



Office of Hazardous Materials Safety

Procedure for Removal of Nonconforming Hazardous Materials Packagings from Service, 7-13-95

When a nonconforming packaging is identified, including during the course of an inspection or investigation, the Research and Special Programs Administration's (RSPA's) Office of Hazardous Materials Enforcement (OHME) will collect all available data on the manufacturing process and the performance of the packaging. In consultation with the Office of Hazardous Materials Technology (OHMT) and the Office of Chief Counsel (OCC), the OHME will make an initial assessment of the hazard and risk presented by the nonconforming packagings using criteria in Appendix A, Assessment Guidelines for Nonconforming Packagings. Should inadequate information be available to make an initial assessment, OHME will request the alleged violator to take immediate action to develop the information necessary to make an assessment of the hazard and risk presented by the nonconforming packaging. At a minimum, such actions must include testing of random samples of the nonconforming packaging and analyses of potential variance in packaging properties and performance. Based upon the initial assessment of hazard and risk, OHME will determine the appropriate action that will be taken, based on the following:

1. If an "imminent hazard" exists (i.e., there is a substantial probability that death or serious injury will occur from frequent worker or public exposure to hazardous materials or frequent packaging failures), OHME will request immediate action by the alleged violator to remove the packagings from service or other action to ameliorate the hazard presented by the suspect packagings. OCC will initiate action under Section 49 U.S.C. 5122 of the Hazardous Materials Transportation Laws if necessary to eliminate or ameliorate the imminent hazard. In addition, RSPA will publish an appropriate notice in the Federal Register and other appropriate publications about the defective packagings, if deemed necessary to protect the public. Finally RSPA will initiate appropriate enforcement action, through OCC, as described below in paragraphs 2 and 3.

2. If a "lesser hazard" exists, RSPA will request that the alleged violator take appropriate and timely corrective action. Such action may include additional analysis and/or testing to determine the nature and extent of the problem and costs and consequences of actions including removal of packaging from service, retrofitting, derating, operational controls and notification to customers. Publication in the Federal Register and other publications will be determined on a case-by-case basis. RSPA will initiate appropriate enforcement action, through OCC, which may include a compliance order under Section 109(a) of the hazardous materials transportation laws or withdrawal of an exemption or approval (if applicable).
3. If "very minimal or no hazard" exists, OHME will initiate appropriate enforcement action through OCC.

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Appendix A, Assessment Guidelines for Nonconforming Packagings

Based upon the type of noncompliance and its consequence, packagings manufactured in noncompliance with their specification may or may not be unsafe for service. DOT Specifications often contain substantial factors of safety to provide a margin of safety, allow for unknown and unexpected factors and unintentional variations in manufacture, and provide long package life. In addition, many packagings are often operated below their design conditions which provides an addition factor of safety and reduced public risk when operated in such a manner. For example, welded low pressure cylinders are often used to transport materials with a vapor pressure well below the service pressure of the cylinder, thus adding an additional factor of safety to that built into the specification. For these reasons, a hazard and risk assessment must be performed on a case-by-case basis. In consideration of safety factors built into specification packagings, a variation of 5% or less from values for material properties, test conditions, acceptance criteria, minimum wall thickness, or marked values are of very minimal or no safety hazard.

Recalls of packagings or removal of specification or exemption markings from a large group of packagings, thereby prohibiting their use in hazardous materials service, is a very serious action with potentially very large economic and safety consequences. Such actions should be taken only when the impact of such actions is understood and taken into consideration. Such actions can often bankrupt a manufacturer and a number of its customers or create health and safety problems greater than they alleviate. A risk assessment matrix and a risk index are provided to give guidance in relating failure consequence and frequency of occurrence and in ranking the resultant risk (Figure 1). The following are factors that must be considered when assessments of hazard, risk and recall or safety countermeasures are performed:

1. What is the expected failure mode? Rupture, leakage, permanent expansion or reduced performance in an accident environment?
2. What are the hazards and consequences of the expected package failure mode and of the release of the hazardous materials transported?
3. How many packagings are involved and in what service are they used?
4. What is the worker and public exposure to the subject packagings?
5. What is the likely packaging failure rate resulting from the package defect? How does this rate compare to other package and transportation system failure rates?

6. Are alternative packagings available? Alternative packagings are often not available for many exemption or specialized packagings.
7. What are the safety consequences of removing packagings from service? Many hazardous materials and packagings provide health and safety benefits for society. Removal of such materials or packagings, particularly when no or few alternatives are available, may create greater health and safety risks than those alleviated by removing nonconforming packagings. A large increase in trips or the number of alternative packagings can increase the probability of deaths and injuries from increases in transportation, loading, and unloading accidents.
8. What are the economic impacts of removing packagings from service on packagings manufactures, shippers and end users of the packaging or materials transported?
9. What other options are available? Derating, operational controls, retrofit, or phased removal from service?
10. What are the best methods of reaching persons who possess nonconforming packagings? What is the probability of success?

A defect should be considered an "imminent hazard" when there is a substantial probability that death or serious injury will occur from frequent worker or public exposure and frequent packaging failures. An imminent hazard requires immediate public notification of the hazard and initiation of actions to eliminate or ameliorate the imminent hazard.

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RISK ASSESSMENT MATRIX

Frequency of Occurrence Categories	Consequence of Occurrence Categories				
	(I) Cata- strophic	(II) Critical	(III) Marginal	(IV) Minor	(V) Neglig- ible
(A) Frequent	(IA) U	(IIA) U	(IIIA) U	(IVA) C-MDR	(VA) A-MRR
(B) Probable	(IB) U	(IIB) U	(IIIB) C-MDR	(IVB) A-MRR	(VB) A-MRR
(C) Occasional	(IC) U	(IIC) C-MDR	(IIIC) A-MRR	(IVC) A-MRR	(VC) A
(D) Remote	(ID) C-MDR	(IID) A-MRR	(IIID) A-MRR	(IVD) A	(VD) A
(E) Improbable	(IE) A-MRR	(IIE) A-MRR	(IIIE) A	(IVE) A	(VE) A

RISK INDEX:

IA, IB, IC, IIA, IIB, IIIA	U	UNACCEPTABLE
ID, IIC, IIIB, IVA	C-MDR	CONDITIONAL - MANAGEMENT DECISION REQUIRED
IE, IID, IIIC, IVB, IVC VA, IVB, VB,	A-MRR	ACCEPTABLE - MANAGEMENT REVIEW REQUIRED
IIIE, IVD, IVE, VC, VD, VE	A	ACCEPTABLE

Figure 1. RISK ASSESSMENT MATRIX AND RISK INDEX