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

Performance Packaging Validation Testing Program
Policies and Procedures
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1.0 Introduction

The Hazardous Materials Regulations (HMR), Title 49 CFR, Part 178, prescribe that all marked and represented hazardous materials DOT specification and UN-standard packaging must be capable of passing all performance tests set forth in the HMR. The performance marking applied to the container is the certification by the manufacturer and/or certifier that the package conforms to all HMR requirements.

In addition to required performance-oriented test requirements for marked and certified DOT specification or UN-standard packaging, the HMR prescribes certain capability and prototype testing for non-DOT specification or non-standard packaging. Examples of capability testing include the requirement that all non-bulk packaging be capable of passing vibration testing; the requirement for internal pressure testing capability for all liquid-rated packaging offered for air transportation; and prototype drop and stack testing for small quantity packaging.

The HMR provides that representatives of the U.S. Department of Transportation may request manufacturers to demonstrate the performance capabilities for packaging for which they have applied certification markings or otherwise represented performance capabilities in accordance with the HMR, or provide samples for independent verification testing by the Department.

In addition to other oversight and inspection duties and functions for packaging manufacturers, remanufacturers, reconditioners, repair facilities, testing facilities, etc., the Pipeline and Hazardous Materials Safety Administration (PHMSA), Office of Hazardous Materials Enforcement (OHME), verifies and validates performance capabilities for non-bulk and intermediate bulk containers (IBC) by subjecting such packaging to HMR performance testing for compliance determination purposes. Packaging failures determined during Validation Testing may be pursued as enforcement actions by PHMSA.

2.0 Mission

The mission of OHME's Performance Packaging Validation Testing Program is to ensure and promote safe hazardous materials packaging, including the oversight of manufacturing, certification, requalification, maintenance, and use in transportation. PHMSA accomplishes this mission, in part, by identifying suspect packaging designs and trends through compliance inspections, investigations, data collection and analysis, and Validation Testing. The data is used to focus OHME's limited resources on the greatest safety implications.

3.0 Objectives

OHME's has three primary objectives for the Validation Testing program, including safety oversight through strategic verification of package testing performance; sharing of test results with industry to address packaging concerns, including testing methods and best practices; and to gauge the effectiveness of the HMR, Special Permits and Competent Authority Approvals provisions related to performance packaging.

4. Program Policies and Procedures

OHME's Performance Packaging Validation Testing Program will be operated in accordance with:

OHME's National Business Strategy

OHME's National Packaging Strategic Plan

U.S. Army Materiel Command, Packaging, Storage and Containerization Center, Logistics Support Activity (LOGSA), Validation Testing Policies, Procedures and Standards

5.0 Definitions and Abbreviations

Validation Testing - PHMSA's program to verify, through independent HMR package testing at a facility selected by the agency, the performance capabilities for hazardous materials packaging represented as meeting HMR requirements. Validation Testing failures may be pursued as enforcement actions at PHMSA's discretion. PHMSA's Validation Testing Program includes the Alternative Validation Testing option.

Alternative Validation Testing (AVT) - PHMSA's initiative to provide packaging manufacturers the option to demonstrate, through full HMR testing at their testing facility or an outside testing facility, the performance capabilities for hazardous materials packaging represented as meeting HMR requirements. AVT participation by the packaging manufacturer is voluntary; however, a manufacturer's acceptance is binding. PHMSA will purchase designs for independent testing at the U.S. Army, LOGSA, Tobyhanna, PA, if the manufacturer chooses not to participate.

AVT projects will be considered official and enforcement action may be taken for testing failures. PHMSA reserves the right to offer AVT on a case-by-case basis. The manufacturer must submit a test report with results for all tests conducted for each project. Failure to comply with the terms of AVT offers may result in the manufacturer or their outside testing facility being prohibited from future offers to participate in the program.

LOGSA - U.S. Army Materiel Command, Packaging, Storage and Containerization Center, Logistics Support Activity (LOGSA), Tobyhanna, PA.

Manufacturer - the person who marks or otherwise represents that a hazardous materials package meets HMR requirements. For the purposes of this document, manufacturer shall also refer to reconditioners, remanufacturers or repair facilities.

