



U.S. Department of Transportation

**Pipeline and Hazardous Materials
Safety Administration**

Approvals Program Desk Guide

Version 2.3

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Disclaimer

The materials contained in this document consist of guidance and other information for PHMSA's Office of Hazardous Materials Safety (OHMS) and its supporting program offices. This document is issued exclusively for the internal management of PHMSA and the guidance of its officers and employees. This document is U.S. government property. Nothing in this document is intended to modify or supersede the Standard Operating Procedures (SOPs) for Special Permits and Approvals set forth in Appendix A to Part 107 of the Hazardous Materials Regulations (HMR).

PHMSA continues to develop, examine, and revise its approvals policies within this document. Any content presented at the date and time of dissemination may be subject to change without prior notice at PHMSA's discretion. This document creates no rights, legal or equitable, in any other person.

Change Control and Documentation

Approvals Program Desk Guide Change Log

Version	Change	Date
2.0	Add language req. documentation of SEE by TO & PO	12/21
2.1	Update with PHC Input	02/09
2.2	Editorial changes and clarifying language on Legal reviews	03/08
2.3	Appendix B – Tier 1 Memo Fitness Requirements	08/04

Table of Contents

Section 1. Executive Summary	5
1.1 Content / Change Management	5
Section 2. Introduction and Overview	6
Section 3. Approvals Program Roles and Responsibilities	10
Section 4. Application Review Process	16
Section 5. Approval Reconsideration Process	17
Section 6. Approval Appeal Process	18
Section 7. Expedited Application Review Process	19
Section 8. Approval Renewal Process	21
Section 9. Agency-Initiated Approval Modification, Suspension, or Termination Process	22
Section 10. Evaluation	23
Section 11. Post-Issuance Responsibilities	26
Section 12. Forms and Documents	26
Appendix: Approval Types, Tier 1 Memo Fitness Requirements	30

Section 1. Executive Summary

This Procedural Desk Guide (PDG) goes beyond the Standard Operating Procedures (SOP) to provide a more in depth description of the Approvals process and the various roles and responsibilities. By documenting in greater detail how OHMS currently makes decisions and the roles and responsibilities of the various positions, we are establishing continuity as well as providing a training tool for new personnel. We are also establishing a clear foundation for further procedural improvements.

1.1 Content / Change Management

This is a living document that is expected to evolve with the organization and develop as we improve our procedures. The PDG will be evaluated at a least annually but it may be more often to incorporate lessons learned and account for upgrades to the data management systems that support the Approvals Program.

The Operations Coordinators will have primary responsibility for maintaining the PDG while the Division staff and leadership will provide complete and specific input to ensure the PDG is up to date and accurate. The approved PDG will be stored in the PHH-30 PHMSANet Library 'Division Policies and Guidance'. We will also publish the PDG on the PHMSA website and on a PHMSANet wiki which will require updates in parallel. Any changes to the PDG will use the following procedure;

- Any change (beyond editorial corrections) will be documented in a Word document and submitted to the Branch Chiefs for review with a copy provided to the Operations Coordinator.
- The Branch Chiefs, or their delegate(s), will document their recommendation within three work days and submit the change request to the Director and copy the Operations Coordinator.
- The Director, or delegate, will approve or deny the change within three work days and inform the Division.
- If the change is approved, the Operations Coordinator will update the approved version of the PDG and any other location where the PDG is actively presented and document the change in the Change Control and Documentation Table.

Section 2. Introduction and Overview

2.1 Purpose of the Document

This document acts as a desk guide for the administration of the Pipeline and Hazardous Materials Safety Administration's (PHMSA's) Office of Hazardous Materials Safety (OHMS) Approvals Program (i.e., approvals issued by PHH-30). This desk guide incorporates and strengthens PHMSA's current procedures (see 49 CFR Part 107, Appendix A).

The desk guide 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 good safety and risk management practices, and to expect the same performance accountability from colleagues across the organization.

2.2 Structure of the Document

The remainder of this document includes the following 11 sections and supporting appendix:

- **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.
- **Reconsideration Process** – Describes the purpose and process 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 process overview for providing applicants and approval holders the opportunity to appeal PHMSA's decision to deny its application or modify, suspend, or terminate its approval.
- **Expedited Application Review Requests** – Describes the purpose and process overview for expediting the application review process for an approval request.
- **Approval Renewal Process** - Describes the purpose and process overview to renew an existing approval.
- **Agency-Initiated Approval Modification, Suspension or Termination Process** – Describes the purpose and process overview to modify, suspend, or terminate an approval.
- **Evaluation** – Describes the purpose and process overview for conducting a Fitness Profile Evaluation of an applicant's safety record and performance and a Technical Safety Evaluation of the approval request.
- **Post-Issuance 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 General Approvals Program processes.
- **Appendix** – Provides supporting desk guide documentation.

2.3 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 HMR (49 CFR Parts 171 through 180).¹

The Associate Administrator or designated Department official issues approvals for a wide array of activities in the hazardous materials transportation industry. These activities may include, but are not limited to, classifying, labeling, package testing, and transporting hazardous materials, under conditions defined in the HMR.

