The Honorable A. J. Eggenberger  
Chairman  
Defense Nuclear Facilities Safety Board  
625 Indiana Avenue, N.W.  
Suite 700  
Washington, D.C. 20004-2901  

Dear Mr. Chairman:

Your May 1, 2006, letter to me concerned the draft DOE manual being developed in response to Board Recommendation 2005-1. Your letter provided Defense Nuclear Facilities Safety Board staff comments and requested a report within 30 days. To address this matter in detail, the DOE 2005-1 working group developed the enclosed DOE comment resolution.

If you have any questions, please call me at 202-586-4693 or Mr. Richard Stark at 301-903-4407.

Sincerely,

C. Russell H. Shearer  
Acting Assistant Secretary for Environment, Safety and Health

Enclosure

cc: J. McConnell, NA-1  
    C. Lagdon, US-1  
    M. Whitaker, DR-1  
    R. Hardwick, EH-2  
    R. Stark, EH-24
The scope exclusion for nuclear materials in a "specifically analyzed and controlled radiological production or processing activity" is inconsistent with DOE's Implementation Plan (IP). Under this broad definition, activities involving nuclear materials in any facility operating under the requirements of either 10 CFR 835, Occupational Radiation Protection, or 10 CFR 830, Nuclear Safety Management, could potentially be excluded from the manual requirements. However, this exclusion appears to be inconsistent with a baseline assumption in the IP, which states, "This plan deals with materials that are stored outside of an improved engineered contamination confinement barrier, such as a glovebox or packages meeting DOE-STD-3013 and/or DOE-STD-3028." This exclusion also appears to be inconsistent with the manual's definition of interim storage, which states, "Interim Storage is on-site storage of materials outside of an approved engineered contamination barrier. Interim storage excludes materials that are stored in accordance with DOE-STD-3013, DOE-STD-3028, or DOE-HDBK-1129." A more defensible approach, consistent with the intent of Recommendation 2005-1, would be to rely on a reasonable time limit to allow for certain processes between removal of nuclear materials from an engineered contamination barrier and placement in packaging that meets the requirements of the manual.

Proposed language in manual: (Located in the Secretarial Cover Letter in Purpose). .....in a manner that protects the worker. The Manual requirements apply to interim storage of nuclear material packages outside of an approved engineered contamination barrier (e.g. hot cell, glovebox line, ventilation hood, liquid transfer line). Interim storage is defined as the period of time that materials can be stored while awaiting further disposition or processing (i.e. to WIPP, 3013 welded container or 3028 welded container) and will be documented in the site technical basis.

I.1.c (1) Nuclear Materials in Scope. ....The Manual requirements apply to interim storage of nuclear material storage packages outside of an approved engineered contamination barrier (e.g. hot cell, glovebox line, ventilation hood, liquid transfer line), where interim storage is defined as the period of time that materials can be stored while awaiting further disposition or processing (i.e. to WIPP, 3013 welded container or 3028 welded container) and will be documented in the site technical basis. The length of time that an item....

The following paragraph will be inserted at I.1.c (1) after the above paragraph and before the paragraph beginning Table 1.1. Applicable isotopes is intended to identify nuclear materials ......

An example of material that is within the intended scope of this manual would be Pu-238 contaminated rags in slip lid storage containers that were stored for an extended period. This resulted in an unacceptable internal exposure risk to the workers (ref. "Type B Accident Investigation of the August 5, 2003 Plutonium-238 Multiple Uptake Event at the Plutonium Facility, Los Alamos National Laboratory New Mexico, December, 2003). Another example of material that is within scope is programmatically owned material awaiting recycle or further disposition for extended periods of time (typically greater than 1 year, but may be material and package dependent).
Comment: The purpose of the draft Nuclear Material Packaging Manual is to safely store nuclear materials for an extended period of time (interim storage) and to ensure worker safety. Interim storage is defined as the period of time that materials can be stored while awaiting further disposition or processing. The DOE working group has attempted to clearly define materials in interim storage while clearly excluding materials in site specific mission oriented operations. Attempts to define mission oriented operations by using the authorization basis documents have met with mixed results. Likewise equivalent attempts to clearly distinguish site specific mission oriented operations from interim storage using simple prescriptive time intervals have also met with mixed results.

