

1200 New Jersey Avenue, SE Washington, DC 20590

December 8, 2023

The Honorable Maria Cantwell Chair, Committee on Commerce, Science, and Transportation United States Senate Washington, DC 20510

Dear Chair Cantwell:

Enclosed please find the report titled "Lithium Battery Safety Working Group Report to Congress" as required by Section 333(c) of the Federal Aviation Administration Reauthorization Act of 2018; Public Law 115-254), which requires the U.S. Department of Transportation (DOT) to establish a Lithium Battery Safety Working Group to coordinate efforts related to the promotion of the safe manufacture, use, and transportation of lithium batteries. The Act requires the Working Group to transmit a report to Congress that identifies and assesses additional ways to decrease the risk of fires and explosions from lithium batteries and cells, additional ways to ensure uniform transportation requirements for both bulk and individual batteries, and new or existing technologies that may reduce the fire and explosion risk of lithium batteries and cells, and include any legislative recommendations to effectuate these safety improvements.

DOT's Pipeline and Hazardous Materials Safety Administration submits this report on behalf of the Working Group. The report provides details on how the Working Group member agencies can positively impact safety by utilizing their existing authorities and enhance the safe manufacture, transportation, and use of lithium batteries.

Please let me know if you require additional information or have your staff contact Damon Hill, Deputy Director of Governmental, International, and Public Affairs, by phone at 202-591-6233 or by e-mail at damon.hill@dot.gov. A similar letter has been sent to the Ranking Member of the Senate Committee on Commerce, Science, and Transportation and to the Chairman and Ranking Member of the House Committee on Transportation and Infrastructure.

histon H. Bown

Tristan H. Brown Deputy Administrator



1200 New Jersey Avenue, SE Washington, DC 20590

December 8, 2023

The Honorable Ted Cruz Ranking Member, Committee on Commerce, Science, and Transportation United States Senate Washington, DC 20510

Dear Ranking Member Cruz:

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December 8, 2023

The Honorable Sam GravesChairman, Committee on Transportation and InfrastructureU.S. House of RepresentativesWashington, DC 20515

Dear Chairman Graves:

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Tristan H. Brown Deputy Administrator



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December 8, 2023

The Honorable Rick Larsen Ranking Member, Committee on Transportation and Infrastructure U.S. House of Representatives Washington, DC 20515

Dear Ranking Member Larsen:

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Lithium Battery Safety Working Group

Report to Congress – Section 333(c) of the Federal Aviation Administration Reauthorization Act of 2018

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Lithium Battery Safety Working Group Report and Key Findings

Section 333(c) of the Federal Aviation Administration (FAA) Reauthorization Act of 2018 ("the Act") mandated the Secretary of Transportation to establish a Lithium Battery Safety Working Group ("Working Group") to coordinate efforts related to the promotion of the safe manufacture, use, and transportation of lithium batteries.¹ The Act requires the Working Group to transmit a report to the Secretary of Transportation and appropriate committees of Congress that identifies and assesses additional ways to **decrease the risk of fires and explosions** from lithium batteries and cells, additional ways to **ensure uniform transportation requirements** for both bulk and individual batteries, and **new or existing technologies** that may reduce the fire and explosion risk of lithium batteries and cells; and include any legislative recommendations to effectuate these **safety improvements**. This report focuses on how the Working Group member agencies can positively impact safety utilizing their existing authorities. The Secretary of Transportation made appointments in accordance with the Act, and the Working Group was chartered in June 2019. Efforts centered on provisions of the Act and the objective to share best practices of federal agencies.

This document contains <u>detailed appendices</u>. Text that is <u>underlined</u> and <u>maroon</u> indicates a bookmark allowing quick navigation to specific detailed portions of the report.

The Working Group is composed of representatives with expertise in lithium battery safety, product safety, and standards development from the following federal agencies:

- The U.S. Department of Transportation (DOT): Federal Aviation Administration (FAA), Pipeline and Hazardous Materials Safety Administration (PHMSA), and the National Highway Traffic Safety Administration (NHTSA)
- The U.S. Consumer Product Safety Commission (CPSC)²
- The Food and Drug Administration (FDA): Center for Tobacco Products (CTP), and the Center for Devices and Radiological Health (CDRH)
- The National Institute of Standards and Technology (NIST)

Through regular meetings and discussions, the Working Group realized the diverse range of respective authorities for lithium battery safety. Every product that reaches an end user represents the cumulative effort of multiple organizations, as represented by this Working Group. Many of those discussions focused on identifying areas that were common across agencies with respect to lithium battery safety, risk mitigation, or oversight. A more detailed discussion on the authorities of the federal agencies comprising the Lithium Battery Safety Working Group can be found in <u>Appendix D</u> of this report. The Working Group also reached consensus that there are actions that can be taken to improve safety throughout the entire lifecycle of a lithium battery.

¹ Public Law 115-254

 $^{^{2}}$ The views expressed in this report are those of the CPSC staff, and they have not been reviewed or approved by, and may not necessarily reflect, the views of the Commission.

In this report, the Working Group:

- Characterizes the **hazards** associated with lithium batteries;
- Examines the existing **statutory authorities** related to lithium battery safety;
- Identifies opportunities for inter-agency coordination; and
- Shares agency efforts to identify **new and existing technologies** to improve the safe manufacture, use, and transport of lithium batteries.

The use of batteries in consumer products, medical devices, and vehicles continues to grow exponentially.³ With the proliferation of batteries and the miniaturization of portable products, manufacturers have sought to increase battery-operating times while reducing size and weight of the battery and the battery-powered product. This has led to battery chemistries that pack higher energy in smaller packages. High-energy chemistry batteries include lithium-ion, lithium-ion polymer, and lithium metal batteries that are thinner, smaller, lighter weight, and contain more energy than traditional rechargeable and non-rechargeable batteries. High-energy density batteries require enhanced safety systems and additional care when in use, while being handled, or when removed from the product. In addition, batteries must be properly tested with the product, in its intended use, and with its charger as a system.

Under normal operation, lithium batteries are generally safe. The high energy density and power they provide make them the preferred choice for portable electronic devices and electric vehicles. However, lithium batteries are susceptible to overheating. Overheating can cause exothermic reactions inside the battery, resulting in the release of greater quantities of heat that can eventually lead to a thermal runaway event. Once in thermal runaway, lithium batteries release large quantities of energy, making them highly susceptible to producing flames, explosions, and potentially producing toxic gases.

In general, the risks posed by lithium batteries are a function of the battery size, chemistry, design, construction and manufacturing processes, use, and use environment. Manufacturing and transport requirements are designed to minimize the likelihood and potential consequences of a thermal runaway event. Thermal runaway events can be triggered by exposure to excessive heat, mechanical damage, overcharge, or over-discharge followed by a subsequent recharge, manufacturing defects, such as foreign particles inside the cells, or the growth of dendrites through charge and subsequent discharge.

Integrated Supply Chain Requires Integrated Oversight

The lithium battery supply chain is global. In the United States, it involves a myriad of <u>federal</u> <u>agencies that share responsibility</u> for regulatory oversight for the manufacture, importation, marketing, transportation, use, and disposal of lithium cells, batteries, and lithium battery-powered devices. This shared responsibility for oversight means that there are many touchpoints

³ C. Pillot. (May 2019). The Rechargeable Battery Market and Main Trends 2018–2030. Presented at Advanced Automotive Battery Conference. <u>https://niobium.tech/en/pages/gateway-pages/pdf/technical-briefings/the-rechargeable-battery-market-and-main-trends-2018-2030</u>, accessed January 2022.

between federal agencies that have oversight responsibilities. Thus, a single cell, battery, or device may be subject to regulation by multiple agencies depending on its application. It is important that federal agencies continue to work with industry to ensure that lithium batteries are safe for use and transportation. It is also important for federal agencies to continue to work together to share information and data on lithium batteries.

Depending on specific agency authorities, Working Group members may have connections with battery and product manufacturers through standards development (NIST, FDA, CPSC); conformity assessment requirements to promote safety and technology oversight over manufacturing and testing (NIST); oversight of manufacturers of FDA-regulated products; control of regulated non-conforming products (CPSC, FDA, NHTSA); packaging for transport (PHMSA); and the movement of products through the supply chain (FAA, PHMSA). To some extent, the actions of one stakeholder to achieve its safety objectives inform or impact every other stakeholder in the transport system.

Improving the quality and capability of lithium batteries from a manufacturing perspective and working within each agency's respective regulatory authority would ultimately improve safety throughout the system. Although individual agencies can develop additional or specific regulatory requirements, industry must acknowledge and enhance its roles and responsibilities by ensuring the necessary processes and procedures are in place for the manufacture of safe, quality products. Safety must be built into the total lifecycle of lithium batteries, from cell/battery manufacture and product integration to transport logistics through end-of-life. Failure to do so will result in the recurrent need to independently address each innovation or new application. Relying solely on a regulatory approach to manage the risks of lithium batteries is unsustainable. A comprehensive systems' approach with noted accountability and collaboration is central to consumer product safety, automobile safety, aviation safety, and overall transportation safety.

Regulations and Voluntary Consensus Standards

Government regulations and voluntary consensus standards are both critical to create a common language and establish a consistent level of safety. Standards that are globally accepted reduce technical barriers to trade and reduce the complexity of designing and demonstrating the safety of products for the global market. Voluntary consensus standards are developed based on research by government, industry, and academia, but they have no legal authority unless recognized or adopted by a regulatory agency. While these standards provide the opportunity to share best practices and establish common expectations for safety performance, they are generally developed independently and sometimes employ different test methods. Reasons for this include the application (automotive, medical, or consumer electronic) and scale of the safety testing (component cells or battery modules). Regulations offer a consistent and legally enforceable standard; however, maintaining current and relevant regulations in an evolving technology environment such as lithium-ion batteries is a challenge for regulators. To address this, Working Group members adopt, recognize, or utilize a variety of voluntary consensus standards in safety regulations. Continued agency participation in standards development activities would facilitate efforts to harmonize global standards. A more detailed discussion on voluntary consensus standards and agency regulations specific to lithium batteries is found in Appendix A of this report.

Lithium Battery Safety Research

Working Group members recognize the importance of technological advancements and the role of government agencies in fostering innovation. Working Group member agencies support innovation by funding research into new packaging schemes and providing technical reviews of proposed alternative packagings for hazardous materials (hazmat), including lithium batteries. We also foster innovation through flexible regulatory schemes that allow for the development of new technologies and new approaches to address safety concerns. The existing research into lithium battery safety follows two main tracks. The first involves investigating how to create safer batteries that will not go into thermal runaway. This includes research into cell and battery safety features such as shutdown separators, vents, and non-flammable electrolytes. The second approach assumes a battery will go into thermal runaway and involves developing mitigation measures. This research includes methods to detect thermal runaway, identifying appropriate cell spacing, and materials designed to prevent propagation of thermal runaway between cells in a battery or in a package. A more detailed discussion on the specific research sponsored by Working Group members is found in Appendix C of this report. It is incumbent upon federal agencies to maintain a focus on safety while allowing for innovation within the regulated community.

Conclusions

While the regulatory approach to risk management provides a robust system for safety, it does not fully address the unique issues specific to rapidly evolving technologies like lithium batteries. The distinct nature of agency-specific missions also leaves the potential for gaps in authorities and inconsistencies in risk management approaches as lithium batteries and products are manufactured, assembled, transported, and used. Recognizing that lithium battery safety is a shared responsibility, and that commonalities in hazard patterns and safety practices exist across agencies, industries, and battery uses, there is an opportunity to collaborate across the Federal Government and industry to identify and advance shared safety objectives. Continued growth of lithium battery usage and the increased reliance on the aviation system for shipping cargo demands a coordinated approach beginning with a risk evaluation compatible with agency safety missions and expertise.

Agencies should <u>continue to form connections with federal partners</u> who have a role in ensuring the safe transportation of lithium batteries. By proactively exchanging data, including emerging trends, sharing the results of technical research on new technology, and partnering on outreach and education initiatives, agencies can achieve tangible safety advances and increase efficiency in the short term. Agencies can foster innovation by allowing for—and encouraging— performance-based testing that is not design restrictive. The Working Group was instructed to identify ways to improve lithium battery safety based on the assessments outlined in this report. Each Working Group member has a unique role to play in lithium battery safety and each brought valuable perspectives and ideas to the working group.

This report focuses on how the Working Group member agencies can positively impact safety utilizing their existing authorities. The <u>Working Group</u> identified four focus areas within two categories that would make positive impacts in lithium battery safety:

(1) Minimize Risk through Design and Quality Management Systems

- 1. Enhancement of safety audit programs designed to assess the operational management and quality control procedures of lithium batteries during their design and manufacture and
- 2. <u>Establishment of a comprehensive systems' approach</u> to product safety through manufacturing practices.

<u>Industries that do not currently have systematic processes</u> in place should consider adopting internationally-recognized manufacturing safety audit programs designed to assess the operational management and quality control procedures of lithium cells, batteries, and devices that use lithium cells and batteries during their design and manufacture. If instituted, such a system would benefit and enhance lithium battery safety for the American public and each federal agency represented by this Working Group, in addition to an array of industry manufacturing and transportation sectors.

While <u>current safety regulations</u> provide an essential framework, the Working Group notes that for minimizing risk, there is no substitute for the use of high-quality cells and batteries. Not all manufacturers have adopted a comprehensive systems approach to lithium battery safety and risk management via their manufacturing practices. Such an approach would improve accountability in meeting an acceptable level of safety not only for the transportation system, but throughout all aspects of manufacturing, as represented by the Working Group. The adoption by industry of such an approach for risk management of lithium batteries would enable manufacturers to leverage their existing risk management processes to enhance lithium battery safety.

(2) Federal Agency Collaboration for Safe Transport of Lithium Batteries

- 3. Continued participation in the development and use of <u>consensus standards</u> to address safety throughout a product's lifecycle, including transportation and end-of-life state; and
- 4. Increased coordination and communication amongst Working Group members, with broadened efforts to work collaboratively for information exchange across <u>federal</u> <u>agencies</u> that may have a stake in lithium batteries.

The Working Group recognizes that it is critical that <u>federal agencies continue to participate</u>, to the extent possible, in the development and use of consensus standards to address safety throughout a product's lifecycle, including transportation and end-of life. Additional consideration should be given to how transportation and storage requirements are integrated into end-use standards and product evaluation. The Working Group also recognizes the need for <u>continued</u>, <u>high-level coordination</u> and communication amongst the Working Group and other federal agencies that may have a stake in lithium batteries; and will continue to work collaboratively to enhance communications and information-exchange efforts across federal agencies.

Appendices

Appendix A: Uniform Transportation Standards, Best Practices, Voluntary Consensus Standards, and FAA's Safety Management System

Appendix B: Inter-Agency Collaboration and Data Collection

Appendix C: Emerging Technology and Fostering Innovation

Appendix D: Authority of Federal Agencies Comprising the Lithium Battery Safety Working <u>Group</u>

Appendix E: Standards Applicable to Lithium Batteries and Devices

APPENDIX A

Ensuring Uniform Transportation Requirements and Standards

The provisions for lithium battery testing and transportation are presented in the United Nations (UN) Model Regulations. The UN Model Regulations serve as the basis for national, regional, and international modal regulations, including the International Maritime Dangerous Goods (IMDG) Code, the International Civil Aviation Organization (ICAO) Technical Instructions (TI) for The Safe Transport of Dangerous Goods by Air, and the U.S. Hazardous Materials Regulations (HMR; 49 CFR parts 171-180).

The HMR also authorize the use of the ICAO Technical Instructions for The Safe Transport of Dangerous Goods by Air, and the IMDG Code for vessel to facilitate international shipments. There is a consensus among regulators, manufacturers, and transporters that alignment of the domestic HMR and the international transport regulations is useful because it eliminates the need to comply with multiple sets of standards. Although U.S. and international regulations are largely aligned in allowing all shippers to use a single set of requirements for both domestic and international transport, there are some differences in requirements depending on the transport mode. Furthermore, regulations can vary depending on the type and size of lithium battery.

