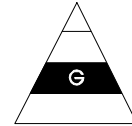


DOE G 460.1-1

06-05-97



IMPLEMENTATION GUIDE
for Use with
DOE O 460.1A,

PACKAGING AND TRANSPORTATION SAFETY



**ASSISTANT SECRETARY FOR
ENVIRONMENTAL MANAGEMENT**

FOREWORD

This *Guide* is approved by the Office of Transportation, Emergency Management, and Analytical Services (EM-76) for use by all DOE Elements and their contractors. Electronic access to this document and beneficial comments to improve this document can be submitted via the packaging and transportation safety home page. The Universal Resource Locator address for this is :

<http://www.ornl.gov/pats/pats.htm>

DOE Guides are part of the DOE Directives System and are issued to provide supplemental information regarding the Department's expectations of its requirements as contained in rules, Orders, notices, and regulatory standards. Guides may also provide acceptable methods for implementing these requirements. Guides are not substitutes for requirements, nor do they replace technical standards that are used to describe established practices and procedures for implementing requirements.

DOE and its contractors are responsible for basic and applied research; product development; and designing, constructing, operating, modifying, and decommissioning DOE facilities and sites to effectively accomplish DOE's missions and objectives. This work must be accomplished while minimizing potential hazards to the public, site or facility workers, and the environment. DOE O 460.1A, *PACKAGING AND TRANSPORTATION SAFETY*, 10-2-96, prescribes a comprehensive safety program for the DOE and DOE-contractor packaging and transportation operations.

This *Guide* provides information concerning the use of current principles and practices, including regulatory guidance from the U. S. Department of Transportation and the U. S. Nuclear Regulatory Commission, where available, to establish and implement effective packaging and transportation safety programs. The intent of this *Guide* is to aid in the development of implementation plans to effectively carry out the requirements and responsibilities of the Order.

CONTENTS

	<u>PAGE</u>
FOREWORD	I
I. INTRODUCTION	1
II. APPLICABILITY	1
1. DEPARTMENT OF ENERGY ELEMENTS	1
2. CONTRACTORS	1
3. EXCLUSIONS	2
III. GENERAL INFORMATION	2
IV. GUIDELINES	4
1. OFFSITE PACKAGING AND TRANSPORTATION SAFETY	4
2. GUIDANCE FOR DEPARTMENT OF ENERGY EXEMPTIONS	6
2.1 CONTENT AND FORMAT FOR SUBMITTAL	6
2.2 REVIEW PROCESS GUIDANCE	8
2.2.1 Operations Office Responsibility Guidance	8
2.2.2 Evaluation Guidance for EM	8
2.2.3 Requesting Organization	8
3. GUIDANCE FOR DEPARTMENT OF TRANSPORTATION EXEMPTIONS	8
4. SPECIAL PACKAGING FOR RADIOACTIVE MATERIALS	9
4.1 INTRODUCTION	9
4.2 DOE APPROVED TYPE A PACKAGES	10
4.2.1 Responsibilities	10
4.2.2 Contractor Testing Facilities Approval	10
4.2.2.1 The DOT Test Program for DOT Specification 7A Type A	

	Package Designs	11
		<u>PAGE</u>
	4.2.2.2 Procedure for Establishing a Test Facility	13
	4.2.2.3 Established Requirements for Type A Packaging	15
	4.2.2.3.1 Documentation Review	15
	4.2.2.3.2 Test Requirements	16
	4.2.2.4 Quality Assurance	17
	4.2.3 Application for Packaging Approval	17
	4.2.4 Use of <i>Blue Book</i> Packagings	20
4.3	DOE CERTIFIED TYPE B PACKAGES	21
	4.3.1 Responsibilities	21
	4.3.2 SARP Preparation and Submission	22
	4.3.3 Review Process Guidance	22
	4.3.4 Renewal of DOE Certificates of Compliance	22
	4.3.5 Use of DOE Certified Packages	23
	4.3.6 The Program for Review of Fabrication, Use, and Maintenance of DOE Certified Packages	23
4.4	USE OF OTHER APPROVED OR CERTIFIED PACKAGINGS	24
	4.4.1 NRC Certified Packaging	24
	4.4.2 DOT Specification Containers	24
	4.4.3 International Atomic Energy Agency (IAEA) Approvals	24
5.	ONSITE TRANSPORTATION SAFETY REQUIREMENTS	25
	5.1 INTRODUCTION	25
	5.1.1 Purpose	26

	<u>PAGE</u>
5.1.2 Discussion	26
5.2 GUIDANCE TO RESPONSIBILITIES	27
5.2.1 Operations Office and Field Office Managers	27
5.2.2 Contractor Management	27
5.3 PREPARATION OF TRANSPORTATION SAFETY DOCUMENTS	27
5.3.1 Introduction	27
5.3.2 Preferred Format for Transportation Safety Documents	28
5.4 Safety Assessment Methodology	33
5.4.1 Use of a Graded Approach	33
5.4.2 Safety Assessment	34
6. REFERENCES	39
 ATTACHMENTS	
1. Selected Chronological Milestones Concerning Department of Energy Orders 1540.2 and 5480.3	43
2. Letter, Judith S. Kaleta, Chief Counsel, U. S. Department of Transportation to Susan H. Denny, Director, Transportation Management Division, U. S. Department of Energy, April 23, 1991	45
3. Letter, E. H. Bonekemper, Assistant Chief Counsel, U. S. Department of Transportation to Jo Ann Williams, Office of Chief Counsel, U. S. Department of Energy, April 26, 1993.	51
4. Capability of Test Facilities for Testing Type A Packagings	57
5. Quality Assurance for Contractor Testing Facilities	63
 FIGURES	
IV.1. Procedural steps for testing and approving a Type A radioactive material packaging	12

PAGE

IV.2. Procedural steps for establishing a Type A test program at a
test facility 14

IV.3. Available options for complying with DOE O 460.1A 35

TABLE

IV.1. DOE O 460.1A responsibility matrix with guidance document 5

PACKAGING AND TRANSPORTATION SAFETY

I. INTRODUCTION

This *Guide* supplements the Department of Energy (DOE) Order, DOE O 460.1A, *PACKAGING AND TRANSPORTATION SAFETY*, 10-2-96, by providing clarifying material for the implementation of packaging and transportation safety of hazardous materials. DOE O 460.1A replaces DOE O 460.1, *PACKAGING AND TRANSPORTATION SAFETY*, September 27, 1995, which replaced 1540.2, *HAZARDOUS MATERIAL PACKAGING FOR TRANSPORT ADMINISTRATIVE PROCEDURES*, September 30, 1986, and DOE 5480.3, *SAFETY REQUIREMENTS FOR THE PACKAGING AND TRANSPORTATION OF HAZARDOUS MATERIALS, HAZARDOUS SUBSTANCES, AND HAZARDOUS WASTES*, July 9, 1985, and contains new requirements for onsite safety and motor carrier safety. In addition, DOE O 460.1A includes aviation safety, pipeline safety, and international packaging and transportation regulations.

II. APPLICABILITY

This *Guide* should be considered when establishing the onsite and offsite packaging and transportation safety programs for a facility. Opportunities exist for demonstration of compliance to the Order by actions other than those set forth in this *Guide*. However, if a provision in this *Guide* is included explicitly in a contract, an enforceable obligation is thereby created through that document.

1. DEPARTMENT OF ENERGY ELEMENTS

Except for the exclusions in paragraph 3, below, the Order applies to all DOE Elements.

2. CONTRACTORS

Except for the exclusions in paragraph 3, below, the *Contractor Requirements Document (CRD)*, which is attached to the Order, sets forth requirements that are to be applied to the universe of

contractors awarded contracts for managing and operating DOE facilities. Contractor compliance with the CRD will be required to the extent set forth in a contract. Contractors shall be directed to continue to comply with the requirements of Orders canceled by the Order until their contracts are modified to delete the reference to the requirements of the canceled Orders.

3. EXCLUSIONS

Activities that are regulated through a license by the Nuclear Regulatory Commission (NRC) or a state under an agreement with the NRC, including activities certified by the NRC under section 1701 of the Atomic Energy Act. Requirements of the Order that overlap or duplicate the requirements of the NRC related to radiation protection, nuclear safety (including quality assurance), and safeguards and security of nuclear material, do not apply to the Office of Civilian Radioactive Waste Management facilities.

Excluded from the requirements of the Order are: classified shipments; shipments of nuclear explosives, components, and special assemblies (see DOE 5610.12, PACKAGING AND OFFSITE TRANSPORTATION OF NUCLEAR COMPONENTS AND SPECIAL ASSEMBLIES ASSOCIATED WITH NUCLEAR EXPLOSIVE AND WEAPON SAFETY PROGRAM, 7-26-94); and facilities and activities of the Naval Nuclear Propulsion Program (see Executive Order 12344).

III. GENERAL INFORMATION.

In 1986, the Office of Environment, Safety and Health (EH) responsibilities for DOE certificates of compliance, U.S. Department of Transportation (DOT) exemption requests, and DOE alternatives were introduced into DOE 1540.2 in Chapters II, III, and IV. These responsibilities have been combined with the hazardous materials transportation requirements of DOE 5480.3 into a new Order, DOE O 460.1. What was formerly known as DOE alternatives are now referred to as DOE exemptions in order to be consistent with the new Directives process. In February 1996, the EH and EM transportation functions were merged into one organization in the Office of Transportation, Emergency Management, and Analytical Services (EM-76). A list of selected chronological milestones concerning DOE 1540.2 and 5480.3 is included for historical reference in Attachment 1.

The basis of the offsite safety requirements for this Order is in Paragraph 4.a.(1)(a) which states that each package and shipment of hazardous materials shall be prepared in accordance with the DOT's Hazardous Materials Regulations (49 CFR 106–199). This statement was the heart of DOE 5480.3 and is carried over here without change. Relief from this requirement is obtained only by a DOT exemption request [Paragraph 4.a.(3)], which is submitted through EM.

For DOE operations that transport packages in DOE vehicles with DOE drivers or DOE contractor drivers who are employees of State agencies, Paragraph 4.a.(1)(b) stipulates that the DOT Hazardous Materials Regulations shall be followed by virtue of this Order. Relief from this requirement is obtained from EM by means of a DOE exemption request [Paragraph 4.a.(2)]. In 1991, in response to an inquiry from Ms. Susan Denny, DOE Transportation Management Division, about the definition of "public highway," DOT replied as shown in Attachment 2. This response restated that DOE and DOE contractors qualify as a "person" within the meaning of the Hazardous Materials Transportation Uniform Safety Act of 1990. The response also restated that DOE contractors must comply with the Hazardous Materials Regulations even when transportation is in a government vehicle if the shipment was deemed "in commerce." Another important provision of this DOT response was to clarify that the meaning of "in commerce" was transport over roads to which the public had unrestricted access. The requirements necessary to prohibit "public access" and meet the definition of "not in commerce" (or the more commonly used term "onsite") were stated in this letter. This important interpretation by DOT is frequently referred to as the *Susan Denny Letter* and is included for its continuing importance to proper DOE operations.

In 1993, DOT declared in a written opinion to DOE that employees of DOE contractors which are State agencies (e.g., University of California) are not subject to all the provisions of the Hazardous Materials Transportation Act. As a result, DOE has included the employees of these exempt entities in this Order as if they were DOE employees, and so states in Paragraphs 4.a.(1)(b) and 4.c.(2). The DOT letter on this subject is included in Attachment 3. The entities determined to exist in this category are:

Los Alamos National Laboratory (University of California)
Lawrence Livermore National Laboratory (University of California)
Lawrence Berkeley Laboratory (University of California)

Ames Laboratory (Iowa State University)

Savannah River Ecology Laboratory (University of Georgia)

The following section contains guidelines for the items in DOE O 460.1A that are unique to DOE requirements; that is, the guidelines do not include counsel for compliance with the DOT or NRC regulations per se.

IV. GUIDELINES.

Some of the responsibilities defined in DOE O 460.1A for EM, other secretarial offices, and the heads of operations or field offices are further clarified in the following sections. Table IV.1 shows a matrix that describes where the responsibilities from DOE O 460.1A may be found in the various subsections of this *Guide*. Where a responsibility was deemed to be self-explanatory in the Order, no further guidance or interpretation is presented herein. The contractor's responsibilities are found in the *Contractor Requirements Document*, Attachment to DOE O 460.1A. Guidance for contractor's responsibilities is provided as appropriate in this *Guide*.

1. OFFSITE PACKAGING AND TRANSPORTATION SAFETY

Hazardous materials shipments prepared or performed by DOE contractors offsite at a DOE facility or, as defined by DOT, "in commerce," are subject to the Hazardous Materials Regulations of DOT, and contractors who operate DOE vehicles in interstate commerce or transport hazardous materials intrastate are also subject to the Federal Motor Carrier Safety Regulations of the Federal Highway Administration. DOE O 460.1A requires DOE employees and contractors who are employees of State agencies to comply with the Hazardous Materials Regulations and the Federal Motor Carrier Safety Regulations as if they were regulated by DOT. Interpretation has been provided by DOT (Attachments 2 and 3) as to what constitutes "in commerce," how facility shipments may be taken out of commerce, and what is the applicability of the Hazardous Materials Transportation Act to State or local entities and their employees. Guidance by DOE for meeting another federal agency's regulations is not appropriate here because this guidance document is focused on the requirements imposed by DOE O 460.1A.

There are some responsibilities related to offsite transportation safety which are imposed by the Order on the DOE Program and Operations Offices. The *Contractor Requirements Document*, when made a part of the contracts, defines the responsibilities of the contractor for compliance with DOT for offsite shipments or with DOE, if a State agency is the contractor. Future editions of this *Guide* may discuss

Table IV.1. DOE O 460.1A responsibility matrix with guidance document.

