



U.S. Department of Transportation

**Pipeline and Hazardous Materials
Safety Administration**

Approvals Program Standard Operating Procedures

Version 2.0

June 2011

Disclaimer

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Change Control and Documentation

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2.0	Roles and Responsibilities for the Disposition Phase updated to reflect changes made in the Certification Agency Approvals Standard Operating Procedures; Minor editorial corrections	June 2011

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Section 1. Introduction

1.1 Purpose of the Document

This document establishes standard operating procedures (SOPs) for the administration of the Pipeline and Hazardous Materials Safety Administration's (PHMSA's) Approvals Program. These SOPs incorporate and strengthen PHMSA's current procedures. The SOPs will be updated periodically to incorporate recommendations and improvements from ongoing program evaluation and upgrades to the data management systems that support the Approvals Program.

The SOP is an important contributor to building and maintaining a strong PHMSA safety culture. It provides the basis for PHMSA leadership and staff to understand and execute required good safety and risk management practices, and to expect the same performance accountability from colleagues across the organization.

The SOP outlines procedures to ensure that PHMSA can demonstrate that safety is its highest priority core value. The SOP also provides a procedural framework for effective performance measurement, and for periodic assessment of the quality of PHMSA Approvals services, provided in the interests of public safety as well as industry.

1.2 Structure of the Document

The remainder of this document includes the following 10 sections and supporting appendices:

- **Introduction and Overview** - Provides an overview of the Approvals Program and an introduction to the types and categories of approvals within the program.
- **Approvals Program Roles and Responsibilities** - Describes the respective roles and responsibilities required to execute processes associated with the Approvals Program.
- **Application Review Process** - Describes the processes for receiving, evaluating, and issuing approvals. The Application Review Process section is organized based on three key phases of the process: (1) Completeness Phase; (2) Evaluation Phase; and (3) Disposition Phase.
- **Approval Renewal Process** - Describes the purpose and procedural overview to renew an existing approval.
- **Approval Modification, Suspension or Termination Process** - Describes the purpose and procedural overview to modify, suspend, or terminate an approval.
- **Reconsideration Process** - Describes the purpose and procedural overview for providing Applicants and Approval Holders the opportunity to request a reevaluation of their denied application or modified, suspended or terminated approval.
- **Appeal Process** - Describes the purpose and procedural overview for providing Applicants or Approval Holders the opportunity to appeal PHMSA's decision to deny its application or modify, suspend, or terminate its approval.
- **Minimum Level of Fitness Review Process** - Describes the purpose and procedural overview for conducting a Minimum Level of Fitness Review of an Applicant's safety record and performance. There are three components of the Minimum Level of Fitness Review process: (1) Tier One Fitness Review Process; (2) Tier Two Fitness Review Process; and (3) Tier Three Fitness Review Process.

- **Post-Approval Responsibilities** – Describes the management and oversight responsibilities of the aforementioned staff with respect to the Approvals Program.
- **Forms and Documents** – Provides the names and descriptions of types of forms and documents used throughout Approvals Program processes.
- **Appendices A-D** – Provides supporting SOP documentation.

1.3 Overview of the Approvals Program

An approval is written consent, including a competent authority approval, from the Associate Administrator or other designated Department official, to perform a function that requires prior consent under the Hazardous Materials Regulations (HMR) (49 CFR parts 171 through 180).¹

The Associate Administrator issues approvals for a wide array of activities in the hazardous materials industry. These activities may include, but are not limited to, classifying, labeling, manufacturing, package and package design, testing and transporting hazardous materials safely, under conditions defined in the Hazardous Materials Regulations.

The OHMS is responsible for administering and overseeing the Approvals Program. Responsibilities include but are not limited to:

- Evaluating new approval applications from industry stakeholders including:
 - Conducting Minimum Level of Fitness Reviews to determine Applicant fitness
 - Completing safety evaluations to verify the activity authorized by the approval meets an acceptable level of safety
 - Issuing approvals and denials
- Modifying, suspending or terminating existing approvals, when necessary
- Managing existing approvals including:
 - Conducting compliance inspections of existing Approval Holders to ensure they are complying with the conditions of their approvals and the requirements of the HMR
 - Monitoring reporting requirements, when necessary.

1.4 Overview of Approval Types and Categories

PHMSA issues several types of approvals in response to applications from many different sectors of the hazardous materials industry. Approvals authorize a range of activities, such as the packaging and shipping of certain radioactive materials; the testing of certain types of cylinders; the certifying that agencies are qualified to perform certain functions, inspections, or the classification of materials; and the transporting of lithium batteries. It is important to note that the agency only grants approvals for activities allowed (if approved) under specific conditions identified in the HMR. Applicants seeking to engage in an activity that is not permitted by the HMR must apply to PHMSA for a special permit.

Approvals granted by PHMSA are authorized by different parts of Title 49 of the CFR. While PHMSA has the regulatory authority to issue different types of approvals, the purpose of this document is to describe the procedures used by PHMSA to issue approvals most commonly requested by industry stakeholders.

¹ 49 CFR 107.1

These approval types are grouped into six categories, based on technical and procedural similarities within each of the categories:

1. Registration Approval Category
2. Classification Approval Category
3. Cylinders Approval Category
4. Certification Agencies Approval Category
5. General Approvals Approval Category
6. Radioactive Material Certificates of Competent Authority Approval Category.

Procedural differences between the categories are based primarily on differences between the nature of the activity to be approved, materials distinctions, complexity of evaluation, and/or involvement of third-party entities.

Table 1-1 displays the approvals most commonly granted by PHMSA, their corresponding categories, and also includes the authorizing sections of the CFR.

Table 1-1: Approvals Issued by PHMSA

Approval Category	Approval Types	CFR Citation
Registration	• M numbers for identification of packaging manufacturers	49 CFR 178.3
	• RIN for visual requalifiers	49 CFR 180.209
Classification	• Explosives	49 CFR 173.56
	• Fireworks	49 CFR 173.56
	• Chemical oxygen generators	49 CFR 173.168(a)
	• Self-reactive materials and organic peroxides	49 CFR 173.124; 173.128
Cylinders	• Domestic cylinder requalifiers	49 CFR 107.805
	• Domestic cylinder repair / rebuild companies	49 CFR 107.805
	• Foreign cylinder requalifiers	49 CFR 107.805
	• Foreign cylinder repair/rebuild companies	49 CFR 107.805
	• Foreign cylinder manufacturers with Independent Inspection Agencies (IIAs)	49 CFR 107.807
	• United Nations (UN)/International Organization for Standardization (ISO) cylinder manufacturers	49 CFR 178.70
Certification Agencies	• Designated approval agencies	49 CFR 107.401
	• Independent inspection agencies	49 CFR 107.803
	• Package certification agencies	49 CFR 107.401
	• Explosive examination agencies	49 CFR 173.56
	• Lighter testing agencies	49 CFR 173.308
General Approvals	• International IMDG/ICAO competent authority approval	49 CFR 107.705
	• General approval	49 CFR 107.705
	• Lithium batteries	49 CFR 173.185
	• Fuel cells	49 CFR 173.230

Approval Category	Approval Types	CFR Citation
Radioactive Materials	<ul style="list-style-type: none"> Radioactive material package designs 	49 CFR 173.471; 173.472; 173.473
	<ul style="list-style-type: none"> Radioactive material classifications 	49 CFR 173.476

For more information on the approvals listed in Table 1-1 see Appendix A.

Based on the method for evaluating approval applications, the following paragraphs provide a brief overview of the approvals granted in each of the six approval categories listed in Table 1-1 above.

- Registration Approval Category:** A registration approval is a unique identification number (e.g., identification of packaging manufacturer) used solely as an identifier or in conjunction with the Approval Holder’s name and address. In addition, a registration number is evidence that the Approval Holder is qualified to perform the function in which it is utilizing its identification number (e.g., visually requalifying cylinders).
- Classification Approval Category:** A classification approval certifies that the hazardous material(s) (i.e., explosives, fireworks, chemical oxygen generators, self-reactive materials and organic peroxides) has been classed for manufacturing and/or transportation based on requirements stipulated in the HMR.
- Cylinders Approval Category:** A cylinder approval certifies that an Approval Holder is qualified to either requalify, repair-rebuild, and/or manufacture cylinders (domestically or internationally) based on requirements stipulated in the HMR.
- Certification Agencies Approval Category:** A certification agency approval certifies that an Approval Holder is qualified to perform inspections and other functions in accordance with the specifications outlined in the approval and the requirements set out in the HMR.
- General Approvals Approval Category:** A general approval certifies that an Approval Holder is providing an equivalent level-of-safety in the transport of hazardous materials as outlined in the approval, HMR regulations, and/or international regulations.
- Radioactive Material Certificates of Competent Authority Approval Category:** A radioactive material certificate of competent authority certifies that a package design or material classification submitted by an Applicant fully complies with the applicable domestic and international regulations. Certificates are only issued to Applicants and registered users who have proven to be qualified to operate within the provisions of the regulations and the specific conditions of the certificate.

This SOP document should be considered a living document that will be revised and updated periodically to improve operations and ensure that policies and procedures remain aligned to the business needs of OHMS.

Specific questions related to the *Approvals Program Standard Operating Procedures* should be addressed to:

Director
 Division of Approvals and Permits
 (202) 366-4511.

Section 2. Approvals Program Roles and Responsibilities

This section describes the roles required for PHMSA to execute processes associated with the review and evaluation of the new or existing approvals listed in Section Section 1. It is important to note that the staff and managers assigned roles may delegate their official responsibilities to others involved in processing approval applications.

