

MANAGEMENT PLAN
for the
PROCUREMENT of
DEPARTMENT of TRANSPORTATION
REGULATED PACKAGING

TPM-QA-2, Revision 8
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Oak Ridge National Laboratory
Transportation and Packaging Management
Organization

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I. INTRODUCTION

The Oak Ridge National Laboratory (ORNL) Transportation and Packaging Management (TPM) Organization has responsibility for helping ORNL ensure packaging and transportation compliance to federal, state, and local regulations; U.S. Department of Transportation (DOT) regulations; Nuclear Regulatory Commission (NRC) regulations; United Nations (UN) Recommendations on the Transport of Dangerous Goods; Department of Energy (DOE) Orders; Price-Anderson Amendment Act (P-AAA) standards; and ORNL Standards-Based Management System (SBMS) governing packaging and transportation operations. TPM provides technical assistance and guidance regarding transportation related program planning, problem solving, regulatory compliance, carrier/modal selection, traffic management operations, and packaging qualification and selection. For Stores items only, TPM is accountable for packaging and transportation cost control, operational efficiency, regulatory compliance, and technical assistance to all ORNL organizations, programs and offices. TPM is the central point for operational interpretation and application of federal, state, and local regulations and DOE Orders which apply to the packaging and transportation function. TPM provides packaging and transportation policy positions for senior management's approval and implementation. Failure to meet assigned responsibilities could result in significant monetary loss to ORNL, potential shutdown of facilities, and could expose ORNL and DOE management to civil and criminal fines and penalties up to, and including, imprisonment.

II. SCOPE

TPM is responsible for maintaining a process for the efficient and effective packaging and shipping of all DOT-regulated non-hazardous materials, classified materials, hazardous materials and wastes, and radioactive materials and wastes from the ORNL site. Unless otherwise directed by DOE, TPM assists with new DOT determinations, or verifies existing DOT determinations. TPM provides for a systematic approach for compliant and efficient off-site shipment of materials. Additionally, TPM is chartered with final release authority for the off-site shipment of all hazardous/radioactive materials and wastes. There are five basic product streams for off-site transport. These product streams are non-hazardous materials, classified materials, hazardous wastes and materials, radioactive wastes and materials, and mixed wastes.

III. PURPOSE

Packaging for hazardous materials in transportation is one of the major elements of the DOT's regulatory system. DOT prescribes details of construction in the form of "specification" or "performance oriented" packagings in 49 CFR Parts 178 through 180. The DOT-regulated packagings are used in applications in which failure of the packaging could cause personal injury, damage or harm to the environment, or jeopardize security or vital ORNL missions. In addition, a violation of packaging regulations could result in significant monetary and/or criminal/civil penalties. Therefore, to minimize the risks associated with noncompliant DOT packaging entering the various ORNL processes, one generic procurement system to manage the purchasing of all DOT-regulated packaging was considered necessary. This plan documents the controls utilized for the generic system for the procurement of DOT-regulated packaging.

It is recommended that all ORNL organizations and programs utilize this procurement system. By utilizing this program, the purchaser is ensured a quality product that complies with DOT regulations and fulfills the quality section of the Price Anderson Amendment Act (PAAA).

NOTE: Unless specifically approved by TPM, credit card purchases of DOT hazardous materials regulated packages are not authorized. This is to ensure appropriate procurement controls are in place to meet DOT and PAAA compliance. See Subject Area: [Small Purchase Cards \(P-Cards\) and Credit Cards \(Sales\)](#).

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CRITERION 1: PROGRAM

1.1 Mission

The mission of TPM is to ensure federal and state regulatory compliance for ORNL on-site and off-site shipments while minimizing the risk of public harm, environmental degradation, corporate fines and penalties, and damage to corporate reputation. In addition, TPM monitors PAAA requirements and issues for packaging and transportation related issues. PAAA quality requirements apply to DOT packaging (depending on application). The quality requirements can be found in 10 CFR 830 Subpart AB. Some on-site shipments are also regulated by PAAA and must conform to PAAA standards (see [ORNL M/808, On-site Transportation Safety Document](#)). TPM also ensures that its process should meet requester requirements and schedules. TPM is responsible for maintaining a process for the efficient and effective packaging and shipping of ORNL material which is non-hazardous materials, classified materials, hazardous materials and wastes, radioactive materials and wastes, and mixed waste from the ORNL site.

1.2 Vision Statement

The TPM vision statement is to provide "best in class" packaging and transportation services exceeding customer expectations and enhancing research and development while ensuring safety for the public and the environment.

1.3 Management Structure

TPM reports through the Laboratory Logistical Services Division (LSD) of the Facilities and Operations Directorate at ORNL. The TPM Manager is responsible for planning, technical direction, monitoring, and overall success of the Organization. (See [Attachment 1](#) for Organization Chart.)

Reporting to the TPM Manager are personnel responsible for activities in Packaging Operations, Shipping Operations, and Quality Assurance (matrixed).

1.4 Functional Responsibilities

Functional responsibilities for the key management areas in the procurement of packaging are:

1.4.1 Requester

- If possible, notifies TPM of the need to procure packaging prior to placing the request in SAP/AVID Plus.
- Ensures that TPM's recommendations, controls, and provisions are included in the procurement documents for packaging prior to procurement.
- As needed, in conjunction with TPM, prepare special receiving inspection plan and Quality Control (QC) Checklist.
- Ensures maintenance of reusable packaging.
- Prepares [ORNL-233](#), "Request for Stores Item Inventory Addition or Change," in conjunction with TPM and submits form to the Materials Management Organization (MMO) If requesting item be stocked in Stores inventory.
- For waste packaging, Lab Waste Services (LWS) must communicate specific Waste Acceptance Criteria (WAC) requirements to TPM.
- The ORNL Waste Certification Officer (WCO) must verify, by approval of specification(s) and drawing(s), compliance with Nevada Test Site Waste Acceptance Criteria (NTSWAC) for packaging on a Nevada Test Site (NTS) Waste Profile (WP).

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1.4.2 TPM

- Distributes packaging documentation, as required.
- Determines correct packaging based on DOT classification of materials and mode of transportation.
- Assists in creating/approving packaging specifications for new hazardous/radioactive packaging for Stores.
- Approves specifications for hazardous/radioactive materials and/or high value packaging.
- Assists in determining make/buy requirements for supplier evaluation/surveillance.
- Assists in creating supplier evaluation checklists
- Creates/approves receiving inspection plans and checklists.
- Ensures that each prospective packaging supplier has been evaluated and found acceptable before procuring packaging, if deemed necessary.
- Dispositions nonconforming packaging.
- Forwards current evaluated suppliers list to Contracts Division, WCO and the Battelle [Integrated Supplier Information System \(ISIS\)](#).
- Acts as subject matter expert for supplier evaluations, as requested.
- Processes Deviation Forms, [ORNL- 313](#), when required for packaging (see [Note under ¶1.4.7](#))
- Notifies WCO of changes in suppliers of packaging approved in NTS waste profiles.
- Requests Quality evaluations.

1.4.3 Procurement Quality Services (PQS)

- Evaluates prospective/current packaging suppliers, as requested.
- Maintains [ISIS](#) supplier evaluation results.
- Advises/assists in the identification of potential suppliers.
- Advises/assists in interfacing with the [DOE Supplier Quality Information Group \(SQIG\)](#), or current equivalent.

1.4.4 Materials Management Organization (MMO)

- Ensures that each [ORNL-233](#), for packaging has been approved by TPM.
- Ensures that Stores packagings are identified in the SAP material record to undergo a special receiving inspection upon receipt when designated by the requester or TPM.
- Ensures Stores packaging are properly stocked in environments conducive to packaging materials.
- Expedites return of Stores noncompliant packaging.
- Provides Stores material number/description coordination.
- Inputs details for Stores packaging, including but not limited to descriptions and stock levels, in SAP material master.
- Assists LWS in tracking NTS packaging issuance from Stores.

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1.4.5 Contracts Division

- Ensures that current TPM approved specifications are forwarded to prospective packaging suppliers when required.
- Coordinates with TPM required/requested supplier specification changes and supplier feedback of ORNL requirements during the purchase of restricted packaging supplies.
- Procures packaging from suppliers as directed by TPM.
- Coordinates with TPM and the requester to ensure all packaging requirements are met before awarding a purchase order for packaging supplies.

1.4.6 Quality Inspector

- Performs special receiving inspections as identified on inspection plans.
- Maintains records of inspections (completed checklists).
- Initiates [ORNL Nonconformance Report \(NCR\), ORNL-311](#).
- Distributes documents received to TPM and other personnel as required.
- Advises/assists in development of appropriate testing and inspection planning and performance.

1.4.7 Quality Assurance (QA)

- Assists in planning, controlling, and assessing packaging procurement activities to ensure compliance and quality output.
- Assists in assessments, as requested.
- Performs process analysis, as requested.
- Assists in supplier evaluations, as requested.
- As required, approves Deviation Requests* and other required documents.
(* Form title on drop down list for ORNL forms shows “Deviation Request Form” but form shows title as “Deviation Form.” Referred to as Deviation Form in ¶1.4.2)

1.5 Levels of Authority

TPM is a service organization designated to ensure federal and state packaging and transportation compliance of the diverse shipments of ORNL research laboratories, nuclear reactors, and other ORNL programs and projects. TPM must ensure adequate packaging and transportation management systems are in place and communicated to ORNL personnel to eliminate disruption of the flow of operations of those programs. When conflicts arise, the TPM Manager has the authority to resolve the problem or, if appropriate, elevate the problem to the appropriate senior management level for resolution.

CRITERION 2: TRAINING AND QUALIFICATION

2.1 Training Responsibilities

It is the responsibility of the managers of the involved organizations to ensure that their employees receive and maintain the necessary level of training and/or qualification to perform the tasks identified in this plan and in compliance with the [Training and Qualifications Management System](#).

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2.2 Qualification of Personnel

TPM personnel, or their designees, who review packaging purchase requisitions and other purchase documents/specifications shall have passed the Advanced Hazardous Material Training Course or equivalent (ORNL specific training qualification). Personnel performing visual and dimensional special receiving inspections shall be qualified by the appropriate site certification and qualification requirements for receiving inspectors, as defined by current [Quality Engineering and Inspection \(QE&I\) requirements](#). Inspectors performing special process inspections, including ultrasonic evaluations or other nondestructive evaluations (NDE), are to be either certified by the Society for Nondestructive Testing (NDT) as either an NDT Level-II or NDT Level-III Inspector, or approved by on-the-job training and instruction by an NDT Level-III Inspector. The on-the-job training by an NDT Level-III requirement may be waived if an approved qualified equal (approved by the TPM Manager) has demonstrated knowledge and experience in the specific NDE application.

CRITERION 3: QUALITY IMPROVEMENT

3.1 Prevention

3.1.1 Supplier Evaluation and Surveillance

A supplier evaluation with satisfactory results should be conducted prior to awarding a contract with the proposed supplier (see [Criterion 7: Procurement](#)), except in cases of small quantity procurements. Small quantity procurements are defined as 50 packagings or less and/or less than \$20,000 total procurement cost. Special receiving inspections for small quantity procurements will be used to verify the quality of the packaging.

Each contract awarded for packaging should have provisions included to allow ORNL to exercise surveillance over the supplier activities to achieve conformance to specifications and fitness for use. This surveillance includes procedural, process, and product audits, as well as inspections.