Responsible Party	DOE O 460.1A	GUIDE
Assistant Secretary for Environmental Management	5.a.(1)	4.3
	5.a.(2)	4.2
	5.a.(3)	4.2
	5.a.(4)	SE*
	5.a.(5)	2.0, 3.0
	5.a.(6)	4.4
	5.a.(7)	SE*
	5.a.(8)	SE*
DOE Secretarial Officers	5.b	4.3
Heads of Operations Offices or Field Offices	5.c.(1)	SE*
	5.c.(2)	5.0
	5.c.(3)	2.0, 3.0, 4.4
	5.c.(4)	4.3
	5.c.(5)	SE*
	5.c.(6)	SE*
	5.c.(7)	SE*

*SE = Self explanatory in the Order. No further guidance or interpretation provided in the *Guide*.

the offsite transportation responsibilities in more detail if it is determined that this type of information is needed.

2. GUIDANCE FOR DEPARTMENT OF ENERGY EXEMPTIONS

DOE may grant temporary or permanent exemptions to its directives provided such requests are not prohibited by law and do not present an undue risk to public health and safety, the environment, or facility workers. This *Guide* describes an acceptable procedure and suggested outline to be used to request and grant exemptions to DOE O 460.1A.

2.1 CONTENT AND FORMAT FOR SUBMITTAL

The requesting organization submits the request for an exemption with supporting justification to the Operations Office Manager. The DOE Manual, DOE M 251.1-1, *DIRECTIVES SYSTEM MANUAL*, October 16, 1995, provides the following as guidance for the contents of the application:

- description of activity or condition;
- reference to the requirements(s) for which the exemption is sought;
- the specific activities that would be necessary to implement the requirement(s) for which an the exemption is sought;
- for environment, safety and health requirements, steps taken to provide protection and statement of whether adequate safety is provided and, if not, assessment of residual risk;
- the alternative or mitigating actions which have or will be taken to ensure adequate safety and protection of the public, the workers, and the environment for the period during which the exemption will be effective;
- identification and justification of the acceptance of any additional risks which will be incurred if the exemption is granted;
- what benefit is realized by not meeting the requirement from which the exemption is sought; and
- whether the exemption being requested is temporary or permanent, and for temporary exemptions, indicate when compliance will be achieved.

In addition to the above material in DOE M 251.1-1, information concerning the quantity to be packaged and transferred and the characterization of these materials should be supplied. Other guidance is provided in the Hazardous Materials Regulations for application for an exemption to a DOT regulation (49 CFR 107.105). Such format would also be acceptable to the DOE and reviewers of the exemption request. Another format, which was formerly used for DOE Alternative requests, was stated in DOE 1540.2, Chapter IV. It suggests:

- a. The text or substance of the portion of the Order from which the exemption is sought.
- b. The name, address, and telephone number of the applicant.
- c. A detailed description of the proposal, including drawings; plans; calculations; procedures; test results; packagings to be used; and any other supporting information.
- d. The chemical name, common name, hazard classification, form, quantity, properties, and characteristics of the material covered by the proposal, including composition and percentage (specified by volume or weight) of each chemical.
- e. All relevant shipping and accident experience.
- f. The proposed mode of transportation, any increased risks that are likely to result if the exemption is granted, the safety control measures which the applicant considers necessary or appropriate to compensate for those increased risks.
- g. The proposed duration for which the exemption is sought.
- h. Why the applicant believes the proposal and safety control measures specified by the applicant will achieve a level of safety which:
 - (1) is at least equal to that specified in that portion of the Order from which the exemption is sought; or
 - (2) is consistent with the public interest and adequately protects against the risks to life and property that are inherent in the transportation of hazardous materials in commerce.

Either format would be a complete and acceptable application and may be chosen based on the subject of the exemption request. The former lends itself to relief from the requirements of the Order, and the latter format is more typical of a request when the Order imposes DOT requirements on those not subject to DOT jurisdiction.

2.2 REVIEW PROCESS GUIDANCE

2.2.1 Operations Office Responsibility Guidance. The first responsibility falls on the Operations Office to review the application and provide a recommendation and support of the evaluation of the exemption request to EM.

The Operations Office also has the responsibility of transmitting the approval/disapproval letter to the requesting organization following the determination by EM. Procedures should be developed and implemented to meet the above responsibilities.

2.2.2 Evaluation Guidance for EM. The request for exemption may be approved, rejected, or returned with directions on how to change the request to make it acceptable. Through consultation with the requesting organization, the request may be modified and EM approve a modified exemption.

2.2.3 Requesting Organization. The requesting organization should (a) provide sufficient detail in the request to support the application, (b) provide additional support and information to EM as requested during the evaluation process, and (c) follow the exemption decision including any terms and conditions to the exemption.

3. GUIDANCE FOR DEPARTMENT OF TRANSPORTATION EXEMPTIONS

Exemptions issued by DOT to the Hazardous Materials Regulations are required if the shipper is unable to comply with any part of the applicable Hazardous Materials Regulations. Such administrative relief to the requirements will only be granted on the basis of equivalent levels of safety or levels of safety consistent with the public interest and the policy of the Federal law. DOE O 460.1A requires that the DOE shipper process applications for DOT exemptions first through the cognizant Operations Office, then to EM for review. Since many contractors may have a need to use the exemption, this method provides issuance of the exemption to DOE as the holder. Each of the contractors that may need to utilize the exemption must submit an application for party status to DOT. Notice of such application should be made to the cognizant Operations Office.

Therefore, all contractors should follow the following steps for obtaining a DOT exemption or existing exemption renewal:

- a. Determine that there is no means other than an exemption to accomplish a necessary transport. Considering the review time that DOT requires and the necessary time required by EM, the contractor should plan his submission accordingly.
- b. Prepare an application for administrative relief following the instructions provided at 49 CFR 107.105 for a new application, 49 CFR 107.107 for party status, or 49 CFR 107.109 for a renewal application.
- c. Submit application to the cognizant Operations Office for transmittal to EM. Applications for modifications to existing exemptions should be transmitted to EM one hundred fifty (150) days before intended use or expiration. Renewal applications should be transmitted to EM ninety (90) days before expiration or intended use.
- d. Once authorized, a copy of the DOT exemption must accompany the applicable shipments and users comply with specific restrictions in each exemption.

EM should provide as thorough a review as warranted on a graded scale. If the application is not for a one-time use or will likely be used by other contractors, EM should technically evaluate the application, assuring that all requirements of 49 CFR for such applications are met, and that the application is necessary or continues to be necessary for the accomplishment of the DOE mission.

EM maintains a current and an available register of DOT exemptions and party-to-exemptions issued to DOE. Displayed on the Internet or DOE home pages is an appropriate means of keeping everyone up-to-date on the status of requested and existing DOT exemptions.

4. SPECIAL PACKAGING FOR RADIOACTIVE MATERIALS

4.1 INTRODUCTION

The Hazardous Materials Regulations address packagings suitable for shipping radioactive materials at 49 CFR 173 and 49 CFR 178. Packaging for Type A quantities of radioactive materials may be either DOT-specification packagings, Type A packagings designed and tested commercially, Type B certified (DOE or NRC) packagings, or DOE-designed and -tested Type A packagings. DOT permits DOE to

certify Type B and fissile packagings for its own use (49 CFR 173.7). In addition, DOT regulations invoke the NRC regulations, 10 CFR 71, for certification of Type B and fissile packagings. The DOE-designed and -tested Type A packagings and the DOE certified Type B packagings are the subject of the following guidance information.

4.2 DEPARTMENT OF ENERGY APPROVED TYPE A PACKAGES

Through several of its operating contractors, DOE has been conducting an evaluation and a testing program to qualify Type A radioactive material packagings per DOT Specification 7A (49 CFR 178). The program is currently administered by the Office of Transportation, Emergency Management, and Analytical Services, EM-76. This section presents guidelines for: (1) establishing a packaging testing facility, including the criteria for package testing that the facility should be capable of performing and quality assurance criteria that it should meet; (2) applying to have a DOE-designed DOT Specification 7A Type A radioactive material packaging approved; and (3) a summary of the information and packagings presented in DOE/RL-96-57, Rev. 0, Volume I, *Test and Evaluation Document for DOT Specification 7A Type A Packaging*, September 1996 (hereafter, referred to as the *Blue Book*).

4.2.1 Responsibilities. In accordance with DOE O 460.1A, EM is responsible for approving the contractor testing facilities and for documenting qualified DOT Specification 7A packagings designed by DOE contractors and tested at DOE facilities. By extension of the latter responsibility, EM approves packagings that it determines have been qualified to meet the test criteria of Attachment 4. Documentation of a qualified packaging entails providing the test report and approved text for entry into the *Blue Book* to Westinghouse Hanford Company (WHC), which maintains the *Blue Book* for EM. If the contractor elects to use a DOE-approved Type A package, it is his responsibility as user and shipper to assure that the packaging is still qualified in the latest revision of the *Blue Book*, compatible with the contents to be shipped, and correctly used.

4.2.2 Contractor Testing Facilities Approval. The purpose of this section is to describe the EM test and evaluation program for DOT Specification 7A Type A package designs for radioactive materials. The responsibilities for operating an EM-approved test facility are given, and the

relationships between the applicant (who desires to have a package design tested and approved), the test facility, and EM are described. If a facility designs packagings and wishes to be designated as a DOE-approved test facility, then it should follow these guidelines.

4.2.2.1 DOE Test Program for DOT Specification 7A Type A Package Designs. DOE O 460.1A required the establishment of a test and evaluation program for DOT Specification 7A Type A radioactive material package designs. The program should be established to ensure that testing and supporting documentation is of consistently high quality. Under this program and in accordance with DOE O 460.1A, Type A packagings developed by DOE facilities will undergo testing by a DOE-approved test facility and then be approved by EM before use by DOE or its contractors. Figure IV.1 illustrates the procedural steps in preparing for and performing the tests and developing supporting documentation.

To have a package design evaluated, an applicant is required to open a docket with EM and then submit a design packet and packaging prototypes to the test facility assigned to the docket by EM. The test facility evaluates the documentation provided by the applicant before performing the Type A tests. Comments generated from the review are provided to the applicant by the test facility and in normal circumstances should be resolved before testing is performed. Copies of the comments and their resolution are forwarded by the test facility to EM.

The regulations of 49 CFR 173.462 should be followed prior to testing each specimen to identify and record faults or damage. The testing of the proposed Type A packaging involves subjecting the prototype containing simulated radioactive contents to the prescribed tests. The packaging test facility must ensure that the hardware tested complies with the design specifications and that the simulated contents impose a maximum stress on the feature being tested. After each of the applicable tests specified in Attachment 4, the packaging and shielding should be tested as required by 49 CFR 173.463. It is the responsibility of the packaging test facility to ensure the adequacy of the techniques used to analyze the package design. This includes verifying that tested prototypes complied with the design and that test results support a determination of successfully passing the tests.

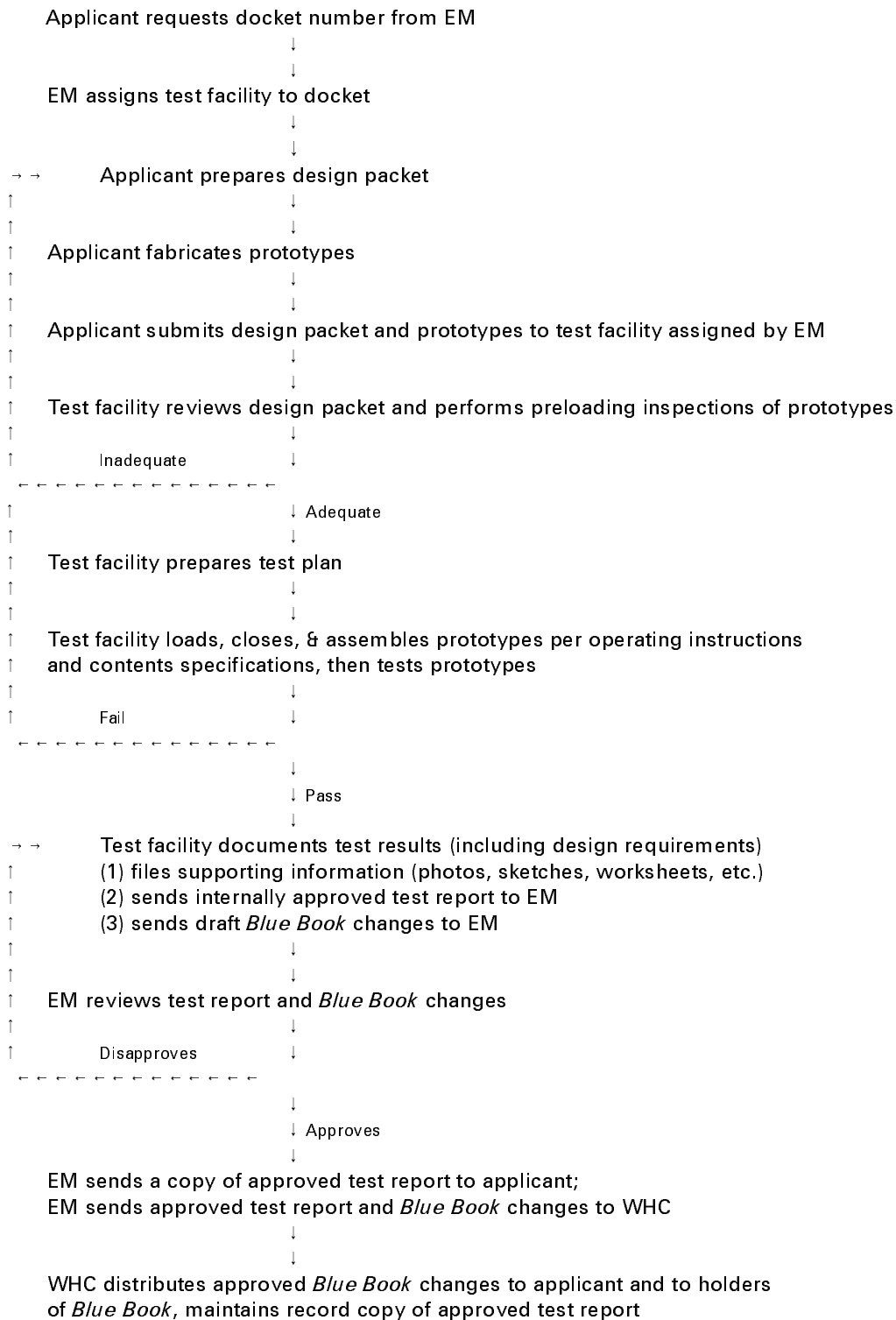


Figure IV.1. Procedural steps for testing and approving a Type A radioactive material packaging.