Table 2-1: Current Organizational Alignment and Roles

Organizational Role	Organization	Current Organizational Position
Administrator	Office of the Administrator	Administrator of PHMSA
Associate Administrator	Office of Hazardous Materials Safety	Associate Administrator for Hazardous Materials Safety
Approving Official	Office of Hazardous Materials Safety	Associate Administrator for Hazardous Materials Safety (Note: The Associate Administrator may delegate his/her authority to OHMS staff, as necessary)
Transportation Assistant	Division of Approvals and Permits	Transportation Assistant
Project Officer ²	Division of Approvals and Permits	Transportation Specialist, Senior Transportation Specialist
Senior Technical Officer	Division of Engineering and Research	Director of the Division of Engineering and Research
Technical Officer	Division of Engineering and Research	Chemists, Physical Scientists, and Engineers
Standards Liaison	Division of Standards and Rulemaking	Director of the Division of Standards and Rulemaking
International Standards Liaison	Division of Standards and Rulemaking	International Standards Coordinator
Enforcement Liaison	Field Operations	Director of Field Operations (or designee)
Legal Counsel	Office of Chief Counsel	Chief Counsel or Assistant Chief Counsel of the Hazardous Materials Safety Law Division
OA Coordinating Official	FAA, FMCSA, FRA, USCG	Designated and authorized by the OAs for the purpose of approvals processing
Safety Review Board	PHMSA	Designated by PHMSA
Independent Test Lab	Industry	Designated by PHMSA
Applicant	Industry	NA

2.1 Administrator

The Administrator is the Administrator of PHMSA. The responsibilities of the Administrator in the approvals process include:

- Reviewing and approving significant approval applications, based on criteria as determined by the Administrator

² For radioactive material certificates of competent authority approvals, the functions of the Project Officer and Technical Officer are performed by the Radioactive Materials Group.

- Granting or denying, in whole or in part, an appeal requested by an Approval Holder or Applicant. The Administrator may delegate this responsibility to another DOT Official
- Participating in discussions to resolve issues among PHMSA staff and OA Coordinating Officials or others, as determined by the Administrator.

2.2 Associate Administrator

The Associate Administrator for Hazardous Materials Safety is the Approving Official. The responsibilities of the Associate Administrator in the approvals process include:

- Acting as the Approving Official, or delegating this responsibility to OHMS staff, and overseeing the conduct of this function
- Granting or denying, in whole or in part, a reconsideration requested by an Approval Holder or Applicant. The Associate Administrator may delegate this responsibility to another DOT Official.

2.3 Approving Official

Under 49 CFR 107.709(c) of the HMR, the Approving Official is responsible for signing approval and denial documents. The Approving Official is also responsible for:

- Determining whether application evaluations are complete and thorough
- Reviewing and approving disposition recommendations
- Approving disposition of approval applications, including rejection letters, denial letters, and approval documents
- Monitoring the volume and status of approval applications, and quality of approvals management
- Resolving process and coordination issues among OAs and other federal agencies
- Approving SOPs and SOP revisions for the Approvals Program
- Making recommendations to the Administrator concerning the disposition of significant approval applications (based on criteria determined by the Administrator)
- Delegating Approving Official responsibility for specific approvals based on criteria related to the operations, transport modes, materials, or other criteria, as appropriate.

2.4 Transportation Assistant

Depending on the type of approval, the Transportation Assistant is responsible for receiving the approval applications that are submitted via email, regular mail, or fax. The Transportation Assistant is also responsible for:

- Reviewing the application and then separating the application into two parts. The two parts are the Request, and the Background
- Forwarding the application to a PHMSA designee for data entry.

Note: Once the application is entered into the Approvals IT System, the system generates a tracking number and forwards the file for action to the assigned Project Officer.

2.5 Project Officer

The Project Officer is responsible for planning and managing the Approval Review Process for a specific approval application. A Project Officer will be designated for each approval application. The Project Officers are responsible for:

- Providing oversight of the entire application evaluation and disposition processes across PHMSA and the OAs
- Coordinating the Application Completeness Phase of an approval application, which may include:
 - Reviewing the application for completeness and accuracy
 - Verifying that the approval is required or authorized by the HMR including researching the HMR, ICAO TI, and the IMDG Code
- Coordinating the Safety Evaluation Review Phase of an approval application, which may include (but not necessarily be conducted by the Project Officer):
 - Conducting Applicant Minimum Level of Fitness Review
 - Conducting equivalent level-of-safety evaluation
 - Coordinating with other PHMSA officials such as the Standards Liaison and International Standards Liaison
 - Coordinating with appropriate OA(s)
 - Coordinating with PHMSA legal staff
 - Drafting and/or reviewing approvals.

2.6 Senior Technical Officer

The Senior Technical Officer is responsible for:

- Assigning and managing approval applications among appropriate Technical Officers
- Overseeing the technical evaluation of approval application evaluations, which may include:
 - Providing input to evaluation plans
 - Reviewing Technical Officer's evaluation and recommendation
 - Conducting equivalent level-of-safety evaluations
 - Coordinating with the OA's, as needed
 - Providing input and/or reviewing input for approvals.

2.7 Technical Officer

The Technical Officer has subject matter expertise in certain aspects of hazardous materials transportation safety. The Technical Officer may be assigned to participate in the review and evaluation of an approval application, if needed. The Technical Officer is responsible for:

- Completing technical evaluations of approval applications, which may include:
 - Conducting equivalent level-of-safety evaluations
 - Participating in on-site inspections of Applicants, as needed

- Coordinating with OAs and others, as needed
- Providing input for approvals.

2.8 Standards Liaison

The designated Standards Liaison is responsible for:

- Making recommendations as to whether the operations proposed for the approval should be addressed through rulemaking
- Reviewing evaluation plans as requested by the Project Officer
- Evaluating whether updates to the HMR are needed to accommodate the Approvals Program
- Reviewing approvals and other dispositions as requested by the Project Officer based on the agreed-upon criteria for the Division of Standards and Rulemaking involvement, which could include:
 - Newly issued regulations
 - Requests with far-reaching effects that may be most appropriately handled under rulemaking.

2.9 International Standards Liaison

The designated International Standards Liaison is responsible for:

- Reviewing evaluation plans as requested by the Project Officer
- Reviewing approvals and other dispositions as requested by the Project Officer based on agreed-upon criteria for the Division of Standards and Rulemaking involvement.

2.10 Enforcement Liaison

The designated Enforcement Liaison is responsible for:

- Performing all tier two and tier three Minimum Level of Fitness Reviews
- Making recommendations for enhancements, denials, and determinations
- Conducting all on-site inspections of Applicants
- Managing and conducting investigations of Applicants and holders of existing approvals
- Coordination of modal on-site inspections.

2.11 Legal Counsel

The Legal Counsel is responsible for:

- Providing legal guidance for policy and procedures that pertain to approvals and other dispositions as requested
- Reviewing and providing input on recommendations for Applicant denial.

2.12 Operating Administration Coordinating Official

An Operating Administration (OA) Coordinating Official is designated by the Federal Aviation Administration (FAA), Federal Motor Carrier Safety Administration (FMCSA), Federal Railroad Administration (FRA), and the United States Coast Guard (USCG) as the point of contact for each agency's review of approval applications. If the type of approval being addressed requires coordination, the OA Coordinating Official is responsible for:

- Reviewing approval applications, Applicant Minimum Level of Fitness Reviews, and equivalent level-of-safety evaluations
- Completing technical evaluations of approval applications, which could include:
 - Conducting additional Applicant fitness reviews
 - Conducting equivalent level-of-safety evaluations
 - Drafting approvals
- Providing concurrence, comments, information, and acknowledgments, as appropriate, to PHMSA in accordance with established coordination schedules and milestones.

2.13 Safety Review Board

The Safety Review Board (SRB) is designated by PHMSA to resolve disputes of professional opinion when such disputes cannot be resolved internally among office and/or program staff and management. The SRB is comprised of the chair,³ legal officer,⁴ board members,⁵ and senior policy advisor. The board conducts several functions including:

- Resolving issues stemming from differences in professional judgment between or among PHMSA staff members on safety matters, decisions, or actions
- Resolving issues referred to it by any PHMSA employee (but only after internal processes for achieving consensus have been exhausted)
- Referring an issue (at its discretion) to the Deputy Administrator and Administrator for resolution or to the Associate Administrator for consideration of an issue or implementation of an action.

2.14 Independent Test Lab

The Independent Test Lab is designated by PHMSA to verify test data conducted by a certification agency approval Applicant during an on-site inspection. The independent test lab is responsible for:

- Receiving test data from PHMSA or from the approval Applicant
- Conducting requested tests
- Providing PHMSA with data findings.

³ The Chief Safety Officer or other senior executive designated in writing by the Chief Safety Officer.

⁴ The PHMSA Chief Counsel or other senior attorney designated in writing by the PHMSA Chief Counsel.

⁵ The Associate Administrator (or a designee) for Pipeline Safety. (The Associate Administrator for the program in which the concern has been raised shall not serve on the SRB). In their place, the Administrator will appoint an individual with subject matter expertise.

2.15 Applicant or Approval Holder

The Applicant or Approval Holder is a person, company or entity requesting an approval to be issued by PHMSA. The Applicant or Approval Holder is responsible for:

- Submitting a complete application for an approval as required under the HMR. Applications that do not meet these requirements may be rejected
- Providing PHMSA with additional information or data if necessary
- Allowing PHMSA to conduct on-site inspections if necessary
- Initiating a reconsideration or appeal if necessary
- Complying with the requirements of an approval when issued
- Providing PHMSA any necessary updated information.

Section 3. Application Review Process

PHMSA evaluates all approval applications using the three phases of the Application Review Process, which are depicted in Figure 3-1 below. Every application received by PHMSA follows the same basic procedures during the Completeness Phase and the Disposition Phase; however, the detailed processes followed during the Evaluation Phase vary based on the proposed approval category (registration, classification, cylinders, certification agencies, general approvals, and radioactive materials). The following sections describe the three phases of the Application Review Process.



