DEC 15 1989

MEMORANDUM FOR: Robert Bernero, Director
Office of Nuclear Materials Safety
and Safeguards

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SUBJECT: TRANSPORTATION PACKAGE SUPPLIER INSPECTION PROGRAM

Phase One of the transportation package supplier inspection program as outlined in my memorandum to you, dated February 22, 1989, has been completed.

Six package supplier inspections were conducted in Phase One. The inspections focused on implementation and procedures of approved quality assurance (QA) programs. The implementation of QA programs by the package suppliers was found to meet, to varying degrees, the commitments made by the suppliers to the NRC in the QA program approval process. The inspections identified a total 46 nonconformances with the requirements of 10 CFR Part 71 and 10 CFR Part 21, ranging from 4 to 15 violations/nonconformances per facility. The majority of the nonconformances were found in the area of records control, definition of management duties and responsibilities, materials control, design changes, and staff training. A series of welding defects was identified through radiography examinations in one of the inspections.

A number of programmatic issues were identified for resolution. These include follow-up inspections, enforcement policy and civil penalties for non-NRC licensees, staff training, and development of fee schedules for inspections.

A report on Phase One including results of inspections and programmatic issues is provided in Enclosure 1. An implementation plan to proceed in the framework of Phase Two with further inspections and to resolve the programmatic issues identified in Phase One is provided in Enclosure 2. Your endorsement to proceed with Phase Two, as outlined in Enclosure 2, is requested.

Robert F. Burnett, Director
Division of Safeguards
and Transportation
Office of Nuclear Material Safety
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Enclosures:
1. Summary of Phase One
2. Phase Two Implementation Plan

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MEMO TO BERNERO FM. BURNETT

Summary of Phase One

1.0 Summary of Inspection Findings

1.1 Approach

Inspections of six package suppliers were conducted in Phase One to determine compliance of the quality assurance (QA) program with regulatory requirements.

The inspections were conducted between April and September 1989, utilizing an inspection guide document and a temporary instruction, both developed in Phase One in order to provide a systematic and comprehensive approach to the inspections. The size of the inspection teams varied between two to four; the SGTB staff conducted inspections with assistance from regional inspectors on two occasions and with contractor support from the Idaho National Engineering Laboratory at three facilities. The length of the inspections varied from 27 to 96 inspection hours on site.

1.2 Findings

The implementation of QA programs by the package suppliers inspected in Phase One was found to meet, in general, the commitments made by the suppliers to the NRC in the QA program approval process. However, the inspections identified a total of 46 violations/nonconformances with the requirements of 10 CFR Part 71 and 10 CFR Part 21, ranging from 4 to 15 nonconformances per facility. The majority of the nonconformances were found in the area of records control, definition of management duties and responsibilities, materials control, design changes, and staff training. A series of welding defects was identified through radiography examinations in one of the inspections.

Figure 1 provides a breakdown of supplier nonconformances by the regulatory requirements contained in 10 CFR Parts 21 and 71. A full description of the nonconformances can be found in Section 4 of the inspection reports.

1.3 Industry Characteristics

A number of features are unique to the container supplier industry distinguishing the inspections from the other types of licensee inspections conducted by NRC:

- the inspections found a wide variation in the size, staffing level, and organization of the suppliers,

- the QA function was found to range from one part-time individual to a full QA department headed by a QA director,

SUMMARY OF VIOLATIONS/NONCONFORMANCES

REGULATION TITLE 10 CFR	SUBJECT	PACKAGE SUPPLIERS						NUMBER OF VIOLATIONS/ NONCONFORMANCES
		PNS	WEST	CNSI	FBF**	NCI**	TAF	
21.6 (a) and (b)	*Posting				1	1		2
21.21 (a)	*Defect Reporting				1	1		2
21.31	*Procurement Documents				1	1		2
71.37(b)	Codes and Standards	1						1
71.103	QA Organization	1	1	1	2			5
71.10[illegible]d)	Training		1		1			2
71.107	Design Control			1				1
71.109	Document Control			1				1
71.111	QA Procedures				1	1	1	3
71.115(a)	Material Control		1		1	1		3
71.115(b)	Specification Conformation	1			2	1		4
71.119	Special Process Control		1		2	1	4	8
71.123	Test Control						2	2
71.125	Test/Measure Equip Control					1		1
71.135	QA Records	1		1	1	1	1	5
71.137	Audits			1	2	1		4
	TOTAL	4	4	5	15	10	8	46

PACKAGE SUPPLIER KEY:
PNS - PACIFIC NUCLEAR SYSTEMS, INC. FEDERAL WAY, WA
WEST - WESTINGHOUSE SYSTEMS DIVISION, MORRISTOWN, NJ
CNSI - CHEM-NUCLEAR SYSTEMS, INC., COLUMBIA, SC
FBF - FBF, INC., KNOXVILLE, TN
NCI - NUCLEAR CONTAINERS, INC., ELIZABETHTON, TN
TAF - PACIFIC NUCLEAR SYSTEMS, INC., CARLSBAD, NM