Following testing, the test facility develops complete documentation of the packaging evaluation and submits it to EM along with a copy to the applicant for comment. The applicant has thirty (30) days to send comments to EM. For designs which perform satisfactorily, this documentation includes draft text for the *Blue Book*, which is maintained by WHC for EM. When the documentation of the packaging evaluation is approved by EM, the packaging is approved for use. When a packaging is approved, EM provides the applicant with a copy of the approved test report for the packaging and sends the approved *Blue Book* text and test report to WHC. For designs which do not pass the Type A tests, documentation of the reason for failure is provided to the applicant by EM.

4.2.2.2 Procedure for Establishing a Test Facility. Figure IV.2 illustrates the procedural steps for establishing a DOE-approved test facility. First, the candidate test facility should develop a detailed set of procedures documenting every aspect of its proposed Type A packaging evaluation activities. Guidance is provided in Section 4.2.2.3.1. regarding recommended content of test procedures. Procedures should also cover interactions between the test facility and the applicant, interactions between the test facility and EM, and preparation and distribution of documentation, including documentation developed by the test facility for incorporation into the *Blue Book*. The procedures should then be submitted to EM for review and approval. If disapproved, the candidate test facility should incorporate comments provided by EM into its procedures. This may also necessitate modifications to the test apparatus described by the procedures. The modified procedures, describing modified apparatus where necessary, should then be resubmitted to EM.

Once the procedures receive preliminary approval, EM will assign a docket number to the candidate test facility for processing. EM will then go to the candidate test facility to observe this first application of the test procedures and equipment. If concerns arise about the application of the procedures or equipment, changes to the test procedures or equipment may be required by EM after this step. Once the test procedures receive final approval, EM issues an approval letter to the test facility, and the test facility is placed on the EM list of DOE-approved test facilities.

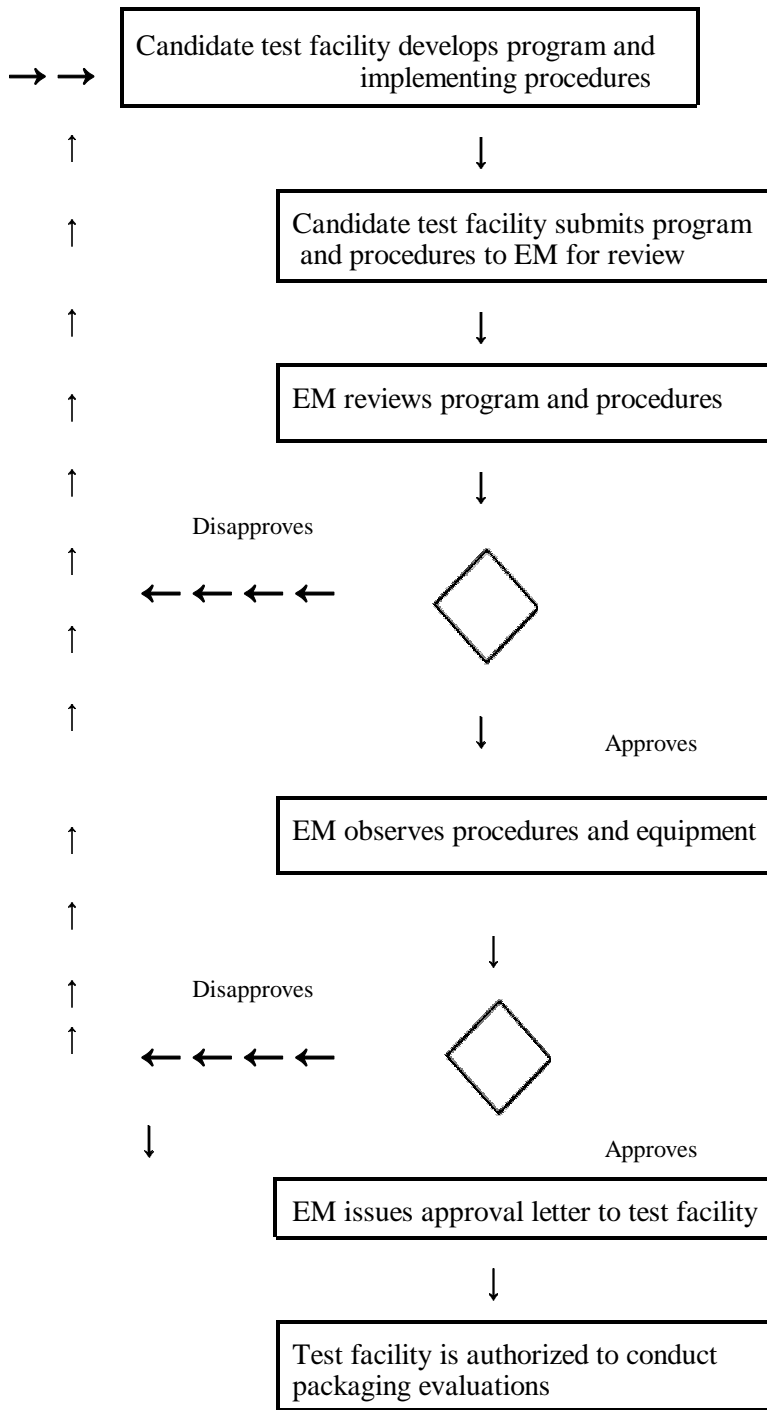


Figure IV.2. Procedural steps for establishing a Type A test program at a test facility.

After the test facility is placed on the approved list, dockets can be processed without any additional direct observation by EM. However, at any time, EM may choose to review any aspect of a test facility's operation, and may require additional changes to the procedures or withdraw its approval of the test facility, as it sees fit. EM approval of a tested packaging is still required before a packaging may be used for transport.

- 4.2.2.3 Established Requirements for Type A Packaging. The test facilities are responsible for ensuring that the regulatory requirements, DOE Orders, and management directives pertaining to the design and performance of Type A packagings are met. The regulatory requirements are contained in 49 CFR 173.24, 173.24a, 173.24b, 173.410, 173.411, 173.412, 173.461–463, 173.465, 173.466, and 178.350. Some of these requirements pertain to all hazardous materials packagings. Others pertain to Type A packagings only. Only those requirements related to packaging design and performance are verified by this program. The test facilities are responsible for ensuring that both types of requirements are met.

These regulatory requirements fall into two general categories: (1) requirements which the test facilities should satisfy by review of documentation provided by the applicant, and (2) requirements which the test facilities should satisfy by performing actual packaging tests. The following sections more fully describe the responsibilities of the test facilities in these two areas.

- 4.2.2.3.1 Documentation Review. The package design as presented to a test facility should be documented in sufficient detail to enable a test facility to verify compliance with all the current 49 CFR design requirements. See Section 4.2.3 for details. The applicant is required to provide this documentation on the packaging qualification checklist included as part of the design packet. The assigned test facility should review this documentation before testing to ensure that the applicant understands the requirements and that the packaging complies with all requirements affecting packaging design and performance.

A test facility should at all times ensure that the packaging qualification checklist covers all the current Type A packaging design requirements, including any which may have been

established by DOE Order or management directive. It is the responsibility of each test facility to ensure that a packaging under its review complies with the latest regulatory and management requirements pertaining to Type A packaging, and not only to those which are documented in the packaging qualification checklist. Each test facility should notify EM whenever modifications to the packaging qualification checklist are needed.

Each test facility is required to review the procedures pertaining to proper loading, unloading, and other handling of the packaging as a part of the package design review in order to ensure that they fully document the required package handling. Further, the test facility should verify that the intended packaging contents for the packaging under review are in a form (e.g., nondispersible solid, dispersible solid, liquid, or gas) suitable to the packaging. If intended radionuclide contents are specified in the packaging documentation, the test facility should verify that the intended contents are indeed Type A quantities. If evaluations of shielding and thermal load are provided by the applicant, the test facility reviewing the documentation should confirm the suitability of the packaging in both these areas. If a plastic packaging or receptacle is to be used to transport liquids, the test facility should perform the required testing of chemical compatibility and rate of permeation in plastic packagings and receptacles.

Each test facility should have staff on hand who are qualified to evaluate the documentation provided by the applicant. In particular, a qualified engineer is needed to evaluate the applicant's demonstration of compliance with the packaging structural requirements, including the lifting attachment requirements of 49 CFR 173.410(b) and the requirements for tie-down failure under excessive loads of 49 CFR 173.412(i). Qualified analysts should be used to verify thermal and shielding evaluations.

4.2.2.3.2 Test Requirements. Each test facility is responsible for performing the tests specified in 49 CFR 173.24(e)(3)(ii), 173.24a(a)(5), 173.412(f), and 173.465–466. Before these tests can be performed, suitable surrogate contents should be selected, the packaging should be inspected for compliance with the documentation provided by the applicant (including examination of packaging components for damage) per 49 CFR 173.462, and the packaging

should be loaded according to the procedure provided by the applicant. For the Type A tests of 49 CFR 173.465–466, compliance should be based on the assumption required in 49 CFR 173.461(b) with respect to the initial conditions of the package that the package is in equilibrium at an ambient temperature of 38°C (100°F). Each test facility should have one or more procedures in place describing how these activities will be performed.

For more detail describing the test facility requirements for Type A packaging tests and the respective pass/fail criteria for each test, see Attachment 4, “Capability of Test Facilities for Testing Type A Packagings.”

4.2.2.4 Quality Assurance. DOE 5700.6C, *QUALITY ASSURANCE*, August 21, 1991, establishes quality assurance requirements for DOE. This Order defines ten quality assurance criteria in three categories: management, performance, and assessment. Application of each of these areas to this program is discussed in Attachment 5, “Quality Assurance for Contractor Testing Facilities.”

4.2.3 Application for Packaging Approval. The applicant who wishes to have a DOT Specification 7A Type A radioactive materials packaging tested and approved by the EM program (qualified to the specifications of 49 CFR 178.350) should perform the following steps:

- a. Submit a written request to EM in which the “need date,” type of packaging, and type of contents are specified.
- b. Upon EM approval, provide the specified packaging test facility with a test plan, a blueprint-like drawing of the container, design packet, representative loads (if requested), and any other materials necessary to perform the testing. After the tester determines how many units are needed, provide the appropriate number of prototype containers.
- c. Provide a technician or staff member, when necessary, to support any of the tests (e.g., in the event of a high priority, immediate need date).
- d. In the event that a container fails a test and modification of the container is desired, provide the test facility with another set of containers and design packet.
- e. Review and provide comments to EM on the draft *Evaluation Report* for the tested/evaluated container.

- f. Provide for the disposition of the containers originally provided to the packaging test facility (e.g., funds for disposal or return shipment). This should nominally be completed within 14 days of the publication of the *Final Evaluation Report* to avoid being billed for disposal costs.
- g. In the event that a container fails a test and modifications are not desired, provide funds as stated in Item 6 for the disposition of the containers.
- h. In the event that after the *Final Evaluation Report* is published and distributed and the applicant wishes to have additional tests performed or to have additional contents approved, perform the same steps as above, beginning with Item a. Another set of containers do not have to be sent if there are still untested containers at the Test Facility and the container has not been modified.

The procedural steps involved in obtaining a packaging approval are presented in Figure 4.1 of Section 4.2.2.2. In the listing above, Item b is the most involved step. The requested design packet consists of detailed drawings and specifications, an analysis report, documented operating instructions, and a completed packaging qualification checklist. The qualification checklist addresses the characterization of the contents for compatibility with the selected packaging and details the following characteristics: (1) radiological, (2) activity limits, (3) thermal, (4) allowable contents (physical and chemical form), (5) packaging design (including shielding), (6) lifting and handling, (6) tie down, and (7) quality assurance provisions.

A properly completed packaging qualification checklist would contain documentation that the applicant has addressed the following regulatory requirements:

- 178.350 Specification 7A; general packaging, Type A
- 173.21 Forbidden materials and packages
- 173.22 Shipper's responsibility
- 173.24 General requirements for packagings and packages
- 173.24a Additional general requirements for non-bulk packagings and packages
- 173.24b Additional general requirements for bulk packagings
- 173.410 General design requirements
- 173.412 Additional design requirements for Type A packages
- 173.415(a) Authorized Type A packages

- 173.441 Radiation level limitations
- 173.442 Thermal limitations
- 173.443 Contamination control
- 173.461 Demonstration of compliance with tests
- 173.462 Preparation of specimens for testing
- 173.463 Packaging and shielding—testing for integrity
- 173.465 Type A packaging tests
- 173.466 Additional tests for Type A packagings designed for liquids and gases
- 173.474 Quality control for construction of packaging
- 173.475 Quality control requirements prior to each shipment of radioactive materials

The applicant is required to provide a set of procedures describing the proper loading, unloading, and other handling of the packaging. Compliance must be demonstrated with the packaging structural requirements, including the lifting attachment requirements of 49 CFR 173.410(b) and the requirements for tie-down failure under excessive loads of 49 CFR 173.412(i).

