



PHMSA's PROCESS FOR ENABLING **NEW** TECHNOLOGIES



Office of Hazardous Materials Safety

Pipeline and Hazardous Materials Safety
Administration (PHMSA)



PHMSA's PROCESS FOR **ENABLING NEW** TECHNOLOGIES





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Enabling New Technologies



Introduction

Stakeholders 2
 Purpose 2
 Initial Review and Regulatory Evaluation..... 4
 Safety Review and Risk Analysis 6
 Additional Testing and Evaluation 8
 Consensus Standards 9

Modal Considerations..... 10

Air 11
 Rail 11
 Highway 11
 Maritime..... 11

Domestic and International Regulatory Introduction..... 12

Special Permits and Approvals 12
 Development of Regulatory Provisions 14
 International Regulatory Process Timeline 18
 Stakeholder Cooperation 18

PHMSA Review of a New Technology – How to Get Started..... 20



U.S. Department of Transportation
 Pipeline and Hazardous Materials Safety

INTRODUCTION

The Department of Transportation's Pipeline and Hazardous Materials Safety Administration's Office of Hazardous Materials Safety (PHMSA/OHMS—hereafter "we") is committed to addressing transportation safety issues involving new technologies while ensuring that regulatory requirements do not inhibit technological innovation and development.

NEW TECHNOLOGIES

...a technology for which **existing regulatory provisions** do not exist, are unknown or have not been assessed, or are inadequate to facilitate the **safe and efficient transportation** or **use of the technology.**

While new technologies often provide opportunities to enhance the safe transportation of hazardous materials, they may at times also pose unique challenges to safety regulators who must develop adequate provisions governing their manufacture, their use and, in our case, their safe transportation. Just as a company will invest significant resources in product development to ensure that target goals are met or exceeded, we also invest time and resources in evaluating new technologies and their potential impact on transportation safety.

This ensures that the public is well protected from potential risks while facilitating technological innovations that advance safety and promote transportation efficiencies.

A consistent method to address new technologies enhances safety by:

- Ensuring appropriate risk management principles are applied uniformly for each new technology.
- Ensuring all available resources are considered in evaluating each new technology on its safety merits.



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New technologies provide opportunities to enhance safety, the integrity of the transportation system and the quality of life for people in every part of the world. We are committed to working with our stakeholders to enable the market introduction of new technologies while ensuring that their introduction does not negatively impact the delicate balance of factors that contribute to safety and our risk reduction efforts. We cannot afford to miss opportunities to harness technologies that can assist us in our risk reduction efforts or in improving the quality of life of individuals, generating jobs, income and economic growth. We hope this guide will provide you with valuable guidance as we work together to enhance the process and improve our ability to address new and emerging technologies.

*Robert A. Richard,
Deputy Associate Administrator for
Hazardous Materials Safety*

There is no simple formula for evaluating new technologies. New technologies come in many forms. Examples include physical products such as a lithium battery or fuel cell, a new packaging design type, or an improved method for testing, such as ultrasonic and acoustic emission testing to detect structural deficiencies in a packaging or container.

For the purposes of this document, a new technology means a technology for which existing regulatory provisions do not exist, are unknown or have not been assessed, or are inadequate to facilitate the safe and efficient transportation or use of the technology.

Generally, a new technology will fall into one of three categories:

- A technology for which existing transportation requirements are adequate — the vast majority of new technologies will fall into this category.
- A new technology of specialized application or requiring specific operational controls which is best addressed via a Special Permit or Approval.
- A new technology with broad applicability warranting rulemaking action. In such cases, a Special Permit or Approval may provide an interim measure to address the technology while rulemaking action is initiated.



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Stakeholders

Stakeholders often have one basic question in common when working with us to address new technologies: "What do I need to bring to the table to expedite this process and ensure a desired outcome is attained?" While the specifics of the information needed will vary depending on the technology in question, generally we are looking for three things, all of which are discussed in greater detail within this document:

- A detailed description of the new technology;
- A description of how the current regulatory provisions do or do not adequately address the new technology; and
- An assessment of the technology's transportation risks.

Recognizing that the first stages of this review are a learning process for both parties, we encourage stakeholders to engage the agency as early in the development process as possible in order to avoid surprises and unnecessary delays. Early engagement allows us and our stakeholders to share information, gain insight, and better assess and understand potential benefits and risks.

Purpose

This document was prepared to help our stakeholders better understand our process for addressing new technologies and to enable stakeholders to work effectively with us to ensure an expedited and satisfactory outcome. This document describes in detail the elements of our new technology facilitation process, which includes:

- an initial regulatory evaluation;
- a safety evaluation and data analysis; and
- a review of any specific considerations for a particular mode of transport.

During every stage of our evaluation, we maintain an open dialogue with our stakeholders in order to work collectively and efficiently towards the successful introduction of the technology within applicable regulations.

NEW TECHNOLOGIES

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“What do I need to bring to the table to expedite this process and ensure a desired outcome is attained?”



For more information on PHMSA's overall mission and regulatory authority, visit the PHMSA website at <http://www.phmsa.dot.gov>

This document describes our process for addressing new technologies, and also provides guidance on how to work with us to that end. We are dedicated to ensuring that the process is transparent and supports the Department's strategic safety, global connectivity, and organizational excellence objectives, while also directly supporting our strategic plan initiative of facilitating the transportation of new energy sources and other emerging technologies.

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Pipeline and Hazardous Materials Safety



Initial Review and Regulatory Evaluation

In this first step, we work with stakeholders to evaluate the technology, acquire a better understanding of the associated risks and benefits, and to determine whether current regulatory provisions may already be sufficiently comprehensive. Recognizing the importance of fostering the development of new technologies, we strive to develop regulatory provisions which are as broad as practicable. The current framework of the U.S. Hazardous Materials Regulations (HMR) is such that in many cases new technologies will already be addressed. For example, performance based package testing requirements help to preclude the need to approve new packaging designs and materials. Provided the package meets the required performance criteria, it may be considered an authorized package.



