J.L. SHEPHERD AND ASSOCIATES

QUALITY ASSURANCE AUDIT

10 CFR 71 SUBPART H

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1.0 INTRODUCTION

Donald R. Neely Associates, was contracted by J.L.Shepherd & Associates (JLS&A) to perform an independent audit of their 10CFR71, Subpart H, Quality Assurance Program.

The independent audit was contractually authorized on September 5, 2000. This began with a request for quality assurance plans and procedures and Nuclear Regulatory Commission (NRC) inspection reports and associated licensee correspondence to be reviewed by the auditor in preparation of the planned audit. The audit preparation, review, and report documentation efforts covered the period September 6, through November 7, 2000.

A Management Oversight Risk Tree (MORT) approach was utilized as the methodology for this independent audit. The MORT approach endeavors to systematically identify all of the essential components of each element of the Subpart H Quality Assurance Program. The elements and components are graded as adequate, marginally adequate and in need of improvement, or inadequate and in need of major improvement. Grading is determined by comparison with applicable regulations, regulatory guides, industry standards such as American National Standards Institute (ANSI), and applicable international codes and standards. A listing of basis documents is included in Appendix 1V-2 to this report. A list of procedures and documents reviewed are included in Appendices 1V-3 and 1v-4, respectively, to this report.

All of the components of a Subpart H Quality Assurance Program have been presented in a fault tree so that the individual components can be taken together to form the whole. It is important to note that actions were being taken by the JLS&S staff to enhance the Quality Assurance Program during the course of the independent audit. The details presented herein represent the status of the program at the time of the independent audit.

The format of the report was chosen to follow the MORT. Each section of the MORT used is given its own chapter in the report. Each chapter begins with a summary of the findings for that MORT section and ends with a categorized list of recommendations. Key elements from the Mort are used as chapter headings followed by the performance objective for the key area and the findings for the area.

The sections of the MORT chart are color coded to reflect the status of that section as follows: red – inadequate and in need of major improvement; yellow - marginally adequate and in need of some improvement; green – adequate; and, blue – not reviewed.

Assessment findings were based primarily on personnel interviews, plant tours, procedure and documents reviews. A list of staff members contacted is included in Appendix 1V-1 of this report.

EXECUTIVE SUMMARY

JLS&A Company Profile

Since 1967, JLS&A have maintained a business of developing and providing gamma, beta, and neutron irradiation and calibration devices to the nuclear industry. Manufactured systems include uses for bio-tech, bio-med, radiation hardness testing research, blood bank irradiators, and radiation detection instrument calibrations.

JLS&A is a small family owned business with twenty-eight (28) employees, of which five (5) members of the family, serve as corporate officers and managers of the operating organization.

The accumulated experience of JLS&A staff members includes over 150 man-years of direct experience related to the design and manufacturing of radiation research, clinical and test facilities, including decommissioning of the equipment.

The professional staff is comprised exclusively of Certified Health Physicists, Radiation Safety Officers, and mechanical engineers, manufacturing specialists and radiological trained personnel. The JLS&A engineering staff possesses over 90 years of combined experience in the design of hot cells, radiation research and test facilities. JLS&A have experienced little turnover of key personnel during the last twenty years.

JLS&A Regulatory History

In 1991 and 1996, respectively, the Nuclear Regulatory Commission (NRC), approved and renewed JLS&A applications for a 10CFR71 Subpart H Quality Assurance Program. The current NRC approved Quality Assurance program approval expires January 31, 2001. A corporate quality assurance program has been in place and implemented since 1980. This quality assurance program is incorporated by reference into the State of California Radioactive Materials License issued to JLS&A for activities associated with the encapsulation, handling and manufacturing of radioactive sources and Type A packages/shielded devices.

During the last twenty (20) years, JLS&A have been operating under 10 CFR Part 71 regulations, involving the inspection, maintenance, and repair of Type B packages (over packs).

Since receiving their NRC approval to operate under the Subpart H Quality Assurance Program, limited regulatory inspection and oversight has been undertaken by federal or state regulatory agencies, regarding the evaluation of the implementation and adequacy of the Subpart H program.

In July of 1999, JLS&A issued formal notification to the NRC, that they had been made aware of a nonconforming situation regarding the use of one of their Type B packages.

Following this required notification, during the period November 3-4, the NRC staff implemented a special onsite inspection, to review the facts and details related to the reported nonconformance. The results of this inspection identified an additional nonconformance and several violations related to the nonconforming packages.

Subsequent to this, on April 18, 2000, JLS&A was requested to participate in an NRC enforcement conference with the Spent Fuel Project Office, to discuss the concerns identified by the NRC.

As a follow up to this NRC meeting, on April 18, 2000, the NRC formally issued to JLS&A a Confirmatory Action Letter (CAL), requiring that certain package verifications be under taken before further use and that an independent auditor be retained to perform an audit of the 10CFR Part 71 Subpart H Quality Assurance Program.

Independent Audit Regulatory and Licensing Bases

NRC Regulations:

The independent auditor used 10CFR71.37 (a), "Packaging and Transportation of Radioactive Material', and 10CFR71.101, (a), (b), (c), (d), (e), and (f) of Subpart H as the primary regulatory bases for the conduct of the independent audit of the JLS&A quality assurance program. Applicable requirements contained in 10CFR71 were utilized, as necessary, to evaluate the overall effectiveness of the JLS&A quality assurance program and implementation to ensure that activities were being performed in accordance with the 10CFR71 requirements.

Primary regulatory requirement bases are defined as follows:

- 10CFR71.37

  (a) " The applicant shall describe the quality assurance program (see Subpart of this part) for the design, fabrication, testing, maintenance, repair, modification, and use of the proposed package".

  (b) "The applicant shall identify any specific provisions of the quality assurance program that are applicable to the particular package design under consideration, including a description of the leak testing procedures.

  10CFR71 101

  (a) *Purpose*. "This subpart describes quality requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this part, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate

confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality actions related to control of the physical characteristics and quality of the material or component to predetermined requirements".

(b) *Establishment of program.* "Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensees' activities including procurement of packaging. The licensee shall apply each of the applicable criteria in a graded approach, i.e., to an extent that is consistent with its importance to safety".

(c) *Approval of program.* "Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain Commission approval of its quality assurance program. Each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied,..."

NRC Regulatory Guidance:

Regulatory Guide 7.10, "Establishing Quality Assurance Programs For Packaging Used In The Transport of Radioactive Materials", Revision 1, dated June 1986, was used as a second tier bases for evaluating the development, establishment and maintenance of the JLS&A quality assurance program.

Several guidance characteristics established in the Regulatory Guide are important to be highlighted as background information in order to understand the basis for conclusions and findings identified by the independent auditor. Important information and provisions included in the regulatory guide are as follows:

- Regulatory Guide Section A " Introduction"

  Paragraph one (1) reiterates the requirements of 71.31 (a) that applicants for package design approval are o identify the NRC-approved quality assurance (QA) program to be applied to the design, fabrication, assembly, testing, maintenance, repair, modification, and use of the proposed packaging.

  Paragraph two (2) reiterates the requirements of 71.101 that licensees have a quality assurance program that has been submitted to and approved by NRC as satisfying the provisions of Subpart H of Part 71. Subpart H requires, in part, that licensees' quality assurance programs satisfy each of the applicable criteria specified in Section 71.101 to an extent consistent with their importance to safety.

  Paragraph three (3) indicates that the regulatory guide provides persons subject to the QA requirements of Part 71 with information on the essential elements

needed to develop, establish, and maintain a quality assurance program acceptable to the NRC for packages to transport radioactive materials.

- Regulatory Guide Section B "Discussion"

  Paragraph one (1) discusses the fact that the quality assurance program is intended to provide control over all activities important o safety that are applicable to the design, fabrication, assembly, testing, maintenance, repair, modification, and use of packaging for transporting specified types of radioactive materials. In addition, it explains that the control should be applied to the various activities in a graded approach, i.e., the QA effort expended on an activity should be consistent with its importance to safety. Finally, it references Appendix A, "A Graded Approach to Developing Quality Assurance Programs for Packaging of Radioactive Material", to this guide, as method for developing a QA program with a graded approach.

  Paragraph two (2) discusses the fact that activities covered by the QA program may be divided into two major groups: those activities culminating in completed packaging and those activities associated with procurement and use of the completed packaging. Annex 1, to this guide, provides guidance on the essential elements needed to develop, establish, and maintain a quality assurance program for the design, fabrication, assembly, and testing of packaging. Annex 2, of the guide, provides similar guidance for activities regarding procurement, use, maintenance, and repair of all types of packages.

- Regulatory Guide Section C "Regulatory Position"

  Paragraph one (1), states, "The essential elements of a quality assurance program acceptable to the NRC staff for complying with the quality assurance requirements of Subpart H of 10 CFR Part 71 are contained in Annex 1 of this guide for activities related to design, fabrication, assembly, and testing of packages and in Annex 2 for activities related to procurement, use, maintenance, and repair of completed packages"

  Paragraph three (3), states, "The recommendations of this guide apply to the general QA criteria contained in Subpart H of 10 CFR Part 71. Subpart G, "Operating Controls and Procedures" of 10 CFR Part 71 and NRC certificates of compliance applicable to particular packages contain specific criteria and requirements that should be incorporated into the QA program".

  Paragraph five (5), states, "Establishment of a QA program implies that all activities important to safety applicable to the design, fabrication, inspection, testing, purchase, use, maintenance, repair, and modification of packages are implemented with written procedures approved by appropriate levels of management and are contained in quality assurance/quality control (QC) manuals".

- Regulatory Guide Section D "Implementation"

  This section provides information to applicants and licensees regarding the NRC staff's plan for using the regulatory guide. Specifically, the guide is to be used to evaluate submittals by applicants for establishing quality assurance programs for packages that transport radioactive materials and to assess licensees' performance with respect to developing, establishing, and maintaining such quality assurance programs.

- Regulatory Guide Appendix A

  Paragraph one (1) of this appendix documents the fact that the design effort and the requirements for a quality assurance program are interrelated and should be developed simultaneously. Also, addressing them as independent functions may result in an overly stringent QA program.

  Furthermore, it is explained in this paragraph that in order to develop a quality assurance program in which the application of QA requirements is commensurate with their safety significance, it essential that engineering personnel perform a systematic analysis of each component, structure, and system of packages to assess the consequence to the public health and safety and environment resulting from the malfunction or failure of such items.

  Paragraph two (2) recommends that each component, structure, or system be logically sequenced to identify the requirements to be applied by 1) classifying the item safety significance as either "Q" or "non-Q", (2)-grouping items classified as important to safety into quality categories, and (3) specifying a level of quality assurance effort applicable to each category.

  Section three (3) of the appendix provides guidance for assigning a level of quality assurance effort to be applied based on the classification and quality categories determined for the relative safety significance of each Q item.

Licensing Documents:

The JLS&A Subpart H Quality Assurance Program Plan (QAPP) approved and renewed by the NRC in 1991 and1996, respectively, was the next tier of criterion and program commitments to be use as the audit bases. The QAPP was developed and established by JLS&A, addressing all of the eighteen (18) criterion required by 10 CFR Part 71 Subpart H, supported by the guidance set forth in Annexes 1 and 2 of Regulatory Guide 7.10.

Program Implementation Documents:

The last tier of documents or plans utilized for establishing the bases for the quality assurance program were organized in the form of a Quality Assurance Manual (QAM).

The QAM was considered by the auditor to be the quality program administration and implementation methodology vehicle. The QAM was developed and established by JLS&A to provide for a more detailed description of the essential program elements and sub-elements applicable to the eighteen criterions committed to in the QAPP. Various implementing procedures, with more specific actions and information, were attached to the individuals sections of the QAM, as deemed applicable by JLS&A management.

Overview of Independent Audit Results

Audit Methodology:

The independent audit utilized a Management Oversight Risk Tree (MORT) approach to systematically identify and evaluate all of the essential elements of an adequate 10CFR71 Subpart H Quality Assurance Program. Evaluations were conducted of the JLS&A Quality Assurance Program by comparing existing program elements with applicable regulations, regulatory guides, standards and good industry practice. Grading of individual program elements and components was divided into three categories; as adequate, marginally adequate and in need of some improvement, or inadequate and in need of major improvement.

The format of the audit report follows the MORT and is sectioned accordingly. Each chapter summarizes the finding for a MORT section and concludes with a categorized list of recommendations.

Audit Technicalities:

At the commencement of the independent audit, the auditor became aware that JLS&A were operating under two (2) distinctly different required applications of quality assurance programs. These required quality assurance programs are approved and regulated by the United States Nuclear Regulatory Commission (USNRC) and the State of California (Agreement State status), independently. The USNRC regulates the quality assurance program from a 10 CFR Part 71 Subpart H, perspective, while the State of California regulates the quality assurance program from a radioactive material license, perspective.

The auditor determined, based upon the audit results, that JLS&A had extreme difficulty in the consolidation of the state and federal required quality assurance programs into a cohesive plan or manual.

An additional technicality that appeared to impact JLS&A ability to establishing an effective quality assurance program deals with the classification and categorization of the components, structures, and materials relative to their safety significance.

JLS&A maintain a corporate technical philosophy that the metal capsule enclosing the radioactive source serves as a primary safety barrier and that the shielded device or containment housing the encapsulated radioactive source satisfies the condition required

for a secondary containment application. Finally, JLS&A must not exceed certain levels of radioactive heat decay loading during the transportation of Type B packages. Department of Transportation (DOT) Type B packages must not exceed100 watts and NRC Type B (COC) packages have a maximum limit of 500 watts of radioactive decay heat.

Lastly, the Type B packages (with approved NRC Certificates Of Compliance) being maintained as part of the JLS&A transport package inventory, were incorporated into the 10 CFR Part 71.13 requirements "Previously approved package" under a grandfather clause enacted in 1985, with major restrictions applied to their modifications and continued construction. These package restrictions have limited JLS&A activities to merely inspection, repair and transporting thereby complicating the establishment and execution of the entire scope of the current quality assurance program.

Summary of Audit Findings;

QAPP Evaluation

The JLS&A QAPP, as currently written, appears to meet the basic requirements for the development and establishment of quality assurance program criterion, administration, and control. The QAPP addresses the entire quality criterion required by 10 CFR Part 71 Subpart H, specifications 71.101 through 7.137. Furthermore, the QAPP includes the combined guidance documented in Annexes 1 and 2 of Regulatory Guide 7.10.

Based upon a detailed review of the types of activities that are currently being conducted by JLS&A with respect to Type B packages, the auditor believes that JLS&A have over committed their corporation to quality assurance requirements. The current mode of Type B package application by JLS&A is narrowly confined to the operation and use, repair and maintenance activities related to metal and wooden Type B over packs. JLS&A are not implementing Type B package activities such as design, fabrication, assembly, and testing at this time.

A further review of the QAPP revealed that the document was not formulated utilizing a graded approach methodology as allowed by the regulations, Accordingly, the auditor had to consider that JLS&A had committed to an all encompassing Subpart H quality assurance program, which is applicable to fuel transport packaging and dry storage containers and other types of large quantity type packages, as well as, Type B packages owned and used by JLS&A.

Based on discussions with the JLS&A Quality Assurance Manager, it was learned that, JLS&A intentions at the time of submittal to the NRC, were to implement the Subpart H quality assurance program in a graded approach operational philosophy. The auditor noted that the QAPP was not documented with that methodology or philosophy applied.

Quality Assurance Manual (QAM) Evaluation

The QAM is currently organized into eighteen distinct quality criterion, with the QAPP being incorporated, as one the essential criterions. Most of the eighteen criterions provide

for a further description regarding the implementation and maintenance of the quality assurance program. Also, most of the eighteen criterions had implementing procedures attached that contained major variations with regard to adequacy of task content and specificity, for conduct and over-sight of the day-to-day program implementation.

This lack of program formality and specificity appears to have existed from the time of receipt of the NRC license approval for JLS&A to conduct quality related activities under 10CFR71.12. Over the years JLS&A have developed and implemented many Quality Procedures (QP's) as a means to implement the essential quality related program elements as they understood the regulatory requirements. Unfortunately, the reliance on the exceptional experience and knowledge maintained by the JLS&A staff biased the need to appropriately and adequately formalize the day-to-day inter workings of the program elements.

Also, the continued non-structured approach utilized for the incorporation of additional procedures and instructions into the QAM over the last many years has resulted in a very confusing and convoluted quality assurance program.

The auditor determined, that a major casual factor contributing to the less-than adequate formulation of the QAM and associated procedures/instructions, was directly impacted by JLS&A having to strive to satisfy duel applications of quality assurance programs. The initial quality assurance program established by JLS&A in 1980 was required by both the NRC 10 CFR Part 71 license and the State of California Radioactive Material License, The QAM was developed to serve both required quality assurance programs and was modified, as necessary, to include changes either self-imposed or regulator imposed.

The audit revealed that with regard to the Type B package design control activities, the quality assurance program is being implemented on an as needed basis Audit findings in this area indicated that application of formality for the design control activities were exceptionally lacking, with regard to implementation detail. This does not preclude the fact, that on an informal basis, design drawings and reviews are being implemented adequately for other core products designed and manufactured by JLS&A.

The Measuring and Test Equipment (MT&E quality related program element was found to be in major need of improvement. Several items of noncompliance were identified in this area related to the use and calibrations of MT&E. Required calibration frequencies were not met, as well as, some MT&E being utilized by inspectors was not authorized by JLS&A management.

Finally, the audit revealed that the implementation of the of the Quality Assurance Audit Program has not been effective in the application relative to conducting internal type audits and oversight. The main causal factor for this identified weakness is considered to be in the area of lack of auditor experience and personnel having a less than adequate understanding and basis for carrying audit operations, This conclusion is supported by the fact, that over a three (3) year period, not a single program deficiency was identified during the audits conducted.

Review of JLS&A Corrective Actions Developed and Implemented.

In response to the items of non-conformance and violations issued to JLS&A by the NRC in April 2000, JLS&A developed and implemented several corrective actions relative to their quality assurance program.

Corrective actions developed by JLS&A were mainly specific to package use activities. These actions primarily addressed the development of explicit conformance checklists for various operational aspects of Type B package inspection and transportation activities. Also, JLS&A enhanced their management controls with the addition of a "Manufacturing Control Release" for requiring regulatory compliance reviews on new packages/jobs.

Procedures and written instruction were either revised or initiated for implementation of the corrective actions. The independent auditor reviewed these documents during the course of the audit and found the corrective actions to be adequate in addressing the NRC items of non-compliance.

In addition, JLS&A management required that staff members be trained on the applicable revisions and changes to the implementing procedures. This was done by conducting formal classroom training sessions for those employees stationed at JLS&A facilities in San Fernando, California and requiring staff members assigned to off-site locations carry out required reading of the revisions and changes.

Audit Conclusions:

The independent auditor identified that a significant dilemma exists for the NRC and JLS&A regarding how the JLS&A program audit results should be evaluated as it pertains to corrective actions that should be taken by JLS&A in response to the independent auditors findings.

As described and discussed above, the independent auditor determined, that as developed and documented in the current QAPP, JLS&A has committed the corporation to a quality assurance that is broad in nature with basically no limitations as to its applicability to the 10CFR Part71 activities being carried out by JLS&A. Accordingly, the integrated MORT audit findings depicted in Figure ES-1 to this report, are based on the QAPP as currently documented.

Based on the criterion and commitments contained in the QAPP the independent auditor found the Subpart H quality assurance program to be marginally adequate. The primary casual factors supporting this judgement are related to the lack of adequate program implementing details, combined with, a lack of adequate procedure formatting and task sequencing.

If the independent auditor applied the MORT process assuming that JLS&A had in fact, documented the QAPP applying the allowed graded approach for classifying and categorizing the components and materials importance to safety, the integrated MORT audit

results would be less significant as depicted in Figure ES-2 to this section of the re-port. This audit alternative would reflect that the Subpart H quality assurance program would most likely be adequate relative to the limited effort required to be applied as recommended in Category C of Regulatory Guide 7.10, Appendix A.

Audit finding recommendations:

Major recommendations are as follows:

1) The QAPP should be re-established using a graded approach methodology for the determining the safety significance of components, parts, and materials relative to quality assurance application as provided for in the NRC Regulatory Guide 7.10, Appendix A.

2) The QAPP, administrative, and implementing documents should be developed using a systematic approach with regard to procedure hierarchy, including procedure format and consistency, task oriented, task analysis, and field testing prior to issuance.

Figure ES-1

QUALITY ASSURANCE PROGRAM MANAGEMENT OVERSIGHT RISK TREE

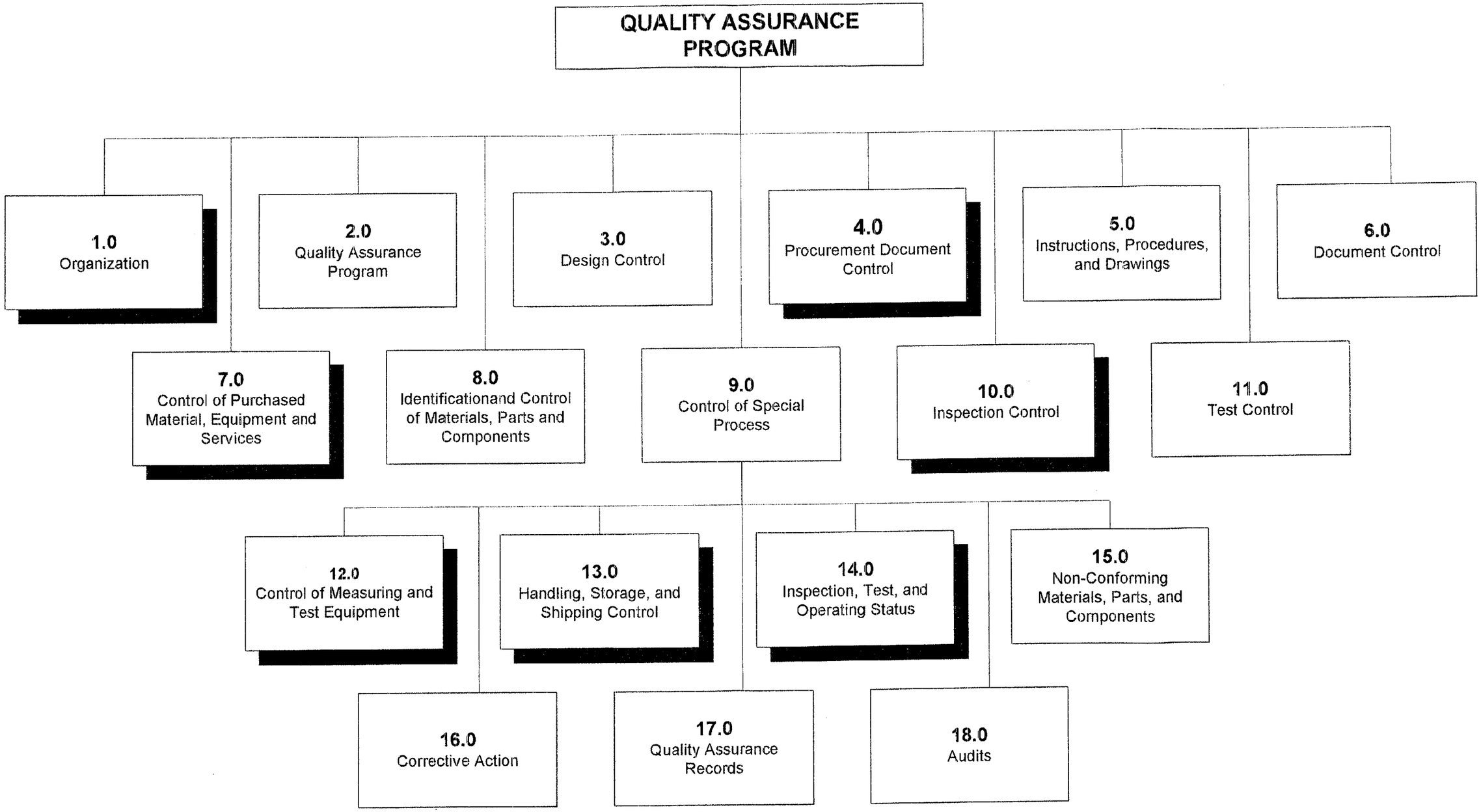
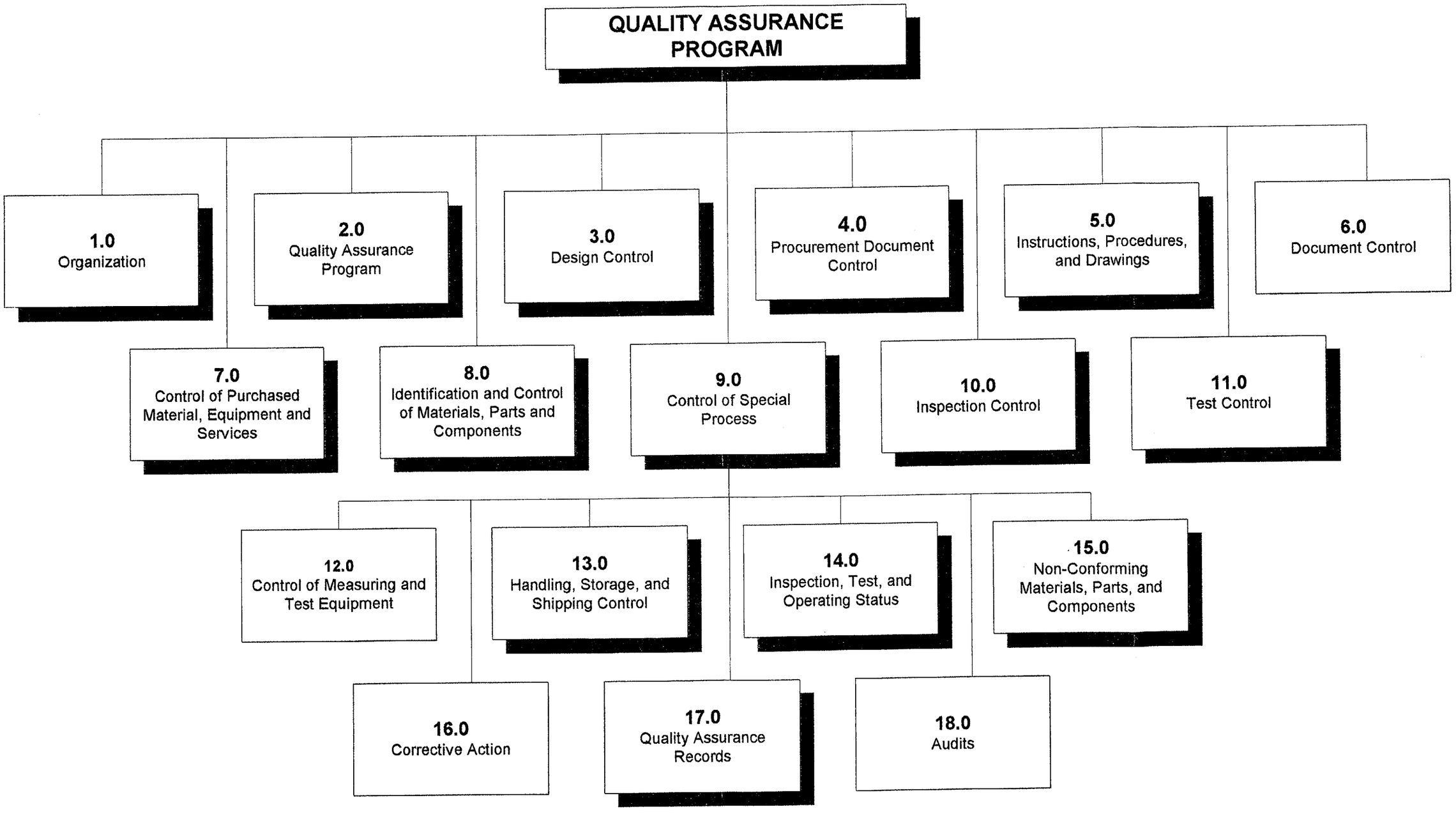


Figure ES-2

QUALITY ASSURANCE PROGRAM MANAGEMENT OVERSIGHT RISK TREE



1.0 QUALITY ASSURANCE ORGANIZATION

1.1 SUMMARY

A formal organization chart depicting the functional protocol for the management and implementation of the Quality Assurance Program has been established and is being maintained as part of the Quality Assurance Program Plan (QAPP). An independent reporting chain for the individual assigned responsibility for the management and over sight of the quality assurance program has been clearly established and implemented. Resource availability to effectively implement the QAPP is currently somewhat strained due to a staff vacancy that has not been filled. This area of the program was found to be adequate.

