

The CHALLENGES OF USING STATIC DATA

These are some of the concrete problems and inefficiencies that technical professionals encounter when using industry standards in static PDF format.

Little or No Interoperability

Most engineering documents contain dozens of references and explicit and implicit connections to other documents, many of them belonging to third-party owners (e.g., an IEEE standard linking to an ASTM standard or a Boeing internal spec linking to an SAE standard), but there is no way for users to easily click between them.

It's also very difficult to move between documents and systems. For example, product life cycle management (PLM) systems (a common desktop application used by manufacturers) often contain hundreds or thousands of references to internal and external standards. But rather than clicking directly from PLM into the relevant document or piece of data, users must go silo-hopping, leaving one system and hunting down the document in another. Not only do they have to find the document itself, but they also must find the exact piece of data inside that document (which could be 5 or 50 or 500 pages long), then somehow export that data into the desired application.

Copy/Paste and Manual Rekeying

Companies use bits and pieces of engineering standards throughout their operation. Some requirements here, an equation there. One very common task is to copy/paste or even manually rekey data from these documents into other documents or applications (e.g., to create work instructions or test

plans or supplier specs). Copying/pasting and manually rekeying data is tedious manual labor and heightens the risk of potential human errors that occur when manually rekeying equations or recreating tables from PDF files.

Impact Assessment is Tedious and Risky

Nearly every company that builds a product must deal with changing standards and regulations. As mentioned, parts and pieces of standards are embedded in their operation and indeed in the DNA of their product design and manufacturing. When changes are made to the source material (for example, a new or revised standard), companies have a difficult time monitoring and assessing the impact of that change on their operation and communicating the impacts to stakeholders up and downstream. For companies that build products with very long lives—50 years or more for aircraft, refineries, and other infrastructure—the 2–3-year life of standards poses an even bigger challenge than for companies with very short product shelf lives (like mobile phones or medical devices).

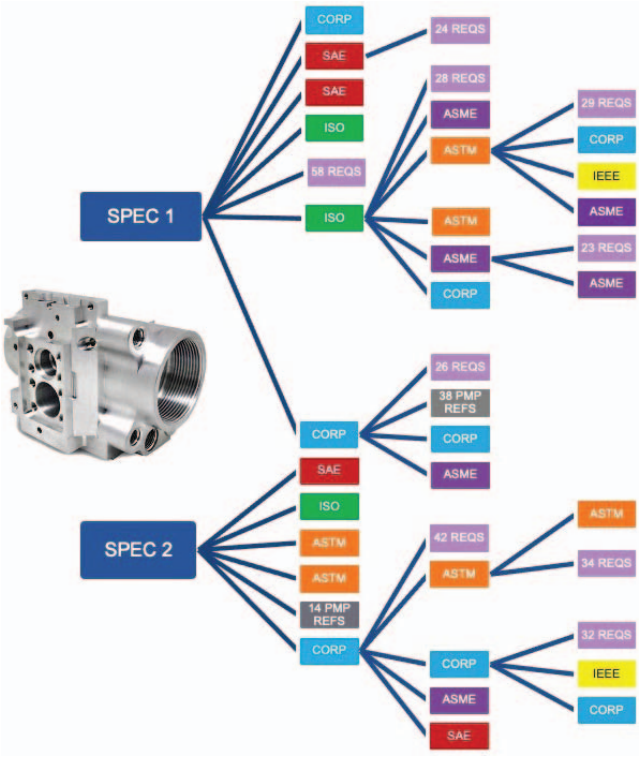

Figure 3. *One small project involving just 2-3 primary standards can quickly cascade into dozens of references with requirements distributed across many different documents.*

