



WOULD YOU PROCURE RADIOACTIVE CONTAINERS WITHOUT A SUPPLIER QUALITY EVALUATION?

Mark Hawk, Oak Ridge, TN, USA
Ashok Kapoor, Albuquerque, NM, USA
Ronald B. Natali, Tracy, CA, USA

1. Introduction

U.S. Department of Energy (DOE) sites/contractors purchase several different types of containers (such as boxes, drums, large bulk dump trucks, railcars, cargo containers, burrito wraps, and super sacks) for use in the storage and transportation of low-level waste. These containers are purchased from several suppliers—all of whom must be pre-approved according to DOE rules, orders and guidelines—and the suppliers must manufacture the containers to exact specifications and designs supplied by the DOE site/contractor. DOE studies and qualitative evaluations indicate that the current supplier evaluation process is too costly and inefficient. Therefore, DOE, in coordination with sites/contractors, instituted a corporate approach to centralize the supplier quality evaluation program for the procurement of containers. That effort resulted in the development of this Container Supplier Evaluation Program. The program was implemented when two suppliers were evaluated using this program.

In the course of any day, DOE may have in progress hundreds of shipments of material regulated by the Department of Transportation (DOT). This regulated material may be in the form of radioactive sources, normal regulated material, or liquid or solid waste. The quantities can range from a few milligrams to thousands of pounds. Each one of these shipments is made in a packaging that has been designed and/or tested specifically for the type and form of the item being offered for transportation into commerce.

In the United States, DOT governs the method by which radioactive materials are to be packaged and introduced into commerce. The regulations for DOT are identified in U.S. Title 49 *Code of Federal Regulations* (CFR), Parts 100 to 185. Within these regulations are identified packaging standards, performance requirements, and quality assurance (QA) requirements that the shipper must meet as it identifies the appropriate package for the item being offered into commerce. For shipments with less than Type B activities, the shipper usually procures packaging from commercial sources. Thus the shipper could procure packaging through a manufacturer's catalog or by contacting the sales representative of a local supplier of DOT packaging. Once the packaging, the closure instructions, and the applicable documentation have been obtained, how is the shipper to know whether this package meets the same specifications as the package that passed the performance requirements identified in the regulations? This dilemma raises the question, "Would you procure radioactive containers without a supplier quality evaluation?"

DOE's National Transportation Program (DOE/NTP) recognized the need to establish a process whereby suppliers of commonly used packaging would be evaluated to determine that they are meeting regulatory and QA requirements. The DOE/NTP-sponsored Packaging Management Council (PMC) was tasked not only to centralize supplier evaluations but also to establish standardized packaging specifications for various packaging types (e.g., metal drums, waste boxes) and to establish one method of procurement that could take advantage of DOE's buying power. Thus DOE and its contractors would reduce duplication of effort by multiple DOE contractors and avoid unnecessary costs by having a standardized specification for all contractors to use, performing only one supplier evaluation that all the contractors could rely on, and using one central procurement method to obtain the best pricing. To accomplish this, the PMC established a working group that included subject-matter experts (SMEs) in DOT packaging, and quality professionals from the DOE Supplier Quality Information Group (SQIG), an organization that routinely performs supplier evaluations. This working group had as its goal to establish a "management plan" that would be used to govern this centralized activity. As part of the development of the management plan, the working group established a model that identified the packaging procurement process (see Figure 1). This process, when implemented, allows for the development of a standardized specification, supplier evaluation methodology, centralized procurement, and feedback process to determine the performance of each selected supplier.