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Similarly, many novel articles or materials may already be properly described by existing shipping descriptions with prescribed conditions already delineated in the HMR. In short, existing regulatory provisions in many instances may already fully or partially address a new technology. After a thorough assessment, if it is determined existing regulatory provisions are insufficient to address the safe transport of a new technology, we will work with the affected party and begin the safety review component of our process.



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Safety Review and Risk Analysis



In addressing a new technology, we work with stakeholders to ensure a comprehensive safety review and risk analysis is undertaken. This analysis is critical to ensure that regulatory provisions provide a high degree of safety consistent with our safety mandate. Due to wide variations in scope and application, there is no single evaluation process which can be applied universally to each new technology.



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It is incumbent upon the interested party requesting the review to provide detailed information that will facilitate our evaluation process. This should include a full risk analysis documenting failure modes and effects, a complete systems safety evaluation, and an explanation of the measures imposed to ensure each risk factor has been addressed to ensure an appropriate level of safety. In considering risks and transportation safety, we strive to implement 21st century solutions and state of the art review to ensure appropriate transportation conditions are established consistent with our safety mandate. Considerations include application of the technology, its transportation risks, and mechanisms to alleviate those risks. When feasible, we assess risk mitigation factors and safety analysis of new technologies by analogy to requirements in place for technologies posing similar risks in order to expedite this review.



Additional Testing and Evaluation

During the review process, we may determine that additional testing or evaluation is necessary in order to fully assess potential transportation risks posed by a new technology. In some cases we may utilize external organizations to conduct such testing and evaluation. In addition, the new technology may be under review by other agencies with safety mandates, for example the Environmental Protection Agency, the Consumer Product Safety Commission, or the National Highway Traffic Safety Administration, among others. We encourage interested parties to provide any relevant testing or evaluation performed by other agencies which may assist in the review. In all cases we strive to thoroughly consider all available data to ensure a complete and accurate assessment of a new technology's potential transportation risks.

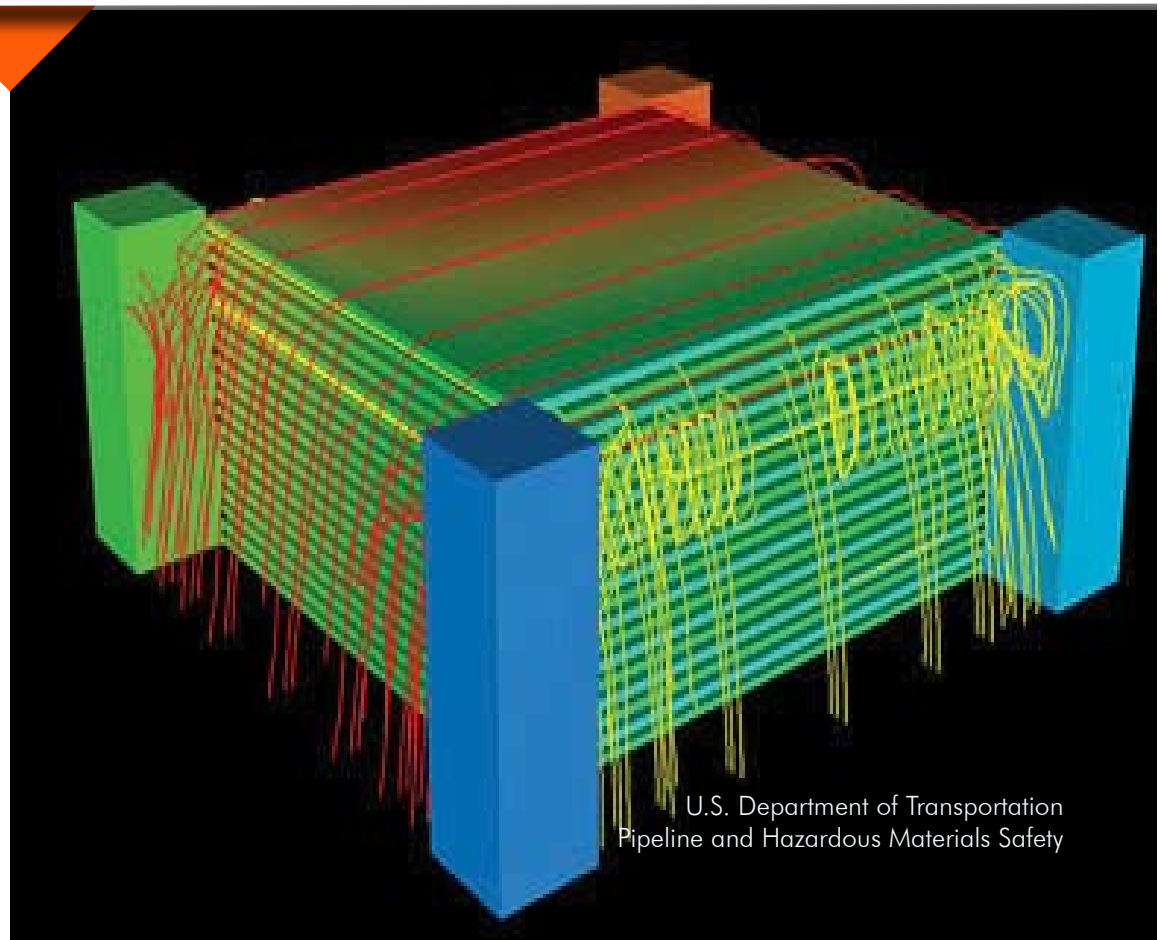
A complete assessment of the technology's transportation risks should include:

- a full failure modes and effects analysis;
- a complete systems safety evaluation; and
- relevant test data applicable to a determination of safety in transport.

Consensus Standards

The development of consensus standards such as those promulgated by the International Organization for Standardization (ISO), the American National Standards Institute (ANSI), the International Electrotechnical Commission (IEC), and others is often extremely helpful to our work in addressing new technologies. These organizations provide a forum where diverse technical expertise is utilized to ensure that essential elements of design, construction, and use of a new technology are adequately considered. Often, these standards include specific provisions to address safety aspects of the technology. We encourage stakeholders which work with such organizations to consider transportation safety concerns during the development of the standards. In many cases, we may choose to participate on standards development teams in order to ensure transportation concerns are considered.