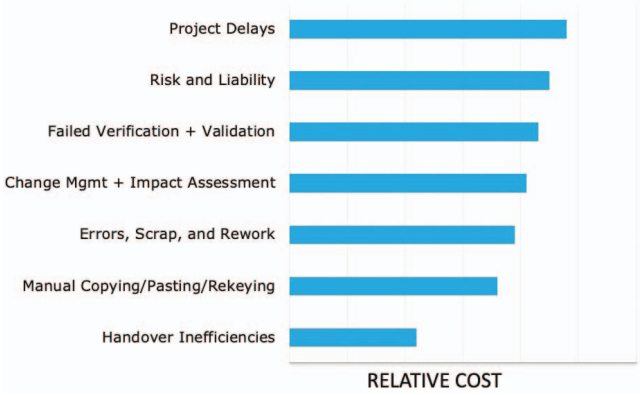

Figure 4. *The relative costs and inefficiencies of using static documents in modern engineering workflow.*

Finding Requirements

Engineers often spend hours, days, or weeks analyzing specs, standards, customer orders and other documents to identify the specific requirements that they need to do the job at hand. Extracting those requirements and classifying them according to the part or material or process is painstaking manual labor. One small project involving just 2-3 primary standards can quickly cascade into dozens of references, with requirements distributed across many different documents (See Figure 3).

THE MODEL-BASED REVOLUTION, AKA "SPECX"

We previously mentioned the 1990s conversion of 2D drawings and GD&T design data into CAD files. This type of digital artifact is called a digital model. A digital model is a data-centric model of a physical object that describes the form, character, and context of that object. A CAD model provides a three-dimensional visual representation of a physical object along with geometric dimensions, textures, materials, tolerances, and more. Likewise, a digital model, or "digital

twin," of a building or a part or a system of parts provides all the critical data associated with the object or system.

A PDF file was never meant to be an engineering information tool, let alone a digital model. It is merely a static and non-editable and non-descript copy of the source document. Sometimes it is nothing more than an image of the physical document. It does not describe the form, character, and context of the information contained therein. It does not know when changes at the source occur and how they might affect the content in the PDF file, the associated product(s), or the broader operation of the business. And any data taken from the document and used elsewhere remains as unintelligent, unaware, and disconnected as the source document. ***A PDF is a poor container of data, and a PDF document can only be understood and acted upon by having a human read it*** (See Figure 4).

If the design and manufacturing information chain is defined by its weakest link, engineering documents and industry standards are now often the weakest links. The public-private industry standards partnerships (i.e., SDOs) have done a good job embracing the DX of its members' products and services. We believe it is time now for the industry to embrace the process by which members consume standards information and help them leverage the full benefits of their DX investment. It's time for engineering documents to get the same royal transformation treatment that 2D drawings got in the 1990s and have benefited from ever since.

Static industry standards must now become "SpecX" digital models. A SpecX model is more than just a document; it's a collection of actionable, intelligent, and dynamic data elements that are organized in a database and connected to each other in relevant ways. A SpecX model enables a whole new world of capabilities and value-added benefits that are impossible to achieve with PDF files. We believe this information needs to be freed (though not free of charge) from PDF documents and moved to interoperable, change-aware, machine-readable digital models.

THE EIGHT CORE PRINCIPLES OF SPECX DIGITAL MODELS

To convey more clearly what SpecX is, consider these core principles that we believe should be at the heart of any digital transformation strategy involving engineering documents.

1. Engineering data should be available from a single, authoritative source of truth, and changes should be communicated to all stakeholders. The primary means of communication for this information must move from stand-alone static documents to interoperable and change-aware SpecX models. This information must be held in a common set of digital models managed in a query-capable Semantic Web database or knowledge graph in which each IP owner manages and controls their respective data. As a result, authorized human and machine stakeholders will have the current, complete, authoritative, and consistent information for use over the product life cycle. When changes are made to the source material by IP owners, the changes can be automatically communicated up- and downstream to all relevant stakeholders.

2. Advanced AI technology should be used to enable scalable transformation to SpecX. The transformation of engineering artifacts to digital models cannot scale with manual modeling of the semantic information described by the engineering documents. Expecting different people in different organizations to tag documents in a consistent way is a fool's errand; even expecting organizations to have the resources to tag is a tall order. An ensemble of AI tools—from ontology-based to modern language models based on neural networks—can now be deployed to model syntactic and semantic information from various engineering sources inside and outside an organization.