Figure 3-1: Application Review Process

3.1 Completeness Phase

3.1.1 Purpose

The purpose of the Completeness Phase is to determine whether:

- The Applicant submitted the information required under the HMR for PHMSA to begin the evaluation of the proposed approval, and
- The proposed approval is required or authorized by the HMR.

3.1.2 Procedural Overview

During the Completeness Phase, an Applicant may use the online application system available on PHMSA’s website, email, or provide a paper approval application submittal by mail or fax. The Completeness Phase involves two basic procedures: (1) conduct completeness review; and (2) evaluate necessity of application, as shown in Figure 3-2 below.

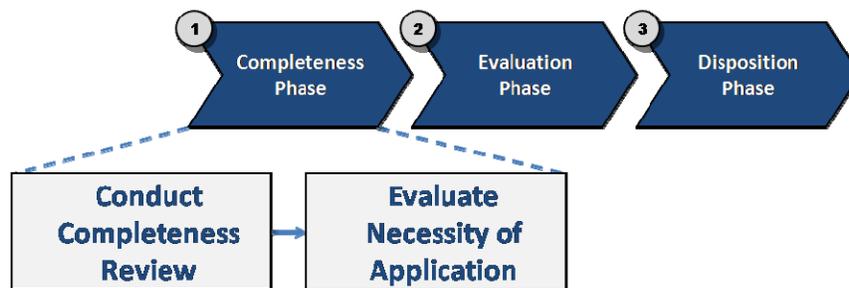


Figure 3-2: Completeness Phase Overview

3.1.2.1 Conduct Completeness Review

If an Applicant submits an application through the online application system, the system automatically reviews the application materials and informs the Applicant if the application is incomplete. The online application system effectively prevents an Applicant from submitting an incomplete application. If an

Applicant emails, mails or faxes an application to PHMSA, the application is in-processed and routed to a Project Officer based on the content of the application.

The Project Officer conducts an initial completeness review to ensure the information provided meets all of the application requirements defined under the HMR. If the application materials are incomplete, PHMSA notifies the Applicant in writing that the application is incomplete. This notification may be in the form of a *Denial Letter*, or a *Rejection Letter* depending on approval type.

3.1.2.2 Evaluate Necessity of Application

If an Applicant submits a complete application, the Project Officer reviews the application to confirm that an approval is necessary for the activity the Applicant intends to perform. In the event an approval is unnecessary, the Project Officer notifies the Applicant in writing of this fact via a *Denial Letter* based on the type of approval. Once the Project Officer determines an application is complete and necessary, the Applicant, applicable OAs, and applicable PHMSA offices are informed and the evaluation of the application begins.

3.2 Evaluation Phase

3.2.1 Purpose

The purpose of the Evaluation Phase is to determine whether an Applicant or registered user is qualified to hold and comply with the approval and the application is safe and complies with the regulations in the:

- Registration Approval Category
- Classification Approval Category
- Cylinders Approval Category
- Certification Agencies Approval Category
- General Approvals Approval Category
- Radioactive Material Certificates of Competent Approval Category.

3.2.2 Procedural Overview

After PHMSA determines that an application is complete, the agency evaluates the application to determine whether the Applicant is qualified to hold the type of approval for which it has applied. The evaluation process for all approval types involves two basic procedures: (1) an Applicant Minimum Level of Fitness Review and (2) an evaluation of the information provided by the Applicant, as shown in Figure 3-3 below. Note that the processes within these procedures vary based on the approval category.

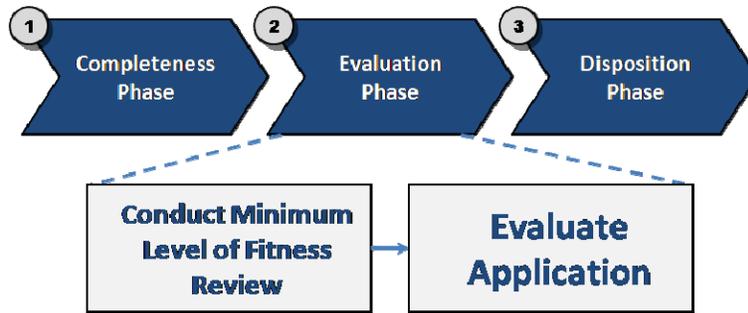


Figure 3-3: Evaluation Phase Overview

3.2.2.1 Conduct Minimum Level of Fitness Review

The purpose of the Minimum Level of Fitness Review is to determine whether an Applicant is fit to conduct the activity authorized by the proposed approval, renewal, or modification being requested.⁶ PHMSA conducts a Minimum Level of Fitness Review for all approval categories. See Section Section 8 for a detailed description of the Minimum Level of Fitness Review process. Note that the Minimum Level of Fitness Review occurs after the application is evaluated for approvals in the Radioactive Material Certificate of Competent Authority Category. Additionally, cylinder approvals and certification agencies approvals do not follow the same three tiered Minimum Level of Fitness Review model.

3.2.2.2 Evaluate Application

If the Applicant is determined fit after the Minimum Level of Fitness Review, the subsections below describe application evaluation for each approval category.

3.2.2.2.1 Registration Approval Category

Approvals in the Registration Approval Category include:

- M Numbers for Identification of Packaging Manufacturers
- Visual Cylinder Requalifiers.

If the Applicant is determined to be fit after review, the Project Officer drafts an *Approval Document* that includes a unique identification number (M Number or Visual Requalifier Identification Number) generated by the Approvals IT System. The agency does not typically conduct an on-site inspection of the Applicant's facilities prior to granting or denying an approval application under this category. However, PHMSA may conduct an inspection as necessary. Inspections by certification agencies are also not required for approvals in this process category. Once drafted, the *Approval Document* or *Denial Letter* and remaining application materials are sent to the Approving Official for review. At this point, the Disposition Phase begins.

3.2.2.2.2 Classification Approval Category

Approvals in the Classification Approval Category include:

- Explosives
- Fireworks

⁶ 49 CFR 107.709(d)(5)

- Chemical Oxygen Generators
- Self-Reactive Materials and Organic Peroxides.

After the Applicant is determined fit, PHMSA reviews the proposed approval to verify that the Applicant is attempting to obtain the correct classification for its products. PHMSA performs this review on all classification approvals. During the review, PHMSA⁷ checks the application to determine whether the Applicant followed the requirements of the HMR. The agency does not typically conduct an on-site inspection of the Applicant's facilities prior to granting or denying an approval application under this category. However, PHMSA may conduct an inspection as necessary. Inspections by certification agencies are also not required for approvals in this process category. After the application is reviewed, the Project Officer determines whether to approve or deny the Applicant's request and drafts either an *Approval Document* or *Denial Letter*. Once drafted, the *Approval Document* or *Denial Letter* and remaining application materials are sent to the Approving Official for review. At this point, the Disposition Phase begins.

3.2.2.2.3 *Cylinders Approval Category*

Approvals in the Cylinders Approval Category include:

- Domestic Cylinder Requalifiers
- Domestic Cylinder Repair/Rebuild Companies
- Foreign Cylinder Requalifiers
- Foreign Cylinder Repair/Rebuild Companies
- Foreign Cylinder Manufacturers with Independent Inspection Agencies (IIAs)
- United Nations (UN)/International Organization for Standardization (ISO) Cylinder Manufacturers.

To assess an approval application in the Cylinders Approval Category, PHMSA uses two sets of similar but distinct processes (based on whether the Applicant is foreign or domestic). After a domestic application is deemed complete, PHMSA reviews the inspection reports provided by the domestic cylinder manufacturer or requalifier Applicant's IIA. For a domestic repair/rebuild Applicant, PHMSA reviews application materials provided by the Applicant. PHMSA may perform an on-site inspection of a domestic Applicant's facilities. After a cylinder Applicant operating outside of the United States has submitted a complete application, PHMSA conducts an on-site fitness inspection. At the successful conclusion of the procedures described, PHMSA grants an approval; otherwise, PHMSA issues the Applicant a denial. Once drafted, the *Approval Document* or *Denial Letter* and remaining application materials are sent to the Approving Official for review. At this point, the Disposition Phase begins.

3.2.2.2.4 *Certification Agencies Approval Category*

Approvals in the Certification Agencies Approval Category include:

- Independent Inspection Agencies
- Packaging Certification Agencies
- Explosive Examination Agencies

⁷ The Project Officer is responsible when evaluating fireworks applications. The Technical Officer is responsible when evaluating all other explosive types.

- Lighter Testing Agencies
- Designated Approval Agencies.

Once an application is deemed complete, and the application is determined to meet the necessary technical requirements, PHMSA performs an on-site fitness inspection of the Applicant to verify that the Applicant is qualified to perform inspections and other functions in accordance with the specifications outlined in the approval and the requirements set out in the HMR.⁸ Depending on the outcome of the inspection, PHMSA grants an approval. Several of the certification agencies that PHMSA grants approvals to must submit reports to PHMSA that detail their activities on a monthly, biannual, or annual basis upon receipt of the approval. Once drafted, the *Approval Document* or *Denial Letter* and remaining application materials are sent to the Approving Official for review. At this point, the Disposition Phase begins.

Note: Supplemental SOPs detailing each approval type within the Certification Agencies Approval Category are being developed. These documents will be used by staff as a reference when evaluating new applications and existing Approval Holders of these specific certification agencies. The document titles will be:

- *Standard Operating Procedures for Independent Inspection Agencies Approvals*
- *Standard Operating Procedures for Packaging Certification Agencies Approvals*
- *Standard Operating Procedures for Explosive Examination Agencies Approvals*
- *Standard Operating Procedures for Lighter Testing Agencies Approvals*
- *Standard Operating Procedures for Designated Approval Agencies Approvals.*

3.2.2.2.5 General Approvals Approval Category

Approvals in the General Approvals Approval Category include:

- International IMDG Code/ICAO TI General Approval
- General Competent Authority Approval
- Lithium Batteries
- Fuel Cells.

