

CONF-970520--3

**Development of guidance on applications of regulatory requirements  
for regulating large, contaminated equipment and  
large decommissioning and decontamination (D&D) components**

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JUL 28 1997  
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To be presented at the 4<sup>th</sup> International Conference on Transportation for the Nuclear Industry,  
May 13-15, 1997, in Bournemouth, England

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† Oak Ridge National Laboratory is managed by Lockheed Martin Energy Research Corp. under contract DE-AC05-96OR22464 with the U.S. Department of Energy.

## **ABSTRACT**

In 1985, the International Atomic Energy Agency issued revised regulations for the safe transport of radioactive material. Significant were major changes to requirements for Low Specific Activity material and Surface Contaminated Objects. As these requirements were adopted into regulations in the United States, it was recognized that guidance on how to apply these requirements to large, contaminated/activated pieces of equipment and decommissioning and decontamination objects would be needed both by the regulators and those regulated to clarify technical uncertainties and ensure implementation. Thus, the U.S. Department of Transportation and the U.S. Nuclear Regulatory Commission, with assistance of staff from Oak Ridge National Laboratory, are preparing regulatory guidance which will present examples of acceptable methods for demonstrating compliance with the revised rules for large items. Concepts being investigated for inclusion in the pending guidance are discussed in this paper. Under current plans, the guidance will be issued for public comment before final issuance in 1997.

## **INTRODUCTION**

The U.S. Department of Transportation (DOT) [1] and the U.S. Nuclear Regulatory Commission (NRC) [2] regulations for transportation of radioactive materials, revised for compatibility with those of the 1985 version of the International Atomic Energy Agency (IAEA) [3] regulations, became effective April 1, 1996. The revisions changed the regulatory framework under which Low Specific Activity (LSA) material and Surface Contaminated Objects (SCOs) are characterized, classified, categorized, packaged and transported. In addition to affecting many smaller shipments in the United States, these changes will impact the manner in which large objects which are contaminated, activated, or both, are prepared, packaged and transported. Many such objects will need to be shipped in the future either as a result of maintenance activities related to the continued operation of nuclear facilities or as a result of decommissioning and decontamination (D&D) activities associated with shutdown of old facilities. Because the new regulations represent a substantial change from their predecessors, many questions have arisen from individuals who must ship or who regulate shipment activities relative to the classification, preshipment processing, handling, packaging, and transport of large objects which might be categorized as LSA materials or SCOs.

Under the revised regulations, it would be useful to consignors and regulators alike to have guidance on approved methods for preparing, categorizing and packaging large objects—such as steam generators (SGs), reactor pressure vessels, pumps, and large D&D items—as LSA materials or SCOs. This guidance will facilitate compliance assurance, ensuring workers will not receive unreasonable or unnecessary radiation exposure, keeping such exposures as low as reasonably achievable (ALARA), while reducing the administrative burden on both consignors and regulators relative to such shipments.

## **JOINT DOT—NRC DRAFT GUIDANCE**

To address the questions which have been raised regarding the proper and consistent implementation of the new LSA material and SCO requirements specifically as they apply to large objects, and at the request of industry in the United States, NRC and DOT will be issuing joint guidance on the packaging and transport of large, contaminated and/or activated objects and pieces of equipment in the near future. In addition, separate and complementary guidance is being developed for LSA material and SCOs in general; this activity is discussed in a companion paper at this conference [4].

This paper presents initial thoughts on the content of the joint guidance being considered for publication by NRC and DOT; it describes some of the questions on how the new regulations should be applied, and the corresponding guidance under development. Current plans are to issue the joint guidance, in draft form, for public comment in 1997. As a result of the public comments, peer review, and internal discussions, the content of both the draft and final guidance may be significantly different from that presented in this paper.

The guidance being developed will provide a basis which a consignor may use either (a) to classify, categorize and package large objects for shipment in full compliance with the regulatory requirements; or (b) to identify situations that may indicate the need for regulatory relief through the exemption process. In demonstrating equivalent levels of safety for the requirements set forth in the regulations. The DOT and NRC regulations specify what must be satisfied to obtain "administrative relief . . . on the basis of equivalent levels of safety or levels of safety consistent with public interest." This administrative relief is known in the United States as an exemption. Included in the development of the guidance has been a review of practices which have been previously followed in preparing, packaging and shipping large objects; development of proposed definitions for application within the guidance, and methods to be used for satisfying the classification, preparation, packaging, and transport regulatory requirements for large objects.