Over the last 15 to 20 years, the transport regulations for lithium batteries have become increasingly complex and are characterized by detailed requirements. These detailed requirements evolved, in part, from efforts to restrict the broad regulatory relief that previously permitted pallet load quantities of lithium batteries to travel on aircraft without any of the standard hazard communication associated with other hazmat. The complexity of the current regulations is due, in part, to efforts to achieve a balance between preserving the ability to transport lithium batteries and battery-powered products across the globe quickly and at a relatively low cost, while ensuring the regulatory provisions are not abused. Further, incremental amendments to the regulations occurred nearly every two years between 2005 and 2020. These amendments clarified various aspects of the regulations and addressed new shipping scenarios not previously envisioned.

Recognizing that the behavior of lithium batteries in a fire or thermal runaway is influenced by more than just lithium content or energy ratings, the UN Sub-Committee of Experts on the Transport of Dangerous Goods formed an informal working group to develop an evidence-based classification system for lithium batteries. Preliminary work is underway to systematically test and characterize the hazards inherent to cells and batteries. Once that work is completed, it may be possible to determine corresponding conditions for transport. A new classification and regulatory scheme might focus on three performance areas to: (1) determine intrinsic cell/battery safety; (2) ensure packaging or other transport requirements address the identified hazards; and (3) prevent the propagation of thermal runaway from a cell to adjacent cells in a package or battery.

Current Transportation Safety Regulations

Classification for the transportation of lithium batteries is governed in the United States by the HMR. The HMR promote the safe transportation of hazmat by all modes of transportation and

provide minimum requirements. The focus is to mitigate hazards posed for conditions normally encountered during transportation. It can be inferred that conditions outside of normal transportation present a risk that is typically not accounted for or fully considered.

Key focus areas of the HMR include:

- Properly classifying the material;
- Selecting the appropriate packaging;
- Communicating the hazard;
- Limiting the quantity of the hazardous material being transported;
- Mode of transportation; and
- Segregation requirements.

The level of regulation to which lithium batteries are subject differs depending on battery type (lithium-ion versus lithium metal), battery size, and whether the batteries are packed in equipment or contained in equipment. The philosophy here is that all else being equal, larger quantities of higher energy batteries are more hazardous than smaller quantities of lower energy batteries. Large quantities of densely packed lithium batteries placed into a package are more hazardous than smaller quantities. Lithium batteries packed with equipment or contained in equipment pose less hazard than batteries on their own because of the level of protection provided by the equipment and the relatively few batteries in any given package. Finally, as observed through testing, lithium metal batteries tend to burn more vigorously, and fires involving such batteries are more difficult to suppress than equivalent sized lithium-ion batteries. The hazardous materials table (49 CFR § 172.101) reflects these differences and identifies separate entries depending on whether the contents of the package are lithium metal batteries or lithium-ion batteries or lithium-ion batteries are packed with or contained in equipment they are intended to power:

- UN 3090, Lithium metal batteries;
- UN 3480, Lithium-ion batteries;
- UN 3091, Lithium metal batteries contained in equipment;
- UN 3091, Lithium metal batteries packed with equipment;
- UN 3481, Lithium-ion batteries contained in equipment; and
- UN 3481, Lithium-ion batteries packed with equipment.

These UN Identification Numbers are harmonized with international standards for the transportation of lithium batteries. The UN Identification Numbers and descriptions have corresponding packaging and communication requirements that are appropriate for the type of battery and configuration.

While the basic requirements for shipping lithium batteries are uniform, the regulations also include alternative provisions for small lithium batteries. These provisions provide relief from certain packaging, hazard communication, and hazmat training requirements, provided various conditions are met. These conditions include limits on the size of the batteries, the number of the batteries in the package, and the number of packages in each shipment. These provisions were designed to permit individuals and businesses to ship one or two batteries, or a limited number of consumer electronic devices containing those batteries, in accordance with streamlined requirements.

The requirements for transporting lithium batteries by air are more stringent than those for ground or vessel due to the increased consequences resulting from an in-flight fire, should one occur. For transport by air, there are state of charge limits (for lithium-ion), requirements to ensure batteries are separated from flammable hazmat, and strict quantity limits. These requirements, unique to air transport, are in addition to the design testing, packaging, and hazard communication requirements applicable to all transport modes. These requirements are intended to reduce the likelihood of an incident and reduce the consequences should an incident occur. While the regulations for transporting lithium batteries by air are the most protective, they are also the most restrictive. Requirements for transporting lithium batteries, such as those used in electric vehicles, prototype batteries, batteries manufactured in small quantities, and lithium batteries that have reached end-of-life.

Reducing the Risk of Fires and Explosions

Risks associated with different lithium battery types are assessed by regulators and addressed in various ways including voluntary consensus standards and agency regulations. These risks are also addressed with administrative actions, including product recalls and enforcement for non-conforming or unsafe products. However, risk management and risk analysis are not uniform among agencies and can vary based on statutory authority, product type, and experience. Many best practices start with research and evolve into industry practice before they are enacted into agency regulations. Here we discuss many of the current practices and trends toward safer batteries.

Technological solutions to create inherently safe batteries and develop new packagings capable of containing hazardous effects from a thermal runaway are potential opportunities to build safety into the system without extensive new regulation; however, this would come at a cost. Many state-of-the-art lithium-ion cells have one or more passive safety features such as a positive temperature coefficient (PTC), a current interrupt device (CID), safety vents, and ceramic coated separators to improve resistance to melting. Other approaches to battery and assembly design involve providing greater separation between cells to minimize cell-to-cell heat transfer, placement of heat absorbing materials between cells, and improved internal diagnostics that can monitor battery health. Solid state batteries that use solid electrolyte instead of the flammable liquid electrolytes found in typical lithium-ion batteries offer the prospect of a safer battery with higher energy potential. The "Report on Emerging Energy Storage Technologies," discussed later, identifies many current and alternative lithium battery technologies. Packaging solutions and methods to make transport of lithium batteries safer are also discussed later in the report.

Improved testing offers another option. Current testing standards are designed to ensure that batteries are capable of withstanding certain use and abuse conditions without undergoing thermal runaway. Battery designs are thus qualified against a standard and not meant to ensure that lithium batteries are safe in all conditions, such as extreme heat or damage. Abuse testing addresses this shortcoming. Such testing involves forcing the battery into situations that will drive it to fail, permitting an evaluation of the results. Changes can then be made in the design of the battery, device, or package to mitigate these failures. This process of "test, fail, change" can be expensive and time-consuming. Further, these are high level requirements that assess capability of a battery design at the time of testing and do not ensure continued quality. Changes in source material, manufacturing practices, and new cell and battery designs introduce variability that can impact the results.

Additionally, prismatic and pouch cells can be designed into any unique size and shape of electronic enclosures, and each manufacturer may have variations in their chemistry and manufacturing process based on its intended application and manufacturing equipment. Thus, many batteries are subject to variations and unique manufacturing processes for safety, and not all products are subjected to mandatory requirements or voluntary standards.

Utilizing Voluntary Consensus Standards

Standards are defined as a level of quality or attainment, an idea or thing used as a measure, norm, or model in comparative evaluations, and are commonly used in the manufacturing of products or related processes and production methods, and related management systems practices. Voluntary consensus standards (VCS) are generally national in scope, developed by a committee of experts within a particular field, and are developed through subject subcommittees. Such standards are critical for products that have safety concerns. Standards that are globally accepted reduce technical barriers to trade and reduce the complexity of designing and demonstrating the safety of products for the global market. Organizations in the U.S. that produce voluntary safety standards that are relevant to lithium batteries and battery-powered consumer products include, but are not limited to, Underwriters Laboratories Inc. (UL), Institute of Electrical and Electronics Engineers Standards Association (IEEE SA), ASTM International (ASTM; formerly known as American Society for Testing and Materials), American National Standards Institute (ANSI), and SAE International. <u>Appendix E</u> of this report contains a list of standards applicable to lithium batteries and devices.

Safety standards for lithium batteries need to address a wide variety of battery types and applications. The scope of such standards is generally limited to a single aspect of a battery lifecycle such as manufacturing, transportation, or end use. For a complete product or system and application, several standards need to be considered. Further, there may be component battery standards that apply to a certain type of batteries, e.g., product-specific standards that reference component battery standards and include additional requirements based on how the battery is used, as well as the battery and device operating environment.

Standards and conformity assessment (testing and certification) are risk reduction tools that are used widely throughout industry, society, and government. Product performance and construction standards are used to provide state of the art approaches for measuring safety

critical product attributes and establish agreed upon performance limits for safety. Product testing and certification can provide confidence that products meet these standards. Industry has long adopted these risk reduction approaches voluntarily to avoid or lessen the need for safety regulations. In turn, government regulators often rely on these voluntary actions to have confidence in conforming products in the market.

Voluntary consensus standards can be a valuable resource for industry and regulators by providing a common set of requirements, vocabulary, and baseline expectations of safety and/or performance. The use of consensus standards can increase predictability, streamline premarket review, clarify expectations, and facilitate market entry for safe and effective products. The value and efficiency of voluntary consensus standards were recognized by Congress when it passed into law the National Technology Transfer and Advancement Act (NTTAA). The NTTAA requires agencies to participate in the development of and use VCS in lieu of government-unique standards when they are available and meet their mission needs. This makes the use of technically sound standards good practice for regulators. Often VCS will have safety requirements beyond minimum regulatory requirements and in many sectors, there is substantial compliance with these voluntary standards without regulation. In cases where compliance with a standard is necessary, an agency may choose to incorporate the standard into its regulations, either whole or in part, or with additional requirements.

Federal regulatory agencies approach the use of VCS in various ways. PHMSA, for example, incorporates VCSs by reference into the Hazardous Materials Regulations. This incorporation process requires rulemaking including publication in the Federal Register and an opportunity for public comment prior to incorporation. For lithium batteries, PHMSA incorporates by reference the tests identified in the UN Manual of Tests and Criteria, Part III, subsection 38.3 (UN 38.3 tests). These tests simulate common transport conditions such as changes in altitude, mechanical shock and vibration, and certain abuse scenarios such as overcharge. Batteries pass these tests if they withstand these conditions without fire or disassembly. Manufacturers are responsible for ensuring battery designs meet these tests and maintain records of successful completion of the tests. While this process makes this VCS mandatory and enforceable, this impact is somewhat limited in rapidly evolving areas such as lithium batteries. The UN 38.3 tests are the only tests formally recognized in the PHMSA regulations, and as new and revised standards are developed, PHMSA must complete a notice and comment rulemaking to adopt those new and revised standards as appropriate.

CPSC recognizes a variety of battery related, voluntary consensus standards, but mandates only one by reference for battery-operated toys (ASTM F963 Standard Consumer Safety Specification for Toy Safety). By statute, CPSC staff must first try to address hazards through voluntary standards. CPSC holds manufacturers, suppliers, and distributors responsible for ensuring their products are safe for consumers and comply with appropriate mandatory standards. To mitigate and address safety hazards with battery-powered consumer products, CPSC staff participate in the development and revision of voluntary standards by using incident data as justification to continuously improve voluntary standards as needed. CPSC staff recommends:

• Components and battery-powered products comply with applicable voluntary standards.

- New components and products that are not yet subject to voluntary standards be designed considering the best practices from similar voluntary standards.
- Battery-powered products be designed with a system approach addressing thermal protection, charge and discharge protection, and use in product, including:
 - Cells suitable for intended loads and conditions and manufactured with good quality control.
 - Battery packs with proper Battery Management Systems (BMS), including charge control, short-circuit protection, and cell balancing.
 - Chargers that comply with applicable voluntary standards and are suitable for the product.
 - End-product systems (including cells, batteries, chargers, and products) are tested together for safe function and appropriate conditions.

CPSC may pursue rulemaking if the voluntary standards have not been effective at adequately addressing hazards or if there is not substantial industry compliance with the standard. Voluntary standard activities and regulatory activities may occur concurrently, as CPSC staff works to address a product hazard. CPSC publicly available incident data can be found at: <u>SaferProducts.gov</u>, and at: <u>www.cpsc.gov/Data</u>.

NHTSA utilizes voluntary consensus standards and portions of those standards to develop the Federal Motor Vehicle Safety Standards but does not incorporate standards by reference or recognize the voluntary use of consensus standards in lieu of the Federal Regulations. Manufacturers of motor vehicles and motor vehicle equipment attest that their products comply with all applicable safety standards. It is up to the individual manufacturer to determine what data, test results, or other information it needs to support this attestation that its product complies with the applicable requirements. NHTSA conducts spot checks of new motor vehicles and motor vehicle equipment after they have been marketed as complying with applicable FMVSS by purchasing and testing the products according to the procedures specified in applicable standards. Manufacturers must also ensure that their products are free of safety-related defects.

In addition to requiring compliance with applicable FMVSS, the National Traffic and Motor Vehicle Safety Act itself expressly established the requirement for compliance: the exercise of reasonable care. Specifically, a manufacturer may not certify a vehicle's compliance if, in exercising "reasonable care," the manufacturer has reason to know the certification is false or misleading in any material respect. Industry standards and voluntary consensus standards are tools used by manufacturers in exercising reasonable care.

The FDA-CDRH relies on voluntary consensus standards in its approach to certain aspects of the evaluation of device safety and effectiveness, such as testing methods, acceptance criteria, and processes to address areas such as risk management and usability. FDA can recognize all, or part of, an appropriate standard established by a nationally or internationally recognized standard development organization. The term "recognize" refers to FDA's formal identification of a standard after a determination that it is appropriate for manufacturers of products to declare conformance to meet relevant requirements in the Federal Food, Drug, and Cosmetic Act

(FD&C) Act, including premarket submission requirements. Voluntary consensus standards are generally timesaving and allow the Agency to rely upon consensus-driven standards as an efficient way to meet certain relevant requirements in the FD&C Act. The ability of FDA to recognize portions of a standard, and for manufacturers to declare partial conformance, allows for streamlined premarket review of well-characterized issues and focuses regulatory attention on more novel or complex issues.

In November 2019, the FDA-CTP issued guidance, titled, "<u>Compliance Policy for Limited</u> <u>Modifications to Certain Marketed Tobacco Products</u>." This guidance describes a policy concerning industry utilization of a consensus standard for battery-powered tobacco products, UL 8139 "Standard for Safety for Electrical Systems of Electronic Cigarettes and Vaping Devices." The FDA-CTP published the guidance to support manufacturers who were making changes to comply with UL 8139 and address the battery safety of Electronic Nicotine Delivery System (ENDS) and other battery-powered tobacco products. Battery-operated ENDS products marketed without FDA authorization are generally subject to immediate enforcement upon modification. In the guidance, the FDA-CTP set out that, for certain battery-operated ENDS products (specifically, those on the market as of August 8, 2016) that are modified solely to comply with UL 8139, the FDA-CTP did not intend to initiate enforcement action against such modified products on the basis of these modifications. This policy reflected the FDA-CTP's current thinking that battery-operated tobacco products that comply with UL 8139 have a significantly reduced risk of battery-related adverse events.

For many of the agencies referenced above, VCSs provide a starting point for establishing baseline expectations of safety and performance. Agency risk evaluation processes and use of VCS align with their safety missions and expertise. For agencies that do not have authority over the transportation portion of a battery lifecycle, the transport requirements may not be known or perceived as applicable, presenting the potential for gaps in risk evaluation. For example, while lithium batteries are generally safe in their intended use environment, manufacturers do not always consider the transport environment. Depending on the application, VCS requirements may not be sufficiently protective, or manufacturers and shippers may not understand the scope of a particular standard or adhere to them.

Further, as an increasing number of lithium batteries and battery-powered products reach the end of their useful life, new safety concerns regarding the transport of spent batteries, damaged batteries, and devices subject to voluntary recalls have been identified. As such, the risks posed by a battery can move across the regulatory and jurisdictional boundaries throughout its lifecycle. Agency participation in the standards development process and recognition of a variety of well-developed standards with appropriate testing and conformity could lead to streamlined review processes. Greater coordination among agencies could ensure more consistent application of transportation-related risk management and the associated mitigation measures throughout a product lifecycle. An Inter-Agency Committee on Standards Programs could be a way to further the inter-agency coordination on lithium battery standards after the Working Group completes its report.