Contents for the packaging under review should be in a form (e.g., nondispersible solid, dispersible solid, liquid, or gas) suitable to the packaging. The applicant is not required to specify radionuclide contents; however, if intended radionuclide contents are specified in the packaging documentation, then the intended Type A contents should be provided or simulated. If the representative load is simulated, the physical properties of the test contents should be demonstrated to be equivalent to the working load. The representative load should be acceptable to EM and the test facility. If evaluations of shielding and thermal load are provided by the applicant, the test facility reviewing the documentation should confirm the suitability of the packaging in both these areas. If the applicant desires to transport liquids using a plastic packaging or receptacle, the liquid contents should be fully described by the applicant so that the test facility can perform the required testing of chemical compatibility and rate of permeation in plastic packagings and receptacles.

Any comments generated from the review of the documentation are provided to the applicant by the test facility and in normal circumstances should be resolved before testing is performed. For designs which perform satisfactorily, documentation is developed by the test facility which includes draft text for the *Blue Book*. The *Blue Book* is a compilation of all DOE-approved Type A packagings which provides documentation enabling DOE facilities to use the packagings. When the documentation of the packaging evaluation is approved by EM, the packaging is approved for use.

When a packaging is approved, EM provides the applicant with a copy of the approved test report for the packaging so that the applicant may begin to use the packaging immediately. EM also sends the approved *Blue Book* text and test report to WHC. WHC then transmits the new *Blue Book* text to the applicant and to all holders of the *Blue Book*, and maintains a record copy of the approved test report for EM.

For designs which do not pass the Type A tests, documentation of the reason for failure is provided to the applicant by EM. The applicant may then either modify the design and have the packaging reevaluated and retested by the DOT 7A Testing Program or abandon the design effort.

4.2.4 Use of *Blue Book* Packagings. The *Blue Book* summarizes the evaluation and testing performed for all the Type A packagings successfully qualified by the evaluation and testing program administered by EM. Previously, the *Blue Book* was known as the *Red Book*. The purpose of the *Blue Book* is to provide technical documentation of packagings qualified to the requirements of DOT-7A (49 CFR 178.350) and considered acceptable for transport of Type A quantities of radioactive material subject to the applicable restrictions and specifications.

The specific packaging data contained in the *Blue Book* serve to meet the requirements of 49 CFR 173.415(a) for “. . . documentation of tests . . .” when the packagings are used as prescribed. The *Blue Book* does not contain all the documentation needed for offering a package for transportation. In addition to the documentation of tests, the user of the packaging must maintain on file other appropriate data applicable to the shipment, including

(1) evaluation of the properties of the actual contents to be shipped for compatibility with the packaging and that their characteristics are bounded by the simulated contents used in qualification testing, and (2) the quality control program—and its implementation—developed to ensure that the packaging materials, components, and arrangement are in accordance with the qualified design.

Blue Book currently lists about 300 qualified packagings. The main family of containers shown are (1) steel drums, (2) steel boxes, (3) wooden boxes, (4) fiberboard containers, (5) UF₆ cylinders, and (6) containers for liquids and gases. Other miscellaneous, specialized containers are presented and updates, including deletions, are made to the groups yearly. As mentioned in Section 4.2.2, EM sends updates to WHC of approved packagings for entry into the *Blue Book* once a design is qualified. It is the users responsibility to assure that the packaging that he uses is still qualified and meets any necessary revisions.

In addition to information on packagings, the *Blue Book* contains useful information such as applicable DOT regulations, procurement practices, quality assurance requirements, and alternative packagings that can be used. These alternative packages that are permissible to be used are NRC certified Type B packagings. In authorizing the use of NRC certified packages for transportation of Type A quantities of radioactive material, DOT regulations specify, in 49 CFR 173.415, that certain conditions must be met. One condition (49 CFR 173.471) is that the shipment of the package be made in compliance with the terms of the NRC Certificate of Compliance. Alternatively, an NRC certified package may be shipped under the provisions of 49 CFR 173.415(a) as a DOT-7A package. Conditions for this scenario are mentioned in the pertinent text of *Blue Book*. The same would be applicable for DOE certified Type B packagings.

4.3 DEPARTMENT OF ENERGY CERTIFIED TYPE B PACKAGES

4.3.1 Responsibilities. The flow of the documents for certification by EM of Type B packagings is as follows:

- a. Contractor prepares the application for a Type B packaging including a *Safety Analysis Report for Packaging* (SARP) and submits all to the cognizant Field or Operations Office. Guidance for the application is found in Section 4.3.2.
- b. The Field or Operations Office reviews the application for completeness and forwards it to the Secretarial Officer responsible for those facilities or activities requesting the certification.
- c. The Secretarial Officer reviews the application and, if appropriate, forwards it to EM. The purpose of this review is for the responsible line management to: (1) be aware of the application, (2) determine that there is a need and adequate funding for the project, and (3) declare the Office's support for the project.
- d. On receipt of the application, EM establishes a docket for the application and assigns a review team to the project. When the review is completed, EM may issue a Certificate of Compliance if the review indicates that the design meets the standards of or is equivalent in safety to 10 CFR 71, as well as any special requirements that EM may determine applicable. The approved Certificate will return to the requestor through the same channels as received. Guidance for the review process is discussed in Section 4.3.3.

4.3.2 Safety Analysis Report for Packaging Preparation and Submission. The SARP should be sufficiently detailed so as to permit the reviewer to determine that the package is designed and analyzed in sufficient detail and should document the adequacy of the packaging with respect to 10 CFR 71 standards or the equivalency thereto. These regulations state that a package must meet certain containment, radiation control, and subcriticality assurance requirements when subjected to specified normal transport and hypothetical accident conditions.

The SARP format preferred is described in NRC Regulatory Guide 7.9, *Standard Format and Content of Part 71 Applications for Approval of Packaging of Type B, Large Quantity, and Fissile Radioactive Material*, January 1980. Additional guidance for SARP preparation may be found in other NRC Regulatory Guides and in the UCID-21218, *Packaging Review Guide for Reviewing Safety Analysis Reports for Packagings* October 1988, or the *Packaging Handbook* (Section 6 REFERENCES).

4.3.3 Review Process Guidance. DOE O 460.1A requires that EM execute the certification program for the Department and that the Headquarters Certifying Official come from EM. DOE 1540.2, which was replaced by DOE O 460.1A, had established procedures and review

policies for obtaining certification of packaging used by DOE and its contractors for Type B radioactive materials. Such procedures are absent from DOE O 460.1A; instead, this *Guide* offers the established references for consultation to the reviewer for use in determination of the adequacy of the packaging design to meet the standards of NRC or the safety equivalent thereto. Reasonable use of these references will maintain the quality and uniformity of the reviews.

4.3.4 Renewal of DOE Certificates of Compliance. DOE certificates are issued for a specified period of time. To qualify for use under "timely renewal" application, the contractor requesting the renewal should submit documentation to the Headquarters certifying official, through the appropriate field office, justifying renewal of the certificate. Such documentation should include (but not limited to):

- a. The necessity for renewing the certificate;
- b. That the SARP has been reviewed and complies with applicable requirements and standards; and
- c. A summary of the history of past usage.

Documentation should be received by headquarters a minimum of 90 days prior to expiration of the certificate.

4.3.5 Use of Department of Energy Certified Packages. DOE Field or Operations Offices and contractors may use any packaging whose design has been certified by the Headquarters Certifying Official provided the user meets the requirements specified in the Certificate, maintains full component of the latest version of the SARP and Certificate of Compliance, and meets all other DOE packaging and transportation safety requirements in accord with DOE O 460.1A.

4.3.6 The Program for Review of Fabrication, Use, and Maintenance of Department of Energy Certified Packages. A program was begun by EH in 1994 to evaluate the status of the DOE certified packagings in use throughout the DOE complex. The objectives of the evaluation program are to:

- a. determine that the condition and usage of packaging is in compliance with the applicable federal regulations, DOE Certifications, facility quality assurance plans, and other program requirements;
- b. determine the effectiveness of Operations or Field Office oversight of contractor organizations' quality assurance programs for hazardous materials packaging for transportation; and
- c. provide Operations Office management with effective feedback to aid in continuous improvement of the overall safe use of hazardous materials packaging.

The guidance for this program was contained in a draft EH-30 Instruction, *Quality Assurance Assessment Program for Packaging Used in the Transportation of Hazardous Materials*. The team leader is from Headquarters staff; team members are designated by the respective team leader. One evaluation was performed in 1994 using these guidelines; it is expected that the program will sponsor at least one evaluation per year. These evaluations will be a part of the EM technical assistance program and should not be considered by the reviewed facility or Operations Office as oversight assessments.

4.4 USE OF OTHER APPROVED OR CERTIFIED PACKAGINGS

DOE contractors may use any of the following in addition to the DOE approved packagings, as long as all regulatory requirements and any special provisions for the packagings are met.

- 4.4.1 Nuclear Regulatory Commission Certified Packaging. If the contractor or DOE is registered as a user and the contractor possesses a copy of the latest NRC Certificate of Compliance and the packaging's SARP, the contractor may use an NRC certified packaging.

All requests for NRC Certificates of Compliance should follow the same process flow as for DOT exemptions (Section 3).

- 4.4.2 Department of Transportation Specification Containers. Packaging designs which have been published in the Hazardous Materials Regulations as specification packagings may be used provided that all provisions of the DOT specification and applicable quality assurance

requirements are met and provided that use of the packaging is not prohibited by DOE O 460.1A [i.e., the restriction on plutonium packagings at DOE O 460.1A, 4.a.(4)(c)].

- 4.4.3 International Atomic Energy Agency (IAEA) Approvals. DOT is the authorized agency to administer international approvals as the Competent Authority for the United States. Domestic shippers receive certification of the suitability and compliance of domestic packaging to foreign countries through DOT. This means that any DOE or NRC certified packaging or DOT specification packaging must receive additional approval in the form of a U.S. Competent Authority Certificate for shipment into foreign countries. Copies of current U.S. Competent Authority Certificates covering the approval of packaging designs are sent prior to shipment to the Competent Authority of each country into or through which the packages will be transported. Foreign packaging of origin may be used only for import/export shipments when an IAEA certification has been issued and a U. S. (DOT) endorsement has been granted. This means that a foreign national competent authority has certified the packaging's suitability and compliance and such certification has been validated by DOT. This validation or endorsement typically takes the form of a separate annex or supplement to the IAEA certification.

Additionally, radioactive material shipped as "special form" must have been first certified by a national competent authority as meeting the IAEA requirements for special form based on encapsulation or physical characteristics prior to any import or export shipments (49 CFR 173.476). DOT issues such certification for international shipments; domestic shipments do not have this requirement.

DOE contractors may use any international certification to which they or DOE are registered as a user, provided all requirements of the certification, special provisions, and other applicable regulations are met. New applications for Competent Authority approval or special form authorization should be submitted following the same process flow as for a DOT exemption (Section 3).

5. ONSITE TRANSPORTATION SAFETY REQUIREMENTS

5.1 INTRODUCTION

The onsite portion of DOE O 460.1A (Paragraph 4.b) stems from the general realization throughout DOE some years ago that there was a need to have onsite transportation requirements spelled out in an Order. This realization was emphasized when the packaging and transportation community held a workshop on the subject in Denver in August 1990. The result of these deliberations was that an Order was needed and that it should mandate an Onsite Transportation Safety Document for each site or facility in DOE. Already, before the workshop, sites and facilities had begun to develop such documents and to define “onsite” and “offsite” for transportation purposes. At that time, detailed contents of such documents were specified but later dropped from the proposed Order because individual site requirements varied greatly from one another.

In May 1994, again in Denver, a second workshop was held, this time to discuss a draft Order in the 5480 series. By this time, many sites and facilities had developed onsite safety documents. The draft was finalized at the workshop and was ready for formal coordination throughout DOE when the EH Process Improvement Team suggested its inclusion with the revised DOE 5480.3, which has been done (by reference) in DOE O 460.1A, Paragraph 4.b. Also, at that time it was realized there were jurisdictional “grey areas,” which were left to the sites to be discussed in their Transportation Safety Documents (TSDs).

5.1.1 Purpose. The purpose of this section is to provide guidance to DOE Field Elements and DOE contractors for implementation of the requirements of DOE O 460.1A, Paragraph 4.b, “Onsite Safety Requirements.”

5.1.2 Discussion. The guidance provided herein supports the requirements of DOE O 460.1A. Responsibility for managing DOE hazardous material packaging and transportation activities in a safe and an environmentally sound manner resides with line management at DOE Headquarters, at each DOE Field Element, and within each DOE contractor organization.

In the performance of onsite packaging and transportation activities, assurance must be given that proper safety, health, and environmental protection are maintained. For onsite transfers

of hazardous material at DOE sites, this assurance can be provided by specification of operational safety procedures in the site-specific TSDs. Adherence to federal regulations normally applicable to offsite transportation is an acceptable approach to meeting the onsite safety requirements. However, an alternative, integrated approach which considers the packaging in combination with specified communication and control measures is also acceptable.