These tools can act as a human expert to characterize and contextualize the information at scale. For example, a document containing dozens of finishing requirements under various conditions can be summarized and classified according to those conditions, the types of finishes, or other selectable criteria. A user seeking finishing requirements for a specific material and use case can simply click and extract the requirements needed rather than wading through the entire document.

3. Data must be interoperable across IP owners, repositories, and applications. Information users spend too much time "silo-hopping" from disconnected repositories and applications to find the information they need. Nearly every engineering document references many others, often from third parties, but users are left to their own devices to obtain those references and verify their status and currency. This is time-consuming and repetitive manual labor that could easily be eliminated using the linked-data structure of digital models and the automation capabilities of AI.

Much like the Crossref system enables reference linking between journal articles, AI and machine learning can automatically identify and activate reference links from document to document (with proper licensing from the IP owners, of course), and each data element can be stored in a unique location in the semantic web or knowledge graph. Combined with an open API (application programming interface), the result is a consistent method for users to find, cite, link to, assess, and reuse data elements contained within SpecX models. Most importantly, users can easily discover requirements distributed across documents, their dependencies, and the impact of change up and down the requirements' value stream (See Figure 5).

Note that IP owners of the native engineering documents (whether OEMs, SDOs, or government) will continue to own their data and documents. SpecX models and a knowledge graph simply make their data more usable and more readily accessible to more users from more applications—arguably making their information more valuable. With proper licensing and access and e-commerce tools layered upon the knowledge graph, IP owners can benefit from wider usage and any number of new business models and new net revenue.

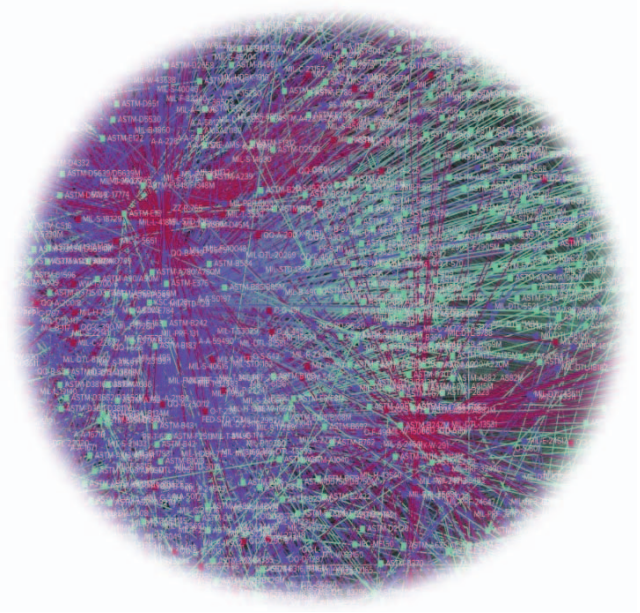

Figure 5. *Data stored in a knowledge graph can activate contextual connections across content sets.*

4. Engineering information should be delivered to the point of use in existing applications (e.g., PLM and authoring tools) using an open API. Engineers don't need more workbenches or applications. The information engineers need from ASTM, DoD ASSIST, or their own corporate standards can be brought via API into MS Word, PowerPoint, PLM systems, manufacturing execution systems (MES), authoring tools, and more. Developers using a robust, open API with a variety of microservices can quickly develop apps such as shop floor wizards, executable calculations, quality checklists, table look-ups, and PLM plugins.

Delivering content in this way also aligns with the principles of the Digital Thread currently being adopted by the engineering and manufacturing communities. Data used in an

engineering workflow must be available at the point of need, but it should always be connected to its authoritative source. Changes made at the source should be communicated up- and downstream throughout the Digital Thread so that the single source of truth is always known to all.

5. Legacy documents cannot be left behind; the creation of SpecX models must accommodate new and old content. Microservices using AI/ML, machine vision and other technologies can be dedicated to analyzing and transforming legacy content. That includes the transformation of MS Word-based specifications or PDF files into digital models, the extraction of key semantic concepts from 2D PDF drawings (including legacy raster drawings), and the transformation of ISO-STS/NISO-STS XML standards, and other XML formats.