1.2 ASSIGNMENT OF GROUP AND INDIVIDUAL RESPONSIBILITIES AND AUTHORITIES

1.2.1 Program Objective

Responsibilities and authorities for the Quality Assurance Group and individuals are adequate for the functions normally placed with such a group and individuals, the responsibilities and interfaces with other company organizations are established and sufficient to carry out their functions, and responsibilities and authorities are understood.

1.2.2 Findings

The audit results for this area reveal and confirm that the Vice President, Special Projects and Licensing (Acting Quality Assurance Manager), has adequate authority for the overall development, implementation, maintenance, and oversight of the 10 CFR 71 quality assurance program. Functional organizational responsibilities and authorities are clearly defined in QAPP implementing document QP1.1. These results were based on several factors, a review of the QAPP and associated implementing procedures, discussions with the President of JLS&A, observations of work activities, and observation of the Vice President's interfacing with department managers and regulators.

All of the line managers have been formally assigned responsibility for implementing their respective functional areas of the QAPP. Specific procedures for implementing the interfaces between organizations are not formally defined. However, in lieu of established formality, the managers appear to be interfacing effectively in carrying out their combined quality related responsibilities. The apparent success of this informal interface is mainly due to the fact that the JLS&A organization is small and consists

of a staff only twenty-eight people with insignificant turn over of personnel over the last many years.

Based on interviews with personnel and observations of work in progress it appears that the most staff members clearly understand their assigned functional responsibilities as well as well as an adequate understanding of the responsibilities of the departments that they interface with on a daily basis.

1.3 ORGANIZATION CHARTS

1.3.1 Program Objective

An organization chart should exist that depict the company Quality Assurance Program and clearly shows an independent reporting chain of responsibility and authority.

1.3.2 Findings

Management at JLS&A have established and are maintaining a current organizational chart which depicts an independent reporting protocol for the Vice President, Special Projects, who has been assigned overall responsibility for the maintenance and oversight of the JLS&A Quality Assurance Program. The current organization chart reflects that the Vice-President, Special Projects and Licensing is serving in this position in an acting capacity. However, this "acting" designation appears to be having no negative impact regarding the full execution of the overall functional responsibilities for the purpose of compliance with the quality assurance requirements of 10CFR71.

Functional responsibilities for the day-to-day implementation of the 10CFR71 Quality Assurance Program have been assigned to senior staff members for execution and are clearly depicted on the organizational chart. The organizational chart as currently designed, portrays an integrated emphasis on quality assurance, by assignment of equal responsibility and accountability to all line management for full execution of the required quality assurance program activities. .

1.4 STAFFING FOR PROGRAM RESPONSIBILITIES

1.4.1 Program Objective

There should be adequate staffing of personnel to provide for day-to-day independent verification and oversight of all quality related activities required by 10CFR71 to ensure compliance with the conditions of the JLS&A NRC approved Quality Assurance Program.

1.4.2 Findings

The function of providing independent oversight for the day-to-day aspects of the quality related activities applicable to the 10 CFR Part 71 packaging and transportation program are being carried out primarily by the Vice President, Special Projects and Licensing. This effort is mainly applied to the inspection and verification of compliance for receipt and shipment of Type B packages.

At the present time, there are no new Type B packaging design or fabrication activities taking place that require extensive independent quality assurance oversight. The current level of effort being applied to the quality assurance program by the Vice President, Special Projects focus on developing and implementing corrective actions in response to past NRC findings, licensing (re-writing the QAPP for renewal), supporting the independent audit effort, and preparation applications for re-certification of Type B packages. The Vice President, Special Projects, also spends time dealing with licensing matters related to the California State licensed Radiation Safety Program.

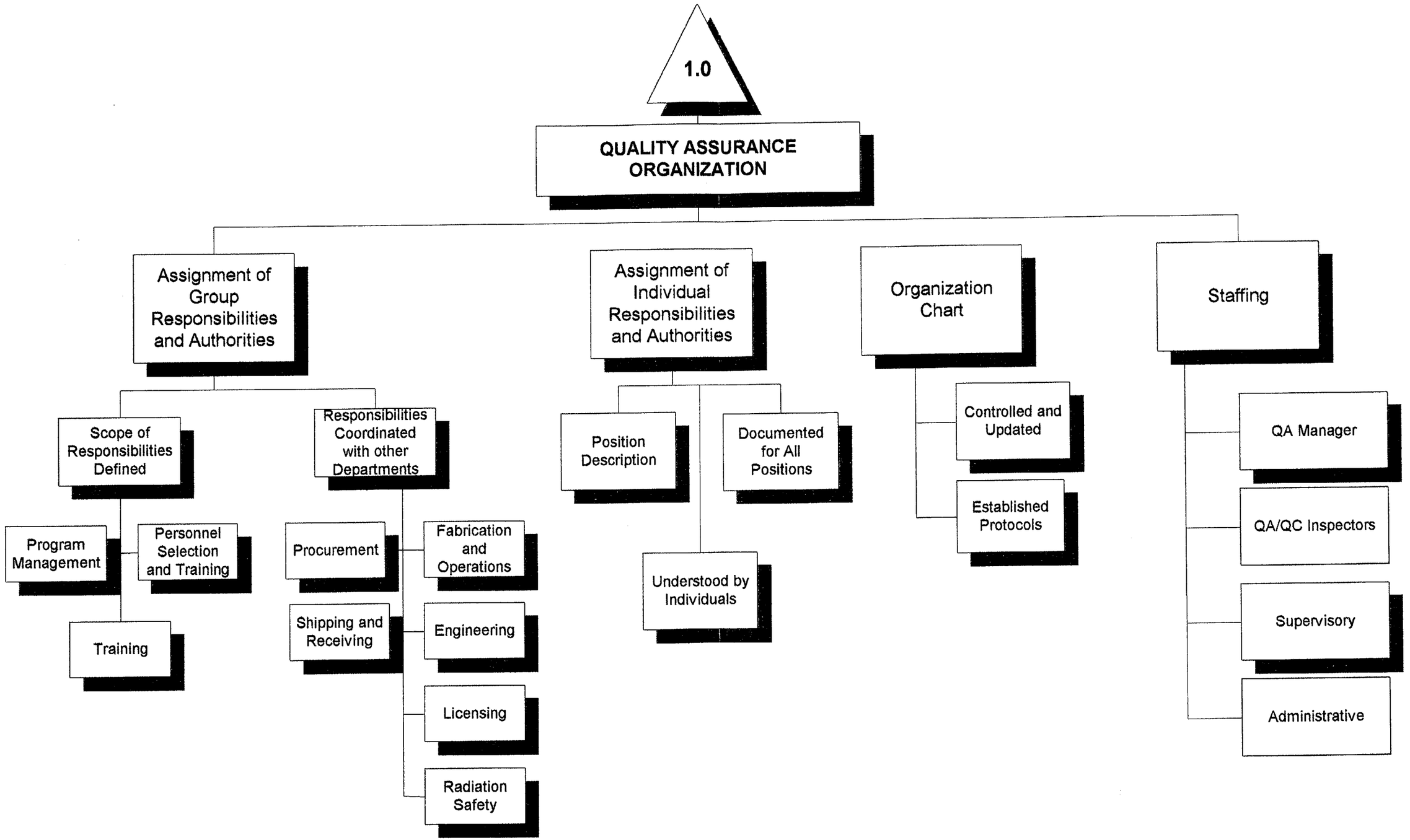
A staff position for providing independent inspection of fabricated parts and materials currently exists within the corporate structure. However, this individual has not received the necessary training and certification by JLS&A and is administratively restricted from being involved in the 10 CFR Part 71quality assurance inspection and verification activities.

During past years, the Vice President, Special Projects was able to receive support from the company Assistant Radiation Safety Officer in carrying out some of the independent inspection and verification responsibilities applicable to the quality assurance program. Unfortunately, that position has been vacated and that support is not available to the Vice President at this time. Efforts are on-going by the company to recruit a replacement candidate to function as the company Assistant Radiation Safety Officer and provide support as necessary to the Vice President or performing inspections, verifications, and independent oversight of 10CFR71 quality Assurance Program.

Based upon the minimal level of activity currently on-going with regard to the quality assurance related aspects for design, fabrication, inspection, package maintenance and repair, and package transportation activities, the staffing level is adequate but strained.

1.5 RECOMMENDATIONS

1.5.1 Management should continue the recruiting efforts for the position vacancy that can support quality oversight activities. This should be planned for, following the re-structuring of the QAPP and associated implementing procedures.


1.0
QUALITY ASSURANCE ORGANIZATION
Assignment of Group Responsibilities and Authorities
Scope of Responsibilities Defined
Program Management
Personnel Selection and Training
Training
Responsibilities Coordinated with other Departments
Procurement
Fabrication and Operations
Shipping and Receiving
Engineering
Licensing
Radiation Safety
Assignment of Individual Responsibilities and Authorities
Position Description
Documented for All Positions
Understood by Individuals
Organization Chart
Controlled and Updated
Established Protocols
Staffing
QA Manager
QA/QC Inspectors
Supervisory
Administrative

2.0 QUALITY ASSURANCE PROGRAM

2.1 SUMMARY

The review of this area revealed that a basis for the Quality Assurance Program has been established by the establishment of the NRC approved QAPP and the integration of the applicable eighteen-(18) quality related criterion into a single QAM. The major weakness identified in this program area relates to the lack of detail and specificity required to be contained in implementing procedures. This area was found to be marginally adequate and in need of some improvement.

2.2 PROGRAM DEVELOPMENT

2.2.1 Program Objective

A quality assurance program should be established implemented and maintained that is commensurate with the requirements of 10CFR71, Subpart H, and approved by the Nuclear Regulatory Commission.

2.2.2 Findings

JLS&A have in place, a Quality Assurance Program Plan (PLAN), that is approved by the Nuclear Regulatory Commission and valid until January 31, 2001. JLS&A plan new submittals of the QAPP prior to the expiration date.

The JLS&A QAPP consists of many elements which collectively provide details and commitments for conducting activities affecting quality under suitably controlled condition; implementation of environmental and special controls; use and maintenance of appropriate equipment; conduct of inspections and tests; and the qualification of personnel performing activities affecting quality. Several discrete areas of quality activity are also covered by the QAPP including management, performance and verification, and assessment.

The Quality Assurance Manager is responsible for ensuring that the QAPP is properly established, documented and approved. Department managers are responsible for those applicable requirements of the QAPP are properly implemented. Managers are also responsible for assessing the effectiveness of their respective functional areas of operation.

Oversight and audits necessary to evaluate the adequacy and effectiveness of the quality assurance program are addressed in the QAPP.

The QAPP was determined by the auditor to adequately address all of the

Eighteen- (18) criterion required by 10CFR71,Subpart H, and applicable guidance contained in Regulatory Guide 7.10, Annexes 1 & 2.

2.3 QAPP IMPLEMENTATION METHODOLOGY

2.3,1 Program Objective

The quality assurance program should be documented, such, that those areas of design, purchasing, fabrication, and testing having a safety importance should be described in written procedures or instructions.

The applicability of the quality assurance program should take into consideration the complexity and impact on safety, the need for special controls, demonstration of compliance through inspection and testing, and the degree of standardization of the packages.

2.3.2 Findings

The QAPP is considered to be the top tier document that describes the policies and practices for a planned approach to achieving quality. JLS&A have incorporated the QAPP into an all encompassing quality document titled as, "Quality Assurance Manual" (QAM), that is used as the basis to describe and implement the quality assurance program though the use of Quality Procedures (QP'S). These QP's cover the entire required quality assurance criterion and are supported by various operational implementing procedures as determined by JLS&A.

Based upon a detailed review of the QP's the auditor determined that all the QP's provided adequate descriptions regarding the procedures purpose and associated implementation methodologies. The auditor characterized the QP's as being the 2nd tier level of documents that provide for a more or further detailed description of the process or methodologies as to how the requirements, policies, and commitments stated in the QAPP are to carried out by JLS&A. Many of the QP's have technical or administrative type operational implementing included, as an extension of the QP's. These procedures have varying ranges of specificity and details depending on their respective application in support of the quality assurance program.

With regard to formatting of the QP's, the auditor determined that the QP's have not been established using a standardized protocol for procedure formatting. This was observed by the auditor to be the situation for the attached operational implementing procedures.

A master list of QA/QP documents and the respective implementing procedures have been established and are being maintained by the Quality Assurance Manager.

JLS&A maintain a controlled copy distribution list of the QAPP. The list currently documents the fact that over one hundred controlled copies have been issued to organizations outside of JLS&A. During the review of the distribution list, the auditor noted, that several of the JLS&A departments were not identified as being issued a controlled copy of the QAPP. A review of documents located in the office area of the Lead Engineer and the Production/Operations Manager revealed that they had uncontrolled and outdate versions of the currently approved QAPP. The documents in their possession were issued in1991 rather than the valid 1995 version. It is worthy to note those that the latter version of the QAPP had minor revisions to the earlier QAPP.

The auditor also reviewed this area to determine if the managers had controlled copies of the QP's associated implementing procedures. This review indicated that the managers could not readily find their respective copies of the QP's or the associated implementing procedures. I t appeared obvious to the auditor that these managers did not have system in place for maintaining these controlled documents nor did they appear to have adequate knowledge of the types or contents of the quality assurance documents.

During discussions with the Quality Assurance Manager, regarding this matter, it was revealed that distribution of controlled copies of the QAPP were only provided to corporate officers of JLS&A. It was stated that the staff members could review or utilize controlled copies of the QAPP and QP's maintained in the Quality Assurance Manager's office area.

Based upon the over all review of this area, the auditor, concludes that while the QAPP and associated QP'S establish an appropriate basis for defining the program and describing the specific characteristics of how each of the sub-elements of the program are to be carried out, an adequate level of details does not exist in formally established procedures and written instructions. The operational procedures that currently exist for the activities associated with t package inspection and transportation are the exception to the auditor conclusion. This subject is further discussed in Section 5.0 to this audit report.

2.4 PERSONNEL, TRAINING, AND TRAINING

2.4.1 Personnel Selection

2.4.1.1 Program Objective

There should be established formal selection and qualification criteria for all positions in the organization which are related to the job. Criteria should include, as appropriate, measurable

formal education and experience factors.

2.4.1.2 Findings

Formal selection and qualification criteria have been established by JLS&A and are formally documented in Sections 1.1 & 2.1 of the QAPP. Minimum job qualifications appear to be established for the functional staff functions established by JLS&A. A review of selected resumes' revealed that the established selection and qualifications criteria was being appropriately administered by JLS&A management during the hiring and employment process. The resumes also indicted that most of the staff had technical and experience that greatly exceeded the minimum qualification criteria.

2.4.2 Personnel Training

2.4.2.1 Program Objective

The qualification-training program should be based upon clearly defined qualification criteria. The training program should focus on those personnel in the organization performing activities affecting quality in order to assure that suitable proficiency is achieved and maintained. Also, those personnel should receive training respective to the Quality Assurance Program elements associated job related procedures, which implement the program.

2.4.2.2 Findings

JLS&A implements a radiation safety program authorized by the State of California for the manufacturing and use of radioactive sources and equipment. Under this state authorization they are required to provide training and re-training with regard to the use and handling of radioactive materials and components. Also, since JLS&A routinely transports radioactive sources and packages under Department of Transportation regulations they are required to provide training to employees on the safe handling of hazardous materials.

Annually, JLS&A provides re-fresher training to the staff relative to 10 CFR Part 71 requirements applicable to any changes in regulations or revisions to JLS&A procedures. New employees are provided an overview perspective of the 10 CFR 71 regulations and the JLS&A QAPP, including applicable implementing procedures , as necessary.

A review of the training records being maintained by JLS&A revealed that employees are provided initial and annual radiation safety orientation. Also, the employees are provided initial and annual re-training regarding the use and handling of hazardous materials. Certificates are maintained for these training areas to validate that the training was satisfactorily accomplished. Attendance lists are also maintained for those employees who had received training

.

The training being performed by JLS&A is not formally established and does not describe training objectives to be accomplished. The training materials utilized by JLS&A are an informal compilation of industry standards and regulations, assorted industry training text, custom developed handouts, and various training outlines.

There appears to be major emphasis placed on the radiation safety and hazardous material training with less emphasis being placed on the 10CFR71 requirements and the required implementation of the program. The rational for the major emphasis being applied to the radiation safety and hazardous material training is appropriate; however, the safe transportation of radioactive materials on public roadways should receive the same level of training importance covered under DOT functional specific training.

Based upon the reviews of this area the auditor concluded that a formalized training, re-training and qualifications program has not been established that includes applicable training objectives, standardized training course outlines and examinations, instructor qualification, training attributes, training and qualification tracking method, schedules and an adequate system of records management.

2.5 RECOMMENDATIONS

2.5.1 Develop, implement, and maintained a standardized format for developing QP's.

2.5.2 Revise all of the QP's in accordance with the standardized procedure format.

2.5.3 Develop, implement, and maintain an appropriate formal writer's guide for the preparation and revisions of implementing procedures.

2.5.4 Develop and maintain quality related implementing procedures in accordance with standardized procdures, as appropriate, in order to ensure effective implementation of the QAPP and the associated QP's. Develop

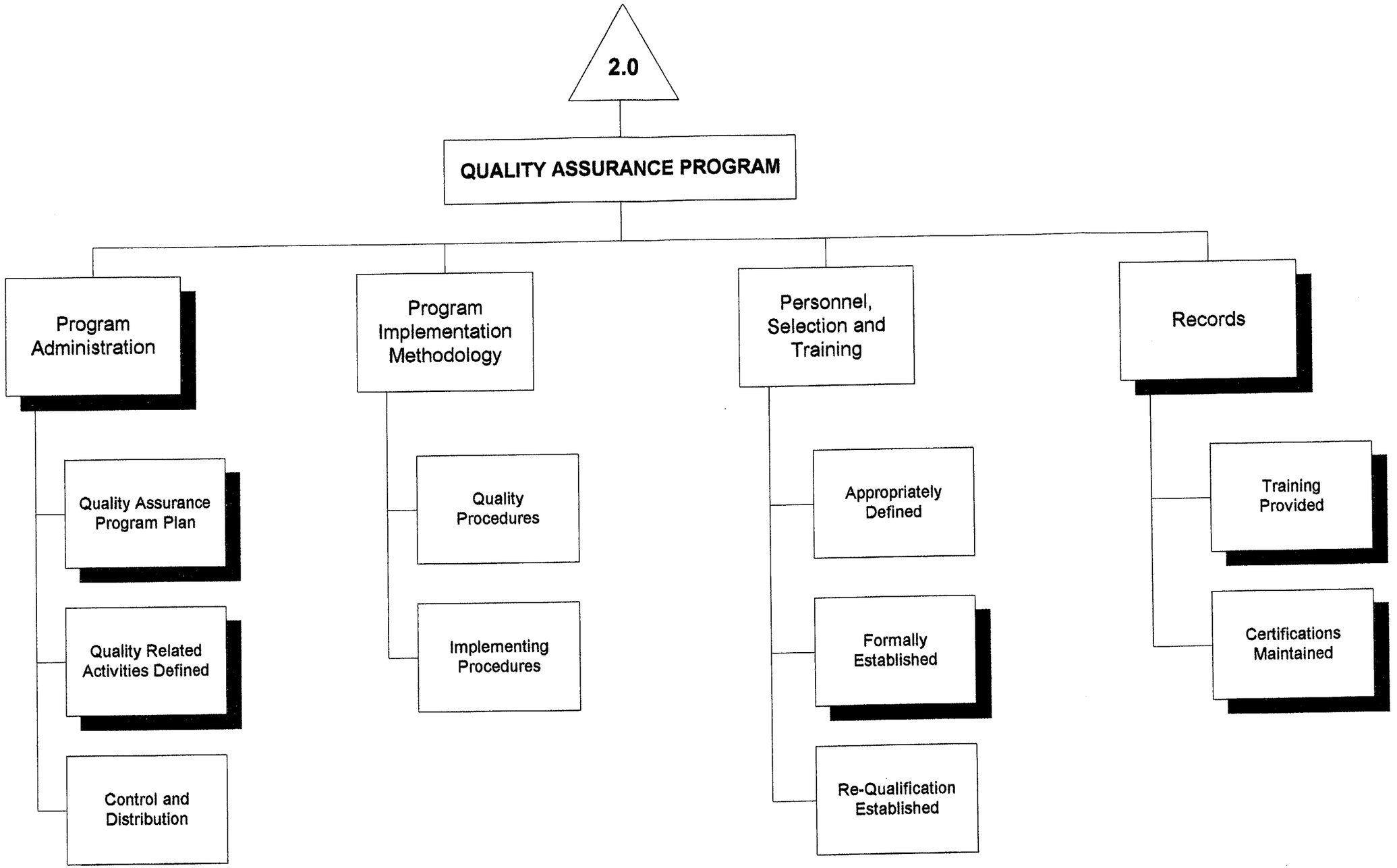
the procedures incorporating the level of detail and personnel actions required appropriate to the importance of the quality related activity being implemented and controlled.

2.5.5 Provide controlled copies of the QAPP and the QP's, with associated implementing procedures, to all department managers responsible for implementing the quality assurance program.

2.5.6 Require that the department managers maintain the documents current and that they maintain an adequate knowledge level of the contents of the documents commensurate with their need for functional implementation.

2.5.7 Develop and implement a formalized training and re-training program that will provide for standardization of required training and consistency. Include provisions for defining job specific related training required for new employees and for the subsequent re-certifications of all staff personnel.

2.5.8 Develop and implement a filing system for training records that will ensure that validation of personnel training ,qualification and certifications are controlled and maintained current.


2.0
QUALITY ASSURANCE PROGRAM
Program Administration
Quality Assurance Program Plan
Quality Related Activities Defined
Control and Distribution
Program Implementation Methodology
Quality Procedures
Implementing Procedures
Personnel, Selection and Training
Appropriately Defined
Formally Established
Re-Qualification Established
Records
Training Provided
Certifications Maintained

3.0 PACKAGE DESIGN CONTROL

3.1 SUMMARY

JLS&A have not had the need to design and develop new Type B packages for use. Accordingly, the application of the requirements of 10 CFR Part 71, related to design control, have been used mainly in support of the use and repair of previously approved NRC Type B wooden and metal over packs.

Based on this determination, the auditor focused on assessing the adequacy of the design control as it was being applied to other non-safety related design activities. Specifically, radiation type irradiators being designed and fabricated for industry were used as a basis for determining the overall implementation and adequacy of the design control program. Customer projects involving design and fabrication activities selected for review are as follows:

- # MK 453, "Case Western Reserve University";
- # 4615, "University of California Los Angeles (UCLA)";
- # Dartmouth /Hitchcock Medical Center"; and
- # 4608, "National Institute of Health (NIH)"

Using this approach as a basis for the review of the design control program, it was determined by the auditor that the basic elements, were being implemented adequately on a very informal basis, but there was a lack of procedural formality established to document and control the design activities.

The area of the program was determined to be marginally adequate, and in need of improvement, related to the development, maintenance, and control of the required formal administrative and technical/implementing procedures.

3.2 DESIGN INPUT

3.2.1 Program Objective

Design inputs, such as, design basis, performance requirements, codes, and standards should be identified and documented, and their selection reviewed and approved by the design organization.

Changes from approved design inputs, including the reasons for the changes, should be identified, approved, documented, and controlled.

3.2.2 Findings

A review of engineering drawings for the project files listed above, revealed that, applicable material and parts specifications were listed

on the drawings. Specific codes and standards, performance requirements and design basis is described in the respective customer procurement documents, as appropriate, to the customer's needs.

Drawings are initialed by senior management to signify concurrence and approval of the design basis. Changes to drawings appear to receive the same level of review and approval, however, there does not appear to be documented evidence regarding the purpose of the changes.

QP No.3.0 was developed by JLS&A for describing and implementing the Design Control Program. The auditor found that that QP contained little information and instructions regarding the actual implementation for the administration of the program and the detailed actions to be carried out by staff members for adequate execution of responsibilities and requirements.