3.1.2 Review of Purchase Requisitions and ORNL-233s for Packaging

TPM has been given review and approval authority in SAP to review purchase requisitions of packaging to be procured. When the requester enters a purchase requisition with the material group designated for packaging (“Containers/Package/Packing Supplies, 81”), TPM will receive the purchase requisition for review and approval. TPM will determine if the packaging is intended to be used for the shipment of hazardous materials. When applicable, the requester will be contacted to make this determination. If the packaging is to be used to transport hazardous materials, TPM will review the technical requirements, specifications, and/or codes referenced in the purchase requisition. TPM will work with the requester to ensure appropriate procurement documentation, specifications, and other controls (such as special receiving inspection required) are included in the purchase requisition to assure DOT and PAAA compliance. [ORNL-233s](#) for DOT-regulated packaging should be forwarded by MMO to TPM for review prior to submittal of Stores purchase requisitions to Contracts Division. TPM will review the technical requirements, applicable drawings, specifications, special receiving inspection citation, and/or codes referenced or attached to the purchase requisition or [ORNL-233](#). See [Attachment 5](#) for Hazardous Materials Packaging Procurement Cycle.

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3.1.3 Lessons Learned

To learn from the experiences of others (both positive and negative) and to share the operational experiences of TPM, the organization will participate in the [ORNL Lessons Learned Subject Area](#).

3.1.4 Performance Metrics

Performance metrics should be used by all organizations involved in packaging procurement to help identify problem trends and/or help illustrate process controls. The TPM Quality Assurance Specialist (QAS) will provide assistance to the organization in identifying appropriate areas/activities for performance metrics and providing advice to the appropriate managers on the structure of the indicators (i.e., type of chart or graph, increment periods, statistics, goals, etc.).

3.1.5 Special Receiving Inspection

Purchase requisitions and [ORNL-233s](#) for packaging should be marked to indicate that a special receiving inspection is required upon receipt. The level of special receiving inspections conducted is related to the amount of other controls in place to evaluate supplier performance (i.e., supplier surveillance, past history, etc.). By utilizing a special inspection at receipt, the risks of noncompliant packaging entering the operations of ORNL programs are minimized and failure costs are reduced. Controls for the special receiving inspection (planning, checklist, records, etc.) are identified in [Criterion 8: Inspection](#).

3.2 Detection of Nonconformance and Corrective Actions

3.2.1 Control of Nonconforming Items

All nonconforming items are to be segregated, if practical, and identified by tagging per the Quality Management System SBMS Subject Area: Nonconformance Control; Procedure: [Identifying, Reporting and Closing Nonconformances](#). If identification of each nonconforming item is not practical, the container, package, or the storage area should be physically identified.

All nonconforming packaging purchased or fabricated in-house is to be documented on a Nonconformance Report (NCR) [[ORNL-311](#)] and in compliance with the Quality Management System SBMS Subject Area: [Nonconformance Control](#). The process for issuing NCRs is included on the attached flow diagram ([Attachment 7](#)). Copies of NCRs will be provided to TPM and the Quality Services Division (QSD) Assessment Tracking System (ATS) coordinator, or alternate, for filing, analysis and entry into ATS. TPM will notify the appropriate supplier of the nonconformance.

NCRs are tracked in ATS. The ATS roles are as follows:

- Inspector – Owner
- QSD ATS coordinator – Owner delegate
- TPM – Condition owner
- QAS – Independent reviewer
- Contracts Division Subcontract Administrator (Buyer) – Distribution
- Customer, if not Stores or if critical to operations – Distribution
- WCO, when NTS approved packaging is involved – Distribution
- LSD ATS Coordinator – Distribution
- ORNL ISIS Coordinator – Distribution

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3.2.2 Corrective Actions

Problems should be evaluated as appropriate to determine the root cause and/or to identify specific corrective and preventive actions to preclude recurrence of the problem. Typical action-specific documents through which corrective actions can be identified are reports of:

1. Management reviews,
2. Nonconformances,
3. Occurrences,
4. Performance-assessments,
5. Problem investigations, *and*
6. External appraisals, reviews, and audits.

Corrective actions from applicable evaluations or problem identification sources should be handled in compliance with the Performance Based Management SBMS Subject Area: [Performance Planning and Assessment](#). Corrective actions resulting from internal self-assessments should be performed in accordance with ORNL Facilities and Operations Directorate Procedure [F&O-ADM-009, Rev.0](#).

3.2.3 Occurrences

All designated occurrences should be handled in accordance with the Performance Based Management SBMS Subject Area: [Occurrence and Non-Routine Event Response and Reporting](#).

3.2.4 Suspect/Counterfeit Items and Disposition

Suspect items may occur due to intentional or unforeseen errors in the manufacturing process. These errors may, or may not, affect packaging certification - thus the need for disposition of the item. Suspect/counterfeit items include, but are not limited to, [steel grades and bolts](#). Purchase Orders, and/or ORNL Packaging Specifications, reflect the requirement that no suspect/counterfeit components are to be used. The receiving inspections will verify that packagings are free of any evidence that the said packaging has been manufactured from/with counterfeit materials.

For containers that become suspect after receiving inspections have taken place and the items are in Stores stock, the following steps, which are consistent with the Senior Nuclear Managers Group recommendations, will be taken.

1. Segregate and put Stores item on hold.
2. Check to see if any containers have been purchased from Stores.
3. If so, notify requester to stop use until disposition is decided.
4. Investigate suspect containers for disposition determination.
5. Document the investigation per the Performance Based Management SBMS Subject Area: [Occurrence and Non-Routine Event Response and Reporting](#) in conjunction with DOE 5000.3B and subsequently report to the Inspector General.
6. Disposition containers according to findings.
7. If item is acceptable as-is, then continue use by notifying Stores and requesters of container disposition.
8. If item is not acceptable, notify Stores and requesters of unacceptable disposition.
9. Contracts Division works out agreement with supplier for replacement of containers.

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3.2.4 Suspect/Counterfeit Items and Disposition (continued)

Non-Stores stock items that become suspect after receiving inspection are in control of the owning Division and should follow SBMS Quality Subject Area: [Suspect/Counterfeit Items and Defective Items](#).

CRITERION 4: DOCUMENTS AND RECORDS

4.1 Document Control

Documents generated within TPM should be controlled and should provide support for the configuration control of documents, as required in the ORNL Records Management SBMS Subject Area: [Document Control](#). The term **Document Control** is defined as “the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.” The documents controlled in this criterion are only those which specify quality requirements or prescribe activities affecting quality such as instructions, procedures, drawings, purchase requisitions (as appropriate), inspection/test plans, quality plans, Safety Analysis Reports for Packaging (SARPs), loading instructions, and specifications. A listing of documents to be controlled within the scope of this activity is included as [Attachment 2](#).

4.1.1 Document Preparation, Review, Approval, and Issuance

A listing of documents included in this control system is represented as [Attachment 2](#) of this plan. The control for non-listed documents should provide for:

1. Identification of documents to be controlled and their specified distribution,
2. Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents,
3. Specification of actions to be taken with existing documents when revisions are made or former documents are canceled, *and*
4. Identification of unique revisions and copies.

4.1.2 Change Control

Revisions to controlled documents should be controlled and reviewed by the same personnel that reviewed and approved the originals. When appropriately authorized by the TPM Manager, alternate personnel may be used, based strictly on their individual capability and knowledge of the original criteria used for the approved documents. A flow diagram illustrating the change control process for descriptions of the [ORNL Packaging Specification Catalog](#) is included in this plan as [Attachment 3](#). Changes to the specifications and/or drawings require the signatures of the originator of the revision, the user organization (designated design interface, if applicable), and the WCO (for NTS packaging).

See [Criterion 6: Design/Drawing Control](#) for specific design control processes.

4.2. Records

Records contain information that is retained for its expected future value. Records should be sufficient to support technical and regulatory decisions. A listing of records to be maintained is included in this plan as [Attachment 4](#).

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CRITERION 5: WORK PROCESSES

5.1 Work Processes

A flow diagram illustrating the process for the [ORNL-233s](#) and purchase requisitions is included as [Attachment 5](#). Specific activities for accomplishing the tasks in the management process should be accomplished using organization specific procedures/instructions. These procedures/instructions should be in accordance with ORNL SBMS Subject Areas. The authorities, responsibilities, and interfaces of organizations involved in packaging procurement are identified in this plan.

5.2 Identification and Control of Items

Purchase requisitions are accessible in SAP, and [ORNL-233s](#) for packaging should be forwarded to TPM for oversight and assistance in correctly classifying the material to be packaged. After the material is classified, TPM will ensure that the correct packaging requirements are included in the procurement document(s) to be transmitted to the supplier.

Upon receipt, packaging should undergo the standard receiving inspection conducted by MMOs Receiving personnel. The standard receiving inspection consists of visual monitoring of packaging for obvious damage, leaks, shortages, overages, and, when it can be determined by observation, nonconformance with purchase order descriptions or specifications. If approved, receiving documentation and all associated documents received with the packaging should be attached (or otherwise forwarded) for subsequent delivery to the inspector/inspection facility. The packaging should be physically segregated and/or tagged (with purchase order number indicated on tag) to receive a special receiving inspection and forwarded to the appropriate inspector/inspection facility.

If the results of the inspection indicate that the packaging received are not in compliance with requirements for packaging integrity specific for the material, an NCR should be generated by the inspector (see [13.2.1](#)) and a "HOLD" or "REJECT" tag should be affixed to it to prevent further processing or use until a proper disposition is made. TPM should be notified to make disposition of any discrepancy (the disposition should be documented in ATS). If the disposition is reject/return to supplier, either TPM, the appropriate QAS, or the inspector should complete and attach a "REJECT" tag, if not already affixed, to the packaging or segregated packaging storage area.

5.3 Control of Special Processes

Inspection or packaging testing may not readily identify quality deficiencies in some fabrication processes. These processes are defined as special processes and include sampling, analytical work, metal joining, welding, heat treating, plating, cleaning, and nondestructive examinations. They are controlled through the use of qualified personnel using the proper equipment and approved qualified procedures.

5.3.1 Identification of Processes

Special processes, when applicable, should be identified in various documents, including drawings, specifications, regulations, codes, and standards. Additional controls should be included as part of the procurement documents.

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5.3.2 Personnel Qualifications

Special processes are performed in accordance with qualified procedures developed by the supplier performing the activity or in accordance with nationally accepted standards. Qualified individuals should be required to perform these special processes and should be qualified through education, training, and testing. Qualification/certification records should be retained by their company and should be made available to the requesting organization, Contracts Division, and supplier evaluation. TPM will ensure that the requirement for copies of the certifications will be included in the procurement specifications for special processes.

5.3.3 Verification

When considered as necessary by TPM and/or the requester, or as dictated by procedures, surveillances, inspections, and/or audits are performed at ORNL and at suppliers' sites as an additional control to assure that activities are performed by qualified personnel using adequate equipment and working to approved qualified procedures. These verification activities are conducted by site inspection personnel, QAS, and/or individuals from the line organization who are technically qualified but not directly responsible for the activity.

5.4 Handling, Storage, and Shipping

TPM should review all purchase requisitions and [ORNL-233s](#) for DOT-regulated packaging to ensure adequate handling, storage, shipping, cleaning, shelf life, and preservation requirements are included. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture and temperature levels may be specified.