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 fitness profile evaluations to determine applicant fitness;
 - Completing technical safety evaluations to verify the activity authorized by the approval meets an equivalent level of safety;
 - Issuing approvals and denials;
- Modifying, suspending or terminating existing approvals, when necessary; and
- Managing existing approvals

2.4 Overview of Approval Types and Categories

PHMSA issues several types of approvals in response to applications from many different sectors of the hazardous materials transportation industry. Approvals authorize a range of activities, such as the testing of certain types of cylinders; 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 PHMSA 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 processes used by PHMSA to issue approvals most commonly requested by industry stakeholders.

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

1. Registration Approval Category;
2. Classification Approval Category;
3. Cylinders Approval Category;
4. Certification Agencies Approval Category; and
5. General Approvals Approval Category

Methodological 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.

¹ 49 CFR 107.1

Table 2-1 displays the approvals most commonly granted by PHMSA, their categories, and the authorizing sections of the CFR.

Table 2-1: 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 107.805; and 180.205
Classification	Explosives	49 CFR 173.56
	Fireworks	49 CFR 173.56; 173.64; and 173.65
	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 107.809
Certification Agencies	Designated approval agencies	49 CFR 107.401
	Independent inspection agencies	49 CFR 107.803
	UN Third-Party Packaging certification agencies	49 CFR 107.401
	Explosive examination agencies	49 CFR 173.56
	Lighter certification agencies	49 CFR 107.401; and 173.308
	Fireworks certification agencies	49 CFR 107.401
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

For more information on the approvals listed in Table 2-1 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 2-1 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) (e.g., explosives, fireworks, chemical oxygen generators, self-reactive materials and organic peroxides) has been classed for 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.

This desk guide will be reviewed and updated as appropriate annually, or as needed, to improve operations and ensure that policies and processes remain aligned to the business needs of OHMS.

Specific questions related to the *Approvals Program Desk Guide* should be addressed to:

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

Section 3. 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 2. 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 3-1: 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 designate his/her authority to OHMS staff, as necessary)
Transportation Assistant	Approvals and Permits Division	Transportation Assistant
Project Officer	Approvals and Permits Division	Transportation Specialist, Senior Transportation Specialist
Senior Technical Officer	Engineering and Research Division	Director of the Division of Engineering and Research
Technical Officer	Engineering and Research Division	Chemists, Physical Scientists, and Engineers
Fitness Coordinator	Field Operations and/or FAA, FMCSA, FRA, USCG	Director of Field Operations (or designee) or as designated and authorized by the OAs for the purpose of approvals processing
Standards Liaison	Standards and Research Division	Director of the Division of Standards and Rulemaking
International Standards Liaison	Standards and Research Division	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
Operating Administration (OA) Representative	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

3.1 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;
- 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; and
- Participating in discussions to resolve issues among PHMSA staff and OA Coordinating Officials or others, as determined by the Administrator.

3.2 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 designating this responsibility to OHMS staff, and overseeing the conduct of this function; and
- Granting or denying, in whole or in part, a reconsideration request by an approval holder or applicant. The Associate Administrator may designate this responsibility to another DOT Official.

3.3 Approving Official

Under 49 CFR 107.709(c) of the HMR, the Associate Administrator for Hazardous Materials Safety, or designee. 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 desk guide and desk guide revisions for the Approvals Program;
- Making recommendations to the Administrator concerning the disposition of significant approval applications (based on criteria determined by the Administrator); and
- Delegating Approving Official responsibility for specific approvals based on criteria related to the operations, transport modes, materials, or other criteria, as appropriate.

3.4 Transportation Assistant

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 ; and
- 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.

3.5 Project Officer

The Project Officer is responsible for planning and managing the Application 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 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 Hazardous Materials Regulations (HMR), International Civil Aviation Organization (ICAO), and the International Maritime Dangerous Goods (IMDG) Code;
- Coordinating the Evaluation Phase of an approval application, which may include (but not necessarily be conducted by the Project Officer):
 - Conducting fitness profile evaluation;
 - Conducting technical safety evaluation;
 - Ensure the technical safety evaluation is properly documented on the current form and included in the application folder;
 - Coordinating with other PHMSA officials such as the Standards Liaison and International Standards Liaison;
 - Coordinating with appropriate OA(s);
 - Coordinating with PHMSA legal staff; and
 - Drafting and/or reviewing approvals.

3.6 Senior Technical Officer

The Senior Technical Officer is responsible for:

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

3.7 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:

- Assisting in the Completeness Review Phase of special permit application evaluations;
- Completing technical evaluations of approval applications, which may include:
 - Conducting equivalent level-of-safety evaluations;
 - Ensuring the technical safety evaluation is properly documented on the current form and included in the application folder;
 - Participating in on-site inspections of applicants, as needed;
 - Coordinating with OAs and others, as needed; and
 - Providing input for approvals.

3.8 Fitness Coordinator

The Fitness Coordinator is a PHMSA Field Operations Division officer or an authorized representative or special agent of DOT, such as an OA coordinating official, and is responsible for conducting reviews regarding an organization's hazardous materials operations to determine whether a Special Permit Holder or Applicant is fit to conduct an authorized activity. The Fitness Coordinator is responsible for:

- Reviewing a Special Permit Holder or Applicant's incident history or compliance data
- Conducting On-Site Inspection of the Special Permit Holder or Applicant
- Reviewing other available safety and transportation records

3.9 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 Standards and Rulemaking Division involvement, which could include:
 - Newly issued regulations; and
 - Requests with far-reaching effects that may be most appropriately handled under rulemaking.