3.3 DESIGN PROCESS

3.3.1 Program Objective

The design process should be described and controlled though approved approved procedures.

Appropriate design documents should be developed to support the design process including construction/manufacturing and operation.

Quality standards should be identified, documented, and approved by the cognizant staff members.

3.3.2 Findings

As indicated above, the Design Control Program is not formally developed and established using written instructions and procedures to ensure the adequate and effective implementation and documentation of design activities. Some broad information is formally documented relative to specific areas, such as, assignment of design responsibilities, review and approval protocols, and drawing distribution.

With regard to the application of quality standards, they are not required by the JLS&A current NRC approved Quality Assurance Program Plan. As such, there is little documented reference to specific industry standards to be utilized. The exception to this, however, is the reference to using industry and international standards for the testing and qualification of Type B packages.

3.4 DESIGN ANALYSIS

3.4.1 Program Objective

Design analysis should be performed in a planned, controlled and documented manner.

The analysis should be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a subject matter expert could review the adequacy of the results with out recourse to the originator.

3.4.2 Findings

Design of equipment and devices are conceptually identified and developed by the President of JLS&A. The Lead Engineer and staff carry out the actual formulation of the design detail. The design analysis methodology currently implemented is very informal and not covered by formally established procedures. Despite the lack of required formality, this activity appears to be functioning adequately.

3.5 DESIGN VERIICATION

3.5.1 Program Objective

Design verification should be performed in accordance with formally established procedures.

Design verification methods should include formal design reviews, alternate calculations, and qualification testing.

The extent of design verification should be based upon the complexity of the design, regulatory requirements, importance to safety, degree of standardization, and the state of the art.

3.5.2 Findings

Design verification activities are implemented, as necessary by JLS&A, based on the complexity of the design and operating characteristics defined. The are no formally established technical or administrative implementing procedures in existence for this program element.

3.6 DESIGN REVIEWS

3.6.1 Program Objective

Design reviews should be performed at appropriate phases of the design process utilizing formally established procedures.

Independent reviews should include design input selection, design methods, design outputs, design input incorporation to design, and assumptions described.

3.6.2 Findings

A review of this area revealed that, on an informal basis, design reviews are carried out as needed by JLS&A. Formally established procedures are not in place to plan and control these design review activities.

3.7 CHANGE CONTROL

3.7.1 Performance Objective

Changes to design documents should be reviewed using the same process as the original design.

3.7.2 Findings

Audit findings revealed that design changes appear to be reviewed appropriately, however, this area is not formally established utilizing written instructions or implementing procedures.

3.8 DESIGN INTERFACE CONTROL

3.8.1 Program Objective

Formal design controls should be established, as necessary, for multiple organization involvement in the design process.

Procedures should be established to document responsibilities and authorities for the transmittal, review, approval, release, distribution, and revision of design inputs and design output documentation.

3.8.2 Findings

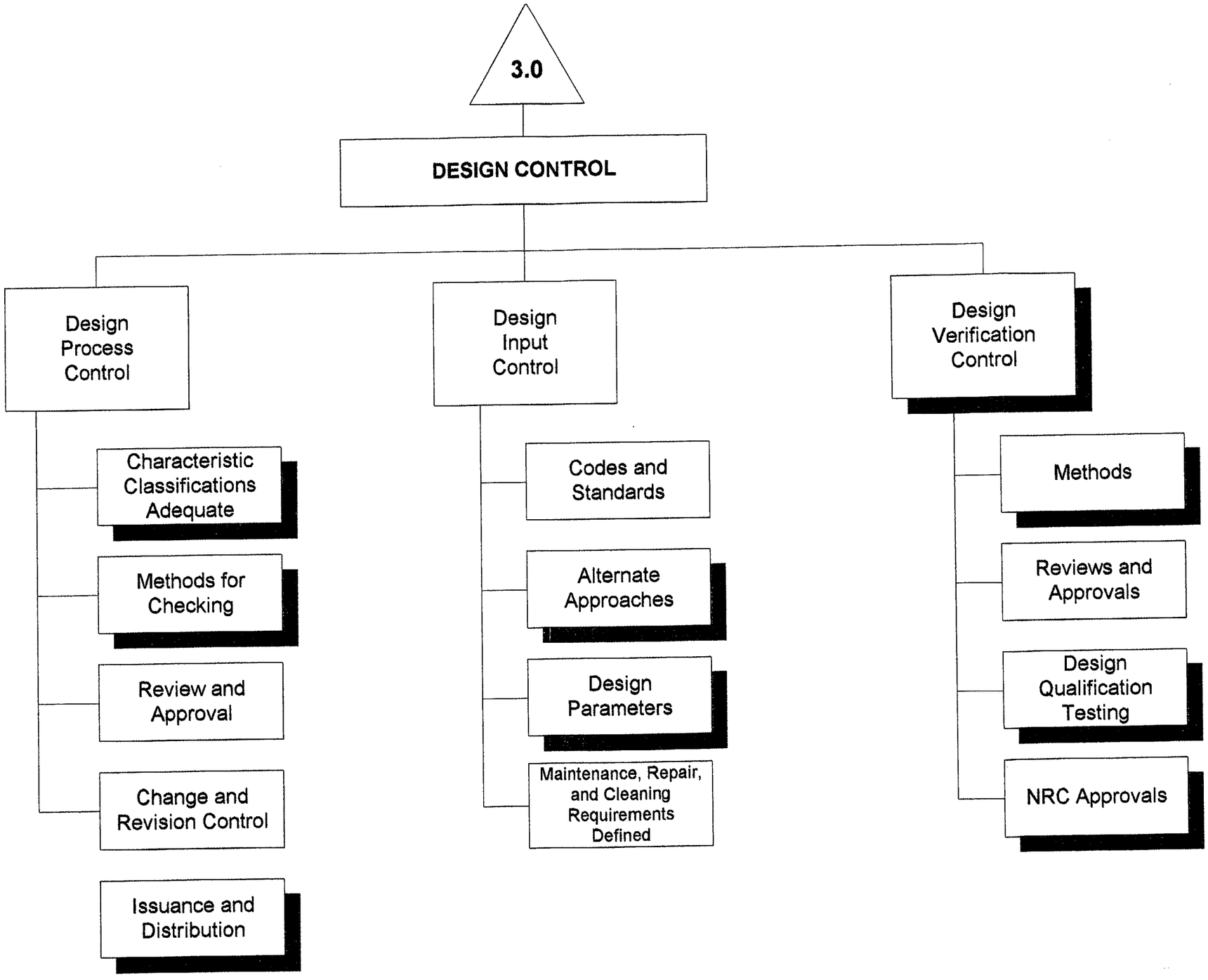
This area of the program is implemented between JLS&L functional departments on an as need basis. The company staffing is minimal and therefore communications between departments is not complex and this tends to allow for informal interfacing related to design control.

3.9 RECOMMENDATIONS

3.9.1 Perform a detailed task analysis (needs analysis) of the Design Control Program to determine what elements of the program need to be covered by administrative and technical implementing procedures.

Include an evaluation as the extent of detail that should be included in the procedures for proper execution of requirements and group responsibilities.

3.9.2 Based on the task analysis, establish and implement formal type administrative and implementing procedures for the conduct of activities associated with the package design and control process.


3.0
DESIGN CONTROL
Design Process Control
Characteristic Classifications Adequate
Methods for Checking
Review and Approval
Change and Revision Control
Issuance and Distribution
Design Input Control
Codes and Standards
Alternate Approaches
Design Parameters
Maintenance, Repair, and Cleaning Requirements Defined
Design Verification Control
Methods
Reviews and Approvals
Design Qualification Testing
NRC Approvals

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 SUMMARY

The area of procurement document control was found to lack formally established procedures or written instructions for adequate implementation of the program. The program is being implemented on a very informal basis. This element of the program was found to be marginally adequate and in need of some improvement.

4.2 PREPARATION AND ISSUANCE OF PROCUREMENT DOCUMENTS

4.2.1 Program Objective

Procedures or written instructions should be formally established for controlling and implementing the procurement processing for the areas of; preparation, concurrence, and approval of services, materials, parts, and components.

4.2.2 Findings

References to the Procurement Document Control program are contained in several of the QAM QP's, that have been established for implementing and controlling the process. These QP's contain minimal description as to how the procurement processes is to be implemented and controlled. As written, the QP's only address specific requirements that must be applied and implemented for the procurement activities.

The auditor also noted that there appears to be at least two versions of the QP 4.0 that has been established for describing and implementing the procurement process. One version of the QP appears to be established to, generically address the procurement control process, while the other version specifically describes its applicability to packages controlled and regulated by NRC and DOT.

Based upon a review of these quality documents, the auditor, determined that appropriate administrative and operational implementing procedures have not been adequately established and implemented, as required. Also, the auditor, believes that a program weakness exists regarding the lack of control and maintenance of controlled procedures.

4.3 PROCUREMENT DOCUMENT PROVISIONS

4.3.1 Program Objective

Procurement documents should include as applicable:

- *scope of work statements,*
- *design basis technical and regulatory requirements,*
- *guidelines for review by Quality Assurance,*
- *quality criteria for items and services,*
- *quality assurance requirements for supplier's and their sub-tier supplier's,*
- *applicable documentation requirements,*
- *requirements for reporting and approving of identified non-conformances,*
- *right of access to supplier's facilities and records for inspection and audit purposes,*
- *identification of record retention protocols between supplier and purchaser, and*
- *supplier record documentation requirements to be prepared, maintained, and submitted to purchaser.*

4.3.2 Findings

As described above in Section 4.3.1, implementing procedures have not been established that control or define the functions and actions required to ensure that the types of documents and requirements listed above, are appropriately incorporated, into the procurement process activities.

The procurement process in place, currently, mainly relies upon the knowledge and experience of the department managers for applying the applicable criterion to procurement activities.

Specific purchasing requisitions related to procurement activities related to replacement parts and materials for Type B over packs were reviewed for content and adequacy. This review revealed that the purchase requisitions contained the applicable design drawings, specifications, 10CFR21 statement of application and the right-of-access statement, However, statements related to many of the several attributes listed above were not appropriately specified.

4.4 PROCUREMENT DOCUMENT REVIEW

4.4.1 Program Objective

Formal administrative controls should be established for review of procurement documents by technical, safety, and quality personnel, as applicable, prior to procurement issuance.

4.4.2 Findings

Protocols have been established by JLS&A related to opening job orders

and the preparation of purchase requisitions. Engineering is responsible for identifying and providing the design drawings to be used and attached to the purchasing requisition. The Production/Operation Manager takes the drawings and develops a bill of materials to be applied to the purchase requisition.

This process, while not formally documented, appeared to be functioning adequately.

4.5 PROCUREMENT DOCUMENT CHANGES

4.5.1 Program Objective

Formal controls should be established to ensure that changes and revisions to procurement documents receive the same levels of review undertaken for the original document.

4.5.2 Findings

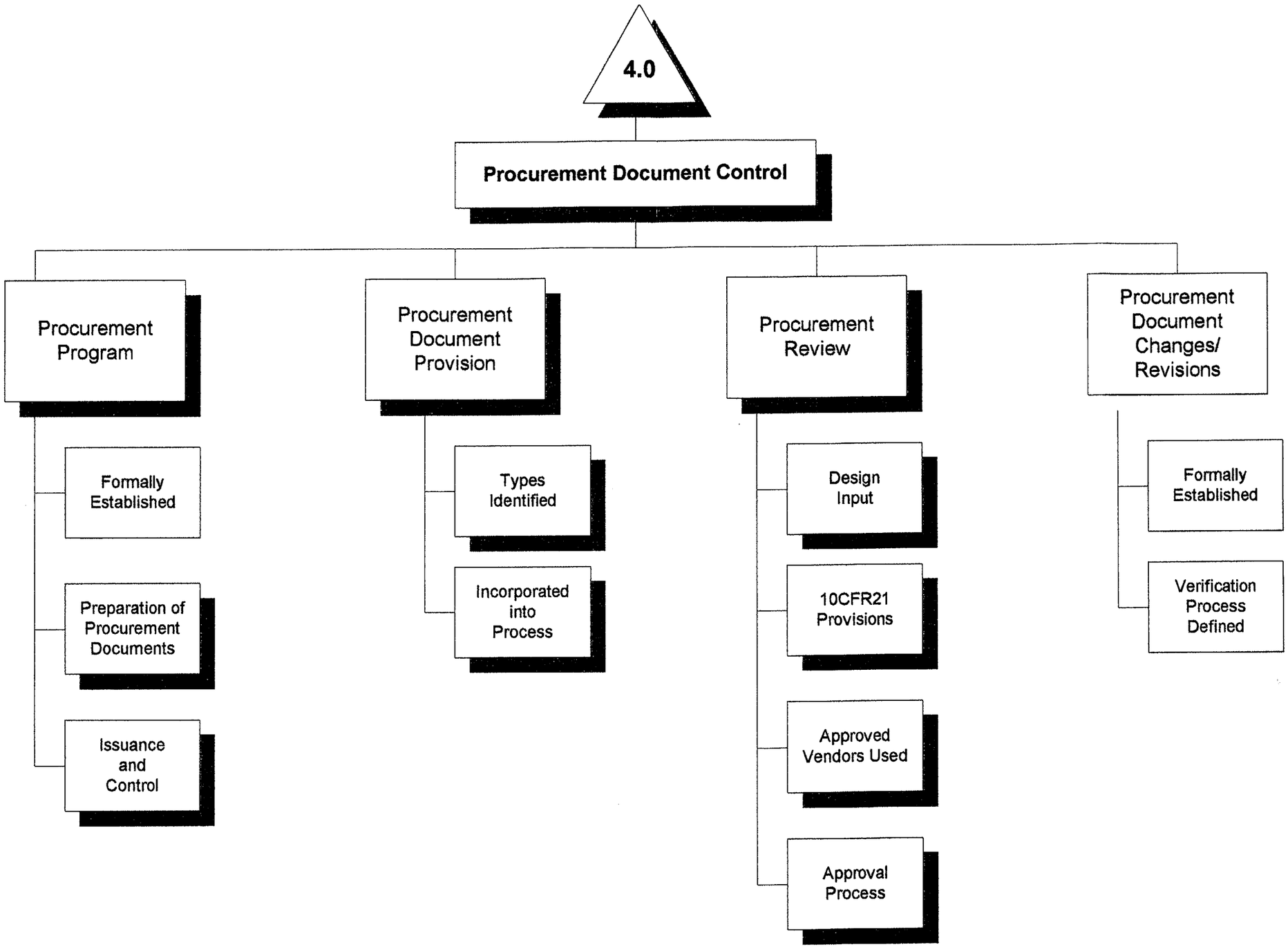
Details and actions for reviewing changes and revisions to procurement documents have not been formally incorporated into written implementing instructions or procedures. During the course of reviewing procurements the auditor did not identify any situations were changes or revisions to the original procurement documents had been required.

RECOMMENDATIONS

4.6.1 Establish and implement formalized administrative and operational type implementing procedures for the conduct of the entire procurement control program

4.6.2 Rewrite the QP's in Section 4.0, as necessary in order to clearly define the purpose of the QP and include an adequate description of the activities to be implemented.

4.6.2 Develop and implement procedures to define the sequence of actions and controls to be applied for the procurement document activities applicable to review, authorization, and changes/ revisions.


4.0
Procurement Document Control
Procurement Program
Formally Established
Preparation of Procurement Documents
Issuance and Control
Procurement Document Provision
Types Identified
Incorporated into Process
Procurement Review
Design Input
10CFR21 Provisions
Approved Vendors Used
Approval Process
Procurement Document Changes/ Revisions
Formally Established
Verification Process Defined

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 SUMMARY

The program for formally establishing and maintaining written instructions and procedures is inadequate and in need of major improvement. Major program weaknesses relate to the lack of an adequately defined hierarchy system for the application of types, need analysis, format and content, distribution, and control of procedures

5.2 QUALITY ASSURANCE PROGRAM PROCEDURES

5.2.1 Program Objective

Measures should be established to ensure that:

- ***Activities important to safety are prescribed and implemented in commensurate with formal procedures, instructions, or drawings***
- ***Methods for complying with each of the applicable 18 criterion of Subpart H 10CFR Part71 are specified in instructions procedures, and drawings.***
- ***Instructions, procedures and drawings include appropriate quanitative and qualitative acceptance criteria to verify that activities important to safety have been accomplished.***
- ***Responsibilities for the development, review, approval and maintenance of the procedure program are formally defined.***

5.2.2 Findings

Program Bases and Requirements

As previously discussed in Section 2.0, to this report, JLS&A has established a Quality Assurance Manual (QAM) that is organized using Quality Procedures (QP's) as a basis to describe and implement the requirements of the Quality Assurance Program. All of the eighteen (18) criterion required by 10CFR71, Subpart H, are addressed in the QAM, including the NRC approved QAPP. Also, some formally established operating procedures are included as an extension of various QP's. Some of the operating procedures are incorporated into multiple QP'S based upon the quality area being implemented.

QP, s, appear to have been developed by JLS&A to serve as 2nd tier documents that are intended to procedurally implement the conduct of the Quality Assurance Program. The QAM /QP, s tend to serve as instructions and administrative procedures that describe the actions and regulatory requirements to be taken for implementing the specific element of the Quality Assurance Program.

A wide variation of quality exists with in these implementing QP's, as it regards to detail, editorial clarity, procedure interface, and the use of broad reference to sections of the QAPP. Also, QP, s are incorporated with implementing procedures that have generic application to other QP, s.

Based upon a review of the QAM and associated implementing procedures, it appears that JLS&A have not performed a structured task analysis for the planning and development of quality related implementing procedures. This conclusion is supported by the fact that all activities or tasks affecting quality are not covered by implementing procedures and that the implementing procedures that have been prepared lack sufficient detail and task sequencing.

Procedure Methods Documented

Assignment of responsibilities for procedure requirements, development, review, approval, and maintenance appears to be lacking in detail and the appropriate staff managers do not appear to be included in the overall procedure review and approval process. QP, s contain statements that specify department managers are to develop and implement procedures appropriate to the effective implementation of their assigned functional responsibilities.

It appears that the Quality Assurance Manager has assumed overall responsibility for determining what quality related activities are required to be implemented utilizing procedures. Accordingly, the Quality Assurance Manager, develops, approves and issues quality procedures, as necessary, for implementation of the overall program.

Procedure Hierarchy

The review of the procedure program was evaluated for consideration of structure adequacy and implementation effectiveness. The review revealed that a procedure hierarchy encompassing all of the necessary administrative, technical/operational implementing procedures for the conduct, verification, monitoring, and the evaluating of the required quality related activities had not been formally established. Specifically, those procedures of an administrative type containing policies, commitments, regulatory bases, program responsibilities, and authorities are combined with

technical/operational type implementing procedures, in such a manner, that the procedures are cumbersome, conflicting, and non-user friendly.

The procedure system, currently used, does not include provisions for a cohesive listing and numbering protocol for maintaining procedures by its function, category, type or departmental assignment. Basically, there is no clear distinction between administrative, technical, and operational type of procedures for preparation and use purposes.

Procedure Format and Content

Based upon a review of QP, s and associated implementing procedures, it was determined, that a system or process for defining and structuring the Format and content of procedures had not been formally established. The implementing procedures as currently maintained do not follow a format or development basis that provide for any consistency. Some procedures provide for more detail than others do. Procedures should be formally established using industry accepted format standards, as applicable, to the nature and use of the procedure for the adequate control and instruction of activities.

With regard to procedure content, the auditor found the implementing procedures, to be lacking in detail and action sequencing regarding the execution of tasks and activities.

Procedure Review and Approval

A formally documented process for reviewing and approving procedures has not been established and implemented. It appears that only the Quality Assurance Manager is performing the review and approval of procedures.

There appears to be no documented evidence maintained that QP, s and associated implementing have been circulated to the functional department managers or review and approval prior to being signed of by upper levels of management.

Procedure Distribution and Control

A program for the distribution and control of quality related procedures for staff use has not been formally established and implemented. Copies of individual procedures are distributed to staff members as changes or revisions occur. There are no formal controls established for validating that the department managers received the revised procedures and have replaced the old version of the procedure. Industry practice, is to attach acknowledgement forms to the distribution item, requiring department manager sign off.

The procedure program does not make provisions for consolidating and organizing the entire procedure hierarchy into binders or booklets, with associated master list indexing.

The QAM Master list was found to be outdated, in that, several of the procedure revisions documented in the Master List did not coincide with the revisions specified on the implementing procedures.

An audit of the Lead Engineer and Production/Operations Manager office areas revealed that a controlled set of QP, s and implementing procedures were not being maintained by either manager. The Production/Operations Manager did not appear to be well informed regarding the location of his particular procedures nor their controlled purpose. Tours of the operating areas of the facility revealed that there were no controlled copies of the QAPP, QP, s and implementing available for workers to access.

Procedure Change/Revision Controls

The Quality Assurance Manager is revising QP, s and implementing procedures, as necessary. Most revisions and changes to implementing procedures have taken place over the last several months, as corrective actions taken in response to past NRC inspection findings.

Procedure Training

Based upon a review, of training attendance lists and company directive's issued, JLS&A have taken appropriate measures to ensure that those staff members responsible for implementing the revised procedures received training.

Safety/Task Analysis

The quality of the QP, s and associated implementing procedures varies considerably. These documents lack appropriate sequencing of tasks and de-tailed instructions for personnel to implement effectively. Also, the lack of proper sequencing impedes the quality assurance verification process.

Field Test Verifications

Formal requirements requiring that new and revised procedures be field tested prior to approvals and implementation have not been developed and implemented.

5.3 RECOMMENDATIONS

5.3.1 Perform an in-depth review of all QP, s and implementing procedures to determine accuracy, consistency, clarity, task breakdown, and step-by-step sequencing requirements, user friendliness, and applicability so as to ensure usability.

5.3.2 Initiate a formal action plan for procedural upgrade. The action plan should include a schedule, assignment of responsibilities, and resource commitments.

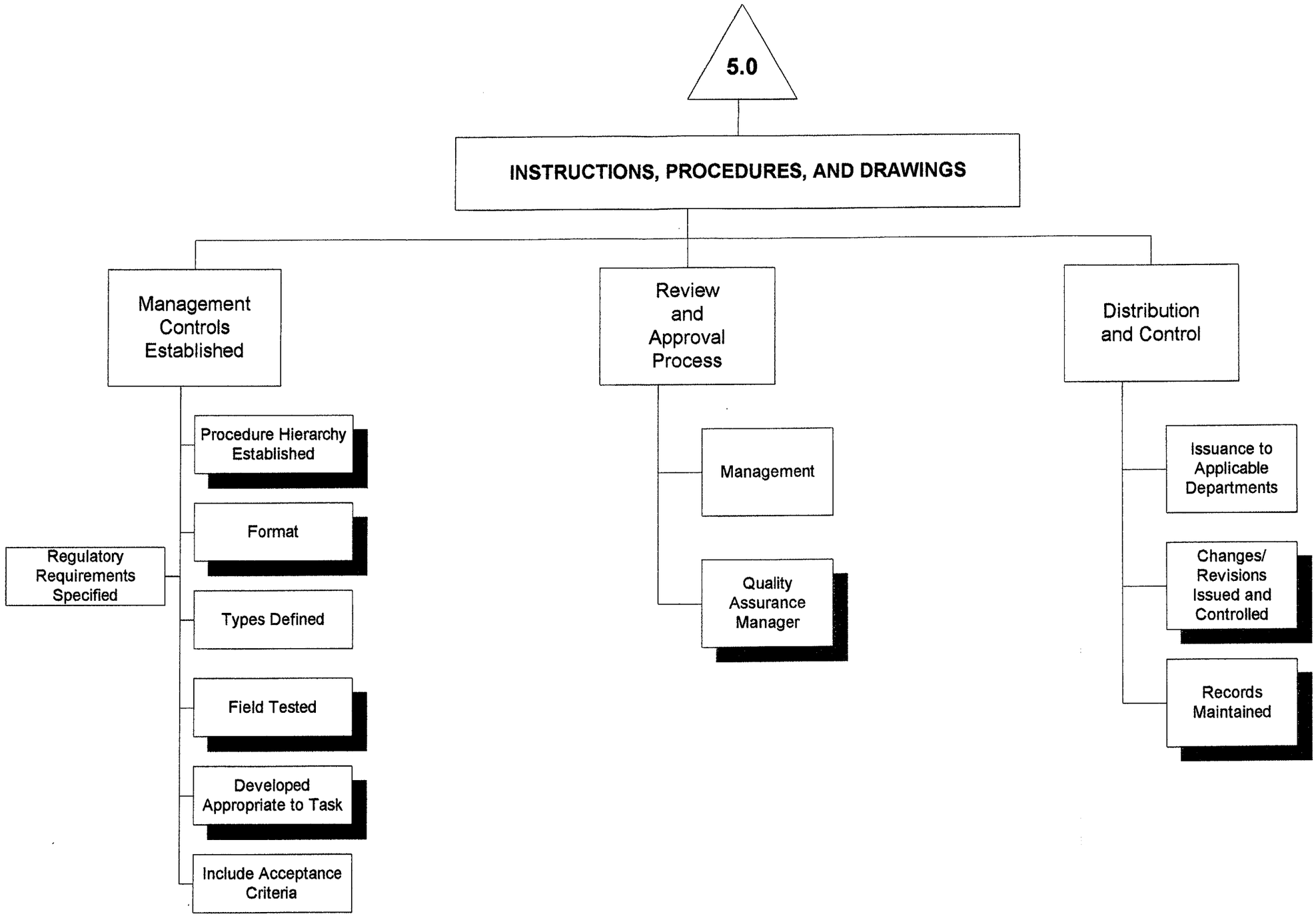
5.3.3 Perform a need analysis to identify additional actions and processes, which should be documented in procedures.

5.3.4 Develop and implement a writers guide for use in procedure selection and preparation.

5.3.5 Formally establish and implement a procedure structure hierarchy.

5.3.6 Compile all of the quality related program procedures into some type of ringed Binder(s).

5.;3.7 Distribute and locate complete sets of controlled procedures, as necessary, to ensure they are available for access by all employees. Require those managers implement appropriate measures to maintain and control the procedures.