Packaging is to be handled in such a manner to not cause damage. Packaging, either in-transit or in Stores stock, is to be stored in a manner which is conducive to the packaging construction. Outside storage is discouraged unless protection from the environmental elements is provided. Packaging should not be stored directly on the ground, limestone, or other natural elements which are not compatible with packaging construction materials. The first-in, first-out method of inventory should be used for packaging maintained in Stores.

CRITERION 6: DESIGN/DRAWING CONTROL

All packaging at ORNL should be designed to withstand (at a minimum) conditions normally incident to transportation. All packaging designs should provide protection and containment of contents based on characteristics of the contents and the environmental conditions for which the package should be exposed.

A design is defined as the description of a packaging that enables the packaging to be fully identified. The description may include specifications, engineering drawings, reports showing compliance with regulatory requirements, and other relevant documentation. Design controls have been placed on packaging at ORNL to ensure sound engineering and scientific principles and appropriate standards commensurate with the importance to safety and protection of the environment. The requester's Division Director, or designee, will ensure special design controls, responsibilities, and interfaces are communicated to TPM.

Management Plan for the Procurement of Department of Transportation Regulated Packaging Revision 8

6.1 Types of Design

All ORNL packaging designs should meet applicable performance requirements, regulatory requirements, codes, and standards. For packaging used to transport hazardous materials, packaging designs shall be in compliance with the applicable DOT regulations, Nuclear Regulatory Commission (NRC) regulations, United Nations (UN) Recommendations on the Transport of Dangerous Goods, DOE Orders, and PAAA standards along with the codes and standards specified in these regulations. Other design inputs include customer requirements and preferences for the features and performance of the end product and the customer's additional constraints on the design process. Waste Acceptance Criteria for packaging are to be communicated to TPM by Laboratory Waste Services in order to ensure all requirements are met. Any packaging design which is included in an NTS waste profile is to be verified for compliance with NTSWAC by the ORNL WCO.

There are three types of designs for packaging of hazardous material at ORNL, based on level of control, considering end use application. Design responsibility rests with the supplier for the first two types of design and, when required, calculations or any test results shall be approved by the supplier's licensed professional engineer.

- The first type of packaging is commercially available (off the shelf) packaging. Items which are commercially available and also Stores items will have a specification in the [Oak Ridge National Laboratory \(ORNL\) Packaging Specification Catalog](#). Use of the catalog on the TPM website ensures current versions of the approved specifications are utilized. The specifications for commercially available packaging are only to define the minimum requirements for such packaging and, in some cases, to delineate additional company requirements for which the actual design of the packaging is not compromised (e.g., ORNL Stores catalog marking). These specifications do not require the manufacturer to provide drawings. Purchase requisitions for packaging which are commercially available are verified for compliance with intended use and approved by TPM. The customer for a Stores stocked/commercially available item approves the packaging through the [ORNL-233](#) and signature pages for the specification.
- The second type of packaging design used at ORNL is one which is a commercially available product which is altered to an extent that retesting for DOT certification is required. Manufacturer drawings and testing documentation will require special design features. These drawings and specifications shall be prepared through a qualified engineering group in accordance with appropriate engineering procedures and/or site QA procedures. Performance testing must be in accordance with applicable regulations for the specified packaging. In some cases, engineering evaluations can be used for testing requirements. If the packaging for this type of design is to be stocked in ORNL Stores, then the customer approves both the specification and the drawing.
- The third type of design is for requisitioning of project specific packaging in which the project contributes to the design. This type of design is one that is not stocked in ORNL Stores and requires special features to transport the intended material. This type of packaging is a requisitioned purchase order entered in SAP/AVID Plus. The project requisitioning the packaging must be technically competent for packaging determination; if not, TPM will assist with the determination. TPM will review the purchasing documents and confer with the customer on the appropriate levels of controls and approvals necessary to comply with all regulations pertaining to the packaging. The design of this type of packaging must be under specific engineering controls defined within the project plan and approved by appropriate levels of authority. Many times, this packaging will require Facility Safety approval.

Management Plan for the Procurement of Department of Transportation Regulated Packaging Revision 8

6.1 Types of Design (continued)

Additionally, this type of packaging will usually possess specific maintenance and use criterion (such as a SARP) which must be addressed within the project work processes. It is the responsibility of the owning division to ensure compliance with all work instructions provided with the packaging. TPM will review work processes upon request by the owning division.

The various regulations, codes and standards may require testing to be performed. The applicable tests, or test results, shall be included as a part of the base design to assure adequate quality during the fabrication of the applicable packaging and/or after the final packaging is completed.

6.2 Design Verification

Prior to the completion of a design, which is comprised of specifications and/or drawings, the design documents or criteria shall be independently reviewed. A signature page has been implemented to document the approval process. Signature requirements are based on the complexity of the packaging and the applicable regulations. The following independent review verifications shall apply.

Different degrees of independent verification are required for designs depending on their graded-approach categories. The adequacy of design inputs and changes shall be verified or validated by the following:

- Level 1 – Verification and validation by individuals or groups independent from those who created the design and who will not benefit from, or have the appearance that they could benefit from, any lack of objectivity. This will apply to the second and third type of design.
- Level 2 – Verification and validation by individuals or groups other than those who created the design but who may be supervised or managed by the same person. This will apply to the first type of design.

6.3 Design Changes

If a change to an existing design of TPM controlled packaging is required, then an Update Request for Packaging Designs, Specifications, and Drawings (TPM-UR-yy-*nnn*, where *yy* is the last two digits of the current year and *nnn* is the consecutively assigned number to a specific request) shall be submitted. These requests will be justified by a consensus of affected parties and, if deemed appropriate, changes shall be initiated. All changes to packaging designs shall be subject to the same control as that of the original design approval sequence. A design change is defined as a change which affects the integrity and functionality of the packaging. Retesting of packaging may be required. Retesting criterion for UN certified packaging is defined in 49 CFR ¶178.601. Packaging for radioactive material will require retesting when directed by 49 CFR ¶173.461. Generally, this occurs when containment is altered. When a greater degree of control is required than provided by this document, distribution of such control shall be detailed in the project QA plan.

Reference [Attachment 9, Drawing Change Needed](#) and/or [Attachment 10, Specification Review Needed](#) for work flow process for these changes.

**Management Plan for the Procurement of
Department of Transportation Regulated Packaging
Revision 8**

CRITERION 7: PROCUREMENT

7.1 Procurement of Packaging

During FY 1999, ORNL changed the management system and policy for the procurement of materials (including DOT regulated packaging) from a specialized, locally controlled system to a commercial off-the-shelf computer system (SAP). As such, responsibilities for assuring that quality provisions and controls are placed in the procurement documents have been assigned to the requester. However, material "containers/Package/Packing Supplies, 81," has a feature which requires TPM approval of such purchases in SAP/AVID Plus (see [Attachment 8, Purchase of DOT Regulated Packaging](#)). Credit card purchases of DOT packages to transport hazardous material **ARE NOT** authorized unless prior approval from TPM is obtained.

The procurement of packaging to be fabricated from an outside source should be in accordance with government procurement regulations, ORNL procurement procedures, and applicable QA requirements. The procurement documents should include the specified technical requirements, applicable drawings, specifications, or codes, as well as shelf life requirements, special storage, handling, and shipping instructions, when applicable. The procurement documents should designate the applicable inspection requirements to be performed by ORNL personnel. As a minimum, procurement documents for packaging should be designated as such that a special receiving inspection (incoming inspection) is to be performed per site procedures. Inspections are based on a graded approach system. Quality significant items are given special consideration. To the extent necessary, procurement documents should require suppliers to have a quality assurance program consistent with the applicable quality provisions required by the various regulations, codes, and standards and, if testing services are requested, a calibration schedule or evidence of equipment calibration is required. Quality clauses should be included in procurement documents identifying suspect/counterfeit fasteners and other parts as applicable requiring that no suspect/counterfeit parts be included in procured items.

Orders placed through the Avid Plus system will include standard PAAA clauses.

7.2 Evaluated Suppliers

Prospective packaging suppliers should be evaluated prior to packaging procurement. Efforts should be made to eliminate the use of multiple suppliers for the same product; however, any procurement can be competed among the approved suppliers per procurement procedures. Suppliers should be evaluated by ORNL supplier auditing activities or by utilizing the evaluation results of other established groups. Evaluated supplier information is available through the Battelle ISIS database. If other groups' supplier surveillance results are used to approve suppliers, the surveillance report should be reviewed by qualified personnel and kept on file by the TPM or the ISIS Coordinator. Suppliers should be re-evaluated on a frequency of no less than every three years.

A supplier evaluation with satisfactory results should be conducted prior to awarding a contract with the proposed supplier except in cases of small quantity procurements. Small quantity procurements are defined as 50 packaging or less and/or less than \$20,000 total procurement cost.

Special receiving inspections for small quantity procurements will be used to verify the quality of the packaging. Sampling plans will not be utilized for small quantity procurements (inspection will be 100% of incoming packaging.)

Management Plan for the Procurement of Department of Transportation Regulated Packaging Revision 8

7.2 Evaluated Suppliers (continued)

When possible, evaluated suppliers should be involved in the procurement process. They should be afforded an understanding of ORNL's needs and participate (as appropriate) in the planning which established those needs. Suppliers should also be involved in evaluating the performance of their products.

7.3 Control of Purchased Items and Services

7.3.1 Supplier Selection

Suppliers and manufacturers should be evaluated by established methods. When possible, the requester, designer, or other knowledgeable personnel may provide a list of evaluated suppliers and manufacturers to Contracts Division. TPM provides a list of evaluated suppliers of Stores items to Contracts Division. When a distributor is used to procure packaging, verbiage must be added to the purchase requisition which states that quality provisions must be flowed down to the supplier.

7.3.2 Supplier Evaluation

When requested by responsible management, the requester, the TPM Manager, or when specified in a QA Plan, supplier evaluations are performed by the site inspection groups, QASs, other technically qualified persons, or by utilizing the results of other established organizations outside of ORNL. These evaluations are performed, prior to awarding the contract, to evaluate the supplier's or manufacturer's QA Program and ability to provide the desired item or service; and after the contract is awarded, to verify that quality-related requirements are met during performance of the contract and prior to shipment of items to ORNL. Prior to conducting the evaluation, the requester, responsible management representative, TPM representative, and a QAS should meet to document a supplier evaluation plan. In the case of a Package Broker, the broker must provide a systematic method to ensure that suppliers meet the ORNL specifications in the purchase requisition and that a flowdown of quality provisions applies to the suppliers. Evaluation type can either be a site evaluation or a desk top evaluation.

7.3.2.1 Supplier Evaluation Plan

Prior to conducting supplier evaluations, the requester, TPM, Quality Auditor, Contracts Division personnel, and other technically qualified persons, as appropriate, should meet to discuss the conduct of the assessment. The group should discuss such items as logistics, responsibilities for the activity (lead assessor, official contact, checklist construction, evaluation planning, etc.), requirements, and other pertinent data. The results of the group's efforts should be a supplier evaluation plan which will satisfy the ISIS required documents:

- **Notification Letter** (unless justification is entered in the evaluation history field of the ISIS record — e.g. lack of lead time),
- **List of Entrance and Exit meetings' attendees** (separate attendance form or cited in the Audit Report and/or Audit Report Cover Letter),
- **Audit Checklist** (scan hand written documents),
- **Audit Report Cover Letter** and/or **Audit Report**
- **Audit Responses Letter** (Not required if no Findings),
- **Response Evaluation Letter** (Not required if no Findings), *and*
- **Close-Out Letter** (Not required if no Findings)

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7.3.2.1 Supplier Evaluation Plan (continued)

This evaluation plan should be submitted to the supplier as soon as practical prior to the assessment. The completed plan should be included in the official supplier evaluation files.