This issue was also raised and debated with several DOE Technical Review Board members. The Department now believes that the manual must tell the DOE field and DOE contractors what is expected relative to the safe interim storage of nuclear materials and yet allow each site to determine exactly how to distinguish between their mission specific oriented operations and interim storage.

The manual will be modified to state that the requirements apply to the interim storage of nuclear materials outside of an approved engineered contamination barrier. The manual will instruct the site to examine their nuclear material issues and to determine the distinction between mission oriented operations and interim storage and to ensure that the requirements in the manual are met.

Site determinations will be included in their technical basis documentation. The local DOE Site management will review and approve the contractor’s basis for making such a determination.

The options for calculating material thresholds have significantly different technical and regulatory origins and result in substantially different values. No justification is provided for allowing field activities to choose between the two methodologies, which in some cases may result in differences in threshold quantity of several orders of magnitude for identical materials. This inconsistency could result in

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excluding packages with sufficient quantities of material to be within the scope of the manual, or in categorizing materials as low risk that would otherwise be high risk, depending on which methodology is used. The manual ought to provide consistent protection of workers from equivalent quantities of nuclear material.

The methodology derived from DOE-HDBK-3010, Airborne Release Fractions/Rates and Respirable Fractions for Nonreactor Nuclear Facilities, employs a dilution factor in the calculation, and does not appear to have been reviewed previously or approved for use in safety basis calculations for determination of controls to protect facility workers. Such a calculation is inconsistent with the requirements in DOE-STD-3009 CN2, Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Documented Safety Analyses, which emphasize the difficulty of developing conservative quantitative consequences to facility workers. The methodology derived from DOE-HDBK-3010 requires significant knowledge of the nuclear material's physical characteristics (e.g., particle size distribution), which are not commonly determined under current practices. Assuming adequate information is available, the methodology then requires difficult technical judgments to ascertain appropriate values for respirable release fractions from DOE-HDBK-3010. The values listed in DOE-HDBK-3010 were developed experimentally for estimating macro source terms resulting from significant facility accidents (e.g., facility fires); those source terms were to be included in airborne plume models used to determine consequences for receptors located at relatively large distances from the facility. The use of these values in conjunction with a dilution factor for calculating consequences impacting safety to workers in the immediate vicinity of a radioactive material release from a package is highly questionable. The drawbacks of using this methodology to calculate threshold material quantities for the packaging manual are exacerbated by the lack of an explicit mechanism for review and approval by subject matter experts to provide a level of consistency across sites.

The methodology derived from DOE-HDBK-3010 contrasts with the technical simplicity and regulatory precedence associated with the more conservative methodology based on net intake factor used to calculate the A2 values specified in 49 CFR 173.435, Shippers-General Requirements for Shipments and Packagings. The A2 values have long been accepted as adequately conservative by numerous regulatory bodies, including the U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission, and the International Atomic Energy Agency. The purposes of the manual.

Attachment 4 "Calculating the MAR for the 5 rem and 100 rem Thresholds" will be modified and additional alternative means which can provide more realistic limits will be included, providing the methodologies have been reviewed and approved by appropriate peer groups, standards committees, and/or national or international regulators.

The 2005-1 working group finds that the dispersion model used by the IAEA (and thus in 49 CFR 173.435) to determine material respirable fractions that would expose a transportation worker in a transportation scenario and to calculate material limits (A2 values) is a conservative default model. The A2 table, while included as an option available to sites, is very conservative, since the isotope limit per container is based upon a hypothetical transportation accident which is much more severe than the accidents we deal with in the manual.