In anticipation of ultimately issuing this document, the NRC issued, in late 1996, a policy issue (information) document, providing interim guidance on the transportation of one category of large, contaminated objects—steam generators (SGs) [5]. This documented the steps required to allow SGs to be shipped within the United States, noting that if an SG were categorized as an SCO and, in particular it satisfied certain requirements relative to the unshielded dose rate requirement imposed in the revised regulations, it could be shipped as an SCO and would not require NRC package certification. This was a change relative to previous practice within the United States. The information provided in Ref. 5 has been used to assist in the development of the guidance discussed herein.

## **BACKGROUND**

Before implementation of the 1985 edition of the IAEA regulations [3], SCOs were treated as a subcategory of LSA material. For large, contaminated objects, U.S. consignors historically

determined the quantity of radionuclides present on their surfaces, estimated the average concentration of the radionuclides per area of the contaminated object, and categorized and shipped the objects as LSA material. This practice proved to be convenient and efficient for consignors and regulators for several reasons, including the factors that:

- (a) the structural integrity of many large pieces of contaminated equipment and large components was such that the equipment or object, with minor modifications and addition of some outer structure, and possibly some inner structure, could then be demonstrated as being adequately packaged;
- (b) because of the relatively robust nature of much of this equipment, extensive internal decontamination of large pieces of equipment and large objects was not always necessary before shipment, and, if performed, could have resulted in significant exposure of personnel;
- (c) general radiation surveys of such large items, combined with process knowledge and reasoned argument, were often used to assess, or estimate, the total quantity of contamination that was present for a package's contents; and
- (d) when uncertainty arose over the levels of surface contamination that was on internal surfaces, the activity was often fixed in place with grout.

With the new regulations, a "surface contaminated object" (SCO) is now identified as a separate category for transport in non-accident-resistant packages {i.e., industrial packages (IP-1, IP-2 and IP-3 [3]) and, in the United States, in either strong, tight packages (which are still allowed for domestic shipments only) or in Type A packages as defined in 49 CFR Part 173.427 [2]}. Specific conceptual models of SCO behaviour under various conditions were developed [6] to estimate maximum levels of surface contamination that would provide approximately the same level of health protection for a member of the public as that afforded by a Type A package containing an  $A_2$  quantity of radionuclides.

Because SCOs are now a completely different category from LSA material and are no longer considered a subset of LSA material, it was determined in the United States that guidance on procedures for categorizing and preparing large objects for shipment was needed. In addition, guidance was needed on satisfying—for large objects—the requirement that the radiation level 3 m from the unshielded radioactive material or objects, in a single package, categorized as LSA material or SCOs shall not exceed 10 mSv/h (1 rem/h). This determination has radiation-protection implications specifically related to demonstrating compliance with this requirement in practice without incurring unreasonable personnel exposure.

Furthermore, once the object is categorized, it must then be properly packaged for shipment. The objects considered in this paper can be extremely large. For example, SGs, pressure vessels, and some other large objects can exceed 180 metric tonnes (t) and could require use of packaging

which goes far beyond that which is commercially available to consignors of radioactive material when, in fact, it may not be realistically capable of being packaged at all using commonly available packagings. In these cases, special preparations, consideration of packaging requirements, alternate methods for providing adequate levels of worker and public safety, and special operational controls are expected to be required for shipment.

The guidance being developed is expected to establish reasoned and practical approaches for (a) defining "large" (in the context of "large contaminated and/or activated object"); (b) establishing the bases for classifying and categorizing outage and other large equipment and objects (e.g., pumps, SGs, and reactor vessels) as LSA materials or SCOs; (c) defining practical methods for determining the extent to which the internals of the equipment or object may be contaminated, and for treating—from a regulatory standpoint—residual liquids that might exist in the inaccessible parts of the equipment (e.g., pump mechanisms) or object; (d) establishing and documenting a generic approach that might be used for seeking regulatory relief through the U.S. regulatory exemption process when an object cannot be readily packaged in commercially available packaging or cannot be practically subdivided into smaller elements for packaging; and (e) establishing approaches for satisfying requirements in the regulations pertaining to contamination and radiation level determinations on large pieces of equipment and objects.