7.3.2.2 Supplier Evaluation Checklist

The evaluation team, with the assistance of other technical experts as appropriate, will document a supplier evaluation checklist to be used to conduct the assessment. This checklist should include all of the requirements necessary to perform a complete evaluation of a supplier's capabilities to produce compliant, quality products and services. The completed checklist should be included in the official supplier evaluation file. The scope of the audit should reflect a standard, systematic evaluation system (i.e., NQA-1, 10 CFR, ISO), appropriate to the level of packaging.

7.3.2.3 Supplier Evaluation Final Report

After the completion of the evaluation, the lead assessor is responsible for issuing a final report of the conduct, results, and conclusions of the assessment. The final report should be included in the official supplier evaluation files. The final report and associated support documentation are to be input into ISIS.

7.3.3 Deviations

Supplier Deviation Request requirements should be specified in ORNL purchase requisitions per Acquisition Management SBMS subject area [Purchasing Supplies and Services](#). These requests require approval by the requester and/or TPM before a supplier can depart from technical specifications and other quality-related requirements contained in the contract.

7.3.4 Acceptance of Packaging or Service

The acceptability of a packaging or service should be determined by either evaluation at the supplier prior to delivery, by special receiving inspection, by operational tests at ORNL, Certificate of Conformance, satisfactory prior history of quality, or a combination of any of the above. The packaging or service is evaluated against the requirements of the purchase order, inspections, and tests of packaging, and examination of documentation furnished by the supplier. These services are offered by site inspection groups, QASs, or other technically qualified persons as specified in the procurement documents.

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CRITERION 8: INSPECTION AND ACCEPTANCE TESTING

8.1 Inspection

8.1.1 Inspection Applications

Inspection activities should be performed for both new packaging and packaging to be reused. Inspection activities for packaging are primarily identified by procurement documents, drawings and specifications; DOT and NRC regulations; and other applicable standards and codes. Inspection of packaging and processes at suppliers' sites should be provided by site inspection groups, QASs, or other qualified individuals.

Inspections range from those performed at suppliers' sites before packagings are shipped to ORNL to special receiving inspections by site inspection groups on incoming packaging to verify conformance to the purchase order requirements.

Inspections for reusable packaging require the integrity of the reused packaging to meet the original requirements or for the reusable packaging to be reconditioned to meet the original requirements. Inspections should be documented on a checklist. QE&I personnel can complete these inspections as requested; these inspections can be performed by personnel authorized by the user's Division or TPM.

8.1.2 Inspection Plans

All packaging inspections, source or special receiving inspection, should be performed as specified in a documented inspection plan. The inspection plan should identify:

1. Frequency of inspection, if applicable,
2. Method of inspection, such as the procedure to be used,
3. Sampling procedures or reference to them, if applicable,
4. Inspection personnel qualification requirements, if applicable,
5. Tests that are required to be monitored or witnessed,
6. Mandatory hold points, if required,
7. Acceptance criteria,
8. Data to be recorded including pertinent allowable parameters, *and*
9. Inspection records to be retained and retention periods.

The requester or the owner of the packaging is responsible for providing TPM with the technical requirements of the packaging. For packagings which are to be procured from outside suppliers, inspection plans should be developed by the requester in association with site inspection personnel, TPM, and/or other qualified individuals and groups. An inspection checklist is developed for each packaging type. The checklist will be utilized by the appropriate inspection personnel and maintained as a quality record. These inspection checklists should be attached to the purchase requisition and forwarded to the supplier. For packaging which is governed by a SARP, inspection plans are developed and included in the applicable chapter entitled, "Acceptance Tests and Maintenance Program." For combination performance-oriented packaging designed at ORNL, tests and inspections should be required to be performed in accordance with an inspection plan at an approved testing facility after the packaging is developed.

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8.1.3 Inspection Records

Records of inspection results and the identification of maintenance and retention responsibilities should be included in the inspection plans. These inspection records should be maintained for at least one year after the last use of the packaging. Inspection checklists are maintained by the inspector at a minimum. If copies are needed by a project, the requesting organization should request a copy of the checklist.

8.1.4 Sampling Plans

Sampling plans, when required, should be made available to the inspection personnel. If a sample is used to verify acceptability of a group of items, the recommended sampling plan is based on ANSI/ASQC Z1.4-1993, "Sampling Procedures and Tables for Inspection by Attributes." The amount, or level, of sampling should be based on the amount of other quality related activities conducted to evaluate supplier packaging. Such activities as supplier evaluation, past history, new suppliers, etc., should be used to determine the amount of sampling necessary.

Note: Sampling plans will not be utilized for small quantity procurements (inspection will be 100% of incoming packaging.)

8.2. Test Plans

8.2.1 Test Plans

Test plans are prepared for evaluating the performance of packaging or containment systems with packaging prior to their use or acceptance at ORNL or at stated intervals during the life of a packaging. The need for test plans should be identified by procurement documents; drawings and specifications; SARPs; or through performance-oriented packaging standards, regulations, standards, and codes.

8.2.2 Test Plan Preparation

All test plans should be prepared in accordance with applicable regulations, standards, and codes. Test plans should be developed by packaging designers or other technically qualified individuals. It is recommended that test plans prepared by others are reviewed by TPM and QA personnel to assure that all prerequisites have been specified. Prerequisites include: identifying qualified testing organizations; identifying suitable environmental, operating, and testing conditions; specifying test/inspection personnel qualifications; and stating clear and concise acceptance or rejection criteria.

8.2.3 Test Performance

Packaging testing may be performed at ORNL or at a supplier's site by either the supplier or by an independent testing organization. Required testing should be witnessed by the packaging designer, site inspection personnel, an assigned QAS, TPM, or other qualified personnel.

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8.2.4 Test Results

All test results identified in Plan Preparation should be documented. The documented results should be submitted to the requesting organization when requested or when items or systems tested fail to meet specified requirements. Following evaluation, the test reports are filed by, or for, the requesting organization. The period of time these test reports are maintained depends on the document, regulation, standard, or code that required the testing. Testing documentation is required as a deliverable for certain packaging and should be available from the supplier upon request.

8.3 Control of Measuring and Test Equipment

All measuring and test equipment utilized for the inspection or testing associated with packaging that requires calibration should be either calibrated by a qualified user or placed in a recall program to assure that it is maintained and calibrated on a basis that provides sufficient accuracy. All calibrated measuring or test equipment should be categorized, calibrated, and identified as such in accordance with the site-specific calibration directives. The existence of a calibration and maintenance program whose calibrations are performed with measuring and test equipment or calibration standards traceable to national standards should be a prerequisite for test laboratory contracts.

8.4 Inspection, Test, and Operating Status

The inspection and/or test status should be indicated by the use of markings such as stamps, tags, labels, or other suitable means on individual packaging/package or groups of bound packaging/packages. The status should include an identification of items which have satisfactorily passed required inspections and tests to preclude inadvertent bypassing of the inspections and tests. In addition, the operating status of critical or safety-related components of the packaging, such as valves and switches, should be identified to prevent inadvertent operation.

CRITERION 9: MANAGEMENT ASSESSMENT

TPM participates in ORNL's [Performance-Based Management System](#) by implementing the division's approach for continuous improvement in maintaining a vigorous program of critical self-assessments, thus ensuring implementation of appropriate management practices and operational processes to maximize performance. TPM is committed to self-assessments as a routine managerial function integral to daily operations. Managers ensure that the self-assessment discipline is implemented in their respective areas and that the identified assessments are conducted, evaluated, and implemented in an efficient and timely method. Employees are responsible for continually assessing and measuring their performance in order to find better and more efficient means of accomplishing tasks. Managers routinely communicate self-assessment information and lessons learned to employees. Corrective actions are initiated, tracked, and closed in assessments that have identified needed improvement by the ATS system.

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CRITERION 10: INDEPENDENT ASSESSMENT

10.1 QAS

The QAS assigned to TPM may conduct periodic documented assessments/surveillances of activities within the organization. The QAS has sufficient authority and freedom from the TPM line organization to carry out this responsibility. These planned assessments/surveillances should be conducted and the results documented and submitted to the TPM Manager. Corrective actions required for deficient areas should be entered in the ATS and tracked until completion.

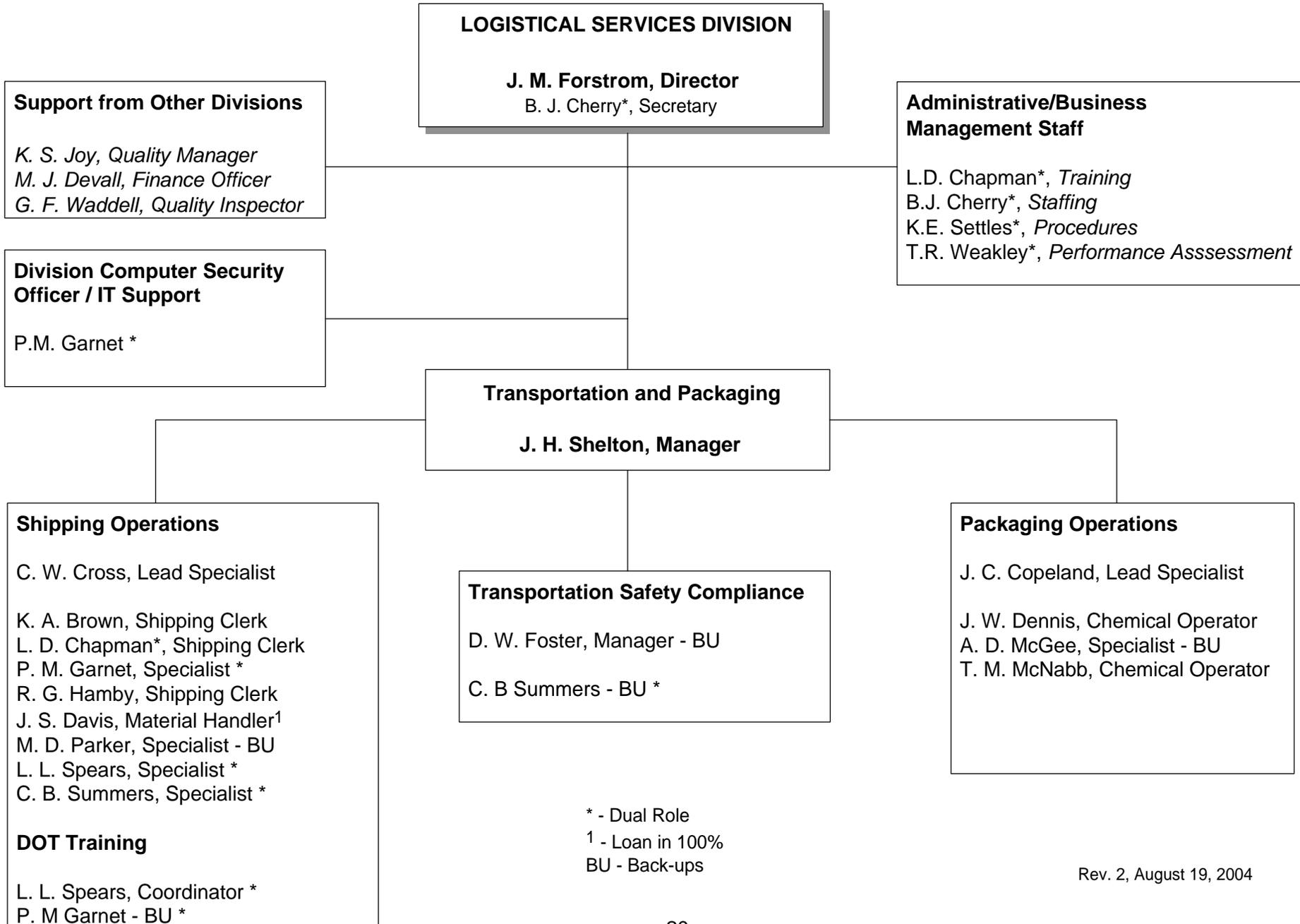
10.2 ORNL Transportation Safety Compliance

The TPM Transportation Safety Compliance Manager, or designee, has the authority to conduct reviews of different activities and organizations involved in packaging at that site. The reports of the reviews are documented and submitted to ORNL senior management and the TPM Manager.

