Transcript of 2021 CPSC Podcast Series, "ENHANCING THE SAFETY OF EMERGING TECHNOLOGY THROUGH RISK ASSESSMENT: WEARABLES"

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The slides used in this podcast are not a comprehensive statement of legal requirements or policy, and thus, should not be relied upon for that purpose. You should consult official versions of U.S. statutes and regulations, as well as published CPSC guidance, when making decisions that could affect the safety and compliance of products entering U.S. commerce. Note that references are provided at the end of the presentation.

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Hi, my name is Sylvia Chen, and I want to welcome you to this podcast presentation today.

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As you heard in the video, "design of safe products at the outset is critical." CPSC is a United States federal government agency charged with protecting the public from unreasonable risks of injury or death associated with the use of consumer products under the agency's jurisdiction. We have developed this podcast series not only to inform about regulations, standards, and other safety requirements, but also to emphasize the importance of designing products with safety considerations in mind, and to offer best practices for enhancing the safety of a variety of common consumer products.

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The series covers six common consumer products and the requirements for keeping consumers safe, focusing on products affecting millions of consumers, such as children's sleepwear, wearables, batteries, gates and enclosures, micro mobility, and cribs and play yards. In this podcast series, you can expect to learn about the key hazards and risks of the product, important design and manufacturing considerations, regulations and standards that CPSC uses to ensure product safety, best practices you can employ, and what resources are available to assist you in understanding and implementing the requirements.

The podcasts include English and Chinese slide decks and Chinese narration to make this important safety information as accessible as possible. Additionally, CPSC has established a dedicated email box, where listeners, at their convenience, can send in any questions, in English or Chinese. Our staff will monitor the email box and respond to your questions. Transcripts in English are available on this site.

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And now, we will begin our presentation on an approach to enhance the safety of consumer products with emerging technologies using risk assessment, focusing, in particular, on wearable products.

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Innovation has always been a driver for gaining market share and competing for consumer attention. In recent years, an unprecedented number of new and traditional consumer products have begun to include innovative features, such as wireless connectivity, activity tracking, and fitness monitoring. When navigating the integration of new technologies and functionalities into consumer products, manufacturers have a dizzying array of decisions before them. With little experience of the short- and long-term implications of incorporating these new technologies, manufacturers are presented with both opportunities and risks. In this presentation, we will discuss how to approach these technologies in consumer products, with a focus on designing and sourcing safe products.

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"Connected products" are defined by ASTM F3463, the Standard Guide for Ensuring the Safety of Connected Consumer Products, as *"—any consumer device or physical object that is capable of connecting to the internet or other network directly or indirectly and is assigned an internet, Bluetooth, or other communication protocol address or identifier."*
Recently, many consumer products have been outfitted with connected technology.

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These advances are not just limited to new products.
There are many traditional, even iconic, products that have been outfitted with connected technologies. These technologies increase the functionality of products, broadening the consumer experience by allowing for new uses for products that may have just had one or two purposes before the addition of new technology. For example, this jacket, previously worn for warmth and style purposes, is outfitted with controls that connect to a smart phone, allowing for streamlined use of calling, navigation, and other features.

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As a manufacturer or retailer, how do you approach products that encompass these new technologies while keeping consumer safety in mind? Although there are some general guidelines and best practices for introducing safer products, this presentation will provide a risk assessment approach to enhancing the safety of products with these new technologies with a focus on wearable technology.

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Wearables are just one type of connected product. These products are worn by the consumer and increasingly use "smart" technology to enhance user experience. For example, such technology may suggest activities or provide services relevant to a location. Typically, the product communicates with an external device, such as a smart phone. Although a wearable product could be just about anything worn on or in the body, the form factors for these products often follow those of traditional products, such as watches, rings, or apparel, allowing for more than one function from the product. For example, connected watches no longer just tell time, but they can also notify the wearer of their daily schedule, level of activity, and suggest restaurants in an area.

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Wearable tech is definitely catching on. Current forecasts estimate a market for wearable tech in excess of $150 billion annually by 2027. It is not difficult to believe that kind of growth is possible, given that global wearable shipments increased 35.1 percent from 2019 to 2020 (3Q20), resulting in total shipments of 125 million units, according to a recent report from the International Data Corporation (IDC) Worldwide Quarterly Wearable Device Tracker. This indication of consumer interest suggests that we will be seeing more of these products in the coming years.