Sites that have adequate information regarding their material type and form are encouraged to calculate material specific threshold quantities, using appropriate mathematical models, including DOE and consensus standards, for the Respirable Release Fraction (RRF) and the Dilution Factor (DF) for their site specific material. This provides an adequate level of worker protection and avoids the cost and personnel exposures resulting from unnecessary repackaging of material. Information used in site calculations will be independently peer reviewed and documented in the site technical basis for interim nuclear material storage. Independently peer reviewed means that the peer reviews should be conducted by individuals who are organizationally independent from the organizations responsible for developing the site technical basis documents.

These methodologies include the IAEA Q system, from IAEA Safety Standard Series, Advisory Material for the IAEA.
A2 methodology, as applied in the manual, offers a simple, defensible way to determine material thresholds for facility workers by adjusting dose consequences to account for the receptor differences between a nuclear facility worker and a member of the public (e.g., shipping courier or first responder). The methodology derived from DOE-HDBK-3010 ought to be dropped in favor of the A2 methodology. Regulations for the Safe Transport of Radioactive Material, Safety Guide No. TS-G-1.1 (ST-2). This document (ST-2), discusses the Q system of calculating the A1 and A2 limits.

In the explanatory material for the IAEA Regulations it is stated “A person is unlikely to remain at 1 meter from the damaged package for more than 30 minutes…..[ST-2, 1.9 = IAEA Safety Standard Series, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Safety Guide No. TS-G-1.1 (ST-2)]

“In the revised Q system [which it used to use to calculate limits] the reference dose of 50mSv (5 rem) has been retained on the grounds that, historically, actual accidents involving Type A packages have lead to very low exposures. In choosing a reference dose, it is also important to take into account the probability of an individual being exposed as a result of a transportation accident: such exposures may, in general, be considered once in a lifetime exposures. Clearly, most individuals will never be exposed.” [ST-2, 1.10]

The IAEA regulations have flexibility regarding packaging and shipping constraints. Regarding inhalation dose due to alpha and beta emitting radioactive materials, there is no dose to the public or transportation worker except during package failure during an accident. The limits and the requirements for the packaging are based upon a worst case hypothetical transportation accident scenario. Therefore, the limits are set very conservatively.

Another alternative method to calculate A2 limits is using the methods and data in ANSI/ANS-5.10-1999, “Airborne Release Fractions at Non-reactor Nuclear Facilities”.

Also, the DOT 49 CFR 173.433 methodology allows the ratioing of the A1 and A2 limits where a solid and a powder are in the same shipment, versus the A2 limit for a uniform material. The A1 and A2 limits are typically several orders of magnitude apart for the same radionuclide.
This approach of using multiple material characteristics, i.e. solid and powder, or ratioing of isotopic mixtures to determine limits, is relevant for certain DOE materials to be placed in interim storage.

In the case of this DOE packaging manual, this set of published limits (A2 values for the radionuclides) is an easy way (conservative default value) to screen material out of scope for this manual since the material will be addressed by the normal Radiation Protection Program (RPP).

From this level to 20 times the A2 level (Low Risk Category), DOE will require that storage containers (storage packages) meet certain requirements to minimize the risk to workers to acceptable levels. At quantities greater than 20 times the A2 level (High Risk Category), DOE will require that the containers (storage packages) be more robust to bring the potential risk to the worker of a package failure down to similar acceptable levels.

This approach, establishing conservative default values and allowing a more precise determination based on availability of site specific data, is common in establishing and implementing national and international standards and requirements (e.g., IAEA and DOT (49 CFR 173) transportation regulations, 10 CFR 20 and 10 CFR 835 Occupational Radiation Protection derived air concentration (DAC) calculations and ANSI/ANS-5.10-1999 calculations). Several options for deriving threshold values are discussed in the manual. This does not imply that these are the only acceptable methods. Sites should use available information regarding material type and form to calculate material specific threshold quantities using mathematical models which they have determined to be most appropriate for their site specific material.