3.10 International Standards Liaison

The designated International Standards Liaison is responsible for:

- Reviewing evaluation plans as requested by the Project Officer; and

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

3.11 PHMSA Field Operations Division Officer

The designated PHMSA Field Operations Division officer is responsible for:

- Performing responsibilities of the Fitness Coordinator as specified in Section 3.8;
- Making recommendations for enhancements, denials, and determinations;
- Managing and conducting investigations of applicants and holders of existing approvals; and
- Coordinating of modal on-site inspections.

3.12 Legal Counsel

The Legal Counsel is responsible for:

- Providing legal guidance for policy and processes that pertain to approvals and other dispositions as requested;
- Reviewing and concurring with *Show Cause Letters* prior to issuance;
- Reviewing and providing input for applicant denial when requested, including denial letter justification language;
- Advising the Administrator on the disposition of Appeals; and
- Reviewing evaluation plan as applicable and as requested by the Project Officer

3.13 Operating Administration Representative

An Operating Administration (OA) representative 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. Coordination with the OA Representative is determined and conducted in accordance with the *Operational Workflow Document: Special Permits & Approvals Governance Framework*. If the type of approval being addressed requires coordination, the OA Representative is responsible for:

- Performing responsibilities of the Fitness Coordinator as specified in Section 3.8;
- Reviewing approval applications and technical evaluations;
- Completing technical evaluations of approval applications as applicable, which could include:
 - Conducting technical evaluations;
 - Drafting approvals; and
- Providing concurrence, comments, information, and acknowledgments, as appropriate, to PHMSA in accordance with established coordination schedules and milestones.

3.14 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,² legal officer,³ board members,⁴ 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); and
- 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.

3.15 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; and
- Providing PHMSA with data findings.

3.16 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; and
- Providing PHMSA any necessary updated information.

² The Chief Safety Officer or other senior executive designated in writing by the Chief Safety Officer.

³ The PHMSA Chief Counsel or other senior attorney designated in writing by the PHMSA Chief Counsel.

⁴ 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.

Section 4. Application Review Process

PHMSA evaluates all approval applications using the three phases of the application review process. Every application received by PHMSA follows the same basic steps during the completeness phase, disposition phase, and reconsideration/appeal phase; however, the detailed processes followed during the Evaluation Phase vary based on the proposed approval category (i.e., certification agencies, approvals). The following sections describe the three phases of the Application Review Process.

4.1 Completeness Phase

4.1.1 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.

4.1.2 Process 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 processes: (1) conduct completeness review; and (2) evaluate necessity of application.

4.1.2.1 Conduct Completeness Review

If an applicant emails, mails or faxes an application to PHMSA, the application is in-processed and assigned to a Project Officer based on the subject area of the application.

The Project Officer conducts an initial completeness review to ensure the information provided meets all of the application requirements in 49 CFR 107.705. 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 *Rejection Letter* depending on approval type.

4.1.2.2 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 *Rejection Letter*. 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.

4.2 Evaluation Phase

4.2.1 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 meets the equivalent level of safety and complies with the regulations in the:

- Registration Approval Category;
- Classification Approval Category;

- Cylinders Approval Category;
- Certification Agency Approval Category; and
- General Approvals Approval Category

4.2.2 Process Overview

After it is determined that an application is complete, PHMSA 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 at least one of the following two processes: (1) the safety profile evaluation; and (2) the technical evaluation. Note that the processes vary based on the approval category.

4.2.2.1 Fitness Profile Evaluation

The purpose of the fitness profile evaluation is to determine whether an applicant is fit to conduct the activity authorized by the proposed approval, renewal, or modification being requested.⁵ PHMSA conducts fitness profile evaluation for all non-classification approvals, however, certification agency approvals do not follow the same safety profile evaluation model. *Refer to Appendix B for Tier 1 Memo Fitness requirements.*

4.2.2.2 Technical Safety Evaluation

The application is assessed to see whether it provides an equivalent level-of-safety to that required by the regulations or, if a required safety level does not exist, considers whether the proposed approval is consistent with the public interest and adequately will protect against the risks to life and property inherent in hazardous materials transportation. For certification agencies, the applicant must demonstrate that they are qualified as required by 49 CFR Part 107, subparts E and I. The assessor – which may be the Project Officer or Technical Officer, reviews the application and any supporting documentation to make a determination and ensures that the technical safety evaluation is documented on the appropriate form and saved to the application folder. If the assessor determines that the proposed approval has met an equivalent level of safety is consistent with the public interest and adequately protects against the risks to life and property or, in the case of certification agencies, are qualified, PHMSA may grant an approval. If the application does not meet these requirements, PHMSA issues a denial. An application for an approval may be denied in whole or in part and, therefore, both an *Approval Document* and a *Denial Letter* may be issued for the same application. 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.

If at any point in the Technical Safety Evaluation it is determined that additional information is required to complete the evaluation, an Information Request Letter may be drafted and sent to the applicant. The letter documents the information needed and provides a date by which the additional information must be submitted. If the information is not submitted by the required date or if the applicant has not requested an extension, a *Denial Letter* may be drafted and the application may be denied.

The subsections below describe application evaluation for each approval category.

4.2.2.2.1 Registration Approval Category

Approvals in the Registration Approval Category include:

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

⁵ 49 CFR 107.709(d)(5)

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. Although on-site inspections are not typically included in the M number or VIN holder technical evaluation process, on-site inspections may be performed on a case-by-case basis. Once drafted, the *Approval Document* or *Denial Letter* and remaining application materials are sent to the Approving Official for review. Legal counsel may review denial letters. At this point, the Disposition Phase begins.