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How then should a manufacturer approach using this technology in its products? While each product may have aspects requiring a specific approach, there are general guidelines and best practices that can help manufacturers, as well as buyers, retailers, and others in the consumer product supply chain, to enhance the safety of their connected consumer products.

Throughout this presentation, we will use the example of a wearable that is a connected apparel product intended for exercise use. As we move through our topics, it will provide a concrete example of how to approach requirements, evaluate risk, and implement a safety strategy. Note that this example is hypothetical and used for explanatory purposes only. Please consider the specific facts related to your product when determining the best way to approach enhancing the safety of your specific products.

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Given all the excitement about these products and growth of their market, how are regulatory entities responding? Regulation occurs within an established legal framework, while technology growth is based on innovation and research. Long-standing U.S. government policy has generally been to regulate only if industry cannot or will not create and implement appropriate and effective standards. Historically, regulation is reactive, and there is a lag in implementing and enforcing requirements. When new products challenge established

frameworks, there can be uncertainty for those attempting to bring new technology products safely and compliantly to market. Additionally, regulating new technology too quickly can have the unintended consequences of stifling invention or implementing requirements that are outdated by the time the regulation is in place.

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The regulating authority with jurisdiction is important because jurisdiction will dictate the requirements for that product. The jurisdiction under which a product falls depends on a number of factors.

One example is the difference between a *medical device*, regulated by the U.S. Food and Drug Administration, and a *consumer product*, regulated by the U.S. CPSC.
A "medical device" is defined by the FDA in Section 201(h) of the Food, Drug, and Cosmetic Act, in part, as "intended for use in the diagnosis of disease or other condition" and "to affect the structure or any function of the body of man . . .."

A "consumer product" is defined by the United States Code, in part, as "any article, or component part . . ., produced or distributed… (ii) for the personal use, consumption or enjoyment of a consumer in or around a . . . household or residence, a school, in recreation, or otherwise."

Jurisdiction can be especially confusing when the same technology falls under different regulatory authority, based on marketing claims, or a specific function. In the example of our wearable exercise garment, it would likely be considered a "consumer product" under the jurisdiction of the CPSC because it is intended for personal use during recreation, and it makes no medical claims. However, if the same garment made medical claims and was marketed to consumers with an illness, the product would likely be considered a "medical device" under the jurisdiction of the FDA.

Why does this matter? Medical devices and consumer products have very different requirements for entering the marketplace. Medical devices typically require premarket approval that may require research and testing to substantiate claims and show safety. Consumer products subject to a rule, standard, or ban require certification based on a test of every product or a reasonable testing program; and in the case of products intended for children 12 years of age and younger, third party testing by a CPSC-accepted laboratory is required.

Be sure to research thoroughly the potential jurisdiction of your products, and reach out to the regulating entities for guidance on the best way to be compliant with requirements. There are many additional regulating authorities, including state and local jurisdictions, which should be considered when formulating your compliance strategy.

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In addition to regulations, there are a number of industry consensus standards that focus on the safety of consumer products. This is important because the Commission may rely on an industry consensus standard to determine if products or aspects of a product not subject to a regulation have a safety defect. Consensus standards are well-positioned to address emerging technology. Because these standards are developed using a consensus-based process with a range of stakeholders and can be updated on a relatively short time scale, the standards tend to be robust and current. With frequent product changes due to innovation, these standards may be able to more quickly respond to evolving products. These efforts allow stakeholders to participate, so it is a good idea to approach these standards organizations to find out how you can have a voice in the process that may affect your products, market sector, or consumer base.

If there is no current, adequate standard, or there is not substantial compliance with a current standard, the Commission may initiate a rulemaking effort that may lead to a technical regulation. Additionally, the public may petition the Commission to undertake a rulemaking effort.

