

# **REPORT**

## **ROOT CAUSE ANALYSIS**

*Scope: Evaluation of the 10CFR71 Subpart H Quality Assurance Program Breakdown Related to the Use of Type B Package, Serial Number 22197-3, for Shipments in a Nonconforming Condition.*

### **Prepared For:**

**J. L. SHEPHERD & ASSOCIATES**

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### **Prepared By:**

**Donald R. Neely Associates**

***INDEPENDENT AUDITOR***

## 1.0 INTRODUCTION

The Nuclear Regulatory Commission issued a Confirmatory Action Letter to J. L. Shepherd & Associates (JLS&A), dated April 24, 2000, related to an inspection that identified items of non-compliance relative to 10CFR71. Item (2) of the letter required that JLS&A obtain the services of an independent Quality Assurance (QA) auditor to assure that the JLS&A QA program was established and implemented in accordance with the requirements of Subpart H of 10CFR71.

An additional requirement, in the same section of the letter, was to have the independent auditor perform a root cause evaluation of the breakdown in the QA program that allowed the package with serial number 22197-3 to be shipped in a non-compliant condition.

Results of this root cause evaluation is contained in the following report sections.

## 2.0 EVENT DESCRIPTION

The NRC identified several inspection findings relative to Type B packages that were determined to be in noncompliance with certain 10CFR71 requirements; The nonconforming conditions were identified as being relative to:

- 10CFR71.12 (a), (c)(2), "General License: NRC-approved package":

*During the period January 22, 1997 to September 29, 1999, on (4) occasions, JLS&A shipped licensed radioactive material in a package (serial no. 22197-3) which did not comply with the terms and conditions of the NRC Certificate of Compliance.*

- 10CFR71.13 (a), " Previously approved packages":

*JLS&A shipped licensed material under 10CFR71.12 using Type B package serial number 22197-3 which was fabricated after August 31, 1986, while the applicable CoC was not designated as B (U) or B (M) in the identification number.*

## 3.0 METHOD OF IDENTIFICATION

On November 3-4, 1999, an inspection team from the United States Nuclear Regulatory Commission (NRC) performed an announced inspection at the JLS&7 facilities in San Fernando, California. The purpose of the inspection was to follow up on corrective actions taken by JLS&A in response to a required notification relative to a nonconforming condition of a Type B container owned and used by JLS&A.

During this onsite inspection of the JLS&A facility and Type B containers, the NRC inspectors, identified additional containers that were not in compliance with 10CFR71 requirements.

#### **4.0 EVALUATION METHODOLOGY**

Several core and advanced analytical techniques were developed, implemented and incorporated, as necessary, by the independent auditor to perform the root cause evaluation and are identified as follows:

- 1) The required independent audit described above was conducted using a fault tree analysis, commonly known as a "Management Oversight Risk Tree (MORT)".

The MORT approach endeavors to systematically identify all of the essential components of each element of the JLS&A 10CFR Part 71 Subpart H Quality Assurance program for determining conformance to Nuclear Regulatory Commission requirements. The results of this analysis are documented in a separate report.

The applicable findings from the MORT analysis were used as a basis to support many of the casual factors and root causes identified in this report.

- 2) A second analytical method was applied utilizing an "Events and Causal Factors" charting and analysis. This methodology provided for a graphical display of the 22197-3 package non-conforming condition chronology and was used primarily for compiling and organizing critical information to portray the sequences leading up to the no-conforming condition.
- 3) A third analytical method applied was a barrier analysis type. The barrier analysis was used to identify the causal factors associated with the 22197-3 non-conforming condition and the administrative and physical barriers that should have been established and implemented to prevent the NRC violations from occurring.

#### **5.0 REFERENCES**

- NRC Inspection Report No. 71-0122/99-201, "Notice of Violation and Notice of Nonconformance", dated March 2, 2000.
- JLS&A letter to NRC, dated November 5, 1999, titled, "1<sup>st</sup> Notification of Non-compliance, COC 6280 Package S.N. 22197-3".
- JLS&A letter to NRC, dated December 6, 1999, titled, "1<sup>st</sup> Response to Notification of Non-compliance-COC 6280 Package S.N. 22197-3".