5.0
INSTRUCTIONS, PROCEDURES, AND DRAWINGS
Management Controls Established
Procedure Hierarchy Established
Format
Regulatory Requirements Specified
Types Defined
Field Tested
Developed Appropriate to Task
Include Acceptance Criteria
Review and Approval Process
Management
Quality Assurance Manager
Distribution and Control
Issuance to Applicable Departments
Changes/ Revisions Issued and Controlled
Records Maintained

6.0 DOCUMENT CONTROL

6.1 SUMMARY

The document control program was reviewed and found to be marginally adequate and in need of some improvement. Some program sub-elements could be enhanced, such as, distinctive marking or stamping of documents to highlight that they are quality related documents and the establishment of a computerized data base for identifying and controlling design drawings. Also, quality related procedures are not distributed to work locations as required.

6.1 DOCUMENT CONTROL PROGRAM

Management Controls

6.2.1 Program Objective

A document control system should be formally established such that documents under the control of the Quality Assurance program are properly identified, maintained and kept current. Controlled documents should include documentation for activities affecting quality such as:

- ***Design documents,***
- ***Procurement documents,***
- ***Quality Assurance Manuals and implementing procedures,***
- ***Operating, maintenance, and modification procedures,***
- ***Inspection and test procedures,***
- ***Non-conformance reports,***
- ***Design change requests, and***
- ***Corrective action reports***

6.2.2.2 Findings

An informal type document control system currently is being implemented by JLS&A. A document control philosophy put into effect many years ago, and still implemented, provides for a protocol that requires all documents to be filed and maintained in their customer or project files. A review of selected 10 CFR Part 71 Type B package files revealed that the appropriate quality related documents are being maintained. These include, drawings results of package inspections, non-conformances identified, procurement requisitions, and applicable corrective actions documentation.

6.3 DOCUMENT PREPARATION, REVIEW, APPROVAL AND ISSUANCE

6.3.1 Program Responsibility

6.3.1.1 Program Objective

Formal controls should be established that defines responsibility, authority, review, approval, issue, use, and revision of controlled documents.

6.3.1.2 Findings

Design Drawings

A shared responsibility for drawing development, review, and approval are undertaken by the company President and the Lead Engineer. The Lead Engineer has functional responsibility for the issue, revision and control of documents.

A review of the drawing master file and selected project files indicated that this program area appeared to be implemented adequately. However, there is some question regarding the adequacy and effectiveness of the manual drawing indexing (3 x 5 index file) currently utilized. The auditor noted that the metal file drawer used for drawing controls, appeared to contain hundreds of index cards describing drawings numbers and respective revisions. The files, are dated as far back as 1969, are a combination of all drawings developed and maintained by JLS&A. A specific set of file cards are not established separately for quality related drawings.

Quality Procedures

Quality Assurance related procedures are developed, approved, and issued by the acting, Manager Quality Assurance. The documents include the QAM and associated quality related implementing procedures. On an, as needed basis, these documents are issued to the staff by the Quality Assurance Manager.

6.3.2 Document Generation

6.3.2.1 Program Objective

Administrative controls should be established that ensures documents have been developed in accordance with prescribed procedures and are systematically integrated into the quality activities program.

6.3.2.2 Findings

Engineering Drawings

Formal administrative controls, have not been established for the design document preparation, review, and control process. As indicated above, the program is being carried out on an informal basis. However, a review of this quality related area revealed that since 1991, new Type B package designs have not been undertaken by JLS&A.

Implementing Documents

A review of Type B package files revealed that applicable forms certifications, drawings, operating procedures, inspection results, procurement requisitions, and purchase orders are being generated and maintained as required by implementing institutions and procedures.

6.3.3 Review and Approval of Documents

6.3.3.1 Program Objective

Documents should be reviewed for, adequacy, completeness, and correctness by qualified persons prior to issuance.

Document approval authority should be formally established in procedures.

6.3.3.2 Findings

A review of this area indicates that appropriate management reviews and approval of quality related documents are being implemented. The area of audit reports appeared to be the only program area, that was noted to have minor deficiencies related to management review and acceptance of quality documents. Details regarding these minor deficiencies are documented in Section 18.0, to this report.

6.3.4 Document Changes

6.3.4.1 Program Objective

Administrative controls should be established to ensure that major changes to documents receive the same level of review and approval, using the same process as the original document.

The controls should clearly define the types of changes to documents that are considered minor or major in nature and that changes are made in accordance with configuration control procedures by those individuals authorized to do so.

6.3.4.2 Findings

Specific administrative measures have not been formally established and documented that address changes to documents. Document change protocols have not been formally documented which specify the differences between minor and major changes and what level of review and approvals are required for the type changes.

It is worthy to note that management's controls regarding changes to documents are being implemented on an informal basis by JLS&A.

6.3.5 Document Issuance

6.3.5.1 Program Objective

Administrative controls should be established to ensure that current copies of applicable controlled documents are made available at the locations where quality activities are being performed to preclude the use of obsolete or superseded documents.

6.3.5.2 Findings

copies of quality related procedures are not being adequately maintained and controlled at the facility Based upon a review of this area it appears that controlled locations where the quality related functions are being implemented. The Quality Assurance Manager believes that the "locations", implied, refers to having a single con-

trolled copy of the quality related procedures at the main operating location, rather than just being maintained at the corporate offices for companies.

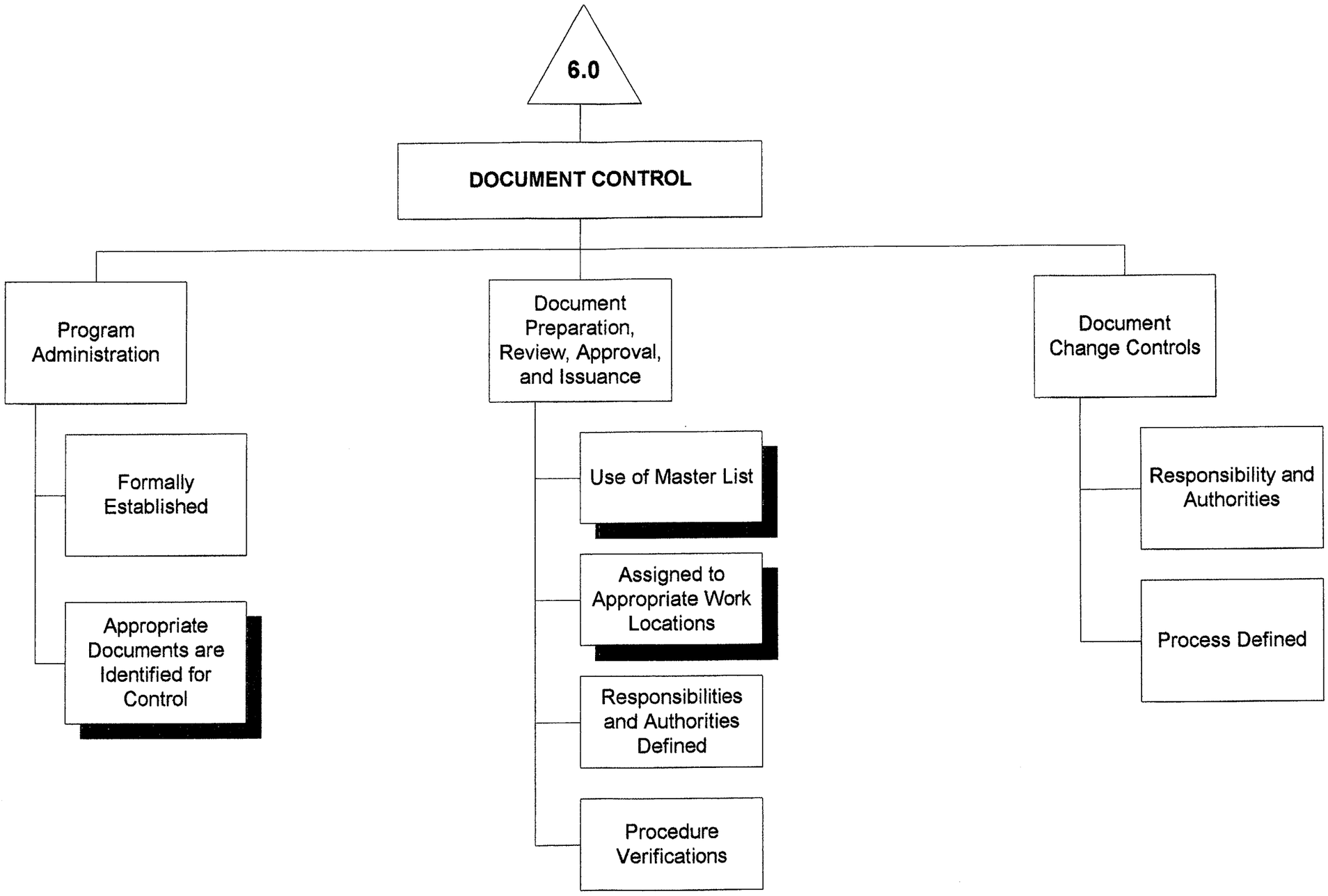
Further discussion of the distribution and maintenance of controlled procedures in are contained in Section 5.0, to this report.

6.4 Recommendations

6.4.1 Develop and implement administrative type procedures that defines and controls the, preparation, review, distribution and retention of quality related documents.

6.4.2 Formally document the engineered drawing review and approval process and provisions.

6.4.3 Distribute and maintain controlled copies of quality related procedures are appropriate to the functions being conducted under the requirements of the quality assurance program.


6.0
DOCUMENT CONTROL
Program Administration
Formally Established
Appropriate Documents are Identified for Control
Document Preparation, Review, Approval, and Issuance
Use of Master List
Assigned to Appropriate Work Locations
Responsibilities and Authorities Defined
Procedure Verifications
Document Change Controls
Responsibility and Authorities
Process Defined

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7.1 SUMMARY

This area of the Quality Assurance Program was found to be acceptable. This was primarily, due to the fact, that materials and parts required for Type B package repairs and maintenance are of commercial grade specifications and require minimal control.

7.2 PROCUREMENT PLANNING

7.2.1 Program Objective

Procurement activities should be planned and documented to assure a systematic approach to the procurement process. Provisions should be established to document procurement methods and organizational responsibilities.

7.2.2 Findings

QAM-QP No. 7.0, "Control of Purchased Material, Equipment, and Services", has been prepared by JLS&A to describe the individual and departmental responsibilities and actions to be implemented for the conduct of the procurement planning activities. Procedure QP No. 7, also, incorporates the use of QP No 5.0, "Instructions, Procedures, and Drawings", and "Standard Shop Policies and Procedures" for implementing the program.

Detailed implementing procedures using sequencing and step-by-step actions for each of the areas of the program have not been established, as necessary, to ensure effective and adequate implementation of the overall program.

7.3 SUPPLIER SELECTION

7.3.1 Performance Objective

The selection of suppliers should be based on evaluation of there capabilities to provide items commensurate with the requirements of the procurements prior to award of contracts.

7.3.2 Findings

QP No. 7.0 contains checklists and instructions for determining the qualifications and capabilities of the vendors and subcontractors being con-

sidered for approval to provide quality related items and services. One checklist "Vendor and Subcontractor Qualification" is forwarded to the subject vendor, in advance, for preliminary screening purposes. The other checklist is intended to provide the basis for conducting audits of the vendor's facilities.

7.4 BID EVALUATION

7.4.1 Performance Objective

Bid evaluation should determine the extent of conformance to procurement documents. Specific areas that should be addressed relate to; technical, competence, quality assurance requirements, production capability, past performance, and supplier personnel.

7.4.2 Findings

JLS&A, as a matter of practice, maintain sa computerized listing of approved vendors and service suppliers. The database was reviewed by the auditor and found to contain the identities of those vendor's approved to provide quality related materials and services to JLS&A.

JLS&A normally do not conduct competitive bidding. This is based on the fact that, parts and materials, required for repair and maintenance of Type B over packs is of a generic commercial grade. Typically, these commercial grade items can be purchased at local commercial suppliers, such as, Home Depot or Lowes.

A review of JLS&A purchase requisitions and associated vendor bills of sale revealed that this area of the procurement program was being implemented adequately.

7.5 SUPPLIER PERFORMANCE EVALUATION

7.5.1 Performance Objective

Measures should be established, as necessary, for interfacing and verification of the supplier's performance.

7.5.2 Findings

A review of this area revealed that there is little need at the present time to audit or provide over sight of vendor performance, based on the fact, that essentially all of the materials and parts procured are of a commercial type grade only.

This area was found by the auditor to be effectively implemented and controlled based on interviews with JLS&A management and a review of records.

7.6 CONTROL OF SUPPLIER GENERATED DOCUMENTS

7.6.1 Performance Objective

Supplier generated documents should be controlled, handled, and approved in accordance with established procurement methods. Methods should include provisions for; the acquisition, processing, and recorded technical evaluations of technical, inspection and test data against acceptance criteria.

7.6.2 Findings

A review of the procurement records revealed those appropriate material and equipment certifications and other technical supporting documents were being required, as necessary, reviewed, evaluated, and maintained by JLS&A.

This area appears to be adequately established and is being implemented.

7.7 CONTROL OF CHANGES IN ITEMS OR SERVICES

7.7.1 Performance Objective

Measures to control changes in procurement documents should be established, implemented, and documented.

7.7.2 Findings

Based upon a review of purchase requisitions issued by JLS&A it appears that changes to the original purchase requisition has not been necessary for materials and services provided in support of the Type B over pack repair and maintenance activities.

It is important to note that QP No.7.0 does contain management protocols requiring appropriate review and approval of procurement changes.

7.8 ACCEPTENCE OF ITEMS OR SERVICES

7.8.1 Performance Objective

Methods should be established for the acceptance of items or services being furnisher by a supplier.

Documentary evidence should be required from the supplier who validates that items conform to applicable codes, regulations, and codes.

7.8.2 Findings

This item is covered in Section 7.6 above. Specific grades and sizes of materials are specified on the applicable purchase requisitions and inspected by shipping and receiving personnel upon receipt. Certificates of calibration are required to be supplied by those approved vendors that calibrate the measuring and test equipment and radiation monitoring instruments.

A review of the records associated with these activities were found to be adequate

7.9 CONTROL OF SUPPLIER NOMCONFORMANCES

7.9.1 Performance Objective

Methods should be established and documented for disposition of items and services that do not meet procurement document requirements.

7.9.2 Findings

Based upon a review of nonconformance documents and interviews with staff members this area was found to be adequately controlled and implemented.

7.10 COMMERCIAL GRADE ITEMS

7.10.1 Performance Objective

When commercial grade items specified in design documents, are being substituted with alternate commercial grade materials, verification activities should be implemented to ensure that the substitute materials would perform the intended function satisfactorily.

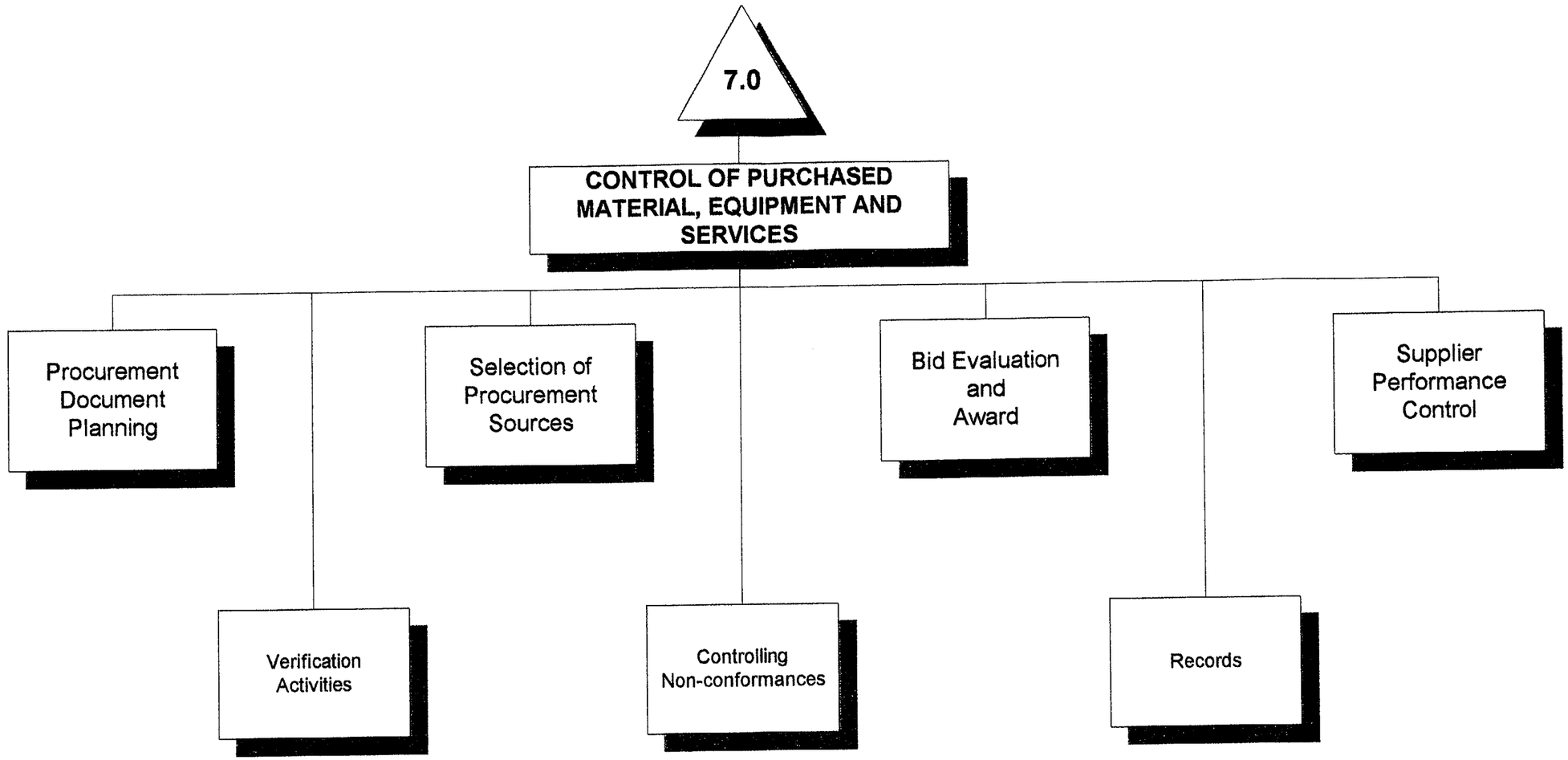
7.10.2 Findings

This area of the program has not been affected by the need to substitute commercial grade materials. As discussed above, materials required for the Type B over packs are of a commercial grade quality and do not require substitution. The auditor verified that procedural control for substituting materials is specified in QP No. 7.0. The controls require that the engineering department review and verify that proposed substitutions

of parts and materials will perform the intended function of and will meet applicable design requirements.

7.11 RECOMMENDATIONS

None Necessary


7.0
CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES
Procurement Document Planning
Selection of Procurement Sources
Bid Evaluation and Award
Supplier Performance Control
Verification Activities
Controlling Non-conformances
Records

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

8.1 SUMMARY

The program required for the identification, controlling, and releasing of materials lacks formal procedure specificity and is not adequately being implemented. This element of the program was found to be marginally adequate and in need of some improvement.

8.2 IDENTIFICATION AND CONTROL

8.2.1 Identification

8.2.1.1 Program Objective

Methods should be established to ensure that materials, parts, and components, including partially fabricated assemblies, are adequately identified to prevent the use of incorrect or defective items.

Measures should provide for physical identification such as batch, lot, serial number, or part number through out fabrication, installation, and use.

8.2.1.2 Findings

QP No. 8.0, "Identification and Control of Materials, Parts and Components," was established by JLS&A to describe procedures for the identification. controlling, and release of materials, parts, and components, including clear sequencing of actions applicable to the implementation process.

The master list of QA/QP documents maintained by the JLS&A assigns two-(2) implementing documents to this QP for carrying this quality related function. They include; "Manufacturing Control - Instructions, Procedures and Drawings"; and "Standard Shop Policies and Procedures".

The review of these documents, in there entirety, revealed that that they contained minimal implementing detail and specificity for the required execution of tasks associated with this element of the quality assurance program.

Tours of the facility receiving and inspection areas were made to determine if materials, parts and components were, in fact, being identified and controlled as committed to and required. This review indicated that the program for the identification and control of materials and parts were not being implemented as required.

8.2.2 Markings

8.2.2.1 Program Objective

Markings should be applied using materials, which are clear, legible, and do not detrimentally affect the function or service life of the item

8.2.2.2 Findings

A review of this area reveals that materials or parts do not appear to be marked appropriately for identification, control and release purposes. Specifically, manufactured materials and components observed in the inspection area of the operating facility, revealed many items either inspected or that was awaiting inspection did not bear any type of identification what-so-ever.

8.2.3 Trace-ability

8.2.3.1 Program Objective

Procedural controls should be established to specify methods for requiring identification or trace-ability of items to applicable codes, standards, or specifications.

8.2.3.2 Findings

Detailed implementing procedures have not been established and implemented by JLS&A for validating the identification and trace-ability of items. Upon receipt of materials, parts and components, the shipping clerk, compares the items on the bills of lading to the purchase order and then forwards the items on to the appropriate requestor for technical inspection, As to how these functions are carried out and documented by all parties involved is not formally defined.

8.2.4 Shelf/Operating Life

8.2.4.1 Program Objective

Controls should be established for items having limited calendar or operating life to preclude use of items after the shelf life or prescribed operation time has expired.

8.2.4.2 Findings

The types of materials and parts specified in the Type B package COC'S, currently utilized by JLS&A, consist of basic commercial grade quality and do not have a limited shelf life and therefore do not require any special controls to be applied.

8.2.5 Maintaining Identification in Storage

8.2.5.1 Program Objective

Formal provisions should be established and implemented for maintenance or replacement of markings and identification due to damage from handling or aging, excessive deterioration due to environmental exposure, and for updating records while in storage.

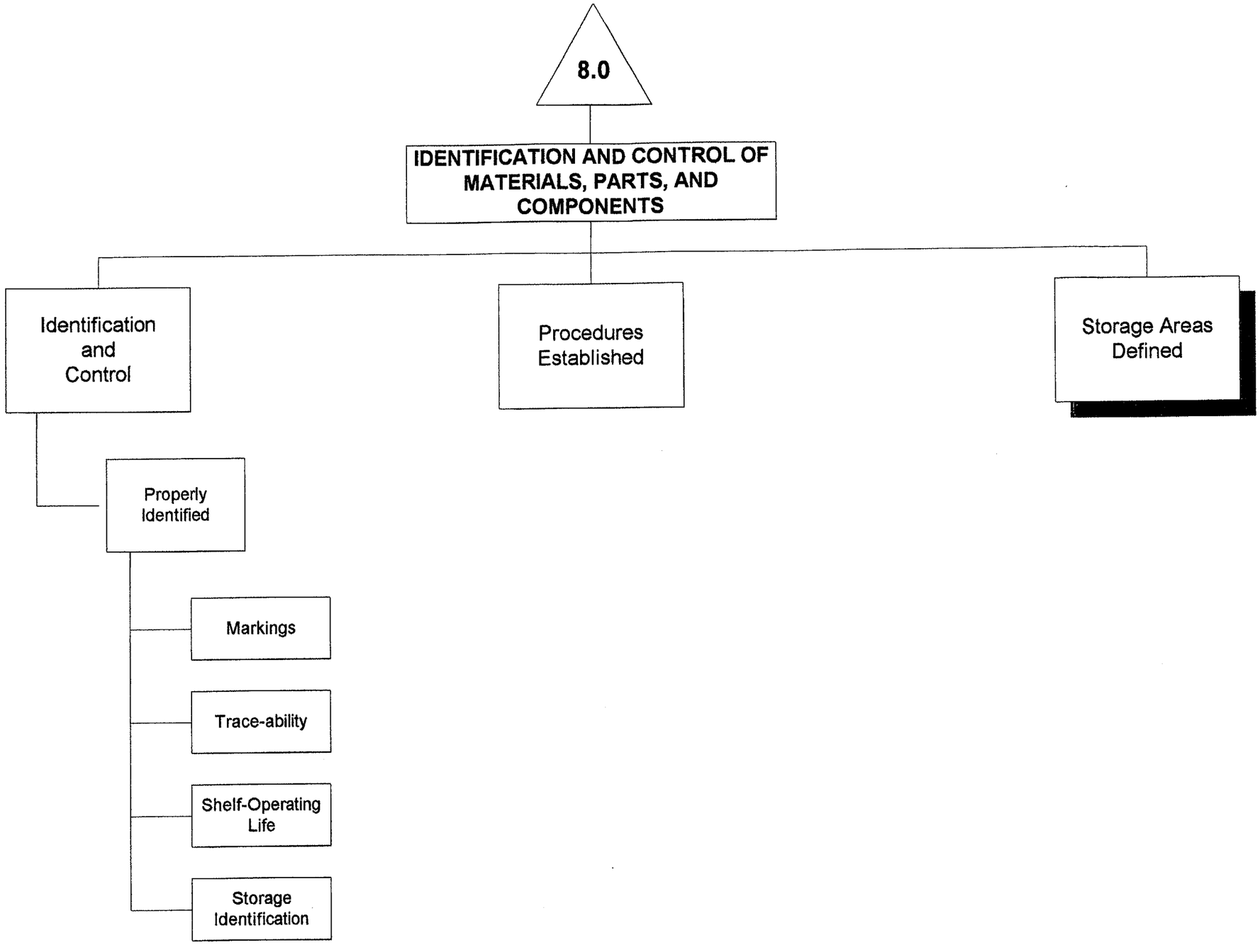
8.2.5.2 Finding

The review of this area revealed that appropriate controls and actions have not been formally established and implemented for this area. As noted above, during the course of the audit, many of the materials and parts in the inspection area and surrounding areas contained items that had no marking designations. It appeared that personnel were not being held accountable for ensuring those parts materials, and components were maintained tagged or marked, as applicable.

8.3 RECOMMENDATIONS

8.3.1 Develop and implement detailed procedures or written instructions for properly carrying out the functions required for the effective implementation of identifying, controlling, and releasing materials, parts, and components.