Once we have determined a standard adequately addresses transportation risks, the standard may be referenced within the transportation regulations.



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Pipeline and Hazardous Materials Safety



Modal Considerations

When conducting our safety review and risk analysis, we work closely with the Federal Aviation Administration, the Federal Railroad Administration, the Federal Motor Carrier Safety Administration, the United States Coast Guard, and other government agencies to ensure that specific modal considerations are addressed. This may include additional evaluation and/or testing specific to conditions encountered in an individual transportation mode. The following provides an indication of some of the unique factors inherent to each mode that are considered during our evaluation.

We're in this together.

Other government agencies may be involved to ensure that specific modal considerations are addressed.



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Air— Many factors make air transport unique from other modes. A primary concern is the limited ability to respond to, and mitigate the effects of, an incident during flight. Packages may be stored in confined spaces not easily accessible during transport, for instance in inaccessible cargo holds, or may be stored in areas where fire detection or suppression systems are not present. In addition, cabin pressures may vary, depending on the type of aircraft used. The potential effect of a hazardous materials release upon passengers and crew during flight must also be evaluated, as well as their effect on the aircraft's structural components. Most importantly, air incidents can be of high consequence resulting in significant loss of life. Based on these and other factors, regulatory requirements for air transport are generally more conservative and protective in nature as compared to those of the surface modes.

Rail— Our nation's fixed track transportation system is composed of passenger, cargo, and mixed use trains. Most routes traverse populated areas to more easily distribute passengers and commodities. As with transportation by air, access to cargo during transport presents challenges to rail crews. Rail cars are not within easy access to crews during transport. In addition, a high volume of bulk packages of hazardous materials (i.e. rail tank cars, portable tanks, etc.) are transported by rail. These packages are subjected to unique forces during rail transportation during loading, changing of tracks, changing of rail cars, and off loading. A particular concern is the possibility of derailment and a large scale release in populated or environmentally sensitive areas, or in rural areas where emergency response capabilities may be limited.

Highway— Highway transportation is by far the most common mode of hazardous materials transportation in the United States due to its convenience and cost. Due to the dynamic nature of highway transportation, it is the mode of travel most frequently vulnerable to inadvertent releases of hazardous materials. This is in part due to the fact that only the highway mode is exposed to large numbers of vehicles operated by the public. No other mode realizes such a great number of independently operated vehicles which travel together in such close proximity. Therefore the likelihood of a traffic incident is greatly increased as compared to other modes.

Maritime— International transportation of high volume and containerized shipments of hazardous materials is most common by this mode. Packages may be subjected to high levels of turbulence during transit, due in part to weather conditions and vessel design. Furthermore, containers used to house packages are often exposed to moisture, humidity, and temperature extremes. Inadvertent releases of hazardous materials can cause serious and far reaching pollution to the marine environment. As with the air mode, response capabilities aboard a vessel at sea may also be more limited than with other modes of transportation such as by highway or rail.