## DEFINITIONS

In order to address issues relating to large objects, it was necessary to provide—for the purposes of the guidance being developed—definitions of some key terms. Other related definitions were developed for the more generic LSA material and SCO guidance being developed, and these were discussed in Ref. 4. The key definition for the large objects is to clearly specify what is meant by large. To that end, consideration is being given to defining the term *large* as:

*Large* (as used in large object or large piece of equipment) means an object or piece of equipment which

- (a) can be classified as either LSA material or SCO, and
- (b) because of size, weight, geometry, or construction or physical makeup,
  - (i) cannot be practically divided into smaller entities for packaging and transport; and
  - (ii) cannot be readily packaged using commercially available packagings that satisfy the requirements for containing LSA material or SCO as required in DOT and NRC regulations; and
- (c) is therefore prepared for shipment in either

- (i) an alternative, custom packaging which is demonstrated by the consignor to comply with the applicable regulatory requirements, or
- (ii) an unpackaged state, if excepted by DOT, with appropriate safety control measures to compensate for not placing the object in a packaging.

In addition, because the terms *practically divisible* and *commercially available packaging* are used in this definition, these terms will also be defined. Included in the definition of the former will be a criterion addressing the need to keep the exposure of workers ALARA when considering whether an object is *practically divisible*. If excessive exposures are expected to be incurred in subdividing the object into smaller elements simply to facilitate packaging, then the consignor should consider shipping the object without such subdivision and as a large object, following the guidance being developed. Relative to *commercially available packagings* for a large object, the definition is expected to address the issue of size, wherein a packaging with external dimensions not exceeding those of a standard ISO-container would be deemed to be commercially available. However, it will be noted that the assessment of what is commercially available must be left to the consignor. If an "off-the-shelf" packaging is not commercially available, the consignor then may either apply the procedures defined in the large-object guidance; or—if practical—choose to custom-build a packaging and demonstrate that it satisfies the applicable packaging requirements.

## **METHODS AND ALTERNATIVES FOR TRANSPORTING LARGE OBJECTS**

Although many large objects may not be practically packaged for transport using a readily available commercial packaging, compliance with the technical requirements of the regulations is necessary. In the United States, compliance with all requirements must be achieved unless certain requirements are specifically exempted by the DOT.

As noted previously, some objects may be so large, massive, or of such configuration that commercially available (even custom) packaging may be impractical. In addition, the physical and radiological characteristics of such large objects may often make it impractical or injudicious to directly measure associated concentrations and distributions of radioactive materials. This is not to say that these objects cannot be transported safely. Examples of large objects that have been transported which required special consideration of the shipment configuration by United States regulatory authorities include the Shippingport Reactor pressure vessel [7], and Yankee Atomic's Yankee Rowe and Portland General Electric Company's Trojan SGs [8]. SGs might be considered as SCOs [5], after which they would be required to be shipped in appropriate packaging (e.g., an industrial package). However, an SG which has its outer shell penetrations welded shut may be deemed to be as robust as (or more robust than) an industrial package.

The guidance being developed is expected to suggest that technical and administrative means will be acceptable if they:

- (a) demonstrate levels of public safety equivalent to those that would be achieved if compliance with the requirements of the regulations were possible and
- (b) ensure consistency with provisions of hazardous materials transportation law.

Specifically, the guidance is expected (a) to discuss alternative approaches which may be employed in categorizing large objects as LSA materials or SCOs; (b) to present information on preparing large objects for shipment including preparations that enhance packaging functions of the large objects; (c) to examine alternatives for packaging large objects; and (d) to provide information for consignors who apply to the DOT for exemptions from the requirements of the Hazardous Material Regulations.

### **Characterizing Large Objects**

The provisional guidance discussed herein will first be directed toward assisting in categorizing a large object as LSA material or an SCO. Clearly, for a large object to qualify as LSA material or an SCO, the object must satisfy the limits for LSA material and SCO given in their respective definitions. Practical approaches are needed for satisfactorily determining:

- (a) the specific activity of a large object which is being considered for qualification as an LSA material;
- (b) the levels of fixed and non-fixed contamination on surfaces (both accessible and inaccessible) of a large object which is being considered for qualification as an SCO;
- (c) radiation levels for the unshielded object which is being considered for qualification as either LSA material or an SCO; and
- (d) the leachability of an object which is being considered for qualification as LSA-III material.

To make these determinations safely and at reasonable cost, the guidance is expected to focus on:

- the requirement to maintain doses ALARA;
- the impact that different packaging and transport alternatives will have on potential non-radiological risks to workers and the public, and on potential degradation of the environment; and

- the relationships between the waste acceptance criteria (WAC) if the material is to be disposed of, preshipment processing, transport packaging, transport, postshipment processing, and disposal packaging.