Such an integrated approach should include hazard classification of the material, hazard containment, hazard communication, and control measures commensurate with the hazard of the material being transported, such as:

- a. identification of the physical characteristics, chemical characteristics, and potential property damage of the designated hazard classification;
- b. containment requirements for each hazardous material transfer that ensure retention of materials under normal onsite transport operations;
- c. hazard communication requirements that provide sufficient information to personnel handling the material and to emergency responders, such that the hazards of the material being handled or transferred can be assessed prior to having direct contact with the material; and
- d. control requirements appropriate for the level of containment and communication provided that take into account the possibility and consequences of credible accidents. These control requirements should result in minimal acceptance of risk above the risks accepted in the context of existing Hazardous Materials Regulations. For radioactive materials, appropriate controls also need to be provided to ensure nuclear criticality safety and minimize personnel exposures in accordance with As Low as Reasonably Achievable (ALARA) principles.

5.2 GUIDANCE TO RESPONSIBILITIES

5.2.1 Operations Office and Field Office Managers. In accordance with DOE O 460.1A, Paragraph 5.c, Heads of Operations Offices or Field Offices shall implement the requirements of this Order and ensure that contractors under their purview fully implement and comply with the requirements of the Order. Responsibility specified for implementation of the onsite requirements is review and approval of transportation safety documents.

5.2.2 Contractor Management. Contractor Management should ensure for onsite transfers of hazardous materials that the Hazardous Materials Regulations are complied with or that an approved site- or facility-specific TSD meeting equivalent safety requirements is followed. Contractor management should ensure that a site- or facility-specific TSD exists which satisfies Section 5.3 of this *Guide* and is updated and maintained.

5.3 PREPARATION OF TRANSPORTATION SAFETY DOCUMENTS

5.3.1 Introduction. DOE O 460.1A requires that deviations from the Hazardous Materials Regulations of DOT for onsite transfers be documented in an approved site-specific TSD. This document describes (explicitly or by reference) the methodology and compliance process to meet equivalent safety measures relative to deviations from the Hazardous Materials Regulations. This TSD is expected to include:

- a. identification of responsibilities, lines of authority, and program approval procedures;
- b. definition of minimum safe packaging requirements including necessary design, fabrication, and quality assurance elements, using appropriate codes and standards;
- c. description of transportation systems and operational controls utilized to restrict personnel and public access and minimize the probability and consequence of credible accidents;
- d. a description of the process and analysis is used to ensure that equivalent safety requirements are established. This should include a technically justified basis for equivalency. For example, this could include a hazards analysis associated with the transfer, an assessment of the risks associated with the transfer, and a discussion of the mitigating measures proposed to ensure the equivalent safety requirements will be employed. This analysis would be performed for each deviation from the Hazardous Materials Regulations;
- e. site description, including maps identifying boundaries, railways, and roadways, which clearly delineates offsite and onsite areas, and procedures for clearing and establishing access control for any area having occasional public access;
- f. provisions for effective emergency response and recovery under credible accident conditions; and
- g. process for accomplishing nonroutine packaging and transportation activities.

DOE O 460.1A requires that each TSD be approved by the cognizant DOE Field Element. Approval shall constitute acceptance of the site program as meeting DOE transportation safety requirements. This is a new requirement, but existing site programs may remain in effect until this requirement is met. DOE O 460.1A states that no later than one year from the date of incorporation of the *Contractor's Requirements Document* into the contractor's contract, all onsite transfer shall comply with either the Hazardous Materials Regulations or an approved TSD.

- 5.3.2 Preferred Format for Transportation Safety Documents. Following is a preferred format for the TSDs. The level of detail required in each TSD is dependent on the complexity of operations, demographic conditions at the site, quantities and types of materials being transported, number and complexity of site transport routes, and need for special controls (including safeguard controls) to meet DOE transportation safety requirements.

Sites which already have a well-developed TSD do not need to rewrite their document to this format; instead, they may provide a crosswalk from the existing format to this one and add relevant sections where needed. However, existing TSDs lacking significant amounts of information and therefore requiring significant revision should consider revising to this format.

a. Chapter I. Purpose, Scope and Applicability

Purpose. The purpose should state that the TSD documents the onsite packaging and transportation program and demonstrates its compliance with DOE transportation safety requirements.

Scope. The scope should state that the TSD covers all transfers of hazardous materials, substances and wastes. Although the term "transfer" refers only to onsite transportation of hazardous materials, readers not familiar with this definition may find a statement of this definition helpful at this point.

Applicability. The applicability statement should describe how the requirements of the document are applied to site and facility operations. It should be written so that someone needing to move hazardous material can understand whether or not the requirements of the document apply to the movement in question. This section should also state who is responsible for control of document distribution and for preparation and distribution of document updates. In addition, it should explain how controlled distribution and maintenance of the document will be accomplished.

b. Chapter II. Definitions and Acronyms

Definitions and Acronyms. This section should define all terms or acronyms used in the TSD which are relevant to onsite packaging and transportation operations. Site-specific terms should be defined for the benefit of new employees or external reviewers of the document. Reference to definitions from the ORNL-M-3077, *Transportation and Packaging Resource Guide*, December 1994, would be helpful.

c. Chapter III. Site Description

Maps. This section should identify the physical location of the site and associated facilities on legible maps. Site boundaries should be clearly marked. Fences and other restrictions to public access should be identified. All features of the site which are mentioned in any part of the document, such as facilities, buildings, entryways, storage areas, transport routes, and transportation hazards, should be clearly identified on one or more maps, and the appropriate maps should be referenced when site-specific features are mentioned in the text. The goal of this section should be to provide enough information to enable a reader unfamiliar with the site (such as a new employee or an independent reviewer) to comprehend all site-specific discussion in the TSD.

Vehicles. A list should be provided of the transport vehicles used for onsite hazardous materials movements or reference to the location of such listing.

d. Chapter IV. Organizational Responsibilities

This chapter should describe the packaging and transportation organizational structure within the framework of the entire site organization. Organization charts are encouraged for clarity. The authority and responsibilities of principal organizations and key positions within those organizations should be clearly described, so that lines of authority and reporting may be understood. Independence of oversight organizations should be demonstrated. Program approval procedures should be cited.

e. Chapter V. External Regulations

This chapter should reference the principal Federal, State, and local regulations, DOE Orders, and other requirements affecting onsite packaging and transportation activities which have been imposed by organizations external to the site organization. It should provide a complete picture of all the externally-imposed requirements with which the onsite packaging and transportation activities must comply. It should also identify any Government and industrial standards used as benchmarks in the development of the onsite packaging and transportation program.

f. Chapter VI. Site-Specific Standards, Procedures, and Instructions

This chapter should identify the site-specific standards, procedures, and instructions applicable to onsite packaging and transportation activities. This section should only present the general requirements governing the development of specific procedures for individual hazardous material transport activities. Any packaging standards, performance criteria, and design, fabrication, and quality elements identified in this chapter should be supported by applicable codes and standards. Site-wide procedures for subjects such as securing of loads and tie-downs, load compatibility, contamination and radiation exposure control, and criticality control should be identified and/or referenced. All relevant site policy and procedures Documents (e.g., radiological protection manuals and health and safety manuals) should be referenced.

g. Chapter VII. Safety Assessment Methodology

This chapter should provide a description of the methodology used to achieve and demonstrate compliance with DOE O 460.1A, Paragraph 4.b. The description of the methodology should include a description of any problematic or risk-based approaches used.

Guidance on developing and applying a safety assessment methodology is provided in Section 5.4 of this document. This guidance recommends development of a hazardous materials hierarchy and associated performance requirements and documentation of these requirements in this chapter. In developing an onsite packaging and transportation system for hazardous materials, it is recommended that the primary emphasis be placed on packaging design and packaging performance to ensure containment of materials during normal onsite transfer activities. A well-designed packaging can lessen both the probability and the consequences of a hazardous material release for a given package handling scenario.

h. Chapter VIII. Routine Transfers

This chapter should identify the major categories of hazardous materials or hazard classes routinely transferred onsite, the packagings used for each, and the specific procedures followed. The procedures may cover such topics as identification and classification of material, packaging selection, packaging preparation and use, transport vehicle scheduling and use, hazard communication, hazard control, and routine approvals.

i. Chapter IX. Non-Routine Transfers

This chapter should present the procedures for processing and approving a request for an exception to the routine transfer requirements of Chapter VIII. These procedures should address the required format, content and control of this type of request, conditions under which approvals should be sought and given, approval authorities, maintenance of documentation, period of approval, and exclusions.

Except under emergency conditions, approval should only be granted after the proposed transfer has been formally demonstrated in a safety assessment.

j. Chapter X. Personnel Qualification and Training

This chapter should define or reference the training requirements for personnel involved with onsite hazardous material packaging and transportation activities. It should identify required courses, course content, testing, and qualification requirements for various packaging and transportation personnel as a function of the jobs to be performed. Documentation of training, qualification, and recertification should be specified.

k. Chapter XI. Documentation and Record Keeping

This chapter should identify all site-specific documentation to be maintained to support the onsite transportation safety program. The records requirements should include retention of such items as packaging documentation (e.g., SARPs, test reports, or other packaging evaluations), personnel training and qualification records, vehicle maintenance and inspection records, and documentation associated with both routine and nonroutine transfers. This chapter should specify what records must be maintained, who is responsible for maintaining the records, how the records are to be stored, and how long the records are to be retained.

l. Chapter XII. Incident Reporting and Emergency Response

This chapter should describe the incident reporting and emergency response plans for the site. The lines of communication and the roles and responsibilities of key personnel involved in an emergency response or incident report should be presented. Relevant procedures may be referenced. Planning should be adequate to cover all credible emergency situations to ensure effective response and recovery after a transport accident or incident.

m. Chapter XIII. Transport Vehicle Operations

This chapter should identify or reference maintenance and inspection requirements and associated procedures for onsite vehicles. It should identify routine operator duties and procedures.

n. Appendices and Other Pertinent Information

This section might include additional site specific guidance to assist transport operations such as:

- Examples of labels, markings, placards
- Site material transfer documents (shipping papers)
- Lists of packagings (packaging directory)
- Maps (roads, railways, site boundaries, facilities, crossings, adjacent streams, waterways and wetlands)
- Incident reporting forms
- Vehicle maintenance forms
- Other forms

5.4 SAFETY ASSESSMENT METHODOLOGY

5.4.1 Use of a Graded Approach. DOT regulations are structured so that materials representing a greater hazard are subject to greater containment, communication, and control requirements. DOT regulations may be applied to onsite transfers to ensure compliance with the Order. Where DOT regulations are not used to ensure compliance with the Order for onsite movements, a graded approach to compliance may be established.

A site seeking to establish a graded approach to compliance with DOE O 460.1A should develop a hierarchy in which hazardous materials are grouped into a series of hazard levels. For each hazard level, the performance requirements for the transport system (where the transport system consists of the packaging plus the controls and communication requirements imposed on its transport) should then be established. For materials representing low hazards, the transport system would be expected to prevent loss of containment during normal onsite

handling, and may also be expected to survive minor mishaps (e.g., a 3-ft drop or a low-impact collision of the transport vehicle). For higher hazards, the transport system would be expected to withstand more severe handling (e.g., a 5-ft drop or a moderate-impact collision of the transport vehicle) without loss of containment. For hazardous materials, such as Type B radioactive materials, the transport system would be expected to prevent loss of containment both for normal handling and for all credible onsite accidents.

The performance requirements imposed on each hazard level in the hazardous materials hierarchy should be documented in Chapter VII of the TSD. This documentation should enable a site to establish containment, control, and communication requirements for onsite movements in a consistent and justifiable manner, and should ensure that requirements established for an onsite movement will be commensurate with the hazard of the material being transported.

- 5.4.2 Safety Assessment. Reliance on packaging performance is a preferred way to ensure overall safety; however, an integrated approach which considers the packaging in combination with specified communication and control measures is also acceptable.

Figure IV.3 presents the options available to a site for complying with DOE O 460.1A, and indicates the evaluations that would support each. As a first step, the packaging should be placed into one of three categories: (1) DOT packaging, (2) equivalent packaging, or (3) non-equivalent packaging. DOT packaging is packaging which meets the regulations of DOT for offsite shipment of the hazardous material to be transported onsite. Equivalent packaging is packaging which can be shown conclusively to provide performance equivalent to packaging meeting the requirements of DOT for offsite shipment. Packaging falling into this category will generally be a slight modification of a DOT packaging. Non-equivalent packaging is any packaging which cannot be demonstrated to be either DOT or equivalent packaging. As the figure shows, DOT packaging requires no special evaluation. It need only be documented as approved packaging. Equivalent packaging should be supported by a documented evaluation in which this equivalence is formally established. Once established, equivalent packaging may be used interchangeably with DOT packaging for onsite movements.

Still following the logic of Figure IV.3, DOT and equivalent packagings may be used onsite in two ways. First, they may be used in compliance with all DOT control and communication requirements for offsite movements. The use of full DOT control and communication requirements should be documented in the TSD. No further evaluation is then required.

Second, these packagings may be used with site-specific control and communication requirements. To ensure that DOE O 460.1A is met, the site-specific requirements should be evaluated to demonstrate that (1) transport conditions provided by the onsite controls are no more severe than would be encountered by a package being transported offsite and (2) personnel potentially involved with the transport and emergency response teams receive adequate communication regarding the hazards involved with the transport. The final option represented in Figure IV.3 involves the use of non-equivalent packaging. Because this packaging has not been demonstrated to function equivalently to DOT packaging, the use of full DOT control and communication requirements may not be adequate for this type of packaging.

Before non-equivalent packaging may be used for onsite transport, a performance envelope should be established for the packaging and specific control and communication requirements should be developed which ensure that the transport system will operate safely within the performance envelope.