Once determined fit, and depending upon the complexity of the application, PHMSA drafts an *Evaluation Plan* and timeline for processing the application. For approvals in this category, PHMSA may involve OAs to assist or to concur with the equivalent level-of-safety evaluation. The Applicant is assessed to see whether he/she is providing an equivalent level-of-safety in the transport of hazardous materials. The assessor – which may be the Project Officer or Technical Officer, depending on the nature of the application – verifies whether the Applicant is qualified, based on the information listed in accordance with the specifications outlined in the approval, HMR regulations and/or international agreements. If the Applicant has met the safety intent of the HMR, PHMSA grants an approval. If the Applicant has not met the safety intent of the HMR, PHMSA issues a denial. No on-site inspection is typically required for these types of approvals, although PHMSA may conduct an inspection as necessary. Once drafted, the *Approval Document* or *Denial Letter* and remaining application materials are sent to the Approving Official for review. At this point, the Disposition Phase begins.

⁸ 49 CFR 107.803

3.2.2.2.6 *Radioactive Material Certificate of Competent Authority Category*

Approvals in the Radioactive Materials Certificate of Competent Authority Approval Category include:

- Radioactive Material Package Designs
- Radioactive Material Classifications.

Upon receipt of an application for certification, three evaluations are conducted: sufficiency of application; safety evaluation of application; and fitness evaluation of the Applicant and registered users of the certificate.

Sufficiency Evaluation: The Project/Technical Officer ensures the application contains the information required by the regulations. For package design certifications, the application must contain an application letter, a copy of the package design certificate from the NRC, DOE or foreign country, and a safety analysis report meeting the application guidelines of NRC Regulatory Guide 7.9 or US and Canada Package Design Applicant's Guide. For material classification certifications, the application must include an application letter, description and specification of material design and technical data showing compliance with regulations and testing. When an application is incomplete, the Project/Technical Officer has the option of requesting additional information from the Applicant or rejecting the application as incomplete. For most cases, the Project Officer requests the data by phone or email. In some cases, letters requesting additional information are sent. Letters are sent for all rejected applications.

Safety Evaluation: Once the application is complete, the Project/Technical officer determines if the design or material classification is safe and complies with the applicable domestic and international regulations. This evaluation is documented by a safety evaluation report for package designs and a special form evaluation sheet for material classifications.

Fitness Evaluation: The Project/Technical officer determines if the Applicant and parties registered to use the certification are fit to conduct the activity authorized by the competent authority certification. Fitness evaluation entails review of the Applicant's compliance, incident and event history.

3.3 Disposition Phase

3.3.1 Purpose

The purpose of this phase, which is uniform across all approval types, is to review the recommendation to deny or issue an approval and inform the Applicant of the decision reached by PHMSA.

3.3.2 Procedural Overview

After a recommendation is made by the Project Officer and an *Approval Document* or *Denial Letter* is sent to the Approving Official to review, the Approving Official makes a final determination regarding whether to grant the approval. This procedure is standard for all approval types. The Disposition Phase for proposed approvals involves two basic procedures: (1) review the *Approval Document* or *Denial Letter* and (2) issue a final determination to the Applicant, as shown in Figure 3-4 below. Note that Applicants may petition for reconsideration (Section Section 6) and appeal (Section Section 1) if the application for approval is denied.

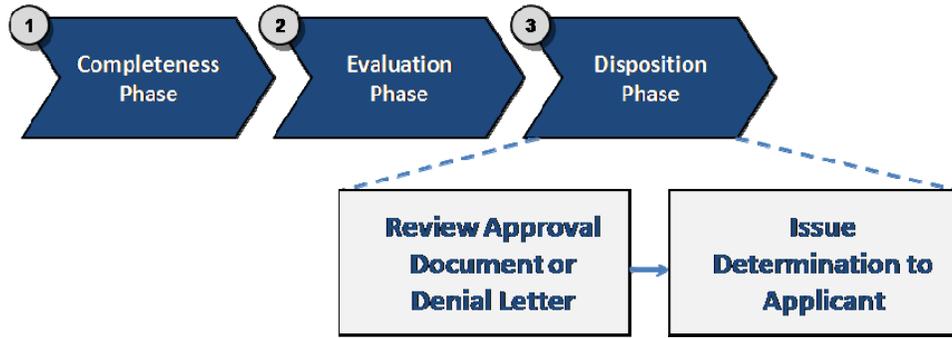


Figure 3-4: Disposition Phase Overview

3.3.2.1 Review Approval Document or Denial Letter

The Approving Official reviews all supporting application materials as well as the *Approval Document* or *Denial Letter* to make a final decision on whether to grant or deny the approval. The Approving Official will sign off on either the *Approval Document* or the *Denial Letter*. The signed document is then sent to the Applicant and relevant PHMSA offices.

Note: If the approval is denied, the Approving Official may elect to send the *Denial Letter* and supporting justification to Legal Counsel for additional review. Legal Counsel may recommend that a denial is unnecessary, and if so will provide legal justification. If the Approving Official and Legal Counsel do not concur, a meeting can be requested between the Associate Administrator and the Chief Counsel to make the final decision to issue an *Approval Document* or *Denial Letter*.

3.3.2.2 Issue Determination to Applicant

If the Applicant is granted an approval, PHMSA sends an *Approval Document* to the Applicant and the application status is updated on the PHMSA website. If the Applicant is denied an approval, PHMSA gives the Applicant the opportunity to submit a request for reconsideration and, if necessary, follow that request with a request for an appeal. If the Applicant chooses not to submit a request for reconsideration, then the application status is updated on the PHMSA website. If the Applicant is not granted an approval through the reconsideration or the appeals process, the application status is updated on the PHMSA website.

Note: The status of radioactive material certificates of competent authority approvals are not published on the PHMSA website.

3.4 Dispute Resolution around Approval-Related Topics

PHMSA’s OHMS developed procedures to resolve differences of professional judgment on hazardous materials safety issues (PHMSA Order 3770.1 “Safety Review Board”).⁹

Dispute resolution begins with the Director of the office or program having differences of professional opinion. It is the responsibility of the Director to provide all sides with an equal opportunity to present their views in an open and fair environment. If consensus cannot be reached, it becomes the responsibility of the Associate Administrator (AA) and Deputy Associate Administrator (DAA), responsible for the program or office, to reach a resolution. If consensus still cannot be reached, the issue is elevated to PHMSA’s Safety Review Board (SRB) for a final decision.

⁹ Cynthia Quarterman, PHMSA Order 3770.1, Subject: Safety Review Board, April 5, 2010.

Section 4. Approval Renewal Process

4.1 Purpose

The purpose of the Approval Renewal procedure is to renew existing approvals in accordance with the requirements of the HMR. The following sections provide an overview of the Approval Renewal Process.

This process does not apply to Radioactive Material Certificates of Competent Authority. Renewals for radioactive authority approvals are handled as new applications.

4.2 Procedural Overview

Approval Holders may request a renewal of their approval from the Approving Official. Renewal applications should be received by the Approving Official at least 120 days before the approval expires.

Once PHMSA receives a renewal application, the Project Officer completes a review of the Approval Holder to determine whether the Approval Holder has consistently complied with the terms of their approval. Upon successful completion of the review, the Project Officer follows the procedures outlined in the Completeness Phase of the Application Review Process in Section 3.1. The agency then conducts a brief evaluation of the renewal application that involves two basic procedures: (1) An assessment to determine if a complete evaluation of the application can be conducted prior to the approval expiration date; and (2) A decision on whether to issue an extension of the approval if sufficient time to conduct a full evaluation does not exist. Once a decision has been made, the Project Officer follows the procedures outlined in the Evaluation Phase and Disposition Phase of the Application Review Process in Section Section 3.

4.2.1 Conduct Evaluation

Upon receipt of the renewal application, the Project Officer reviews the Approval Holder's record for compliance and, if acceptable, evaluates application completeness using the procedures outlined in the Completeness Phase of the Application Review Process in Section 3.1. If the renewal Applicant submits an application 120 days before the expiration date of its approval, or if the Project Officer determines there is sufficient time to conduct an evaluation prior to the expiration date of the approval, then the Evaluation Phase procedures of the Application Review Process, outlined in Section 3.2, are used to evaluate the application for renewal.

4.2.2 Issue Approval Extension

If the Applicant submits an application for renewal within more than 60 days prior to the expiration date of its approval, upon written request from the Applicant then the Approving Official will grant an extension of the approval. After the extension is granted by the Approving Official, the application undergoes a full evaluation as outlined in the Evaluation Phase procedures of the Application Review Process in Section 3.2.

Once the evaluation is complete, the Project Officer recommends whether to grant a renewal or issue a denial and drafts either an *Approval Document* or *Denial Letter*. Once drafted, the *Approval Document* or *Denial Letter* and remaining application materials are sent to the Approving Official for review. At this point the Disposition Phase of the Application Review Process (Section 3.3) begins.

Section 5. Approval Modification, Suspension, or Termination Process

5.1 Purpose

The purpose of the approval Modification, Suspension, or Termination Process is to provide a standard process for PHMSA to take action to modify, suspend or terminate an approval.

5.2 Procedural Overview

The Approving Official may modify, suspend, or terminate an approval under the authority of 49 CFR 107.713 for an array of reasons, including:

- The approval represents a risk of significant harm to persons or property
- The approval no longer is needed or no longer would be granted if applied for because of a change in circumstances
- The original application contained inaccurate or incomplete information, and the approval would not have been granted had the application been accurate and complete
- The original application contained deliberately inaccurate or incomplete information
- The holder knowingly has violated the terms of the approval or an applicable requirement of this HMR in a manner demonstrating lack of fitness to conduct the activity for which the approval is required
- The holder displays a risk of failure to adhere to the approval based on compliance and safety history.