In addition, the guidance may also address specific characterization issues such as those relating to an object which is contaminated with radionuclides having an unlimited  $A_2$  value (such as those arising from the D&D of mining, milling, feedstock, and uranium enrichment facilities). The type of guidance being considered is discussed below for two of the generic characterization issues only, namely practical approaches for determining radiation levels for the unshielded item and for determining the levels of fixed and non-fixed contamination on surfaces.

**Practical Approaches for Determining Radiation Levels at 3 m from an Unshielded Large Object.** Regulatory requirements now limit the dose rate external to LSA materials or SCOs to 10 mSv/h (1 rem/h) at 3 m from the unshielded contents. In the United States, this requirement is viewed as providing some protection from ionizing radiation for members of the public or emergency personnel who would respond to a transportation accident.

The issues associated with meeting this requirement involves the question of how to physically make such measurements without unduly exposing radiation workers to excessive radiation fields, or, alternatively, how to properly analyse the shipment of a large object so that physical measurements do not need to be taken. Physical radiation-level measurements for numerous large-object shipments could lead to substantial dose commitments for the radiation worker population and possibly be inconsistent with the goal of keeping exposures to ionizing radiation of workers ALARA. To satisfy ALARA requirements, the following methods are being considered for recommended use:

- remotely taken, direct measurement of radiation levels at representative areas;
- extrapolations and calculations;
- reference to a previous, satisfactory compliance demonstration of a sufficiently similar object that had operated under similar conditions; and
- process knowledge.

**Practical Approaches for Determining Contamination Levels for Large Objects.** The regulatory requirements address the limits for fixed and non-fixed contamination on accessible and inaccessible surfaces of SCOs. In determining compliance with contamination limits, consideration is being given to providing guidance as follows:

- (1) For accessible surfaces of objects, it is up to the consignor to establish the basis for (and document, as necessary) the wipe efficiency used to

determine the contamination levels on these objects. Otherwise, the consignor will need to document that the default value of 10% (as specified in Appendix II of Ref. 6) has been used.

- (2) Non-fixed (removable) contamination on external surfaces may be fixed in place using a weatherproof coating or paint. The coating or paint must be shown to limit contamination to levels as specified in 10 CFR Part 71.87 and 49 CFR Part 174.443 immediately before transportation. Any shielding effects of the coating or paint must be accounted for in determining compliance with SCO limits.
- (3) Non-fixed (removable) contamination on accessible surfaces on the inside of an object can be fixed and made inaccessible through the use of cement, grout, or other binding agent. Any surfaces made inaccessible through this process must be shown to meet the appropriate contamination limits for SCO before adding grouting or binding agents.
- (4) Large objects with external contamination must not exceed applicable limits at any time during transportation.

In developing this guidance, U.S. regulators recognize that, in practice, there will be many instances where accessible surfaces of an object are contaminated with both fixed and non-fixed contamination, and the contamination which is determined to be fixed before shipment will remain fixed during normal transport. However, there may be instances where what is determined to be fixed contamination on the accessible surfaces of an object before shipment may become non-fixed during transit. Thus, the guidance is expected to indicate that account should be taken before dispatch of any object that might be subject to this phenomenon to ensure that the object remains within compliance throughout transport.

A number of methods can be used to evaluate fixed and non-fixed contamination levels on external surfaces of SCOs as will be outlined in the generic guidance (discussed in Ref. 4). It is expected that the guidance being developed will consider each of these methods and provide specific direction on the preferred approaches.

### **Packaging Large Objects**

A number of packagings are readily available from commercial sources which can be used to ship LSA materials and SCOs; however, as the size and mass of objects increase, choices of readily available packagings are reduced. As a result, alternative approaches are required and may entail (a) providing custom packaging that meets all applicable requirements of the regulations, (b) providing custom packaging that is exempted from one or more of the regulatory requirements, or (c) demonstrating that the large object meets some or all of the applicable regulatory packaging requirements.

Regardless of the approach taken by a consignor, the general packaging requirements for radioactive materials provides the basis for their safe transport, and the manner in which these requirements are satisfied should be documented for any custom-built package meeting all of the requirements of the regulations [as in (a) above], or referenced in any application for exemption [as in (b) or (c) above]. The guidance being developed is expected to focus on each of the three alternatives available to a consignor of a large object and to provide specific insight into and examples of methods to demonstrate how each situation may be handled.

