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December 29, 2000

Dr. Susan F. Shankman
Deputy Director
Licensing and Inspection Directorate
Spent Fuel Project Office
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Fax: 301-415-8555 15 Pages

Please copy to Mr. Paul Narbut.

Reference: Confirmatory Action Letter (CAL), NMSS-00-001, Completion Letter.

Dear Dr. Shankman:

This letter is an additional response per Mr. Neely's and my phone conversations of December 18, 19 and 21, 2000 with Mr. Narbut and Mr. Temps of your office to confirm that all three actions covered by the above referenced CAL have been successfully completed by J.L. Shepherd and Associates.

Action 1. Type B Transportation Package Compliance Inspections and Verifications.

Completion date: 12/04/00, as confirmed in our December 6, 2000 letter to your office.

Action 2.(a) Independent Audit of JLS&A's QA Program.

Completion date: 12/05/00, as confirmed in our December 6, 2000 letter to your office.

and

Action 2.(b) Near Term Audit Deficiency Corrective Action Plan per the Notice of Violation and Completion Dates.

Completion date: 12/06/00, as amended 12/29/00.

Per our discussions with your office, the Root Cause Analysis Report has been amended to include Sections 5.0 for additional references and 8.0 Judgments of Need, Corrective Actions and Conclusions. The 8-1 Table has been expanded to include more specific corrective actions taken by JLS&A.

ADD: Susan Shankman to IRIDS

NMSS01 Public

Mr. Neely completed his audit report and root cause evaluation report on December 5, 2000, and it has been amended and expanded as of December 29, 2000. To meet our anticipated deadline of December 29, 2000 for this report, one copy will be faxed with this letter and two copies, one for the PDR and one, for your office will be forwarded next week.

In the amended Root Cause Analysis Report, Mr. Neely's near term audit and review of JLS&A's current Quality Assurance Program concludes that "the program deficiencies identified in the NRC Notice of Violations (Reference 5.1) and the independent auditor's Root Cause Analysis, the program is considered to be in compliance with the applicable criteria of 10 CFR Part 71."

JLS&A took a proactive position and performed our own corrective action analysis and implemented new procedures prior to Mr. Neely's program audit and root cause analysis. New procedures and implementing documents to correct the nonconformances were in place or developed during Mr. Neely's audit and are covered in his amended Root Cause Analysis Report and audit review. With the near term correction of these QA Program deficiencies, the types of nonconformances and violations for which the CAL was written, are now corrected with procedural and administrative controls.

Action 2.(b) Long Term Program Expectations, Audit Recommendations Action Plan.

Milestone Projection Report of reformulated Quality Assurance Program: anticipated to be finished by January 15, 2001.

Interim Plans: In our phone conversations with your office, after the amended Root Cause Analysis and Milestone Projection Reports have been received and evaluated, and Mr. Neely and I have requested a meeting with your staff to review the new Program enhancements and commitments, if necessary.

Final Completion Date: dependent upon acceptance of Quality Assurance Program Plan renewal and actual implementation of all 18 areas covered by the Milestone Projections. Anticipated milestone completion dates will be identified in the Milestone Projection Report.

The independent audit has observations and recommendations for the enhancement of the entire Quality Assurance Program, which encompasses a total revision of the QA Program Plan, QA Manual and implementing documents. These recommendations are essentially guidelines to streamline the Program so that it will be more clearly defined and more user friendly for our staff and for outside auditors. These auditor recommendations will be captured in the reformulation of the Program and ongoing tracking thereof will be accomplished by enhanced management surveillance and program audit reviews.

The QA Program Plan has been rewritten as of December 19, 2000, formulated to a graded approach specific for the types of packages manufactured and used by JLS&A and to distinguish the separately licensed JLS&A activities which are important-to-safety concerning Type B package shipments. It was submitted to the NRC on December 19, 2000, as part of the Plan renewal application.

Action 3. Submittal of New or Amended COC Package Design Requests.

JLS&A has not submitted requests to the NRC for either amendments requests for current COC approvals or for new package designs during the actions called for in Action 2. We do not anticipate submitting any such requests until after the acceptance of the Program Plan renewal application or until after proposed rule making for ST-1 has been published.