4.2.2.2.2 Classification Approval Category

Approvals in the Classification Approval Category include:

- Explosives;
- Fireworks ;
- Chemical Oxygen Generators; and
- Self-Reactive Materials and Organic Peroxides.

PHMSA performs this review on all classification approvals. During the review, PHMSA⁶ checks the application to determine whether the applicant followed the requirements of the HMR. 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. Legal counsel may review denial letters. At this point, the Disposition Phase begins.

4.2.2.2.3 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); and
- 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 *Refer to Appendix B for Tier I Memo Fitness requirements*. At the successful conclusion of the process 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. Legal counsel may review denial letters. At this point, the Disposition Phase begins.

⁶ The Project Officer is responsible when evaluating fireworks applications. The Technical Officer is responsible when evaluating all other explosive types.

4.2.2.2.4 *Certification Agencies Approval Category*

Approvals in the Certification Agencies Approval Category include:

- Independent Inspection Agencies;
- UN Third-Party Packaging Certification Agencies;
- Explosive Examination Agencies;
- Lighter Testing Agencies;
- Designated Approval Agencies; and
- Fireworks Certification Agencies.

Once an application is deemed complete, and the application is determined to meet the necessary technical requirements, PHMSA may perform 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.⁷ Depending on the outcome of the inspection, PHMSA may grant an approval. Once drafted, the *Approval Document* or *Denial Letter* and remaining application materials are sent to the Approving Official for review. Legal counsel may review denial letters. At this point, the Disposition Phase begins.

4.2.2.2.5 *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; and
- Fuel Cells.

Once determined fit, and depending upon the complexity of the application, PHMSA completes an *Evaluation Form*. 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 an equivalent level of safety to the HMR or is consistent with the public interest and adequately protects against the risks to life and property, PHMSA may grant an approval. If the applicant has not met equivalent level of safety to the HMR or is consistent with the public interest and adequately protects against the risks to life and property, PHMSA issues a denial. No on-site inspection is typically required for these types of approvals, although PHMSA or an OA 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. Legal counsel may review denial letters. It is the Project Officer's responsibility to ensure the application and all supporting documentation are ready for disposition prior to sending to the Approving Official. At this point, the Disposition Phase begins.

⁷ 49 CFR 107.803

4.3 Disposition Phase

4.3.1 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.

4.3.2 Process 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 process is standard for all approval types. The disposition phase for proposed approvals involves two basic processes: (1) review the *Approval Document* or *Denial Letter* and (2) issue a final determination to the applicant. Note that applicants may petition for reconsideration (if the application for approval is denied). It is the Project Officer's responsibility to ensure the application and all supporting documentation are ready for disposition prior to sending to the Approving Official.

4.3.2.1 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, deny, or partially deny the approval. Legal counsel may review a denial letter.

If the Approving Official determines the supporting application materials, fitness recommendation, safety evaluation, Approval Document or Denial Letter, or other information does not support a final determination or if they contain errors, the application is returned to the project officer.

The Approving Official will sign either the *Approval Document* or the *Denial Letter*, or both in the case of a partial denial.

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*.

4.3.2.2 Issue Determination to Applicant

If the applicant is granted an approval, PHMSA sends an *Approval Document* to the applicant. If the applicant is denied an approval, PHMSA sends a *Denial Letter* to the applicant and gives the applicant the opportunity to submit a request for reconsideration and, if necessary, follow that request with a request for an appeal (Section 5 and Section 6, respectively).

4.4 Dispute Resolution around Approval-Related Topics

PHMSA's OHMS developed processes to resolve differences of professional judgment on hazardous materials safety issues (PHMSA Order 3770.1 "Safety Review Board").⁸

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.

⁸ PHMSA Order 3770.1, Subject: Safety Review Board, April 5, 2010.

Section 5. Approval Reconsideration Process

5.1 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.

5.2 Process Overview

Applicants and approval holders may request 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; and
- State in detail the modification of the final decision sought.

The reconsideration process involves two basic processes: (1) completeness review; and (2) evaluation. Once a reconsideration decision has been made, the Project Officer follows the process outlined in the disposition phase of the application review process in Section 4.3.

5.2.1 Completeness Review

Upon receipt of the request for reconsideration, the Project Officer reviews the request to determine whether the reconsideration materials are satisfactory and complete. This review assesses whether the request includes information required by 49 CFR 107.715.

5.2.2 Evaluation

If satisfactory, the request is evaluated by either a Project Officer or Technical Officer (based on the nature of the approval). Once a decision is made, a recommendation is drafted to issue an approval or a denial letter. After PHMSA completes its evaluation, the Project Officer may request a review by Legal Counsel particularly if it is a unique situation or politically sensitive. The Project Officer then determines whether the request for reconsideration needs to be reviewed by any of the OAs. 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 reconsideration request materials are sent to the approving official for review. It is the Project Officer's responsibility to ensure the request for reconsideration and all supporting documentation are ready for disposition prior to sending to the Approving Official. Refer to the disposition phase of the application review process (Section 3.3) for the approving official's final decision

Section 6. Approval Appeal Process

6.1 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.

6.2 Process Overview

Applicants and approval holders may request an appeal if an application is denied or an approval is modified, suspended or terminated after a request 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; and
- State in detail the modification of the final decision sought.