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Manufacturers, importers, distributors, and retailers are required to report to CPSC under Section 15 (b) of the Consumer Product Safety Act (CPSA) within 24 hours of obtaining information that a product does not comply with a safety rule issued under the CPSA, or contains a *defect* which could create a substantial risk of injury to the public or presents an unreasonable risk of serious injury or death.
The majority of CPSC recalls are not for regulated products. Most recalls are for products determined to have defects, a product issue that could create a substantial risk of injury to consumers.
When appropriate, the Commission relies on industry consensus standards as a baseline safety threshold for products without specific technical safety regulations. It is important to know what consensus standards could apply to your product and use those standards to characterize the safety of your product. In some cases, there may not be a standard for your exact product. Companies are still required to introduce only safe products into the marketplace, so it is important to work with in-house experts, testing laboratories, and others to develop safety-focused performance requirements.

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Now we will discuss developing a risk-assessment strategy.

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There are many types of risk associated with consumer products. This definition of "risk" is focused on product safety.

For purposes of this strategy, "risk" is defined as a combination of three elements:
1. The hazard scenario or scenarios that could lead to a potential injury or death,
2. The likelihood of the hazard scenario or scenarios occurring, and
3. The consequence or consequences of these scenarios as they relate to hazard severity.

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CPSC staff has developed an approach for assessing product risk that is focused on a stepwise analysis of the product.

These steps are:
- Characterization of the product,
- Categorization of the hazard or hazards,
- Identification of the hazard patterns and potential consequences, and
- Determination of the potential risk.

To arrive at a robust safety enhancement strategy, these steps should be expansive and iterative, and undertaken by a team of diverse experts with knowledge of the product, hazards, or other relevant factors.

Please note that this strategy is offered as a general approach to assessing product safety risk. There are a number of approaches that may be available for specific products that may be more relevant or refined for that product. However, this strategy offers a good starting point for developing a risk assessment strategy from scratch or auditing an existing strategy.

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Before any safety risk assessment can be undertaken, the assessor must understand certain key facts about the product.

What is the purpose of the product? What does it do? There may be multiple answers to this question. Many products have both functional and aesthetic purposes. Additionally, products may have more than one functional purpose.

Who is the intended user of the product? Knowing your consumer can help determine risk. For example, products intended for children will often have different risk considerations than those intended for adults. Children are considered a vulnerable population because they may not have the life experience or physiological maturity to recognize hazards or know how to respond to them.

Beyond the intended purpose or purposes of the product, are there any other foreseeable uses? Consumers are ingenious when it comes to finding alternate uses for products, many highlighted on social media channels and online forums. Be sure to spend time looking at potential alternate uses of your product and their safety implications.

Finally, how will the product be marketed and sold? The claims made, the purchasing location, and other factors give insight into the consumer using the product and the consumer's perception of the product.

A potentially helpful reference for these analyses is the *Guidance on the Application of Human Factors to Consumer Products,* a joint CPSC and Health Canada-sponsored publication that was developed to help consumer product manufacturers integrate human factors principles into their product development process.

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Once the product has been characterized, potential hazards should be identified and categorized. A good place to start is determining the purpose of the product and its functionality. This slide shows a small selection of different wearable functionalities identified by CPSC staff from a survey of current products.

When examining function for the identification of potential hazards, consider not just the function, but also the situations and environments in which the product will be used. These factors are just as important for identifying potential safety issues.

For example, virtual reality headsets may pose potential light or stress damage to vision, a direct and easily identifiable hazard. However, they may also pose a tripping or impact hazard from interacting with a real environment while seeing a virtual one, an indirect hazard of using the product.

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When categorizing the hazard, consider the location in or on the user's body as the product is being used. Consider the impact of sweat, heat dissipation, and other conditions that can be expected in proximity to the body. Additionally, certain areas of the body are more prone to the uptake of harmful chemicals. For example, wearables that may come into contact with the mouth will have different considerations than those in contact with the arm. Products located close to the eye should be examined for any issues that could cause eye injury, such as shattering or bright lights. It is a good idea to engage an expert on physiology, toxicology, or other pertinent disciplines to review potential hazards.

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Features of the product may introduce risks of hazardous exposure, such as biological, electrical, chemical, thermal, and other types of exposure.

It's imperative to consider types of exposure, intended and unintended, and in the context of foreseeable use, environments and locations on or in the user's body. Remember, just because the product isn't marketed to be used in a certain way, doesn't mean the product won't be used in that way. Design features can invite unintended uses, even uses contrary to warning messages, depending on the user's expectations from past experiences with the same or similar products and features. Due diligence to predict user behavior and potential consequences related to use of the product can help prevent deaths and serious injuries.