The evaluation of the transport system described in Figure IV.3 should take the form of a safety assessment. The safety assessment may be straightforward or very complex, depending primarily on the packaging to be used for the hazardous materials movement. As a first step, the packaging should be evaluated and placed into one of the three categories described earlier: (1) DOT packaging, (2) equivalent packaging, or (3) non-equivalent packaging. The details of the required evaluation then follow from Figure IV.3.

Is the packaging. . .



DOT?

Document this.

Equivalent?

Demonstrate packaging equivalence.

Non-Equivalent?

Establish performance envelope of the packaging and evaluate the transport system (including controls and communication).



Are controls and communication. . .

Demonstrate that the system operates safely within the performance envelope.



Full DOT?

Document this.
No additional evaluation required.

Site-Specific?

Demonstrate that transport conditions provided by onsite controls are not more severe than would be encountered offsite.

Demonstrate adequacy of communication with personnel and emergency response team.

Figure IV.3. Available options for complying with DOE O 460.1A.

The safety assessments for routine onsite hazardous materials movements may be documented in Chapter VIII of the TSD or as stand-alone documents referenced in Chapter VIII. The process by which safety assessments for nonroutine transfers are performed, documented, and approved should be described in Chapter IX of the TSD. Documentation of the safety assessment may cover the following topics:

- a. Description. The onsite hazardous material movement to be evaluated should be thoroughly described. The hazardous material to be transported should be stated, and its hazard level should be indicated. Site-specific details, such as transport routes, should be described where appropriate.
- b. Packaging. The packaging to be used for the onsite transfer should be described, and should be categorized as (1) DOT packaging, (2) equivalent packaging, or (3) non-equivalent packaging. For DOT packaging, the safety assessment documentation should reference the appropriate DOT standard and any packaging test report or other documentation which demonstrates that the packaging is approved for offsite shipment of the hazardous material to be transported onsite. For equivalent packaging, the safety assessment documentation should provide a reference to the DOT packaging to which this packaging is equivalent, and should provide supporting evidence to demonstrate equivalence. For non-equivalent packaging, the safety assessment documentation should provide a detailed analysis of the packaging in which the performance envelope of the packaging is clearly established. To establish the performance envelope of the packaging, evaluation of design basis conditions (DBC) is recommended. DBCs should be site-specific and possibly route-specific conditions under which the packaging should be able to provide containment during onsite transport. DBCs to be considered for a particular hazardous materials transport will depend on the hazard level of the material. Chapter VII of the TSD should include guidance on which DBCs should be developed for each hazard level, and should establish minimum performance requirements for each hazard level. Examples of DBCs which may be appropriate for some hazard levels are shock, vibration, collision, fall, fire, penetration, and immersion. Others may also be appropriate.

To illustrate how the performance requirements established in Chapter VII of the TSD can be used to develop an appropriate DBC, a particular hazardous material may be grouped into a hazard level that requires a packaging to be able to survive a 3-ft drop with no loss of containment. For this hazardous material, a 3-ft drop would then become the DBC for falls, without regard to conditions along the transport route or during handling which might expose the packaging to a fall from a higher distance. If the packaging could not survive a 3-ft drop, additional administrative controls would need to be imposed on the transport system to ensure an adequate level of safety during transport. Guidance regarding appropriate administrative controls should be provided in Chapter VII of the TSD.

As an example of how physical limitations of a site may be incorporated into a DBC, a particular hazardous material may be grouped into a hazard level that requires a packaging to be able to survive a 30-ft drop. For this particular hazardous material shipment, an evaluation of the transport route may show that, for any accident which could occur along the transport route, the packaging could never fall more than 10 ft. If a control on the packaging is also imposed requiring that the packaging never be elevated more than 10 ft during handling, the DBC need only consider a 10-ft fall.

- c. Controls. The controls to be placed on the onsite hazardous materials transport should be described. As shown in Figure IV.3, full compliance with DOT control and communication requirements for offsite transport is an option, unless a non-equivalent packaging is being used. The full compliance option may be documented with no further evaluation. (The tie down and vehicle requirements of DOT would need to be imposed for a hazardous materials transport to be in full compliance with offsite DOT regulations.) For DOT or equivalent packaging, the other option is to provide site-specific controls. These controls need only ensure that the packaging will not be exposed to transport conditions any more severe than the packaging would experience during an offsite shipment.

For non-equivalent packaging, controls should be commensurate with the hazard represented by the package being transported, and should ensure that the packaging operates within its established performance envelope. The hazard levels and associated performance requirements documented in Chapter VII of the TSD will greatly facilitate development and justification of appropriate transport controls. Controls may include establishment of special communication requirements (e.g., radio contact with emergency response personnel) which are required to compensate for packaging inadequacies.

- d. Communication. The communication requirements for the onsite hazardous material transport should be described. Again, Figure IV.3 shows that full compliance with DOT communication and control requirements for offsite transport is an option for DOT and equivalent packaging. This option may be documented with no further evaluation. Full DOT compliance would include strict adherence to use of DOT packaging as well as all marking, labeling, placarding, and shipping papers requirements of DOT. The other option for DOT and equivalent packaging is to develop site-specific communication requirements. Since the purpose of the DOT marking, labeling, placarding and shipping papers requirements is to communicate the hazards of the material being shipped to personnel handling the material and to emergency responders in the event of an accident, sites may develop other methods of communication with personnel involved with the transport and with emergency response personnel.

For non-equivalent packaging, communication requirements need to be established and evaluated as part of the entire transport system. The system should be shown to provide equivalent safety.

As with the establishment of all transport requirements, communication requirements should be commensurate with the hazard of the material being transported. Justification

for communication requirements can best be provided on the basis of the performance requirements documented in Chapter VII of the TSD.

In some cases, special communication requirements will be described as part of the control requirements for the transport. Such requirements should be repeated here.

- e. Conclusion. The safety assessment should conclude that, based on the evidence provided, the transport system provides a level of protection commensurate with the hazard of the material being transported.

6. REFERENCES

- a. Code of Federal Regulations, Office of the Federal Register, Washington, D.C.
 - (1) Title 10, Part 71, "Packaging and Transportation of Radioactive Materials."
 - (2) Title 29, Part 1910, "Occupational Safety and Health Standards."
 - (3) Title 40, Parts 260-281, "Environmental Protection Agency Regulations."
 - (4) Title 49, Parts 106-199, "Hazardous Materials Regulations."
 - (5) Title 49, Parts 350-399, "Federal Motor Carrier Safety Regulations."

- b. American National Standards Institute, American National Standards Institute, New York.
 - (1) N14.1-1995, *Packaging of Uranium Hexafluoride for Transport*, 1995.
 - (2) N14.5-1987, *Leakage Tests on Packages for Shipment*, 1987.
 - (3) N14.6-1993, *Special Lifting Devices for Shipping Containers Weighing 10,000 Pounds (4500kg) or More*, 1993.
 - (4) N14.27-1993, *Carrier and Shipper Responsibilities and Emergency Response Procedures for Highway Transportation Accidents*, 1993.
 - (5) N14.29-1988, *Guide for Writing Operating Manuals for Packaging*, 1988.
 - (6) N14.30-1992, *Design, Fabrication, and Maintenance of Semi-Trailers Employed in the Transport of Weight-Concentrated Radioactive Loads*, 1992.

- c. Arendt, J. W., et al., ORNL/M-3077, *Transportation and Packaging Resource Guide*, Oak Ridge National Laboratory, Oak Ridge, Tennessee, December 1994.
- d. Fischer, L.E., et al, UCID-21218, *Packaging Review Guide for Reviewing Safety Analysis Reports for Packagings, Rev.1*, Lawrence Livermore National Laboratory, Livermore, California, October 1988.
- e. O'Brian, J., WHC-SP-0864, *Performance-Oriented Packaging - A Guide to Identifying, Procuring, and Using*, Westinghouse Hanford Company, Richland, Washington, September 1992.
- f. Shappert, L. B., ORNL/M-5003, *Packaging Handbook*, to be published at Oak Ridge National Laboratory, Oak Ridge, Tennessee.
- g. U.S. Department of Energy, Draft EH-30 Instruction 30.50.02, Rev.0, "Quality Assurance Assessment Program for Packaging Used in the Transportation of Hazardous Materials," Office of Environment, Safety and Health, Washington, D.C., April 1994.
- h. U.S. Department of Energy, U.S. Department of Energy, Washington, D.C.
 - (1) DOE M 251.1-1, *DIRECTIVES SYSTEM MANUAL*, October 1995.
 - (2) DOE O 5700.6C, *QUALITY ASSURANCE*, August 1991.
 - (3) DOE-STD-1075-94, *DOE Standard: Standard for Developing and Issuing DOE Safety Guides and Implementation Guides*, July 1994.
- i. U.S. Department of Energy, WHC-EP-0558, *Test and Evaluation Document for DOT Specification 7A Type A Packaging*, Westinghouse Hanford Company, Richland, Washington, July 1992.

- j. U.S. Nuclear Regulatory Commission, Office of Standards Development, Washington D.C.
- (1) *Regulatory Guide 7.6: Design Criteria for the Structural Analysis of Shipping Cask Containment Vessels, Rev. 1, March 1978.*
 - (2) *Regulatory Guide 7.8: Load Combinations for the Structural Analysis of Shipping Casks for Radioactive Material, Rev. 1, March 1989.*
 - (3) *Regulatory Guide 7.9: Standard Format and Content of Part 71 Applications for Approval of Packaging of Type B, Large Quantity, and Fissile Radioactive Material, Rev. 1, January 1980.*
 - (4) *Regulatory Guide 7.10: Quality Assurance Programs Applicable to Design, Fabrication, Assembly, and Testing of Packaging Used in Transport of Radioactive Material, Rev. 1, June 1986.*
 - (5) *Regulatory Guide 7.11: Fracture Toughness Criteria of Base Material for Ferritic Steel Shipping Cask Containment Vessels with a Maximum Wall Thickness of 4 Inches, June 1991.*
 - (6) *Regulatory Guide 7.12: Fracture Toughness Criteria of Base Material for Ferritic Steel Shipping Cask Containment Vessels with a Wall Thickness Greater than 4 Inches But Not Exceeding 12 Inches, June 1991.*

ATTACHMENT 1

SELECTED CHRONOLOGICAL MILESTONES CONCERNING DEPARTMENT OF ENERGY ORDERS 1540.2 AND 5480.3

- 1985. The Department of Energy (DOE) Order 5480.3 provided for a packaging certification program where each field office was allowed to perform its own certifications.

Following a congressional inquiry, the program was changed, and a centralized certification program was established at DOE Headquarters in 1985 under Defense Programs (DP). This centralized program was proscribed in DOE 1540.2. Management of transportation operations was also under DP at this time.

However, DOE 5480.3, which addresses packaging and transportation safety, was not changed. Therefore, one Order allows certification at the field office level, and one does not. (A memorandum was issued that clearly removed the authority from the field, but DOE 5480.3 was never changed.)

- 1987. Defense Programs requested that the Office of Environment, Safety and Health (EH) update DOE 5480.3 to reflect the current organizational responsibilities as well as correct 21 areas where the Order conflicted with the Department of Transportation/Nuclear Regulatory Commission packaging and transportation regulations used by DOE (essentially Title 10, *Code of Federal Regulations*, Part 71, and Title 49, *Code of Federal Regulations*, Part 173).

EH was also requested to issue a Notice to the Order clarifying the issues until the Order could be revised. Although Notices were issued, the Notices have expired without any revisions to the Order: therefore, the current Order continues to reflect the conflicts.

- 1989–1992 Reorganizations. The Office of Environmental Restoration and Waste Management (EM) was formed, and the management of transportation operations function was transferred from DP to EM. Also, during this period, the certification function was transferred from DP to EH.

These changes left the Orders in a status where they were not only in conflict with one another and with the federal regulations, but no longer reflected any correct organizational structure or responsibilities. For example, both Orders showed DP with the major programmatic responsibilities for packaging and transportation operations and safety.

- 1992. EH and EM began a concerted effort to update the Orders. Since previous reorganizations had transferred major responsibilities from DP and split them between EH and EM, the Order revision effort involved revamping the existing five transportation and packaging Orders 1540.1, 1540.1A, 1540.3, 1540.4, and 5480.3 into eight Orders 1540.1A, 1540.2A, 1540.3A, 1540.4A, 1540.5A, 1540.6A, 5480.3R, and 5480.X (onsite safety).

The intent was to cancel DOE 1540.2 and transfer its safety requirements to DOE 5480.3R, the successor to DOE 5480.3 which was being totally rewritten. DOE 1540.2 was to be reissued as a new Order with a different title and different requirements.

- 1994. Draft Orders 5480.3R, 5480.X, and 5480.3V (Motor Carrier Safety) were completed.
- 1995. As part of the Directives Reduction Initiative, DOE O 460.1 was issued which contained the surviving portions of the three 1994 Safety Orders. At the same time the revisions to the 1540 series took place in the form of DOE O 460.2.
- 1996. DOE O 460.1A replaced DOE O 460.1 when the EH packaging and transportation safety functions were transferred to EM.
- 1997. DOE G 460.1-1 is issued.

ATTACHMENT 2

**LETTER, JUDITH S. KALETA, CHIEF COUNSEL, U. S. DEPARTMENT OF
TRANSPORTATION TO SUSAN H. DENNY, DIRECTOR, TRANSPORTATION
MANAGEMENT DIVISION,
U. S. DEPARTMENT OF ENERGY, APRIL 23, 1991**



U.S. Department
of Transportation

Research and
Special Programs
Administration

Office of the
Chief Counsel

400 Seventh St. S.W.
Washington, D.C. 20590

APR 23 1991

Ms. Susan H. Denny
Director
Transportation Management Program
Office of Technology Development
Department of Energy
Washington, DC 20585

Dear Ms. Denny:

I am responding to your March 25 request for a definition of "public highway" in the context of the Hazardous Materials Transportation Act (HMTA), 49 App. U.S.C. 1801 et seq., and the Hazardous Materials Regulations (HMR), 49 C.F.R. Parts 171-180, issued under the HMTA. Because the applicability of the HMTA depends upon the existence of "transportation in commerce" (49 App. U.S.C. 1801, 1803, 1804), I will discuss the issues in terms of whether there is transportation in commerce rather than whether there is transportation on public highways.