Domestic and International Regulatory

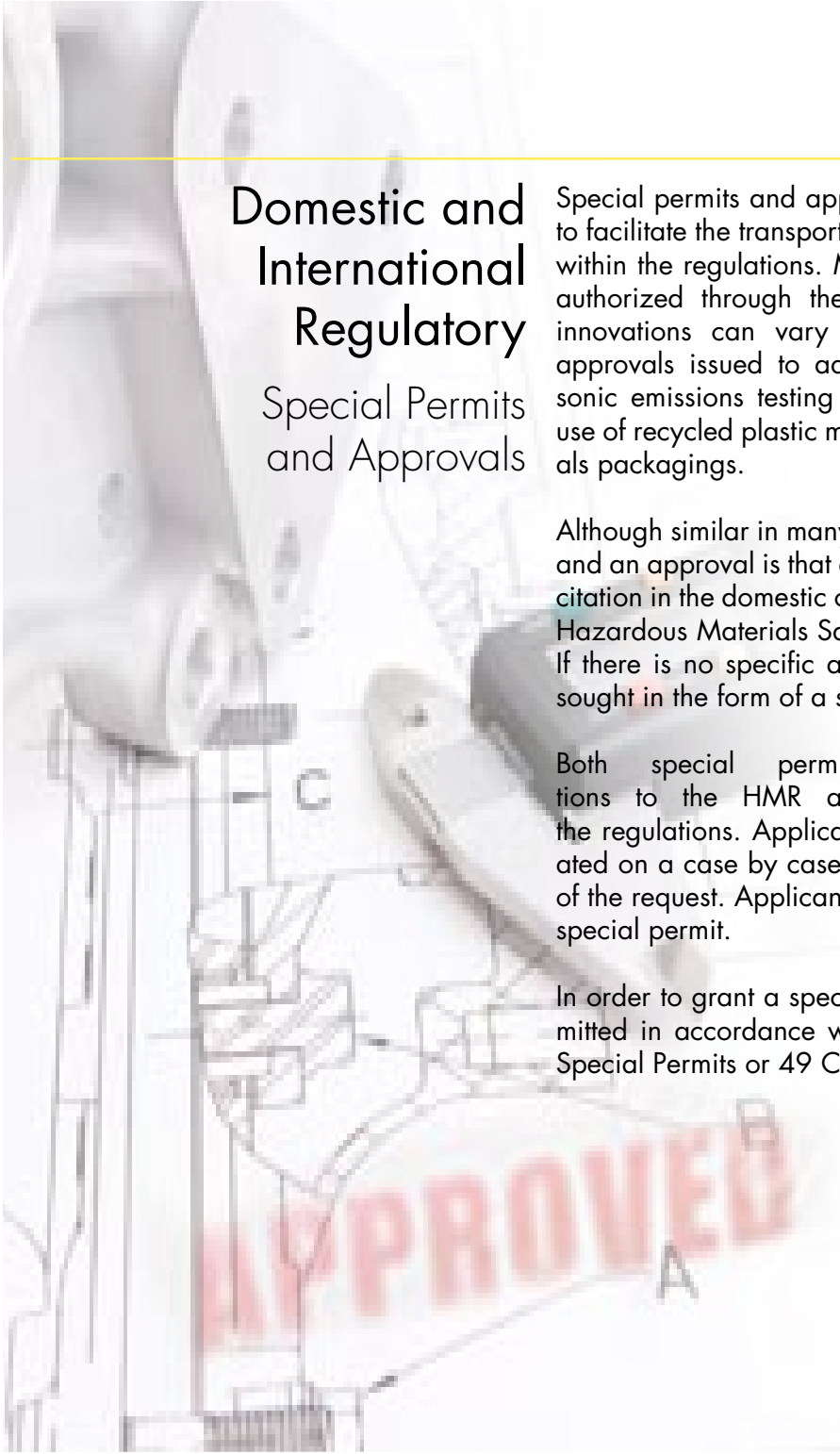
Special Permits and Approvals

Special permits and approvals often provide for an initial interim measure to facilitate the transport or use of a new technology not yet fully addressed within the regulations. Many technological innovations have initially been authorized through the special permits and approvals process. These innovations can vary widely; examples include special permits and approvals issued to address carbon fiber cylinders, acoustic and ultrasonic emissions testing of cylinders, fuel cells and lithium batteries, and use of recycled plastic materials for fabrication of certain hazardous materials packagings.

Although similar in many respects, one distinction between a special permit and an approval is that an approval may only be issued if there is a specific citation in the domestic or international regulations that permits the Office of Hazardous Materials Safety to provide alternative methods of compliance. If there is no specific approval provision, then the authorization must be sought in the form of a special permit.

Both special permits and approvals serve as authorizations to the HMR and may be considered as an extension of the regulations. Applications for special permits and approvals are evaluated on a case by case basis and decisions are made based on the merit of the request. Applicants may also apply to become a party to an existing special permit.

In order to grant a special permit or approval an application must be submitted in accordance with the provisions of 49 CFR 107, Subpart B for Special Permits or 49 CFR 107 Subpart H for Approvals.



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Photos: National Research Council of Canada



It is incumbent upon the applicant to undertake and provide a comprehensive safety review and risk analysis showing how transporting the new technology provides an equivalent level of safety. The information provided should include a full failure modes and effects analysis, a complete systems safety evaluation, and any relevant test data, drawings or engineering analysis that can facilitate and support a determination that the new technology can be safely transported or used for the applicable transportation application. If an equivalent level of safety cannot be justified, then the application may be denied. In addition, we may conduct a "fitness review" of the applicant prior to issuing a special permit or approval to determine if the applicant is capable of meeting the conditions required by the permit or approval. This review may also take into account the applicant's existing safety and compliance record.

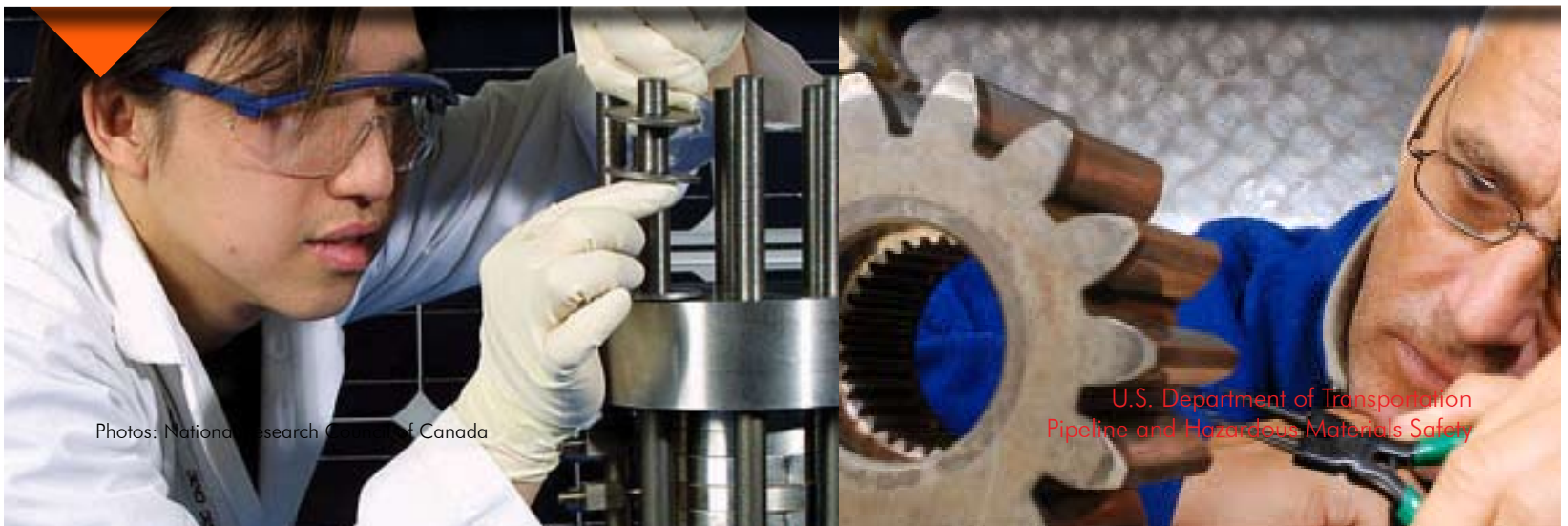
A benefit of the special permit and approval process is that it allows for an interim means of authorizing new technologies in a limited and controlled manner that affords an appropriate level of safety prior to full implementation within the regulations. Once a special permit or an approval is granted, the performance of the items authorized can be monitored and modifications can be made to the special permit or approval that enhances transportation safety. In addition, if the performance of the new technology does not meet expectations, or if the holder fails to meet required conditions, the special permit or the approval may be terminated. This provides us with a greater level of flexibility in comparison to regulatory amendments which require a far greater period of time to incorporate.

More information on special permits and approvals, including the ability to view special permits already issued, is available via our website at <http://phmsa.dot.gov/special-permits-approvals>.