The modification, suspension, or termination of an approval is initiated by the Approving Official through a review of the reasons for modifying, suspending, or terminating the approval. At the conclusion of this review, the Approving Official either: (1) Modifies, suspends or terminates the approval immediately; or (2) Issues a *Show Cause Letter* to the Applicant.

5.2.1 Suspend or Terminate Approval

If the approval represents a significant risk to persons or property, the Approving Official may modify, suspend, or terminate the approval immediately by notifying the Approval Holder and all registered users, as applicable, that their approval is no longer valid.

5.2.2 Issue Show Cause Letter

If the approval does not represent a significant risk, the Approving Official must notify the Approval Holder of their intent to modify, suspend or terminate the approval and provide an opportunity for the Approval Holder to show cause why the approval should remain valid. Once the Approval Holder responds, the Approving Official makes a final determination.

Section 6. Approval Reconsideration Process

6.1 Purpose

The purpose of the reconsideration process is to allow Applicants or Approval Holders the opportunity to request that PHMSA reconsider its decision to modify, deny, suspend, or terminate an application or existing approval.

6.2 Procedural Overview

Applicants and Approval Holders may petition for reconsideration if an application is denied or an approval is modified, suspended or terminated. If Applicants and Approval Holders choose to submit a request for reconsideration, PHMSA OHMS's Associate Administrator, or delegate, will reevaluate the application or approval taking into consideration the new information provided. The Associate Administrator has the authority to grant or deny approvals in whole or in part.

As outlined in 49 CFR 107.715, requests for reconsideration must:

- Be in writing and filed within 20 days of receipt of the decision
- State in detail any alleged errors of fact and law
- Enclose any additional information needed to support the request to reconsider
- State in detail the modification of the final decision sought

The reconsideration process involves two basic procedures: (1) Completeness Review; and (2) Evaluation. Once a reconsideration decision has been made, the Project Officer follows the procedures outlined in the Disposition Phase of the Application Review Process in Section 3.3.

6.2.1 Completeness Review

Upon receipt of the petition for reconsideration, the Project Officer reviews the petition to determine whether the reconsideration materials are satisfactory. This review assesses whether the petition meets all of the criteria required by the HMR.

6.2.2 Evaluation

If satisfactory, the petition is evaluated by either a Project Officer or Technical Officer (based on the nature of the approval). Once a decision is made, the responsible party drafts a recommendation to issue an approval or denial. After PHMSA completes its evaluation, the Project Officer determines whether the petition for reconsideration needs to be reviewed by any of the OA Coordinating Officials. If a coordinated review is needed, the Project Officer communicates with the relevant contacts and handles receipt of concurrence documents. If PHMSA's and the relevant OA's recommendations are not in agreement, the Approving Official is responsible for resolving the dispute. Once concurrence is reached, the *Approval Document* or *Denial Letter* and associated petition materials are sent to the approving official for review. Refer to the Disposition Phase of the Application Review Process (Section 3.3) for the approving official's final decision.

Section 7. Approval Appeal Process

7.1 Purpose

The purpose of the appeal process is to allow Applicants and Approval Holders who were denied a request for reconsideration, the opportunity to appeal PHMSA's decision and provide new information and receive additional review from the agency.

7.2 Procedural Overview

Applicants and Approval Holders may request an appeal if an approval is denied after a petition for reconsideration. If an appeal request is made, PHMSA's Administrator, or delegate, will reevaluate the application or approval taking into consideration the new information provided. As outlined in 49 CFR 107.717, the appeal must:

- Be in writing and filed within 30 days of receipt of the Associate Administrator's decision on reconsideration
- State in detail any alleged errors of fact and law
- Enclose any additional information needed to support the appeal
- State in detail the modification of the final decision sought

The appeal process involves two basic procedures: (1) Completeness Review; and (2) Evaluation. Once an appeal decision has been made, the Project Officer follows the procedures outlined in the Disposition Phase of the Application Review Process in Section 3.3.

7.2.1 Completeness Review

Upon receipt of the request for appeal, the Administrator, or delegate, reviews the request to determine whether the appeal materials are satisfactory. This review assesses whether the request meets all of the criteria required by the HMR.

7.2.2 Evaluation

If satisfactory, the request is evaluated by the Administrator, or delegate. Upon review, the reviewer may require additional information. If such information is necessary, OHMS staff will review the request and provide all necessary information. Once all documents are reviewed, the responsible party decides whether to approve or deny the request for appeal and drafts a justification for issuing an *Approval Document* or *Denial Letter*. Refer to the Disposition Phase of the Application Review Process in Section 3.3 for closing steps.

Section 8. Minimum Level of Fitness Review

Under 49 CFR 107.709(d) PHMSA may only grant an approval on finding that an Applicant is fit to conduct the activity authorized by the approval, or renewal or modification of approval. PHMSA may determine an Applicant's fitness through the information provided in the application, the Applicant's prior compliance history, or other information that is available to the Associate Administrator.

PHMSA currently evaluates an Applicant's fitness through a three-tiered Minimum Level of Fitness Review. The following sections provide an overview of the three tiered review process.

8.1 Tier One Minimum Level of Fitness Review

8.1.1 Purpose

The purpose of the Tier One Minimum Level of Fitness Review process is to determine whether an Applicant is fit to hold an approval or requires further fitness review in the:

- Registration Approval Category
- Classification Approval Category
- Cylinders Approval Category
- Certification Agencies Approval Category
- General Approvals Approval Category
- Radioactive Material Certificates of Competent Approval Category.

Note: As of June 30, 2010 PHMSA is in the process of updating the agency's Minimum Level of Fitness Review procedures for approvals. The following section (Section 8.1.2) includes procedures that are currently in use; however these procedures are being reviewed and revised at this time.

8.1.2 Current-State Procedural Overview

Once PHMSA determines that an application is complete, the agency evaluates the application to determine whether the Applicant is qualified to hold the type of approval for which it has applied. The first step in evaluating an application, regardless of the approval type, is to conduct a Tier One Minimum Level of Fitness Review.

The procedures for conducting a Tier One Minimum Level of Fitness Review vary based on the category of approval. Section 8.1.2 provides a description of the Minimum Level of Fitness Review for each approval category.

Note: These procedures are under review and are subject to change.

Several of the procedures discussed below utilize the Hazmat Intelligence Portal (HIP) and FMCSA's Safety Fitness Electronic Records (SAFER) System to evaluate an Applicant's fitness. HIP provides an integrated information source to identify hazardous material safety trends through the analysis of incident and accident information. This information repository supports all transportation modes, data analysts, field inspectors, and team leaders. HIP includes several hazardous materials data points (e.g., incidents from the 5800 report, PHMSA registrations, approvals, cargo tank registrations, EPA toxic release inventory, inspection/reviews, NRC incidents, one time movements, penalties, PHMSA

complaints, RAM certifications, USCG releases, and violations). HIP data is organized on customized Dashboards to provide data pertinent to the mode, agency, office or group utilizing the system.

FMCSA's SAFER System provides company safety data and related services to the industry and public. SAFER's Company Snapshot is an electronic record of a company's identification, size commodity information, and safety records, including the safety rating (if any), a roadside out-of-service inspection summary, and crash information.

Note: No fitness information will be found in SAFER's Company Snapshot for foreign companies or companies that do not perform carrier functions.

8.1.2.1 Registration Approval Category Fitness Procedures

The Tier One Minimum Level of Fitness Review process for registration approvals includes using information from the HIP and SAFER System to evaluate an Applicant's fitness. Specifically, the Project Officer assigned to the application uses the *Fitness Evaluation Form* to document the review of the HIP and SAFER information. If the Applicant does not meet any of the criteria listed on the form, then the Project Officer refers the Applicant to Field Operations for a Tier Two Minimum Level of Fitness Review, which is described below.

8.1.2.2 Classification Approval Category Fitness Procedure

The Tier One Minimum Level of Fitness Review process for classification approvals includes using information from the HIP and SAFER System to evaluate an Applicant's fitness. Specifically, the Project Officer assigned to the application uses the *Fitness Evaluation Form* to document the review of the HIP and SAFER information. If the Applicant does not meet any of the criteria listed on the form, then the Project Officer refers the Applicant to Field Operations for a Tier Two Minimum Level of Fitness Review, which is described below.

8.1.2.3 Cylinder Approval Category

The Tier One Minimum Level of Fitness Review process for cylinders approvals includes a pre-determination audit followed by an on-site fitness inspection conducted by an IIA. Due to the IIA's inspection, no further review by Field Operations is required and a determination of fitness will be made during the Tier One Minimum Level of Fitness Review.

All foreign cylinder Applicants must supply PHMSA with information based on Minimum Level of Fitness requirements (similar to Training Requirements in 49 CFR Part 172 Subpart G).

8.1.2.4 Certification Agency Approval Category

Prospective certification agencies receive an on-site fitness inspection after they submit a completed application. This on-site fitness inspection, which is described in the Evaluation Phase of the Application Review Process (Section 3.2), constitutes the Minimum Level of Fitness Review for certification agencies approvals.

8.1.2.5 General Approvals Approval Category

The Tier One Minimum Level of Fitness Review process for general approvals includes using information from the HIP and SAFER System to evaluate an Applicant's fitness. Specifically, the Project Officer assigned to the application uses the *General Approvals and International Approvals Fitness Evaluation Form for New Approvals Applications or to Modify an Existing Approval* to document the review of the HIP and SAFER information. If the Applicant does not meet any of the criteria listed on the form,

then the Project Officer refers the Applicant to Field Operations for a Tier Two Minimum Level of Fitness Review, which is described below.