Hazard categorizations will also help in finding the right experts to evaluate the hazards.

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Identifying hazard patterns and consequences may be straightforward or could require making assumptions or modeling outcomes based on different products.

If data exist for the same or very similar products, obtain and review that data. The range of available data may vary from very general or sparse, to complex and robust. Look for firsthand narrative accounts, if possible. There are a number of data sources that can be used, from government-provided, such as the CPSC NEISS database, to data services that may include data analyses with a fee. Many consumer websites now include reviews. Reviews from consumers can provide good insight into how a product is being used and consumer interpretations of hazards.

If the product is new, or data cannot be obtained, data from similar products could be used to assess risk. For example, if analyzing an existing product, such as a toaster, that includes connected technology, an assessor can look at toaster incident data plus data related to other connected cooking appliances, keeping in mind that there may be some product differences, and building uncertainty into the model to account for these differences.

When looking at hazard patterns, the consequences of hazards should be examined in their entirety,
before summary statistics are employed. Based on your company's goals, assessors may choose to weight certain consequences more heavily when assessing risk. For example, low severity outcomes may be acceptable, while mid-to high-severity outcomes may not.

In addition to severity, probability or likelihood of a hazard occurring must be assessed. A low-severity hazard, such as an abrasion, may be unacceptable if the likelihood of occurrence is very high. Likewise, very high-severity hazards, with a nearly zero chance of occurring, may be unacceptable, especially if necessary mitigation measures are not implemented.

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Now that these steps have been taken, the assessor can determine the product risk. In practice, this determination could be quantitative, such as a numerical scale, or qualitative, such as a rating of high, medium, or low. In all assessments, safety risk should be composed of three factors: the hazard scenario, likelihood, and consequence. These factors should include all of the information gathered about the product.

Higher-risk products should be given the most scrutiny. These products might be defined by their intended user, the exposure type, or location of the product, the intended or foreseeable function of the product, and other relevant information. An assessor may choose to provide more scrutiny to a product intended for children, or one that is located in direct contact with the skin, as compared to a general-use product, or one that is not in contact with the body.

Once safety risk has been assessed, the assessor should examine ways that risk can be reduced or mitigated. The CPSC suggests that hazards should be designed out of the product whenever possible. For example, a product that is located against the skin, may be redesigned to be in a less sensitive location away from the body. If the hazard cannot be designed out of the product, the consumer should be protected from the hazard. For example, a product in direct contact with the skin could be redesigned to include a component that provides a barrier between the skin and product while maintaining intended functionality. As a last resort, products may be labeled to warn consumers about a hazard. However, CPSC staff cautions that this mitigation strategy should be used rarely and only after other mitigation strategies have been unsuccessful.

Manufacturers should note that while risk assessment can be implemented generally across a number of products, risk mitigation is very dependent on the specific product. Risk mitigation strategies should be undertaken on a product by product basis.

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Now that we have reviewed the risk assessment strategy, let's revisit our example product and see how this process might be used. Again, this situation is hypothetical and is not addressing a real product. Please consider the specific facts related to your product when determining the best way to approach the safety of your product.

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The product is intended to provide comfortable, fashionable exercise apparel that is instrumented to provide data to the user through connection to a smartphone app.

The intended user is an athlete or athletic adult in the age range of 18 to 65 years.

Although the product is not intended for other uses, the instrumentation could be used for other purposes, but probably not without destroying the product.

The product will be sold through the company website only, using targeted advertising in fitness journals, websites and other similar venues. There is also a plan to use celebrity sports personalities and influencers to promote the product.

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As apparel, the product protects the body during exercise and may have some additional performance attributes, such as moisture management or antibacterial properties. The sensors gather information from the user during wear, and send it to a smartphone app. The product is expected to be used indoors and outdoors and will be exposed to abrasion (from use during exercise and from laundering), moisture (from sweat and laundering), sunlight, and other similar factors.
Because the product is apparel, it is worn against the skin, potentially with no additional barriers. The sensors and other instrumentation need to be in close proximity to the body to function as designed.