10.3 Evaluations by Consultants

When deemed necessary by TPM management, the services of outside consultants may be attained to provide independent assessments of TPM activities and regulatory compliance. When consultants are to be hired to perform assessments on TPM management systems, it is recommended that procurement documents for their services include the requirement for them to conduct the evaluation in compliance with an established auditing standard (i.e., ANSI/ASQC Q1-1986, "Generic Guidelines for Auditing of Quality Systems").

Attachment 1
 Transportation and Packaging Organization Chart
 Reports to UT-Battelle, LLC, Associate Director for Facilities and Operations



* - Dual Role
 1 - Loan in 100%
 BU - Back-ups

Rev. 2, August 19, 2004

Attachment 2
Procurement Plan for DOT-Regulated Packagings
Document Control

| P= Prepare A=Approve I=Computer Input R=Review/Input C=Process/Perform S=Surveillance Blank=Not Required | Customer Division Defined Design Interface** | Packaging Operations | QA Specialist | ISIS/QA | Site Material Services | Contracts Division | Waste Certification Officer ** | Site Receiving Inspection |
|---|--|---------------------------------|--------------------------|----------------|---------------------------------------|-------------------------------|---|--|
| Documents/Actions | | | | | | | | |
| Purchase Requisitions | P/I | A | S | | R | C/R | R | |
| Request for Inventory Addition | P R** | A/P | S | | R | C | R | |
| Nonconformance Reports | R** | A | A/I | | | R | R | P |
| Supplier Evaluation Plans | R* | P/A/R | R | P/C | | R | R | |
| Special Receiving Inspection Plans | P/R * | P/A/R | S | | | | R | C |
| Third Party Evaluations | | R | S | R/A | | | R | |
| Packaging Specifications | P R/A** | P/A/I | | | | C | A/R | |
| Stores Catalog Description | | P/A | | | R | C | | |
| Drawing Revisions | R/A R/A** | R/A | | | | | A/R | |
| Accepted Packaging Inspections Results | | | | | | | R | P/C |
| Loading Instructions | C | R/I/C | | | | | R | |
| Packaging Procedures | C | P/A/C/R | | | | | R | |
| Request for Waiver or Deviation | | A | S | | | C | R | |

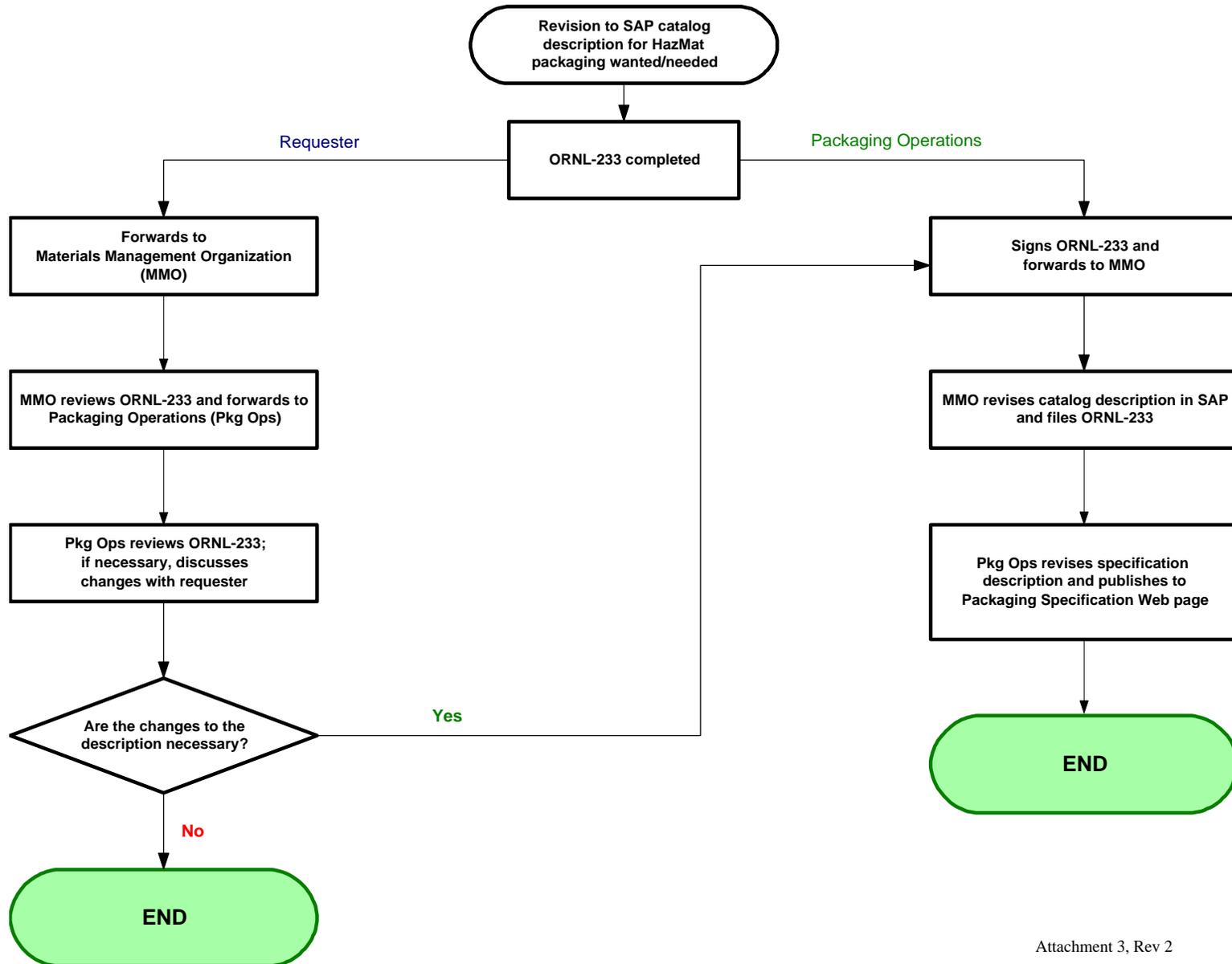
*NOTE: Optional

** For NTS packaging only

Attachment 2, Rev 2

Attachment 3

CHANGE CONTROL FOR THE SAP CATALOG DESCRIPTIONS FOR HAZMAT PACKAGINGS



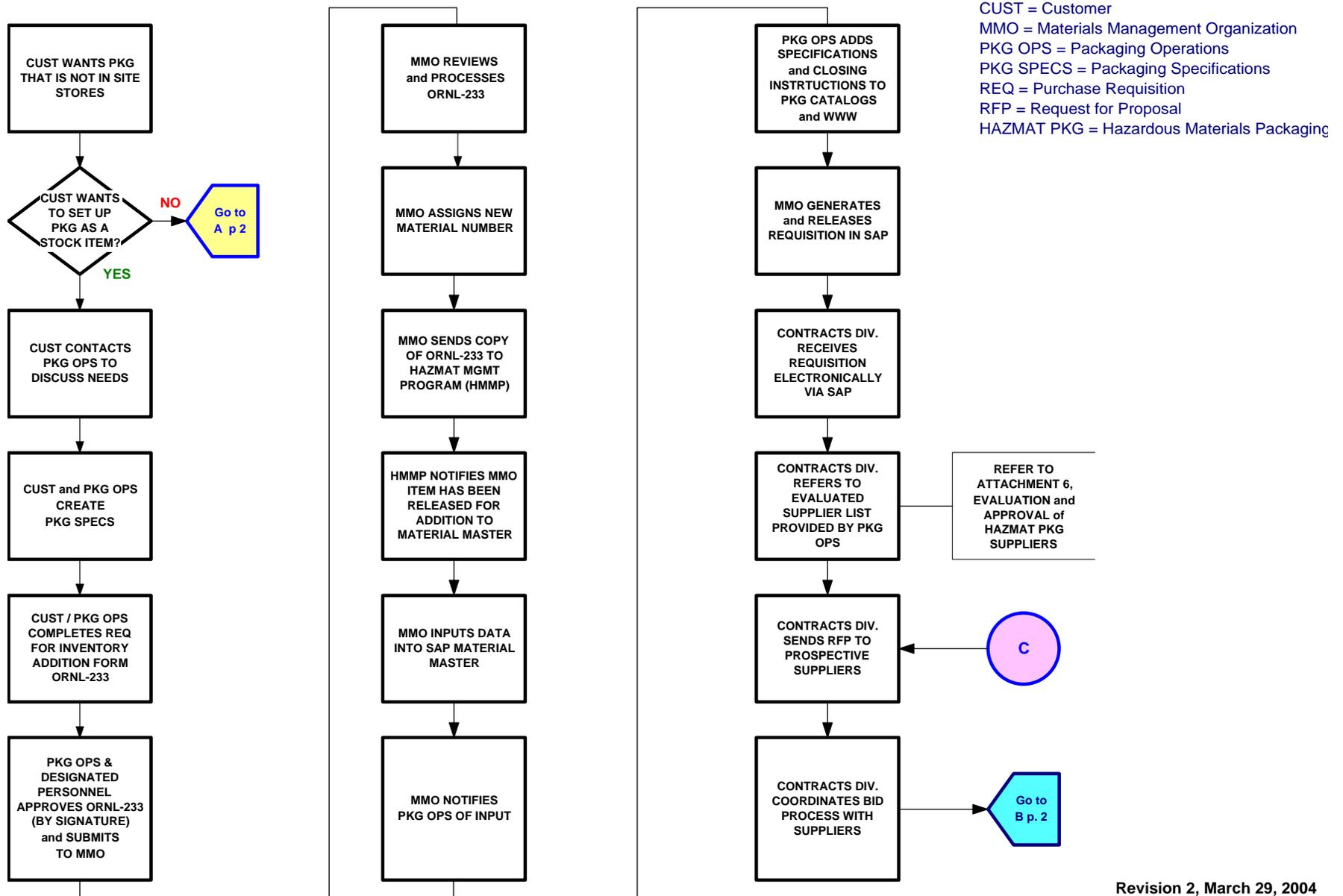
Attachment 4

RECORDS INVENTORY and DISPOSITION SCHEDULE

| QA No: TPM-QA-2, Revision 4 | | Date: December 15, 2003 |
|--|------|---|
| Project Title: Management Plan for Procurement of Department of Transportation Regulated Packagings | | |
| Project Manager: Jeff H. Shelton | | QAS: Keith S. Joy |
| Retention Period (UP) – L (Lifetime) or NP (Nonpermanent), if NP, state number of years. Master File Point – State location of Master File Point. | | |
| NAME OF RECORD | UP | MASTER FILE POINT |
| Stores “UN” Packaging Specifications; Including Approval Signature Page (eff. 7/2003) | L | Packaging Operations (Bldg 3036) |
| Nonconformance Reports (with inspection results) | L | Assessment Tracking System (ATS) |
| TPM Evaluations by External Auditors | L | TPM (Bldg 7001) |
| Purchase Requisitions (Electronic) | NP:6 | SAP |
| Request for Inventory Addition | L | Materials Management Organization (Bldg 7001) |
| Request for Proposal (RFP) | L | Contracts Division (Bldg 1000) |
| Accepted Packaging Inspection Results | NP:5 | Special Receiving Inspection (Bldg. 7001) |
| Request for Waiver or Deviation | L | Packaging Operations (Bldg 3036) |
| Supplier Evaluation Results | L | Procurement Quality |