If your office would like to further discuss any of the actions contained in the CAL, the outside audit, the root cause report and/or our completion thereof, please do not hesitate to contact us.

Sincerely,

J.L. SHEPHERD AND ASSOCIATES

Mary F. Shepherd

Mary F.Shepherd
Vice President
Acting QA Program Administrator

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

December 4 , 2000

Amended: December 29, 2000

Prepared By:

Donald R. Neely Associates

INDEPENDENT AUDITOR

Amendment No. 1

TABLE OF CONTENTS

FIGURES AND TABLES

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 the root cause evaluation are 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 ident-ified 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 causal 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

5.1 NRC Inspection Report No. 71-0122/99-201, "Notice of Violation and Notice of Nonconformance", Dated March 2, 2000.

5.2 JLS&A letter to NRC, Dated November 5, 1999, titled, "1st Notification of Non-compliance, COC 6280 Package S.N. 22197-3".

5.3 JLS&A letter to NRC, Dated December 6, 1999, titled, "1st Response to Notification of Non-compliance-COC 6280 Package S.N. 22197-3".

5.4 JLS&A letter to NRC, Dated November 9, 1999, titled,"Copies of the COC 6280, S.N. 22197-3, incoming and outgoing QA forms".

5.5 NRC letter to J.L. Shepherd, Dated April 24, 2000, titled, "Confirmatory Action Letter".

5.6 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.

5.7 JLS&A letter to NRC, Dated April 21, 2000, titled, "Reply to Notice of Nonconformance".

5.8 JLS&A Quality Implementing Document QAM, QP 5.0, 6.0-6.6, "Manufacturing Control-Instructions, Procedures, & Drawings," Dated, March 7, 1991.

5.9 JLS&A Procedure, "Standard Shop Policies and Procedures", Dated, August 17, 1993.

5.10 JLS&A Quality Assurance Program Plan (QAPP) dated, October 5, 1995.

5.11 JLS&A Master List of QA/QP Documents and Implementing Documents.

5.12 JLS&A Quality Procedure, "Inspection, Operation, Handling and Maintenance Procedures for COC 6280 Overpack, S.N. 22197", Revision 1, Dated December 12, 1997.

5.13 JLS&A Quality Document, "Instructions for Using the Incoming or Outgoing Overpack QA/QC Check Lists", Dated, September 9, 2000.

5.14 JLS&A Quality Document, "Instructions for Using the Initial Compliance and compliance Inspection Overpack QA/QC Check Lists", Dated, September 15, 2000.

5.15 COC 6280 Check Lists:

- Initial Compliance
- Compliance Inspection
- Incoming Shipment
- Outgoing Shipment

5.16 Check Lists for DOT Packages (20-WC-3; 20WC-4; 20WC-5 & 20WC-6)

5.17 JLS&A Quality Document, "Instructions for Using Overpack Red Tag QA/QC Form", Dated, September 9, 2000.

5.18 QA Manager Memorandum, Dated, September 9, 2000; Re: Corrective action relative to color coding of COC 6280 Overpacks.

5.19 QA Manager Memorandum, Dated, September,9, 2000; Re: Corrective action relative to staff notification of new inspection and shipping procedure.

5.20 QA Manager Memorandum, Dated, September 9, 2000; Re: Corrective action relative to staff notification of new Red Tag procedure for overpacks.

5.21 JLS&A Quality Document, "Manufacturing Control Release for New Jobs Only", Revision 2 Dated November 30, 2000.

5.22 JLS&A Quality Document, "Instructions for Using Overpack Binder", Dated September 9, 2000.

5.23 JLS&A Quality Document, "Instructions for Using Non-compliant, Red Tagged Overpacks-Quarterly Surveillance Inspection Checklist", Dated December 26, 2000.

5.24 JLS&A Quality Document, "Instructions for Using the Non-conformance & Corrective Action Report Form", Dated December 27, 2000.

5.25 "Draft", 10 CFR Part 71 "Packaging and Transportation of Radioactive Material" consultant audit report, Dated September 11,2000.