FIGURE 1

* Noncompliances against 10 CFR Part 21 are cited as [illegible]
** Inspection reports have not been issued, number of [illegible] may change

- frequently, the QA program is implemented, particularly in the case of smaller facilities, without thorough documentation; and it was obvious that the success of the program depends to a large extent on the skills of the individual(s) administering the program,

- some package suppliers were not aware that the requirements of 10 CFR Part 21 concerning records management and reporting of defects were applicable to transportation package suppliers,

- the subcontractors, vendors, and materials suppliers for this industry constitute a somewhat unstable group, going out of business, or changing their field of business frequently. This implies that maintenance of records should be of particular importance in the industry.

1.4 List of Inspections

The following six facilities were inspected in Phase One of the container supplier inspection program.

1.	Package Supplier:	Pacific Nuclear Systems, Inc. Federal Way, WA
	Report No.	71-0192/89-01
	Date:	4/24-28/89
	Inspection Team:	J. Jankovich (team leader), NMSS J. Cook, NMSS L. Gordon, NMSS H. Stromberg, EG&G (contractor)
	Inspection Hours:	96 (on site)
	Nonconformances:	4
2.	Package Supplier:	Westinghouse Radiological Services Moorestown, NJ
	Report No.:	71-0024/89-02
	Date:	5/22-25/89
	Inspection Team:	L. Gordon (team leader), NMSS J. Jankovich, NMSS J. Furia, RI
	Inspection Hours:	65 (on site)
	Nonconformances:	4
3.	Package Supplier:	Chem-Nuclear, Inc. Columbia, SC
	Report No.:	71-0231/89-03
	Date:	6/19-22/89
	Inspection Team:	L. Gordon (team leader), NMSS J. Jankovich, NMSS D. Kasnicki, RII
	Inspection Hours:	81 (on site)
	Nonconformances:	5

4.	Package Supplier:	Film Badge Fabricators, Inc. Knoxville, TN
	Report No.:	71-0185/89-04
	Date:	7/10-13/89
	Inspection Team:	L. Gordon (team leader), NMSS R. Petersen, EG&G (contractor)
	Inspection Hours:	48 (on-site)
	Nonconformances:	15
5.	Package Supplier:	Nuclear Containers, Inc. Elizabethton, TN
	Report No.:	71-0179/89-05
	Date:	8/28-8/30/89
	Inspection Team:	L. Gordon (team leader), NMSS C. Haney, NMSS
	Inspection Hours:	27 (on site)
	Violations	3
	Nonconformances:	7
6.	Package Supplier:	Trupact Assembly Facility Pacific Nuclear Systems, Inc. Carlsbad, NM
	Report No.:	71-0192/89-06
	Date:	9/26-28/89
	Inspection Team:	J. Jankovich (team leader), NMSS J. Cook, NMSS C. Haney, NMSS B. Brown, EG&G (contractor)
	Inspection Hours:	87 (on site)
	Nonconformances:	8

2.0 Programmatic Issues

The Phase One inspections identified a number of programmatic issues concerning future inspections. The programmatic issues are discussed below.

2.1 Routine Inspections

The need to continue the inspections is substantiated by the identification of violations/nonconformances at each of the six package suppliers inspected during the pilot program, and that the number of the violations/nonconformances was relatively large ranging from 4 to 15. QA nonconformances of the type identified could result in the improper fabrication of transportation packages. Based on the pilot inspections, it is reasonable to assume that further inspections could similarly identify nonconformances at other suppliers. The NRC can, through inspections and corrective actions, help to assure that transportation containers are fabricated and maintained in accordance with the certificate of compliance.

The results of the Phase One inspections indicate, for example, from the series of weld defects found in one of the inspections, that the QA program may be satisfactory and in compliance with that approved by the NRC, but the program implementation could still result in packages which are in nonconformance with regulatory requirements. Therefore, future inspections must focus both on the QA program and its implementation in the fabrication process. In order to conduct such inspections successfully, the inspection team as a minimum should include 2 QA inspectors and a non-destructive test record examiner. A full team in which the members with specialized expertise complement each other is needed to conduct a comprehensive inspection. A smaller team may miss some aspects of the full range of QA activities.

The inspections are to be performance-based, "routine" inspections, i.e., they are to be designed to address all major activities of supplier, conducted on the basis of a comprehensive and systematic approach, utilizing uniform inspection techniques to provide consistent findings regarding regulatory compliance. Six routine inspections are scheduled for FY90 (see Enclosure 2 for tentative schedule).