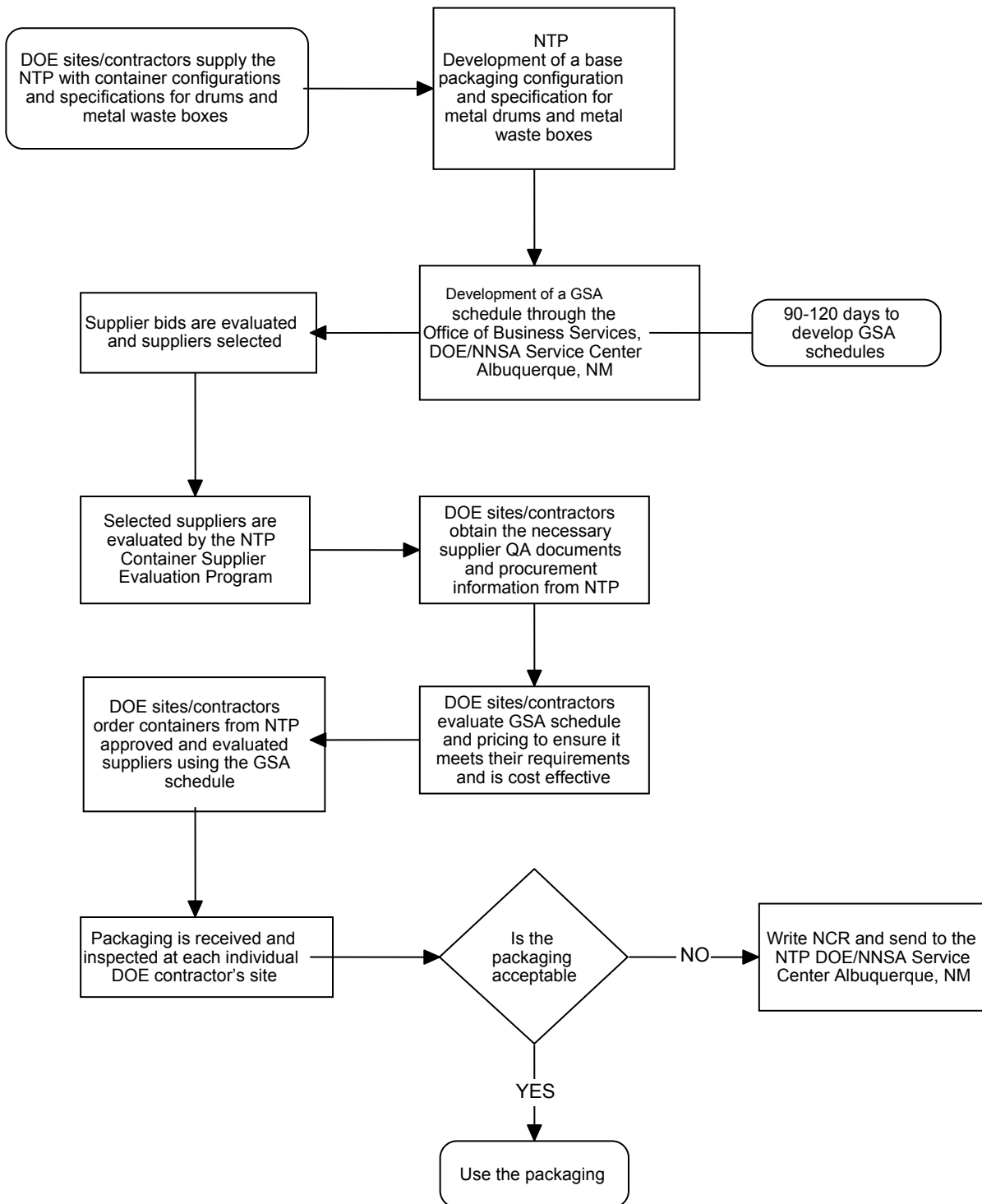


Fig. 1. Packaging procurement process

This article describes the development and implementation of this model. It discusses how DOE/NTP developed a standardized packaging specification involving approximately 29 different DOE contractors, a centralized procurement process, a Container Supplier Evaluation Program Procedure (CSEPP) for performing supplier evaluations, and a feedback system for determining supplier performance.

2. Specification Development

For each packaging type, a committee will be established by the PMC chairperson. This committee will be composed of packaging SMEs and quality professionals. It will be responsible for defining the basic packaging configuration and any additional options that contractors might want; the regulatory requirements the packaging must adhere to, e.g., DOT, Nuclear Regulatory Commission, or DOE; and the quality standards to which the packaging will be manufactured, e.g., NQA-1, ISO 9001:2000. To develop a packaging specification, a survey based on a specific packaging type, e.g., a metal 55-gallon drum, is conducted. This survey obtains regulatory and quality requirements identified for the packaging type and requests the various packaging design features that each contractor used. These design features include material thickness, gasket type, filter vents used, types of internal coatings, and external finish and color. When all the survey forms are returned and compiled, the PMC identifies a basic packaging design on which a supplier could bid and any additional feature options that a contractor could add to the basic design.

Once a specification is completed and accepted by DOE contractors, it is sent to DOE Procurement for its determination as to the best procurement method. DOE Procurement's intent was to allow all DOE contractors that choose to use this process to purchase their packaging from either a single or multiple suppliers. Once multiple suppliers were selected, the PMC Committee identified the suppliers that would undergo supplier evaluations.