Submit special permit or approval applications to the following address:

Director, Office of Special Permits
and Approvals, PHH-30
Office of Hazardous
Materials Safety
Pipeline and Hazardous Materials
Safety Administration
1200 New Jersey Ave., SE
Washington, DC 20590-0001

Tel: (202) 366-4535
Fax: (202) 366-3753
email: approvals@dot.gov or
specialpermits@dot.gov



Photos: National Research Council of Canada

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Development of Regulatory Provisions

Technical Instructions for the Safe Transport of Dangerous Goods by Air



For more information on PHMSA's participation in international forums see
<http://hazmat.dot.gov/regs/intl/intstandards.htm>

For more information on the UN COE visit
<http://www.unece.org/trans/danger/danger.htm>

For more information on the ICAO DGP visit
<http://www.icao.int/anb/FLS/DangerousGoods>

Following the issuance of a special permit, or in tandem with such efforts, we will work to develop regulatory provisions to facilitate the regulatory recognition of the technology when such provisions are warranted. In some instances, stakeholders may submit a petition for rulemaking to initiate the process, and in other cases we may initiate rulemaking on our own initiative. In addition to our responsibility for issuing the U.S. hazardous materials regulations, our regulatory work also includes an international component. In today's global marketplace, unilateral rulemaking action on the part of PHMSA would be of limited value to companies engaged in international commerce. In order to ensure consistent regulatory provisions are adopted by competent authorities world-wide, we actively participate in several key international regulatory and standards writing bodies.

These include:

The United Nations Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System for the Classification and Labelling of Chemicals. The UN COE is the focal point for developing harmonized international requirements for the transport of dangerous goods (hazardous materials).



Recommendations on the
**TRANSPORT
OF DANGEROUS
GOODS**

Volume 2
Enabling New Technologies 15

Model Regulations

15th revised edition



The International Maritime Organization. The International Maritime Organization (IMO) is responsible for maintaining and updating the International Maritime Dangerous Goods Code (IMDG Code) which governs the majority of shipments of hazardous materials by water.

The International Civil Aviation Organization. The International Civil Aviation Organization's Dangerous Goods Panel (ICAO DGP) is responsible for the development of the ICAO Technical Instructions on the Safe Transport of Dangerous Goods by Air (ICAO TI) which contain requirements for the international transport of hazardous materials by air .

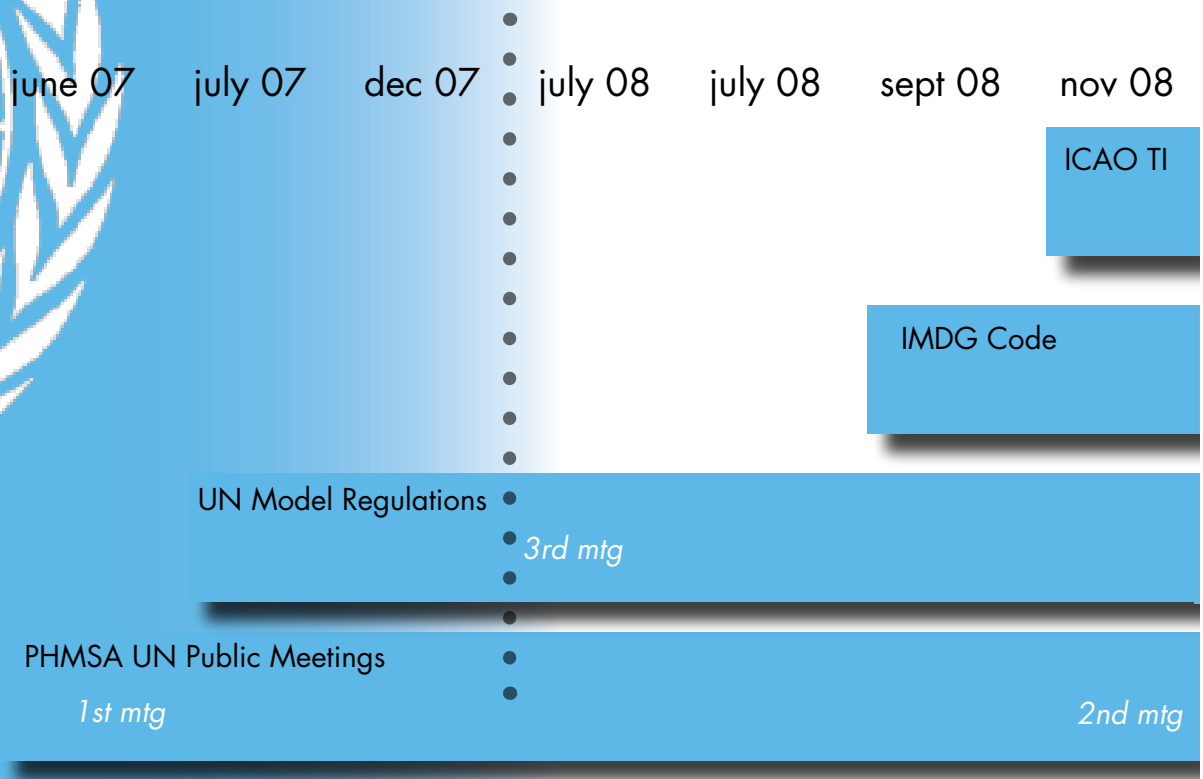
The Joint Meeting of the RID Safety Committee and the Working Party on the Transport of Dangerous Goods. The United Nations' Economic Commission for Europe (ECE) Inland Transport Committee's Joint Meeting of the RID Safety Committee and the Working Party on the Transport of Dangerous Goods is responsible for establishing hazardous materials safety and security requirements for road, rail, and vessel transport within the ECE's 55 member countries.

The International Organization for Standardization. The International Organization for Standardization (ISO) is a network of the national standards institutes of 157 countries with a Central Secretariat in Geneva, Switzerland.