The basis and detailed requirements for an exemption application to DOT are clearly specified in the regulations. For example, for large objects which qualify as LSA material or SCO shipped by exclusive-use vehicle, the application would need to demonstrate safety equivalent to that provided by a strong, tight packaging (i.e., essentially equivalent to an IP-1 packaging) if the contents do not exceed an  $A_2$  value per package. Alternatively, for large objects whose contents exceed an  $A_2$  value per package, the proposed packaging should demonstrate substantial compliance with the Type A package requirements (i.e., equivalent to an IP-3 packaging).

The guidance will also consider the use of internal grout and binding agents to prepare large radioactive or contaminated objects for transportation and for subsequent disposal. Binding agents may be used to: (1) fix contamination, (2) provide shielding to reduce radiation levels, and (3) provide structural support. Although the use of grout and binding agents in general will be covered in the generic LSA material and SCO guidance [4], the use of these agents and the unique problems associated with their use in large radioactive or contaminated objects will be addressed.

### **Exemptions for Transport of Large Objects**

As has been noted above, large objects as defined herein (a) cannot be practically subdivided into smaller entities, (b) would likely result in being shipped as an "OVERWEIGHT" or "OVERSIZE" shipment, and/or (c) cannot be readily packaged using commercially available packaging. In some situations, especially those cases where packagings may not be commercially available, it may be necessary to seek an exemption from the appropriate regulatory authority.

Specifically, within the United States, the DOT regulations specify that a shipment of unpackaged radioactive material is not allowed unless relief from the packaging requirement is obtained from the U.S. DOT. However, some objects may be of such a robust nature that packaging in an industrial package would prove to be superfluous (e.g., see issues related to pressure vessels [7]). Consider, also, an SG, which, if penetrations through the outer shell are seal-welded closed, then the thick-walled outer structure of the SG would in all likelihood be more robust than any industrial package into which it might be placed. In this event, it would be incumbent upon the consignor to demonstrate, in an application for exemption, that the seal-welded penetrations in the outer structure of the SG provides safety equivalent to that which would be provided by an industrial package. If, on the other hand, a consignor is faced with multiple shipments of similar large objects, the U.S. regulations suggest that a single exemption which will cover multiple

shipments of like nature should be sought. This exemption is to be accomplished by including a specification in the application for exemption the proposed duration or a description of the proposed schedule of events for which the exemption is sought.

For very large items having dimensions or weight which would not allow the items to be placed in readily available commercial packagings, then an exemption may need to be sought from DOT to ship the object "unpackaged." In this event, because the object is not to be placed in a packaging, or because alternative packaging materials are added to (e.g., sealed closures on penetrations) or around the outer structure (e.g., filament-reinforced plastic sheeting), the request for exemption should document the basis—through analyses, testing, reasoned arguments or combinations thereof—that the proposed steps to be taken in preparing the object for transport and any safety control measures deemed necessary will achieve a level of safety which is "at least equal to that specification in the regulation from which the exemption is sought."

To demonstrate an equivalent level of safety for very large objects not handled in normal freight, the consignor may be able to show that the Type A packaging tests (particularly the free drop) may not apply as a normal condition of transportation. Relative to applications for exemption from one or more of the regulatory packaging requirements, the applicant must provide evidence of management control over the preparation, packaging arrangements, handling, and shipment to ensure conformance to the appropriate packaging requirements including any special conditions imposed by DOT. For this case in which the "normal condition of transport" drop test that is imposed on various types of packages, the guidance being considered is that:

For very large objects, consideration may be given to seeking an exemption from the requirement to impose the normal condition of transport drop test on the object in an unpackaged state. For objects with robust outer shells (e.g., SGs), complete containment of the structure may be provided using welded closures on shell penetrations. It may then be possible to demonstrate that the outer structure can effectively serve the function of a packaging. Usually, such large robust structures can resist the normal conditions of transport, except possibly the drop test. This drop test must be performed from a specified drop height and in a manner "so as to suffer maximum damage in respect to the safety features to be tested" [3].

These two factors, drop height and orientation, should be considered in developing a basis for an exemption.

Relative to drop height of the object being shipped unpackaged — the regulatory requirement was developed based upon the assumptions that, under normal conditions of transport, smaller packages are often handled at greater heights above a surface than are larger, more massive packages which are likely to be handled using heavy equipment and under better controlled conditions. Specifically, the drop height requirements in the regulations are bounded by:

- (a) smaller packages [less than 5,000 kg (11,000 lb)], where the required drop height is 1.2 m (4 ft); whereas
- (b) for larger packages [greater than 15,000 kg (33,000 lb)], where the required drop height is reduced to 0.3 m (1 ft).