6. While internal corporate content must be interoperable with external industry standards, security and IP protection cannot be sacrificed. Cyber threats evolve rapidly. Cyber security standards try to keep pace with the threat, so they evolve continuously. There are no global security standards for model-based standards; each enterprise has its own security standards, and the overlap between enterprises is not complete. NIST 800-171 (rev2), in compliance with DoD requirements, provides a baseline, and the security solutions will evolve toward the government cloud. Corporations must have confidence that storing their proprietary information alongside external industry information does not mean that unauthorized users will have access to their data.

Similarly, specs and standards have been targets of piracy for decades. The paradigm shift from PDF to SpecX must also bring about a paradigm shift in IP protection. Heightened security around copy/paste and document/data sharing should be combined with new licensing models that enable users to quickly and easily obtain licensed and protected content that is aligned with the needs of their enterprise.

7. Engineering content must evolve from documents to models to digital assistants. AI is evolving rapidly. Neural networks and other machine learning tools are improving by orders of magnitude. There is little reason to doubt that engineering content will be more interactive, in the sense that an engineering document (now model) should eventually be the users' digital assistant. A user should be able to ask the document/model a question and get a contextual reply that may be the result of the system crawling through a graph of requirements threaded across multiple authoritative sources. This 'Alexa-like' functionality will enhance the productivity and accuracy of humans and could also enhance the power of VR/AR tools throughout the product life cycle.

8. Engineering information must be consumable by machines. Many years ago, a major aerospace company fed the torque specifications for various fasteners into a software application used by a fleet of bolt-tightening robots. It was a complex set of specs, organized by the type of bolt (material, thread type, thread class, etc.), the substrate, and many other criteria. Because all the source data was stored in a PDF file, it was a tedious job that required hard-coding data, and any updates also had to be updated manually. The result was a semi-autonomous machine that applied the proper torque based on the situation. This was a monumental achievement at the time, but it was only the seed of what was to come.

A growing number of industrial machines rely on data from specifications and standards to run their processes. Today, humans are the bridge—and the bottleneck—between the data and the machines. For example, a machine operator might enter torque specifications into the machine interface, copying the numbers from a MIL Spec or National Aerospace Standard. This manual process consumes too much time, is prone to human error, and is certainly not scalable. For manufacturers to leverage the full benefits of the digital thread and autonomous manufactur-

ing, the information in engineering documents must be readable and interpretable by machines without human intervention.

Documents, from their general structure down to the most granular data elements (equations, tables, etc.), must be quantified in standardized formats that machines can understand and act upon. Further still, the content must be written and tagged in such a way that machines can analyze the full scope and context of information, combine it with data from other sources, and automatically make decisions and take actions based on the machine's interpretation. In the not too distant future, machines, not humans, will be the primary consumers of engineering data.

YOUNG PROFESSIONALS HATE TEDIOUS MANUAL LABOR

A young aerospace engineer told us of their recent experience fresh from their master's degree and right into the QA department of a major aircraft manufacturer–they were baffled and demoralized by the volume of tedious manual labor. At university, they learned about using AI and analytics tools to process information that would aid and accelerate decision making. In their job, they spend time copying/pasting from document to document. In the interviews leading up to the job, they were told about the modern engineering workflow and the company's passion for digital transformation. Although the company was investing heavily in DX, they were still forced to deal with analog wrenches in the digital thread.

If technology companies and the standards industry in general hope to attract young, skilled professionals to replace the exodus of retiring older professionals, we must walk the talk of DX. Initiatives like SpecX will satisfy a new generation of standards users and standardization professionals. Aside from eliminating non-value-added manual labor, SpecX offers dozens of new ways to take advantage of intelligent standards data to improve productivity, increase speed, and reduce errors.