3. Container Supplier Evaluation Program Procedure

The key point in the packaging procurement process is the supplier evaluation. In this model, the PMC has developed a detailed CSEPP designed to ensure consistent supplier evaluations of DOT packaging [i.e., IP, performance-oriented packaging (POP), Type A, and Type B). Most DOE contractors use the same suppliers for obtaining their DOT packaging. Therefore, the use of this procedure will centralize supplier audits, which will reduce the number of audits performed by contractors who use the same supplier. Suppliers' costs will be reduced because they will no longer be required to host multiple DOE audits. Since those costs are embedded in the cost of packaging, costs to DOE contractors will in turn be reduced as fewer supplier audits are performed.

What follows are brief descriptions of qualification responsibilities for audit participants, checklist development, pre-audit activities required, audit methodology, immediate post-audit functions, audit follow-up activities, and audit report distribution.

Qualifications

For all lead auditors, each contractor will provide the appropriate documentation verifying that each auditor meets the requirements of NQA-1. For SMEs who participate in the audits, each contractor will provide a resume identifying the training and experience of each SME involved.

Responsibilities

The NTP program manager coordinates the supplier evaluation audits to reduce redundancy, duplication, and cost and is responsible for planning and budgeting the audits. The program manager also selects the lead auditor, assists in selection of the audit team, and issues audit notification letters and final audit reports.

The PMC chairperson is responsible for maintaining a list of lead auditors, auditors, and DOT SMEs. The PMC chairperson oversees the formation of audit teams based on geographical location, involvement with the supplier, availability of lead auditors, auditors, and DOT SMEs and ensures that the audit team members come from a diverse group of DOE sites.

The lead auditor is responsible for planning, directing, scheduling, reporting, and carrying out follow-up activities on audits to which he/she is assigned. The assigned lead auditor shall perform the audit in accordance with the

requirements of the CSEPP. The lead auditor and the NTP program manager will evaluate for each audit the need for an SME, commensurate with the importance of items or services provided by the supplier or manufacturer.

Audit team members are responsible for ensuring that their activities are thoroughly performed and appropriately documented in the checklists. Audit team members are required to meet audit commitments established by the lead auditor.

Checklist Development

Development of a checklist for determining if the supplier or manufacturer meets the stated requirements is based on the QA Standard that DOE selects. DOE has two quality standards that contractors are required to follow, DOE Order 414.1A, *Quality Assurance*, and 10 CFR 830 Subpart A. Each of these standards has the same 10 criteria that contractors will pass down to their suppliers or manufacturers. It is the contractor's responsibility when evaluating a supplier or manufacturer to determine if its existing QA program meets the requirements of these 10 criteria. Most contractors will use a recognized quality standard that, when used as a basis for evaluation, will demonstrate implementation of the 10 criteria. The quality standard that most contractors use to implement the 10 criteria is ASME NQA-1-1989 plus supplements, because compliance with that standard is required for DOE contractors that ship materials to the Waste Isolation Pilot Program (WIPP). Therefore, a standardized checklist was developed based on NQA-1-1989 plus supplements.

The regulatory checklists that were developed for the CSEPP were based on the types of packages for which specifications would be developed. Checklists were developed for POP for shipping DOT regulated materials, substances, and waste. This includes the requirements identified in 49 CFR 178 subpart M and the applicable sections of subpart L. For radioactive packaging, a checklist was developed identifying requirements to which the manufacturer would be required to adhere from 49 CFR 178.350. When the time comes for the CSEPP to be used to evaluate type B packaging, a checklist will be developed based on requirements identified in 10 CFR 71.

Pre-Audit Activities

The NTP program manager, with the assistance of the PMC chairperson, selects the lead auditor and the audit team members.

The Audit Plan is developed by the lead auditor and submitted to the NTP program manager for approval. Once approved, the Audit Plan is sent to the supplier or manufacturer.

The audit planning process includes the request for all the applicable QA documents (e.g., QA plan, procedures, work instructions) and regulatory documentation (DOT packaging test reports, DOT testing procedures, training records) from the supplier. The lead auditor works with the supplier or manufacturer to determine any special requirements for the site visit and conducts pre-audit team meetings, if necessary.

The lead auditor makes team assignments and distributes previously developed checklists. After review of the supplier or manufacturer documentation, any additional questions added to the checklist must be approved by the lead auditor.

Conducting the Audit

The lead auditor conducts the opening meeting, during which the audit team members are introduced to the supplier's or manufacturer's personnel who will be escorting them during the course of the audit. The audit team reports audit results to the lead auditor, who reports them to the supplier or manufacturer during the daily out-briefing. At the end of the audit, the lead auditor reports on all the audit results and, if possible, leaves the supplier or manufacturer with a draft report.