6.0 Order of Precedence for Project Selection

Order of Precedence

An exact order of precedence for Validation Testing design selection is not possible due to the vast size and scope of the U.S. packaging system and changing safety priorities. However, all testing projects are focused on risk factors and consequences for transportation related incidents. The following items are primary indicators that drive OHME's design selection for Validation Testing and related manufacturer inspections:

Performance Rating – (Packing group, specific gravity and vapor pressure rating)
Examples: ultra-high performance certifications such as UN1A1/X1.8/300 rated steel drums and composite IBC's with specific gravity ratings of 1.9 or vapor pressure ratings above 80 kPa.

Design-Type of Container (Highest frequency for use)
Examples: UN1A1and 1H1 drums, 31HA1 IBC's, 4G boxes

Capacity of Container (Larger capacity containers increase consequence for failures)
IBC's, 55-gallon drums, etc.

Mode of Transportation – Air, vessel, highway then rail
Example: UN4G combination packaging authorized for liquids by air

Hazard Classification of Material (Precedence set in HMR)
Packaging for high hazard materials; Class 3 and 8 materials as predominant materials, etc.

Special Permit and Competent Authority Approvals (Related to packaging)

Past Validation Testing Experience
Retesting based on past Validation Testing failures**;** Little or no prior Validation Testing for design-type; Little or no prior Validation Testing for manufacturer

Complaints, Accidents and Incidents (Related to performance packaging)

Remanufactured, Reconditioned and Repaired Packaging
55-gallon steel and plastic drums; Repaired and remanufactured composite IBCs

Designs certified based on Selective Testing (Section 178.601(g))

7.0 Validation Testing Options Overview

7.1 Validation Testing by LOGSA

From 1996 through August 2008, all PHMSA Validation Testing projects were tested by LOGSA. LOGSA is the U.S. Department of Defense's primary test facility for hazardous materials transportation packaging. LOGSA also serves as an independent testing facility for PHMSA. As an independent testing facility, LOGSA has no interest in testing outcomes. PHMSA selects all packaging for Validation Testing at LOGSA.

All packaging selected for Validation Testing at LOGSA are tested in accordance with HMR requirements. LOGSA utilizes ASTM D4919 for testing protocols and procedures. LOGSA's Performance-Oriented Packaging Testing Policies and Procedures document can be obtained from PHMSA's website: http://www.phmsa.dot.gov/hazmat/enforcement/programs/packaging enforcement program.

7.2 Alternative Validation Testing (AVT) Option

Subject to PHMSA resources and discretion, packaging manufacturers and their outside testing facility (in most cases the testing facility that last conducted qualification or periodic testing on the design of interest) may be offered the opportunity to conduct Validation Testing, in lieu of LOGSA testing, for designs selected by PHMSA investigative staff to determine performance capabilities based on the marked performance certification. All Validation Testing to be conducted by industry will be described as Alternative Validation Testing (AVT).

PHMSA introduced AVT in response to industry requests for additional options to Validation Testing at LOGSA. PHMSA will also use AVT to gain insight and collect data on industry testing practices in support of efforts to improve packaging safety and reliability, and to strengthen and promote the U.S. packaging system. Best practices recommendations for packaging professionals and evaluation of HMR requirements are important initiatives that PHMSA seeks to promote through AVT.

PHMSA will decide if AVT will be offered on a case by case basis. Validation Testing related to accidents, incidents or other investigations such as complaints may not be eligible for AVT. Packaging qualified based on split-testing at two different locations may not be eligible for AVT due to the added time and expense for PHMSA to observe the testing at different facilities.

AVT may not be offered when an enforcement action is pending against the packaging manufacturer or their outside testing facility. Offers may be rescinded at PHMSA's discretion if an enforcement action against the packaging manufacturer or their outside testing facility arises after the AVT offer has been accepted. AVT may not be offered if probable violations are noted in relation to the selection of a design for testing, an inspection of the manufacturing facility or the outside testing facility.

7.3 Determination of Testing Location – Validation Testing or AVT

PHMSA will make the determination on which testing option will be pursued - Validation Testing at LOGSA or AVT, on a case by case basis. In most routine testing circumstances, PHMSA will offer AVT.