FAA's Safety Management System

The Safety Management System (SMS) centers on safety decision-making throughout an organization. SMS allows FAA and industry to manage activities throughout the aviation community and is recognized as a critical step in the evolution of air transportation safety. FAA's Office of Security and Hazardous Materials Safety uses this systematic approach to ensure that safety remains the top priority in everything it does. In FY20–24, FAA will continue to improve the integration of the SMS data-driven approach that further incorporates risk-based decision-making into business planning, operations, strategic program management, and overall decision-making. FAA will continue to develop avenues for information sharing and collaboration to include members of this multi-agency Working Group.

As part of FAA's safety management approach, it collects data from surveillance activities. Subsequently, FAA conducts data and risk analysis to better identify areas of concern, targets risks for further research, and develops data-driven, risk-based policy, regulatory, and compliance strategies. This approach helps to focus on a key performance indicator to decrease the commercial fatal accident rate, while allocating and prioritizing resources based on risks.

To better manage safety risks to the National Airspace System, FAA is a stalwart proponent of SMS principles. To that end, FAA's Office of Security and Hazardous Materials Safety developed and issued an SMS order consistent with FAA's SMS Order 8000.369B to establish accountability for its safety management responsibilities. FAA's Hazardous Materials Safety Program also developed and issued an SMS order that further expounds upon and aligns with those safety principles. FAA's overarching SMS order established the framework of integrated oversight for developing, implementing, and continuously improving safety within the agency. That order also underscored the interconnection between the four functional components of SMS—Safety Policy, Safety Risk Management, Safety Assurance, and Safety Promotion illustrated in the diagram below. As a result, FAA is now aligned with the U.S. State Safety Program (SSP) and FAA Order 8000.369 – Safety Management System.

SMS is a formal, top-down, enterprise-wide approach to manage safety risk and assure the effectiveness of safety risk controls. It inherently includes systematic procedures, practices, and policies for the management of safety risk. Essentially, SMS is grounded in structured processes that compel organizations to manage safety with the same level of priority that other core business processes are managed throughout organizations. Thus, it has to be a decision-maker's tool, not a traditional safety program that is separate and distinct from business and operational decision-making.

To further enhance levels of safety, FAA established consistent internal and external initiatives. Regulations established minimum standards for certification and the oversight of air operators' activities, while initiatives such as the U.S. SSP, Compliance Program, Integrated Oversight Philosophy, and SMS established concepts to advance aviation safety. As determined by the U.S. SSP, collaboration between the authority and the industry is essential to achieve FAA's mission of providing the safest, most efficient aerospace system in the world. Compliance with the regulations is fundamental for every certificate holder. Maintaining initial and recurrent training and operational procedures, as well as the implementation of SMS to include the establishment of voluntary safety reporting programs, are essential for the operator to reach FAA and public safety expectations. The aerospace system is too large, complex, and dynamic to manage without a system-based approach to safety; hence, the criticality of establishing a formal SMS.

In championing the noted SMS approach, the current emphasis of FAA surveillance is focused on how individual air operators make operational decisions, which fills the gap between the common-cause risk factors addressed by traditional regulations and those that are more specific to the operator's environment and situation. The "common cause" accidents are diminishing in number. To meet future challenges, FAA and its lithium battery stakeholders must continue to collect more safety data points that will enable us to better discern trends and identify precursors.

The cargo transportation system has historically relied on trust, comprised of:

- The carriers relying on what is inside the package is safe; and
- The regulations being the only responsibility for risk mitigation.

As noted above, the HMR generally only regulate to the package level, creating a safety gap related to the total cargo in the cargo hold. The National Transportation Safety Board (NTSB) identified this gap through accident evaluations and recommendations resulting in worldwide attention. Emphasis on cargo safety strengthens connections within FAA to drive safety decisions domestically and positions DOT, namely FAA, as the global leader on cargo safety. The goal within global leadership is to mitigate safety risks introduced by the carriage of air cargo through collaboration, data collection, industry risk-based decision-making, and adoption of industry policy and guidance.

Building relationships within DOT and FAA was a critical initial step to address the global issue. Frequent communication and collaboration between FAA Lines of Business on cargo safety enabled smarter, timelier, and more appropriate decisions regarding air cargo. Risk mitigation must be designed into a system this large and complex. Growth of both technology and aviation will continue to outpace the ability of prescriptive regulatory requirements. To keep pace, the system must begin with a risk evaluation process that by design, regardless of the risk, provides sufficient mitigation to achieve an acceptable level of safety. Therefore, FAA safety culture must continue to evolve beyond the traditional and prescriptive oversight based on black-and-white compliance with regulations, to more performance-based, data-informed, risk-based decision making. Through this cargo safety approach, FAA organizations, industry, and international peers share safety data, thereby collaborating toward a broader spectrum of available data.

Where FAA and other modal administrations comprising DOT have focused their regulatory efforts in the past may not adequately inform how to ensure the safe transport of lithium batteries in the future. For instance, the rules-based approach to safety that has served the U.S. aviation industry for decades has reached critical mass. Industry continues to expand, complexity continues to grow, and resources remain limited. FAA's view of compliance emphasizes a problem-solving approach (e.g., engagement, root-cause analysis, transparency, information exchange), where the goal is to enhance the safety performance of individual and organizational certificate holders. An open and transparent exchange of information requires mutual trust and cooperation that can be challenging to achieve in a traditional, enforcement-focused regulatory model.



To better facilitate risk-based management of FAA's SMS approach, the complementary components of both the prescriptive- and performance-based approaches must be combined. That said, it is important to note that what was in place before the implementation of SMS cannot be disregarded, but rather complemented by concepts of SMS to ensure the safe transportation of hazmat to the maximum extent possible. Given the size, complexity, and dynamics of the national airspace system (NAS), cargo offered for transportation by aircraft must also have the consideration of the diversity of entities and their processes in the supply chain. Hence, everyone in the supply chain is responsible for aviation safety—and more broadly, transportation safety—and must do all that they can to prevent risks that could exceed the airworthiness of the aircraft.

FAA has concluded that for those industries that may not currently have systematic processes in place, it would be beneficial for them to consider adopting internationally recognized manufacturing safety audit programs designed to assess the operational management and quality control procedures of lithium cells, batteries, and devices during their design and manufacture. If instituted, such a system would benefit and enhance lithium battery safety for each federal agency represented by this Working Group, in addition to an array of industry manufacturing and transportation sectors.

Deficiencies in the accountability and reliability of quality control procedures in manufacturing processes have introduced hazards and inconsistencies into the transportation system. As a result, quality control procedures continually present challenges for each agency represented on this Working Group and other stakeholders to manage the entire system, due to the sheer volume of lithium batteries and diversity of devices produced. It is important to recognize that regulations alone cannot satisfactorily address these manufacturing deficiencies. Along with enhanced quality control procedures, there needs to be much stronger accountability placed upon industry.

While safety regulations provide an essential framework, it is also important that a comprehensive systems approach to product safety through manufacturing practices be established. This would apply to manufacturers of lithium cells, batteries, and devices during all phases of design and production. Industries manufacturing products with the potential to introduce hazards into other systems, which may result in unacceptable consequences, have developed and implemented systems to verify that a product or service meets certain established standards. Hazards can be introduced through multiple interfaces, so a reliable system of accountability must be established that would foster confidence overall.

In addition, a comprehensive systems approach would improve accountability in meeting an acceptable level of safety for the transportation system. A safety audit program—developed by manufacturers of lithium cells, batteries, and devices—could be an internationally recognized and accepted evaluation system. This system could be designed to assess the quality control procedures in manufacturing processes and would include general operational management of the manufacturer. Such a safety audit program could be used to achieve a robust, reliable system of industry accountability.

In addition, an accreditation or registry could be developed for device manufacturers and other entities within the supply chain, which would allow the transportation system to build upon the described approach. As noted, the program should be based on industry-proven quality audit principles (i.e., a third-party audit structure) designed to ensure that each audit is conducted in a standardized manner to achieve consistent results. Third-party review is currently being implemented by other industries facing similar challenges and generally offers advantages including, but not limited, to ensuring:

- 1. The product design meets the safety requirements; and
- 2. The manufacturer made a reasonable effort to assure compliance.

Fully instituting a systems approach with a safety audit program would allow better identification and mitigation of possible causes of accidents. That would also increase transparency for touchpoints within the supply chain and promote the use of available analytical capabilities. It is paramount that we identify and mitigate precursors to accidents (i.e., safety risks) to manage aviation safety. This approach would leverage the growing availability of safety data, foster the systematic integration of risk-based decision-making into manufacturing practices, and strengthen our safety mission.

APPENDIX B

Inter-Agency Collaboration and Data Collection

Each federal agency in the Working Group has mechanisms to collect information to investigate failures, tailor safety messaging, and inform policy making. The Working Group members identified increased inter-agency coordination and information sharing as necessary to address the risks of fire and explosion, promote a uniform understanding of transportation requirements, and stay current on industry and technology advancements. These objectives would be achieved through the promotion of safety management systems and increased use of voluntary consensus standards.

While many of the agencies represented by members of the Working Group have regulatory responsibilities for lithium batteries, such as PHMSA and FAA, others affect lithium battery safety through more indirect means. For example, NIST facilitates standards development and conformity assessment requirements to promote safety and technology, and FDA regulates medical devices and tobacco products, some of which use lithium batteries. CPSC supports voluntary standards efforts, considers mandatory requirements, and conducts recalls assuring the safety of consumer products powered by lithium batteries. Additionally, NHTSA regulates safety of electric vehicle propulsion batteries that are currently lithium-ion battery packs. A common experience for Working Group members has been learning about each agency's unique perspective and the way it affects lithium batteries. One recognized way for agencies to better coordinate a potential or realized impact to safety is by looking at how each agency identifies and collects data on lithium batteries, determines safety issues with batteries, and responds to those issues through recalls and communications to stakeholders.

DOT has four operating administrations with civil enforcement programs to inspect for compliance with the federal hazmat law and the HMR.⁴ While not a DOT operating administration, the United States Coast Guard also has certain delegated authorities with respect to the safe transport of hazmat by water. Operating administrations focus inspection or investigation activities on specific areas related to their respective transport mode. For example, FAA focuses on passenger and cargo air carriers (including passenger checked and carry-on baggage), unit load devices, loading and handling procedures, and handling facilities, while PHMSA focuses on cylinder and package manufacturers and requalifiers. PHMSA also conducts inspections of shipper facilities and coordinates these activities with other operating administrations depending on the transport mode. The operating administrations also contribute and share relevant inspection, incident investigation, registrations, special permits, and approvals data to maximize the effectiveness of cross-modal risk management and investigation activities.

Data collection provides agencies with the opportunity to conduct detailed data analysis to identify safety trends to better understand and manage risks. Similarly, data on failures during use or testing also provide insight into emerging issues. Sharing data among agencies reduces

⁴ The four operating administrations are: the Federal Aviation Administration, Federal Motor Carrier Safety Administration, Federal Railroad Administration, and Pipeline and Hazardous Materials Safety Administration.

duplicative data collection and provides agencies with a more well-rounded understanding of lithium battery performance and hazards. Information sharing also provides a larger data set to help enable a more thorough analysis. By sharing information, agencies can identify issues that cross their regulatory authorities and might otherwise go unnoticed. The ability to identify potential issues more quickly reduces the likelihood of negative events such as fires or explosions.

Data related to lithium cells, batteries, and devices, including data on incidents, is collected by federal agencies through three different means: voluntarily and statutorily-required data submitted by each of the Working Group member's respective regulated entities; federal data collection through partnerships with other entities; and detailed investigations of incidents. Federal agencies collect or receive data at many points during the lifecycle of a lithium cell, battery, or device (i.e., creation through end of life) depending on the agency's authority. One area of particular interest is incidents involving malfunction, failure to operate, fire, emission of smoke and/or toxic vapor, violent rupture, explosion, or dangerous evolution of heat (i.e., overheating). These incidents could occur during individual or bulk transportation of lithium batteries, encompassing the manufacture of a product containing a lithium battery, use of lithium battery-powered consumer products, and preparation of the products for transportation. Information sharing and data collection are intended to mitigate risks leading to such incidents.

Voluntary and Required Incident Data

Within 30 days after a reportable incident, the person in possession of the material at the time of the incident is required to submit a written incident report to PHMSA using DOT Form 5800.1 (see 49 CFR §§ 171.15 and 171.16 for reporting requirements). DOT Form 5800.1 contains detailed information on incidents involving hazmat transported in commerce including the packages (e.g., package type), the mode of transportation in which the incident occurred, and the impact of the incident on the transportation system. PHMSA captures, stores, and manages incident data in a data system called HAZMATICS. PHMSA's Operations System Division oversees the management and data quality of the incident report for the analysis of incident data. Through analysis, the Division identifies incident trends and communicates findings with internal and external stakeholders.

PHMSA's Data Operations team works closely with PHMSA's Office of Hazardous Materials Safety Field Operations to identify incident trends that are used in risk modeling and inspection planning. PHMSA collects industry submitted incident reports for all categories of lithium batteries (metal, ion, packed with, or contained in equipment) by all transport modes (highway, rail, vessel, and air). A review of recent data collected from calendar years 2015 through 2019 indicates that most incidents occurred in the highway and air mode, and nearly 75 percent of incident reports were the result of undeclared shipments of lithium batteries discovered in transport. It is important to note that the undeclared shipments did not result in significant thermal events, but the improper packaging and communication of hazards create a situation that could result in more serious incidents occurring.

When deviations from regulatory standards occur, FAA's goal is to use the most effective means to return an individual or entity that holds an FAA certificate to full compliance and prevent recurrence. FAA has several programs that allow voluntary self-disclosure reports through which

regulated entities share information regarding an instance of non-compliance with FAA through a designated program. FAA's Hazardous Materials Voluntary Disclosure Reporting Program (VDRP) allows air carriers to disclose violations of the HMR without incurring civil penalties if the appropriate process is followed.

The historical, reactive approach to making aviation safety improvements is based on reviewing data obtained after an aviation accident or incident. FAA has transitioned into a more proactive strategy that uses the data obtained through surveillance and design reviews of an air carrier's overall operations. Aviation safety improvements can also be obtained when the air carrier shares information about its non-compliance openly with FAA. FAA believes that aviation safety is well served by incentives for operators to identify and correct their own instances of noncompliance, and to invest more resources in efforts to preclude their recurrence. FAA's policy of forgoing civil penalty actions when a covered entity detects violations, promptly discloses the violations to FAA, and takes rapid corrective action to ensure that the same or similar violations do not recur, is designed to encourage compliance with FAA's regulations, foster safe operating practices, and promote the development of Internal Evaluation Programs. FAA maintains a reporting system of voluntarily submitted incident reports from airlines and cargo air carriers. FAA's database includes a significant number of events related to lithium-ion batteries because of the proliferation of portable electronic devices that require these batteries.

NHTSA and CPSC maintain publicly available repositories of incident reports and complaints from consumers submitted through consumer hotlines and public websites. These include reports on lithium battery related incidents in motor vehicles and consumer products, respectively. CPSC's publicly available incident data can be found at: <u>SaferProducts.gov</u>, and at <u>www.cpsc.gov/Data</u>.

NHTSA requires that vehicle and vehicle equipment manufacturers comply with Early Warning Reporting, which includes submission of warranty claims, field report counts, property damage claims, and foreign recalls of similar product. CPSC requires retailers and manufacturers to submit incident reports involving a product they sell to the CPSC Office of Compliance if the product creates an unreasonable risk of injury or death.

The FDA-CDRH requires manufacturers of medical devices (and others) to submit a Medical Device Report (MDR) to FDA when they receive or otherwise become aware of information, from any source, that reasonably suggests that their device: (1) may have caused or contributed to death or serious injury, or (2) has malfunctioned and would be likely to cause or contribute to death or serious injury, if the malfunction were to recur.