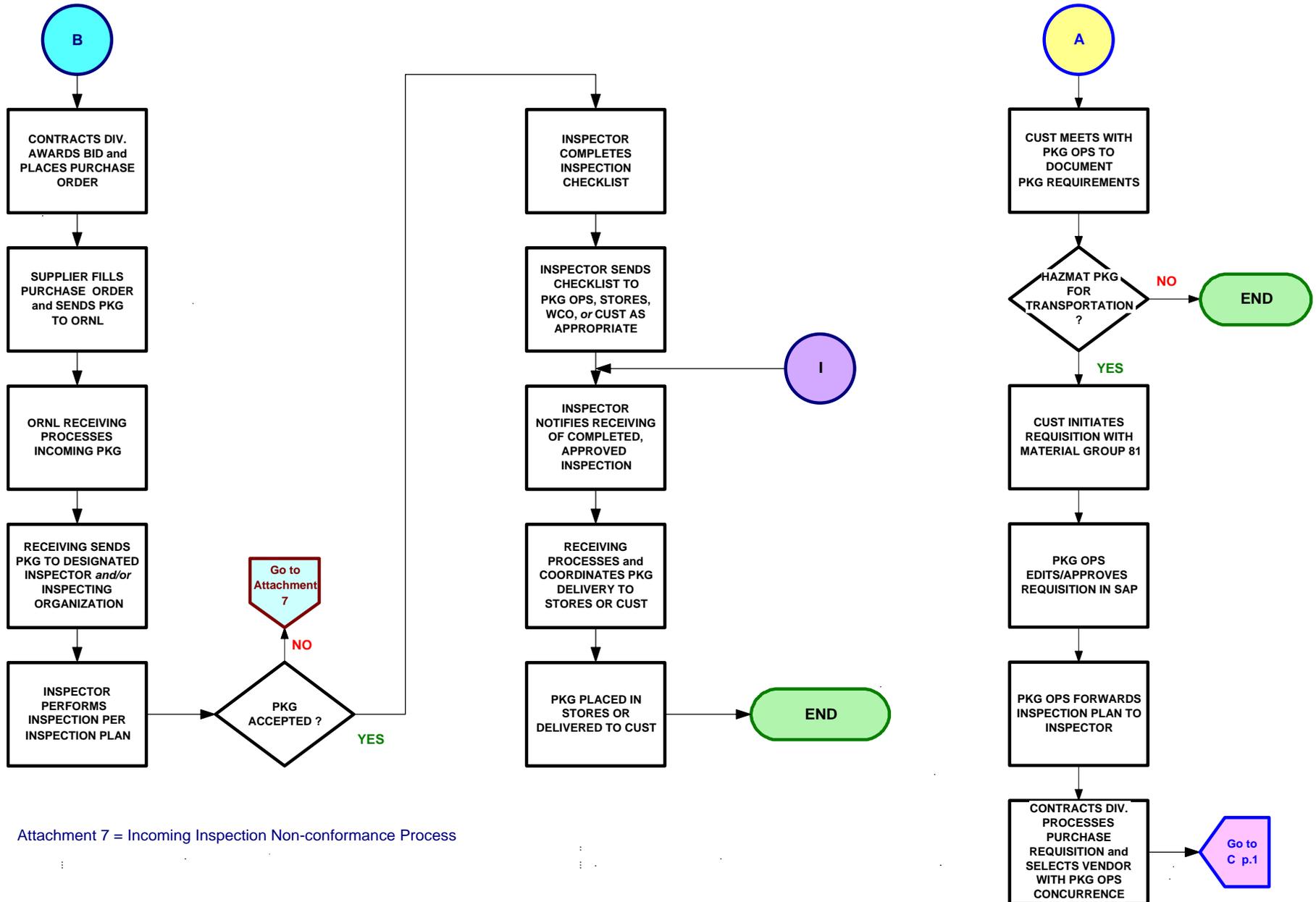
Attachment 5

HAZARDOUS MATERIALS PACKAGING PROCUREMENT CYCLE FOR ORNL-233 AND REQUISITIONED PURCHASES (PAGE 1 of 2)



Attachment 5

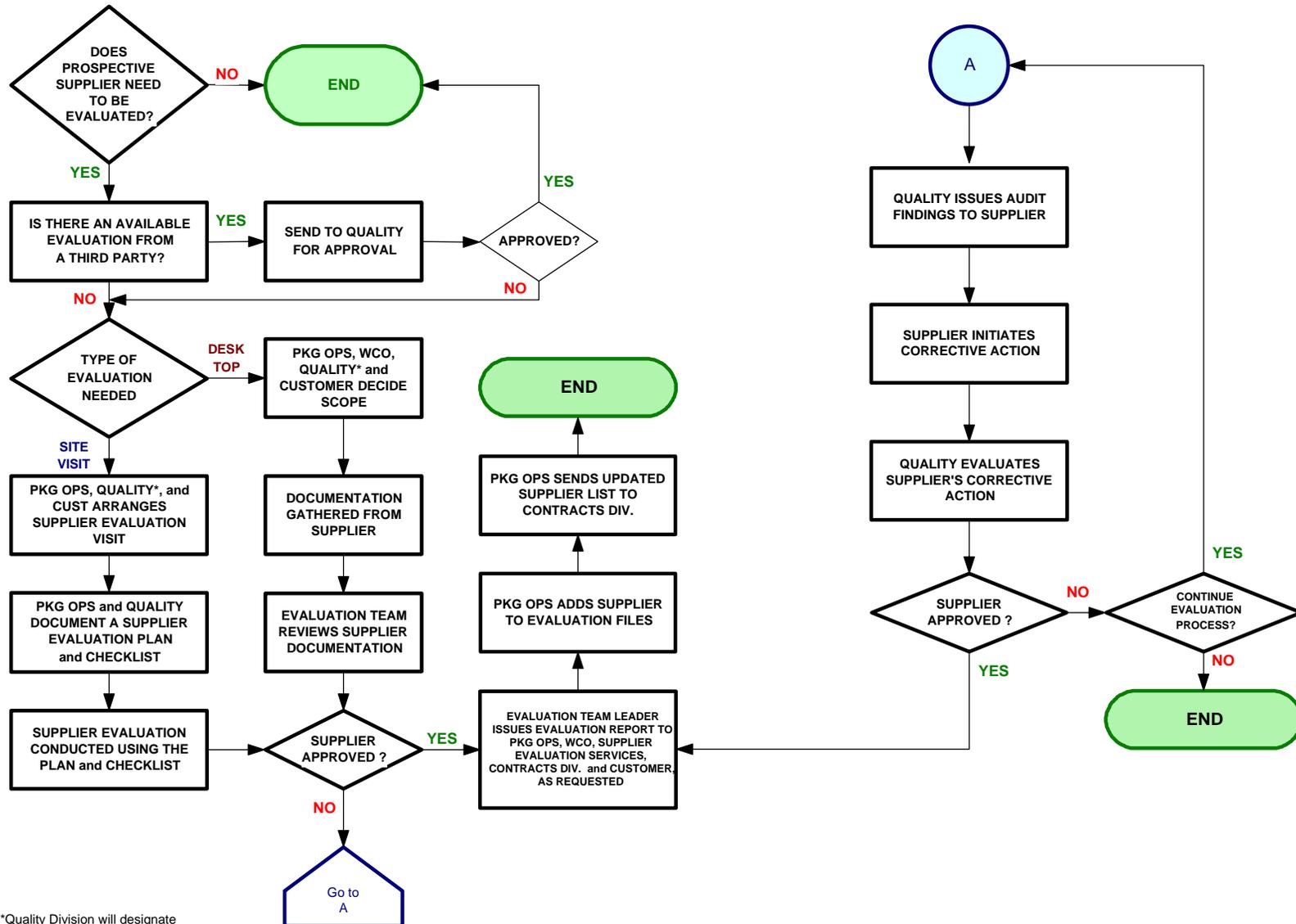
HAZARDOUS MATERIALS PACKAGING PROCUREMENT CYCLE FOR ORNL-233 AND REQUISITIONED PURCHASES (PAGE 2 of 2)