On November 16, 1990, the HMTA was amended by the Hazardous Materials Transportation Uniform Safety Act of 1990 (HMTUSA), Public Law 101-615. Section 3 of the HMTUSA added a definition of "person" to 49 App. U.S.C. 1802 that makes it clear that government agencies offering hazardous materials for transportation in commerce or transporting hazardous materials in furtherance of a commercial enterprise are subject to the HMTA. It states:

The term 'person' means . . . government, Indian tribe, or agency or instrumentality of any government or Indian tribe when it offers hazardous materials in furtherance of a commercial enterprise, but such term does not include (a) the United States Postal Service, or (B) for the purposes of sections 110 and 111 [penalties and specific relief, respectively] of this title, any agency or instrumentality of the Federal Government.

Also, Section 20 of the HMTUSA added 49 U.S.C. App. 1818 to provide that the HMTA applies to contractors with, among others, the Federal Government. It states:

Any person who, under contract with any department, agency, or instrumentality of the executive, legislative, or judicial branch of the Federal government, transports, or causes to be transported or shipped, a hazardous material . . . shall be subject to and comply with all provisions of this title, all orders and regulations issued under this title, and all other substantive and procedural requirements of Federal, State and local governments and Indian tribes (except any such requirements that have been preempted by this title or any other Federal law), in the same manner and to the same extent as any person engaged in such activities that are in or affect commerce is subject to such provisions, orders, regulations, and requirements.

Therefore, the Department of Energy (DOE) is required to comply with the HMR when it offers hazardous materials for transportation or transports them in commerce. DOE, however, is not required to comply with the HMR when it offers or transports hazardous materials in a Government vehicle because those DOE activities are presumed to be for a governmental purpose and thus not in commerce.

DOE's contractors, however, must comply with the HMR even when the transportation is in a Government vehicle -- unless the transportation is not in commerce (a prerequisite to the applicability of the HMTA and the HMR).

Transportation on (across or along) roads outside of Government properties generally is transportation in commerce. Transportation on Government properties requires close analysis to determine whether it is in commerce. If a road is used by members of the general public (including dependents of Government employees) without their having to gain access through a controlled access point, transportation on (across or along) that road is in commerce. On the other hand, if access to a road is controlled at all times through the use of gates and guards, transportation on that road is not in commerce.

One other means of preventing hazardous materials transportation on Government property from being in commerce is to temporarily block access to the section of the road being crossed or used for that transportation. The road would have to be blocked by persons having the legal authority to do so, and public access to the involved section of road would have to be effectively precluded.

The following discussion applies these general principles to the situations described in your letter.

Example 1: Road A is located on DOE-owned property and is maintained by DOE. Speed enforcement is by a DOE contractor. The road has unrestricted public access, but there are signs stating that persons are entering DOE property. Analysis: Road A has unrestricted public access, and, therefore, transportation on or across it is subject to the HMR.

Example 2: Road B traverses a DOE site, but is maintained by the State. Speed enforcement is by the State. The DOE cannot unilaterally block the road. There is unrestricted public access, except for times when DOE/State Police physically block public access in order to make special shipments. Analysis: Because there is unrestricted public access to Road B, transportation on or across it is subject to the HMR. However, effective blocking of public access (as described above) by DOE or State officials would avoid application of the HMR.

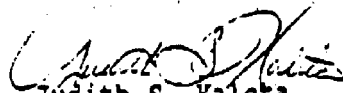
Example 3: Road C connects two DOE sites, is owned by the city and is maintained by DOE under a legal agreement. Speed enforcement is by the city. The public has unrestricted access. Analysis: Road C is not on Government property; thus, the HMR would apply.

Example 4: Road D is on DOE-owned property and is maintained by DOE. Speed enforcement is by a DOE contractor. The road is posted with a sign restricting usage to those on official government business, but there are no physical barriers. Analysis: Because there is public access to Road D, the HMR would apply there. This result could be changed either by effectively blocking public access or by controlling public use at all times through the use of gates and guards.

As indicated above, transporting a hazardous material across a road or doing so along a road both are subject to the HMR unless the section of the road involved is removed from commerce by one of the above-described actions.

I trust that this information will be useful to you in providing guidance to your operating contractors. Please advise me if additional information or clarification is desired.

Sincerely,


Judith S. Kaleta
Chief Counsel

ATTACHMENT 3

LETTER, E. H. BONEKEMPER, ASSISTANT CHIEF COUNSEL, U. S. DEPARTMENT OF TRANSPORTATION TO JO ANN WILLIAMS, OFFICE OF CHIEF COUNSEL, U. S. DEPARTMENT OF ENERGY, APRIL 26, 1993.

93-263



US Department of Transportation
Research and Special Programs Administration

Office of the Chief Counsel

400 Seventh St. S.W.
Washington D.C. 20590

APR 26 1993

*Rec'd at CRM-4
5/3/93*

Ms. Jo Ann Williams
Office of Chief Counsel (GC-12)
U.S. Department of Energy
Washington, D.C. 20585

Dear Ms. Williams:

On April 15, 1993, at a meeting attended by representatives of this office, the Federal Highway Administration, the Department of Energy (DOE) and the University of California, we discussed the application of the Hazardous Materials Transportation Act (HMTA), 49 App. U.S.C. §§ 1801 et seq., to hazardous materials transportation at the Los Alamos National Laboratory (LANL). This meeting followed an inquiry to the Research and Special Programs Administration (RSPA) from the University's LANL Counsel, Ellen M. Castille. Specifically, Ms. Castille inquired whether the HMTA and its implementing regulations, 49 C.F.R. Parts 171-180 (the Hazardous Materials Regulations or HMR), apply to the transportation of hazardous materials by the University in its capacity as operator, under contract to the DOE, of the LANL.

This letter sets out the jurisdictional framework of the HMTA as it applies to hazardous materials transportation by Federal agencies and their contractors. Although RSPA exercises rulemaking authority under the HMTA with respect to all hazardous materials transportation in commerce, enforcement authority over land-based transportation is shared with the Federal Highway Administration and the Federal Railroad Administration.

The HMTA, as amended by the Hazardous Materials Transportation Uniform Safety Act, Pub. L. No. 101-615, 104 Stat. 3244 (1990), applies to "any person" who transports hazardous materials in commerce. 49 App. U.S.C. § 1804(a)(3). The term "person" includes any:

government or Indian tribe when it offers hazardous materials for transportation in commerce or transports hazardous materials in furtherance of a commercial enterprise....



Id. at § 1820(11). Hazardous materials transportation by a Federal, State or local government agency or an Indian tribe, then, is subject to regulation under the HMTA when that transportation is "in furtherance of a commercial enterprise." RSPA defines this term by its converse: governmental transportation is not in furtherance of a commercial enterprise when it is carried out (1) by government personnel and (2) for a governmental purpose.

The sphere of "governmental purpose" cannot be delineated in the abstract. When the activity in conjunction with which the transportation occurs is constitutionally mandated or authorized, when it is a traditional "sovereign" activity or one falling within the police power, or when its benefits accrue to the public as a whole, it is likely to fall within the realm of the governmental purpose. The purpose is more apt to be deemed non-governmental if there is a conscious purpose to generate a profit, if the activity is undertaken by a public corporation with limited liability, or if the activity competes with, or displaces, the private sector. Each case must be considered on its facts.

When the transporter is not the Federal Government itself, but a Federal contractor, the HMTA provides:

Any person who, under contract with any department . . . of the Federal government, transports, or causes to be transported or shipped, a hazardous material . . . shall be subject to and comply with all provisions of [the HMTA], all orders and regulations issued under [the HMTA], and all other substantive and procedural requirements of Federal, State and local governments and Indian tribes (except such requirements that have been preempted by this chapter or any other Federal law), in the same manner and to the same extent as any person engaged in such activities that are in or affect commerce is subject to such provisions, orders, regulations, and requirements.

49 App. U.S.C. § 1818. This provision, added to the statute by the 1990 amendment, merely clarified existing law. See H. Rep. No. 101-444 (Part 2), 101 Cong., 2d Sess. 43 (1990) ("It is the Committee's firm position that [section 1818] simply restates existing law."). The provision means that a Federal contractor cannot claim sovereign immunity and does not share in the

exception from HMTA jurisdiction conferred on the governmental agency itself. Therefore, the contractor's transportation activity is subject to HMTA regulation if that activity is "in commerce."

RSPA accords the "in commerce" requirement its accepted meaning. See 49 App. U.S.C. § 1802(2) (defining transportation in "commerce" as transportation that is or affects interstate trade or traffic). Thus, the HMTA does not apply to transportation that is entirely on private property and neither follows nor crosses a public way. Analogously, transportation by a Federal contractor is not in commerce if it takes place entirely on Federal property to which there is no general public right of access, or if public access legally is denied during the period of transportation.

Were the University of California not itself a government agency, its transportation of hazardous materials in the performance of its contractual duties would be subject to the HMTA, to the extent transportation occurred on public roads. However, because the University is a governmental body, its hazardous materials transportation as the operator of the Los Alamos National Laboratory, on public roads or not, is not subject to the HMTA, provided that transportation is by government personnel and for a governmental purpose.

The HMR, however, may impose requirements on the University of California irrespective of its status as a governmental body or Federal contractor, and whether or not the transportation in which it engages is in commerce. For example, the requirement that every bulk oil transporter prepare and maintain a spill response plan would apply to the University, even as a State agency and a Federal contractor, and even were its transportation not in commerce. 49 C.F.R. at § 171.5 (interim final rule promulgated at 58 Fed. Reg. 6864, February 2, 1993).

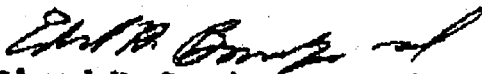
Conversely, governmental bodies are exempt from the registration and fee requirements of 49 C.F.R. Subpart 107.600, even where they transport hazardous materials in commerce. 49 C.F.R. § 107.606. And where transportation otherwise would be subject to the HMTA, it may be exempted from regulation by a specific code provision (e.g., 49 C.F.R. §§ 173.7(b) and 177.806(b), excepting certain national security shipments of Class 7 radioactive materials).

Where the University's hazardous materials transportation, or some part of it, is exempted from HMTA jurisdiction, the University and DOE still may find it desirable to agree, or DOE may choose to require, that transportation shall be in accordance with HMR standards. Such a course may be sensible,

particularly given that it may not always be clear where the line between governmental and non-governmental purpose lies. This decision, however, would be one not of the application of the HMTA, but rather of contractual obligations owed to the DOE by the University apart from HMTA or U.S. Department of Transportation jurisdiction. If the HMR did not otherwise apply, the University's agreement, voluntary or through contract, to comply with the HMR would not invoke U.S. DOT enforcement jurisdiction.

I trust this guidance is of assistance to you. Please feel free to call me at 202-366-4400 if you have any further questions on this matter.

Sincerely,


Edward H. Bonekemper, III
Assistant Chief Counsel
Hazardous Materials Safety &
Research and Technology
Law

cc: Ellen M. Castille ✓
Larry G. Blalock
Paul Brennan

ATTACHMENT 4

CAPABILITY OF TEST FACILITIES FOR TESTING TYPE A PACKAGINGS

The following sections provide additional description to Section 4.2.2.4.2, “Test Requirements,” presenting details on the test facility requirements for the Type A packaging tests and the pass/fail criteria for each test.

a. Chemical Compatibility Test for Plastic Packagings and Receptacles

A chemical compatibility test for plastic packagings and receptacles designed to transport liquid contents is required by 49 CFR 173.24(e)(3)(ii). To perform this test, a test facility should be capable of filling three of the plastic packagings or receptacles to rated capacity with the specific hazardous material to be transported, storing them at one of the specified test temperatures for the test duration required by Appendix B to 49 CFR 173, inverting the containers for the required times at the beginning and end of the storage period, and determining the weight loss of hazardous materials contents during the storage period. After storage, a test facility should be capable of draining, rinsing, and refilling the containers with water to their rated capacity, then dropping the containers at ambient temperature from the height required by Appendix B onto a rigid non-resilient, flat and horizontal surface. A test facility should also be capable of evaluating the containers for visible evidence of permanent deformation due to vapor pressure buildup or collapse of walls, deterioration, swelling, crazing, cracking, excessive corrosion, oxidization, embrittlement, leakage, rupture, or other defects likely to cause premature failure or a hazardous condition. In addition, a test facility should be capable of calculating the rate of permeation over the test period and comparing it to the permeation limits of Appendix B.

Alternative procedures or rates of permeation are permitted by 49 CFR 173.24(e)(3)(iii) if they yield a level of safety equivalent to or greater than that provided by 173.24(e)(3)(ii) and are specifically approved by the Associate Administrator for Hazardous Materials Safety at DOT. Justification and procedures would have to be developed by the test facility and submitted to EM. If EM approved the request and the supporting documentation, EM would then submit the application to DOT.