The FDA-CTP collects voluntary reports on tobacco product problems and harms, such as adverse health effects or product quality issues. Consumers, manufacturers, investigators, and health professionals can voluntarily submit reports about tobacco products. These reports are submitted online via the FDA's Safety Reporting Portal. These submissions can include reports regarding tobacco products that are operated by batteries (e.g., e-cigarettes, electronically heated tobacco products, and other battery-operated tobacco products) and have overheated, caused fires, or exploded. The reported incidence to FDA of tobacco products' batteries overheating, or creating fires or explosions is low (estimated to be less than 0.2 percent) compared with the

volume of sales of battery-operated tobacco products. As the reports to the Safety Reporting Portal are voluntary, the information submitted can include inaccurate or incomplete information. For example, submitted reports may not include information regarding the product name or manufacturer, whether the product was used correctly, or whether an individual also suffered from other medical conditions or used other tobacco products or medications at the same time. As such, the FDA-CTP does not assign or determine causality based on these reports, and the information generally cannot be used to estimate risk or incidence rates, or to compare tobacco products. The FDA-CTP can use these reports as a signal to seek more information on a specific issue or problem associated with certain tobacco products as a category or as a specific brand.

The FDA-CTP also maintains an aggregate of reports from within the United States that involve battery-powered tobacco product (i.e., e-cigarettes) overheating, fire, or explosive events. Additionally, CTP receives and researches other sources of information on battery-operated tobacco product overheating, fires, or explosion events. For example, the FDA-CTP seeks out or receives information from other centers within FDA, and other state and federal agencies; reviews relevant reports in the FDA Potential Tobacco Product Violation Reporting system; and searches both peer-review scientific literature and news outlets.

As part of this research into battery-operated tobacco product events, the FDA-CTP published a research paper in the journal *Tobacco Control* (2017), which sought to identify the number and nature of these domestically occurring events. The FDA-CTP obtained data by searching the databases of five U.S. federal agencies and conducting scientific literature and media outlet searches between January 2009 and September 2015. Over the six-year period, the FDA-CTP found and evaluated 92 reports of domestic events that involved overheating, fires, or explosions associated with battery-operated tobacco products.

The authors found that approximately 60 percent of the events involved a rechargeable tobacco product; approximately half of all events resulted in personal injury (burns, lacerations, fractures, tooth loss or damage); and 73 percent involved property damage. As these reports lacked many details, including the type of battery, the root cause or corrective actions for the events could not be assessed.

As stated above, the FDA-CTP can use voluntary reports submitted through the FDA Safety Reporting Portal as a signal to identify new or concerning trends. Based on the reports submitted, FDA may seek more information on a specific issue or problem associated with certain tobacco products as a category or as a specific brand. However, FDA does not assign or determine causality based on voluntary reports and the information cannot be used to estimate risk or incidence rates, or to compare tobacco products. Issues reported by or specific to a manufacturer's products can also prompt the manufacturer to voluntarily recall the specific product that has the issue.⁵

⁵ <u>https://pubmed.ncbi.nlm.nih.gov/29504085/</u> https://pubmed.ncbi.nlm.nih.gov/31013680/

Post-Market Surveillance Analysts at the FDA-CDRH review and evaluate MDRs for patient risk, device malfunctions, interactions between user and use environment, vulnerable populations, and unexpected complications. After the initial review, an analyst can request additional information from the device manufacturer for any follow-up investigations or corrective actions. In addition, if the analyst identifies trends in adverse event data for a specific device or group of devices over time, the FDA-CDRH can escalate an issue as a patient safety signal based on post market surveillance guidelines. The patient safety signal may result in a recall, patient safety communication, letter to the healthcare providers, or FDA enforcement actions.

Federal Data Collection through Other Entities

NHTSA maintains three publicly available primary data systems of field incidents:

- Fatality Analysis Reporting System (FARS) contains data on all fatal crashes on U.S roads.
- National Automotive Sampling System General Estimates System (NASS-GES) contains data from a weighted, nationally representative sample of police-reported crashes of all severities, including those that result in death, injury, or property damage. The Crash Report Sampling System (CRSS) replaced NASS-GES in 2016.
- NASS Crashworthiness Data System (CDS) is a weighted, nationally representative sample of police-reported crashes that contains detailed data, based on thorough investigation of representative, random samples of thousands of minor, serious, and fatal crashes. The Crash Investigation Survey System (CISS) replaced NASS-CDS in 2016.

FARS and NASS-GES/CRSS were designed and developed to provide an overall measure of highway safety, and these measures can support the identification of traffic safety problems, solutions, and an objective basis on which to evaluate the effectiveness of motor vehicle safety standards and highway safety initiatives. NASS-CDS/CISS was designed to provide details specific to the vehicle characteristics, crash dynamics, vehicle damage, vehicle interior, injury mechanisms, injured body region and type of injury, severity of injury, injury mechanism, restraint type, and use. Incidences related to lithium batteries can be identified in FARS, NASS-GES/CRSS, and NASS-CDS/CISS using the make and model of the vehicle, the vehicle identification number, and incidence of vehicle fire.

NHTSA uses data from FARS, NASS-GES/CRSS, and NASS-CDS/CISS, as well as data from two databases managed by CPSC: the National Electronic Injury Surveillance System (NEISS), and the Consumer Product Safety Risk Management System (CPSRMS). Together these databases support compliance investigations that determine if a safety gap exists that would need to be addressed by further engagement with the respective agencies. Further engagement could include recall proceedings, research to evaluate countermeasures to prevent safety concerns, and upgrading and promulgating standards to address the safety issue.

As mentioned, CPSC collects, manages, and analyzes a wide range of epidemiological data from multiple sources that are stored in two primary databases: NEISS and CPSRMS. The NEISS database provides statistically valid national estimates of consumer product-related injuries and

allows for statistical analyses of trends. Each record in the database provides information on an injury associated with a consumer product, the consumer products involved, patient demographics, and a narrative of the injury incident. Using this statistical sample, CPSC staff can estimate the number of injuries nationwide that are associated with products. Additionally, NEISS estimates must meet minimum criteria for CPSC to consider them reliable, and, therefore, reportable. The standard reporting criteria for NEISS require that the estimated number of injuries be 1,200 or higher; the sample size be 20 or larger; and the coefficient of variation be less than 33 percent.

The CPSRMS database records are anecdotal in nature and include data primarily from three groups of sources: incident reports, death certificates, and in-depth, follow-up investigation reports conducted by CPSC field staff. All fatal injury reports from NEISS are also included in CPSRMS. A large portion of CPSRMS consists of incident reports from consumer complaints, news media reports, medical examiner or coroner reports, retailer or manufacturer reports, safety advocacy groups, law firms, and federal, state, or local authorities, among others. CPSRMS also contains death certificates that CPSC purchases from all 50 states, based on selected external cause of death codes.

CPSRMS records do not constitute a statistical sample representing all incidents related to a specific consumer product, nor do they represent a complete set of incidents that may have occurred involving that consumer product. However, CPSRMS data provide at least a minimum count for the number of incidents related to that consumer product. Although CPSRMS data cannot be used for statistical analysis, the incident descriptions in CPSRMS often focus on the product- and scenario-specific details, which allows staff to assess the product failure modes and hazards associated with the use of a consumer product to develop a case for possible recall action or identify gaps for standard development.

CPSC database entries include a product code to facilitate data retrieval by product type; however, there are no product codes for primary (non-rechargeable) versus secondary (rechargeable) batteries or lithium cells or batteries. Compiling data for incidents attributable to lithium cells/batteries can only be done by searches for keywords in the narrative description, by searching for specific information such as a model number from a product known to use lithium batteries, and manually reviewing data searches.

As mentioned previously, the FDA-CTP receives and researches other sources of information on battery-powered tobacco product overheating, fires, or explosion events. For example, other centers within FDA, other federal agencies, as well as state agencies may send tobacco product incident information to the FDA-CTP. The FDA-CTP actively monitors and researches both peer-reviewed scientific literature as well as news outlets. Additionally, the FDA-CTP reviews relevant reports in the FDA Potential Tobacco Product Violation Reporting system. To further support reporting, data collection, and communications, the FDA-CTP and FAA each updated their websites in 2020 to cross-promote links, infographics, and resources developed by the respective agencies. By doing so, the FDA-CTP and FAA collaborated to increase public awareness of the proper handling of battery-powered tobacco products and the hazards when these devices are improperly handled, especially during air transportation.

Detailed Investigations of Incidents

NHTSA's Special Crash Investigations Division (SCI) investigates vehicle fires and crashes involving electric vehicles with high voltage lithium-ion batteries. The onsite investigations focus on the integrity of the high voltage components, failure modes, and hazards associated with the lithium-ion battery of the vehicles.

CPSC staff conducts investigations (onsite, telephone, or online) to follow up on some of the incident reports, death certificates, or NEISS injury reports recorded initially in the databases described above. Staff documents their completed investigation in an In-Depth Investigation (IDI) report, which is also stored in CPSRMS. IDIs, which provide detailed information about an incident and incident scenario, often include copies of official documents (e.g., fire and police reports) and photographs of the product and setting of the incident.

PHMSA's Accident Investigation Team (AIT) reviews significant incidents and conducts rootcause analysis investigations of accidents that meet their criteria for review. This includes a focus on non-bulk packages (including packaging for lithium batteries), cylinders, Intermediate Bulk Containers (IBCs), and incidents where a package failure was likely responsible for the incident. AIT is PHMSA's lead division responsible for the investigation of accidents involving hazmat, including lithium batteries. As the agency's National Hazmat Incident Coordinator (NHIC), AIT reviews notices of incidents and initiates the investigation of failures. AIT validates preliminary information, obtains additional information, evaluates the severity of the incident, and disseminates the information to internal stakeholders, modal partners, and the National Transportation Safety Board (NTSB). When NTSB deploys to an accident investigation involving hazmat, PHMSA will also deploy and support the NTSB investigation.

Recalls: Effective Intra-Agency Coordination

Agencies with recall jurisdiction over lithium battery products include CPSC for consumer products, the FDA-CDRH for medical devices, the FDA-CTP for tobacco products, and NHTSA for motor vehicles and motor vehicle equipment. These agencies have responsibility for identifying defective products and have various recall authorities to remove defective products from circulation. Lithium battery product safety recalls can be initiated by the manufacturer, distributor, or retailer of the product in conjunction with the federal agency that has regulatory jurisdiction over the product. Most recalls are conducted voluntarily by the responsible manufacturer; however, federal agencies can also mandate recalls, if needed. Adequate public notice—to communicate the presence of the defect and what actions to take to properly dispose of the defective product—is vital to ensure safety. It is beneficial for the notice to include directions for how to transport the potentially hazardous products through the proper transportation channel to mitigate safety incidents. For example, transporting a defective lithium cell, battery, or device by air transportation is hazardous, and therefore prohibited. The HMR require recalled lithium batteries to be packed individually in rigid packaging and restricted to ground transportation.

The Consumer Product Safety Act (CPSA) and its accompanying regulations provide recall authority for batteries and battery-powered consumer products within CPSC's jurisdiction. CPSC

may take enforcement action under the CPSA when a product presents a "substantial product hazard."⁶ A "substantial product hazard" is:

- A failure to comply with an applicable consumer product safety rule under the CPSA or a similar rule, regulation, standard, or ban under any other Act or requirement enforced by the Commission which creates a substantial risk of injury to the public, or
- A product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.⁷

When a manufacturer, distributor, or retailer (firm) obtains information that reasonably supports the conclusion that a product fails to comply with an applicable consumer product safety rule or voluntary standard, or ban under CPSA or any other Act enforced by the Commission; contains a defect that could create a "substantial product hazard;" or creates an unreasonable risk of serious injury or death, the firm must immediately report it to CPSC.⁸ Subsequently a firm may also participate in the Fast Track Recall Program to document a product issue and the proposed corrective action. Under Fast Track, CPSC staff approves the firm's plan but does not make a preliminary determination that the product presents a substantial product hazard. Otherwise, CPSC staff may investigate the matter and make a preliminary determination, then request that the firm voluntarily recall the product.

If a firm does not agree to a voluntary recall after CPSC staff makes a preliminary determination that a product presents a substantial product hazard, staff may request that CPSC authorize issuing an administrative complaint.⁹ If, under such a proceeding, CPSC determines that a product presents a substantial product hazard, it may order a mandatory recall and other remedies.¹⁰

CPSC defines recall effectiveness as, "...the degree to which a recall is successful in improving consumer safety by producing the desired results, including but not limited to: (1) mitigation of the hazard, (2) notifying consumers of the problem, and (3) appropriately encouraging consumers to take action."¹¹ Return rates and online response to social media are measured via monthly progress reports submitted to the CPSC Office of Compliance.

⁶ 15 U.S.C. § 2064.

⁷ 15 U.S.C. § 2064(a).

⁸ 15 U.S.C. § 2064(b); 16 CFR part 1115 (substantial product hazard reports). The term "immediately" means within 24 hours, although a firm may conduct a reasonably expeditious investigation, not normally exceeding 10 days, to evaluate whether it should file a report. *See* 16 CFR § 1115.14(d), (e).

⁹ 15 U.S.C. § 2064(c), (d); 16 CFR § 1115.21(a). The Commission adjudicates complaints in accordance with applicable regulations in 16 CFR part 1025.

¹⁰ Remedies available under section 15 of the CPSA include ordering a manufacturer, distributor, or retailer to: cease distribution; notify the public, each person known to have bought or received the product, state and local health officials, manufacturers, distributors, or retailers of the product; or repair, replace, or refund the product. 15 U.S.C. § 2064(c), (d). In addition, the Commission may seek an injunction from U.S. District Court to restrain the distribution of a product during the pendency of an adjudicative proceeding under section 15(d). *Id.* § 2064(g); 16 CFR § 1115.21(b). Additional remedies available for substantial product hazards include seizing the product or working with U.S. Customs and Border Protection to deny admission of the product to the United States. 15 U.S.C. §§ 2066, 2071.

¹¹ https://www.cpsc.gov/Recall-Effectiveness.

Disclosure restrictions under the CPSA limit staff's ability to share pre-recall announcement information with other federal agencies. However, during pre-notice discussions with firms, staff informs recalling firms about obtaining the necessary permits from PHMSA for proper transport of recalled lithium batteries or products containing lithium batteries, if the firm is requesting the return of the product as part of the corrective action plan. When requested, staff will provide guidance during the PHMSA special permit application process.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) provides recall authority to the FDA-CDRH for medical devices, including those containing lithium batteries. For devices, the agency uses the term "recall" when a manufacturer takes a correction or removal action to address a problem with a device that violates FDA law. Recalls occur when a device is defective; when it could be a risk to health; or when it is both defective and a risk to health. Under 21 CFR § 806.2, FDA defines a "risk to health" as: (1) a reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote. FDA formalizes the recall action by determining that the action meets the definition of a "correction" or "removal" under 21 CFR Part 806 or the applicable definition for "recall" under 21 CFR Part 810 for mandatory recalls conducted under section 518(e) of the FD&C Act. FDA reviews the information, assesses the health hazard presented by the recalled product, and classifies the recall (in accordance with 21 CFR § 7.41) into either Class I, Class II, or Class III. The agency reviews a firm's recall strategy and suggests changes, including the issuance of a public announcement or customer notification letter.

The FDA-CDRH and FDA-CTP notify the firm of the classification of the recall. The agency may issue its own public announcement of a firm's recall and post information about recalls at various locations on the FDA's website. The agency provides recall information to other federal and state government agencies, and to foreign governments. FDA develops and implements a recall audit strategy to ensure that the recall action has been effective, and it determines when a recall should be terminated. FDA may take appropriate regulatory action (or other measures) when the firm fails to recall violative product or when a recall action fails. The FDA-CDRH and FDA-CTP may take appropriate regulatory action (or other measures) when the firm fails to recall violative product or fails. Regulatory actions will be taken in consultation and coordination with the appropriate compliance branch, the appropriate center recall and compliance staffs, and the Office of Strategic Planning and Operational Policy/Division of Enforcement/Recall Operations Branch. When indicated, actions will be taken in coordination with the Office of Chief Counsel when a firm refuses to recall or sub-recall after being requested or ordered to do so by FDA, or the agency has reason to believe that the firm's recall strategy is not effective or is not being implemented effectively.