Attachment 7 = Incoming Inspection Non-conformance Process

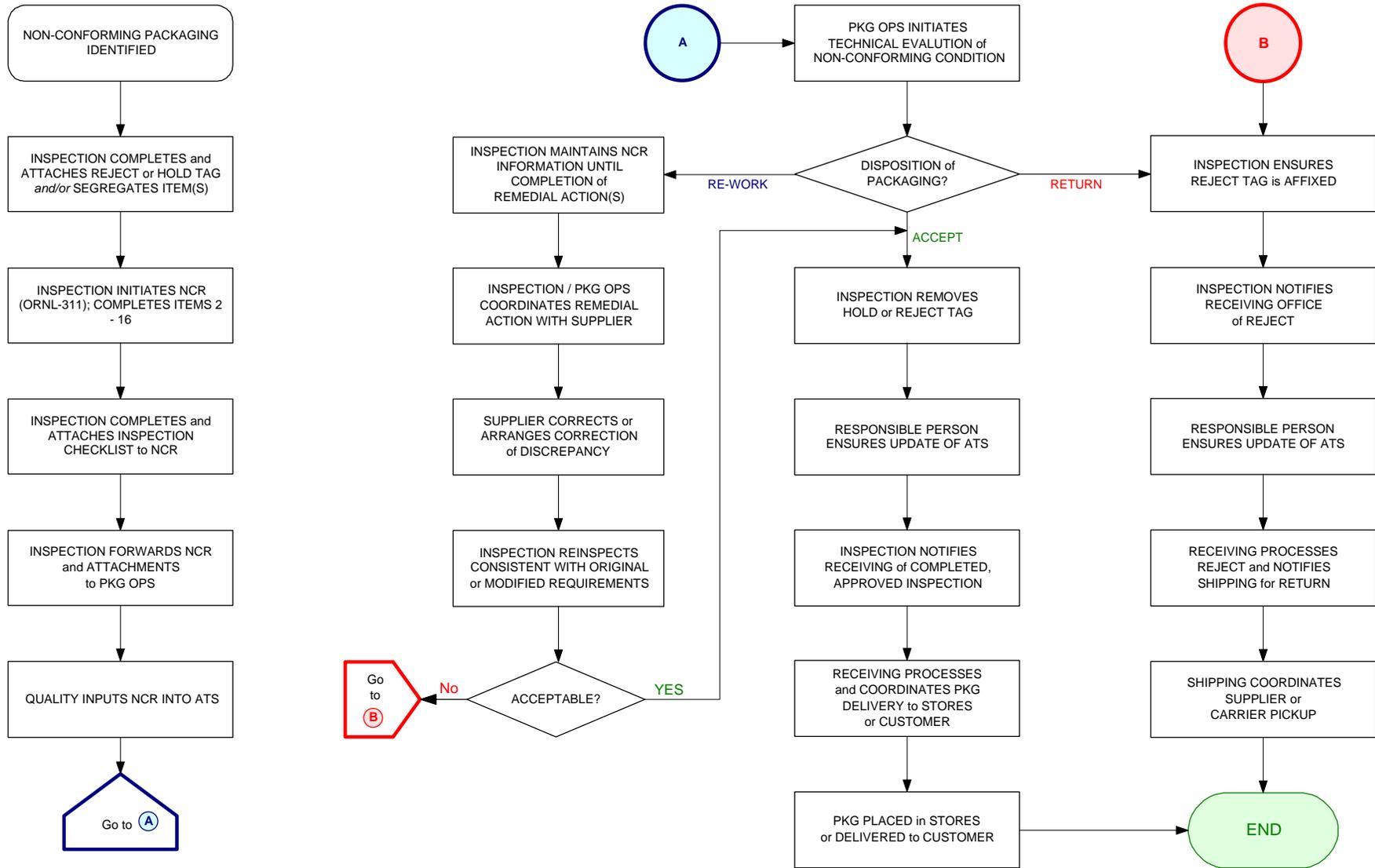
Attachment 6

EVALUATION and APPROVAL of HAZARDOUS MATERIALS PACKAGING SUPPLIERS

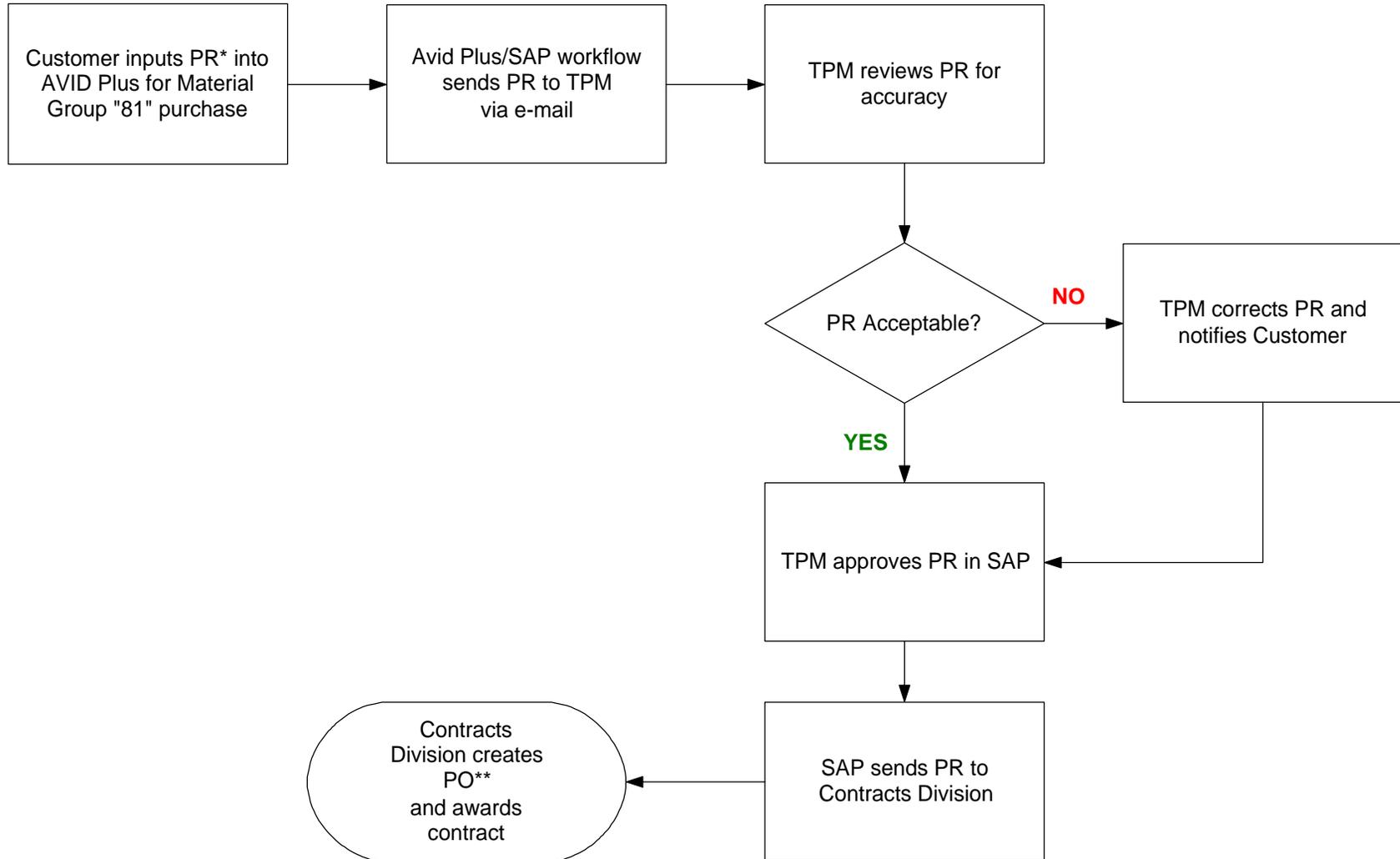


*Quality Division will designate evaluation team members.