After the Audit

Upon completion of the onsite portion of the audit, the lead auditor requests that audit team members complete their checklists in final form and submit them to the lead auditor for review and approval. The final report is then completed and submitted to the supplier or manufacturer for a factual accuracy review. This review enables the supplier or manufacturer to review in final form what has been documented and to ensure the audit team did not

reveal any proprietary information or document results incorrectly. Upon approval by the supplier or manufacturer, the completed report in its final form is submitted to the NTP program manager for acceptance and official transmittal to the supplier or manufacturer.

Audit Follow-up and Report Distribution

If during the course of the audit, the audit team has any findings that require corrective action, an audit follow-up is required. In such a case, the lead auditor obtains and approves the supplier's or manufacturer's Corrective Action Plan. When approved, it is submitted to the NTP program manager for acceptance and official transmittal to the supplier or manufacturer. Any corrective action required is evaluated when completed or at the next audit.

With the report completed and delivered to the supplier or manufacturer, the NTP program manager has the audit report information entered in the DOE SQIG database. The SQIG database is where audit report information is posted for access by DOE contractors.

4. DOE Contractor Participation

DOE sites participate by requesting a copy of the completed report on the NTP audit report of the supplier or manufacturer. Upon obtaining the audit report, site personnel review it and determine whether it meets their needs for both QA and regulatory requirements. If so, the DOE contractor accepts the report and then begins to use the procurement tool that DOE has established to order packaging based on the specification. Upon receipt of the packaging, the DOE contractor performs a receipt inspection to ensure that the packaging complies with the specification developed by NTP. This receipt inspection process is a contractor-specific procedure, even though it is based on the NTP specification. If the packaging is acceptable, the contractor issues the packaging for use. If the packaging does not meet the NTP specification, the contractor issues a site-specific nonconformance report (NCR). The contractor sees the NCR through its conclusion and then sends a copy to the NTP program manager for tracking of the supplier or manufacturer's performance.

5. Phase 1 Implementation

The PMC chairperson and NTP program manager selected SMEs and quality professionals to participate in Phase 1 of the packaging procurement process established in Figure 1. Phase 1 was developing a specification for a 55-gallon drum that is used extensively across the DOE complex.

The committee developed a survey that was submitted to all DOE contractors. This survey requested information from 29 DOE contractors on their annual usage of 55-gallon drums, material thickness, types of gaskets in lids, filter vents, and other design features. Once the information was received from the contractors, the committee compiled the data and began to develop a basic specification for a 55-gallon drum, with additional design feature options from which contractors could select to further customize the drum for packaging specific materials. Next, the committee developed the DOT packaging standards and performance requirements for a drum capable of meeting both POP and radioactive material (Type A) packaging requirements. It identified the quality standard that would be used to evaluate the supplier, ASME NQA-1-1989. As stated earlier, the reason for selecting the 1989 standard is that DOE's WIPP has NAQ-1-1989 as its QA standard, and most DOE contractors ship their transuranic radioactive waste to the WIPP facility.

Once the specification was set, it was provided to DOE to determine the best contract method for all DOE contractors to use. Once the procurement tool was in place and bids were sent out, returned, and evaluated, two drum manufacturers were chosen.

For the purposes of this document, the two manufacturers selected will be referred to as Manufacturer A and Manufacturer B. Each manufacturer was subjected to an on-site audit based on the CSEPP. Following the CSEPP, the audit team was selected, comprising a lead auditor and packaging and QA SMEs. The audit team followed the CSEPP for planning, conducting, and closing an audit. The team used the audit checklist identified for the quality standard (i.e. ASME NQA-1-1989, plus supplements) and a checklist developed for the regulatory requirements identified in 49 CFR 178.350(a) and 178 Subpart L and M. Table 1 identifies the results of the two audits performed. Findings and concerns regarding problem areas were issued to the manufacturer. Findings are defined as items that identify a noncompliance in sufficient detail to enable corrective action to be taken by the evaluated

Action	Manufacturer A	Manufacturer B
Audit Findings, NQA-1 Checklist	0	2
Audit Findings, DOT Rad. Checklist	0	0
Audit Findings, DOT, POP Checklist	2	2
Total Findings	2	4
Audit Concerns, NQA-1 Checklist	3	10
Audit Concerns, DOT Rad Checklist	6	2
Audit Concerns, DOT, POP Checklist	3	2
Total Concerns	12	14

organization. Concerns are any items identified during the evaluation that are not clearly requirement violations but do indicate a weakness in the supplier's QA program.