The FDA-CTP has the authority to recall defective tobacco products. The FD&C Act provides recall authority for the FDA-CTP to recall tobacco products including those containing lithium batteries, such as e-cigarettes and other battery-powered tobacco products under section 908(c) of the FD&C Act. Under this authority, if the FDA-CTP finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health

consequences or death, the agency can issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product.

The National Traffic and Motor Vehicle Safety Act gives NHTSA the authority to issue vehicle safety standards and to require manufacturers to recall vehicles that have safety-related defects or do not meet Federal Motor Vehicle Safety Standards (FMVSSs). FMVSSs set minimum performance requirements for those parts of the vehicle, including lithium batteries, that most affect its safe operation or that protect drivers and passengers from death or serious injury in the event of a crash. A safety related defect is a problem with a group of vehicles or equipment of the same design or manufacture that poses an unreasonable risk to motor vehicle safety.

Manufacturers voluntarily initiate many of these recalls, while others are either influenced by NHTSA investigations or ordered by NHTSA via the courts. If a safety defect is discovered, the manufacturer must notify NHTSA, as well as vehicle or equipment owners, dealers, and distributors. The manufacturer is then required to remedy the problem at no charge to the owner. NHTSA is responsible for monitoring the manufacturer's corrective action to ensure successful completion of the recall campaign.

NHTSA operates the U.S. DOT Vehicle Safety Hotline to collect accurate and timely information from consumers on vehicle safety problems. NHTSA also operates a website (<u>http://www.nhtsa.gov/recalls</u>) for consumers to file complaints related to potential safety defects in motor vehicles or motor vehicle equipment. NHTSA's technical staff conducts a continuous analysis of compiled complaint reports to determine whether an unusual number of complaints of potential safety related problems have been received on any specific line of vehicles or equipment.

The NHTSA investigative process consists of four parts:

- <u>Screening</u> A preliminary review of consumer complaints and other information related to alleged defects is conducted to decide whether to open an investigation. Other information includes data submitted by vehicle and equipment manufacturers, congressional and consumer letters, and social media content.
- <u>Petition Analysis</u> An analysis of any petitions calling for defect investigations and/or reviews of safety-related recalls.
- <u>Investigation</u> NHTSA analyzes information from the manufacturer (including data on complaints, crashes, injuries, warranty claims, modifications, and part sales) and determines whether further analysis is warranted. At this stage, the manufacturer has an opportunity to present its views regarding the alleged defect. The investigation may be supplemented with appropriate inspections, tests, surveys, and additional information obtained from the manufacturer and suppliers. The investigation may be closed if the manufacturer has notified the agency that it will conduct a safety recall or if the agency has not identified a safety-related defect. However, if the investigating office believes that the data developed indicates a safety-related defect exists, the NHTSA investigator prepares a briefing to be presented to a panel of experts from throughout the agency for peer review. If the agency panel concurs with the recommendation that a recall should be

conducted, NHTSA notifies the manufacturer of the panel's concurrence and may, if appropriate, provide a final opportunity for the manufacturer to present new analysis or data. NHTSA then sends a Recall Request Letter to the manufacturer.

- <u>Recall Management</u> NHTSA maintains the administrative records for all safety recalls and monitors these recalls to ensure that the scope is appropriate, and that the recall completion rate and remedy are adequate.
 - Once a safety-defect determination is made, the law gives the manufacturer three options for correcting the defect: repair, replacement, or refund. In the case of a vehicle recall, the manufacturer may choose to repair the vehicle at no charge; replace the vehicle with an identical or similar vehicle; or refund the purchase price in full, minus a reasonable allowance for depreciation. In the case of equipment—including tires, car seats, and boosters—the manufacturer may repair or replace the affected equipment at no charge to the consumer or refund the purchase price.
 - NHTSA's monitoring of recall performance may lead to the opening of a recall investigation if the facts appear to indicate a problem with the recall adequacy or execution. A recall investigation can result in expanding the scope of previously announced recalls, or in adjusting existing recall remedies.

Most decisions to conduct a recall and remedy a safety defect are made voluntarily by manufacturers prior to any involvement by NHTSA. Through their own tests, inspection procedures, and information-gathering systems, manufacturers often discover that a safety defect exists or that the requirements of a federal safety standard have not been met. The manufacturer is obligated to report such findings to NHTSA and take appropriate action to correct the problem.

Once recalls are initiated and corrective actions approved, the goals of these agencies are for consumers to stop using defective products immediately, and to remove the hazardous product from consumers and the market as quickly as possible. To further reduce potential injury and safety hazards during transportation of defective batteries, it is crucial that recall information is passed to consumers as well as federal agencies and other stakeholders involved in the safe transport of lithium batteries.

Intra-Agency Information Sharing with the Public

Outreach and communication to the public are also critical to lithium battery safety. The public entrusts federal regulators to perform the necessary oversight to ensure end-use products that use lithium batteries are safe. This highlights the need for a systems approach to transport safety.

It is critical for those manufacturing, transporting, and using lithium batteries throughout the supply chain to understand clearly the inherent risks associated with products. They should also understand that the regulations are the minimum standards that we expect individuals to meet to ensure safety, while managing the inherent risks. Oversight and enforcement of regulatory requirements are important, but industry has a responsibility to ensure quality manufacturing, along with proper handling and transportation of batteries.

Communication tools are very important to CPSC in ensuring the quick dissemination of information related to recalls. SaferProducts.gov and CPSC.gov are CPSC's publicly available

consumer product safety information websites. CPSC.gov provides consumer education materials, including related injury information, safety alerts, and information on its voluntary standards activities. Through SaferProducts.gov, consumers, child service providers, health care professionals, government officials, and public safety entities can submit reports of harm (Reports) involving consumer products. Manufacturers (including importers) and private labelers identified in Reports will receive a copy of the Report and they can comment on it. Completed Reports and manufacturer comments are published online at www.SaferProducts.gov for anyone to search. CPSC was required to create a public portal and a publicly accessible, searchable database of consumer product incident reports by the Consumer product Safety Improvement Act (CPSIA), which became law on August 14, 2008. Consumer product recalls are also searchable on SaferProducts.gov, which provides a link to Recalls.gov. On the CPSC.gov website, there is a webpage (http://www.cpsc.gov/Data) that allows free public access to search tools for CPSC National Injury Information Clearinghouse (Clearinghouse) data, NEISS data, and for other databases, such as recalls and civil penalties.

NHTSA maintains a website (<u>http://www.nhtsa.gov/recalls</u>) for consumers to check on vehicle and equipment recalls using vehicle identification number (VIN) or the brand name and model. The website also allows consumers to submit complaints and check the status of ongoing investigations. In addition, the website provides a list of all recalls that have occurred in each calendar year.

<u>Recalls.gov</u> was created to provide better service in alerting the American people to unsafe, hazardous, or defective products. Six federal agencies (CPSC, NHTSA, Coast Guard, FDA, USDA, and EPA), with vastly different jurisdictions, collaborated to create www.recalls.gov—a "one stop shop" for U.S. Government recalls. This website provides information for recalled consumer products, motor vehicles, boats, food, medicine, cosmetics, and environmental products. Subscribers of an agency's e-mail service will be notified of product recalls. Furthermore, improved inter-agency communication to address specific lithium battery recalls would be helpful, such as notification to all agencies involved with lithium battery safety of impending recall announcements.

When a product recall involving a hazardous material (e.g., lithium batteries) is initiated, the FAA Office of Hazardous Materials Safety's primary responsibility is to ensure that the subject recalls are effectively communicated to operators, so they are aware of the potential increased risk to air transportation. Currently, there is no formalized system in place that would automatically trigger notification to FAA or other government agencies when a lithium battery recall has been initiated. In most cases, FAA is made aware of product recalls through media reports or direct contact with industry or other government agencies.

Mobile electronic devices such as battery-powered tobacco products, cellular phones, laptop computers, or other personal devices are transported on passenger and cargo aircraft in large quantities daily. Therefore, proactive communication with FAA on lithium battery recalls significantly assists FAA in its ability to provide proactive safety messaging to air operators, passengers, and shippers, rather than reacting to media information, which may delay that messaging. Because of the risks to the traveling public and the national airspace, these activities require proactive coordination of safety messaging among FAA, PHMSA, the manufacturer of the recalled product, and other federal agencies having jurisdiction over the affected product.

The FDA-CTP has a robust regulatory communications effort that regularly issues public messages through several e-mail lists, social media accounts, and web content. Were the FDA-CTP to initiate a recall, these channels would be used to help disseminate this critical information. The FDA-CTP also maintains an ongoing messaging effort on its website and social media channels regarding battery-operated tobacco products, including those powered by lithium batteries. The FDA-CTP's "Tips to Help Avoid 'Vape' Battery Explosions" webpage offers safety tips and downloadable infographics and images for stakeholders and the public to further share and disseminate. The webpage also offers direct links to report battery issues with ENDS products, including a helpful video explaining the reporting process. Links to this webpage and specific messages with safety tips are posted on the FDA-CTP's social media channels on an ongoing, evergreen basis. To further support reporting, data collection, and communications, the FDA-CTP and FAA updated their respective websites in 2020 to cross-promote content, such as FAA's "Vapes on a Plane" infographic sharing tips on how to safely pack battery-operated ENDS for air travel. The FDA-CTP and FAA may continue to collaborate as appropriate by providing messaging to the public with respect to the proper handling of lithium battery-operated tobacco products and to increase public awareness of the hazards when these products are improperly handled, especially during air transportation.

PHMSA and EPA collaborated to target non-traditional hazmat shippers and educate them on the importance of proper packaging and hazard communication when preparing lithium batteries for disposal or recycling. PHMSA is also developing a comprehensive lithium battery guide for shippers that addresses the various requirements for all transport modes. When circumstances dictate a need, PHMSA may issue a Safety Advisory Notice through the Federal Register and include information on Safety Advisory Notices on the PHMSA website. This outreach tool highlights a specific safety concern and provides guidance on appropriate safety practices. PHMSA has issued safety notices in the past to inform the public of the risks associated with transporting damaged, defective, or recalled lithium cells or batteries or portable electronic devices (PEDs) especially in airline checked or carry-on baggage.

NHTSA routinely communicates directly with the public on consumer safety related matters through various multimedia approaches. The agency also provides educational material and communication strategies to highway safety partners and consumers, both on safety related matters and the safe use of motor vehicles and motor vehicle equipment.

NHTSA also has a significant consumer information program related to recall of a motor vehicle or motor vehicle equipment (i.e., battery-powered vehicles and batteries used in those vehicles). After the determination of a safety defect or noncompliance, manufacturers must notify, by firstclass mail, all registered owners and purchasers of the affected vehicles of the existence of the problem and give an evaluation of its risk to motor vehicle safety. The manufacturer must communicate to consumers the potential safety hazards presented by the problem. Names of vehicle owners are obtained from state motor vehicle offices. The letter must also instruct consumers about how to correct the problem or remedy the issue; remind them that recall corrections are free; and inform them when the remedy will be available, how long the remedy will take, and whom to contact if there is a problem obtaining the free recall work. Manufacturers of motor vehicle equipment maintain lists of owners who have registered their products with the manufacturer. When product or equipment recalls are initiated, the manufacturer uses these lists to directly notify owners. Product and equipment manufacturers may also be required to notify the public of recalls through a variety of additional methods (e.g., advertisements, point-of-purchase posters) to ensure that as many owners as possible are aware of the recalls.

If a specific recall involves another agency, NHTSA coordinates with that agency during the investigation and recall and remedy process. Some examples are: (1) a recall of motor vehicle equipment supplied by the vehicle manufacturer, such as OEM provided flashlights, would be coordinated with CPSC; (2) a defect investigation involving all-terrain vehicles (ATVs) that can also be used on the road would be coordinated with CPSC; and (3) an investigation of a potential defect on a transit bus model would be coordinated with the Federal Transit Administration (FTA). Additionally, any recall and remedy action would also be coordinated with the respective agency.

The FDA-CDRH can issue tracking orders for devices whose failure would be reasonably likely to have serious, adverse health consequences; for devices that are intended to be implanted in the human body for more than one year; or for life-sustaining or life-supporting devices used outside of a device user facility. Manufacturers are required to track certain devices from their manufacture through the distribution chain when they receive an order from the FDA-CDRH. The purpose of device tracking is to ensure that manufacturers of certain devices establish tracking systems that will enable them to promptly locate devices in commercial distribution. Tracking information may be used to facilitate notifications and recalls ordered by FDA in the case of serious risks to health presented by the devices. The tracking provision is intended to ensure that manufacturers can expeditiously remove potentially dangerous or defective devices from the market and/or notify patients of significant device problems. Tracking augments FDA's authority to order mandatory recalls and require notification of health professionals and patients regarding unreasonable risk of substantial harm associated with a device.¹²

Each of the federal agencies that participate in this Working Group play a critical role in communicating recalls to the regulated community. CPSC coordinates with the agencies of other Working Group members on the status of recalls. Effective communication is critical to the success of any recall. Most recalls will require some form of transportation so that the violative product (e.g., having safety defects, noncompliant with regulations and standards, poses a public health risk, etc.) can be removed from sale and distribution, or returned by consumers. Through communications and coordination, we can ensure that hazmat, such as lithium cells, batteries, and devices, involved in recalls are transported in accordance with the requirements of the HMR.

Over the past few years, PHMSA, CPSC, and FAA staff have collaborated with other agencies on an ad hoc basis and through the Lithium Battery Inter-Agency Coordination Group (the Coordination Group). The Coordination Group was formed in January 2016, as an outgrowth of the coordinated government response to lithium battery issues with hoverboards and improve cross-agency communications on battery safety issues. The Coordination Group is co-chaired by

¹² "Medical Device Tracking: Guidance for Industry and Food and Drug Administration Staff" (https://www.fda.gov/media/71205/download).

staff of the founding agencies: CPSC and PHMSA. The Coordination Group is open to all federal government agencies and has progressively added numerous agencies that have the following interests:

- Administrative, regulatory, or law enforcement purview over lithium batteries.
- Commitment to partnerships that indicate an ability to consider a broad public policy perspective and openness to support solutions that serve the broader safety interest.
- A willingness to participate in joint safety and/or enforcement efforts.

The Coordination Group's mission is to offset the risks associated with the transportation, use, and remediation of lithium batteries. The Coordination Group seeks to:

- 1) Identify and reduce lithium battery regulatory, safety, and enforcement gaps.
- 2) Encourage the expanded use of clear, consensus-based manufacturing standards. Coordinate and harmonize worker protection, safety, and health standards. Identify and develop additional consumer use standards for the safe transportation, consumer handling, recycling, and disposal of lithium batteries, and their safe charging and use in products and systems.
- 3) Develop and implement internal and external lithium battery training and outreach material for federal agencies and their stakeholders.
- 4) Create and institute lithium battery enforcement strategies across federal agencies and jurisdictions.
- 5) Share information on current and emerging trends regarding lithium batteries.
- 6) Operate as a forum for group members to coordinate on policy development, enforcement, information sharing, research, and education.

The Coordination Group is currently inactive but could serve as a model for continuing interagency collaboration and further developing the ideas identified in this report.

The Global Manufacture of Lithium Batteries and the Effects on Transportation

The major manufacturing sources for lithium batteries are currently China, Japan, and Korea. However, the United States and other countries, such as Indonesia and India, are quickly becoming prominent as well. Due to the time in transportation, along with the quantity transported every day and the risk posed, lithium batteries are a critical risk for air transportation. The National Transportation Safety Board (NTSB) has stated that lithium batteries likely present an unacceptable risk to an aircraft. NTSB concluded that flight crews on cargo-only aircraft remained at risk from in-flight fires involving both primary and secondary lithium batteries.