IF WE DON'T, THEY WILL

The move from flat-text engineering documents to machine-readable, data-centric artifacts is already happening elsewhere. CEN/CENELEC, ISO, and IEC are developing their own independent system, called SMART, that will elevate EU and international standards above U.S. and regional standards. In their own words, "SMART will ensure that IEC and ISO products and services remain the most attractive and relevant to markets and societies, today and tomorrow."[8]

SpecX can certainly be compatible with whatever the EU and international community develop. In fact, core principle #3 dictates such interoperability. Creating a strong independent US-based SpecX—just as we created a strong independent SDO ecosystem—will help American businesses accelerate DX, gain the full benefits of standards adoption, and maintain a competitive edge.

Although there is no dominant or fully formed system anywhere in the world yet, there are seeds of similar solutions in the U.S.

NISO has adopted the ISO STS-XML schema, which dictates a standardized set of syntactic elements of documents such as section headers, tables, lists, etc. But more work needs to be done to characterize and tag the semantic elements such as parts, materials, processes, requirements, test methods, and more.

The Defense Standardization Printing Office (DSPO), an agency of the Department of Defense, has started a project called "Documents as Digital Data,"[9] but it is in very early phases.

SWISS (Semantic Web for Interoperable Specs and Standards)[10] is a neutral, AI-enhanced semantic platform that provides interoperable, reusable, and machine-readable digital-model data that they call "digital twins of engineering documents." SWISS pioneered the concept of SMART standards and SpecX digital models several years ago and has an operational commercial platform available

today. The platform facilitates the transformation of static documents to digital models and then provides ongoing AI enhancement, data management, and an open API to provide enterprise access to companies and users. SWISS is the world's largest engineering knowledge graph, has partnered with the DoD/DLA, ASTM, ASME, and others, and counts three of the five largest aerospace and defense companies as their customers.

ASME formed a Model-Based Engineering (MBE) Standards Committee[11] that oversees the development of rules, guidance, and examples for the creation, use and reuse of model-based datasets, data models, and related topics within a Model-Based Enterprise (MBE).

CONCLUSION: LET'S BEGIN

For over 100 years, industry standards have been the backbone of commerce and the basis for quality and interoperability,[12] driving borderless trade, technical innovation, and digital transformation. Now, standards need to contribute to the success of its industries, not only by the content inside the documents, but by the way the content is consumed outside the document.

"America's leadership in standards has harnessed private sector speed and flexibility to help companies keep pace with technology, foster economic growth, and save government partners and taxpayers billions."[13] We could not have said it better ourselves!

Continuing American leadership for the next 100 years will require the same speed, flexibility, and innovation that we used to get here. But using the same tactics that got us here will not get us where we need to go. Engineering documents have not changed since the 1990s, and they are long overdue for their own DX.

Gerald Kane, professor of information systems at Boston College, said, "The more I study digital transformation, the more I realize that it's not mostly about either 'digital' or 'transformation.'

"Instead, digital transformation is about how technology changes the conditions under which business is done, in ways that change the expectations of customers, partners, and employees."[14]

Technology—indeed, DX itself—has changed the conditions by which companies operate, and in return, companies now have changed expectations of our industry. We must respond thoughtfully but swiftly to meet their expectations.

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Andrew Bank leads strategy and business development for the digital twin documents platform, SWISS, created by XSB. He is the co-founder of Techstreet, Larky, and i2B Strategies.

Rupert Hopkins is president and founder of XSB, Inc. He guides the company's vision and business strategy for automated tools that acquire, organize and enrich data using data mining and artificial intelligence. Rupert has served as an adviser to the Defense Office of Economic Adjustment, the Defense Standardization Program Office, the Council on Foreign Relations, the Soros Foundation and others.

Bob Solomon is a board member of XSB and the principal of Software Platform Consulting, Inc. (SPCI). Bob helps software companies and their investors develop multi-sided platforms and networks.

STANDARDIZATION: JOURNAL OF RESEARCH AND INNOVATION

JSRI 2022;1(5):23–24

Standards in Action: Over-the-Counter Hearing Aids

By Kerri Haresign

In 2017, the bipartisan Over-the-Counter (OTC) Hearing Aid Act was passed. This legislation directed the U.S. Food and Drug Administration (FDA) to allow direct-to-consumer and retail-based hearing aid sales. In October 2022, tens of millions of Americans finally gained access to OTC hearing aids after implementation of the FDA's final rule stemming from the Hearing Aid Act. [1] This allows Americans with mild to moderate hearing loss to buy affordable hearing aids the way they buy reading glasses—without a medical exam, from a local store or online.