The appeal process involves two basic processes: (1) Completeness Review; and (2) Evaluation. Once an appeal decision has been made, the Project Officer follows the process outlined in the Disposition Phase of the Application Review Process in Section 4.3.

6.2.1 Completeness Review

Upon receipt of the request for appeal, the Administrator, or delegate, reviews the request to determine whether the appeal materials are satisfactory and complete. This review assesses whether the request meets all of the criteria required by 49 CFR 107.717.

6.2.2 Evaluation

If complete, the appeal is evaluated by the Administrator or delegate. In most cases, the Adjudication Counsel in the Office of Chief Counsel will act as the Administrator's delegate. The Adjudication Counsel reviews the file and the decisions, and advises the Approving Official on the final agency order – including the drafting of the official Final Order on Appeal. Upon review, the reviewer may require additional information. If such information is necessary, OHMS staff will review the request and provide all necessary information at the request of the Administrator or delegate. After reviewing the materials, the Administrator issues a decision that constitutes the Final Agency Action. Refer to the Disposition Phase of the Application Review Process in Section 4.3 for closing steps.

Section 7. Expedited Application Review Process

Expedited processing may be requested for new approval applications and applications to modify an existing approval. Applicants must clearly justify why expedited processing is necessary and demonstrate that an equivalent level of safety is met or that the request is consistent with the public interest and adequately protects against the risks to life and property.

7.1 Purpose

The purpose of establishing a process for expedited processing of certain approval applications is to provide an efficient and thorough approach for evaluating applications that have an immediate and justifiable need for expedited review. Due to the time sensitive nature of many expedited applications, information is communicated among relevant PHMSA and OA Coordinating Officials, as well as the Applicant, by the most rapid means available.

7.2 Process Overview

7.2.1 Expedited Processing Justification Review

After PHMSA receives an application requesting expedited processing, the Project Officer may send, as necessary, the application to the affected OAs for simultaneous review to determine whether expedited processing is warranted. This determination is made based on the information provided in the application and through communication with the Applicant. Expedited processing may be initiated if the following criteria are met:

- Expedited processing is necessary to prevent significant injury to persons or property (other than the hazardous material to be transported) that could not be prevented if the application were processed on a routine basis; or
- Expedited processing is necessary for immediate national security purposes or to prevent significant economic loss that could not be prevented if the application were processed on a routine basis.

If timely submission of an application could have been made, PHMSA may deny the request for expedited processing despite significant economic loss. Additionally, requests for expedited processing on the basis of potential economic loss must reasonably describe and estimate the potential loss.

If the Project Officer finds that expedited processing is not warranted for the application, then the Approving Official may review the Project Officer's explanation. The decision will be communicated to the Applicant. Applications that are not processed as applications for expedited approvals based on the determination that an emergency does not will be evaluated following the standard process.

7.2.2 Completeness Phase

Upon receipt of the expedited application review request, the Project Officer evaluates application completeness using the process outlined in the completeness phase of the application review process in Section 4.1.

7.2.3 Evaluation Phase

Once the completeness phase is finished the application undergoes a fitness profile evaluation, and technical/safety evaluation as outlined in the evaluation phase of the application review process in Section 3.2. However, when expedited processing is requested, the Fitness Profile Evaluation and Technical/Safety Evaluation may occur concurrently. It is the Project Officer's responsibility to ensure the application and all supporting documentation are ready for disposition prior to sending to the Approving Official.

7.2.4 Disposition

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 8. Approval Renewal Process

8.1 Purpose

The purpose of the approval renewal process is to renew existing approvals in accordance with the requirements of the HMR and the SOPs in Part 107, Appendix A. The following sections provide an overview of the approval renewal process.

8.2 Process Overview

Approval holders may request a renewal of their approval from the Approving Official. If the applicant submits an application for renewal at least 60 days before the approval expires, the approval will not expire until final administrative action on the application for renewal has been taken.

Once PHMSA receives a renewal application, the Project Officer follows the process outlined in the completeness phase of the application review process in Section 4.1. The agency then conducts a brief evaluation of the renewal application that involves two basic processes: (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 process outlined in the evaluation and disposition phase of the application review process in Section 4.

8.2.1 Completeness Phase

Upon receipt of the renewal application, the Project Officer evaluates application completeness using the process outlined in the completeness phase of the application review process in Section 4.1.

8.2.2 Evaluation Phase

Once the completeness phase is finished the application undergoes a fitness profile evaluation, and technical safety evaluation as outlined in the evaluation phase of the application review process in Section 4.2. If there is an existing technical safety evaluation on file that is sufficient and complete in its evaluation of the approval's safety equivalency to HMR, only a fitness profile evaluation is necessary for the completion of the evaluation phase in Section 3.2. It is the Project Officer's responsibility to ensure the application and all supporting documentation are ready for disposition prior to sending to the Approving Official.

If the applicant indicates that operations under the approval continued after the expiration date, then the Project Officer notifies the Enforcement Liaison, who initiates an investigation of the applicant and communicates the results to the Project Officer.

8.2.3 Disposition Phase

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 4.3) begins.

Section 9. Agency-Initiated Approval Modification, Suspension, or Termination Process

9.1 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.

9.2 Process 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 relevant statutes or regulations have been amended;
- The activity the approval authorizes 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; or
- 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 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. When any of these actions are taken the Project Officer must coordinate with Legal Counsel, request a review and concurrence of both the action and Show Cause letter.