<table>
<thead>
<tr>
<th>The manual lacks technical bases for key parameters specified for several significant requirements. While many of the values appear to lead to reasonable results, providing technical bases for key parameters that are specified as requirements would strengthen the overall credibility of the document. Examples of key parameters that ought to be supported with a technical basis include the following:</th>
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<tr>
<td>Technical Basis</td>
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<td>First Bullet. The current annual limit for radiation exposure of radiation workers at DOE sites is 5 rem as prescribed by 10 CFR 835 (which is equivalent to NRC, NCRP, ICRP and IAEA standards). Therefore, the new draft manual requirements do not apply to storage packages containing radioactive materials whose...</td>
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</table>
- Dose values used for the in-scope and low to high thresholds
- Acceptable time limits for leaving materials unpackaged after removal from an engineered contamination barrier
- Packaging performance requirements (e.g., qualification leak rates, drop heights, and post-drop leak rates

postulated failure would result in a worker being exposed to less than the annual dose limit. These storage packages, which are out of scope for this manual, are still required to meet the 10 CFR 835 requirements including ALARA and be in compliance with the facility Radiation Protection Program.

For storage packages containing greater quantities of radioactive materials, i.e. in scope packages, the draft manual invokes additional requirements. The additional requirements have been developed in two major categories.

The Low Risk Category deals with packages containing radioactive materials whose postulated failure could result in exceeding the worker annual dose limit by a factor of greater than 1 but less than 20. For this category, the manual prescribes the functional design criteria, and testing needed to ensure package integrity during periods of interim storage.

For packages whose postulated failure could result in worker doses that are greater than 20 times the annual dose limit, a High Risk Category has been developed. The 20 times the annual dose limit was a consensus value from the working group. For this category, the package functional design criteria and testing are greater than the low risk category.

Both categories will protect the worker from postulated interim storage package accidents. The choice of two categories was selected to provide safe and cost sensitive package requirements while incorporating a graded approach.

Second Bullet. The acceptable time period material may remain outside an engineered barrier before falling within the scope of this Manual will not be specified in the Manual. The purpose of this manual is to establish requirements for the packaging of nuclear materials for interim storage so that the facility workers do not receive radiation exposures above the limits in 10 CFR 835 due to package degradation. Facility radiological control practices
The list of radionuclides covered by the manual appears to be incomplete. A significant number of radionuclides that may fall under the definition of "by-product material" and whose dominant dose contributions are through the inhalation pathway are not included in Table 1.1, and therefore would be excluded from the manual requirements. It is unclear whether some of these isotopes are currently present in the complex or may be separated in the future. Given this possibility and the hazardous nature of these radionuclides, it would be more appropriate to specify an overall methodology for identification of in-scope radionuclides, and present the Table 1.1 as a listing of radionuclides commonly found in the complex.

Proposed language in Manual. Paragraph I.1.c (1) shall read as follows: **Nuclear Materials in Scope.** Nuclear Material, as defined, means any material that is “Special Nuclear Material,” “byproduct material,” or “source material” in the Atomic Energy Act of 1954 as amended. For the purpose of this document nuclear materials are those listed in Table 1.1. The table includes the nuclear materials, most prevalent in the DOE complex, where a hazard analysis for a breached package would identify an internal radiation exposure scenario as more limiting than an external radiation exposure scenario. In addition, the scope is limited to nuclear material containing radionuclides where the total activity in the material exceeds the values specified in the table in 49 CFR 173.435, *Table of A₁ and A₂ Values for Radionuclides,* commonly referred to as the A₂ values. For mixtures of these isotopes, sites shall use 49 CFR 173.433, *Requirements for determining basic radionuclide values,* and for the listing of radionuclides on shipping papers and labels. The Manual requirements apply to interim storage of nuclear material storage packages outside of an approved engineered contamination barrier (e.g. hot cell, glovebox line, ventilation hood, liquid transfer line). Interim storage is defined as the period of time that materials can be stored while awaiting further disposition or processing (i.e. to WIPP, 3013 welded container or 3028 welded container) and will be documented in the site technical basis.
The definition of a "sealed source" requires further clarification to qualify for exclusion from the scope of the manual. Exclusion of sealed sources is consistent with Recommendation 2005-1; however, the Board's expectation was that all excluded nuclear materials would be packaged or protected in a manner that would afford protection to workers substantially equivalent to that provided by packaging meeting the requirements in the manual. Indeed, this is why materials packaged to meet DOE-STD-3013 or DOE-STD-3028 are excluded from the scope of the manual. The definition referenced in 10 CFR 835.2 does not provide adequate criteria to ensure this protection; thus there is a need for greater specificity in the definition (e.g., minimum classification levels under American National Standards Institute [ANSI] N43.6, Sealed Radioactive Sources-Classification, or similar basis).