- JLS&A letter to NRC, dated November 9, 1999, titled, "Copies of the COC 6280, S.N. 22197-3, incoming and outgoing QA forms".
- NRC letter to J.L. Shepherd, dated April 24, 2000, titled, "Confirmatory Action Letter".
- NRC letter to Ms. Mary F. Shepherd, dated March 2, 2000, titled, "Model No. A-0109 Irradiator in A-0117 Over Pack Package". Letter enclosure included Certificate of Compliance No. 8280, Revision No. 7.
- JLS&A letter to NRC, dated April 21, 2000, titled, "Reply to Notice of Nonconformance".
- JLS&A quality implementing document QAM, QP 5.0, 6.0-6.6, "Manufacturing Control-Instructions, Procedures, & Drawings," dated March 7, 1991.
- JLS&A procedure, "Standard Shop Policies and Procedures", dated August 17, 1993.
- JLS&A Quality Assurance Program Plan, dated, October 5, 1995.
- JLS&A Master List of QA/QP Documents and Implementing Documents.
- JLS&A Quality Procedure, "Inspection, Operation, Handling And Maintenance Procedures for COC 6280 Overpack, S.N. 22197", Revision 1, dated 12/05/97.

## **6.0 ANALYSIS DETAILS**

The root cause evaluation was performed incorporating the analytical techniques identified above. The MORT analysis of the overall Subpart QA program was used as the primary analysis basis, with specific evaluation focus applied, using the more definitive cause and effect analytical techniques.

The auditor established tables and figures to chronologically organize and identify casual factors and root causes relative to the 22197-3 non-conforming condition.

In order not to be redundant in describing the details and events leading up to the 22197-3 package non-conforming condition as depicted in the tables and figures, a brief narrative is provided in this section. Summary information is as follows:

- The independent auditor determined that a basis needed to be established for evaluating the management controls that should have been in place, as a minimum, for the conduct of operations and management oversight of JLS&A Subpart QA program. The management barriers and controls, both physical

and administrative that should have existed are listed in Table 6-1, "Types of Barriers" to this report.

Management controls and barriers were identified as a program weakness as a result of the MORT analysis performed on the overall QA program. Based upon a review of the package 22197-3 completed receipt and shipping QA check lists, it is apparent that management controls and barriers experienced a break down at the middle management and executive management levels, due to the fact that these shipments were signed-off and approved for shipment, by persons functioning in these positions. Also, an inadequate level of diligence in the form of management quality assurance oversight contributed to the non-conforming condition. Specifically, the annual internal QA audits performed by JLS&A staff during the period 1996-1999, did not identify to the non-conforming condition. In fact, the audit results did not identify any non-conforming findings or observations related to the overall QA program.

Procedure development and execution was another area that revealed program weaknesses. The procedures used for inspection, operation, handling and maintenance of the COC 6280 S.N. 22197-3 package lacked sufficient detail and specificity regarding the compliance configuration determinations for use. A revision to this procedure took place in December of 1997. Basically, changes to the procedure were specific to meeting revised NRC and DOT radioactive contamination detection (swipes) criteria only. The independent auditor viewed this as a missed opportunity to enhance the procedure to ensure compliance with 10CFR71.

The lack of physical controls and barriers contributed to the nonconformance. Type B package 22197 was removed from active use and placed into a design prototype configuration for a planned French contract. It is assumed that this prototype package did not receive different color designations than those already applied to the approved package fleet. The original serial numbers mounted on the 22197-3 package were removed. The responsibility for the control and storage of these serial numbers and their subsequent authorized use could not be established by JLS&A as a result of their internal investigation effort. Casual factors related to these identified weaknesses include: lack of proper work planning; management and technical reviews; documentation of the reviews; and coordination between company functional disciplines.