8.1.2.6 *Radioactive Materials Certificates of Competent Authority Approval Category*

The Radioactive Materials Branch conducts a fitness evaluation of each company which is issued a Radioactive Material Certificate of Competent Authority (certificate holder and registered user). This fitness evaluation includes using information from the HIP, SAFER System and the Nuclear Material Event Database (NMED) to evaluate an Applicant's fitness and is valid for one year from date of issuance. Specifically, the Project/Technical Officer assigned to the application documents the results of the review of the HIP, SAFER and NMED information. If the Applicant or registered user does not meet Minimum Level of Fitness, the Project/Technical Officer refers the company to Field Operations for a Tier Two Minimum Level of Fitness Review, which is described below.

8.2 Tier Two Minimum Level of Fitness Review

8.2.1 Purpose

The purpose of the Tier Two Minimum Level of Fitness Review process is to assess Applicants who were determined, during the Tier One Minimum Level of Fitness Review, to be in need of further review.

8.2.2 Procedural Overview

Once PHMSA completes the Tier One Minimum Level of Fitness Review process and determines that additional review of the Applicant is needed, the Project Officer sends a fitness referral to Field Operations. Field Operations then reviews the Applicant's information (e.g., compliance history, incidents) to determine whether the Applicant is fit. PHMSA may request additional information from the Applicant in order to make the determination. After reviewing all the requested information, Field Operations recommends that the Applicant is either fit or requires an on-site fitness inspection.

8.3 Tier Three Minimum Level of Fitness Review

8.3.1 Purpose

The purpose of the Tier Three Minimum Level of Fitness Review process is to conduct an on-site fitness inspection of Applicants who were determined, during the Tier Two Minimum Level of Fitness Review, to be in need of further review. During the Tier Three Minimum Level of Fitness Review process, Applicants will either be determined fit or unfit to hold an approval.

8.3.2 Procedural Overview

If a recommendation for fitness is not made during the Tier Two Minimum Level of Fitness Review process, Field Operations conducts an on-site fitness inspection on the Applicant. Depending on the Applicant, the inspection is performed by PHMSA's Field Operations or an OA. Once the inspection is complete, the responsible party will make a fitness recommendation. The Project Officer will make a final fitness determination, using the fitness recommendation provided by the responsible party. Once the determination is made, the Applicant has a right to file a petition for reconsideration to the Associate Administrator. A person who filed a petition for reconsideration may also appeal to the Administrator.

Section 9. Post-Approval Responsibilities

PHMSA is responsible for managing and providing oversight of approvals that it has granted to persons, companies or entities operating in the hazardous materials industry. Management and oversight responsibilities fall into three broad categories:

1. Reporting
2. Compliance Inspections
3. Modification, Suspension, or Termination of Approvals.

9.1 Reporting

It is the responsibility of the Approving Official to ensure that Approval Holders adhere to the reporting requirements associated with their approvals. Depending on the nature of the approval, certain Approval Holders must report to PHMSA at regular intervals with data relating to activities conducted under the authority of their approval. Reporting requirements vary across the different types of approvals PHMSA issues. The Approving Official may modify, suspend, or terminate an approval if the Approval Holder does not comply with its reporting requirements.

9.2 Compliance Inspections

Pursuant to PHMSA's mission to protect people and the environment from the risks inherent in the transportation of hazardous materials, the agency conducts announced and unannounced compliance inspections on persons, companies and entities that hold approvals. PHMSA may impose an array of enforcement actions on findings that a person, company or entity is not abiding by the terms of its approval. It is the responsibility of the Enforcement Liaison to ensure that the agency is maintaining an appropriate compliance regime on Approval Holders and to ensure all pending enforcement actions have been cleared.

9.3 Modification, Suspension, and Termination of Approvals

It is also the responsibility of the Approving Official to monitor approved persons, companies or entities to ensure that they adhere to the terms of their approvals.

The Approving Official may modify an approval on finding that:

- Modification is necessary to conform an existing approval to relevant statutes and regulations as they may be amended from time to time
- Modification is required by changed circumstances to enable the approval to continue to meet the standards of 49 CFR 107.709(d).

The Approving Official may also modify, suspend or terminate an approval, as appropriate, on finding that:

- Because of a change in circumstances, the approval no longer is needed or no longer would be granted if applied for
- The application contained inaccurate or incomplete information, and the approval would not have been granted had the application been accurate and complete

- The application contained deliberately inaccurate or incomplete information
- The holder knowingly has violated the terms of the approval or an applicable requirement of this chapter in a manner demonstrating lack of fitness to conduct the activity for which the approval is required
- Unless the Approving Official finds it necessary to suspend an approval immediately to avoid risk of significant harm to persons or property: before an approval is modified, suspended or terminated, the Associate Administrator notifies the holder in writing of the proposed action and the reasons for it, and provides an opportunity to show cause why the proposed action should not be taken.

Section 10. Forms and Documents

All forms and documents utilized to review approvals should be standardized. Paper forms will be replaced with automated forms where possible and advantageous to PHMSA. The purpose of standardization is to provide clear and consistent information and instructions to Applicants and staff so that the agency will receive and maintain high-quality information in its records.

The following are the types of forms and documents used and issued by PHMSA during the approval process.¹⁰

10.1 Application Completeness Review Form

The Application Completeness Form is prepared and maintained by the Division of Approvals and Permits. Approvals and Permits staff use the form to determine whether information provided by the Applicant is satisfactory to evaluate. Among other information, this form contains:

- Applicant name, address and other identifying information
- Regulatory code for which approval is being requested
- A checklist of items the Applicant must provide to have a satisfactory application.

10.2 Fitness Evaluation Form

The Fitness Evaluation Form is prepared and maintained by the Division of Approvals and Permits. The form is used by Approvals and Permits staff to conduct Tier One Minimum Level of Fitness Reviews. As mentioned previously, the fitness evaluation process is currently under review and may be modified in the future. Among other information, this form contains:

- Data that indicate whether the Applicant has had a hazardous materials incident in the last five years
- Data that indicate whether the Applicant has received a civil enforcement cases, warning letters, or a combination of the two
- Data that indicate the SAFER rating and out-of-service percentage, if applicable.

10.3 Safety Evaluation Form

The Application Evaluation Form is maintained by the Division of Engineering and Research. Engineering and Research staff use the form to evaluate the technical merits of an application received by PHMSA. Among other information, the form contains:

- Applicant name, address and other identifying information
- Hazardous materials covered in the application
- Packaging information
- Safety assessment
- Recommendation to grant or deny the application.

¹⁰ Radioactive material certificates of competent authority approvals forms, letters, and documents, with the exception of those maintained by Field Operations, are prepared and maintained by the Division of Engineering and Research.

10.4 OHME Fitness Memo

The Fitness Memorandum is memorandum that is prepared and maintained by Field Operations. The memorandum is used by Field Operations staff to communicate the results of a Tier Two and/or Tier Three Minimum Level of Fitness Review to the Division of Approvals and Permits.

Among other data, the memorandum contains:

- Background information on the special permits or approvals held by the person, company or entity undergoing the second-level fitness review
- Profile of the person or company undergoing the second-level fitness review
- Information that resulted in the initiation of the tier two and/or tier three fitness review
- Field Operation's review of the information that resulted in the tier three fitness review
- Field Operation's fitness assessment
- Field Operation's fitness recommendation.

10.5 Approval Document

The Approval Document is prepared and maintained by the Division of Approvals and Permits. Approvals and Permits staff use the document to respond positively to a request for approval or renewal. Among other information, the document contains:

- Name of Approval Holder
- Regulatory authority under which the approval is issued
- Conditions and special provisions attached to the approval
- Signature of the Approving Official
- Certain approval types will contain more specific information (e.g., EX number, expiration date of the approval, date that the Applicant should apply for renewal, identification code and symbol issued by certification agency).

10.6 Approval Extension Letter

The Approval Extension Letter is prepared and maintained by the Division of Approvals and Permits. The letter is used by staff in Approvals and Permits to inform an Applicant who has applied for renewal that the expiration date on their existing approval is being extended until PHMSA can process their renewal application. Among other information, the letter contains:

- New expiration date for approval
- Signature of Approving Official.

10.7 Approval Modification, Termination or Suspension Letter

The Approval Modification, Termination, or Suspension Letter is prepared and maintained by the Division of Approvals and Permits. The letter is used by OHMS staff to inform an Approval Holder that PHMSA is modifying, terminating or suspending its approval. Among other information, the letter contains:

- Reasons why PHMSA is either modifying, terminating, or suspending the approval
- Signature of the Approving Official.

10.8 Information Request Letter

The Information Request Letter is prepared and maintained by the Division of Approvals and Permits. Approvals and Permits staff use the letter to request additional information from approval Applicants.

Among other information, the letter contains:

- Date and brief description of the approval request from the Applicant
- Information requested by PHMSA
- Signature of the Approving Official.

10.9 Show Cause Letter

The Show Cause Letter is prepared by the Office of Chief Counsel, in cooperation with the Office of Hazardous Materials Special Permits and Approvals. The letter is used by Approvals and Permits staff to inform an Approval Holder that PHMSA has learned of facts or conduct believed to warrant modification, suspension or termination of the holder's approval. Among other information, the letter contains:

- Reasons why PHMSA is either seeking to terminate, suspend, or modify the approval
- Signature of the Approving Official.

10.10 Rejection Letter

The Rejection Letter is a standard letter prepared and maintained by the Division of Approvals and Permits. The letter is used by Approvals and Permits staff to inform Applicants that their application has been rejected. Among other data, the standard letter contains:

- Date and brief description of the approval request from the Applicant
- Reasons why PHMSA rejected the application
- Signature of the Approving Official.