AVT may not be offered if PHMSA determines that the design was not properly manufactured, tested, certified and marked in accordance with HMR requirements.

AVT may not be offered if the test report does not fully identify the manufacturer and specification for each component of the packaging, or if the assembly and closure description does not allow for exact replication of the design as it was last tested. The test report must be fully descriptive in regard to the testing protocols, methods, packaging orientation(s), fitting placements, etc., to allow for replication during the AVT observation.

One of the goals for the AVT initiative is to allow the manufacturer to demonstrate performance testing for the design selected by PHMSA as it was last tested, using the same methods and protocols as before. Therefore, PHMSA must be able to determine that no unauthorized design changes have been made by the manufacturing since testing and certification and that the packaging preparation and testing for the AVT observation will be in-keeping with the protocols and test methods employed during the previous test project. Promoting consistency in preparation and testing is a primary objective for PHMSA.

8.0 Pre-Requisites for Design Selection, Packaging Sources and Lot Sizes

8.1 Plant Inspection and Compliance Determination

PHMSA prefers to conduct an inspection of the packaging production facility in conjunction with the packaging selection. PHMSA seeks to determine the manufacturer's compliance position prior to determining the location for testing - Validation Testing at LOGSA or the AVT option.

During the production facility inspection, the investigator will determine to the greatest extent possible that the packaging design(s) of interest was properly manufactured, tested, certified and marked in accordance with the HMR. PHMSA's Validation Testing program is designed to confirm performance capabilities for designs as tested and certified. PHMSA intends to conduct Validation Testing/AVT primarily for designs that are HMR compliant. PHMSA does not routinely conduct Validation Testing for designs that are not HMR complaint, except in support of investigations, National Business and Packaging initiatives, research testing at LOGSA, etc.

In the event that PHMSA chooses to test non-HMR compliant packaging designs for enforcement purposes, PHMSA will generally not offer AVT. Samples will purchased for independent Validation Testing at LOGSA.

8.2 Statement on Validation Testing for Reconditioned Drums

Alternative Validation Testing for reconditioned drums will not be offered if the written assembly and closure instructions provided to customers are unclear in exactly how to assembly and close the containers or the instructions do not match the components supplied with the packaging. All reconditioned drums for AVT or Validation Testing will be prepared for testing based on the assembly and closure instructions provided by the reconditioner.

The performance marking applied by the reconditioner to the side of each package may not be higher than the original performance marking embossed on the bottom of the container by the manufacturer, unless the design was tested and certified by the reconditioner (remanufacturer in this scenario).

Steel drums that do not meet minimum thickness requirements for reuse as hazardous materials transportation packaging will not be authorized for AVT because the containers do not comply with HMR provisions.

8.3 Packaging Sources

Although packaging samples may be obtained for AVT or Validation Testing from all sources, PHMSA's preferred source is direct from the packaging manufacturer as part of an inspection of the production facility. If a plant inspection is not possible or warranted, or inventory is not maintained by the manufacturer at the production site, the investigator may seek to obtain samples from the manufacturer's network or direct from packaging distributors or end-users.

PHMSA will not authorize Validation Testing for samples produced by the manufacturer for the purpose of Validation Testing. PHMSA seeks to obtain samples from existing inventory or during production. All packaging samples for AVT or Validation Testing will be physically examined, marked and secured by PHMSA OHME investigative staff when possible.

8.4 Packaging Purchase and Securement

LOGSA will reimburse vendors for packaging, handling and shipping related expenses for samples selected for Validation Testing at LOGSA. The packaging manufacturer or other source for samples may not release shipments to LOGSA for Validation Testing until arrangements are made for payment and shipment release.

AVT expenses will be the manufacturer's responsibility, including packaging, shipping and testing.

All samples will be marked with OHME approved evidence tape, including the investigator's report number. When possible, all packaging samples will be secured with stretch-wrap film to prevent tampering.

8.5 Sample Lot Size for Validation Testing at LOGSA *

Single packaging - 24 units
Combination packaging - 20 units
Intermediate bulk containers (IBCs) – 5 units
Regulated medical waste poly bags (red bags) – 20 units

* The number of samples for Validation Testing exceeds the minimum number of samples required for HMR testing. Additional tests may be conducted at PHMSA's request to confirm failures. Additional samples are also selected in the event of damage in transportation or handling, missing components, etc.