9.2.1 Modify, 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 the proposed action is effective immediately.

9.2.2 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 proposed action should not be taken. Once the approval holder responds, the Approving Official makes a final determination.

Section 10. Evaluation

10.1 Technical Safety Evaluation

Under 49 CFR 107.709(d), each application must 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 risks to life and property inherent in the transportation of hazardous materials in commerce;

Depending on the nature of the application, the Engineering and Research Division, the Approvals and Permits Division, and/or the applicable OA evaluates the application to determine if the level of safety achieved complies with 49 CFR 107.709(d) and that the current form is complete and uploaded to the application folder.

Note: Technical safety evaluations are not required for registration approvals.

10.2 Fitness Profile Evaluation

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. See also the definitions of “applicant fitness” and “fit or fitness” in 49 CFR 107.1. 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 or an OA.

Certification Agency and cylinder approvals do not follow the same minimum fitness review model. Certification agencies may receive an on-site fitness inspection after they submit a completed application. This on-site fitness inspection, which is described in Section 8.3, constitutes the Fitness Profile Evaluation for certification agencies approvals. Additionally, PHMSA does not conduct initial fitness profile reviews as part of processing classification approvals.

PHMSA currently evaluates an applicant’s fitness through a three-tiered Fitness Profile Evaluation. The following sections provide an overview of the three tiered review process.

10.2.1 Automated Review

10.2.1.1 Purpose

The purpose of the automated review process is to determine whether an applicant is fit to hold an approval or requires further review.

10.2.1.2 Process Overview

Once PHMSA determines that an application is complete, the agency or an OA(s) evaluates the application to determine whether the applicant is fit 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 an automated review.

The automated review process utilizes the Hazmat Intelligence Portal (HIP) or other future application processing technology. If an applicant is acting as an interstate carrier of hazardous materials, they will be screened in an automated matter based upon criteria established by the FMCSA such as those contained in the Safety Measurement System (SMS) or 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, and provides access to comprehensive information on hazardous materials incidents, special permits and approvals, enforcement actions, and other elements that support PHMSA's regulatory program.

PHMSA then screens the applicant to determine if, within the four years prior to submitting its application, the applicant was involved in any incident attributable to the applicant or package where two or more triggers for a safety profile review or five or more triggers for an on-site inspection enforcement case referral events occurred. The trigger events are located in Appendix A to Part 107, paragraph 3(b)(i)(1).

The automated review process for approvals includes using information from HIP and SMS or the SAFER System to evaluate an applicant's fitness. If the applicant does not require coordination with an OA and passes the automated review, the applicant is determined to be fit. If the applicant fails the initial automated review, the applicant is subject to a safety profile evaluation.

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 a fitness coordinator for a safety profile review, which is described below.

10.3 Company Fitness Evaluation

10.3.1.1 Purpose

The purpose of the company fitness review process is to assess applicants who were determined, during the automated review process, as meeting any of the criteria listed under the automated review in Appendix A to Part 107, paragraph 3(b)(i), and all applicants whose safety profile evaluations are subject to coordination with an OA.

10.3.1.2 Process Overview

Once PHMSA completes the automated review process and determines that additional review of the applicant is needed, the Project Officer sends a fitness referral to a fitness coordinator (see the Operational Workflow Document for applicability of an OA acting as a fitness coordinator during this review). In a safety profile evaluation, a fitness coordinator performs an in-depth evaluation of the applicant based upon items the automated review triggered concerning the applicant's four-year performance and compliance history prior to the submission of the application. Information considered during this review may include the applicant's history of prior violations, insufficient corrective actions, or evidence that the applicant is at risk of being unable to comply with the terms of an application for an existing approval or the HMR. The fitness coordinator may request additional information from the applicant in order to make the determination. PHMSA performs the review or coordinates with the OA(s), if necessary, if two or more modes of transportation are requested in the application, and coordinates this review with the OA(s) of the applicable modes. The applicable OA performs the review if one mode of transportation is requested in the application. After reviewing all the requested information, a fitness coordinator recommends that the applicant is either fit or requires an on-site fitness inspection. The fitness coordinator will forward the request and supporting documentation to PHMSA's Field Operations Division, or a representative of the Department, such as an authorized OA representative to perform an on-site inspection.

10.3.2 On-site Inspection

10.3.2.1 Purpose

The purpose of the on-site inspection process is to conduct an on-site fitness inspection of applicants who were determined, during the safety profile evaluation, to be in need of further review. During the on-site inspection process, applicants will either be determined fit or unfit to hold an approval.

10.3.2.2 Process Overview

If a recommendation for fitness is not made during the safety profile review process, PHMSA's Field Operations Division or representative of the Department, such as an OA representative conducts an on-site fitness inspection on the applicant at the recommendation of the fitness coordinator if one of the criteria in the Appendix A to Part 107, paragraph 3(b)(iii)(A) applies or according to the OA's procedures. If, either of the criterion in the Appendix A to Part 107, paragraph 3(b)(iii)(B) is met, PHMSA will determine that the applicant is unfit.

Section 11. Post-Issuance 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 transportation industry. Management and oversight responsibilities fall into two broad categories:

1. Reporting; and
2. Modification, Suspension, or Termination of Approvals.

11.1 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.

11.2 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. If an entity fails to adhere to the terms of the approval, the Approving Official may modify, suspend, or terminate the approval. See Section 9 for more information on the Modification, Suspension, and Termination of Approvals.