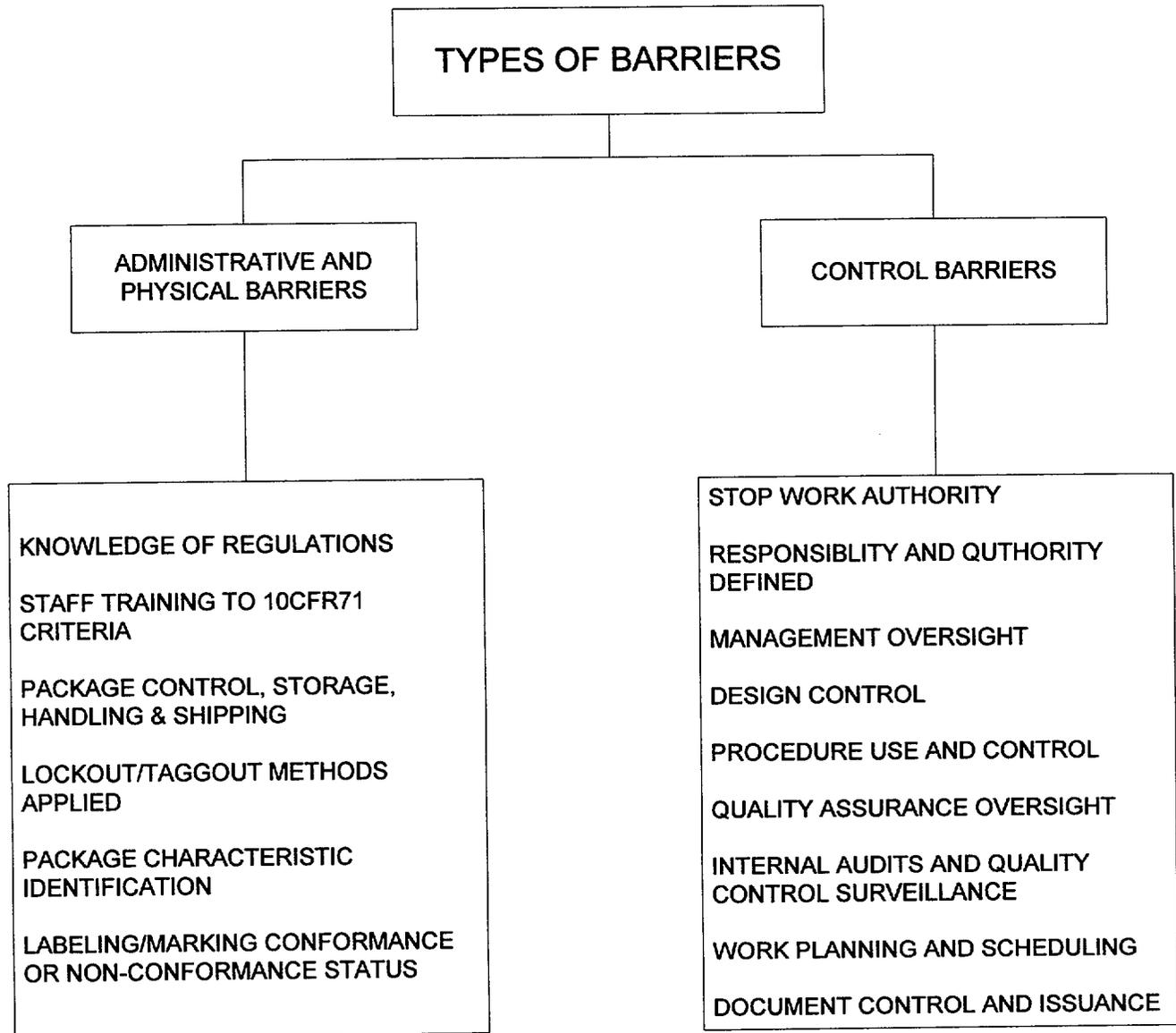
Details supporting the identification of these casual factors are listed in Figure 6-1, "Events and Casual Factor Analysis"; Figure 6-2, "Cause and Effect Diagram"; and Table 6-2, "Barrier Failure Analysis".