8.6 Sample Lot Size for AVT*

Single packaging - 24 units
Combination packaging - 20 units
Intermediate bulk containers (IBCs) – 5 units
Regulated medical waste poly bags (red bags) – 20 units

* The number of samples for AVT exceeds the minimum number of samples required for HMR testing. Additional samples are secured in the event of damage, missing components, etc., or to conduct additional testing in the event of improper procedures or test malfunctions. The manufacturer or its outside testing facility may also use the additional samples to repeat failed tests, but only after official testing is completed and subject to sample availability.

9.0 Program Terms and Procedures

9.1 AVT Offer Terms

AVT offers will be made by PHMSA on a case by case basis. AVT offers that are declined will lead to Validation Testing at LOGSA. AVT expenses related to packaging, shipping and testing will be the responsibility of the manufacturer. AVT results will be official and enforcement action may be taken for test failures.

AVT offers will be recorded with a PHMSA completed AVT Offer Form issued to the packaging manufacturer. If the packaging manufacturer accepts the offer and the testing is to be conducted by an outside testing facility, a separate AVT offer form with terms for the project will be prepared and presented to the outside testing facility. Both parties must agree to the terms of the offers. Failure to abide by the terms of the offers may lead to project termination at PHMSA's discretion at any time in the AVT project process.

AVT must be conducted by the last testing facility that qualified the design. Exceptions may be made at PHMSA's discretion if the outside testing facility is not eligible to participate, declines to participate, or if PHMSA chooses not to allow them to participate.

AVT projects should be concluded, including report issuance, within 12 weeks from the date of the offer subject to PHMSA discretion and scheduling with the packaging manufacturer and outside testing facility, if used.

If HMR provisions for testing and reporting are not met, or for Third Party Lab testing the terms of their Competent Authority Approval, PHMSA may terminate the project or consider the results invalid. AVT projects that are considered invalid will lead to LOGSA testing of a second set of samples purchased when the AVT offer was made to the manufacturer. LOGSA's results will be considered official and enforcement action may be taken for failures.

Failure to comply with the terms of AVT projects may result in rescission of the current offer and/or denial of future AVT project offers for the manufacturer and/or their outside testing facility. PHMSA will document AVT

project results in an exit briefing provided to the packaging manufacturer.

9.2 AVT Offer Acceptance Timeframe

When PHMSA chooses to offer AVT to the packaging manufacturer, the investigator of record will complete the AVT Offer Form (see below) for each design selected for Validation Testing. The completed form(s) will be provided to the manufacturer as soon as possible. In the event that AVT is offered to the packaging manufacturer, the following scenarios are provided as examples of the timeframes for acceptance of the offer -

AVT to be conducted at the production plant: If AVT is offered during an inspection at the manufacturing facility where the design was produced and qualified, the manufacturer should accept or decline AVT during the inspection.

AVT to be conducted at a different packaging manufacturer-owned facility: If AVT is offered during an inspection at the manufacturing facility, but the qualification testing was conducted at a different facility operated by the manufacturer, the manufacturer should decide to accept or decline AVT during the inspection.

AVT to be conducted at a third party laboratory or other outside testing facility: If AVT is offered during an inspection at the manufacturing facility, but the design was last tested by an outside testing facility, the outside testing facility should be contacted as soon as possible to ask if they desire to participate in the initiative on behalf of the manufacturer. In the event that the outside testing facility cannot make a decision at the time of the AVT offer, samples will be secured and marked for LOGSA testing. If the outside testing facility declines to participate in the AVT project, the samples will be purchased for independent Validation Testing at LOGSA.

AVT to be conducted based on samples selected from a distributor or end-user: If AVT is to be offered based on packaging selected from a distributor or end-user, the manufacturer will be contacted immediately. If the manufacturer is unable to accept the offer during packaging selection, the samples will be secured for Validation Testing at LOGSA.

9.3 AVT Project Completion Timeframe

All AVT projects, including report issuance by the testing facility, should be completed as soon as possible, but no later than 12 weeks from the day the offer is accepted by the manufacturer.