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Pipeline and Hazardous Materials Safety

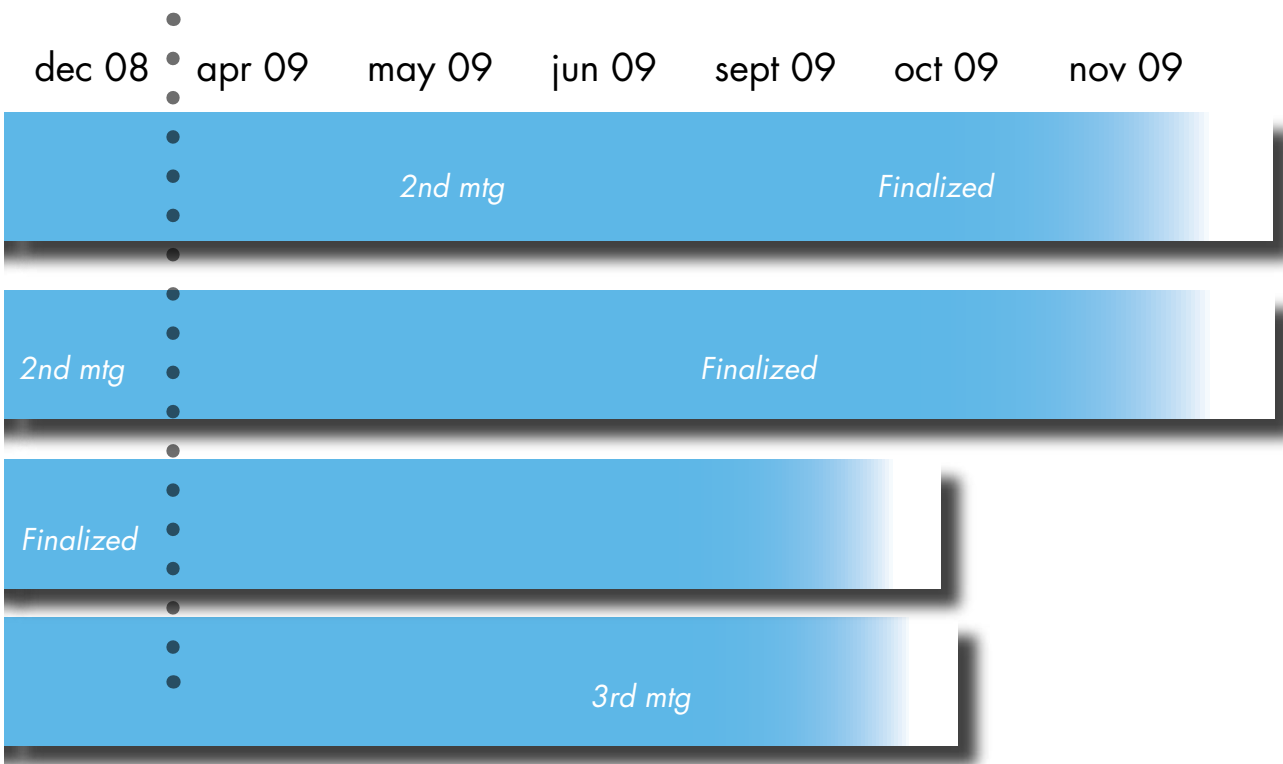
International Regulatory Process Timeline

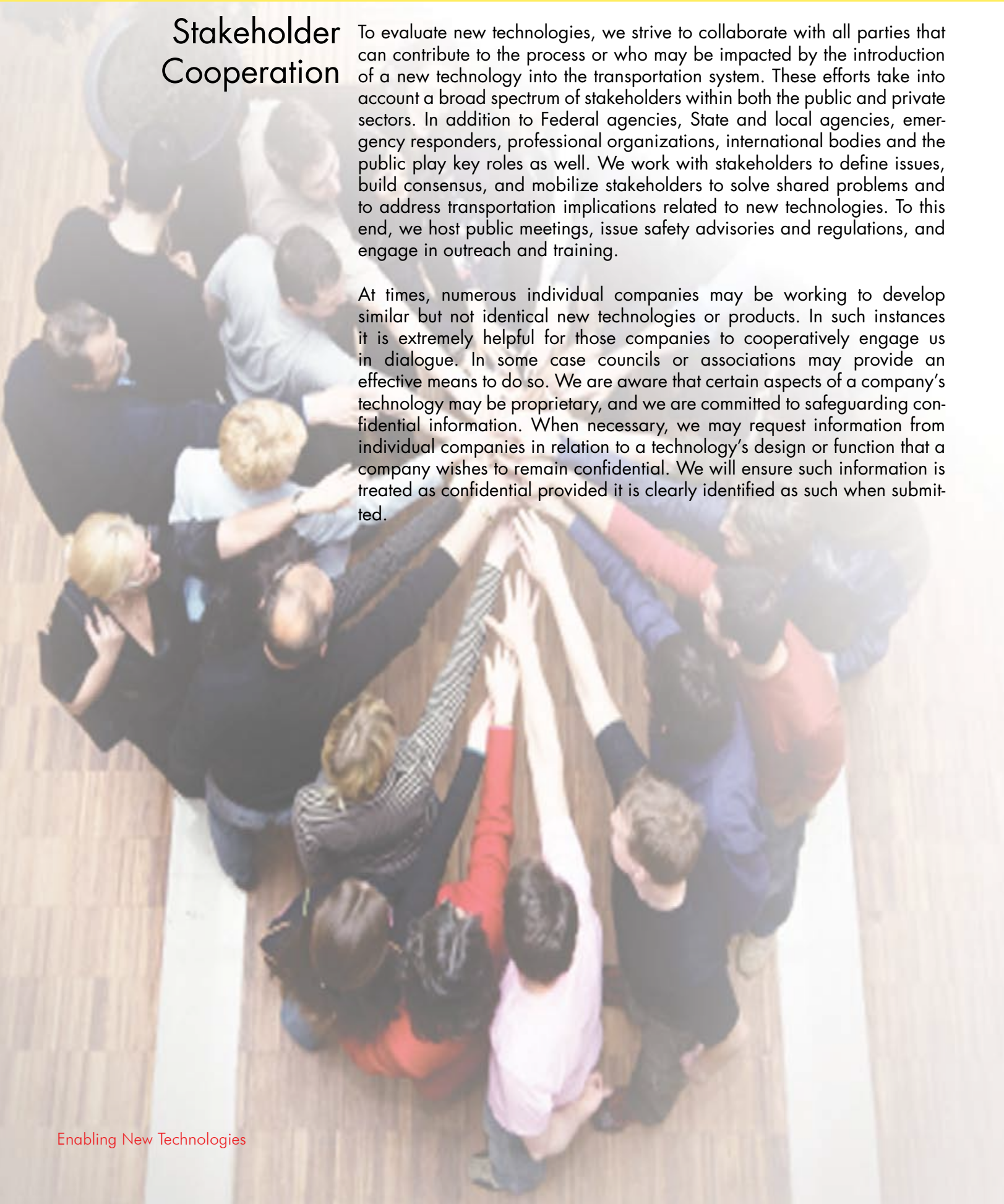
In order to ensure that requirements are uniformly adopted within the international modal regulations and consistently implemented across the globe, new amendments are considered within the international forums, previously described, in order to gain global acceptance. This strategy, in the long term, benefits industry by ensuring that requirements are consistent worldwide. However, amendments to the international regulations involve a multi-step process which generally takes between two and four years, depending on when the proposed change is first introduced within the regulatory amendment cycle. An example of this cycle is shown below:



As is evident, the initial step in addressing a new technology within international regulations is to work within the UN Sub-Committee to discuss appropriate provisions that could be incorporated within the UN Model Regulations. Generally, difficult issues are not resolved in a single session. Therefore, the earlier an issue is discussed during the UN biennium, the more likelihood of gaining acceptance in time for incorporation within the revised Model Regulations which are published every two years.

After amendments to the UN Model Regulations are adopted, it is important to track the adoption of those amendments within the relevant modal regulations (ICAO TI and IMDG Code) as each mode may have specific concerns which must be addressed. PHMSA actively works with both the ICAO and IMO to facilitate this process. Industry participation in the process is encouraged.





Stakeholder Cooperation

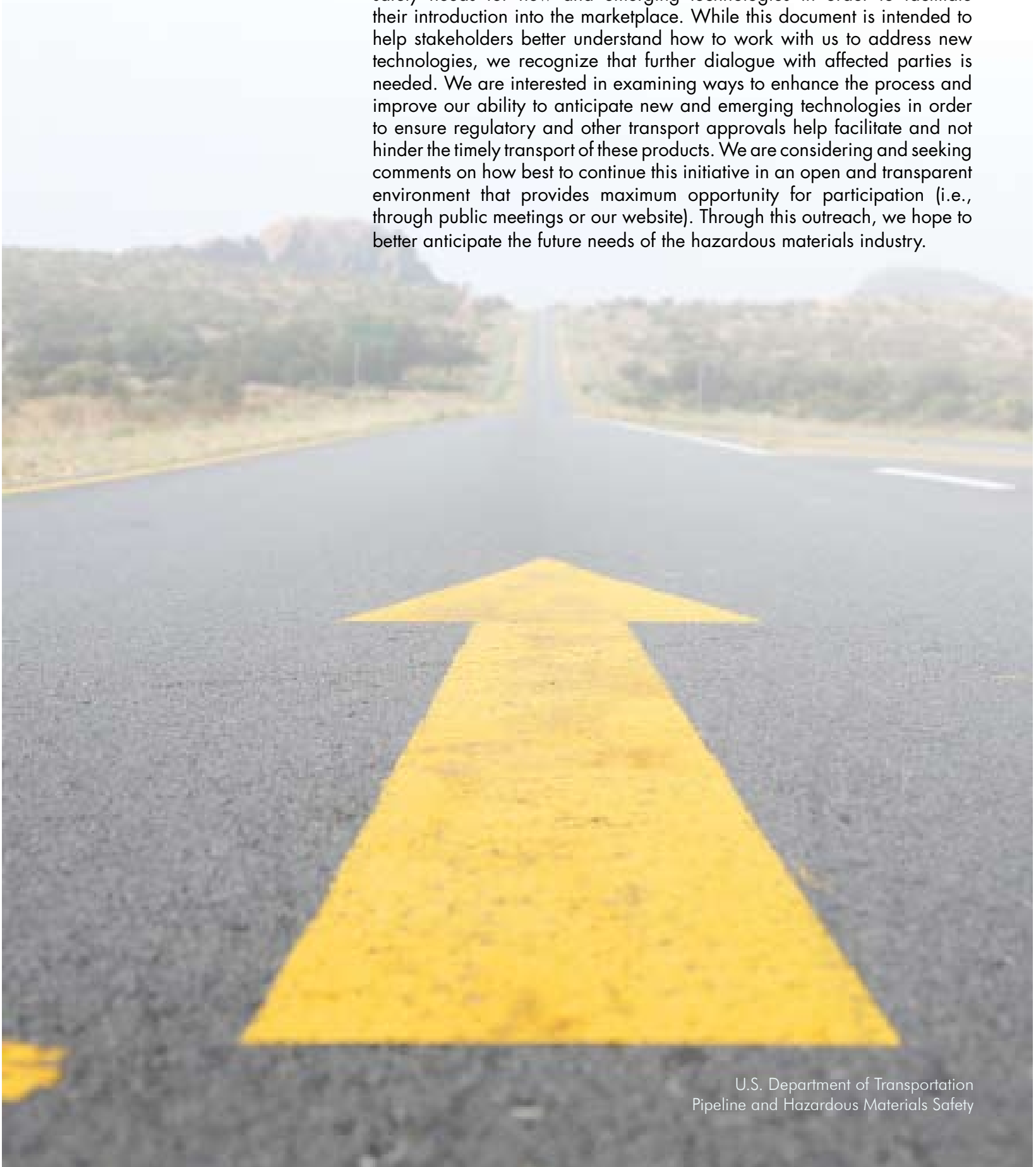
To evaluate new technologies, we strive to collaborate with all parties that can contribute to the process or who may be impacted by the introduction of a new technology into the transportation system. These efforts take into account a broad spectrum of stakeholders within both the public and private sectors. In addition to Federal agencies, State and local agencies, emergency responders, professional organizations, international bodies and the public play key roles as well. We work with stakeholders to define issues, build consensus, and mobilize stakeholders to solve shared problems and to address transportation implications related to new technologies. To this end, we host public meetings, issue safety advisories and regulations, and engage in outreach and training.