5.26 Independent Auditor10 CFR Part 71 Subpart H Quality Assurance Program Audit Report, Dated December 4, 2000.

5.27 JLS&A Quality Assurance Program Plan (QAPP-001), Revision 0, Dated December 19, 2000.

5.28 JLS&A letter to NRC, Dated December 6, 2000, Re: Corrective Action Completion Confirmation (CAL NMSS-00-001).

5.29 QA Manager Memorandum, Dated December 29, 2000; Re: Overpack Repairs/Serial Number Tags.

6.0 ANALYSIS DETAILS

The root cause evaluation was performed incorporating the analytical techniques identified above. The MORT analysis of the overall Subpart H 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 causal 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. This prototype package did not receive distinct color designations than those already applied to those packages maintained as part of the approved package fleet. The original serial numbers mounted on the exterior of the 22197-3 package were removed. JLS&A management as a result of their internal investigation effort could not establish the responsibility for the control and storage of these serial numbers and their subsequent authorized use. Several causal 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 causal factors are listed in Figure 6-1,"Events and Causal 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.

8.0 JUDGEMENTS OF NEED AND CORRECTIVE ACTIONS

8.1 Judgements of Need

Judgements of need are managerial controls and procedural requirements (both physical and administrative) believed necessary to prevent or minimize the probability of recurrence. They are derived from the Root Cause Analysis-conclusions and are directed at guiding management in developing corrective actions.

A summary of the *Judgements of need* identified by the Independent Auditor, which are based on the determination of various causal factors and program weaknesses, are listed in Table 8-1 to this report.

8.2 Corrective Actions

As documented in NRC Inspection Report No. 71-0122/99-201 (Ref.5.1), above, JLS&A was required to implement corrective actions, as necessary, to ensure compliance with the applicable requirements of 10CFR71 as were identified in the Notice of Violations accompanying the Inspection Report.

During the time period that evolved ,following the JLS&A receipt of the NRC Notice of Violation's and initiation of the independent audit process, JLS&A took a pro-active approach to develop and implement immediate type corrective actions in response to the NRC Notice of Violation's. The corrective measures were mainly focused on the repair, receipt, and shipment activities associated with the 10CFR71 Subpart H Quality Assurance requirements and compliance with Certificates of Compliance, as well as, management surveillance's and audits.

Specific corrective actions, undertaken by JLS&A, are listed in Table 8-1 to this report. The Reference Section, above, identifies those documents that define and support the individual corrective measures that were developed and implemented by JLS&A.

During the course of the independent audit, the auditor reviewed the completion status of those JLS&A corrective actions initiated, and also evaluated the effectiveness of the corrective actions implemented. In addition, following the on-site audit efforts, the Independent Auditor performed a review of several additional "Operating Instructions' that had been developed and implemented by the JLS&A QA Manager after the on-site visits. Due to the fact, that these corrective actions were completed following the on-site review activities, the auditor could not ascertain the adequacy of their actual implementation.

Those specific "Operating Instructions" are listed above, as References 5.23 and 5.24.

A summary of the auditor's evaluation findings is described below in Sub-section 8-3 of this Section.

8.3 Conclusions

As indicated above, JLS&A had taken pro-active corrective measures to address the items of non-conformance identified in the NRC enforcement correspondence contained in References 5.1 and 5.5, above. In addition, JLS&A developed and implemented various corrective actions to their QA Program, based on results of audits performed by industry consultants, identified in References 5.25 and 5.26, respectively.

Near Term Program Expectations:

Based on a review of the corrective measures developed and implemented by JLS&A to date, the independent auditor has determined that program deficiencies identified in the NRC Notice of Violations (Reference 5.1) and the Independent Auditor's Root Cause Analysis, the QA program is considered to be in compliance with the applicable criterion of 10 CFR 71.

Long Term Program Expectations:

JLS&A management is planning and committed to addressing and incorporating the recommendations contained in the Independent Auditor's Audit Report (Reference 5.26) as part of their new philosophical approach to developing and implementing their Subpart H QA Program documents and associated operational activities (Reference 5.28).