The number of air shipments of lithium batteries grows each year, largely due to the continued and rapid growth of e-commerce. Industry stakeholders, including air operators and those with interests in the safe transport of lithium batteries, have also recognized the threat posed by lithium batteries. For several years, air operators have devoted significant resources to the research, design, and deployment of technologies to mitigate the threat of onboard fires. Likewise, FAA's William J. Hughes Technical Center's Fire Safety Branch (Fire Safety Branch)

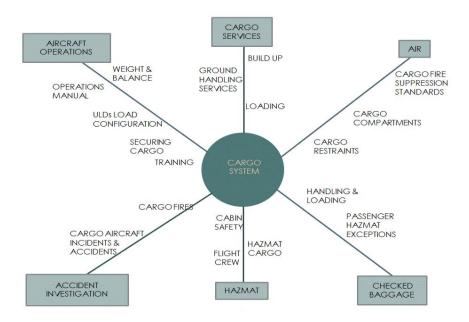
has conducted full-scale tests on aircraft using state-of-the-art unit load devices (ULD) with built-in fire suppression systems. Because of these efforts, the behavior of flammable and toxic gases associated with lithium battery fires has become better understood. Significant variances also have been identified between battery manufacturers, even when comparing batteries with identical chemistries and power ratings. As a result of these studies, air operators and airframe manufacturers were made aware of battery hazards and acted to limit risks.

Air cargo is a crucial enabler of the global economy and the type of hazmat shipped by air has generally been commensurate with consumer product demands. Air cargo volumes of lithium batteries and devices will continue to expand in response to consumer demand for faster delivery, along with the significant rise in e-commerce and companies adjusting logistic plans to remain competitive. Hence, cargo with energetic capabilities—such as lithium batteries and consumer electronics—now constitute a large percentage of cargo moved by air. This trend is only expected to increase as manufacturers work to bring more unique devices to market to satisfy the ever-growing consumer demand. It is important to note that not all of these shipments move as hazmat shipments, since there are some types of lithium battery and device shipments that are not treated as hazardous cargo when shipped below certain quantity per package limits. As such, thousands of pounds of lithium batteries can be shipped in an aircraft cargo compartment without undergoing many of the acceptance checks typically required for other hazmat.

The growing air cargo system is global, as evidenced by the current major manufacturing sources, and it relies on transportation decisions made by employees in both aviation and non-aviation career fields. This can result in inconsistencies in the level of safety between industries and even companies that ship the exact same cargo. In the world of aviation, inconsistencies present risks that aircraft air operators must address. It is critical that FAA and all lithium battery stakeholders take steps to ensure that airframes, safety systems, and air operators fully consider and address the risks of air cargo. The first step is understanding the complexities of the aviation system.

The diagram below depicts the complexities of the aviation cargo system.

CARGO SAFETY SYSTEM



FAA oversees the two largest cargo air operators and eight of the largest cargo hubs in the world. To promote the safe transportation of cargo aboard aircraft, FAA has implemented a safety systems approach that focuses on material classification; cargo preparation (packaging and ULDs); weight and balance; tethering; handling; and proper loading/unloading in the cargo compartment. Several recent cargo-related accidents further highlight the complexity of the air cargo transportation environment. When examining the related cause and operational component of these incidents, it further emphasizes the importance of taking a systems approach to aviation safety into account.

APPENDIX C

Emerging Technology and Fostering Innovation

Working Group members recognize the importance of technological advancements and the role of government agencies in fostering innovation. DOT embraces innovation to drive enhanced safety and improved transportation infrastructure conditions. Because of its importance, DOT has placed a special strategic focus on its research, development, and technology transfer activities. This includes new measures for utilizing research and supporting new technologies.¹³

Safely Packaging Lithium Batteries and Cells for Transportation

A critical component in the safe transportation of lithium batteries is to ensure that the batteries are safely packaged. Based on research demonstrating that a fire involving lithium batteries could exceed the fire suppression capability of the aircraft and lead to a catastrophic failure of the air frame, a clear focus on packaging performance has emerged in recent years. It is important to note that there are many factors (e.g., size or type of lithium battery, total quantity of batteries, packaging types) that will contribute to the severity of an incident with lithium batteries. The ICAO concluded that there is a need to develop performance-based standards on the principle that hazardous effects from the batteries would be contained within the package. In 2016, the SAE formed the G-27 Lithium Battery Packaging Performance Committee, tasked with developing a performance-based packaging standard that supports the safe shipment of lithium batteries as cargo on aircraft. This standard provides test methods to demonstrate and document the mitigation of potential hazards from lithium batteries when transported as cargo on aircraft. It addresses the need to control the hazards within the package.

In response to the unique hazards posed by lithium batteries in the aviation environment, and challenges transporting damaged, defective, or recalled batteries, various companies developed products designed to mitigate or contain these hazards. Most package protection systems currently available rely on passive fire protection and contain various proprietary materials, including high temperature insulating material, cooling techniques using a liquid or phase change material to provide a heatsink, fire retardant coatings, and intumescent fill material. Aerogel, a synthetic ultralight porous material that has excellent heat insulation capabilities, has also been explored as a possible mitigation. Many of these technologies are effective to varying degrees to prevent the propagation of thermal runaway alone or in combination.

Fire containment covers (FCCs) are increasingly common and are used by air carriers to comply with airworthiness requirements. FCCs are intended to cover unitized cargo contained or restrained in an air cargo pallet and net assembly, for loading into aircraft main deck cargo. FCCs are used to contain a possible cargo fire beneath it for a rated period. FCCs are quite effective in containing Class A fires (ordinary combustibles such as wood, fabric, paper, trash, and plastics), but have not been approved for use for lithium battery shipments. However, testing results suggest that FCCs provide at least some level of protection and could be used as part of a layered approach to hazard mitigation.

¹³ <u>https://www.transportation.gov/sites/dot.gov/files/docs/mission/budget/317341/dot-fy-2018-2019-annual-performance-planfy-2017-annual-performance-reportfinal.pdf</u>

Unit load devices (ULDs) are another common method of shipping cargo by air. The ULDs permit the consolidation of many packages into a single unit, making loading/unloading the aircraft more efficient, and permits better utilization of space on the aircraft. Modern ULDs are manufactured from fiber-reinforced plastic composite material capable of containing a fire with a peak temperature of 1,200° F for more than four hours.¹⁴ Active ULDs incorporate built-in fire detection and/or fire extinguishing systems.

Research Initiatives

Working Group member agencies support innovation by funding research into new packaging schemes and providing technical reviews of proposed alternative packagings for hazmat, such as lithium batteries. Below is an overview of some of the initiatives that are currently being developed to improve the transportation safety of lithium batteries.

FAA's Fire Safety Branch—located at the William J. Hughes Technical Center ("Tech Center"), Atlantic City International Airport, Atlantic City, New Jersey—is the world leader in aviation fire-safety research and has been heavily involved in advancing the safe international transportation of lithium batteries. The aviation community relies heavily on Tech Center research and testing to provide technical expertise in several international, collaborative efforts focused on managing the safety risks posed by the carriage of lithium batteries by air. Experts at the FAA's Tech Center have contributed greatly to the development of a baseline test method for the G-27 Packaging Standard (AS6413), and the development of the hazard-based system to classify lithium batteries and cells for transport and improve transportation safety in this subjectmatter area.

Most notably, the Fire Safety Branch has conducted the following extensive lithium battery research:

- Impact of Lithium Battery Vent Gas Ignition on Cargo Compartment Fire Protection
- Lithium battery thermal runaway vent gas analysis
- Fire Resistant Container (FRC)
- Passive Protection of Lithium Battery Shipments

The noted research has been widely publicized in the news and throughout the international aviation community. FAA representatives presented it to international stakeholders at G-27 meetings in November 2018, March 2019, July 2019, and November 2019. A published FAA Fire Safety Branch report contains a compilation of research projects designed to determine the hazards and possible mitigations on the shipment of lithium batteries as cargo on transport category airplanes. That report summarizes 12 years of test data and results on lithium batteries that can be found on the FAA Fire Safety Branch website.¹⁵

¹⁴ <u>https://www.macroindustries.com/website/pages/composites.html;</u>

https://pressroom.ups.com/pressroom/ContentDetailsViewer.page?ConceptType=PressReleases&id=142632998036 1-367

¹⁵ <u>https://www.fire.tc.faa.gov/pdf/TC-16-37.pdf</u>

To complement these efforts and further promote cargo safety, FAA's Tech Center Fire Safety Branch planned, organized, and hosted the Ninth Triennial International Aircraft Fire and Cabin Safety Research Conference that convened in Atlantic City, New Jersey, in October 2019. The conference had five sessions regarding lithium battery safety in aviation with various presentations.

FAA presentations included:

- Hazards Associated with Personal Electronic Devices (PED) Placed in Checked Luggage
- Practical Considerations for Fighting a Lithium Battery Fire in the Aircraft Cabin
- Flight Deck and Cabin Risk Reduction Informational Videos
- Certification and Installation Guidance on Lithium Battery on Aircraft
- FAA Dangerous Goods Program: Incidents and Undeclared
- FAA Testing for G-27 Packaging Standard
- <u>Thermal Runaway Event Analysis Gas Temperature and Pressure</u>
- <u>Electric Energy Storage for Safe Installations</u>

The conference included 645 attendees from 25 countries jointly sponsored by FAA, the European Aviation Safety Agency (EASA), Transport Canada Civil Aviation, the Agencia Nacional de Aviacao Civil of Brazil, the Civil Aviation Bureau of Japan, and the Civil Aviation Authority of Singapore. Attendees shared recent, ongoing, and planned research in the areas of aircraft-fire and cabin-safety research. Attendees represented airlines, aircraft manufacturers, aircraft interior component manufacturers, cabin-safety inspectors, fire-suppression systems manufacturers, human-factors researchers, computer modelers, regulators, safety researchers, and academics. The overall theme of the conference was "*Improving Safety Through Data-Driven Innovation*."

In other research developments, plug-in electric vehicles (PEVs)—including plug-in hybrid electric and all-electric vehicles—are expected to be a significant use for lithium-ion batteries over the next decade. Unlike packages of lithium batteries, electric vehicle batteries are complex connected systems that have unique challenges and built-in active and passive safety mechanisms. NHTSA completed a comprehensive review of potential lithium battery vehicle safety issues with the aim of identifying operational safety concerns and determining whether additional testing is required to address the concerns. The report identified primary failures including heat dissipation/thermal runaway events; overcharge, over-discharge, overcurrent, and short-circuit low and high temperature charging conditions; mechanical shock and damage associated with crashes; and the cumulative effects of stress and cell aging in the vehicle environment. Another safety concern was isolating high voltage components from passengers and emergency responders in the event of a crash.¹⁶

¹⁶ Lithium-ion Battery Safety Issues for Electric and Plug-in Hybrid Vehicles, October 2017, DOT HS 812 418 <u>https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/12848-lithiumionsafetyhybrids_101217-v3-tag.pdf</u>

NHTSA conducted research to develop objective test procedures to evaluate the safe performance of lithium-ion batteries in motor vehicles during normal vehicle operation, during charging, and in a vehicle crash.¹⁷ The test procedures for the battery management system in managing overcharge, overcurrent, over-discharge, and short-circuit failure conditions, and battery operation in high and low temperatures were incorporated into Global Technical Regulation (GTR) No. 20.¹⁸ NHTSA developed test procedures for evaluating the electric shock protection of electric powered vehicles, which have already been incorporated into FMVSS No. 05.¹⁹

NHTSA's research, completed in 2019, on objective test procedures to ensure safety during charging of electric vehicles, can form the basis for requirements for communication between charging stations and the vehicle.²⁰ Research was also conducted on battery pack safety under hard and soft shorts, mechanical crush, and thermal runaway propagation; vehicle fire; water immersion; and extreme temperature cycling.^{21,22} Test procedures for short circuit, mechanical crush, water immersion, temperature cycling, and vehicle fire are included in GTR No. 20.

NHTSA is continuing to conduct research to develop objective system-level test procedures for evaluating battery pack thermal runaway propagation with the international research community. Currently, GTR No. 20 has requirements on documentation from the manufacturer on methods of mitigating thermal runaway propagation risk and on a warning system in the event of a thermal event in the battery pack to allow vehicle occupants sufficient time to safely egress the vehicle. This regulatory approach provides flexibility to manufacturers to choose not just passive methods (such as intumescent materials, air space between cells, and advanced cell designs), but also active methods (such as advanced detection and mitigation) to mitigate thermal runaway propagation events and ensure safety. NHTSA is actively evaluating detection systems to evaluate the health of a battery pack so that early intervention of possible fault events in a battery pack can be done.²³

The increasing demand for lithium-ion batteries for vehicle electrification is changing the typical-use conditions that batteries may see. Over time, batteries may develop defects that are difficult to detect with traditional measurements. It is also possible that batteries may be left in an unknown state after failure of the monitoring system, loss of communication, or a potentially damaging event such as a car crash. It is therefore useful to explore other monitoring and interrogation methods that can better determine the stability of a battery in an unknown state.

¹⁸ UN GTR No. 20 Electric Vehicle Safety (EVS) (ECE/TRANS/180/Add.20),

https://unece.org/fileadmin/DAM/trans/main/wp29/wp29wgs/wp29gen/wp29registry/ECE-TRANS-180a20e.pdf ¹⁹ https://www.ecfr.gov/cgi-bin/text-

idx?SID=d225cf0b33907245b8130a47985a0f3c&mc=true&node=se49.6.571_1305&rgn=div8

¹⁷ System-Level REESS Safety and Protection Test Procedure Development, Validation, and Assessment – Final Report, DOT HS 812 782, October 2019, <u>https://rosap.ntl.bts.gov/view/dot/40791</u>

²⁰ DC and AC Charging Safety Evaluation Procedure Development, Validation, and Assessment, July 2019, DOT HS 812 778, <u>https://rosap.ntl.bts.gov/view/dot/41933</u>

²¹ Ford Safety Performance of Rechargeable Energy Storage Systems, July 2019, DOT HS 812 756, <u>https://rosap.ntl.bts.gov/view/dot/41840</u>

²² Safety Performance of Rechargeable Energy Storage Systems, May 2019, DOT HS 812 717, <u>https://rosap.ntl.bts.gov/view/dot/40791</u>

²³ Battery state of health and stability diagnostics tool set development, January 2020, DOT HS 812 810. https://rosap.ntl.bts.gov/view/dot/43642

NHTSA is continuing research on assessing the health of a battery pack using rapid impedance spectroscopy.²⁴

PHMSA recently awarded a Research and Development grant to Virginia Commonwealth University (VCU), which has proposed to use aerogels as both an insulating and preventative packing solution for the transport of lithium batteries. Traditionally, lithium batteries are transported in fiber-board boxes (i.e., cardboard). In some cases, the batteries are placed in individual compartments or simply grouped in bulk in a box. VCU is proposing to develop a cardboard box that contains aerogels in the walls of the corrugated fiberboard that would extinguish fires should thermal runaway occur. It will additionally prevent the propagation of sparks and debris, which can lead to thermal runaway in other batteries. VCU's work will determine the optimal solution of aerogels to extinguish fires and maintain compatibility with the fiberboard material. In 2021, PHMSA awarded two research contracts through the Small Business Innovative Research Program to develop a transportation packaging for electric vehicle battery modules capable of containing the effects of thermal runaway and another to develop a rapid fire-suppression system capable of being incorporated into standard packaging.