This moment represents years of advocacy by associations, including the Consumer Technology Association® (CTA), industry partners, and allied organizations. It also stems in part from CTA's voluntary OTC hearing aid industry standards, which were developed over the last decade and describe minimum performance criteria.

As North America's largest technology trade association, CTA *is* the tech sector. Our members are the world's leading innovators—from startups to global brands—helping support more than 18 million American jobs. CTA owns and produces CES®, the most influential tech event in the world.

THE IMPACT OF ACCESS TO OTC HEARING AIDS

"Ninety-plus percent of adults with hearing loss have needs that can be served by over-the-counter hearing aids," said Dr. Frank Lin, the director of the Johns Hopkins Cochlear Center for Hearing and Public Health.[2]

Only 20% of people who could benefit from a hearing aid use one, and the new OTC hearing aid category opens a world of sound to Americans with hearing loss. These devices improve accessibility and represent an important, vibrant, and innovative device category for the nearly 40 million adults with mild-to-moderate hearing loss.[3]

Many who could benefit from OTC hearing aids wait for symptoms to worsen before seeking a hearing health solution. While ease of access and lower costs may open the door to more people getting devices, increased comfort with hearing products means people may be more open to prescription devices if their hearing loss progresses.

OTC hearing aids aren't an either-or situation. People under 18, individuals whose test shows more than mild-to-moderate loss, people with compounding health issues, and anyone who isn't seeing results with existing devices should consult an audiologist.

DRIVEN BY INDUSTRY STANDARDS

Industry standards are central to this new category, and CTA has been working with the FDA and other stakeholders for years to help establish industry best practices that are driving innovation (and plans to continue that collaboration). Specifically, the final rule cites

ANSI/CTA-2051, Personal Sound Amplification Performance Criteria,[4] which includes technical performance metrics and associated target values for consumer products that provide personal sound amplification and enhancement to a user.

CTA's Health, Fitness and Wellness Committee recently published ANSI/CTA-2051-A, Wearable Sound Amplifier Performance Criteria,[5] which updates the original standard but maintains the primary technical performance criteria of the 2017 version. Both ANSI/CTA-2051 and ANSI/CTA-2051-A also reference standards developed by the Acoustical Society of America, the International Electrotechnical Commission (IEC), ISO, and IEEE.

To continue to support the growth of this industry sector through standardization, CTA recently launched new work to identify the elements of standard testing methodology for a consumer-facing hearing metric and to establish a common vocabulary for hearing health for consumer-facing hearing solutions, including OTC hearing aids. This standard is expected to be completed in 2023.

WHAT'S NEXT?

This is just the beginning for this new device category. Anytime you have novel innovations and new product categories like OTC hearing aids entering the market, conversations open up and increase awareness about hearing health. Working together, we can help improve health outcomes by addressing issues related to hearing loss like dementia and depression.[6]

As we have seen with other digital health technologies, hearing aids have gone from nice to have to a necessity, and this is an exciting moment for hearing health. At CTA, we look forward to the ways that industry standards for these devices will increase the usage and ultimately improve outcomes, lower costs, and enhance consumer experiences.

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Kerri Haresign is the director of technology and standards at the Consumer Technology Association, North America's largest technology trade association. She is responsible for the oversight of a broad range of technology subjects within CTA's standardization activities, including artificial intelligence, audio systems, health, fitness and wellness technology, and video systems. Additionally, she oversees CTA's Technology Council, a CTO-level group that bridges the areas of business and technology, exploring topics such as consumer radar API, the security of ML-based systems, gesture control, and ultra-HD interoperability. She is vice president of the Society for Standards Professionals (SES) and participates in a variety of other standards activities, including currently serving as the vice-chair of the ANSI Executive Standards Council.