JLS&A intentions and commitment are to completely, re-organize and re-structure their entire QA Program, in such a manner, that it should be user friendly and manageable, with enhanced management oversight applied. Summary information for this philosophical approach is described in (Reference 5.28). JLS&A plans to develop end implement a "Program Improvement Plan" for the new QA Program approach.

The re-structuring, re-organization and re-formatting of QA procedures and instructions, along with the incorporation of corrective actions identified in Table 8-1 and the Independent Audit recommendations, should provide for an adequate Subpart H QA Program commensurate with the 10 CFR Part 71 activities being carried out by JLS&A.

A critical management oversight tool that needs to be enhanced during this complete re-write is the annual audit program The corrective actions taken for the near term period, relative to surveillance and audits, should provide for sufficient management oversight and control of QA activities.

FIGURE 6-1: EVENTS AND CAUSAL FACTORS ANALYSIS

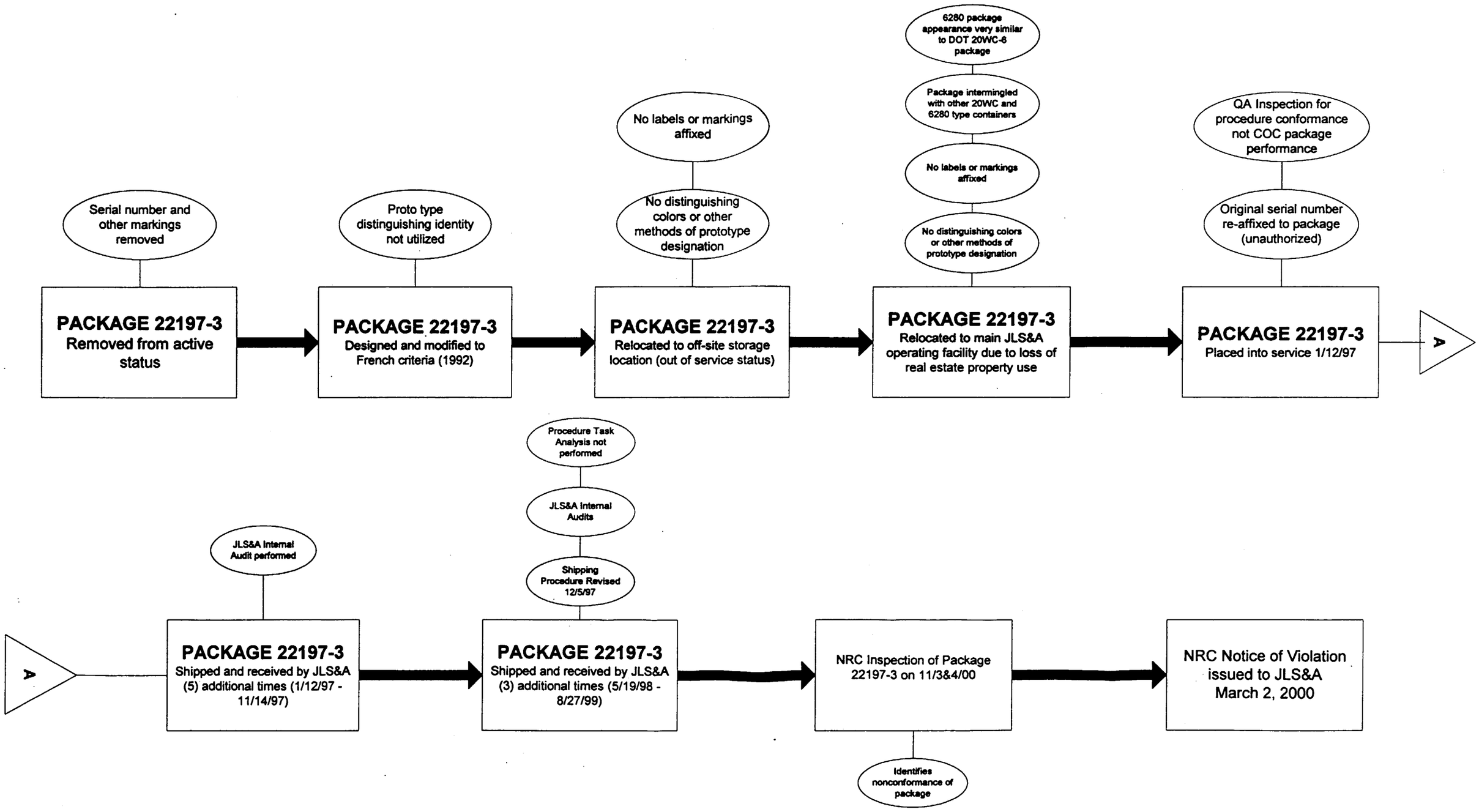

Figure 6-2: CAUSE-AND-EFFECT DIAGRAM

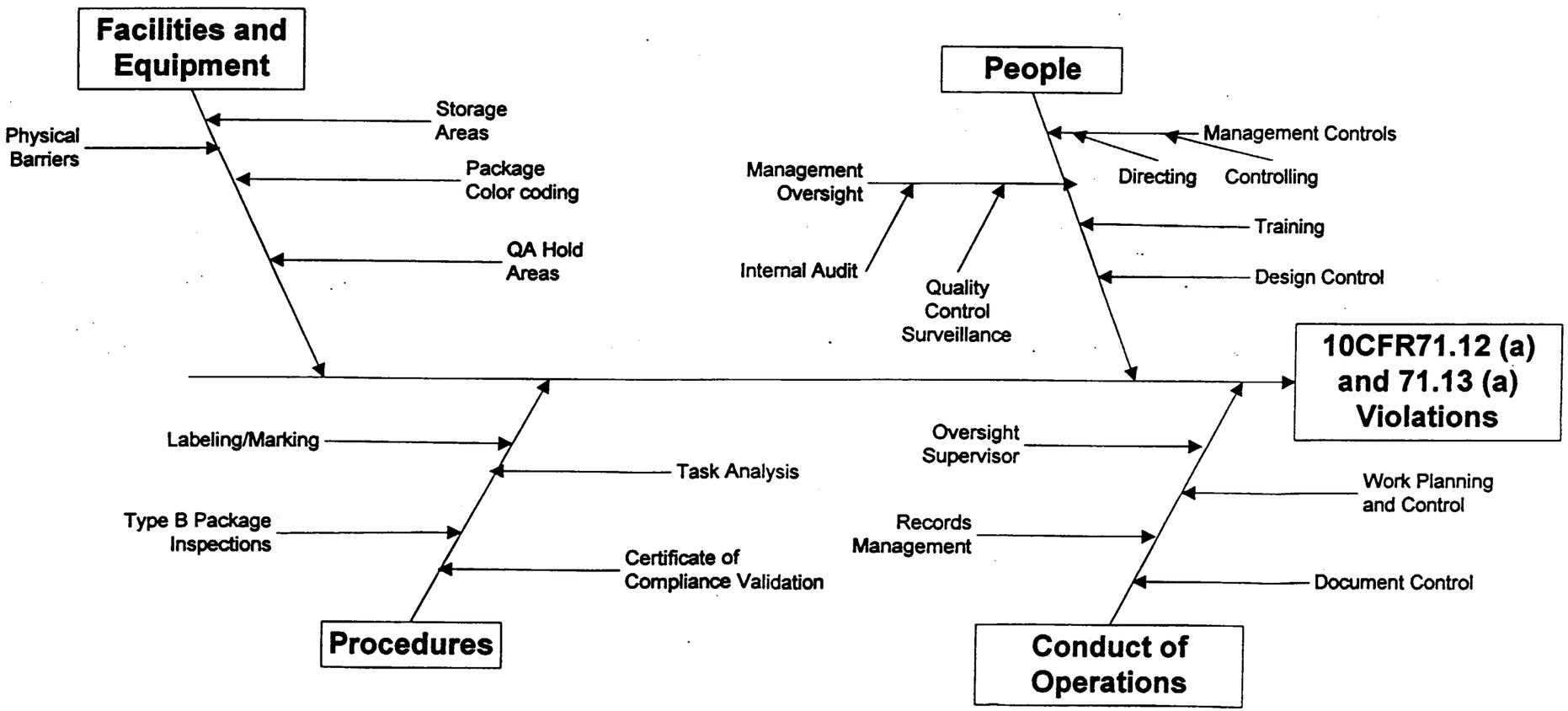

Table 6-1: Typical Barriers Required for Meeting 10CFR71 Compliance

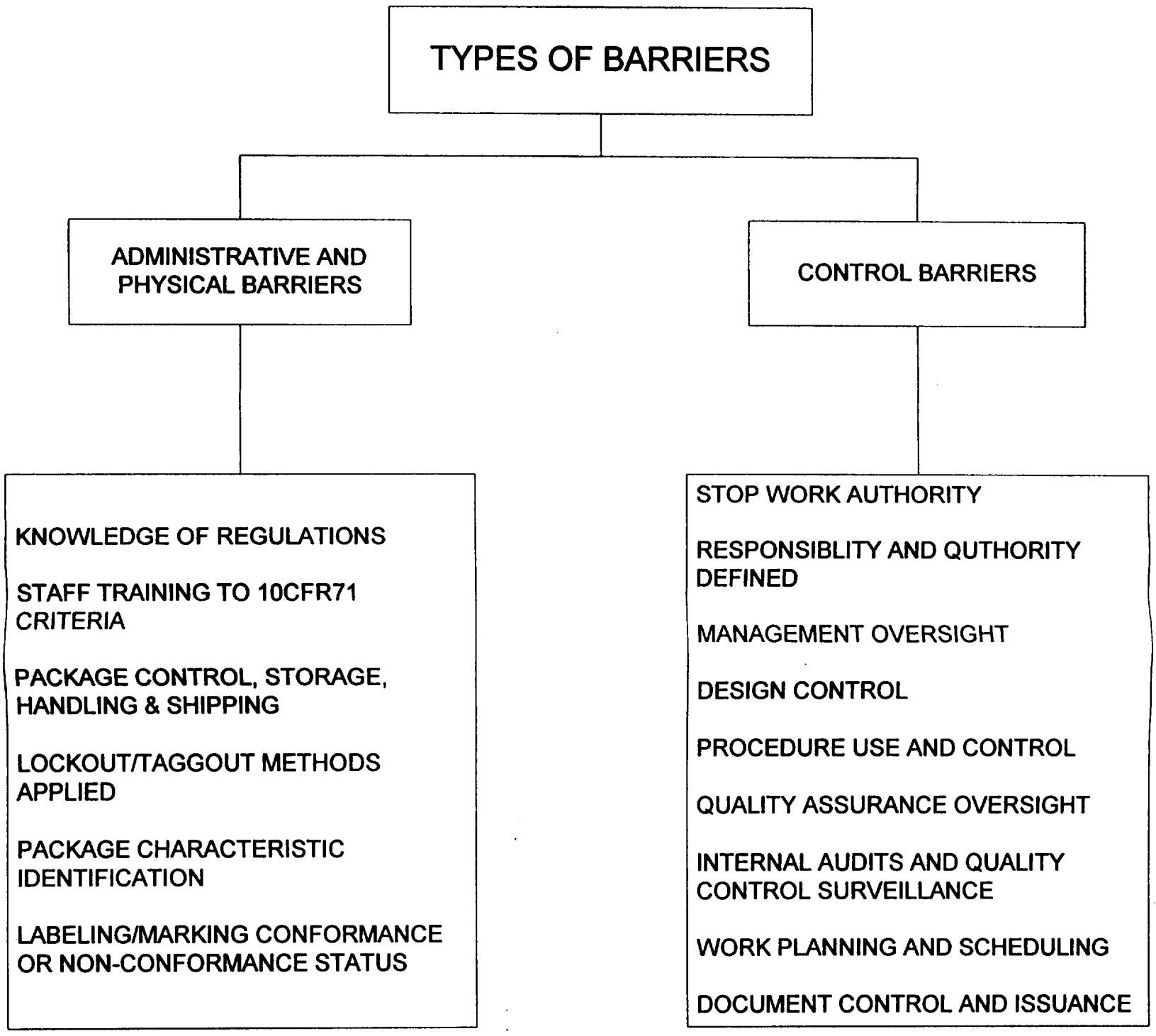

Table: 6-2 Barrier Failure Analysis

10CFR71.12 CONFORMANCE

OBJECTIVE

BARRIERS

REGULATIONS

Barriers failed because:

□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.