If the design was last qualified at the production facility being inspected by PHMSA, the testing should be conducted during the inspection, if possible. If arrangements can be made for the investigator to return at a later time, PHMSA will delay the testing start date.

AVT to be conducted at an outside testing facility will be arranged for the convenience of PHMSA, the manufacturer and the testing facility, in keeping with the 12-week timeline.

9.4 AVT Project Observation, Preparation, Testing and Reporting

AVT projects will be observed by PHMSA during all phases of the process, including unpacking, quality assurance audit (weights and measurements), filling, closing, conditioning and testing, unless authorized by PHMSA. PHMSA may approve limited preparation and testing in advance of the scheduled test dates to facilitate completion, particularly for drop test samples that require conditioning to zero degrees Fahrenheit. All requests must be approved by PHMSA in advance.

AVT packaging will be assembled, filled and closed based on the test report instructions. All testing will replicate the prior testing for protocols and actual test orientations, fixturing, drop angles, etc. Reconditioned drums will be assembled and closed in accordance with instructions provided to customers. AVT packaging will be tested based on the performance marking applied to the containers.

AVT will include all prescribed and capability tests set forth in the HMR. Each test will be conducted on separate sample packaging. If failures are determined during testing, all remaining tests and test series must be conducted. Subject to availability of additional test samples obtained for the project, failed tests may be repeated for information purposes only. The results of additional tests conducted after a failure must be documented in the test report with the outcome. Project outcomes will be in accordance with HMR criteria for pass/fail determination –a failure or failures in any series is considered a project failure.

AVT projects must be documented in a test report, including outcomes for all tests. Test reports for projects conducted by the manufacturer shall be prepared in accordance with HMR, 49 CFR § 178.601(l) or 178.801(l), as applicable. Projects conducted by an outside testing facility (Third Party Lab) on behalf of the manufacturer shall be prepared by the test facility in accordance with the UN Third-Party Certification Agency Approval issued to the laboratory. AVT test reports must be provided to PHMSA within 10 business days after testing.

PHMSA will document the results of the project in an exit briefing to be provided to the packaging manufacturer at the conclusion of the testing.

9.5 AVT Comparison Testing at LOGSA

When AVT is offered, PHMSA will purchase a set of samples for comparison testing at LOGSA in support of the agency initiative to gain more insight on testing methodologies and outcomes. LOGSA's comparison test results will be considered additional information only, except in the event that the AVT testing was not in accordance with HMR provisions for packaging preparation, conditioning, testing and pass/fail determination, when the terms of the AVT offer are not met, or when PHMSA rescinds or terminates AVT offers or cancels projects.

9.6 LOGSA Validation Testing Program Overview

Projects are prioritized by LOGSA in the order that PHMSA designates. All testing will be completed, subject to PHMSA priorities and LOGSA availability, within 12 weeks of packaging receipt.

Packaging will be assembled, filled and closed based on the test report instructions. Reconditioned drums will be assembled and closed in accordance with instructions provided to customers. Packaging will be conditioned and tested in accordance with HMR and ASTM D4919. Packaging will be tested based on the performance marking applied to the containers. Testing will be in accordance with HMR criteria for pass/fail determination and outcome (one fail, all fail).

Projects will be fully documented in a test report, including pass/fail results. Video of each test will be recorded. The test report and video will be provided to the manufacturer. LOGSA maintains all failed samples until disposal is authorized by PHMSA.

10.0 Post-Validation Testing

At the conclusion of all Validation Testing projects, the investigator shall provide the manufacturer with an exit briefing detailing the results of the tests. The manufacturer shall have 30 days from issuance of the exit briefing to exercise, document and forward corrective action to the investigator.

PHMSA's enforcement options for Validation Testing failures include letters of warning, civil penalty actions, compliance orders, public safety notices and corrective action orders. Several factors are considered in PHMSA's determination, including the number, type and the extent of failures. Each project is different and PHMSA weighs all factors when deciding what, if any, action to take for testing failures.

In the event of Validation Testing failures, the manufacturer may submit any evidence of corrective action taken to improve design performance, including additional testing of samples, to the investigator for inclusion in the investigator's inspection report.