One basis for this reduction in drop height with mass might be as is discussed in Ref. 9, which states:

*“The free drop test simulates the type of shock that a package would experience if it were to fall off the platform of a vehicle or if it were dropped under handling. In most cases packages would continue the journey after such shocks. Since heavier packages are less likely to be exposed to large drop heights during normal handling, the free drop distance for this test is graded according to package mass. Should a large package experience a significant drop, this drop might be considered an accident and the package would probably not continue its journey without close examination.”*

Thus, it is argued that the drop height which might be reasonable to consider for normal conditions of transport could be lower than 0.3 m (1 ft) for very heavy objects. For example, if the object had a mass of 150,000 kg (330,000 lb), then a drop height of only 0.03 to 0.06 m (0.1 to 0.2 ft) onto a solid, unyielding surface might be considered reasonable for an exemption. It may be possible to argue that it is highly unlikely to have a free drop by a qualified crane operator of such large objects under the “normal conditions of transport.” This would be especially true with one-of-a-kind shipment exemptions imposing rigidly controlled operational procedures for crane operators. Alternatively, the loading onto the conveyance may not be by crane whatsoever. Rather, the object may be elevated using jacks to a height sufficient for the conveyance to be moved underneath the object, after which the object can then be carefully and slowly lowered onto the conveyance. Also, for such a large item, intermediate handling of the item in transit is highly unlikely. With rigidly imposed handling controls (required in any case for such a massive object), including the requirement to closely monitor all lifting activities, any free-release drop exceeding the height specified in the exemption would be clearly identified. In the event such a drop occurred, then this drop might be considered an accident. The cognizant regulator would be notified, and the package would not be allowed to continue on its journey without close examination and remedial actions, followed by approval of the regulator.

Relative to orientation of the object being shipped unpackaged — a similar set of arguments can serve as the basis for exempting the requirement that the package withstand the drop height in the most damaging orientation.

It should be recognized that the requirement for performing the test in the most damaging orientation was imposed for smaller packages which could be dropped during handling, loading, in-transit transfers between vehicles, and unloading in a random fashion and could fall in almost any orientation. For very large objects, as previously described, their lifting and lowering will generally be accomplished in a very well-specified and well-controlled fashion (e.g., horizontally), and a drop in the most damaging orientation (e.g., vertically) can be administratively avoided.

The basis for the exemption application here could be that, because of such rigid controls, it is highly unlikely the object would be released for a drop of any significant height in a most damaging orientation. The orientation of the object for transport would need to be compared with the orientation required that might be considered to generate the greatest damage. In many cases, these orientations would be significantly different from the proposed shipping orientation. Thus, when this orientation argument is combined with (a) a justified lower drop height, (b) other steps which would be taken in preparing and transporting the object, and/or (c) any other safety control measures, it should be possible to demonstrate that a level of safety would be achieved which is "at least equal to that specification in the regulation from which the exemption is sought."

## CONCLUSION

This paper presents some of the U.S. regulatory staff's initial thoughts on issues relating to questions that have been asked on the revised regulations relative to large objects. Current plans are to issue joint guidance, in draft form, for public comment in 1997. Interested industry and members of the public will be encouraged to provide feedback, especially on the practicality of what is presented. This feedback should include insights into additional "real world" problems, questions, examples, and experiences in implementing the revised regulations. These efforts, when completed, should provide an opportunity for collaboration with personnel from other countries and the IAEA to develop guidance on these issues which can be accepted worldwide.

In addition to the guidance previously discussed, it is anticipated that several other issues related to the preparation, packaging, and transport of large, contaminated or activated objects will be clarified in the guidance and that those addressed above will be more fully elaborated upon. In addition, as noted earlier, complementary guidance is being developed to address issues related to the application of the new regulatory requirements for general issues related to LSA material and SCOs. A companion paper on this effort is provided in this conference.

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## ACKNOWLEDGMENTS

Acknowledgment is made of the contribution to the technical content of this paper by a number of individuals at the U.S. Nuclear Regulatory Commission (R. Lewis and S. Shankman), the Oak Ridge National Laboratory (S. Ludwig, R. Michelhaugh, and L. Shappert), and its subcontractors (R. Best and S. Schmid of Science Applications International Corporation, and J. Goss and S. Schurman of H&R Technical Associates, Inc.).