□Some narrow scope of regulatory requirement knowledge existed among staff managers.

□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.

□Positive external and internal audits.

PROCEDURES

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.

PHYSICAL CONTROLS

Barriers failed because:

□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.

□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.

□ 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.

□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.

CONTROLS

OPERATIONS PLANNING

Barriers failed because Package 22197-3 was placed into service without senior management and quality assurance knowledge and approval.

□Inventory and accountability "master lists" were not established and maintained for package status and use authorization.

QUALITY ASSURANCE SURVEILLANCE AND OVERSIGHT

Barriers failed because:

□Internal audits (annual) performed from 1996-1999 did not identify any items of non-conformance.

□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.

□Implementation procedures did not have provisions for quality assurance hold points or certificate of compliance record validation.

DOCUMENT CONTROL

Barriers failed because:

□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.

□Refurbishment records and other associated planning and approval documents were not adequately maintained.

COMMUNICATIONS AND COORDINATION

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.

DESIGN CONTROL

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.

10CFR71.12 NON-CONFORMING SHIPMENTS

CONSEQUENCE

Table 8-1: Independent Auditor Recommendations and JLS&A Corrective Action Details

Root Cause Analysis Conclusions	Judgements of Need	JLS&A Corrective Actions Implemented
CONCLUSION NUMBER 1: Failure to establish and implement administrative and physical management controls and barriers.	There is a need to establish distinct package designation using various methods, such as, color-coding, markings, and etc. There is a need to establish physical controls applying a system of means to isolate or quarantine non-conforming packages, such as, physical lock out/ tags out controls, package segregation and storage, and etc. There is a need to enhance the methods of affixing labels or other forms of posting that packages are identified as being in a non-conforming condition and are not to be utilized. There is a need to review and validate, prior to use of Type B packages, that specific Certificates Of Compliance (COC) are current and that packages are determined to conform to the listed use criterion. There is a need to establish quality control measures for storage and issuance of package designators removed from the Type B package exteriors (i.e. serial numbers).	JLS&A developed and implemented the following corrective measures relative to management physical an administrative controls: • **Physical controls** -- Non-conforming Type B packages identified in the NRC Inspection Report were removed from the main facility to an off-site JLS&A facility. *(Reference. 5.7)* -- An enhanced non-conformance labeling/tagging system, in the form of a "QA/QC Red Tag", was developed and initiated. *(References. 5.17; 5.20; &5.25)* -- COC 6280 Type B packages are to be distinctly color coded with a 4" blue stripe painted around the outside bottom of the lid where it meets the lid to differentiate them from similar looking Type B Overpacks. (Reference 5.18) • **Administrative controls** -- A Type B Overpack Binder has been developed and implemented to consolidate all of the pertinent package information into one place. The Overpacks are identified by serial number and include the respective conformance status for each with appropriate supporting documentation. The binder tracks both active and inactive Overpacks. *(Reference 5.22)* -- The central file containing all COC's for Type B packages operated by JLS&A were purged and only current and valid COC's are filed for staff use when preparing Type B packages for shipment or incoming receipt. *(Reference 5.22)* -- A status board has been established in the Production Manager's office that is used to identify the operating status of the NRC and Dot Type B Overpacks. (Reference 5.25) -- A revised management control document was put in place by JLS&A to address the " Manufacturing and Control" of new jobs. The document applies to new Overpacks compliance reviews. (Reference 5.21) -- Job planning has been implemented for operational type activities that includes determining the types and numbers of Overpacks to be pre-assigned for particular work packages anticipated. (Reference 5.26) -- The QA Manager established written instructions for control of serial numbers removed from Overpacks. Training was initiated in the details of this control method. (Reference 5.29)