CPSC sponsored research to learn more about the catastrophic failures of multi-cell lithium-ion battery packs, such as those used in hoverboards, from a single cell that enters a thermal runaway condition, and to evaluate several methods to isolate the failure to the one cell. The tests consisted of forcing a single cell in a multi-cell battery pack into thermal runaway, characterizing the propagation to the remaining cells in the pack, and investigating ways to limit the failure to the originating cell, either through spacing cells apart or using separating materials. The "Report on Evaluation of Cell-to-Cell Propagation in Lithium-Ion Batteries Containing 18650 Sized Cells," will support improvements for the voluntary safety standards for electric scooters and e-mobility devices to reduce the severity of fire incidents.²⁵

The "Report on Emerging Energy Storage Technologies"²⁶ presents the results of research conducted by the Naval Surface Warfare Center, Carderock Division, for CPSC under an Inter-Agency Agreement. CPSC funded this research to learn about emerging high-energy-density battery technologies and to identify strategies to mitigate the fire hazards related to battery failures. The research focused on technologies with viability for consumer applications. CPSC staff is using the results to guide future efforts to promote development of safer high-energy-

²⁴ Determination of battery stability and advanced diagnostics, March 2016, DOT HS 812 249, <u>https://one.nhtsa.gov/DOT/NHTSA/NVS/Crashworthiness/Alternative%20Energy%20Vehicle%20Systems%20Safe</u> ty%20Research/812249-BatteryStabilityAdvancedDiagnostics.pdf

²⁵ Waller, Gordon H., Ko, Johnathan K., Hayes, Thomas H, Jiang, Thomas L. Evaluation of Cell-to-Cell Propagation in Lithium-ion Batteries Containing 18650 Sized Cells. Technical Report NSWCCD-63-TR-2020/01. January 2020. <u>https://www.cpsc.gov/s3fs-</u>

public/Consumer%20Product%20Safety%20Commission%20%28CPSC%29%20Staff%E2%80%99s%20Statement %20on%20Naval%20Surface%20Warfare%20Center%2C%20Carderock%20Division%E2%80%99s%20%28NSW CCD%29%20Report%20on%20%E2%80%9CEvaluation%20of%20Cell-to-

Cell%20Propagation%20in%20Lithium-

²⁶ <u>https://www.cpsc.gov/s3fs-public/NSWCCD-63-TR-2020-39</u> <u>Emerging-Energy-Storage-</u> <u>Technologies_DIS_A_VERSION_ForPostingVersion12012020.pdf</u>?wYqrWGArQLL53BlqSYr8RfCwb2eiznIT

density batteries for consumer applications and possibly to develop recommendations for improvements to standards for batteries and battery-powered products.²⁷

Although there have been great advancements in battery technology for both increased energy density and safety in recent years, CPSC staff continues to encourage improvements in technology to advance battery safety. CPSC has encouraged battery safety technology improvements in these areas:

- <u>New Battery Materials</u>: Development of robust battery cells and modules to significantly reduce battery cost, increase life, and improve performance and safety. More stable, better chemistries and/or advanced battery designs may reduce or even eliminate the risk of thermal runaway propagation, currently observed in lithium batteries.
- <u>Advances in charging and power transfer</u>: Extreme DC fast charging (up to 500 kW), wireless inductive charging, and vehicle-to-grid power transfer. Extreme fast charging may require attention to cell heating and lithium plating during charging.
- <u>Advanced battery controls and early detection systems</u>: Advanced battery controls (battery management systems) and early detection systems would enable detection of probable fault conditions developing in a battery and early intervention before a safety problem arises.

In addition, CPSC staff will use field incidents and other information reported to the Commission to initiate or improve voluntary standards development, as warranted, to mitigate the hazards with the use of battery-powered consumer products.

The FDA-CTP has initiated and published preliminary research regarding battery-related safety concerns and information on battery-powered tobacco products. These studies were initiated to gain a basic understanding of the impact of battery-powered tobacco product related injuries as determined through research in various databases or social media reports. FDA further examined data to inform the development of future education campaigns regarding the safety risks posed by battery-powered tobacco products to protect consumers from those risks. In general, a wide range of tobacco products, injuries (from minor to serious and severe), and scenarios were observed in the information obtained on battery-powered tobacco products.

²⁷ https://www.cpsc.gov/s3fs-public/NSWCCD-63-TR-2020-39_Emerging-Energy-Storage-Technologies DIS A VERSION ForPostingVersion12012020.pdf?wYqrWGArQLL53BlqSYr8RfCwb2eiznIT

APPENDIX D

Authority of Federal Agencies Comprising the Lithium Battery Safety Working Group

This appendix presents summary level information on the existing federal authorities associated with lithium cells, batteries, and devices of the Working Group members. Some agencies such as PHMSA and FAA regulate the transport of lithium batteries and devices while other agencies such as NHTSA, CPSC, and FDA regulate specific devices that use lithium batteries to ensure safe and proper functioning.

PHMSA

PHMSA's mission is to protect people and the environment by advancing the safe transportation of energy and other hazmat that are essential to our daily lives. To do this, the agency establishes national policy, sets and enforces standards, educates, and conducts research to prevent incidents. PHMSA also prepares the public and first responders to reduce consequences if an incident does occur.

The Federal Hazardous Materials Transportation Law, 49 U.S.C. § 5101 et seq., is the basic statute regulating hazmat transportation in the United States. Section 5103 provides that the Secretary of Transportation shall: (1) designate material (including an explosive, radioactive material; infectious substance; flammable or combustible liquid, solid or gas; toxic, oxidizing, or corrosive material; and compressed gas) or a group or class of material as hazardous when the Secretary determines that transporting the material in commerce in any amount and form may pose an unreasonable risk to health and safety or property; and (2) issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate, and foreign commerce.

The Secretary has delegated authority to PHMSA, under 49 CFR § 1.96, to administer a national program of safety, including security, in multi-modal hazmat transportation including identifying hazmat safety concerns; developing uniform safety standards, and promulgating and enforcing safety and security regulations; and conducting outreach and providing available grants assistance to increase awareness and emergency preparedness.

In addition, 49 CFR § 1.97 gives the PHMSA Administrator the authority to carry out functions vested in the Secretary by 49 U.S.C. § 5121 (a), (b), (c), (d), and (e), 5122, 5123, and 5124, related to the shipment of hazmat and the manufacture, fabrication, marking, maintenance, reconditioning, repair, or test of multi-modal containers that are represented, marked, certified, or sold for use in the transportation of hazmat. PHMSA has the authority to investigate, conduct tests, make reports, issue subpoenas, conduct hearings, require the production of records and property, take depositions, and conduct research, development, demonstration, and training activities; issue or impose emergency restrictions, prohibitions, recalls, or out-of-service orders, without notice or an opportunity for hearing, to the extent necessary to abate an imminent hazard; and enforce civil and criminal violations of the Hazardous Materials Regulations (HMR; 49 CFR 171-180).

Enforcement authority under the federal hazmat law is shared by PHMSA, Federal Motor Carrier Safety Administration (FMCSA), Federal Railroad Administration (FRA), Federal Aviation Administration (FAA), and United States Coast Guard (USCG). Each of these agencies has authority to enforce the HMR against any person subject to the HMR, but each has an emphasis on its modal enforcement activities.

FAA

The continuing mission of FAA is to provide the safest, most efficient aerospace system in the world. The FAA's authority on aviation safety is found in Title 49 of the United States Code (U.S.C.). Under the authority described in 49 U.S.C. 106(f), FAA vests final authority in the Administrator to carry out all functions, powers, and duties of the Administration relating to the promulgation of regulations, rules, orders, circulars, bulletins, and other official publications of the Administration. Section 44701(a)(5) also requires the Administrator to promulgate regulations and minimum standards for other practices, methods, and procedures necessary for safety in air commerce and national security. Pursuant to Section 44701(b)(1), the Administrator may prescribe minimum safety standards for an air carrier to whom a certificate is issued with certain considerations of safety in the public interest.

For aviation safety of dangerous goods, FAA's Office of Hazardous Materials Safety (OHMS) promotes the safe transport of lithium batteries in commerce through activities that include regulatory oversight of hazmat carried by the flying public or transported on aircraft. That delegated authority to FAA is found within the provisions of Section 1.83(d). In addition, the current International Cooperative Effort was established per Annex 18 of the Chicago Convention, which pertains to the Safe Transport of Dangerous Goods by Air. Annex 18 sets forth broad principles, with one of the standards requiring that dangerous goods be carried in accordance with the Technical Instructions for the Safe Transport of Dangerous Goods by Air. States are required by Annex 18 to have inspection and enforcement procedures to ensure that dangerous goods are carried in compliance with the requirements.

In conclusion, the FAA's authority to issue rules and other actions on aviation safety is found in Title 49 U.S.C. Subtitle I, Section 106, Federal Aviation Administration, which describes the authority of the FAA Administrator. Title 49 U.S.C. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

NHTSA

NHTSA's mission is to save lives, prevent injuries, and reduce economic costs due to road traffic crashes through education, research, safety standards, and enforcement.

The National Traffic and Motor Vehicle and Safety Act of 1966 (the Vehicle Safety Act; recodified at 49 U.S.C. Chapter 301), authorizes NHTSA to prescribe motor vehicle safety standards that are practicable, safe, and stated in objective terms. Under the Vehicle Safety Act, "motor vehicle safety" means the performance of a motor vehicle or motor vehicle equipment in a way that protects the public against unreasonable risk of accidents occurring because of the design, construction, or performance of a motor vehicle, and against unreasonable risk of death

or injury in an accident. NHTSA issues Federal Motor Vehicle Safety Standards (FMVSSs) to fulfill its safety mission.

Under the Vehicle Safety Act, manufacturers of motor vehicles and motor vehicle equipment self-certify that their products comply with all applicable safety standards. The Vehicle Safety Act specifies that a manufacturer may not certify a vehicle if, in exercising "reasonable care," the manufacturer has reason to know the certification is false or misleading in any material respect. If a motor vehicle or motor vehicle equipment is determined not to comply with applicable standards, the manufacturer is subject to recall responsibilities.

The Vehicle Safety Act also gives NHTSA the authority to require manufacturers to recall vehicles that have safety-related defects or do not meet federal safety standards. A safety-related defect is a problem in a motor vehicle or motor vehicle equipment that poses an unreasonable risk to motor vehicle safety and may exist in a group of vehicles of the same design or manufacture, or motor vehicle equipment of the same type or manufacture. If a safety defect is discovered, the manufacturer must notify NHTSA, as well as vehicle or equipment owners, dealers, and distributors. The manufacturer is then required to remedy the problem at no charge to the owner. According to the Vehicle Safety Act, NHTSA is responsible for monitoring the manufacturer's corrective action to ensure successful completion of the recall campaign.

CPSC

CPSC is charged with protecting the public from unreasonable risks of injury or death associated with the use of the thousands of types of consumer products under the agency's jurisdiction. CPSC protects consumers and families from consumer products that pose risks from a range of hazards including fire, electrical, chemical, or mechanical hazards.

The <u>Consumer Product Safety Act (CPSA)</u> is the agency's umbrella statute that established the CPSC. It was enacted in 1972 and codified at 15 U.S.C. §§ 2051–2089. This law defines CPSC's basic authority and authorizes the agency to develop standards and bans. It also gives CPSC the authority to pursue recalls and to ban products under certain circumstances. CPSC encourages manufacturers, retailers, and importers of all products to meet the requirements of industry voluntary safety standards. Currently, battery operated toys are the only CPSC regulated lithium battery products (through Section 106 of the <u>Consumer Product Safety Improvement Act</u> (<u>CPSIA</u>) and adoption of ASTM F963, Standard Consumer Safety Specification for Toy Safety).

FDA-CDRH

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. Two organizations, the Center for Devices and Radiological Health and the Center for Tobacco Products were represented in the Working Group.

FDA's Center for Devices and Radiological Health (CDRH) is responsible for providing reasonable assurance of the safety and effectiveness of medical devices, and eliminating unnecessary human exposure to man-made radiation from medical, occupational, and consumer products.

FDA reviews devices to provide a reasonable assurance that they are safe and effective. These include batteries—including lithium batteries—that are used as a main, supplemental, standby, or backup power source for such devices. FDA's evaluation of battery performance is based on the potential harm to a patient if the battery malfunctions or if the device loses power. FDA only regulates lithium batteries intended for use with battery powered medical devices and based primarily on the risk that the <u>device</u> presents to the patient while also considering the risk to user (i.e., health care provider) and environment. Batteries intended for general use (e.g., off-the-shelf 9V, AA, or AAA) are not subject to FDA oversight.

FDA-CTP

The FDA-CTP is responsible for regulating the manufacturing, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Electronic nicotine delivery systems (ENDS) and other battery powered tobacco products are subject to the FD&C Act, as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA regulates the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of ENDS, including components and parts of ENDS but excluding accessories. Examples of components and parts of ENDS include cartridges, atomizers, and certain batteries.

- Section 901(b) of the FD&C Act provides FDA with the authority to regulate "cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Secretary by regulation deems."
- In May 2016, FDA issued the final deeming rule, under which it deemed all products that meet the statutory definition of a "tobacco product," except accessories of newly deemed products, to be subject to FDA's tobacco product authority in Chapter IX of the FD&C Act.
- FD&C Act section 201(rr) defines "tobacco product," in part, to mean "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." FDA regulations, in turn, define "component or part," in part, to mean "any software or assembly of materials intended or reasonably expected: [t]o alter or affect the tobacco product's performance, composition, constituents, or characteristics; or [t]o be used with or for the human consumption of a tobacco product."
- Under 21 CFR § 1140.3, where a lithium battery is "intended or reasonably expected: [t]o alter or affect the tobacco product's performance, composition, constituents, or characteristics; or [t]o be used with or for the human consumption of a tobacco product," it meets the definition of "component or part," and thus also meets the statutory definition of "tobacco product" and is subject to FDA's tobacco product authority. Examples of components and parts of ENDS include cartridges, programmable software, and certain batteries.

NIST

The National Institute of Standards and Technology (NIST) promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life. NIST supports the development of standards by identifying areas where they are needed, convening stakeholders, and providing technical and scientific guidance and expertise to help stakeholder groups reach a consensus.

The National Technology Transfer and Advancement Act of 1995 (NTTAA) directs federal agencies to adopt voluntary consensus standards wherever possible (avoiding development of unique government standards) and establishes reporting requirements. Under the NTTAA, federal agencies are responsible for evaluating the efficacy of their conformity assessment activities. NIST coordinates federal, state, and local documentary standards and conformity assessment activities.

APPENDIX E

Standards Applicable to Lithium Batteries and Devices

Standard	Title	Scope
ANSI AIAA S-144- 2018	American National Standard, Specification: Space Battery Cell, Large, Prismatic Format	Under development
ANSI C18.2M, Part 2	Portable Rechargeable Cells and Batteries - Safety Standard	Specifies performance requirements for standardized portable lithium-ion, nickel cadmium, and nickel metal hydride rechargeable cells and batteries to ensure their safe operation under normal use and reasonably foreseeable misuse, and includes information relevant to hazard avoidance.
ANSI C18.3M, Part 2	Portable Lithium Primary Cells and Batteries - Safety Standard	Specifies tests and requirements for portable primary lithium cells and batteries, both the chemical systems and the types covered in ANSI C18.3M, Part 1, to ensure their safe operation under normal use and reasonably foreseeable misuse.
IEC 60086-4	Primary Batteries – Part 4: Safety of Lithium Batteries	Specifies tests and requirements for primary lithium batteries to ensure their safe operation under intended use and reasonably foreseeable misuse.
IEC 61960	Secondary Cells and Batteries containing Alkaline or other Non- Acid Electrolytes – Secondary Lithium Cells and Batteries for Portable Applications	Specifies performance tests, designations, markings, dimensions, and other requirements for secondary lithium single cells and batteries for portable applications.
IEC 62133	Secondary Cells and Batteries containing Alkaline or other Non-	Specifies requirements and tests for the safe operation of portable sealed secondary cells and batteries (other than button) containing

	Acid Electrolytes – Safety Requirements for Portable Sealed Secondary Cells, and for Batteries made from them, for use in Portable Applications	alkaline or other non-acid electrolyte, under intended use and reasonably foreseeable misuse.
IEC 62133-2	Secondary Cells and Batteries containing Alkaline or other Non- acid Electrolytes – Safety Requirements for Portable Sealed Secondary Cells, and for Batteries Made from them, for Use in Portable Applications – Part 2: Lithium Systems.	Specifies requirements and tests for the safe operation of portable sealed secondary lithium cells and batteries containing non- acid electrolyte, under intended use and reasonably foreseeable misuse.
IEC 62281	Safety of Primary and Secondary Lithium Cells and Batteries During Transport	Specifies test methods and requirements for primary and secondary (rechargeable) lithium cells and batteries to ensure their safety during transport other than for recycling or disposal.
IEC 62660-3	Secondary Lithium-ion Cells for the Propulsion of Electric Road Vehicles – Part 3: Safety Requirements	Specifies test procedures and the acceptance criteria for safety performance of secondary lithium-ion cells and cell blocks used for the propulsion of electric vehicles (EV) including battery electric vehicles (BEV) and hybrid electric vehicles (HEV).
IEC 62928	Railway Applications – Rolling Stock – Onboard Lithium-ion Traction Batteries	Specifies the design, operation parameters, safety recommendations, data exchange, and routine and type tests, as well as marking and designation for onboard lithium-ion traction batteries for railway applications. Battery systems described in this document are used for the energy storage system (ESS) for the traction power of railway vehicles such as

		hybrid vehicles as defined in IEC 62864- 1:2016.
IEEE 1679.1	Guide for the Characterization and Evaluation of Lithium- Based Batteries in Stationary Applications	Guidance for an objective evaluation of lithium-based energy storage technologies by a potential user for any stationary application is provided in this document.
IEEE 1625	Rechargeable Batteries for Multi-Cell Mobile Computing Devices	Establishes criteria for design analysis for qualification, quality, and reliability of rechargeable battery systems for multi-cell mobile computing devices.
IEEE 1725	Rechargeable Batteries for Cellular Telephones	Establishes criteria for design analysis for qualification, quality, and reliability of rechargeable lithium-ion (Li-ion) and lithium-ion polymer (Li-ion polymer) batteries for cellular telephone applications.
ISO 12405-3	Electrically Propelled Road Vehicles – Test Specification for Lithium- Ion Traction Battery Packs and Systems – Part 3: Safety Performance Requirements	Specifies test procedures and provides acceptable safety requirements for voltage class B lithium-ion battery packs and systems, to be used as traction batteries in electrically propelled road vehicles.
ISO 17546	Space Systems – Lithium- Ion Battery for Space Vehicles – Design and Verification Requirements	Specifies design and minimum verification requirements for lithium-ion rechargeable (including lithium-ion polymer) batteries for space vehicles.
RTCA DO-311	Minimum Operational Performance Standards for Rechargeable Lithium Batteries and Battery Systems	Applies to rechargeable lithium batteries and battery systems that are permanently installed on aircraft.