8.3.2 Audit, mark and tag, and store separately those quality related materials, parts, and components applicable to the Type B packaging and transportation program


8.0
IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS
Identification and Control
Procedures Established
Storage Areas Defined
Properly Identified
Markings
Trace-ability
Shelf-Operating Life
Storage Identification

9.0 CONTROL OF SPECIAL PROCESSES

9.1 SUMMARY

The inventory of Type B packages presently in use and maintained by JLS&A's is limited to specific types of wooden over packs with metal outer shells. These NRC certified over packs are designed and constructed with materials in such a manner that special processes are not required at the present time. However, this does preclude the fact that formally established procedures for special processes are currently in place at JLS&A's facilities and are being applied to other on-going operations at the facility. This area was found to be marginally adequate and in need of some improvement.

9.2 SPECIAL PROCESSES

9.2.1 Program Objective

Special process should be conducted commensurate with applicable instructions that include or reference procedure, personnel, and equipment qualification requirements.

9.2.2 Findings

At the present time, JLS&A's core business activities relative to the use and transport of Type B packages is limited in nature. Applicable designs and associated fabrication activities for new Type B packages by JLS%A's are not currently taking place. Plans or schedules have not been formally established as to when new packages will be designed and applications submitted for regulatory approval.

The responsibility for procedural control of special processes have been assigned to the JLS&A's Shop Foreman for each project or job which requires welding, heat tracing, nondestructive testing and cleaning of items. This responsibility is implemented in conjunction with applicable periodic quality assurance inspections.

The currently approved QAPP includes references to industry standards, such as, ISO, SNT, ASME, AWS, and ANSI to be used as applicable for special processes. The Engineering Department and Shop Foreman, in conjunction with the Quality Assurance Department, have been assigned overall responsibility for maintaining appropriate procedures, equipment, and personnel utilizing industry codes, standards, and specifications as appropriate for special processes or non-destructive testing.

Procedures and written instructions have been established and are being maintained and controlled for special processes, such as, welding and dye penetrates. These procedures contain applicable provisions related to personnel qualifications, equipment capabilities, material, workmanship, and inspection.

9.3 ACCEPTANCE CRITERIA

9.3.1 Program Objective

The requirements of applicable codes and standards, including specific acceptance criteria for the process, should be specified or referenced in procedures or instructions.

9.3.2 Findings

Written instructions and procedures for welding applications are established in support of the special process program and include references to the American Welding Society practices specific to weld join design acceptance criteria.

9.4 RECORDS

9.4.1 Program Objective

Records of personnel qualification, special processes utilized, and equipment used should be filed and kept current.

9.4.2 Findings

Personnel certification and qualifications records are being filed as required for the two individuals approved to carry out welding functions. However, based on reviewing the welders certification records is was revealed that the one of the individuals appeared to have been last certified in 1991 while the other individuals certificate was not dated and therefore could not be validated as to when that certification was issued.

Equipment and special process control records for safety related items are basically non existent due to the fact that the Type B packages and associated Certificates of Compliance do not warrant the use of particular special processes. However, records of this type can be found in other files maintained as part of the JLS%A's DOT 7A package program.

9.5 RECOMMENDATIONS

9.5.1 The original records created to document special processes and the assoc-

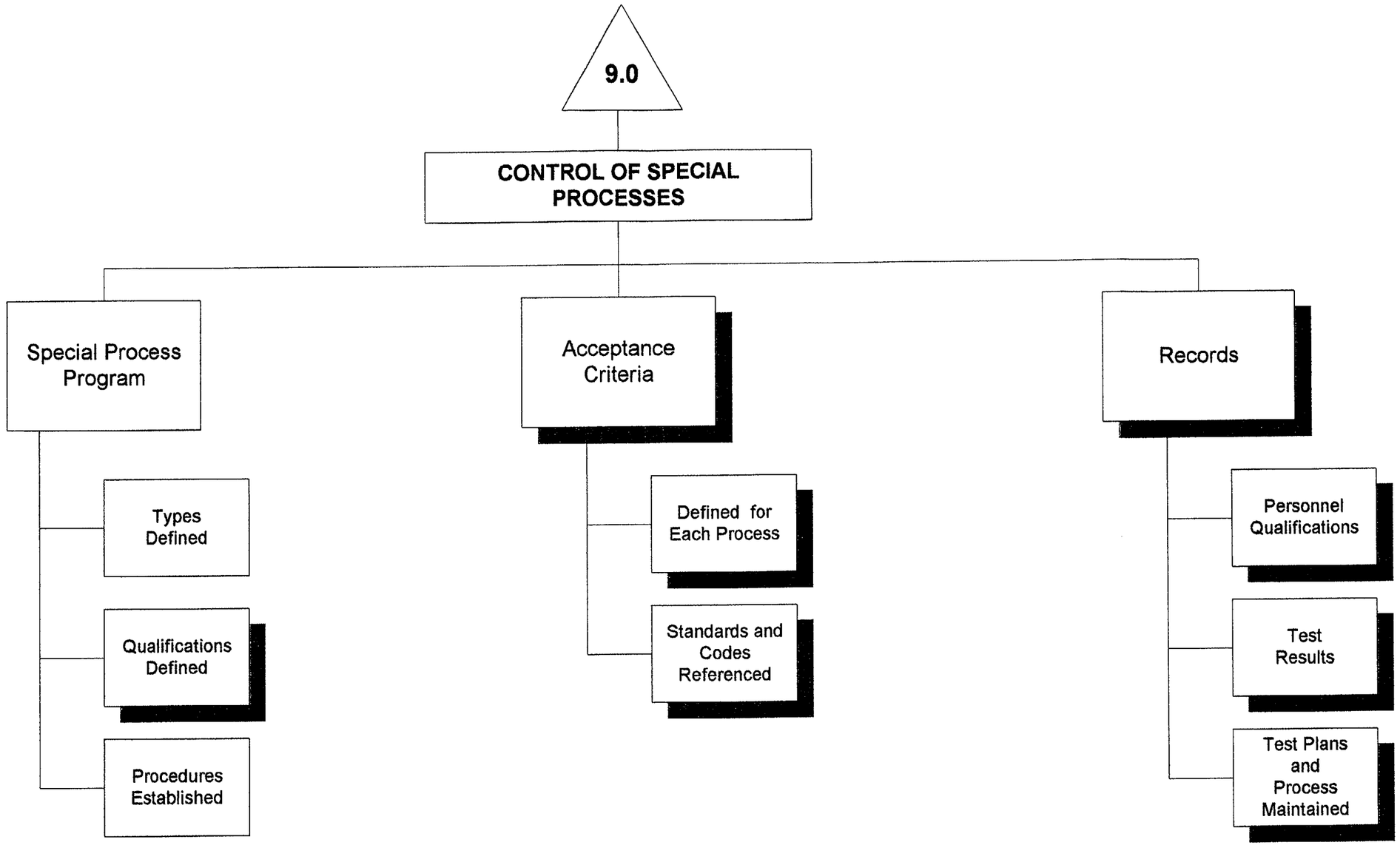
iated results/verifications should be maintained in the controlled files of the Quality Assurance Manager for all special process operations carried out by JLS&A's when operating under the 10CFR71 Quality Assurance Program.

9.5.2 Process procedures and written instructions should be re-organized and revised to allow for a formal designation of procedure hierarchy;

9.5.3 Enhance the instructions and procedures by incorporation of all applicable references to codes, standards, and industry specifications.

9.5.4 Include a basis provision in the procedures and instructions for the distribution of special process results that should require applicable management review and approval.

9.5.5 As appropriate, include in the procedures and instructions, notification and hold points when Quality Assurance inspections need to be applied.


9.0
CONTROL OF SPECIAL PROCESSES
Special Process Program
Types Defined
Qualifications Defined
Procedures Established
Acceptance Criteria
Defined for Each Process
Standards and Codes Referenced
Records
Personnel Qualifications
Test Results
Test Plans and Process Maintained

10.0 INSPECTION CONTROL

10.1 SUMMARY

The inspection control program currently implemented is mainly for support of the radiation instrument calibrator and blood irradiator core businesses. Inspection of new materials and parts for the Type B packages are performed and evaluated for compliance with procurement issued. Inspections of Type B packages are being carried out in accordance with formally established procedures. Personnel authorized to perform the package inspections have been trained and qualified as required for the functions. This area was found to be acceptable, overall.

10.2 INSPECTION PLANNING

10.2.1 Program Objective

Inspection planning should be established to ensure that inspection procedures, instructions, or check lists include identification of the specific characteristics and activities to be inspected; acceptance and rejection criteria; the organization or individuals responsible for performing the inspection; and the recording of objective evidence of the inspection results.

Inspection planning should account for hold or witness points; data approval by supervision to ensure that all inspection prerequisites and requirements have been satisfied, including operator and equipment qualifications; and establishment of sampling methods commensurate with approved procedures or plans.

10.2.2 Findings

Combined sections 1.10 and 2.10 of the QAPP describe the application of the how the basic elements of the Inspection Control Program are intended to be implemented. The associated QP No. 10.0 further describes and implements the program through written instructions and procedures that have been included. One of these procedures, "Standard Shop Policies & Procedure", specifies required protocols to be implemented and specific acceptance criteria application for quality related type activities involving inspection for receipt and fabrication of materials, parts and components in support of the repair and maintenance of Type B over packs. Formal instructions as to how the inspection process is to be carried out are not contained in this procedural document. or any other procedures.

Procedures do exist for the Type B Package program related to inspections for initial use. repair, maintenance and incoming and out going shipments.

These procedures provide adequate detail and instructions for conducting the required inspection activities related to Type B over packs including; acceptance and/or rejection criteria; loading and unloading procedures; QA/QC check lists; and the conformance criteria specified for each of the NRC approved Certificate of Compliance.

10.3 INSPECTIONS

10.3.1 Receipt

10.3.1.1 Program Objective

Measures should be established to ensure that items important to safety that is received meet the specifications of the purchase order. Provisions should be established for the control of items until such time they are accepted and placed into stock as well as for the appropriate disposition of rejected items.

10.3.1.2 Findings

Provisions are established and responsibility is assigned in the "Standard Shop Policies & Procedures" document that address requirements to compare incoming materials against applicable purchase orders. Materials or parts requiring in depth verification and acceptance are re-located to the facility inspection area for final acceptance.

10.3.2 In-Process

10.3.2.1 Program Objective

Provisions should be established to ensure that process criteria and specifications with appropriate supporting documentation should provide for indirect control by monitoring processing methods, equipment, and personnel, when direct inspection is impractical.

10.3.2.2 Findings

The inspection personnel are directed to use those drawings that are applicable to the particular materials or items that they are inspecting. Most of the staff assigned to the manufacturing areas have worked at the facility in the same positions for many years and require very little day-to-day supervisory oversight for the type of core business being implemented by JLS&A at this time. The only activities on going in the manufacturing area are

limited for Type B Packages, except for minimal repair activities and parts replacements applicable to COC type over packs.

10.3.3 Final

10.3.3.1 Program Objective

Final inspection functions should include a review of the results of inspection and the resolution of non-conformances identified in previous inspections.

Inspected items should be identifiable and traceable to specific records and adequately protected from physical or environmental damage.

10.3.3.2 Findings

With regard to manufacturing activities, inspection personnel, are instructed to notify the their supervision, as necessary, when the required inspections result in materials or parts being rejected. Materials or parts that are found not to meet drawings or inspection criteria are either disposed of or returned the respective supplier. Inspection activities in this area have been limited, due to the fact, that the wooden Type B over packs currently authorized to be used by JLS&A have limited application of quality related materials or parts.

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Various staff members' function to provide inspection of Type B packages that are authorized to be used and maintained by JLS&A. These include on-site and off-site package inspections. The Quality Assurance Manager reviews the results of the off-site inspections and authorizes or rejects the planned use of the package for transportation. All other onsite inspections related to the initial use, receipt of packages, or packages prepared for shipment are specifically inspected and approved or rejected by the Quality Assurance Manager.

10.4 INSPECTORS

10.4.1 Qualifications and Certification

10.4.1.1 Program Objective

Methods should be established to ensure that inspection personnel are qualified commensurate with appropriate codes, in-

dustry standards and company programs.

10.4.1.2 Findings

JlS&employment practices tend to focus on recruiting mostly individuals with extensive nuclear experience for the areas dealing with radiation sources and shipping packages. Also, they rely on recruiting personnel with extensive mechanical engineering and manufacturing backgrounds appropriate to specific needs of the company. The technical and experience qualifications of those individuals authorized to perform or verify inspections were reviewed and found to meet acceptable inspector qualification standards.

Based upon a review of training records it was determined that these individuals had received the appropriate inspector indoctrination training by JLS&A, necessary for them to be certified to perform 10CFR71 Package inspections.

JLS&A have an employee on staff who is specifically responsible for the inspection of new materials and manufactured parts. This individual is only authorized to inspect non-quality related items at this time, due to the fact, that he has not been fully trained and qualified to inspect those quality related activities required by 10CFR 71 regulations.

Formally established training and qualifications program for inspection type personnel does not currently exist. Training performed in the past to certify inspectors has usually been provided as part of the annual radiation safety orientation.

10.4.2 Re-Training for Inspectors

10.4.2.1 Program Objective

Programs should be established and maintained for ensuring that inspector's qualifications and certifications are being kept current.

10.4.2.2 Findings

Programs have not been formally established for this type of re-training and re-qualification process.

10.4.3 Organizational Reporting Protocol

10.4.3.1 Program Objective

Organization structures should be defined and implemented that place the inspection personnel functions in a reporting protocol that is clearly independent of the supervisors responsible for performing the work being inspected.

10.4.3.2 Findings

The individual assigned to perform inspections on materials and parts manufactured in the shop areas has a direct line of reporting to the Production/Operations Manager. This inspection person is not currently authorized to perform inspections on quality related items.

Those personnel authorized to performing inspections on approved Type B packages routinely work on the packages. However, the Quality Assurance Manager conducts QA/QC compliance type inspections on the containers to ensure that the required inspection independence is maintained.

10.5 INSPECTION RECORDS

10.5.1 Program Objective

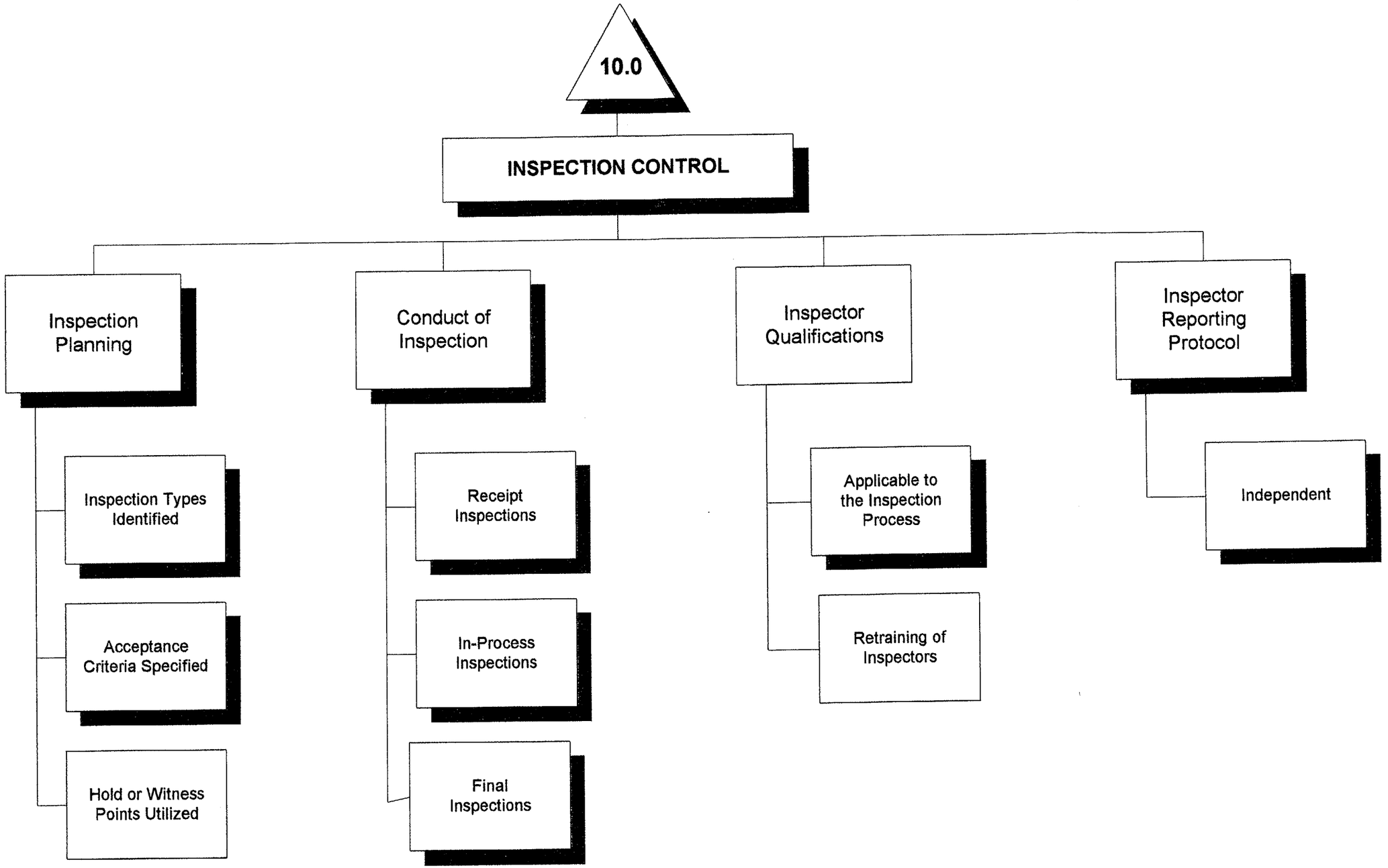
Inspection records should include, as a minimum, the item inspected, specific dates of inspection, inspector, type of observation, results acceptability, and reference to non-conformances.

10.5.2 Findings

Inspection records for various Type B package activities were reviewed for conformance and adequacy. Appropriate QA/QC check lists are being utilized as required and are being maintained in their respective COC, project or customer files.

10.6 RECOMMENDATIONS

10.6.1 Establish a formal re-certification and re-training for those inspectors assigned responsibility for inspection of materials and parts associated with the fabrication activities.


10.0
INSPECTION CONTROL
Inspection Planning
Inspection Types Identified
Acceptance Criteria Specified
Hold or Witness Points Utilized
Conduct of Inspection
Receipt Inspections
In-Process Inspections
Final Inspections
Inspector Qualifications
Applicable to the Inspection Process
Retraining of Inspectors
Inspector Reporting Protocol
Independent

11.0 TEST CONTROL

11.1 SUMMARY

Formalized management controls for day-to-day administration of the JLS&A Test Control Program have not been established and implemented using specific and structured procedures. Broad descriptions related to program responsibilities and accountabilities are stated in the QAPP and associated QP's. Procedures for the conduct of package transportation activities, as they apply to test control, are adequate. This element of the program is considered to be marginally adequate and in need of some improvement.

11.2 TEST CONTROL PROGRAM

11.2.1 Program Objective

A formalized test control program should be developed, implemented and maintained for the program areas associated with package designs, modifications, and repair or replacement.

11.2.2 Findings

A broad description of the Test Control Program is included in the QAPP, Annex 1,1.11, which addresses, two major components of the JLS&A test program related to the testing of new types of package designs and the preparation of packages for shipments. Policy statements are included in the QAPP that make commitments to establish, as applicable, documented specifications and associated records. Also, policy statements address the commitments for establishing procedures to appropriate test requirements and acceptance criteria as well as the protocol related for documentation, evaluation, and acceptance of test results.

Policy statements contained with in QAPP Annex, 2,2.11, address specific commitments to having an established program for package shipment preparation. These include departmental responsibility protocols related to defining acceptance criteria and documentation requirements, prior to shipments being authorized. Also, commitments to the program, address package maintenance test measures relative to maintaining them usable and for controlling them frees of excessive levels of contamination and radiation.

11.3 TEST PROGRAM PROCEDURES

11.3.1 Program Objective

Specific test requirements, prerequisites, and acceptance criteria should be incorporated into test plans, or checklists, and procedures, to ensure that packages and equipment will perform satisfactorily in service and that they are in accordance with the original design.

11.3.2 Findings

QAPP implementing procedure QP No. 11.0, Revision 0, dated 3/4/91, was developed by JLS&A to further define and implement the Test Program related to prototype package design, manufacturing and test. This QP does not address the area of package modification, maintenance, and repair or replacement. The QP format includes two specific sub-areas. These sub-areas contain information relative to commitments to industry guidance and standards defining and meeting test criteria, as well as, stating that all test results are fully documented, evaluated, and determined acceptable by appropriate departments.

Based on a review of the information provided in the QAPP and QP 11.0, the independent auditor found that there is inadequate procedural detail established regarding the administration and full implementation of the Test Program. The independent auditor was not provided or able to identify any other documents during the audit which specifically dealt with implementing this element of the QAPP.

The management of JLS&A's believe the management controls and implementing procedures will be established at the initial design stages, at which time, they will determine the specific type of required prototype testing that will be necessary and the applicable standards criteria that would need to be applied. Their reasoning for this is, that due to the fact, that they currently are not using or have in their approved inventory any Type B packages that require testing other than that testing required for determination of contamination and radiation levels for package shipments.

With regard to the area of test control for packages being prepared for shipment procedures have been established are being maintained and revised as necessary to reflect current receiving and shipping operations. The implementing procedures and associated checklists for the conduct of these operations are issued and controlled under QP's 10.0 and 13.0, respectively.

Based upon a review of these particular procedures the independent auditor determined that sufficient procedural detail regarding criteria, actions, acceptance/rejection protocols, review, and documentation had been established and that the procedures were implemented appropriately.

11.4 TEST RESULTS

1.4.1 Program Objective

Test results should be documented and reviewed by a qualified individual in order to assure that test requirements were satisfied. Provisions should be established for re-testing when it is determined that acceptance criteria was not met.

11.4.2 Findings

There were no test results associated with the design of new or prototype packages available during the course of the audit, due to fact, that there are no activities under development in this area or that have taken place in the past that require such testing. However, tests/ measurements results, for the packages implemented under the 10CFR71 transportation aspects of the program appeared to be performed documented in accordance with established implementing procedures.

11.5 RECORDS

11.5.1 Program Objective

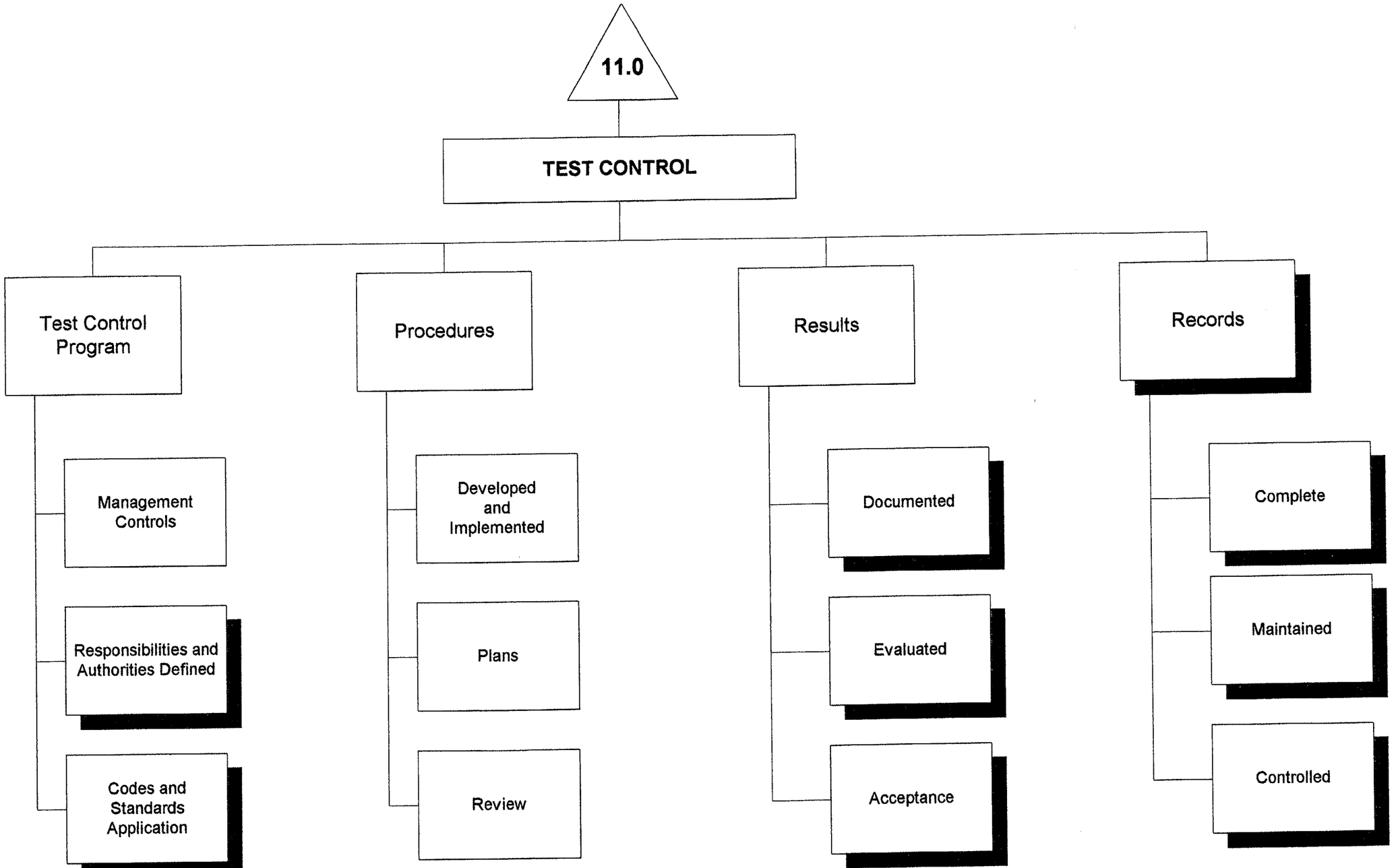
Records should be maintained that include such information as identification of the item tested, date of test, tester, observations, results and acceptability, action taken for deviations identified, the individual evaluating the results.

11.5.2 Findings

Records reviewed relevant to the Type B package transportation aspects for incoming and out going shipments revealed that forms were being completed and package inspections were performed in accordance with established procedures.

11.6 RECOMMENDATIONS

11.6.1 Develop and implement procedures that contain applicable instructions and management controls for effective implementation and maintenance of the test control programs appropriate to the design of prototype or manufactured packages.