Attachment 7 INCOMING INSPECTION PROCESS for NON-COMFORMING PACKAGING

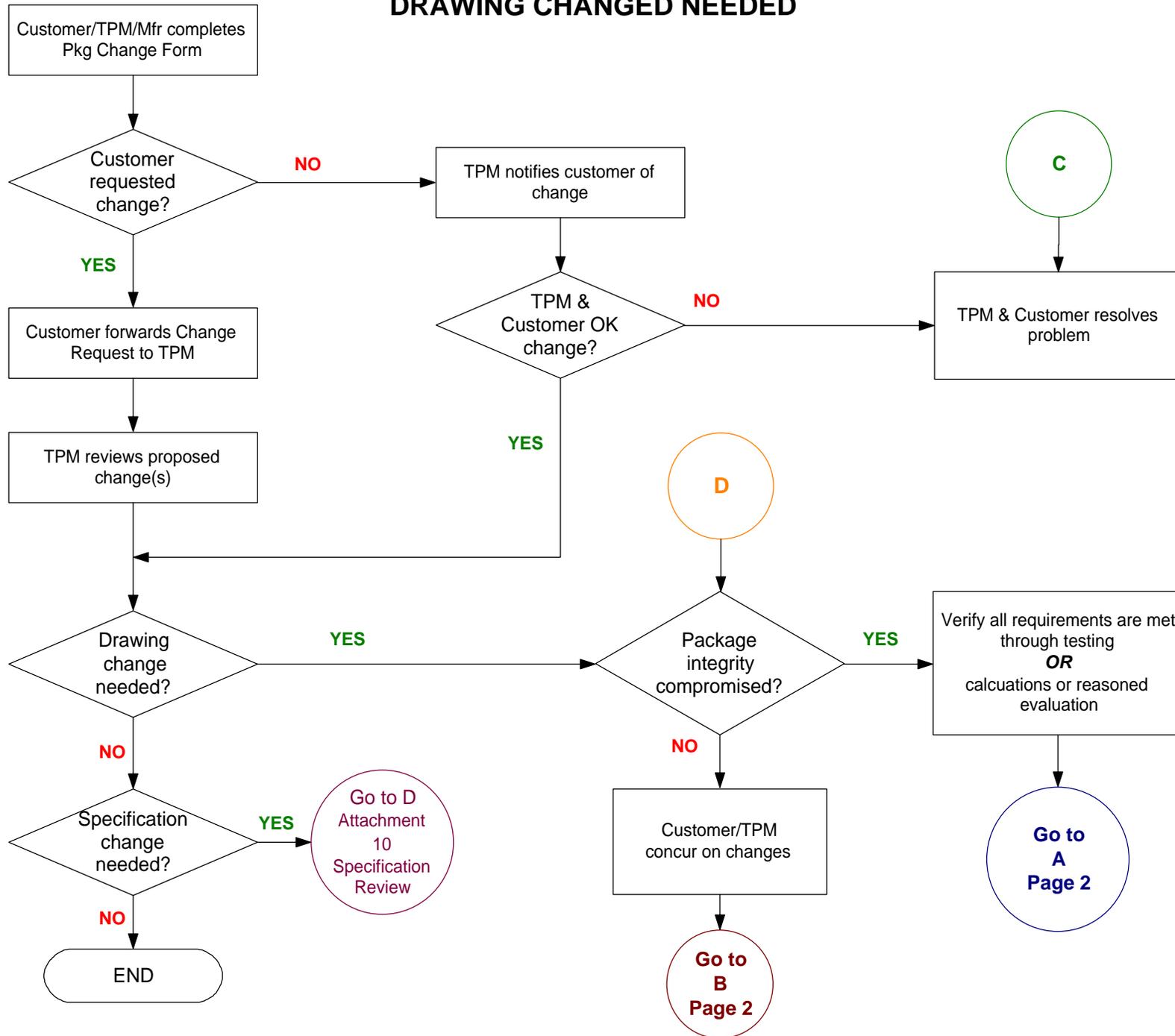


Attachment 8 PURCHASE of DOT REGULATED PACKAGING

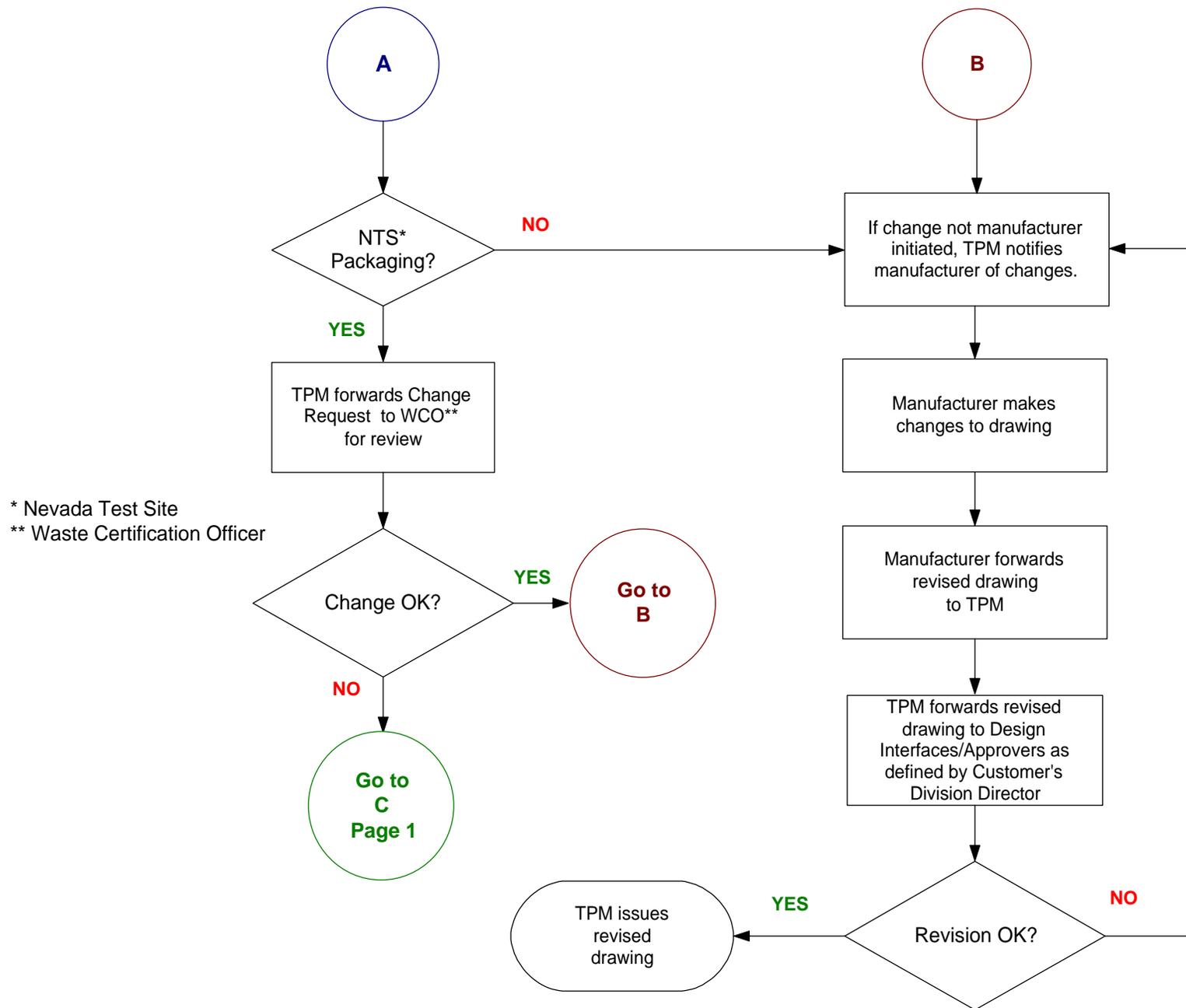


* PR = Purchase Requisition
** PO = Purchase Order

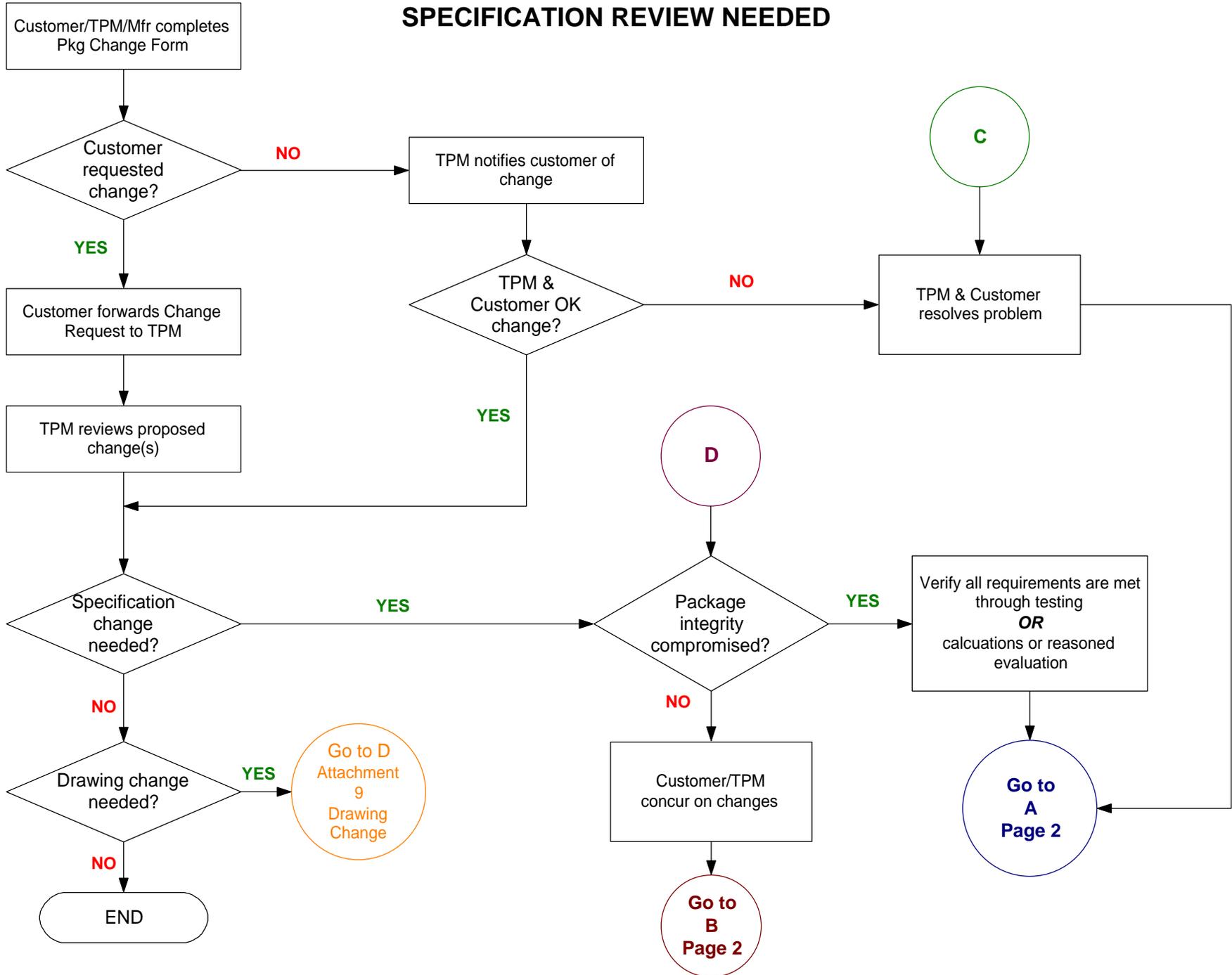
Attachment 9 DRAWING CHANGED NEEDED



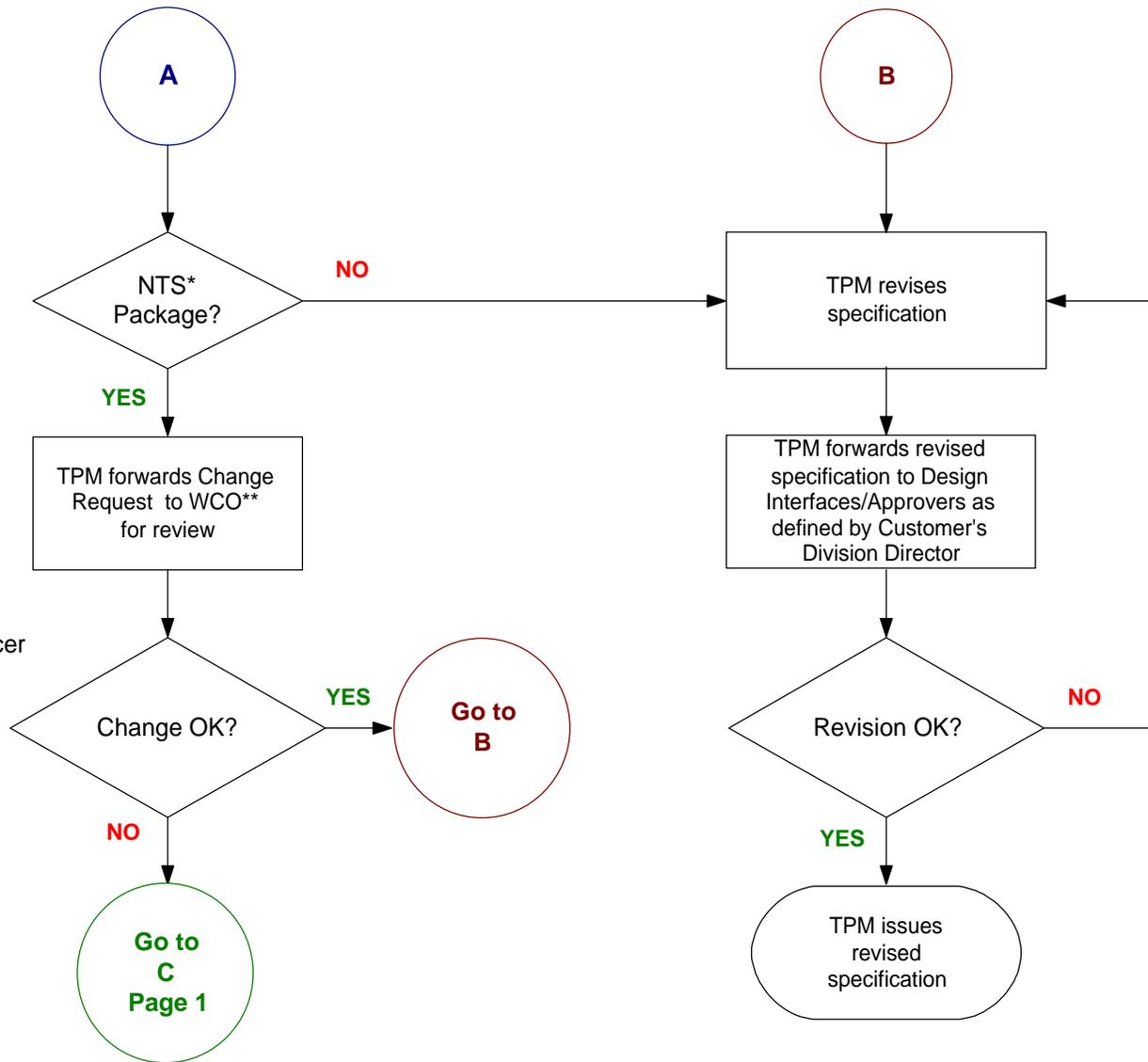
Attachment 9 DRAWING CHANGED NEEDED



Attachment 10 SPECIFICATION REVIEW NEEDED



Attachment 10 SPECIFICATION REVIEW NEEDED



* Nevada Test Site
** Waste Certification Officer

Appendix A

ACRONYM — INITIALISM LIST

| | |
|---------------------|---|
| ATS | Assessment Tracking System |
| CoC | Certificate of Compliance |
| DOE | Department of Energy, The |
| DOT | Department of Transportation, The |
| ISIS | Integrated Supplier Information System |
| LSD | Logistical Services Division |
| LWS | Laboratory Waste Services |
| MMO | Materials Management Organization |
| NCR | Nonconformance Report |
| NDE | Nondestructive Evaluations |
| NDT | Nondestructive Testing |
| NRC | Nuclear Regulatory Commission |
| NTS | Nevada Test Site |
| NTSWAC | Nevada Test Site Waste Acceptance Criteria |
| ORNL | Oak Ridge National Laboratory |
| PAAA | Price-Anderson Amendment Act |
| PQS | Procurement Quality Services |
| QA | Quality Assurance |
| QAS | Quality Assurance Specialist |
| QC | Quality Control |
| QE&I | Quality, Engineering & Inspection |
| QSD | Quality Services Division |
| RIA | Request for Inventory Addition |
| SARP | Safety Analysis Reports for Packaging |
| SBMS | Standards-Based Management System |
| SQUIG | Supplier Quality Information Group |
| TPM | Transportation & Packaging Management |
| UN | United Nations |
| WAC | Waste Acceptance Criteria |
| WCO | Waste Certification Officer |
| WP | Waste Profile |