

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).

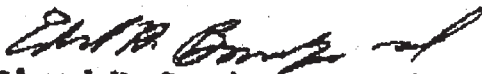
Conversely, governmental bodies are exempt from the registration and fee requirements of 49 C.F.R. Subpart 107.600, even where they transport hazardous materials in commerce. 49 C.F.R. § 107.606. And where transportation otherwise would be subject to the HMTA, it may be exempted from regulation by a 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.