11.0
TEST CONTROL
Test Control Program
Management Controls
Responsibilities and Authorities Defined
Codes and Standards Application
Procedures
Developed and Implemented
Plans
Review
Results
Documented
Evaluated
Acceptance
Records
Complete
Maintained
Controlled

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT (MT&E)

12.1 SUMMARY

The MT&E program was found to be ill defined; lacking formal implementing procedures; MT&E inventory tracking lists revealed that many of the equipment calibrations over due; unauthorized MT&E was being utilized; and less than adequate management controls and oversight were being implemented. This element of the program was found to be inadequate and in need of major improvement

12.2 PROGRAM RESPONSIBILITY

12.2.1 Program Objective

Program responsibilities for the control and oversight of M&TE used for activities affecting quality should be clearly defined, implemented, and controlled in accordance with established procedures.

12.2.2 Findings

Based on a review of the QAPP and the associated QP it was determined that responsibility for the oversight and control of the MT&E program has not been established formally in procedures or written instructions. The independent auditor was informed by JLS&A management that general re-ponsibilities for the MT&E program, such as, equipment specification selection, tracking, calibration and maintenance were assigned to the Lead Engineer. A further review of the program validated this designation. It was further determined that the Production/Operations Manager assumes program responsibility related to the operational uses and the appropriate processing of MT&E (procurement) for the annual calibrations and re-certifications, as required.

12.3 SELECTION OF MT&E

12.3.1 Program Objective

A formalized system for the selection of appropriate types, ranges, accuracy, and tolerances of MT&E devices should be developed and implemented for purposes of verifying conformance to specified requirements.

12.3.2 Findings

The responsibilities for defining and the selection of MT&E has been

assigned to the Engineering Department. Their selection criteria is based n the need to measure materials, equipment, or component characteristics necessary to meet design specifications established. The review of this area established the fact, that these responsibilities assigned to the Engineering Department, are not formally established using written instructions of procedures.

12.4 CALIBRATION OF MT&E

12.4.1 Program Objective

MT&E should be calibrated, adjusted, and maintained at scheduled intervals against certified equipment or standards having been validated through nationally recognized standards.

The method and interval of calibration should be based on the type of device, its stability characteristics, required accuracy, purpose, the frequency of usage, environmental conditions, and other factors affecting the device's performance.

12.4.2 Findings

JLS&A has established MT&E calibration intervals of quarterly for radiation measuring instruments and an annual frequency for non-radiation types which are maintained in accordance with approved industry standards.

JlS&A use a computerized inventories tracking method for maintaining accountability of MT&E devices. The MT&E inventory tacking list, titled, "Metrology equipment @ JLS&A as of July 1999" was reviewed and found to document the fact that three (3) types of MT&E were over due for calibration, were still out in the inspection area available for use, and had not been tagged out nor been removed from service for required re-calibrations.

Specific MT&E determined to be over due for required calibrations were as follows:

- 0-12" Inside Micrometer, Model No. 141.33, S N. 1027, (Due 01/19/2000)
- 0-6" Outside Micrometer, Model No. 104-137A, SN. 81116631 (Due 01/19/2000)
- (7) piece Gage Block Set, Model No. N/A, SN. CC25182 (Due 04/12/2000)

It is important to note that a vendor audit was performed on the JLS&A Qual-ity Assurance Program, the day before the start of the "independent" on-site audit effort, which identified some MT&E that was coming due for required calibrations in the latter part of September and mid-October time frames. As a follow up to this information, JLS&A management instructed other staff members to remove them from service and ship them out for re-calibration and determine if other MT&E needed similar processing. Unfortunately, the MT&E that was in current calibration, was removed, but types identified by the independent auditor were not removed as instructed by Operations supervision.

It was also identified during this area of the audit, that the vendor, who is contracted to calibrate the MT&E, has placed the measuring equipment on a six- (6) month frequency with out notifying JLS&A management of the frequency changes. JLS&A did not authorize this frequency change nor were they aware of the basis for the change. It was explained to the auditor that this vendor routinely contacts a member of the JLS&A about a month in advance regarding the status of MT&E coming due for calibration.

12.5 MT&E CONTROL

12.5.1 Program Objective

Provisions for control of MT&E should be developed, implemented, and maintained which includes tagging, labeling, and controlled use.

Special controls for usage, handling and storage should be applied and documented when situations arise that are impacted by factors, such as temperature, humidity, cleanliness, or operating characteristics of the devices.

Calibration methods should be documented and performed by only qual-fied personnel in environments that do not adversely affect the calibra-tion.

12.5.2 Findings

Formal measures in the way of written instruction or procedures have not been established for the control of MT&E. Based upon a walk down of the various office and operational areas with in the main facility several locations were identified that contained various types of MT&E either stored or lying out in the open. It was very apparent, that based on these observations, a formal system for control accountability and issuance had not been established and implemented.

All of the MT&E reviewed and observed had the necessary labeling affixed to the respective containers signifying the dates when calibrations were due. There are no specific tagging provisions established for the MT&E program. MT&E observed by the auditor in the inspection areas of the facility did not bear any sort of tagging signifying that the MT&E should not be used. However, the individual authorized to perform inspections was aware that that the specific MT&E was over due for calibration. In lieu of using this disqualified measuring equipment, with out the authorization or knowledge of JLS&A management, he brought in his privately owned MT&E as replacements. JLS&A management indicated that they expect employee's to bring in their own tools for use, as necessary.

It important to note that the individuals (personal) uncertified measuring equipment nor that of JLS&A had been used previously on quality related materials, parts, components, or equipment. However, that does not eliminate the concern for inadequate control of measuring equipment that is to be maintained under the 10CFR71 Quality Assurance Program .

MT&E required for measuring external radiation and contamination levels to ensure compliance with 10 CFR Parts 71.47 and 71.87, respectively, were reviewed. The review revealed that JLS&A routinely uses Eberline Model 5 E-520's for determining external radiation levels for package transportation purposes. Also, laboratory type radiation monitors are used to measure/count smears for determining non-fixed radioactivity levels on packages received or being shipped. The inventory of this MT&E is required to be calibrated on a quarterly basis.

Records of calibrations for this MT&E were reviewed and found to be in non-compliance in several instances with regard to being calibrated with in the time intervals. Specifically, Eberline E-520's #5444 exceeded the criterion on more than one occasion. The auditor noted to JLS&A that acceptable industry practice allows for this type of radiation measuring equipment to be calibrated on semi-annual frequency. Accordingly, JLS&A current calibration frequency is conservative in nature.

A further review, of the calibration records, revealed a program weakness related to documenting calibration data on established forms. There is little consistency being implemented with reference to utilizing data forms established by the supervisor in charge of the calibration program. Several staff members have taken the unauthorized liberty to write in changes to pre-established measurement specifications and acceptance criteria. This is apparently resulting from the individual's philosophy or experience or for ease of the performing the task.

The radiation instrumentation program is authorized, controlled and being implemented under the JLS&A license issued by the State of California. Formal administrative and implementing procedures are not specifically required under that license. Accordingly, necessary formal procedures for the conduct of the calibration of radiation measuring equipment are non-existent to for implementing the applicable provisions of 10 CFR Part 71.

The requirement to maintain appropriate types of radiation instruments under the 10CFR71 Quality Assurance Program was discussed with the Quality Assurance Manager who indicated that there was not a mutual understanding as to the applicability of this matter under 10CFR71. This difference of opinion, on the part of the Quality Assurance Manager, was based on previous discussions with NRC staff who indicated that radiation instruments did not apply to the 10 CFR Part 71 Quality Assurance Program.

This is an area that needs to be resolved between the NRC and JLS&A in order to ensure that the administration of the MT&E program meets regulatory requirements.

12.6 OUT-OF -CALIBRATION EQUIPMENT

12.6.1 Program Objective

Administrative controls should be established for controlling the continued use of out- of-calibration MT&E devices, such as, tagging or segregation. Provisions should be established to evaluate and validate the acceptability of items previously inspected by the MT&E devices.

12.6.2 Findings

Administrative controls for controlling MT&E found to be over due or out-of-calibration are not established and implemented. Additionally, informal type measures for controlling unqualified MT&E appear to be non-effective. Formal provisions for initiating and completing a review of data for acceptance when MT&E is found over due or out-of-calibration have not been established.

12.7 RECORDS

12.7.1 Program Objective

Records of calibration history should be maintained and MT&E devices should be marked to indicate calibration status.

12.7.2 Findings

Records documenting the results of calibrations and validation certificates are being filed and retained as required. Records applicable to the inventory and accountability of MT&E are not being maintained current. Specifically, inventory lists for non-radiation type MT&E identify that many of the measuring tools are considerably past the required dues dates, going back as far as 01/19/2000. The Lead Engineer last updated the inventory list in July 1999. With regard to radiation type MT&E, current inventory lists, maintained by JLS&A, accounted for two (2) Eberline E-520 instruments that were found to be no longer in the possession of JLS&A.

12.8 RECOMMENDATIONS

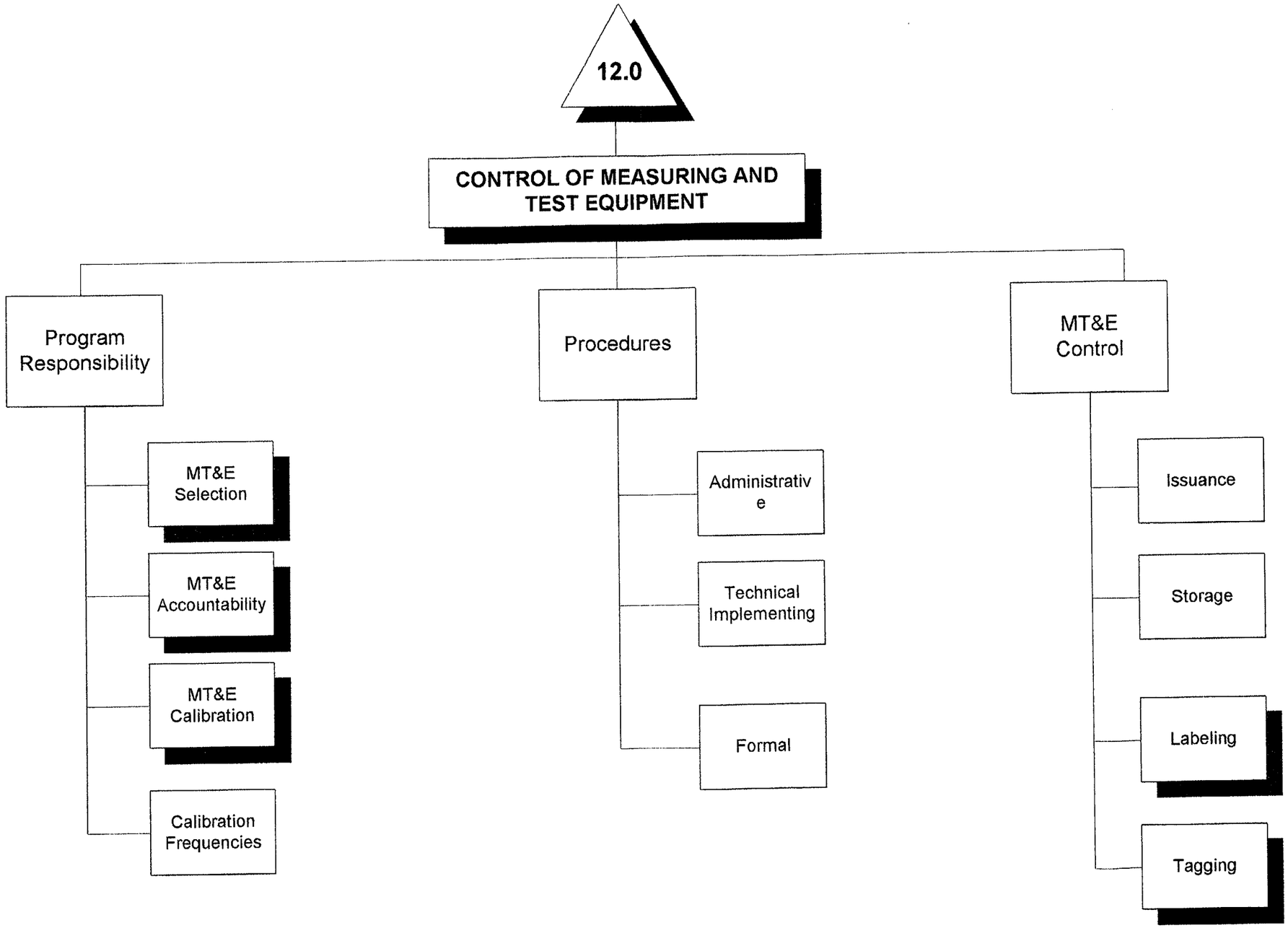
12.8.1 Establish specific MT&E responsibility to staff managers, appropriate to functional use and expertise, utilizing formally established procedures. Include specifics responsibilities related to the determination and criteria for measuring equipment, inventory accountability, use, and calibration.

12.8.2 Establish and implement formal controls for removing and processing of over due or out-of calibration MT&E. Include a system of tagging and quarantine for the applicable disqualified equipment. Include provisions for requiring the evaluation and acceptance of test data for those situations when MT&E are found out-of-calibration.

12.8.3 Establish administrative and technical procedures, as appropriate, for on-site and off-site calibration and processing of MT&E.

12.8.4 Establish a system for periodically updating MT&E inventory lists so they are maintained current and accurate.

12.8.5 Train and hold the staff accountable for completing calibration forms and records in accordance with established formats and criterion.


12.0
CONTROL OF MEASURING AND TEST EQUIPMENT
Program Responsibility
MT&E Selection
MT&E Accountability
MT&E Calibration
Calibration Frequencies
Procedures
Administrative
Technical Implementing
Formal
MT&E Control
Issuance
Storage
Labeling
Tagging

13.0 HANDLING, STORAGE, AND SHIPPING CONTROL

13.1 SUMMARY

The handling, storage, and shipping program is very limited in nature as it directly applies to safety related activities. This being, there is very little need for materials to be procured and stored, for the type of packages being repaired and maintained by JLS&A. However, there is storage and shipping controls necessary for the transportation activities. Those activities were audited under section 14.0 to this report. This program area overall was found to be adequate.

13.2 INSTUCTIONS AND PROCEDURES

13.2.1 Program Objective

Procedures or instructions should be developed and implemented as necessary to ensure that cleaning, handling, storage, and shipping are accomplished as required by package deign requirements.

As necessary, provisions should be identified for the use of special handling, lift-ing, or storage.

13.2.2 Findings

Procedures are established and maintained by JLS& which specifically address the safe handling and storage of over pack type packages. Specific provisions are included in the procedures for loading and unloading the over packs with regard to transportation activities. Cleaning of the over pack packages is done, as necessary, based on radiation smear testing protocols.

13.3 TOOLS AND EQUIPMENT

13.3.1 Program Objective

Specialized handling tools and equipment should be utilized as necessary to ensure safe and adequate handling.

13.3.2 Findings

The handling of over packs requires minimal engineered or tested tooling for the opening and closing of the over packs used by JLS&A.

Fork lifts and crane hoists are used for support, as necessary, for the opening and closing of packages and movement.

JIS&A provide training and certification for the staff members authorized to operate the forklifts.

13.4 MARKINGS

13.4.1 Program Objective

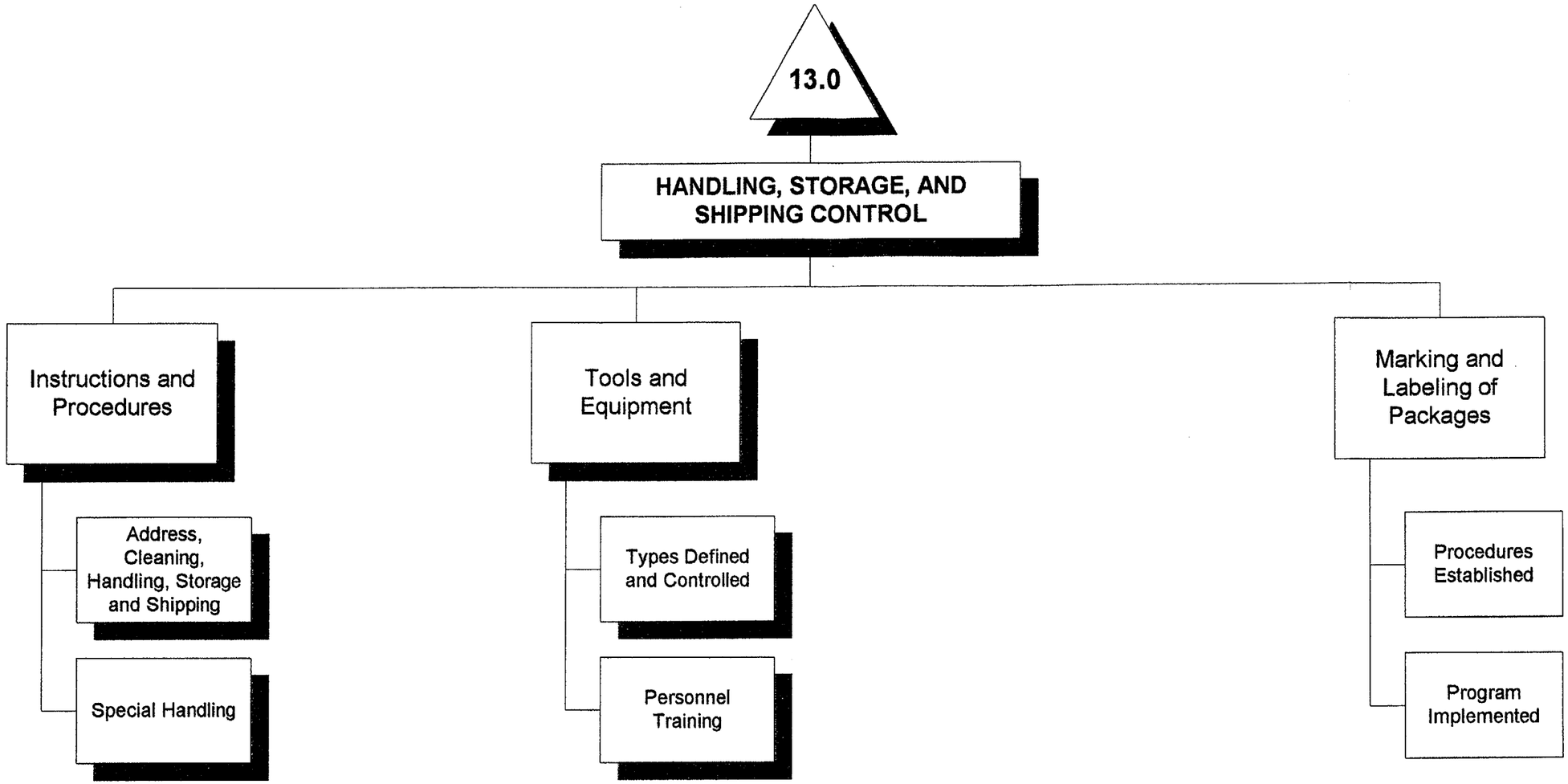
Instructions or procedures for marking and labeling packages for shipment, handling, and storage should be provided as necessary to adequately identify the need for special controls.

13.4.2 Findings

Controlled implementing procedures exist that provide for the verification that shipments involving the use of the Type B packages are properly marked and labeled in accordance with applicable NRC and DOT regulations. Effective implementation of these procedures was considered adequate based on a review of shipment records and packages in storage.

13.5 RECOMMENDATIONS

None necessary


13.0
HANDLING, STORAGE, AND SHIPPING CONTROL
Instructions and Procedures
Address, Cleaning, Handling, Storage and Shipping
Special Handling
Tools and Equipment
Types Defined and Controlled
Personnel Training
Marking and Labeling of Packages
Procedures Established
Program Implemented

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 SUMMARY

This area of the program regarding inspection, testing, and operations is formally established, implemented, and is being maintained appropriately. Some critical areas of the Type B package program implementing procedures have been revised to enhance the inspection process and the control of the packages. The audit of the associated package COC's, inspection results, and shipment records indicate that the package transportation activities are carried out as required. This element of the program was found to be adequate.

14.2 INSPECTION AND TEST STATUS CONTROL MEASURES

14.2.1 ADMINISTRATIVE CONTROLS

14.2.1.1 Program Objective

Formal controls should be developed and implemented that identify inspection and test status in order to assure that required inspections and tests are performed and that the acceptability of tested and inspected items are made known to facility operation personnel, with non-conforming items being clearly identified.

14.2.1.2 Findings

Formal procedures have been established and implemented that include provisions for performing inspection of packages and associated controls. Implementing procedures for each series or type of packages contain detailed check lists specifying all of the COC conformance criteria that must be satisfied in order for the package to be determined acceptable for use. Quality assurance staff sign off is required on the inspection forms attached to the implementing procedures. The Quality Assurance manager as a rule is the signing authority for this important verification.

14.2.2 STATUS INDICATORS

14.2.2.1 Program Objective

Controls should include appropriate provisions for the use of status indicators, such as, the physical location and tags, markings, shop travelers, stamps, or inspection records

including authority for application and removal of indicators.

14.2.2.2 Findings

Appropriate controls are contained in implementing procedures that address the tagging and removal from service packages that are found to be non-conforming based on inspection results.

The auditor reviewed packages that have been declared by the Quality Assurance Manager to be of a non-conformance nature and subsequently removed from service. This review determined that all non-conforming packages were properly tagged and removed from service. As an added management, control the non-conforming packages had been re-located to a separate facility for quarantine.

14.3 LOCKOUT AND TAGOUT CONTROLS

14.3.1 Program Objective

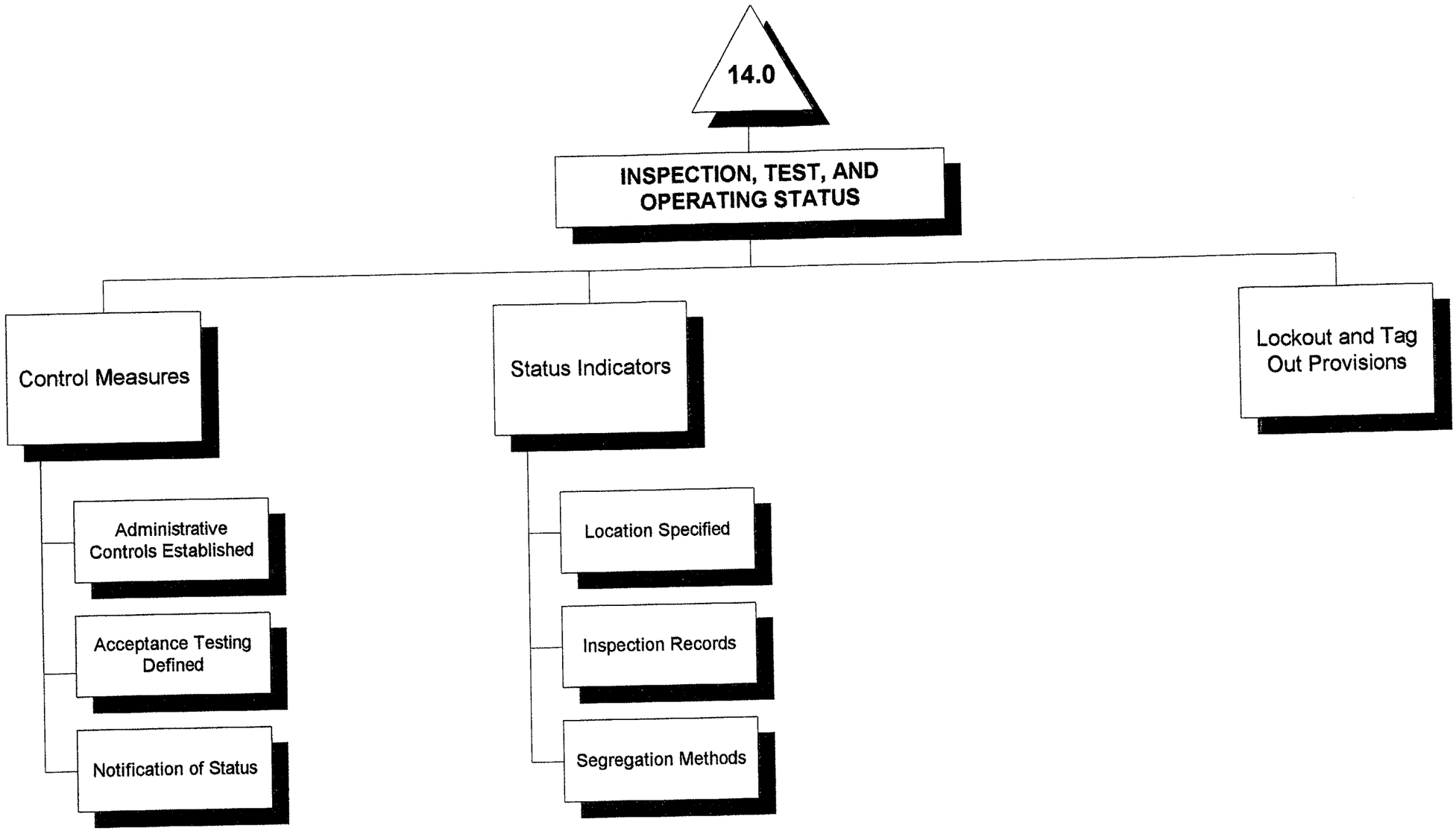
Administrative controls should be developed and implemented that provide for identifying the operating status of components of the packing, such as tagging valves and switches, to prevent inadvertent operation.

14.3.2 Findings

The current Type B packaging authorized and used by JLS&A are not designed such that valves and switches are included in the package configuration. Accordingly, there are no findings in this area.

14.3 RECOMMENDATIONS

None necessary


14.0
INSPECTION, TEST, AND OPERATING STATUS
Control Measures
Administrative Controls Established
Acceptance Testing Defined
Notification of Status
Status Indicators
Location Specified
Inspection Records
Segregation Methods
Lockout and Tag Out Provisions

15.0 NONCONFORMING MATERIALS, PARTS, AND COMPONENTS

15.1 SUMMARY

The area of the program was found to be acceptable. Non-conformances appear to be identified and required actions for dispositioning non-conforming materials and packages are implemented satisfactorily.