**Comment.** The sited definition is from 10 CFR 835 which is the source document for the manual. The ANSI N43.6 definition as recommended in the DNFSB comment reads as follows: "sealed source" - radioactive source sealed in a capsule or having a bonded cover, the capsule or cover being strong enough to prevent contact with and dispersion of the radioactive material under the conditions of use and wear for which it was designed.

The definition from DOE M 441.1-1 is as follows: Sealed Radioactive Sources. A radioactive source manufactured, obtained, or retained for the purpose of utilizing the emitted radiation. The sealed radioactive source consists of a known or estimated quantity of radioactive material contained within a sealed capsule, sealed between layer(s) of non-radioactive material, or firmly fixed to a non-radioactive surface by electroplating or other means intended to prevent leakage or escape of the radioactive material (10 CFR 835.2).
The working group believes that the present definition in DOE M 441.1-1 is more applicable for DOE operations.

At DOE sites, sealed sources are managed as sources until their disposition as either reuse at another DOE site, returned to vendor, or disposal as LLW or TRU waste. Those sources containing accountable materials that have been removed from use or storage are transferred to a sites waste management organization. The waste management organizations have Material Balance Areas (MBA) where these materials remain under MC&A standards until the material is repackaged, if needed, for disposal; the appropriate documentation is completed; a formal termination of safeguards is completed; and a declaration of waste is made. The DOE site’s Sealed Source coordinator maintains these sources in the site inventory according to 10 CFR 835 requirements.

The Off Site Recovery (OSR) program staging area at LANL TA-54, has received ~12,000 neutron and actinide sources. These sources have all been repackaged into a very robust special form container, over packed in a 6 inch SST pipe, and then placed inside of a poly shielded 55 gal drum. This is the approved disposal packaging system (S-100) for WIPP.

Other transuranic sources not requiring the S-100 can are disposed with other transuranic material in standard waste drums destined for WIPP.

Beta/gamma sources are managed differently. The vast majority of these sources are in hot cell storage, underwater storage, in equipment for which the source was designed, or, in a few rare instances, original shipping or storage containers. DOE 10 CFR 835 ALARA practices drive the sites to maintain these sources in safe configuration.

The surveillance techniques required to be considered may result in inconsistent or inadequate detection of vulnerable packages. The overall surveillance system will need to be revised to include greater specificity in the performance.

**Proposed language in Manual.** The second sentence in I.3.c will be revised to include greater specificity in the performance.
objective of providing early indications of container degradation is appropriate. However, implementation of the surveillance techniques listed for consideration does not appear to be required. The result could be significantly different levels of rigor applied in determining the state of the packaging depending on which techniques the sites implement. Greater specificity in either the performance of the objective or the required use of techniques may be necessary to ensure that sites perform adequate surveillance.

Comment. The new wording will be:

Surveillance techniques shall be specified to provide early indications of container degradation, seal failure or loss of venting capability (if present).

Recommended language in Manual. A new section will be added to the Manual in I.4.b (4) Technical Basis Information. As a minimum, the records shall include materials pertaining to the technical basis for packaging and storing applicable nuclear materials, including interim storage determinations for the site, threshold calculations, and surveillance and monitoring information.

I.4.c ... materials and packages. The Data Base shall contain Material Information, Packaging Information, and Surveillance Information. Use of a database....