10.11 Denial Letter

The Denial Letter is prepared and maintained by the Division of Approvals and Permits. Approvals and Permits staff use the letter to inform Applicants and/or Approval Holders that their application for approval, renewal, reconsideration or appeal has been denied. Among other information, the standard letter contains:

- Date and brief description of the approval request
- Reasons for denial of the request
- Signature of the Approving Official.

10.12 Inspection Form

The Inspection Form is a form prepared and maintained by the Field Operations. It is used to conduct on-site inspections.

10.13 Inspection Notification Letter

The Inspection Notification Letter is a form prepared and maintained by Field Operations. This form is used to provide international and certain domestic Applicants with the details surrounding an impending on-site facility inspection. Among other information, the standard letter contains:

- Date, time and location(s) of the on-site facility inspection(s)
- Procedures, equipment and documents to be inspected during the on-site facility inspection
- Methods for reimbursing PHMSA allowable expenses
- Signature.

10.14 Inspection Report

The Inspection Report is a standard form prepared and maintained by the Field Operations and developed in coordination with Engineering and Research, and Approvals and Permits to document the results of an inspection.

Appendix A: Approval Types

Table A-1 presents brief definitions for the different types of approvals granted by PHMSA.

Table A-1: Types of Approvals

Approval	Definition
M numbers for Identification of Packaging Manufacturers	M numbers are unique registration symbols that are required to appear on certain types of packagings (e.g., specification 39 non-reusable cylinders), as stipulated in the HMR, and which are marked on a package as an identifier in lieu of marking a company's full name and address. For more information, see 49 CFR 178.3.
RIN for Visual Cylinder Requalifiers	PHMSA issues approvals to inspect and requalify certain types of low pressure cylinders using visual inspection methods in accordance with the requirements of the HMR. For more information, see 49 CFR 180.209.
Explosives	All explosives offered for transportation in the United States must be classed and approved for transportation. An explosive classification approval (also known as an "EX Approval"), is a document prepared by the DOT that assigns the proper shipping name, hazard class and identification number for an explosive substance or an explosive article. The EX approval number is product specific. For more information, see 49 CFR 173.56.
Fireworks	All fireworks offered for transportation in the United States must be classed and approved for transportation. A fireworks classification approval (also known as an "EX Approval"), is a document prepared by the DOT that assigns the proper shipping, hazard class and identification number for the fireworks device. The EX approval number is product specific. For more information, see 49 CFR 173.56.
Chemical Oxygen Generators	A chemical oxygen generator that is shipped with an explosive or non explosive means of initiation must be classed and approved by the DOT. A chemical oxygen generator classification approval (also known as an "EX Approval"), is a document prepared by the DOT that provides recommendation regarding the proper shipping, hazard class and identification number for the chemical oxygen generator. For more information, see 49 CFR 173.168.
Self-Reactive Materials and Organic Peroxides	A self-reactive material and an organic peroxide that is not identified by technical name in the Self- Reactive Materials Table and the Organic Peroxides Table must be approved by the DOT before being offered for transportation. For more information on self-reactive materials, see 49 CFR 173.124. For more information on organic peroxides, see 49 CFR 173.128.
Domestic Cylinder Requalifiers	PHMSA issues approvals to US operating entities to inspect, test, and re-certify DOT specification cylinders. Each approved Applicant receives a Requalifier Identification Number (RIN) which is unique to the facility where cylinder recertification is conducted. For more information, see 49 CFR 107.805.
Domestic Cylinder Repair/Rebuild Companies	PHMSA issues approvals to US operating entities to repair and rebuild DOT specification cylinders. Prior to approval, US operating entities must receive an on-site inspection from either an approved independent inspection agency or PHMSA. Each approved Applicant receives a Requalifier Identification Number (RIN) which is unique to the facility

Approval	Definition
	where cylinder repair/rebuilding operations are conducted. For more information, see 49 CFR 107.805.
Foreign Cylinder Requalifiers	PHMSA issues approvals to foreign operating entities to inspect, test, and re-certify DOT specification cylinders. Prior to approval, foreign operating entities must receive an on-site inspection from PHMSA. Each approved Applicant receives a Requalifier Identification Number (RIN) which is unique to the facility where cylinder recertification is conducted. For more information, see 49 CFR 107.805.
Foreign Cylinder Repair/ Rebuild Companies	PHMSA issues approvals to foreign operating entities to repair and rebuild DOT specification cylinders. Prior to approval, foreign operating entities must receive an on-site inspection from PHMSA. Each approved Applicant receives a Requalifier Identification Number (RIN) which is unique to the facility where cylinder repair/rebuilding operations are conducted. For more information, see 49 CFR 107.805.
Foreign Cylinder Manufacturers with IIAs	PHMSA issues approvals to foreign operating entities to manufacture DOT specification cylinders. Prior to approval, foreign operating entities must have an approved independent inspection agency on-site to monitor production and receive an on-site inspection from PHMSA. For more information, see 49 CFR 107.801.
United Nations (UN)/ International Organization for Standardization (ISO) Cylinder Manufacturers	PHMSA issues approvals to foreign operating entities to manufacture UN / ISO specification cylinders. Prior to approval, foreign operating entities must have an approved independent inspection agency on-site to monitor production and receive an on-site inspection from PHMSA. For more information, see 49 CFR 107.807.
Designated Approval Agencies	PHMSA issues approvals to act as designated approval agencies. Designated approval agencies issue approval certificates and certifications for UN portable tanks and multiple element gas containers in accordance with the requirements of the HMR. For more information see 49 CFR 107.401.
Independent Inspection Agencies (IIAs)	PHMSA issues approvals to act as independent inspection agencies. Independent inspection agencies perform, witness, and verify tests and inspections, verifications, and certifications of DOT specification cylinders or UN/ISO pressure receptacles in accordance with the requirements of the HMR. For more information, see 49 CFR 107.803.
Package Certification Agencies	PHMSA issues approvals to act as packaging certification agencies. Packaging certification agencies test and certify UN packagings in accordance with the requirements of the HMR. For more information, see 49 CFR 107.401.
Explosive Examination Agencies	PHMSA authorizes laboratories to perform explosive classification evaluations and provide a classification recommendation on the basis of an approval issued to the laboratory. Explosive test laboratories examine and test explosives and issue classification recommendations to PHMSA (i.e., recommended shipping description, division, and compatibility group) in accordance with the requirements of the HMR. For more information, see 49 CFR 173.56.

Approval	Definition
Lighter Testing Agencies	PHMSA issues approvals to act as lighter testing agencies. Lighter testing agencies examine and test new lighter designs in accordance with the requirements of the HMR. For more information, see 49 CFR 173.308.
International Maritime Dangerous Goods/ International Civil Aviation Organization (IMDG/ICAO) Competent Authority Approval (CAA)	PHMSA issues an IMDG/ICAO competent authority approval when either set of international regulations (i.e., IMDG or ICAO codes) requires an approval or exemption from the Competent Authority of the United States to conduct authorized activities.
General CA	PHMSA issues general approvals when authorization from the Associate Administrator or other designated Department official is required to perform a function that needs prior consent under the HMR.
Lithium Batteries	PHMSA issues approvals for alternative testing and the transportation of lithium batteries. For more information, see 49 CFR 173.185.
Fuel Cells	PHMSA issues approvals for to transport fuel cells. For more information, see 49 CFR 173.230.
Radioactive Material Package Designs	PHMSA issues Competent Authority approval certifications for packages designed to transport radioactive material. The certifications are issued after PHMSA conducts a detailed review to ensure the package design (packaging and contents) satisfy domestic and international regulations. The evaluation involves, as necessary, the following elements: package design; contents; structural and material analysis; normal and accident condition testing; thermal performance; containment; shielding; criticality; and operating and maintenance instructions. PHMSA also evaluates the Applicant and registered user ability to operate within the regulations and conditions of the Certificate of Competent Authority. For more information, see 49 CFR 173.471; 173.472; 173.473.
Radioactive Material Classifications	PHMSA issues Competent Authority approval certifications for the classification of radioactive materials. The certifications are issued after PHMSA conducts a detailed review to ensure the material is classified in accordance with international and domestic regulations. A majority of these reviews involve special form (encapsulated) material where the evaluation addresses general design requirements; impact, percussion, bending and heat testing; leach testing (containment). Other material classifications conducted include determination of excepted quantities and concentrations and determination of "A" values. PHMSA also evaluates the Applicant and registered user ability to operate within the regulations and conditions of the Certificate of Competent Authority. For more information, see 49 CFR 173.476.