15.2 CONTOL OF NONCOFORMANCES

15.2.1 Program Objective

Program and procedures are developed, implemented, and maintained for reporting; identifying, documenting, evaluating, segregating, disposition of nonconforming items and notifying affected entities.

15.2.2 Findings

Implementing procedures applicable to the non-conformance program have been developed and implemented. Recent enhancements to the implementing procedure developed for inspection and use of the Type B overpacks have been initiated and completed.

15.3 IDENTIFICATION, SEGREGATION, AND DISPOSITION

15.3.1 Identification

15.3.1.1 Program Objective

Procedures or instructions should be established and implemened to identify non-conformances along with those individuals or groups responsible for approval of the disposition nonconforming items.

15.3.1.2 Findings

Implementing procedures established contain provisions for the receipt and inspection of parts and materials procured in support of the Type B package repair and maintenance activities performed by the shop. Packages approved for use by JLS&A contain commercial grade constituents (i.e., balsa wood, steel, bolts, and plywood) that are normally found to be in conformance when inspected.

Type B packages in their entirety, are controlled and inspected upon receipt, following repairs, and prior to shipment for conformances with Certificate of Compliance issued for approval of the package. Operations type personnel (on-site and off-site) are assigned responsibility for the initial inspections of the packages, with oversight and approval of inspection results, by the Quality Assurance manager.

15.3.2 Segregation

15.3.2.1 Program Objective

Procedural controls should be established to ensure that nonconforming items are quarantined or placed in controlled holding areas, or in the case of large items, special storage marking or roping should designate areas.

15.3.2.2 Findings

As described above, the Certificate of Compliance specifications for Type B packages used by JLS&A require generic or commercial types of parts and materials. If these items are found to be of a non-conforming nature, when inspected, they are normally returned to the supplier for replacement. Many of the parts and materials are purchased at local industrial retailers such as Home depot, etc.

With respect to Type B overpacks, if they re inspected and found to be of a non-conformance nature, they are tagged and relocated (quarantined) at a separate JLS&A approved facility.

15.3.3 Disposition

15.3.3.1 Program Objective

Formal controls using written procedures should be established for ensuring that the acceptability of nonconforming items is verified by re-inspection or re-testing including 10 CFR Part 21 reporting.

15.3.3.2 Findings

Formal controls are clearly stated in procedures regarding the appropriate disposition protocols for Type B packages. The Quality Assurance Manager has been assigned responsibility

and held accountable for re-inspection, re-testing and acceptance of the Type B package nonconformance activities.

15.3.4 Evaluation

15.3.4.1 Program Objective

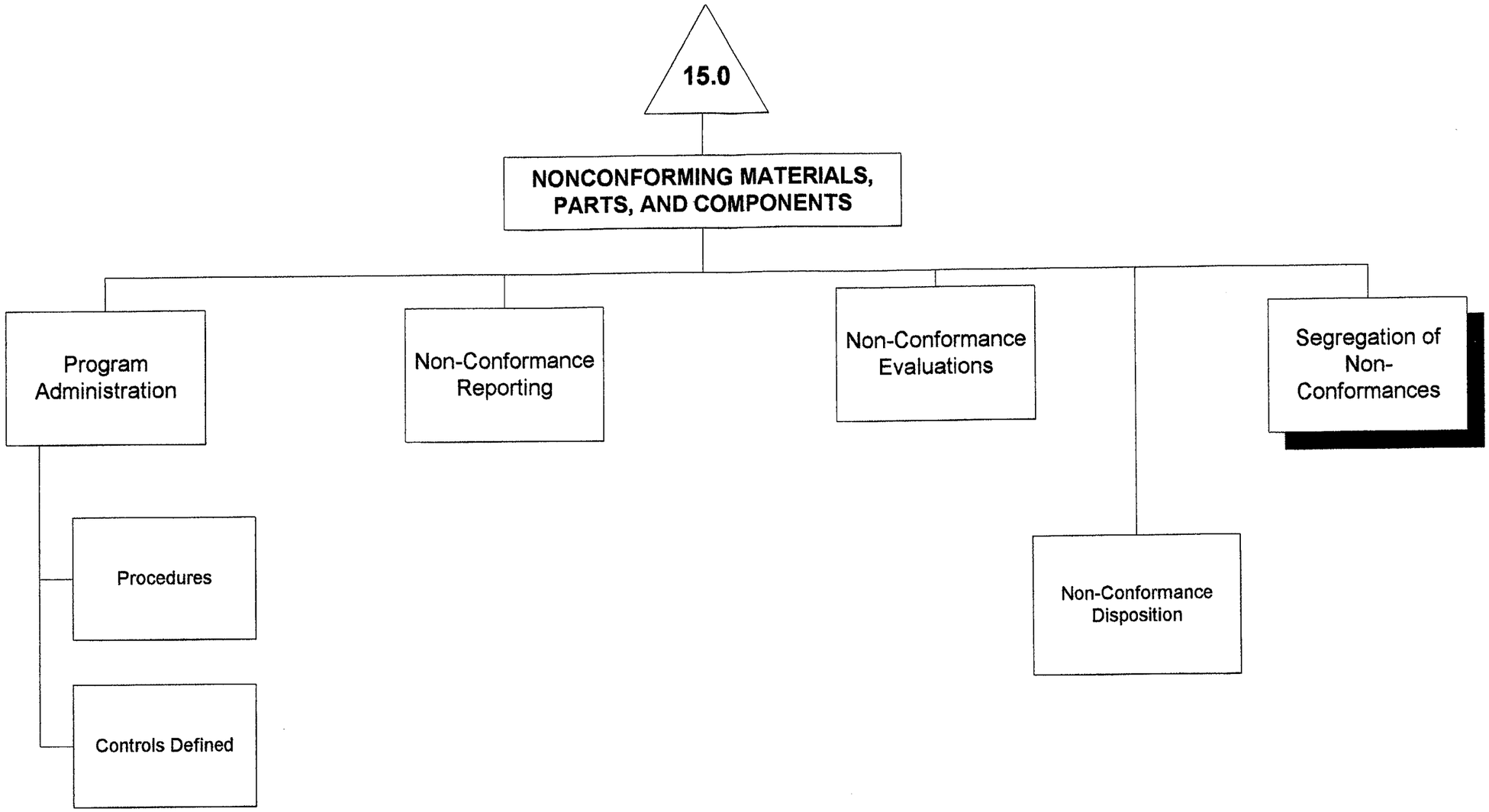
Reports of conditions that are adverse to quality should be analyzed in order to identify trends in quality performance for appropriate management review and action.

15.3.4.2 Findings

The Quality Assurance Manager has the responsibility to evaluate Nonconformance for adverse quality trends. This trending is not formally documented. However, the Quality Assurance Manager indicated that a binder for consolidating reports identifying conditions adverse to quality has been established.

15.4 RECOMMENDATIONS

15.4.1 Establish a method to formally track, evaluate and report trending of all nonconformance. Issue reports to management personnel on a scheduled basis.


15.0
NONCONFORMING MATERIALS, PARTS, AND COMPONENTS
Program Administration
Procedures
Controls Defined
Non-Conformance Reporting
Non-Conformance Evaluations
Segregation of Non-Conformances
Non-Conformance Disposition

16.0 CORRECTIVE ACTION

16.1 SUMMARY

This area of the quality assurance program is found to have a minimal level of formality in the way of instructions and procedures necessary to ensure that non-conforming materials, components, and services are adequately identified, corrected, reported, monitored and closed out. A minimal level of information and instruction is formally documented in the QAPP and associated QP. Several findings identified during the course of this audit are considered symptomatic of a program weakness do to the lack of procedural formality as it pertains to the ability of the operating staff to identify, report and correct nonconformance. This element of the program was found to be marginally adequate.

16.2 CORRECTIVE ACTION PROGRAM

16.2.1 Program Objective

Formal programs should be established which define requirements and responsibilities for identifying, documenting, reporting, verifying and closing out corrective actions applicable to departures from specific quality related requirements.

16.2.2 Findings

The QAPP section that governs this area of the quality assurance program provides only a description of the activities that are to be carried out rather than an appropriate level of detail to adequately implement the key elements of the corrective action process. The document refers to several sections of the QAPP for implementation purposes. However, based upon a review of the referenced procedures, there is an inadequate level of detail or written instruction provided to effectively execute the management controls that are relative to the Corrective Action Program. QAPP implementing procedure QP 16.0 "Corrective Action Reports", in a limited way, contains provisions for utilizing a special form, entitled, "Material Rejection" to identify and initiate corrective actions relative to non-conforming parts and materials.

JLS&A has also developed and implemented an additional method of corrective action control in the form of a "QA/QC Red Tag". This control mechanism is formally established as an implementing instruction. Only the Quality Assurance Manager (or designee) can affix or remove the Red Tag from the non-conforming pack-age.

Assignment of responsibilities for implementing specific areas of the Corrective Action Program is broad and generic in nature. Basically, as the program is currently implemented, it is appears that the full execution of the corrective action process is maintained and carried out by the Quality Assurance Manager.

16.3 PROGRAM IMPLEMENTATION

16.3.1 Program Objective

Procedures should be established, implemented and maintained for corrective and preventive action related to:

- ***Investigation and reporting of the root cause of non-conformances relating to processes, services, and the quality system.***
- ***Determination of corrective actions necessary to eliminate the cause of non-conformities.***
- ***Implementation of controls for ensuring that corrective actions are taken is effective.***

16.3.2 Findings

A formal program for conducting investigations and the reporting of the root causes for major non- conformances have not been established and implemented.

A formal program for initiating and conducting root cause analysis has not been established for those situations involving non-conformance of programs, materials services, or equipment at a magnitude that requires an in-depth understanding to clearly identify the reasons for failure and appropriate corrective actions to prevent recurrence.

16.4 REPORTING AND NOTIFICATIONS

16.4.1 Program Objective

Formal methods are developed and implemented for reporting to appropriate levels of management, significant conditions adverse to quality supported with the causes and associated corrective actions.

16.4.2 Findings

Formal methods used to report non-conformances to management are implemented by using the Material Rejection form attached to QP 16.0 as discussed above. There are no formal mechanisms established to report non-conformances resulting from formal audits or daily surveillance of operating activities. Formal documented measures have not been estab-

lished that addresses the reporting and notification of 10CFR21 reportable events.

16.5 10CFR21 REPORTING

16.5.1 Program Objective

Corrective actions under the purview of 10CFR21 are reported, distributed, tracked, and closed in accordance with approved procedures.

Required 10CFR Part 21 documents should be posted in areas frequened by the company staff.

16.5.2 Findings

Based on inspections of the operating areas during the audit of the JLS&A facilities it was verified that required 10CFR Part 21 documents were conspicuously posted in at least two major areas frequented by staff members.

16.6 DOCUMENTATION AND RECORDS

16.6.1 Program Objective

Documentation of corrective actions includes such information as root cause analysis, logs, formal reports, objective evidence of satisfactory implementation, and the cost of conformance. Records are maintained as quality related by quality assurance management.

16.6.2 Findings

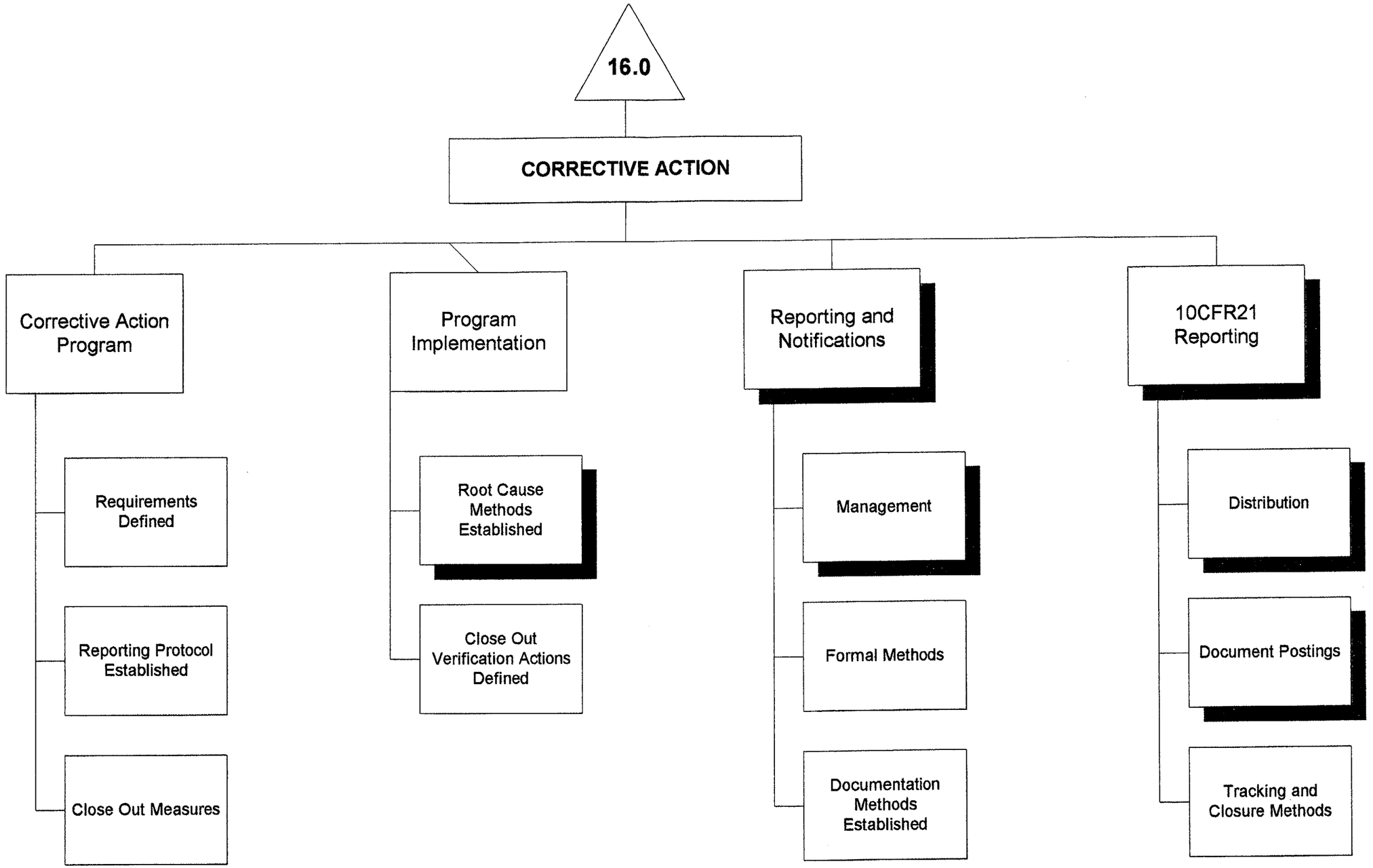
There is no designated filing system formally established and maintained for documentation that is directly related to non- conformance and corrective action events. The current company record filing methodology is to file all documents in their related project or customer file. Designation of these particular records as having "safety significance" has not occurred and thusly is inter- mingled in with all the non-safety related documents

16.7 RECOMMENDATIONS

16.7.1 Formally establish and implement procedures, which clearly define all of the pertinent aspects, required for the effective implementation of the Corrective Action Program.

16.7.2 Establish and implement a formal reporting and notifications protocol for the program, as appropriate.

16.7.3 Develop and implement a formal program for the filing and retention of quality related records generated under this program.


16.0
CORRECTIVE ACTION
Corrective Action Program
Requirements Defined
Reporting Protocol Established
Close Out Measures
Program Implementation
Root Cause Methods Established
Close Out Verification Actions Defined
Reporting and Notifications
Management
Formal Methods
Documentation Methods Established
10CFR21 Reporting
Distribution
Document Postings
Tracking and Closure Methods

17.0 QUALITY ASSURANCE RECORDS

17.1 SUMMARY

A formalized system of records currently does not exist for the 10CFR71 Quality Assurance Program. A system for designating records as "life time or non-permanent" and for stamping or marking records to indicate that they are quality records has not been established and implemented. However, records relating to quality are currently being maintained in user files with limited control. Licensing documents, such as, required NRC Certificates of Compliance and the associated drawings and instructions are filed separately and maintained in office area of the Vice President, Special Projects and Licensing. This element of the program is considered to be marginally adequate. This finding is mainly focused on the lack of formality associated with record management. However, appropriate quality related records are being maintained as required, in spite of program formality.

17.2 RECORDS ADMINISTRATION

17.2.1 Program Objective

A comprehensive system of records management should be in place that furnishes documentary evidence of the quality of safety related parts, components, licensed packages, services or activities that implement federal requirements.

17.2.2 Findings

The currently approved NRC 10CFR71, Subpart H, Quality Assurance Program Plan does not commit to or make reference to industry guidance or standards for establishing, implementing, and maintaining a quality related system of records management. The historical practice or quality records management being implemented by JLS&A's is to consolidate all records, including quality records, into designated customer or project files. This philosophy, as indicated by JLS&A'S management, is for ease of access to historical information for a particular project.

Quality related records, such as, license documents authorizing the use and transportation of Type B packages are maintained in separate file cabinets in the office area of the Vice President, Special Projects. Also, documents related to licensing matters for 10 CFR 71 applications and compliance are maintained in file cabinets located in the office area of the Vice President, Special Project & Licensing. Records documenting training and personnel qualifications are also filed separately in file cabinets.

17.3 RECORD AUTHENTCITY

17.3.1 Program Objective

Systems or processes should be implemented and maintained that specify the validating of records through means, such as, stamping, initialing, or signing and dating by authorized personnel or other authenticating methods.

17.3.2 Findings

Based upon a review of selected quality related records it was verified that applicable forms and records are being signed of by personnel assigned responsibility for their functional areas. It was noted that form used for review and approval, inspection and acceptance of quality-related items or verifications appear to be signed off by only those individuals authorized.

Quality records reviewed appeared to be made up of a mix of the original documents or copies of the original document. There is no identifying markings or stampings that distinguishes between an original document and a copy of the original document.

17.4 RECORD RETENTION

17.4.1 Program Objective

Records should be indexed and classified as to the duration of time they are to be preserved as specified by regulatory requirements. This may include "life time" or "nonpermanent" type classifications.

17.4.2 Findings

A formal system for indexing and classifying records with regard to their life span has not been established or implemented. Currently, the practice established by JLS&A's management is to maintain all quality-related records beyond the time frames required by federal or state regulations.

17.5 STORAGE, PRESERVATION, AND SAFEKEEPING

17.5.1 Program Objectives

Record retention responsibility should be defined for the controlling and safekeeping of quality records. Quality records should be indexed, filed, and maintained in facilities that provide for a suitable environment to minimize deterioration or damage and to prevent loss.

17.5.2 Findings

JLS&A' are maintaining records in an informal manner. Basically, the Vice president, Special Projects and Licensing appears to be the overall custodian for record retention with regard to quality related documents and records require by regulations. The records required to be maintained to meet regulatory requirements are stored in metal file cabinets, inside JLS&A facilities.

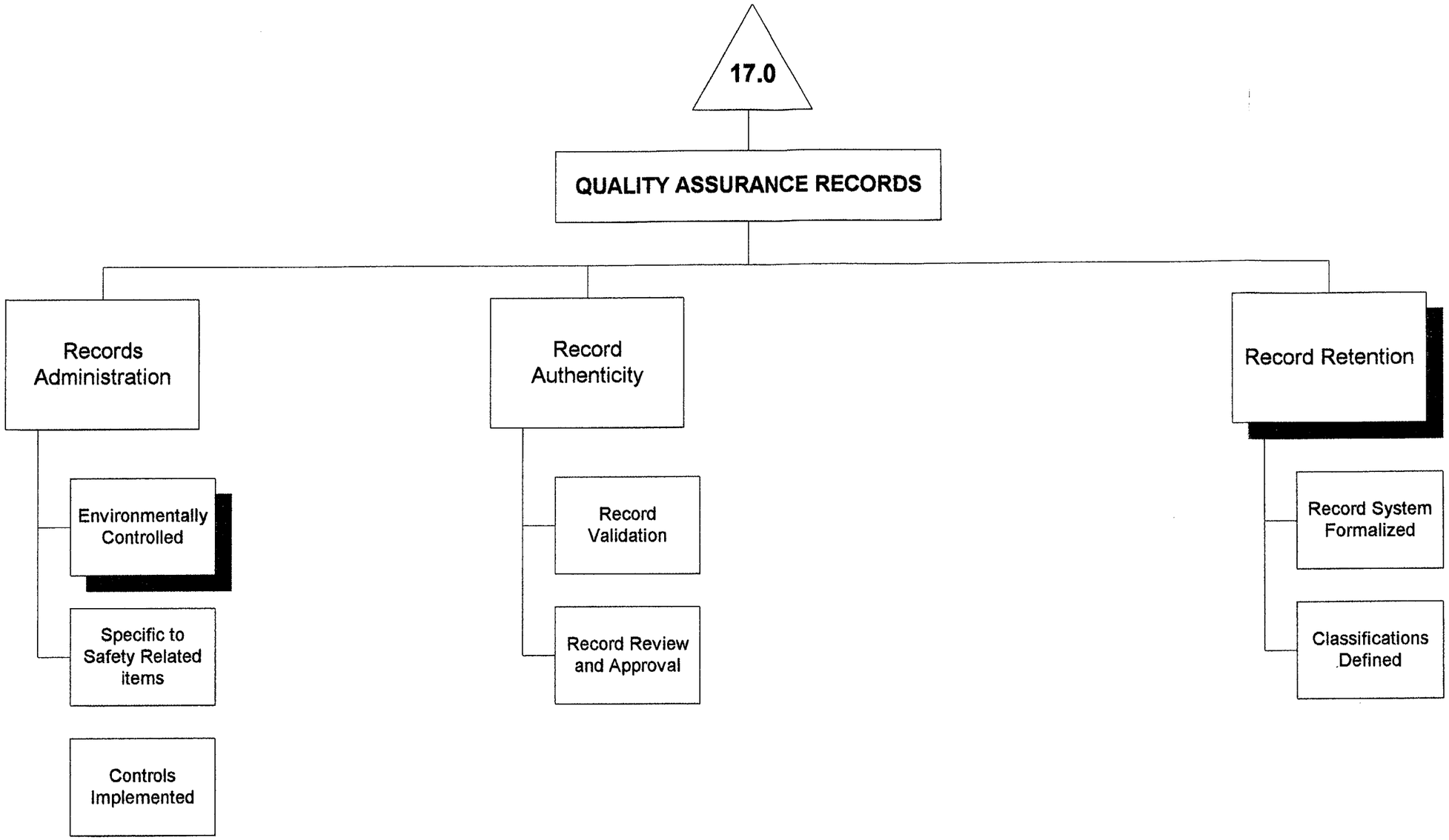
17.5 RECOMMENDATIONS

17.5.1 A formal system of records should be established and implemented that includes provisions for staff processing of required quality records, visual designation of quality records, indexing, filing, control, and the retention duration.

17.5.2 Designate separate locations within the JLS&A facilities for storage and the controlled access to quality related documents and records.

17.5.3 Provide the necessary resources to establish the formal records system.

17.5.4 Purge company files to ensure that all original quality related documents and records are collected and arranged in cohesive manner in a single location, as appropriate.


17.0
QUALITY ASSURANCE RECORDS
Records Administration
Environmentally Controlled
Specific to Safety Related items
Controls Implemented
Record Authenticity
Record Validation
Record Review and Approval
Record Retention
Record System Formalized
Classifications Defined

18.0 AUDITS

18.1 SUMMARY

A formal audit program has been developed, implemented, and maintained by JLS&A's which ensures that a review of the entire quality assurance criterion committed to in the QAPP is carried out. It appears, that the audit program is being performed as required, however, the effectiveness of its implementation is questionable. Audit scopes, as currently utilized, are of a simplified checklist methodology only. The checklists used by the JLS&a's staff are primarily used as a means to validate or confirm that required documents are being maintained. Performance based type auditing or compliance oriented reviews of quality assurance activities are being marginally implemented by staff members with minimal auditing experience. One compliance deficiency was identified based on a review of this area.

18.2 AUDIT PROGRAM PERFORMANCE

18.2.1 Program Objective

A formalized audit program should be established that provides for a comprehensive system of planned and documented audits in order to ensure that all aspects of the Quality Assurance Program are being implemented and are in compliance.

18.2.2 Findings

A formal audit program has been developed and implemented which includes provisions for schedule, team selection, pre & post audit conferences, reporting, audit responses and follow up actions. Audits are being performed on an annual basis as required by the QAPP.

Internal audits, covering the last three years, were reviewed to evaluate the breadth and depth of the audits performed and findings to determine the overall effectiveness of the audit, including audit personnel performance. The audit reports reviewed consist of detailed checklists addressing the criterion that have been established in the QAPP. All three audit reports revealed no adverse findings or deficiencies for those program areas audited. However, the audit report covering the audit period of 10/27/97 through 01/09/98) was found to be deficient, in that, one specific area of the QAPP required to be audited by JLS&A's personnel" Section 17.0, QA Records", had been signed off by the lead auditor and a member of senior management without the check list having been filled out. Based on discussions with JLS&A staff members it could not be established whether or not that area of the program had in fact been audited.

18.3 AUDIT PLANS

18.3.1 Program Objective

Audit plans should be developed using written procedures or instructions and check lists that provide for a comprehensive review of all the Quality Assurance Program criterion contained in the NRC license. Audit plans should be supported by specific regulations and policy requirements, which should be used to establish the basis for determining program compliance.

18.3.2 Findings

Internal audit plans have been formally developed, implemented and are being maintained using QP No.18.0, Revision 0, dated 8/5/91. This audit procedure consists of a single cover page of defined audit prerequisites and instructions along with criteria checklists to be implemented for the conduct of the audit process. A specific checklist exists in the QP that allows for the validation that the entire QAPP criterion has been audited. Other checklists in the procedure, which encompass the QAPP'S eighteen criterion, contain specific attributes or items to be reviewed by the auditors. Audit plans currently do not include any specific regulatory or policy references for use as a basis for evaluating the quality assurance areas being audited.

18.4 AUDIT TYPES

18.4.1 Program Types

Internal audits of the Quality Assurance Program elements should be performed as necessary to ensure effective implementation of all areas of the program.

External audits of suppliers and contractors providing quality related equipment, products, or services should be audited as necessary to ensure that their quality assurance program is adequate and is being implemented and maintained as required.