The potential exposure hazard types identified here are:
- Electrical (from the biometrics and communication instrumentation),
- Thermal (from the power source of the instrumentation),
- Chemical (from insulation materials on instrumentation and any finishes on the apparel), and
- Flammability (from the textile material and other flammable components).

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In this example, data were gathered from three main activities:
- Examining a competitor's products with similar performance and claims,
- Testing relevant performance attributes of the subject product, both in-house and at a commercial laboratory, and
- Conducting a wear testing panel with a group representing expected product users.

The examination of the competitor's product included not just physical examination and testing of the products, but also review of consumer feedback and any reporting of safety issues. This activity also allows for benchmarking performance between the products in a controlled environment and an understanding of the materials and components used and how they perform with real-world consumer use.

Both in-house and commercial testing of the subject product were conducted, following all regulations and consensus standards to which the product is subject. Testing should be performed at multiple points in the product development lifecycle to identify any issues early, making necessary changes as low cost and low impact as possible. At a minimum, verification

testing of the subject product should be performed, even if you are buying an off-the-shelf product for private labeling. Even with testing reports provided, due diligence requires verifying those results.

Once commercial testing was complete, a cohort representing the probable product user was identified, and a wear test was conducted with the group. A wear test is a testing protocol that attempts to mimic "real-world" use. In this test, the subject product was sent to a group of non-professional athletes identified by a consulting firm. The users were given instructions on how to care for the apparel, use the app, and other relevant instructions; and they were asked to use the product as they would use regular athletic apparel. There was a set reporting structure for data gathering and a closing interview conducted individually with each user.

From these data, as well as the analyses performed by the in-house team to characterize the product and categorize the hazards, three hazard patterns were identified.
A potential electrical shock hazard was identified when testing showed that there was some degradation of the connectors used in the instrumentation. Although none of the wear test participants reported the hazard, the internal team found the hazard when reviewing data on similar competitor products.
Likewise, a thermal hazard was identified when one of the wear test users reported getting burned by the power source in the garment after repeated laundering. The hazard appears to be related to the same connector degradation causing the shock hazard. The burn did not require medical attention and was reported as minimal.

Finally, commercial laboratory testing identified some chemical components of the fabric finishes as potential irritants to some individuals. This finding was confirmed when one wear test user reported a rash after the first use of the product. The user reported that they had a specific skin condition, as well.
Based on these findings, the team concluded that the hazard consequences of the current product were low-to-medium in nature. However, the team felt that they could improve the hazard outlook.

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Although the risk assessment showed a low-to-medium risk with the information found during this process, the team proposed a risk-mitigation strategy that would remove the existing hazards. By changing the connector design and chemical finish used in the product, the three hazards were eliminated. Subsequent testing was performed to verify that no new hazards were introduced from the changes. These actions moved the product safety risk to low. By identifying the hazards before introducing the product into commerce, the company was able to mitigate the hazards and bring a safer product to market.

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What are the specific CPSC requirements for this hypothetical product?

Given the scenario described, this product would be subject to the clothing textiles flammability standard, 16 CFR part 1610, and thus, would require the issuance of a general certificate of conformity based on a test of each product or a reasonable testing program. Because it is a general-use product, not intended for children, testing performed does not need to be conducted by a CPSC-accepted, third party laboratory.

Based on the electrical components used, any applicable consensus standards for those components or systems would need to be followed.

Other considerations specific to the usage and interaction of components should be characterized to determine if the product has potential defects. Testing for the impact of laundering, abrasion, flexing and other relevant performance tests could provide insight on the safety of the components when in the hands of the consumer. Additionally, any product in contact with the skin should be evaluated for potential sensitivity issues. Depending on other product details, there may be additional testing.
Because this garment is a hypothetical product, it provides an example of the types of requirements that may be relevant so that you have an understanding on the best way to approach your own product safety strategies.

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Beyond the risk assessment strategy discussed in this presentation, CPSC suggests some general best practices for safely bringing consumer products with new technologies to market.

Establish a formal design review team.

Assemble a team with the right balance of knowledge – not just technical, legal, or marketing. Bring in outside experts when needed (*e.g*., human factors experts). Identify key elements that can impact safety early in the process and discern how hazards can be avoided. The review should be robust and encompass the lifecycle of the product.