Appendix B: Definitions

- **Administrator:** The Administrator, Pipeline and Hazardous Materials Safety Administration.
- **American Pyrotechnics Standard 87-1:** Industry standard developed by the American Pyrotechnics Association (APA) that outlines the types of products that can be approved by PHMSA as fireworks.
- **Approval:** Written consent, including a competent authority approval, from the Associate Administrator or other designated Department official, to perform a function that requires prior consent under subchapter C of this chapter (49 CFR parts 171 through 180).¹¹
- **Associate Administrator:** The Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.
- **Cylinder:** A pressure vessel designed for pressure higher than 40 psia and having a circular cross section. It does not include a portable tank, multi-unit tank car tank, cargo tank or tank car.
- **Competent Authority:** A national agency that is responsible, under its national law, for the control or regulation of some aspect of hazardous materials (dangerous goods) transportation. Another term for Competent Authority is “Appropriate authority” which is used in the International Civil Aviation Organization’s (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air. The Associate Administrator is the United States Competent Authority for purposes of 49 CFR part 107.¹²
- **Competent Authority Approval:** An approval by the competent authority that is required under an international standard (for example, the ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air and the International Maritime Dangerous Goods Code). Any of the following may be considered a competent authority approval if it satisfies the requirement of an international standard: (1) A specific regulation in subchapter A or C of this chapter. (2) A special permit or approval issued under subchapter A or C of this chapter. (3) A separate document issued to one or more persons by the Associate Administrator.¹³
- **EX Number:** A number preceded by the prefix “EX”, assigned by the Associate Administrator, to an item that has been evaluated under the provisions of 49 CFR 173.56.
- **Equivalent Level of Safety:** An approvals application must demonstrate that the proposed activity will achieve a level of safety that is at least equal to that required by the regulation, or if the regulations do not establish a level of safety, is consistent with the public interest and adequately will protect against the risk of life and property inherent in the transportation of hazardous materials in commerce.¹⁴
- **Federal Hazardous Materials Transportation Law:** 49 U.S.C. 5101 *et seq.*
- **Minimum Level of Fitness:** An Applicant is assessed to determine if they are fit to conduct the activity authorized by the approval, or renewal or modification of approval. This assessment may

¹¹ 49 CFR 105.5

¹² 49 CFR 105.5

¹³ 49 CFR 105.5

¹⁴ 49 CFR 107.709(d)

be based on information in the application, prior compliance history of the Applicant, and other information available to the Associate Administrator.¹⁵

- **Fuel Cell:** An electrochemical device that converts the energy of the chemical reaction between a fuel, such as hydrogen or hydrogen rich gases, alcohols, or hydrocarbons, and an oxidant, such as air or oxygen, to direct current (d.c.) power, heat, and other reaction products.
- **Hazard Class:** Means the category of hazard assigned to a hazardous material under the definitional criteria of part 173 of this subchapter and the provisions of the 49 CFR 172.101 table. A material means the category of hazard assigned to a hazardous material under the definitional criteria of part 173 of this subchapter and the provisions of the 49 CFR 172.101 table.
- **Hazardous Material:** A substance or material that the Secretary of Transportation has determined is capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and has designated as hazardous under section 5103 of Federal Hazardous Materials Transportation Law (49 U.S.C. 5103). The term includes hazardous substances, hazardous wastes, marine pollutants, elevated temperature materials, materials designated as hazardous in the Hazardous Materials Table (see 49 CFR 172.101), and materials that meet the defining criteria for hazard classes and divisions in part 173 of subchapter C of this chapter.¹⁶
- **Hazardous Materials Regulations:** The regulations at 49 CFR parts 171 through 180.¹⁷
- **IAEA:** International Atomic Energy Agency.
- **ICAO:** International Civil Aviation Organization.
- **IMO:** International Maritime Organization.
- **Jerrican:** A metal or plastic packaging of rectangular or polygonal cross-section.
- **Lighter:** A mechanically operated flame-producing device employing an ignition device and containing a Class 3 or a Division 2.1 material. For design, capacity, and filling density requirements for lighters containing a Division 2.1 material, see 49 CFR 173.308.
- **Multiple Element Gas Container:** An assembly of UN cylinders, tubes, or bundles of cylinders interconnected by a manifold and assembled within a framework. The term includes all service equipment and structural equipment necessary for the transport of gases.
- **Oxygen Generator (Chemical):** A device containing chemicals that upon activation release oxygen as a product of chemical reaction.
- **Package:** A packaging plus its contents. For radioactive materials, see 49 CFR 173.403.
- **Packaging:** A receptacle and any other components or materials necessary for the receptacle to perform its containment function in conformance with the minimum packing requirements of this subchapter. For radioactive materials packaging, see 49 CFR 173.403 of this subchapter.
- **Portable Tank:** A bulk packaging (except a cylinder having a water capacity of 1000 pounds or less) designed primarily to be loaded onto, or on, or temporarily attached to a transport vehicle or ship and equipped with skids, mountings, or accessories to facilitate handling of the tank by

¹⁵ 49 CFR 107.709(d)

¹⁶ 49 CFR 105.5

¹⁷ 49 CFR 105.5

mechanical means. It does not include a cargo tank, tank car, multi-unit tank car tank, or trailer carrying 3AX, 3AAX, or 3T cylinders.

- **UN Cylinder:** A transportable pressure receptacle with a water capacity not exceeding 150 L that has been marked and certified as conforming to the applicable requirements in part 178 of this subchapter.
- **UN Portable Tank:** An intermodal tank having a capacity of more than 450 liters (118.9 gallons). It includes a shell fitted with service equipment and structural equipment, including stabilizing members external to the shell and skids, mountings or accessories to facilitate mechanical handling. A UN portable tank must be capable of being filled and discharged without the removal of its structural equipment and must be capable of being lifted when full. Cargo tanks, rail tank car tanks, non-metallic tanks, non-specification tanks, bulk bins, and IBCs and packagings made to cylinder specifications are not UN portable tanks.
- **UN Pressure Receptacle:** A UN cylinder or tube.

Appendix C: Information Technology Resources

PHMSA uses several information systems as resources to help manage the Approvals Program. Table C-1 lists the IT resources currently used by PHMSA and its fellow OAs. These systems support specific functions, including document management and fitness reviews of approval Applicants.

Table C-1: Information Technology Resources

Application	Description
Approvals IT System	The Approvals IT System is a web-based application that maintains and provides access to information on the Approvals Program. The application serves as a document management system for processing approval applications and oversight of active approvals. Staff at PHMSA and the other OAs have access to the system and use it to collaborate when evaluating approval applications. ¹⁸
ISYS	ISYS is an application that functions as a search tool for the Approvals IT System. Users can search for existing approvals or other documents using keywords.
Hazmat Intelligence Portal (HIP)	HIP is a web-based application that allows the OAs to collaborate on hazardous materials-related data. HIP seeks to support government hazardous materials professionals by providing enforcement and other information on companies involved in the hazardous materials industry. The system is currently under development.
Safety and Fitness Electronic Records System (SAFER)	SAFER is an FMCSA web-based system that offers motor carrier company safety data to government and industry professionals, as well as the public. Users can search FMCSA databases, register for a US DOT number, pay fines online, order company safety profiles, challenge FMCSA data using the DataQs system, access the Hazardous Material Route registry, obtain national crash and out-of-service rates for hazardous materials permit registrations, get printable registration forms, and find information about other FMCSA Information Systems.
RAMCERT	RAMCERT is a web-based application that serves as a document management system for processing applications for radioactive material competent authority certifications.

¹⁸ Approvals dealing with radioactive materials and packaging are typically processed using the RAMCERT instead of the Approvals IT System.

Appendix D: Field Operations Fitness Criteria

The section below describes inspection and fitness recommendation criteria used by Field Operations when conducting a Tier Two and Tier Three Minimum Level of Fitness Review. Note that these criteria are subject to change.

Inspection Criteria

- An inspection is required for any of the following reasons:
 - Manufacturer marks and/or sells packaging
 - Packing Group 1 (PGI) and Table I materials
 - Company had more than 30 HazMat incidents in the previous two years
 - Company had packages recalled in the previous six years
 - Company had an inspection result in a case within the previous six years and/or a packaging recall
 - Company is on PHC's most current special case list
- An inspection is deemed unnecessary for any of the following reasons:
 - Other Regulated Materials (ORM-D)
 - Limited quantity requirements
 - Class 9
 - PG III in five gallons or less (i.e., paint and paint related materials 49 CFR 173.173)
- Inspection location(s) are determined based on:
 - Risk - ten to twenty percent of locations are chosen for inspection
 - 10 percent of locations inspected when dealing with lower hazard/lower risk material
 - 20 percent of locations inspected when dealing with higher hazard/higher risk material
 - Locations where Approvals are used
 - Locations that have had incidents within the previous three years
 - Locations that had a case result from an inspection within the last six years
 - Remainder of locations inspected per PHMSA's discretion. (PHMSA reviews several criteria to determine whether additional locations will be inspected. No more than 20% of locations are subject to inspection)
- Inspection Agency is determined based on:
 - Inspection will be conducted by an OA if:
 - Applicant is a carrier only
 - Approval includes blocking, bracing, stowage, and/or segregation
 - Approval includes a carrier marking package
 - Approval includes carrier specific regulations
 - Applicant is a manufacturer of bulk packaging
 - Inspection may be conducted by an OA if:¹⁹

¹⁹ Final decision regarding inspection agency is dependent on the approval or special permit request. The unique nature of these requests results in decisions made on a case-by-case basis.

- Applicant is a manufacturer-shipper-carrier
- Applicant is a shipper-carrier
- Applicant is an Non-Vessel Owned Common Carrier (NVOCC)-Freight Forwarder
- Applicant is an indirect air carrier
- Applicant is an NVOCC-carrier
- Applicant is an indirect air carrier-carrier
- Applicant is a freight forwarder-carrier
- Inspection will be conducted by PHMSA OA if:
 - Applicant is a shipper
 - Applicant is a manufacturer of non-bulk packaging

Fitness Criteria

- An Applicant is recommended unfit for any of the following reasons:²⁰
 - Failure to comply with terms of approval
 - Failure to have required equipment to comply with terms of approval
 - Failure to have quality assurance measures in place to ensure equipment is operating as designed
 - Enforcement inspection provides other documentation as to why Applicant is unfit
 - Facts, false statements and/or misleading statements on documents and/or application
 - Failure to complete any prior or pending enforcement actions issued by this agency
- An Applicant is capable but not compliant for any of the following reasons:
 - Failure to have some quality assurance measures in place
 - Failure to train in accordance with the approval (Applicant has demonstrated they have the ability to comply but do not currently have the documentation to support the necessary training)
 - Multiple inspections conducted; however, not all (under 35%) locations compliant (if 35% or more locations are non-compliant, the Applicant is recommended as unfit)
 - Non-compliant without communication requirements
 - Modify request if some but not all of the locations are compliant

²⁰ Unfit does not include communication requirements excluding declared shipments.