## **7.0 CONCLUSIONS-ROOT CAUSE**

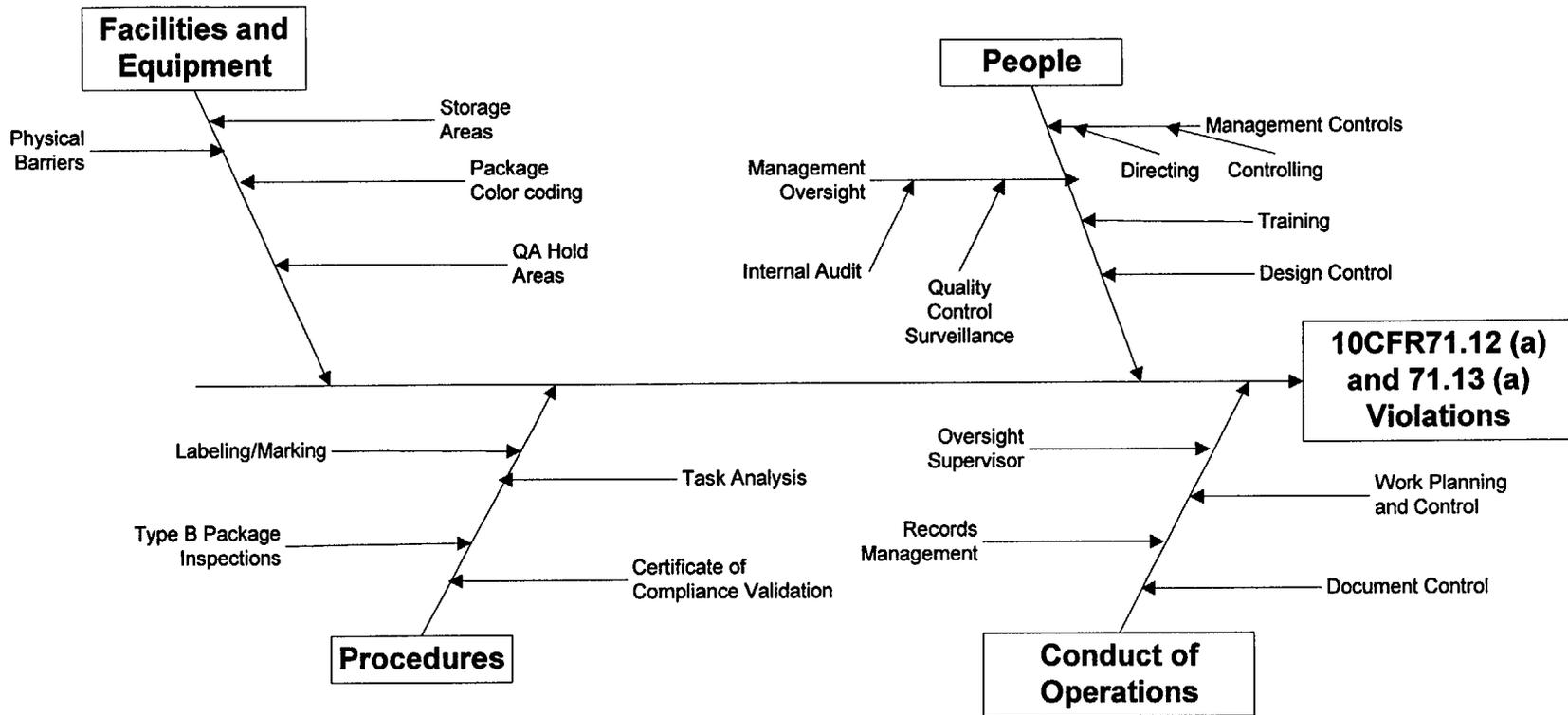
The primary root causes identified as a result of the analytical techniques applied revealed the following:

- Failure to establish and implement administrative and physical management controls and barriers.
- Failure to establish detailed operational inspection procedures for determining the conformance status of COC 6280 packages during receipt and shipping activities.
- Failure to effectively implement the JLS&A QA program relative to adequate performance of internal audits and the lack of quality surveillance over the day-to-day operational transportation activities related to 10CFR71.