At times, numerous individual companies may be working to develop similar but not identical new technologies or products. In such instances it is extremely helpful for those companies to cooperatively engage us in dialogue. In some case councils or associations may provide an effective means to do so. We are aware that certain aspects of a company's technology may be proprietary, and we are committed to safeguarding confidential information. When necessary, we may request information from individual companies in relation to a technology's design or function that a company wishes to remain confidential. We will ensure such information is treated as confidential provided it is clearly identified as such when submitted.



A Way Forward

We are interested in improving our ability to anticipate future transportation safety needs for new and emerging technologies in order to facilitate their introduction into the marketplace. While this document is intended to help stakeholders better understand how to work with us to address new technologies, we recognize that further dialogue with affected parties is needed. We are interested in examining ways to enhance the process and improve our ability to anticipate new and emerging technologies in order to ensure regulatory and other transport approvals help facilitate and not hinder the timely transport of these products. We are considering and seeking comments on how best to continue this initiative in an open and transparent environment that provides maximum opportunity for participation (i.e., through public meetings or our website). Through this outreach, we hope to better anticipate the future needs of the hazardous materials industry.



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PHMSA Review of a New Technology — How to Get Started

Requests should be sent to:

Associate Administrator for Hazardous Materials
Safety, PHH-1
Pipeline and Hazardous Materials Safety
Administration
1200 New Jersey Avenue, S.E.
Washington, D.C. 20590

Requests should include the following information:

- The applicant's contact information.
- A detailed description of the new technology, including:
 - Drawings, illustrations or visual examples of the technology.
 - Specifications including a full description of any hazardous components and the components' classification under the provisions of the HMR and how the product will be packaged and transported.
 - A description of possible applications for use of the technology.
- A description of how the current regulatory provisions do or do not adequately address the new technology.
- Assessment of the technology's transportation risks, including:
 - failure modes and effects analysis
 - complete systems safety evaluation
 - relevant test data applicable to a determination of safety in transport
- Proposed regulatory requirements may be included but are not required. In such cases, the request should provide justification for the proposed requirements which show an equivalent level of safety.



NOTES



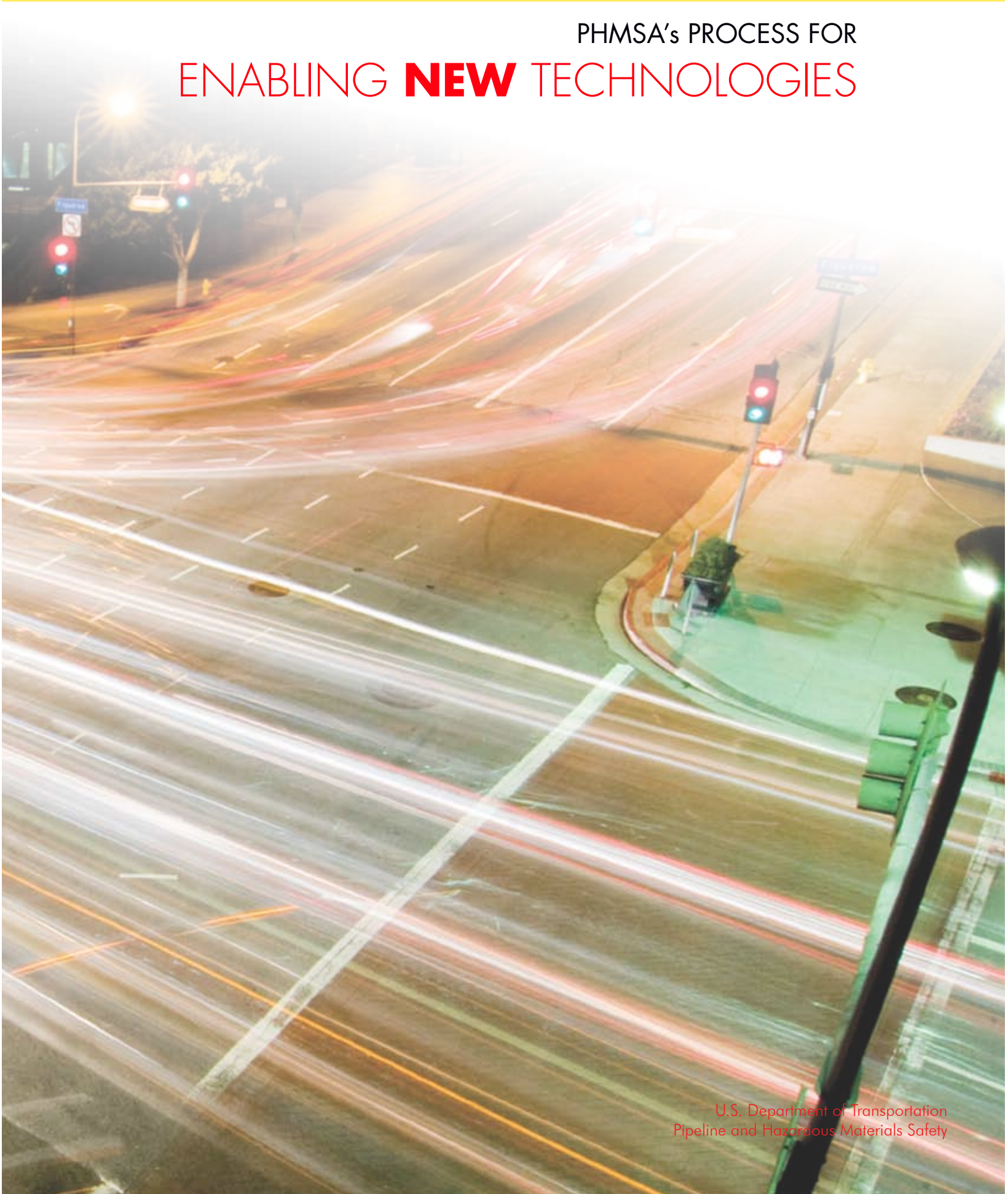


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