Root Cause Analysis Conclusions	Judgements of Need	JLS&A Corrective Actions Implemented
CONCLUSION NUMBER 2: Failure to establish detailed operational inspection procedures for determining the conformance status of COC 6280 packages during receipt and shipping activities.	There is a need to enhance the Quality Assurance Manual implementing procedures that are currently used for the inspection activities relative to the receipt and shipment of Type B packages to include more detail and specificity, such as, package acceptance criterion and verification of COC conformance. There is a need to re-train all JLS&A staff members (both permanent and consultant/temporary) in the revised procedures, with increased emphasis placed on the basis for the procedural requirements and the need to be increasingly more diligent in inspection activities, to prevent recurrence of a similar non-conforming condition.	Subpart H Type transportation operations and inspection procedures were enhanced by JLS&A developing and implementing the following specific major changes: • NRC and DOT Type B Overpack checks were enhanced and made more specific by incorporating their respective Overpack design and operating specifications and requirements into the body of the compliance inspection check of lists. (References 5.13; 5.14; 5.15; 5.16; and 5.19) • The compliance inspection checklists also contain provisions to verify that the Type B package has a COC on file and that it is current. (Reference 5.15) • COC 6280 compliance check lists include specific transportation activities for: - incoming shipments, - out going shipments, - initial use compliance, and - compliance (annual and following repairs) (Reference 5.15) • Formal "Use Instructions" were developed, issued, and implemented for each activity identified above. DOT type Overpack compliance checklists were also developed and implemented. (References 5.13; 5.14; and 5.16) • The staff members assigned responsibility for implementing the 10CFR71 transportation activities were provided training/re-training in procedures, checklists, and written instructions that were either revised or developed. This was carried out utilizing formal classroom training or required reading for those staff members on off-site assignments. (References 5.18; 5.19; & 5.20) • Specific requirements have been established in the newly developed and issued "Instructions" that address the authorization for the Shipping Department to arrange for the transportation of Type B Overpacks. The controls established require that the Shipping Department have a valid Overpack Inspection Conformance Checklist issued by the JLS&A Health Physics Department indicating that the Overpack is approved for shipment. (Reference 5.13)

Root Cause Analysis Conclusions	Judgements of Need	JLS&A Corrective Actions Implemented
CONCLUSION NUMBER 3: 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.	There is a need to enhance the JLS&A operational surveillance activities relative to the independent inspection for the receipt, repair, and shipment/transportation of Type B packages. There is a need to develop and implement a methodology for the surveillance and control of non-conforming Type B packages, to include, that only valid and approved packages are accessible to staff personnel and that required markings, labels, or other appropriate packages designators are current, accurate, and properly affixed to the packages. There is a need to routinely track and status the inventory of active and inactive JLS&A Type B packages. Make the information available to staff managers and personnel responsible for implementing the transportation inspection activities.	JLS&A has undertaken several corrective measures regarding the weaknesses identified with respect to their internal audit process and are listed as follows: • The Quality Assurance Manager has implemented an independent surveillance of all Type B packages identified and posted or labeled to reflect that the status of the package is of a non-conforming state. The package surveillance's/audits ate conducted on a quarterly basis. (Reference 5.23) • Upon receiving the NRC Notice of Violations, JLS&A conducted an in-depth self-audit of the activities and circumstances surrounding the non-conforming Type B packages. (Reference 5.7) • Following their self-audit of the 10CFR71 transportation activities, JLS&A management retained the services of a consultant to review 10CFR71 program activities and to recommend corrective actions. (Reference 5.25) • Also, a condition of the NRC Confirmatory Action Letter, JLS&A, retained the services of an Independent QA Auditor (approved by the NRC) to conduct a thorough review of their 10CFR71 Subpart H QA Program. (Reference 5.5; 5.26 & 5.28) • JLS&A has established and implemented a management surveillance of on going Overpack repairs. Designated members of management perform confirmatory verifications and acceptance of the repairs. (Reference 5.23 & 5.24) • Ongoing and enhanced management audits and surveillance are underway by JLS&A. Management intends to use the results of those efforts in formulating the QA Manual and implementing documents for the new Quality Assurance Program Plan (QAPP). (Reference 5.27)