Each test facility should have procedures which describe the equipment to be used for the required storage, permeation evaluation, and drop test. The test procedure should describe the test equipment, discuss the method by which the storage temperature would be maintained, state how the various storage configurations would be achieved and timed, describe how the rate of permeation would be determined, document the maximum package size (external dimensions and weight) the apparatus is capable of testing, describe the means by which the proper drop height is assured, provide the pass/fail criteria for the test, and list the records to be kept of the testing and results. Any package design which exhibited a rate of permeation in excess of the permeation limits of Appendix B or any visible evidence of permanent deformation of any of the containers due to vapor pressure build-up or collapse of walls, deterioration, swelling, crazing, cracking, excessive corrosion, oxidization, embrittlement, leakage, rupture, or other defects likely to cause premature failure or a hazardous condition as a result of this test would fail this test.

b. Vibration Test

A vibration test for non-bulk packaging is required by 49 CFR 173.24a(a)(5). Non-bulk packaging is defined in 49 CFR 171.8 as a packaging which has (1) an internal volume of 450 liters (119 gallons) or less as a receptacle for a liquid; (2) a capacity of 400 kg (882 lb) or less or an internal volume of 450 l

(119 gal) or less as a receptacle for a solid; or (3) a water capacity of 454 kg (1,000 lb) or less as a receptacle for a gas. The ability to withstand vibration is also required of all Type A packagings in 49 CFR 173.410(f).

To perform the vibration test, a test facility should be capable of placing three sample packagings, filled and closed as for shipment, on a vibrating platform that has a vertical double-amplitude (peak-to-peak displacement) of 1 in.. The packages should be constrained horizontally to prevent them from falling off the platform, but should be left free to move vertically, bounce and rotate. The test should be performed for 1 hour at a frequency that causes the package to be raised from the vibrating platform to such a degree that a piece of material of approximately 1.6 mm (0.063 in.) thickness (such as steel strapping or paperboard) can be passed between the bottom of any package and the platform. Immediately following the period of vibration, each package should be removed from the platform, turned on its side and observed for any evidence of leakage. Other methods, at least equally effective, may be used, if approved by the Associate Administrator for Hazardous Materials Safety.

A test facility should provide documentation describing its vibration test apparatus and demonstrating that it meets the test requirements specified in 49 CFR 178.608. The vibration test procedure should describe the vibration test equipment, document the maximum package size (external dimensions and weight) the apparatus is capable of testing, describe the means by which the proper vibration height is assured, provide the pass/fail criteria for the test, and list the records to be kept of the testing and results. Any package design showing evidence of rupture or leakage as a result of this test would fail this test.

c. Reduced Ambient Pressure Test

A reduced ambient pressure test should be conducted to verify the Type A package design requirement found in 49 CFR 173.412(f). To perform this test, a test facility should be capable of subjecting the containment system to a reduced ambient pressure of 25 kPa (3.5 lb/in.²) or otherwise creating an equivalent pressure differential. A test facility should have procedures which describe the equipment to be used for the test, the range of packaging sizes which can be tested with this equipment, the way in which the test will be conducted, the test duration, the pass/fail criteria for the test, and records to be kept of the testing and results. Any package design showing evidence that the containment system would not retain its radioactive contents under the conditions of this test would fail this test.

d. Water Spray Test

A water spray test is required for Type A packages by 49 CFR 173.465(b). To perform this test, a test facility should be capable of simulating exposure to rainfall of approximately 5 cm (2 in.) per hour for at least 1 hour. Water spray should either be applied from four different directions simultaneously, in which case an interval of 2 hours should elapse before the next test is performed on the packaging, or from each of four directions consecutively in which case no time should elapse before the next test is performed.

Each test facility should have procedures which describe the equipment to be used for the test, any calibration which is required to ensure a water spray of 5 cm (2 in.) per hour how the test will be conducted and timed, the pass/fail criteria for the test, and records to be kept of the testing and results. Any evidence of the following as a result of this test would constitute failure of this test: (1) loss or dispersal of the radioactive contents, or (2) any significant increase in the radiation levels recorded or calculated at the external surfaces of the packaging. Because any radiation level increase would be dependent on the radioactive package contents, this criterion should be evaluated for specific package contents whenever damage to the packaging occurs as a result of the test. The test facility should document any decrease in

effectiveness of the shielding in a way that will enable a determination of acceptability to be made by any package user for any contents. This documentation should be incorporated into the *Blue Book*.

e. Free Drop Test

A free drop test is required for Type A packages by 49 CFR 173.465(c). For liquids and gases, an additional test is specified in 49 CFR 173.466(a)(1). To perform these tests, a test facility should be capable of dropping a packaging onto a flat and horizontal surface of such mass and rigidity that any increase in its resistance to displacement or deformation upon impact by the specimen would not significantly increase the damage to the specimen. The test apparatus should be capable of handling both small and large packagings, and should be capable of performing drops ranging from 0.3 m (1 ft) to 9 m (30 ft).

Each test facility should provide documentation describing its drop test apparatus and demonstrating that its target surface meets the mass and rigidity requirements of 49 CFR 173.465(c)(5). The drop test procedure should document the maximum package size (external dimensions and weight) the apparatus is capable of testing, the means by which packagings of various sizes and types would be lifted and dropped, the manner in which a maximum-damage drop orientation would be determined for each packaging, the means by which the appropriate drop orientation and drop height would be ensured during testing, the pass/fail criteria for the drop tests, and records to be kept (including photographs and/or videotape) of the testing and results. Any evidence of the following as a result of this test would constitute failure of this test: (1) loss or dispersal of the radioactive contents, or (2) any significant increase in the radiation levels recorded or calculated at the external surfaces of the packaging. Because any radiation level increase would be dependent on the radioactive package contents, this criterion should be evaluated for specific package contents whenever damage to the packaging occurs as a result of the test. The test facility should document any decrease in effectiveness of the shielding in a way that will enable a determination of acceptability to be made by any package user for any contents. This documentation will be incorporated into the *Blue Book*.

f. Stacking

A compression test is required for Type A packages by 49 CFR 173.465(d). To perform this test, a test facility should be capable of applying a compressive load uniformly to two opposite sides of a packaging specimen, one of which should be the base on which the package would normally stand, for a period of at least 24 hours.

Each test facility should have procedures describing the apparatus used for compression tests, how the compression test is performed for various packaging sizes and shapes, how the compressive load is determined for each packaging, the pass/fail criteria for the test, and records to be kept of the testing and results. Any evidence of the following as a result of this test would constitute failure of this test: (1) loss or dispersal of the radioactive contents, or (2) any significant increase in the radiation levels recorded or calculated at the external surfaces of the packaging. Because any radiation level increase would be dependent on the radioactive package contents, this criterion should be evaluated for specific package contents whenever damage to the packaging occurs as a result of the test. The test facility should document any decrease in effectiveness of the shielding in a way that will enable a determination of acceptability to be made by any package user for any contents. This documentation will be incorporated into *Blue Book*.

g. Penetration Test

A penetration test is required for Type A packages by 49 CFR 173.465(e). An additional test for Type A packagings designed for liquids and gases is specified in 49 CFR 173.466(a)(2). To perform these tests, a test facility should be capable of evaluating a packaging to determine where it is most vulnerable to puncture, then placing a packaging specimen on a rigid, flat, horizontal surface that will not move while the test is being performed and dropping a 3.2 cm (1.3 in.) diam, 6 Kg (13.2 lb) bar with a hemispherical end onto the most vulnerable part of the packaging, from a distance of 1 m (3.3 ft) or greater and with its longitudinal axis vertical.

Each test facility should have documented procedures describing the means by which the part of the packaging most vulnerable to penetration is determined, the way in which the test is conducted, the pass/fail criteria for the test, and records to be kept (including photographs and/or videotape) of the testing and results. Any evidence of the following as a result of this test would constitute failure of this test: (1) loss or dispersal of the radioactive contents, or (2) any significant increase in the radiation levels recorded or calculated at the external surfaces of the packaging. Because any radiation level increase would be dependent on the radioactive package contents, this criterion should be evaluated for specific package contents whenever damage to the packaging occurs as a result of the test. The test facility should document any decrease in effectiveness of the shielding in a way that will enable a determination of acceptability to be made by any package user for any contents. This documentation will be incorporated into the *Blue Book*.

ATTACHMENT 5

QUALITY ASSURANCE FOR CONTRACTOR TESTING FACILITIES

The following criteria pertain to establishing quality assurance for contractor testing facilities and provide additional guidance to Section 4.2.2.5, "Quality Assurance."

a. Management

DOE 5700.6C specifies four management quality assurance criteria.

Criterion 1—Program. Organizations shall develop, implement, and maintain a written quality assurance program (QAP). The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work. The QAP shall describe the management system, including planning, scheduling, and cost control considerations.

Each test facility should operate under a documented QAP. This documentation should be provided to EM for review as part of the approval process for the test facility.

Criterion 2—Personnel Training and Qualification. Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained.

The various review and testing tasks which should be performed as part of this program should be defined. Minimum personnel qualifications should then be established for each of these tasks. Personnel reviewing the applicant's documentation and evaluating test results should be technically qualified to do so, particularly in mechanical design areas such as lifting and tie down requirements. Personnel determining worst-case drop orientations should also be qualified to do so. Personnel performing the tests should be trained in the test requirements and test procedures. Documentation of the defined tasks and qualification requirements for each should be provided to EM for review as part of the approval process for each test facility.

A procedure for qualifying personnel to perform the defined tasks should also be provided to EM. The procedure should include establishment and maintenance of training records, where appropriate.

Criterion 3—Quality Improvement. The organization shall establish and implement processes to detect and prevent quality problems and to ensure quality improvement. Items and processes that do not meet established requirements shall be identified, controlled, and corrected. Correction shall include identifying the causes of problems and preventing recurrence. Item reliability, process

implementation, and other quality-related information shall be reviewed and the data analyzed to identify items and processes needing improvement.

Each test facility should provide documentation demonstrating that the test facility organization has established quality improvement processes and that the test facility operates under these established processes. This documentation should be provided to EM for review as part of the approval process for the test facility.

Criterion 4—Documents and Records. Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained.

As discussed in Section 4, each test facility is required to have a set of procedures fully documenting the way in which it processes an application for a Type A package evaluation. The procedures should cover both the review of the applicant's documentation and the testing which is performed on the packaging subsequent to the documentation review. These procedures should be provided to EM for review as part of the approval process for the test facility.

The procedures should be prepared, reviewed, approved, issued, used, and revised under a formal document control system. Documentation of the formal document control system should also be provided to EM for review as part of the approval process for the test facility.

Each procedure should document the records to be maintained as a result of implementation of that procedure. The records should provide adequate detail to ensure that the procedure was correctly implemented and the proper conclusions regarding the packaging were reached. For some tests (e.g., the drop tests) a visual record (photographs and/or videotape) may be appropriate. Appropriate records include:

- a. applicant's design packet;
- b. documentation of review of applicant's design packet, including comment resolution where appropriate;
- c. records of the testing and results, including photographs and/or videotape where appropriate;
- d. documentation developed by test facility of testing and results, including *Blue Book* changes where appropriate; and
- e. records of review and approval of the documentation by EM.

Records to be maintained should also include documentation of the test facility program and procedures, including:

- a. documentation of procedures and procedure revisions;
- b. documentation of equipment qualification and maintenance, where appropriate;
- c. documentation of review and approval of test facility procedures and equipment by EM;
- d. task descriptions; and
- e. personnel qualifications for individuals performing defined tasks.

Records should be maintained under a formal records maintenance system covering retention, protection, preservation, traceability, accountability, and retrievableness of records. Documentation of the records maintenance system for the test facility organization should be provided to EM for review as part of the approval process for the test facility.

b. Performance

DOE 5700.6C specifies four performance quality assurance criteria.

Criterion 5—Work Processes. Work shall be performed to established technical standards and administrative controls. Work shall be performed under controlled conditions using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.

Section 4.2.2.4 of this document discusses the content expected in procedures describing work to be performed under this program.

Criterion 6—Design. Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.

This program performs design verification activities rather than design work. As such, most of the elements of this criterion do not apply. Careful documentation of the design being reviewed, including

documentation of any design changes resulting from the review, should be assured so that verification of the correct design is established. This program already ensures that verification and validation of the package design are completed before the packaging is approved for use. Independence of personnel performing design verification from package design should also be ensured. Documentation should be provided to EM demonstrating that (1) the test facility will ensure that verification of the correct design is established and (2) personnel performing the design verification activities are independent of package design efforts. This documentation should be provided to EM for review as part of the approval process for the test facility.

Criterion 7—Procurement. The organization shall ensure that procured items and services meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. The organization shall ensure that approved suppliers can continue to provide acceptable items and services.

This criterion should be applied to the procurement of test apparatus and any other items procured in support of this program. Each test facility organization should have a documented procurement program to accomplish this. Documentation of the procurement program for the test facility organization should be provided to EM for review as part of the approval process for the test facility.

Criterion 8—Inspection and Acceptance Testing. Inspection and acceptance testing of specified items and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained.

Inspection and acceptance testing of test apparatus should be specifically addressed in the test procedures, where appropriate.

c. Assessment

DOE 5700.6C specifies two assessment quality assurance criteria.

Criterion 9—Management Assessment. Management at all levels shall periodically assess the integrated quality assurance program and its performance. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

Each test facility should provide documentation demonstrating that the test facility organization has an established management assessment program, and that the test facility operates within this management

assessment program. This documentation should be provided to EM for review as part of the approval process for the test facility.

Criterion 10—Independent Assessment. Planned and periodic independent assessments shall be conducted to measure item quality and process effectiveness and to promote improvement. The organization performing independent assessments shall have sufficient authority and freedom from the line organization to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.

Each test facility should provide documentation demonstrating that the test facility organization has an established independent assessment program, and that the test facility operates within this independent assessment program. This documentation should be provided to EM for review as part of the approval process for the test facility.