**Figure 6-1: Typical Barriers Required for Meeting 10CFR71 Compliance**



**Figure 6-2: CAUSE-AND-EFFECT DIAGRAM**



**FIGURE 6-1: EVENTS AND CAUSAL FACTORS ANALYSIS**

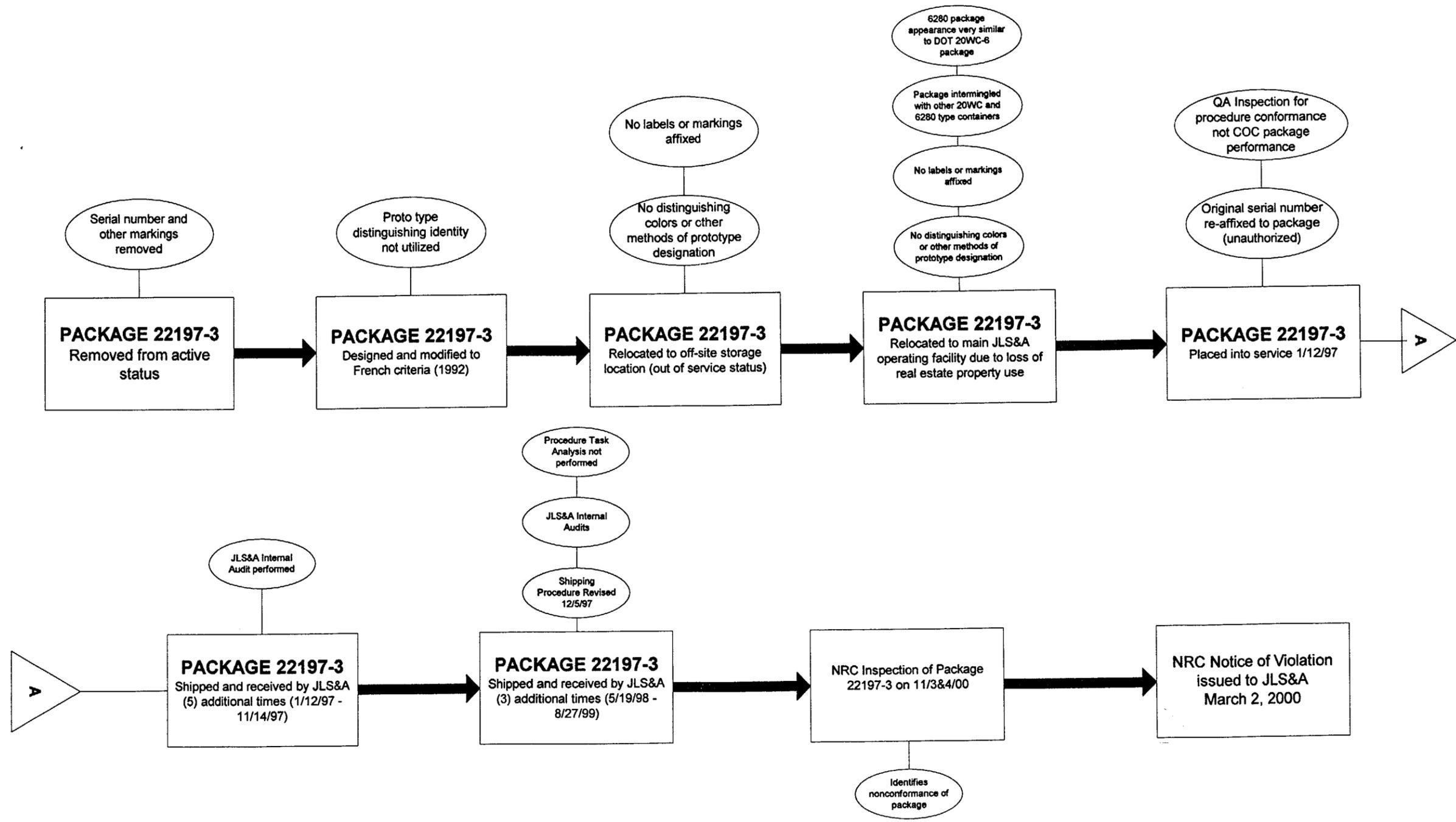


Table: 6-2 Barrier Failure Analysis

10CFR71.12 CONFORMANCE		OBJECTIVE
<b>BARRIERS</b>	<b>REGULATIONS</b>	
	<p>Barriers failed because:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/>The management team placed less emphasis on 10CFR71 regulations and applied more focus and emphasis on meeting the conditions of the State of California Radiation Material License in considering safety related significance as the safety significance factor. Management philosophy considered the encapsulated source and the Type A containers as the primary and secondary barrier, respectively, and viewed these as having more safety significance than the Type B Package.</li> <li><input type="checkbox"/>Some narrow scope of regulatory requirement knowledge existed among staff managers.</li> <li><input type="checkbox"/>A mode of complacency or lack of diligence was allowed to set into the mindset of some of the staff. This was mainly due to the lack of routine regulatory inspection and oversight beginning from initial license approval also until the 1999 NRC inspection took place.</li> <li><input type="checkbox"/>Positive external and internal audits.</li> </ul>	
	<b>PROCEDURES</b>	
<p>Barriers failed because the inspection implementing procedures established for the receipt and shipment the type B package, model 6280 series did not adequately define the package inspection and acceptance criteria. Specifically, there were no certificate of compliance (6280) specifications defined in the book of the procedure.</p>		
<b>PHYSICAL CONTROLS</b>		
<p>Barriers failed because:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/>Package 6280, 22197-3, was removed from a remote off-site storage location, to the main facility where it most likely became intermingled with similar shape and size of 20WC-6 DOT Type B Packages.</li> <li><input type="checkbox"/>Package 22197-3 was painted the similar color of the NRC COC 6280 and 20WC-6 DOT containers and therefore, had no distinguishing color coding or markings.</li> <li><input type="checkbox"/> Package 22197-3 was not "red tagged" or affixed with "non-conformance tags" to identify its unacceptable use when brought to the main plant. Accordingly, barrier controls failed.</li> <li><input type="checkbox"/>Metal serial numbers and other required container identifications items pervasively affixed to package 22197-3 before it had undergone design modifications, were not physically controlled by management. Subsequently they were applied to the package without senior management knowledge or authority.</li> </ul>		