SAE J 2929	Electric and Hybrid Vehicle Propulsion Battery System Safety Standard - Lithium - Based Rechargeable Cells	Defines a minimum set of acceptable safety criteria for a lithium-based rechargeable battery system to be considered for use in a vehicle propulsion application as an energy storage system connected to a high voltage power train.
SAE J 2464	Electric and Hybrid Electric Vehicle Rechargeable Energy Storage System (RESS) Safety and Abuse Testing	SAE Recommended Practice is intended as a guide toward standard practice and is subject to change to keep pace with experience and technical advances. It describes a body of tests that may be used as needed for abuse testing of electric or hybrid electric vehicle Rechargeable Energy Storage Systems (RESS) to determine the response of such electrical energy storage and control systems to conditions or events that are beyond their normal operating range.
UL 1642	Lithium Batteries	Requirements cover primary (non- rechargeable) and secondary (rechargeable) lithium batteries for use as power sources in products.
UL 1973	Standard for Batteries for Use in Stationary, Vehicle Auxiliary Power, and Light Electric Rail (LER) Applications	Requirements cover battery systems as defined by this standard for use as energy storage for stationary applications such as for PV, wind turbine storage or for UPS, etc. applications.
UL 2054	Household and Commercial Batteries	Requirements cover portable primary (non- rechargeable) and secondary (rechargeable) batteries for use as power sources in products.
UL 2271	Standard for Batteries for Use in Light Electric Vehicle (LEV) Applications	Requirements cover electrical energy storage assemblies (EESAs) such as battery packs and combination battery pack- electrochemical capacitor assemblies and the subassembly/modules that make up these

		assemblies for use in light electric-powered vehicles (LEVs).
UL2272	Standard for Electrical Systems for Personal E- Mobility Devices	Requirements cover the electrical drive train system including the battery system, other circuitry, and electrical components for electric powered scooters and other devices to be referred to as personal e-mobility devices as defined in this standard.
UL 2580	Batteries for use in Electric Vehicles	Requirements cover electrical energy storage assemblies such as battery packs and combination battery pack-electrochemical capacitor assemblies and the subassembly/modules that make up these assemblies for use in electric-powered vehicles as defined in this standard.
UL 8139	Standard for Electrical Systems of Electronic Cigarettes and Vaping Devices	These requirements cover the battery- operated electrical systems that use consumables containing varying compositions of flavorings, propylene glycol, glycerin, and other ingredients, with or without nicotine, which is heated into an aerosol that the user inhales. Examples include but are not limited to vaporizers, vape pens, hookah pens, e-hookah, e-shisha, e-pipes, electronic cigarettes, e-cigarettes, and electronic nicotine delivery systems (ENDS). These systems encompass their charging systems, components, parts, and accessories.
UN Manual of Tests and Criteria Seventh Revised Edition, ST/SG/AC.10/11/Rev.7. Part III, subsection 38.3	Lithium Metal and Lithium-Ion Batteries	Presents the procedures to be followed for the classification of lithium metal and lithium-ion cells and batteries (see UN Nos. 3090, 3091, 3480 and 3481, and the applicable special provisions of Chapter 3.3 of the Model Regulations).

Origin	Standard	Description
United Nations	Global Technical Regulation 20	Electric Vehicle Safety
U.S.	The United States of America – FMVSS 305	Electric-Powered Vehicles: Electrolyte Spillage and Electrical Shock Protection
United Nations	UN Regulation No. 100	Uniform provisions concerning the approval of vehicles regarding specific requirements for the electric power train
Japan	Attachment 101	Technical Standard for Protection of Occupants against High Voltage in Fuel Cell Vehicles
Japan	Attachment 110	Technical Standard for Protection of Occupants against High Voltage in Electric Vehicles and Hybrid Electric Vehicles
Japan	Attachment 111	Technical Standard for Protection of Occupants against High Voltage after Collision in Electric Vehicles and Hybrid Electric Vehicles
China	GB/T 31484	2015 Lifecycle Requirements and Test Methods for Traction Battery of Electric Vehicle
China	GB/T 31485	2015 – Safety Requirements and Test Methods for Traction Battery of Electric Vehicle
China	GB/T 31486	2015 – Electrical Performance Requirements and Test Methods for Traction Battery of Electric Vehicle
China	GB/T 31467.3	2015 – Lithium-Ion Traction Battery Pack and System for Electric Vehicles— Part 3: Safety Requirements and Test Methods

Regulations and Standards Applicable to Electric-Powered Vehicles

China	GB/T 18384.1	2015 – Electrically Propelled Road Vehicles- Safety Specifications-Part 1: On-Board Rechargeable Energy Storage System (REESS)
China	GB/T 18384.2	2015 – Electrically Propelled Road Vehicles- Safety Specifications-Part 2: Vehicle Operational Safety Means and Protection against Failures
China	GB/T 18384.3	2015 – Electrically Propelled Road Vehicles- Safety Specifications-Part 3 Protection of Persons Against Electric Shock
China	GB/T 31498	2015 – The Safety Requirement of Electric Vehicle Post-Crash
China	GB/T 24549	2009 – Fuel Cell Electric Vehicles - Safety Requirements
Canada	CMVSS 305	Electric Powered Vehicles: Electrolyte Spillage and Electrical Shock Protection
Republic of Korea	Motor Vehicle Safety Standard, Article 18-2— High Voltage System, Test Procedure Table 1 – Part 47	Safety Test for High Voltage System
Republic of Korea	Motor Vehicle Safety Standard, Article 18-3 – Rechargeable Energy Storage System (REESS), Test Procedure Table 1 – Part 48	Safety Test for REESS
Republic of Korea	Motor Vehicle Safety Standard, Article 91-4 – High Voltage System in Crash test, Test Procedure Table 1 – Part 47	Safety Test for High Voltage System

Standard	Title	Description
ISO 6469-1	2009 Electrically Propelled Road Vehicles – Safety Specifications – Part 1	On-Board Rechargeable Energy Storage System (Remark: Standard is under review to incorporate the requirements from ISO12405-3 to apply all types of REESS.)
ISO 6469-2	2009 Electrically Propelled Road Vehicles – Safety Specifications – Part 2	Vehicle Operational Safety Means and Protection Against Failures
ISO 6469-3	2011 Electrically Propelled Road Vehicles – Safety Specifications – Part 3	Protection of Persons Against Electric Shock
ISO 6469-4	2015 Electrically Propelled Road Vehicles – Safety Specifications – Part 4	Post-Crash Electrical Safety
ISO 17409	2015 Electrically Propelled Road Vehicles	Connection to an External Electric Power Supply – Safety Requirements
ISO/TR 8713	2012 Electrically Propelled Road Vehicles	Vocabulary
ISO/IEC 15118-1	2013 Road vehicles – Vehicle to Grid Communication Interface – Part 1	General Information and Use-Case Definition
ISO/IEC 15118-2	2014 Road vehicles – Vehicle to Grid Communication Interface – Part 2	Network and Application Protocol Requirements
ISO/IEC 15118-3	2015 Road vehicles – Vehicle to Grid	Physical and Data Link Layer Requirements

Relevant Standards for Electric Vehicle Safety

	Communication Interface – Part 3	
ISO/IEC 15118- 4(draft) Road vehicles	Vehicle to Grid Communication Interface – Part 4	Network and Application Protocol Conformance Test
ISO/IEC 15118-5draft) Road vehicles	Vehicle to Grid Communication Interface – Part 5	Physical Layer and Data Link Layer Conformance Test
ISO 26262 series	2011 Road Vehicles	Functional Safety
ISO 6722-1	2011 Road Vehicles – 60 V and 600 V Single-Core Cables – Part 1	Dimensions, Test Methods, and Requirements for Copper Conductor Cables
ISO 6722-2	2013 Road Vehicles – 60 V and 600 V Single-Core Cables – Part 2	Dimensions, Test Methods, and Requirements for Aluminum Conductor Cables
ISO 12405-1	2011 Electrically Propelled Road Vehicles – Test Specification for Lithium-ion Traction Battery Packs and Systems – Part 1	High-Power Applications (Remark: This standard will be withdrawn and replaced with ISO12405-4.)
ISO 12405-2	2012 Electrically Propelled Road Vehicles – Test Specification for Lithium-Ion Traction Battery Packs and Systems - Part 2	High-Energy Applications (Remark: This standard will be withdrawn and replaced with ISO12405-4.)
ISO 12405-3	2014 Electrically Propelled Road Vehicles – Test Specification for Lithium-Ion Battery Packs and Systems – Part 3	Safety Performance Requirements (Remark: This standard will be withdrawn and merged into ISO6469-1.)

ISO 12405-4(draft)	Electrically Propelled Road Vehicles - Test Specification for Lithium- Ion Traction Battery Packs and Systems – Part 4	Performance Testing (Remark: ISO12405-1 and ISO12405-2 will be merged as this standard.)
IEC 61851-1	2017 Electric Vehicle Conductive Charging System – Part 1	General Requirements
IEC 61851-21	2001 Electric Vehicle Conductive Charging System – Part 21	Electric Vehicle Requirements for Conductive Connection to an AC/DC supply (Remark: This standard is under review and will change into EMC standards (IEC61851- 21-1 and IEC61851-21-2); the relevant requirements for electrical safety were moved to ISO 17409.)
IEC 61851-21-1(draft)	Electric Vehicle Conductive Charging System – Part 21-1	Electric Vehicle On-Board Charger EMC Requirements for Conductive Connection to AC/DC Supply
IEC 61851-21-2 (draft)	Electric Vehicle Conductive Charging System – Part 21-2	EMC Requirements for Off-Board Electric Vehicle Charging Systems
IEC 61851-23	2014 Electric Vehicles Conductive Charging System – Part 23	DC Electric Vehicle Charging Station
IEC 61851-24	2014 Electric Vehicles Conductive Charging System – Part 24	Digital Communication between a D.C. EV Charging Station and an Electric Vehicle for Control of D.C. Charging
IEC 62196-1	2014 Plugs, Socket- Outlets, Vehicle Connectors, and Vehicle Inlets – Conductive	General Requirements

	Charging of Electric Vehicles – Part 1	
IEC 62196-2	2011 Plugs, Socket- Outlets, Vehicle Connectors, and Vehicle Inlets – Conductive Charging of Electric Vehicles – Part 2	Dimensional Compatibility and Interchangeability Requirements for AC PIN and Contact-Tube Accessories
IEC 62196-3	2014 Plugs, Socket- Outlets, and Vehicle Couplers – Conductive Charging of Electric Vehicles – Part 3	Dimensional Compatibility and Interchangeability Requirements for Dedicated DC and Combined AC/DC Pin and Contact-Tube Vehicle Couplers
IEC 62660-2	2010 Secondary Lithium- Ion Cells for the Propulsion of Electric Road Vehicles – Part 2	Reliability and Abuse Testing
IEC 62660-3	2016 Secondary Lithium- Ion Cells for the Propulsion of Electric Road Vehicles – Part 3	Safety Requirements of Cells and Modules
IEC 62752	2016 In-Cable Control and Protection Device for Mode 2 Charging of Electric Road Vehicles (IC-CPD)	This standard applies to portable devices performing simultaneously the functions of detection of the residual current, of comparison of the value of this current with the residual operating value, and of opening of the protected circuit when the residual current exceeds this value.
SAE J1766	2014 Recommended Practice for Electric and Hybrid Electric Vehicle Battery Systems Crash Integrity Testing	Adequate barriers between occupants and the high voltage systems are necessary to protect from potentially harmful electric current and materials within the high voltage system that can cause injury to occupants of the vehicle during and after a crash.

SAE J1772	2016 Electric Vehicle and Plug in Hybrid Electric Vehicle Conductive Charge Coupler	This SAE Standard covers the general physical, electrical, functional, and performance requirements to facilitate conductive charging of EV/PHEV vehicles in North America.
SAE J2578	2014 Recommended Practice for General Fuel Cell Vehicle Safety	This SAE Recommended Practice identifies and defines requirements relating to the safe integration of the fuel cell system, the hydrogen fuel storage and handling systems (as defined and specified in SAE J2579), and high voltage electrical systems into the overall Fuel Cell Vehicle. The document may also be applied to hydrogen vehicles with internal combustion engines.
SAE J2929	2013 Safety Standard for Electric and Hybrid Vehicle Propulsion Battery Systems Utilizing Lithium-Based Rechargeable Cells	This SAE Standard defines a minimum set of acceptable safety criteria for a lithium-based rechargeable battery system to be considered for use in a vehicle propulsion application as an energy storage system connected to a high voltage power train.
SAE J2464	2009 Electric and Hybrid Electric Vehicle Rechargeable Energy Storage System (RESS) Safety and Abuse Testing	This SAE Recommended Practice describes a body of tests that may be used as needed for abuse testing of electric or hybrid electric vehicle Rechargeable Energy Storage Systems (RESS) to determine the response of such electrical energy storage and control systems to conditions or events that are beyond their normal operating range.
SAE J2344	2010 Guidelines for Electric Vehicle Safety	This SAE Information Report identifies and defines the preferred technical guidelines relating to safety for vehicles that contain High Voltage (HV), such as Electric Vehicles (EV), Hybrid Electric Vehicles (HEV), Plug-In Hybrid Electric Vehicle (PHEV), Fuel Cell Vehicles (FCV), and Plug-In Fuel Cell Vehicles (PFCV) during normal operation and charging, as applicable.

SAE J2380	2009 Vibration Testing of Electric Vehicle Batteries	This SAE Recommended Practice describes the vibration durability testing of a single battery (test unit) consisting of either an electric vehicle battery module or an electric vehicle battery pack.
UL 2580	2013 Batteries for Use in Electric Vehicles	These requirements cover electrical energy storage assemblies such as battery packs and combination battery pack-electrochemical capacitor assemblies and the subassembly/modules that make up these assemblies for use in electric-powered vehicles as defined in this standard.