During the course of the audit teams' preparation, it was discovered and discussed that two separate and distinct activities are being evaluated in these audits. One is the manufacturer's QA program. This is the program that the manufacturer uses as a management tool to ensure every product is produced to the required specification consistently. Some of the findings and concerns identified during the QA portion of the audit are identified in Table 2.

Audit Action	Manufacturer A	Manufacturer B
Finding	No QA findings were identified during the audit of manufacturer A.	Lining thickness determination is not appropriately defined in the work instruction
		Training records for facility primary welder were not complete
Concern	Lead auditor qualification files are incomplete	Two of the three facilities had quality audits performed
	Documentation was missing for internal audits that were performed, e.g. audit plans	There is no evidence to confirm that quality records are being maintained in containers bearing the UL label (or equivalent) for 1-hour fire protection

The second activity (discussed below) concerned the regulatory requirements that were evaluated using the previously developed checklist. These checklists were developed for POP for shipping DOT-regulated materials, substances, and waste, based on 49 CFR 178 subpart M and the applicable sections of 178 subpart L. For radioactive packaging, a checklist was developed based on the applicable requirements of 49 CFR 178.350. In going through these checklists with the manufacturer, the team was able to determine, by reviewing objectives, how the manufacturer qualifies its packages as meeting the stated requirements in our specification and the regulatory requirements. Some of the findings and concerns that were discovered during the review of regulatory requirements are identified in Table 3.

Upon completion of these audits, each manufacturer (A and B) submitted completed corrective actions for each finding and a corrective action plan for all concerns. During these audits, the CSEPP worked well and provided a systematic methodology for performing the audits. Performing these audits provided the audit team with objective evidence that each manufacturer meets the appropriate DOT standards and performance requirements for packaging. Also, there is objective evidence that the manufacturer's QA program can introduce a defined package specification into its system and consistently build a package that is the same as the qualified package.

Table 3. Findings and concerns identified in the audit of regulatory requirements

Audit Action	Manufacturer A	Manufacturer B
Finding	Test reports did not indicate how the drums were closed Hydrostatic test was not performed for the required 30-minute test duration	Test lab technician had not received function-specific training required to perform the tests identified in the 49 CFR for POP and radioactive packaging Chime cuts were improperly documented
	Concern	There is no indication that the Type A test data were verified by an independent reviewer
	No documentation of pre-testing conditions was performed	DOT training records were out of date for a final inspector
	There is no indication by the manufacturer regarding the Type A test procedure or the test report of the sequencing of the water spray test	The manufacturer's test summary book was missing current test reports on two styles of metal drums

6. Benefits to DOE Packaging Procurement Process

The CSEPP linked to the partially centralized container procurement management program has resulted in the following benefits to DOE sites:

- **Procurement Savings:** The initial estimate indicated drum savings of \$1.47 million (9.1%) over a 10-year period based on all sites using current pre-negotiated blanket purchase orders (BPA). Using a similar approach to other low-level waste steel box containers, it is estimated that DOE would save \$12 million (10%) over a 10-year period by gaining unit price efficiencies through economies of scale.
- **Elimination of Duplicative Manufacturer Evaluation:** The Container Supplier Evaluation Program avoids duplication of evaluations and would yield cost savings of more than \$200,000.
- **Procurement Control by the Sites:** Each DOE site would remain in control of its respective procurements, would determine the best price for its individual site based on drum and shipping costs, and would have the required drums drop-shipped to its location.
- **Shorter Procurement Time:** Multiple approved suppliers with pre-determined drum specifications would allow some flexibility in meeting individual site needs, but without formal bid solicitation.
- **Improved Packaging Quality:** A standardized family of container specifications and the Container Supplier Evaluation Program continuously improves the packaging quality, leading to improved safety during handling and transportation of waste.

7. References

1. Title 49, *Code of Federal Regulations*, Parts 172, 173, and 178, U. S. Department of Transportation
2. U.S. Department of Energy, *Disposal of Low-Level and Low-Level Mixed Waste*, Office of the Inspector General, Audit Report, September 1998,
3. U.S. Department of Energy, *Evaluation of the Container Working Group Long-Term Recommendation Related to Standardization of Waste Containers and Adoption of Transport Packaging Policy*,
4. National Transportation Program, 1999.
5. *Quality Assurance Program Requirements for Nuclear Facilities*, ANSI/ASME NQA-1-1989.