Section 12. 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.

12.1 Application Completeness Review Form

The Application Completeness Form is prepared and maintained by the Approvals and Permit Division. Approvals and Permits Division 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; and
- A checklist of items the applicant must provide for a complete application.

12.2 Fitness Report

The Fitness Report is prepared electronically by the HIP system and maintained by the Approvals and Permits Division. The report is used by Approvals and Permits Division staff in completing the automated review within the Safety Profile Evaluation (refer to 10.2.1). Among other information, this form contains:

- Data that indicate within the four years prior to submitting its application, the applicant was involved in any incident attributable to the applicant or package where two or more triggers for a safety profile review or five or more triggers (located Appendix A to Part 107, paragraph 3(b)(i)(1)) for an on-site inspection enforcement case referral events occurred. The trigger events are located in Appendix A to Part 107, paragraph 3(b)(i)(1)
- Data that indicate the SMS or SAFER rating and out-of-service percentage, if applicable.

12.3 Fitness Evaluation Form

The Fitness Evaluation Form is prepared and maintained by the Approvals and Permits Division to document the findings of the automated review portion of the safety profile evaluation and any shipping history and incident information that is provided by the applicant.

12.4 Safety Evaluation Form

The Application Evaluation Form is maintained by the Engineering and Research Division. Engineering and Research Division staff uses 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; and
- Recommendation to grant or deny the application.

12.5 Field Operations Division Fitness Memo or OA Recommendation

The Fitness Memorandum or OA recommendation is prepared and maintained by the Field Operations Division or the OA. The memorandum or recommendation is used by Field Operations Division or OA staff to communicate the results of a safety profile evaluation or an on-site review to the Approvals and Permits Division.

Among other data, the memorandum or recommendation contains:

- Background information on the special permits or approvals held by the person, company or entity undergoing the safety profile evaluation or on-site inspection;
- Profile of the person or company undergoing the safety profile evaluation or on-site inspection;
- Information that resulted in the initiation of the safety profile evaluation or on-site inspection;
- Field Operations Division or OA's review of the information that resulted in the safety profile evaluation or on-site inspection;
- Field Operations Division or OA's assessment; and
- Field Operations Division or OA's recommendation.

12.6 Approval Document

The Approval Document is prepared and maintained by the Approvals and Permits Division. Approvals and Permits Division 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; and
- Certain approval types will contain more specific information (e.g., identification code and symbol issued by certification agency).

12.7 Approval Extension Letter

The Approval Extension Letter may be prepared and maintained by the Approvals and Permits Division. The letter is used by Approvals and Permits Division staff to inform an applicant who has applied for renewal that the expiration date on their existing approval is being extended until final administrative action is taken on the application.

12.8 Approval Modification, Termination or Suspension Letter

The Approval Modification, Termination, or Suspension Letter is prepared and maintained by the Approvals and Permits Division. The letter is used by the Approvals and Permits Division 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; and
- Signature of the Approving Official.

12.9 Information Request Letter

The Information Request Letter is prepared and maintained by the Approvals and Permits Division of. Approvals and Permits Division 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; and
- Signature of the requestor.

12.10 Show Cause Letter

The Show Cause Letter is prepared by the Approvals and Permits Division; the Office of Chief Counsel may be consulted in the preparation but must provide concurrence. The letter is used by Approvals and Permits Division 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 proposes to terminate, suspend, or modify the approval; and
- Signature of the Approving Official.

12.11 Rejection Letter

The Rejection Letter is a standard letter prepared and maintained by the Approvals and Permits Division. The letter is used by Approvals and Permits Division staff to inform applicants and/or approval holders 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; and
- Signature of the Approving Official.

12.12 Denial Letter

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

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

12.13 Inspection Form

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

12.14 Inspection Notification Letter

The Inspection Notification Letter is a form prepared and maintained by the Field Operations Division. 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; and
- Signature.

12.15 Inspection Report

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

Section 13. Appendix A: Approval Types

The following Table presents brief definitions for the different types of approvals granted by PHMSA.

Table: 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, unless otherwise excepted, 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. An EX Approval may also prescribe packaging notes. 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 is a document prepared by the DOT or, as applicable, a fireworks certification agency that assigns the proper shipping, hazard class and identification number for the fireworks device. For more information, see 49 CFR 173.56, 173.64 and 173.65.

Approval	Definition
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 CFR173.124. 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 49CFR 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 where cylinder repair/rebuilding operations are conducted. For more information, see 49 CFR 107.805.

Approval	Definition
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 an Independent Inspection Agency (IIA) along with <i>Appendix B for Tier 1 Memo Fitness requirements</i> . 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 an Independent Inspection Agency (IIA) along with <i>Appendix B for Tier 1 Memo Fitness requirements</i> . 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 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.
United Nations (UN)/ International Organization for Standardization (ISO) Cylinder Manufacturers Approval and Certification Agencies for Portable Tanks and MEGC's	PHMSA issues approvals to act as designated certification agencies. Formerly known as Designated approval agencies (DAA's), these companies 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 and 107.402(f).
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.