18.4.2 Findings

Historically, JLS&A's have performed internal audits on an annual basis. More frequent audits of the quality assurance program have not been performed base on the fact that audits completed have not indicated that there was cause to perform additional audits rather than meet the required annual audit frequency. However, this current approach by JLS&A's has changed in recent months due to the need to increase oversight of the

quality assurance program as a results of program deficiencies identified during past regulatory inspections.

The extent to the implementation of the external-auditing program for determining compliance of vendors and suppliers providing material, components, and services is limited in nature. This is due to fact that the most of the materials specified in the Certificates of Compliance for the Type B over packs being utilized by JLS&A's can be procured through many retail stores or speciality suppliers with little or no quality related conformance requirements necessary.

18.5 AUDIT SCHEDULES

18.5.1 Program Objective

Schedules of audit activities should be formally established for reviewing internal and external quality assurance programs. Measures are established that assigns priorities for assuring that key elements of the quality assurance programs for those areas important to safety receive top consideration.

18.5.2 Findings

Currently, JLS&A's internal audits are being performed on an annual basis and are determined to be commensurate with the commitments documented in the QAPP. Areas being audited annually include all of the eighteen criterion contained in the QAPP.

Based upon a review of the QAPP and the associated QP it appears that the each of the eighteen criterion areas established in these documents receive an equal level of safety importance rather than identifying those criterion that should be prioritized, as being top candidates, for the annual audit process. Utilizing a prioritizing methodology would provide for the carrying out of a more in-depth and diligent review of the major areas that are important to safety.

Presently, external audit schedules are established or planned based on an "as needed basis". External audits normally apply to suppliers or vendors who provide quality related material or services to JLS&A's for use in their packaging fabrication and repair activities. Based on discussions with the Quality Assurance Manager it was determined that all of their vendors had been approved during the initial procurement processing and that subsequent audits of those approved vendors will be done as necessary based on vendor performance. Due to the fact that vendor performance has been satisfactory in the past and present JLS&A's has not seen a need to audit their vendors for quality assurance purposes.

18.6 AUDIT PERSONNEL

18.6.1 Program Objective

Trained and qualified personnel not having direct responsibilities in the areas audited should only perform audits. Audit personnel should have sufficient audit and technical experience commensurate with the areas they are responsible to audit.

18.6.2 Findings

The current methodology implemented by JLS&A for conducting internal audits is to utilize their management resources and assigning them to audit areas for which they are not responsible in order to avoid program conflicts of interest.

There are several members of the management staff who have been trained and certified by JLS&A to conduct audits of the quality assurance program. Oral exams were administered to these staff members as part of the auditor certification process. The results of the exams are clearly documented indicating that the entire QAPP criterion was addressed. The auditors who have been approved for auditing appear to have extensive technical and experience for the discipline for which they are assigned responsibility for managing. However, some of these individuals have had limited opportunity for performing comprehensive audits in the past appear to be somewhat narrow in the depth of audit knowledge that they can apply. Consequently, this may be an underlying weakness in the effectiveness of the internal audit, due to fact, that in the three annual audits conducted by JLS&A staff members their reviews did not reflect any negative program findings.

18.7 AUDIT DOCUMENTATION AND REPORTING

18.7.1 Program Objective

Criteria should be formally established to define time constraints for issuing audit reports as well as time frames for corrective-actions necessary.

18.7.2 Findings

Formally established controls utilizing procedures or written instructions to define time constraints for the distribution of audit reports and associated responses for corrective action do not exist. The internal practice currently in place for dealing with program deficiencies is handled verbally

between respective staff members, as necessary, or to establish timelines as appropriate.

18.8 RESPONSES AND FOLLOW-UP ACTIONS

18.8.1 Program Objective

A program should be established to evaluate the adequacy of audit responses and for verifying that corrective actions have been carried as scheduled.

18.8.2 Findings

Formal measures have not been established that addresses the adequacy of audit responses, corrective action tracking, management oversight and close out requirements and schedules. This area of the quality assurance is also discussed in Section 17.0 to this Audit Report.

18.9 RECORDS

18.9.1 Program Objective

A system of records should exist that includes, as a minimum, audit plans, audit reports, audit responses, and documents validating completion of corrective actions.

18.9.2 Findings

Completed internal and external audit reports audit plans are maintained as formal records by the Quality Assurance Manager. There have not been any deficiencies or corrective actions documented as a result of the past three annual audits performed and therefore the records system does not contain such information. However, there are reportedly some non-conformance files maintained that go back to the 1991 timeframe. There is no criteria established by JLS&A that defines what records are to be maintained in the audit records file.

18.10 RECOMMENDATIONS

18.10.1 JLS&A should solicit the services of professional auditor resources that possess the necessary experience and knowledge relative to auditing 10 CFR Part 71 quality assurance and related transportation activities.

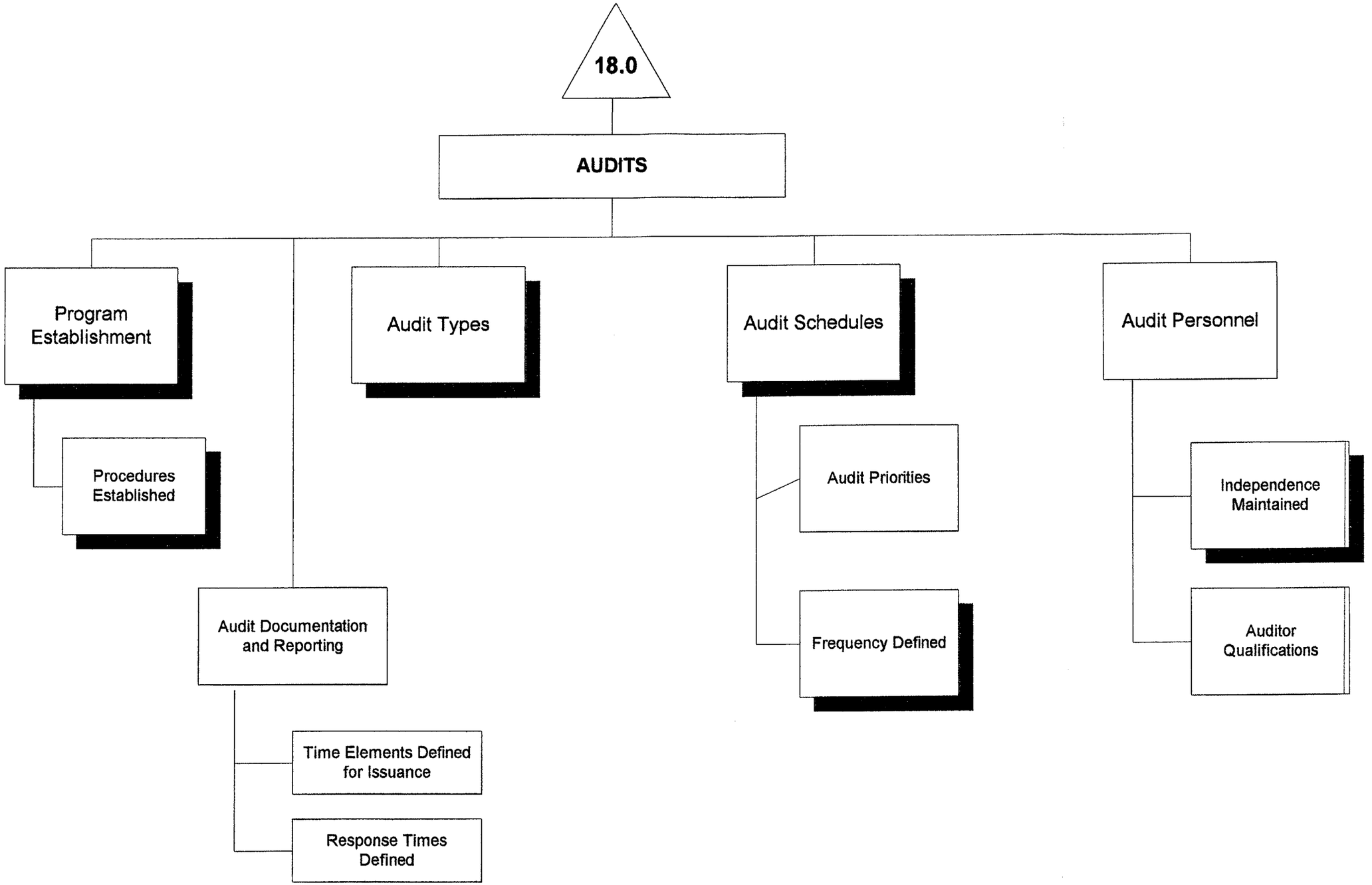
18.10.2 Audit frequencies and priorities should be planned and organized, such that, a comprehensive audit process is carried out in a defined manner

commensurate with the need and focus of the quality related activities on-going.

18.10.3 Establish and implement a formal internal assessment program, to be implemented by staff managers for conducting overview of their respective assigned operational responsibilities. Assessment frequency should be established, on a semi-annual bases, as necessary.

18.10.4 Establish and implement a defined protocol for the completion, submittal, review, follow up and close out, and tracking of audits and associated findings.

18.10.5 Define a system of audits that establishes focus and priority on those safety related functions that are considered by JLS&A to be of the highest safety importance. Schedule these safety-related areas for audit on an annual bases, as a minimum. Ensure that all of the Subpart H eighteen criterions are audited on a frequency, not to exceed three (3) years.


18.0
AUDITS
Program Establishment
Procedures Established
Audit Types
Audit Documentation and Reporting
Time Elements Defined for Issuance
Response Times Defined
Audit Schedules
Audit Priorities
Frequency Defined
Audit Personnel
Independence Maintained
Auditor Qualifications

APPENDIX A

PERSONNEL CONTACTED

FULL NAME	ORGANIZATION	TITLE
J.L. Shepherd	JLS&A	President and General Manager **
M.F. Shepherd	JLS&A	Vice President, Special Projects, and Licensing *
D. C. Shepherd	JLS&A	Vice President, Electronics **
T. Shepherd	JLS&A	Lead Engineer **
L. Weiss	JLS&A	Contracts Administrator
P. Shepherd	JLS&A	Field Service Coordinator
Q. V. PHO	JLS&A	Production/Operations Manager **
B. Peabody	JLS&A	Assistant, Radiological Operations

- Attended Entrance Interview on September 13, 2000
- Attended Exit Interview on October 9, 2000

APPENDIX B

AUDIT BASES

FEDERAL REGULATIONS	
10CFR71	Packaging and Transportation of Radioactive Materials
10CFR71, Subpart H	Quality Assurance

REGULATORY GUIDES	
7.10, Revision 1, 1986	Establishing Quality Assurance Programs for Packing Used in the Transport of Material

NUCLEAR REGULATORY COMMISSION LETTES AND NOTICES	

AMERICAN NATIONAL STANDARDS INSTITUTE	

INTERNATIONAL CODES AND STANDARDS

APPENDIX C

PROCEDURES REVIEWED

Number	Title	Issue Date
	PROGRAM PLANS	
QA-RM-001-A. Rev. 3:	Quality Assurance Program Plan	10/05/95
	QUALITY PROCEDURES	
QAM, QP 1.0, Rev. 2	Structure, and Authority-JLS&A Organizational Chart	01/17/02
QAM, QP 1.1, Rev. 0	JlS&A Job Descriptions	05/14/95
QAM, QP 2.0 Rev.3	QA Program Plan	10/05/95
QAM, QP 3.0, Rev. 1	Design Control	08/05/91
QAM, QP 4.0, Rev. 0	Procurement Document Control	03/07/91
QAM, QP 5.0, Rev. 2	Manufacturing Control-Instructions, Procedures and Drawings	03/07/91
QAM, QP 6.0, Rev.0	Document Control (Same procedure as 5.0 above)	03/07/91
QAM, QP 7.0, Rev. 1	Control of Purchased Material, Equipment, and Services	03/08/91
QAM, QP 8.0	Identification and Control of Materials, Parts, and Components.	No date
QAM, QP 9.0	Special Processes	No date
QAM, QP 10.0	Inspection Control	No date
QAM, QP 11.0, Rev. 0	Test Control	03/04/91
QAM, QP 12.0, Rev.0	Calibration Equipment	03/04/91
QAM, QP 13.0, Rev.1	Handling, Shipping, and Storage	01/17/97
QAM, QP 14.0	Inspection, Test and Operating Status	No date
QAM, QP 15.0 Rev.1	Control of Nonconforming Materials, Parts or Components	08/05/91
QAM, QP 16.0 Rev.1	Corrective Action	08/05/91
QAM, QP 17.0 Rev.0	QA Records	03/07/91
QAM, QP 18.0, Rev.0	Audits	08/05/91

APPENDIX D

DOCUMENTS REVIEWED

• NRC approval letter, dated, January 24, 1996, " Quality Assurance Program"
• NRC Certificates of Compliance Nos. 5984; 5796; and 6280
• JLS&A internal audit report, for period, 12/14/99 through 01/20/00
• JLS&A internal audit report, for period, 11/03/98 through 12/28/98
• JLS&A internal audit report, for period, 10/27/97 through 01/09/98
• MT&E Inventory List, dated July, 1999
• MT&E calibration records and certificates
• Staff training, re-training and qualifications records
• Welder certification records
• Auditor training, qualification and certification records

APPENDIX E

INDEPENDENT AUDITOR RESUME'

DONALD R. NEELY

SUMMARY OF EXPERIENCE

Over 35 years experience in the nuclear energy field with particular emphasis in radiation protection, emergency preparedness and radioactive waste management, and decontamination and decommissioning programs and operations. His special expertise is applied to the conduct of appraisals and evaluations, the development, and implementation of improvement plans for customer management relative to the technical areas of radiation protection, emergency preparedness and radioactive waste programs, and decontamination and decommissioning. He has participated in directing many executive level program assessments at utility and government installations. In addition to his experience as a lead health physics inspector at Three Mile Island, he has also updated a number of order items contained in the supplement to NUREG-0680, " TMI-1 Restart Evaluation, " and provided testimony for the TMI-1 Restart Hearings. Mr. Neely developed and managed the senior level radiological and radioactive waste consulting services upon joining Hydro Nuclear Services. He also directed the division functional areas of quality assurance, research and development, radiation protection operations, corporate by-product license, and radioactive waste engineering. Mr. Neely was appointed by the President of Westinghouse Electric Corporation to serve as a member of the Westinghouse Spent Fuel and Decontamination and Decommissioning Task Force for purposes of reviewing and developing strategic business plans for entry into this market sector.

Lead responsibility for the remediation of property, equipment, waste containers, sea land transports, and facilities in preparation of the sale of assets to GTS Duratek. Mr. Neely has served on several executive level nuclear review committees for major utilities. Reporting to the Presidents of Duratek, Inc. and Scientific Ecology Group, Inc. he had overall responsibility for the management and direction of the Radiological Engineering and Field Services business division, which included both commercial (reactors and by-product licensees) and federal (NRC and DOE) market sectors. Specific areas included wet and dry waste processing, packaging and cask maintenance; sea-land container maintenance and disposition; decontamination and decommissioning project management and technical services; senior consulting services; and free release programs relative to disposition of materials and equipment. Also, he had executive oversight and management of providing services (internal to SEG/Duratek divisions, and externally in support of customer projects) for the full calibration, maintenance, repair and rental/lease of analytical and survey/radiation monitoring instrumentation which had a book/investment value of five (5) to (6) million dollars.

Mr. Neely managed and directed a staff of over 900 personnel including radiation protection, chemistry, emergency preparedness, training, and radioactive waste management professionals and technicians who were instrumental in providing site services that resulted in achieving annual sales revenues of approximately 70 million dollars. In addition, he had overall responsibility for the management and conduct of operations of a 15-acre site with over 200,000 square feet of licensed facilities for the maintenance and storage of radioactive materials and equipment.

Mr. Neely also served as President of Hittman Nuclear Transport, being responsible for the management, safety and conduct of operations for a trucking fleet of 67 tractors and 200 trailers whose primary business was transporting nuclear waste (shielded and unshielded) including new reactor fuel.

EXPERIENCE

12/1/98 – Present	Donald R. Neely Associates President and Chief Executive Officer Mr. Neely provides senior level consulting services to clients in the nuclear industry. Areas of expertise include strategic planning and business development, technical services, program evaluations and expert testimony. Serves on nuclear review boards when called upon.

Recent consulting projects ongoing and/or completed:

- Arizona Public Service Company- performed assessment of the Palo Verde Nuclear Generating Emergency Preparedness (EP) program and currently providing consulting services and guidance in support of reengineering efforts for the "Conduct of Operations" portion of the EP program.
- Serving as facilitator for the Site Specific Advisory Board relative to institutional controls and financial assurances in support of the public input process for the Molycorp, Inc. Decommissioning Plan.
- Performing independent technical and regulatory reviews for the Big Rock Point NRC license submittal relative to release of materials.
- Provide business development consulting services to Safety and Ecology Group relative to commercial reactor site markets.

04/97 - 11/30/98

GTS Duratek (formerly Scientific Ecology Group, Inc.)
Senior Vice President, Radiological Engineering and Field Services

Overall responsibility for the management and direction of the Radiological Engineering and Field Services Division profit center. Areas of specific responsibility included Hittman Trucking operations; outage staff augmentation services; radiological engineering and decommissioning services; Gallagher Road Nuclear Services Operations; sealand and waste container refurbishment operations; training services; and DOE projects at Sandia and Rocky Flats. Assigned responsibility as corporate executive for company-wide decommissioning and decontamination services which included business development, operations and strategic planning. Responsible for meeting annual sales revenue objectives of approximately $70 million.

01/90 - 04/97

Scientific Ecology Group (SEG)
Vice President, Field Services and Transportation

Directly responsible for business development and management of all activities and personnel associated with Radiological Engineering and Decommissioning Consulting Services. Executive responsibility for the SEG Radiation Protection Program Operations. Responsible for the mobile and fixed base liquid radioactive waste operations. Directed the operations and maintenance activities at SEG's Gallagher Road licensed facilities.

Served as Executive Project Director under contract to the State of Nebraska for conducting health physics and radioactive waste reviews of the license application for the Low Level Radioactive Waste (LLRW) site in Nebraska. Also, responsible for defining and developing the State of Nebraska Regulatory Program for implementing the LLRW Regulatory responsibilities. Served as a consultant member on the Long Island Lighting (Shoreham) Nuclear Review Board. Served as a consultant member of the Long Island Lighting (Shoreham) Decommissioning Oversight Committee as well as the Portland General Electric Company Trojan Nuclear Operations Board. Participates as a consultant member on the Maine Yankee Nuclear Power Plant Executive Committee overseeing the *Radiological Protection Enhancement Program.* Directed the Maine Yankee Radiological Controls Program assessment.

Provided executive oversight and direction for developing and implementing SEG Radiation Protection and Radioactive Waste program responsibilities relative to the Fort St. Vrain Decommissioning Project.

Directly supervised the assessment of the Radiation Protection and Radioactive Waste Programs at Iowa Electric Company's Duane Arnold Energy Center. Responsible for directing assessments of the James A. Fitzpatrick Radiation Protection Programs. Directed the assessment of the Trojan Nuclear Plant Radiation Protection and Radioactive Waste Programs.

Provided executive management oversight and direction of the decontamination and decommissioning of the Army Materials Testing Laboratory in Watertown, MA. Provides oversight and direction for developing the characterization, cost estimates and Decommissioning Plan for the Westinghouse Waltz Mill Reactor Facility.

1989- 1990

Westinghouse Radiological Services, Inc.
Vice President, Special Projects

Directly responsible for business development, implementation, and overall project management of Decommissioning Services related to commercial research and Department of Energy reactors, both domestic and foreign. Mr. Neely also had responsibilities for project management and oversight of major programs dealing with Radioactive Waste and Radiological Control enhancements. Served as a consultant member of the Long Island Lighting Nuclear Review Board. Served as a member of the Westinghouse Task Force chartered to review the Savannah River Site Reactor Restart Plan. Directly supervised the assessments, development, and implementation of the Omaha Public Power District, Fort Calhoun Station, for the enhancement of the Radiological Protection, Radioactive Waste and Reactor Chemistry programs.

1987-1988

Westinghouse Electric Corporation
(Hydro Nuclear Services)
Manager of Engineering, Radiological Services Division

Reported directly to the Manager, Radiological Services Division. Directly responsible for the Advance Systems and Product Development Division. Provided direction and coordination for all professional consulting aspects of the division including radioactive waste management and engineering, radiation protection, chemistry, environmental monitoring, emergency planning, and research and development. Was responsible for marketing direction, quality assurance and executive liaison functions internally within the division and also with client and regulatory executive management. Served as consultant member of the Long Island Nuclear Review Board. Performed consulting services for the Department of Energy related to the review of the radiological controls program for the restart of the High Flux Isotope Reactor at Oak Ridge National Laboratories.

1986- 1987

Westinghouse Electric Corporation
(Hydro Nuclear Services)
Radiological Services Division
Manager, Integrated Projects

Reported directly to the Manager, Westinghouse Radiological Services Division and interfaced with the presidents of other Westinghouse divisional subsidiaries (Numanco, Inc. and Hittman, Inc) in providing integrated radiological services. Responsible for implementing all divisional projects in which the services of each subsidiary are provided as part of an integrated package. This responsibility included the radiological services portions of all projects integrated with other Westinghouse Divisions as part of its comprehensive service module program. Mr. Neely also provided technical and project assistance to support the marketing of integrated radiological services to utility, corporate and institutional customers. Served as a consultant member on the Long Island Nuclear Review Board.

1985- 1986

Hydro Nuclear Services, Inc. (HNS)
Vice President

Provided overall executive management, direction and coordination for the senior level consulting services, plant operations, and field service aspects of Hydro Nuclear Services, Inc. Responsible for all business development, marketing, quality assurance, operations, and executive liaison functions both internally with HNS and external to client executive management. Responsible for developing and implementing radiological services in the areas of radiological engineering, radioactive waste processing/disposal, emergency planning, chemistry, environmental monitoring, and licensing support. Responsible for the overall direction development, implementation, and project management of the radiation protection and radioactive waste programs for the Georgia Power Company, Plant Hatch recirculation pipe replacement project. Performed an in-depth assessment of the Boston Edison Company Pilgrim Station Radiation Protection Program and directed the follow up Radiological Improvement Program.

1982- 1983

Hydro Nuclear Services
Radiological Services Division
Division Director

Provided project management for professional Health Physics consulting services in all phases of radiation protection, radioactive waste, and emergency preparedness programs. Among areas of involvement were: ALARA program development, outage health physics program management, and health physics program evaluations.

1981- 1982

TERA Corporation
Senior Radiological Engineer

Provided professional Health Physics consulting services in all phases of radiation protection and emergency planning. Responsible for on-site project management, including technical direction and line management, principal client liaison, financial controls and budgets, scheduling, task definition and

assignment, as well as the technical review of results. Performed in-depth program assessments at Union Electric - Calloway Plant, Louisiana Power and Light, and Pennsylvania Power and Light Susquehanna Plant. Provided senior level consulting services to the Niagara Mohawk - Nine-Mile Point Plant. Performed an in-depth ALARA review at the Louisiana Power and Light - Waterford III Nuclear Plant facility during pre-operational activities.

1980- 1981 U.S. Nuclear Regulatory Commission
Inspection Specialist

Responsibilities included assisting in developing performance appraisal methodology and procedures, conducting performance appraisal inspections at nuclear facilities and performing major investigations and special inspections directed by the Headquarters for Inspection and Enforcement. Served as a Team Leader for the NRC Health Physics Appraisal Program.

1975- 1980 U.S. Nuclear Regulatory Commission
Senior Radiation Specialist

Responsible for inspection of radiation protection and radioactive waste management programs at nuclear power reactors, test and research reactors, and fuel facilities during testing, startup, maintenance, refueling, and normal operations.

Also served as Team Leader of the radiological inspection team during the initial response to the March 28, 1979, accident at Three Mile Island and as Shift Leader, directing other NRC health physics inspectors during the eight weeks subsequent to the accident.

Lead Health Physicist for the NRC TMI Recovery Operations Office from May through October 1979. Appointed by the Director of Nuclear Reactor Regulation to serve on the special panel chartered to review the radiation protection program at Three Mile Island Unit 1. Co-author of NUREG0640, "Three Mile Island, Unit 2, Radiation Protection Program. " Served as Team Leader for the special health physics evaluation of Unit I of the Three Mile Island Nuclear Station conducted during July-August, 1980 as part of the TMI-1 Restart evaluation. Assigned responsibility for updating certain order items contained in the supplement to NUREG-0680, "TMI-1 Restart Evaluation," and providing testimony for the TMI-1 Restart Hearings. Responsible for effecting the upgrade of many radiation protection programs in NRC's Region 1.

1974-1975 Nuclear Plant Services
Division of Chem-Nuclear Services
Specialist and Supervisor

Supervised health physics technicians during refueling and maintenance outages at nuclear power reactors. Served as an instructor of health physics technicians, plant operations, maintenance personnel, and other plant staff at commercial nuclear power reactors during pre-operational, startup, and refueling phases. Also consulted on radiation protection program development at nuclear power reactors.

1962-1974

General Electric Company
Vallecitos Nuclear Center
Specialist

Provided radiation protection services for more than ten reactor facilities and analytical laboratories containing highly radioactive materials in all phases of their operation. Supervised health physics technicians who provided support to clients during maintenance and refueling outages. Performed reactor fuel inspections and reconstitution, reactor instrumentation removal, non-destructive testing and waste disposal. Participated in cask loading operations, radioactive waste handling, underwater operations, decontamination, shipping of radioactive materials, personnel monitoring, area monitoring, environmental sampling, gamma scanning, whole body counting, outage planning, and the development of radiation protection procedures. Activities involved field service in nuclear facilities in the United States as well as Japan and Switzerland.

AWARDS

Outstanding performance while assigned to the NRC Three Mile Island Recovery Operations Office.
Westinghouse Marketing Award, 1987-1988

PROFESSIONAL AFFILIATIONS

Health Physics Society
American Nuclear Society
Delaware Valley Society for Radiation Safety

PUBLICATIONS

Contributing Author - NUREG 0640, *Three Mile Island, Unit 2, Radiation Protection Program,* December 1979.

Contributing Author - NUREG 0680, *TMI-1 Restart Evaluation,* June 1980.

Contributing Author - NUREG 0680, Supplement 1, TMI-1 *Restart Evaluation,* November 1980.