DOE's review process for Recommendation 2005-1 deliverables requires improvement. As was the case with the draft repackaging prioritization methodology, many of the substantive technical issues concerning the manual that were identified by the Board's staff were also identified by DOE's technical review board (TRB). Some of the TRB's comments do not appear to have received the appropriate level of consideration and technical resolution. For example, significant

Information on the technical basis for packaging and surveillance is not explicitly required in Section I.4, Documentation. Although this information is generally specified as a requirement under the Packaging Criteria sections, it is unclear where this information would be documented for review. Stipulating a complete list of documentation requirements for a centralized technical basis document for packaging and surveillance would assist the field element managers in their review and approval process.

The DOE Technical Review Board (TRB) is an additional internal Departmental review process that is composed of DOE Federal employees and DOE contractors. There are five TRB members. They are knowledgeable DOE individuals who are not a part of the DOE 2005-1 complex wide working group tasked with developing new DOE requirements (in a Manual) for safe interim
Comments generated by several TRB members pertaining to the problems outlined in the staff's comments 1-3 above resulted in only trivial changes in the wording of the manual. In its acceptance of the IP, the Board noted it was encouraged by DOE's decision to use a TRB to review and comment on the principal activities related to the resolution of safety issues. Unfortunately, DOE has failed to incorporate substantive changes to both the draft manual and the draft repackaging prioritization methodology required to adequately resolve significant comments made by the TRB. A mechanism for consistently developing balanced, technically valid responses to the TRB's comments is needed.

Storage of certain nuclear materials. The DOE 2005-1 Implementation Plan approved by the Secretary of Energy on August 17, 2005 described the DOE TRB role and the intervals of activities of the DOE TRB. The DOE TRB has two specific Implementation Plan actions dealing with the draft interim storage requirements manual.

Per the Implementation Plan the DOE TRB is to review the draft manual twice. Also per the Implementation Plan the DOE TRB review products are to be sent to the DOE 2005-1 responsible manager for DOE disposition using the DOE 2005-1 working group. The first specific DOE TRB action is to review the draft manual at an early stage. Later in the process the DOE TRB must also review a final draft of the manual. The DOE working group and the DOE TRB have completed the first (early stage) review. The second review has not yet started.

In early April 2006, the Department sent, at the request of the DNFSB, a summary of the DOE TRB comment resolution documentation generated during the first draft manual DOE TRB review. The summary shows the 167 initial DOE TRB comments that were received. The DOE working group accepted 88% of the original DOE TRB comments, 12% were not initially accepted and were the subject of a detailed discussion with the DOE TRB member. During that discussion some of the TRB original comments that were not initially accepted were modified by the TRB member based on the discussion with the working group, some remained as originally written, and some were left open. Remaining open at this time is an acceptable option to DOE because the document is still under development.

The standard comment resolution form sent in early April to the DNFSB at their staff's request does not lend itself to capturing the full extent of the discussions among the working group and between the DOE responsible manager/DOE working group and the DOE TRB. By its nature, the comment resolution form is only intended to provide a brief synopsis of the disposition. It is not

* TYPE - Essential or Suggested (E or S)
intended to fully document all the dialogue that preceded the final disposition. This is especially true for the comments that were not accepted, since these are the comments that required the greatest amount of discussion prior to being dispositioned.

The DOE TRB provides valuable advice to the DOE 2005-1 responsible manager. The final responsibility for the contents of the manual rests with the DOE working group and the responsible manager. All TRB comments were carefully considered by the working group and the responsible manager before they were dispositioned. By accepting nearly 90% of the TRB comments, the working group and the responsible manager have demonstrated that the internal review process is functioning effectively. The working group and manager have exercised prudent technical judgment in addressing the TRB first review comments and will continue to do so for the TRB final review comments. See the Department’s response to comments 1-3 above for additional discussion.

The Department believes that the DOE TRB is functioning adequately, but will remain mindful of the DNFSB concern.