Approval	Definition
UN Third-Party Packaging Certification Agencies	PHMSA issues approvals to act as UN Third-Party packaging certification agencies. Packaging certification agencies test and certify UN packagings in accordance with the requirements of the HMR. For more information, see 49CFR 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, compatibility group, and packaging) in accordance with the requirements of the HMR. For more information, see 49 CFR 173.56.
Fireworks Certification Agencies	PHMSA issues approvals to fireworks certification agencies to certify consumer fireworks meeting the requirements of UN0336 as found in American Pyrotechnic Assoc. APA 87-1 standard. For more information see 49 CFR 107.402, 173.64 and 65
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. PHMSA issues an IMDG/ICAO competent authority approval when either set of international regulations (i.e., IMDG Code or ICAO TI) requires an approval or exemption from the Competent Authority of the United States to conduct authorized activities.
International Maritime Dangerous Goods/ International Civil Aviation Organization (IMDG/ICAO) Competent Authority Approval (CAA) General CAA	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.

Appendix B: Tier 1 Memo Fitness Requirements

WHEN/WHAT TO REFER FOR A SAFETY PROFILE REVIEW AND DESKTOP REVIEW ELIGIBILITY*

<u>TYPE/DESCRIPTION</u>	<u>REFER FOR REVIEW</u>	<u>DO NOT REFER FOR REVIEW</u>	<u>ELIGIBLE FOR DESKTOP ONLY**</u>
New Cylinder Manufacturer Applications	<u>X</u>		<u>X- Conditional Only</u>
Renewal Manufacturer Applications with favorable enforcement history within last 84 months and no incidents; and an IIA renewal application also received and complete			
Renewal Manufacturer Applications with favorable enforcement history within last 84 months and no incidents; and an IIA renewal application also received and complete		<u>X</u>	
Renewal Manufacturer Applications with no inspection history within last 84 months	<u>X</u>		<u>X</u>
Renewal Manufacturers with enforcement history within last 84 months (safety violations written or incidents)	<u>X</u>		
Cylinder Manufacturer Administrative Modifications		<u>X</u>	
Cylinder Manufacturer General Modifications	<u>X</u>		<u>X</u>
Cylinder Manufacturer Process Modifications	<u>X</u>		<u>X</u>
Manufacturer Design Changes with positive Technical Review and favorable enforcement history within last 84 months		<u>X</u>	
Manufacturer Design Changes with positive Technical Review and no inspection history within last 84 months	<u>X</u>		<u>X</u>
Manufacturer Design Changes with a positive Technical Review and negative enforcement history within last 84 months (written safety violations or incidents)	<u>X</u>		
Change of Manufacturer IIA	<u>X</u>		<u>X</u>
Manufacturer and REQUALIFIER Changes:		<u>X</u>	

Appendix: | Approval Types, Tier 1 Memo Fitness Requirements

Facility Name, Address, Ownership, Management, Equipment Changes (with no concerns), Testing Personnel			
Manufacturer Equipment Changes (with concerns)	<u>X</u>		<u>X</u>
New REQUALIFIER App with a positive IIA recommendation with no findings noted		<u>X</u>	
New REQUALIFIER App with a positive IIA recommendation with corrected findings	<u>X</u>		<u>X</u>
Renewal REQUALIFIER App with a positive IIA recommendation with no findings noted and a favorable enforcement history within last 84 months		<u>X</u>	
Renewal REQUALIFIER (International RINs) App with a positive IIA recommendation with no findings noted and no inspection history within last 84 months	<u>X</u>		<u>X</u>
Renewal REQUALIFIER (Domestic RIN)- App with a positive IIA recommendation with no findings noted and no inspection history within last 84 months		<u>X</u>	
Renewal REQUALIFIER App with a positive IIA recommendation with no findings and a negative enforcement history within last 84 months (safety violations written)	<u>X</u>		
Renewal REQUALIFIER App with a positive IIA recommendation with corrected findings and a favorable enforcement history within last 84 months	<u>X</u>		<u>X</u>
Renewal REQUALIFIER App with a positive IIA recommendation with corrected findings and no inspection history within last 84 months	<u>X</u>		<u>X</u>
Renewal REQUALIFIER App with a positive IIA recommendation with corrected findings and a negative enforcement history within last 84 months (safety violations written)	<u>X</u>		<u>X</u>
New Cylinder Repair/Rebuild Facility	<u>X</u>		
Modification of Cylinder Repair/Rebuild	<u>X</u>		<u>X</u>

Appendix: | Approval Types, Tier 1 Memo Fitness Requirements

approval, if the modification sought pertains to the repair/rebuild process. Not for administrative changes			
Renewal Cylinder Repair/Rebuild Facility	<u>X</u>		<u>X</u>
New IIA applications	<u>X</u>		<u>X- Conditional Only</u>
Modification of IIA approval (non-safety critical change)		<u>X</u>	
Modification of IIA approval (safety critical change)	<u>X</u>		<u>X</u>
Renewal IIA applications	<u>X</u>		<u>X</u>
New DAAs	<u>X</u>		<u>X- Conditional Only</u>
Modification of DAA approval (non-safety critical change)		<u>X</u>	
Modification of DAA approval (safety critical change)	<u>X</u>		<u>X</u>
Renewal DAAs	<u>X</u>		<u>X</u>

***This document supersedes all prior policies regarding eligibility for safety profile evaluations and applies to international and domestic applications**

****Desktop fitness reviews will be conducted in accordance with the Desktop Approval Desk Guide. A recommendation of Conditional Fit results in a recommendation for a 2.5 year approval and the company will be scheduled for an inspection.**

*****On-site inspection is required for any manufacturer that has never been inspected by PHMSA.**

******Deviations from the criteria must be approved and documented**