Design safety into the product

Product safety should be a design consideration from the outset. Communicate this commitment throughout your supply chain. It doesn't hurt to also highlight this commitment to your customers as a value-added feature!

Plan for intended and foreseeable use, including misuse.

Although we are sometimes completely blindsided by the ways consumers use products, perform due diligence. Don't rely on marketing and labeling to define your product's usage. If something goes wrong, that is not always a compelling argument – especially if the alternate use is foreseeable. Have experts evaluate products with usage – ALL USAGE - in mind. If there

are concerns, explore ways to warn, protect against, or eliminate the hazard, with eliminating the hazard being the primary goal.

Maintain quality standards throughout the product lifecycle.

We have all learned to be cautious about "golden sample" test results from samples specifically manufactured to pass required tests. Sample for quality checks throughout the production cycle. In many cases, these checks do not need to be destructive tests, and the tests can have a big impact on improved quality assurance, without substantially impacting costs. This step is especially important if you do not have control of the manufacturing and cannot be on site to view practices. Make this a requirement in your contracts.

Develop a rigorous test program that goes beyond the minimum standards or regulatory requirements.

It is important to remember that CPSC requirements are minimum standards. Definitely know which voluntary consensus and mandatory standards need to be a part of your test program. Additionally, look for other testing that can further characterize safety issues related to your product. That might mean designing an ongoing testing and sampling plan, testing extra samples, or requiring more stringent test limits than those defined in the standards. In the case of emerging technology products, there may not be a straightforward existing test program. Work with knowledgeable experts to design one.

Institute a proactive compliance program.

Don't wait until you have a problem to make a plan. Have a compliance plan in place that clearly communicates compliance requirements and safety-related changes to your supply chain. Everyone involved with a product should know the what, when, and why of safety enhancements. Finally, report all safety issues to the CPSC – even when you are not positive that there is a safety issue.
CPSC views our stakeholders in the consumer product supply chain as partners in safety. We know that you are the first line of defense against dangerous and noncompliant products. The tools discussed today can help in your efforts.

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In closing, the question was posed earlier in this presentation: "how are regulatory entities responding?" Although we cannot speak for other regulating entities, we can highlight the efforts CPSC is taking to enhance the safety of consumer products with emerging technology.

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Since the 2014 recall of a fitness tracker that caused skin rashes on some consumers, CPSC staff has monitored emerging technologies, such as wearables, 3-D printing, and artificial intelligence

in consumer products. In 2017, a staff white paper laid out these emerging technology products and how the agency should address them. In 2018, the Commission gathered input and feedback from stakeholders in a public hearing on the Internet of Things (IoT) and consumer product hazards. In recent years, CPSC has formed an IoT working group, participated in the ASTM development of a standard guide for safety in connected products, and we partnered with the National Institute of Standards and Technology in an interagency agreement to explore safety in consumer connected products. Additionally, staff has published status reports on IoT, wearables, and micromobility products. Recently, the agency hired a Chief Technology Officer to focus on artificial intelligence in consumer products, and CPSC will hold a stakeholder forum on the topic in 2021.

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Thank you, and we hope you enjoyed this podcast. If you have any questions on the presentation, please do not hesitate to submit your questions in English or Chinese to the mailbox mentioned earlier: CPSCinChina@cpsc.gov. This mailbox is routinely monitored.

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We wish to remind viewers that CPSC has many technical documents and resources available in Chinese.

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We encourage viewers to be sure to check out CPSC's Regulatory Robot, available in English, Chinese, and several other languages. The Regulatory Robot is an automated tool that can help identify safety requirements for many different types of products. Many companies have found this tool to be extremely helpful.

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Listed here are some industry consensus standards and certifications related to wearable technology and "smart" textiles.

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Human Factors is the study of how people use products, and how design can guide this usage. Mentioned in this presentation, the CPSC and Health Canada's Consumer and Hazardous Products Safety Directorate have developed this guidance document to help consumer product manufacturers integrate human factors principles into their product development process.

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CPSC hosts publicly available data repositories, including the National Electronic Injury Surveillance System (NEISS) and the Consumer Product Safety Risk Management System (CPSRMS).