<b>CONTROLS</b>	<b>OPERATIONS PLANNING</b>	
	<p>Barriers failed because Package 22197-3 was placed into service without senior management and quality assurance knowledge and approval.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/>Inventory and accountability "master lists" were not established and maintained for package status and use authorization.</li> </ul>	
	<b>QUALITY ASSURANCE SURVEILLANCE AND OVERSIGHT</b>	
	<p>Barriers failed because:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/>Internal audits (annual) performed from 1996-1999 did not identify any items of non-conformance.</li> <li><input type="checkbox"/>The non-conforming package 22197-3 Certificate of Compliance was maintained in the "active" central filing system for Certificate of Compliance and available for use by authorized personnel.</li> <li><input type="checkbox"/>Implementation procedures did not have provisions for quality assurance hold points or certificate of compliance record validation.</li> </ul>	
	<b>DOCUMENT CONTROL</b>	
<p>Barriers failed because:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/>The non-conforming package 22197-3 Certificate of Compliance was maintained in the "active" central filing system for Certificate of Compliance's and was available for use by authorized personnel.</li> <li><input type="checkbox"/>Refurbishment records and other associated planning and approval documents were not adequately maintained.</li> </ul>		
<b>COMMUNICATIONS AND COORDINATION</b>		
<p>Barriers failed because the conduct of operations related to designs modifications and fabrication was carried out in a somewhat informal manner. Formal planning and coordination meetings involving managers from critical operational disciplines apparently did not occur.</p>		
<b>DESIGN CONTROL</b>		
<p>Barriers failed because formal administrative controls were not established and implemented in such a manner as to plan and coordinate the design and modification of package 22197-3. This lack of control contributed to the inadvertent activation of the package for transportation activities.</p>		
10CFR71.12 NON-CONFORMING SHIPMENTS		CONSEQUENCE