2.2 Special Inspections

The nature of some of the nonconformances which were identified in the pilot inspections requires that the effectiveness of corrective actions of the package supplier must be inspected. For example, weld defects were found in some of the Trupact-II containers (Pilot Inspection No. 6); a follow-up inspection is scheduled in FY 90 to review the repairs on the defective containers as well as the fabrication of new packages under corrective measures implemented by the supplier.

Follow-up inspections are also warranted at some other package suppliers in a year or at some later time after the initial routine inspection. These inspections assure that the corrective actions implemented by the certificate holder in response to the nonconformance identified in the original inspection report achieve the desirable effect. Approximately two of the suppliers inspected in 1989 could be candidates for follow-up inspection (none scheduled at this time).

Further inspections are to be conducted of two package suppliers whose QA programs were reinstated by NRC on the basis of in-house review of submitted documentation. Inspections at the facilities are warranted in order to verify, on the basis of performance-based inspections, the implementation of the QA program. Two such inspections are scheduled for FY90 (see Enclosure 2 for tentative schedule).

2.3. Regulatory Issues

A number of regulatory issues were identified which need clarification in order to facilitate further inspections:

2.3.1 Enforcement Scheme

NRC's enforcement scheme is related to the applicable regulations and license status of the facility being inspected. All package suppliers of NRC-certified of Type B packages have an NRC Approval for their quality assurance program. The supplier usually, although not necessarily, has an NRC Certificate of Compliance for packages being supplied. The supplier usually does not have an NRC or Agreement State specific license, although they might for other activities.

Since package suppliers are not in most cases specifically licensed, noncompliances identified concerning 10 CFR Part 71 during inspection are treated as nonconformances, an approach similar to that for vendors. At specifically licensed facilities, noncompliances may be treated as violations, the attendant advantage being that violations can be enforced by civil penalities (fines) without revoking the license. However, for NRC approved QA programs, the only method to enforce nonconformance is for NRC to withdraw the QA Program Approval, which totally suspends the package supplier's activities. This all-or-nothing enforcement situation is not as desirable as the graded fines; at the same time, it does not appear that violations and/or fines can be imposed on non-NRC licensed facilities under the current regulatory structure. It may be appropriate to pursue with OGC and OE, other feasible approaches in order to achieve a graded enforcement scheme for package suppliers. The current nonconformance scheme will be employed until such time as a graded scheme can be developed.

2.3.2 Civil Penalties

If the application of civil penalties to package suppliers is deemed appropriate, the definition of civil penalties in 10 CFR Section 2, App. C would need to be modified accordingly. Presently, no civil penalties are defined for fabricators, suppliers, or distributors of transportation containers when in nonconformance with the quality assurance regulations as issued by NRC.

2.3.3 Inspection of Subcontractors

The inspections identified that the quality of transportation packages depends to a significant degree on the subcontractors including fabricators and materials vendors. The issue of contractor inspections may be of particular importance in view of

the fact that NRC has issued 15 Information Notices within the last two years on misrepresented vendor products and substandard, counterfeit, or fraudulent replacement parts. Legal opinion is needed to define whether fabricators and materials vendors are subject to the QA requirements and, consequently, should be inspected.

In industry practice, the package supplies exercise control over the subcontractors and vendors to assure that their QA program is equivalent to that of the package suppliers (i.e. to the NRC approval). The package suppliers accomplish this by conducting periodic audits of the subcontractors and maintaining a list of potential subcontractors, the so called "approved vendor list." However, these audits usually do not extend to material vendors.

Presently, the NMSS inspections are limited to package suppliers, although in practice, the inspection teams have visited fabricators and reviewed their records. A determination should be made that this practice is appropriate. In addition, the results of the pilot inspections indicate that records management at subcontractors and materials vendors and as well as the certificates of materials issued by the vendors should also be inspected similarly to the NRR practice of vendor inspections.

2.4 Inspector Training

Chapter 1245 of the NRC Inspection Manual described the training programs which inspectors must complete for a number of specific inspections, e.g. safeguard inspections, and vendor inspections. The process is designed to assure that the NRC staff, conducting inspections of a specialized nature, possess the knowledge of the specific subject matter as well as the general skills of effective inspection techniques. Inspection of the container suppliers is a new area, different from transportation shipment inspections. The SGTB staff who conducted the pilot inspections has extensive background and broad experience in conducting inspections. However, it is desirable to formalize inspector training requirements suitable for the mission of the container supplier inspections in order to assure that all members of the present staff are qualified, to provide NRC management greater freedom in making personnel assignments for the inspections, and to have a set of training objectives established for new employees. To meet these needs a formalized set of training requirements and a record keeping system in the form of a qualification journal will be developed in FY90.

2.5 Regional Support

In two of the inspections, inspectors from the regional offices (RI and RII) were members of the team and provided valuable contributions toward the effective completion of the inspections. However, the time which these inspectors spent on the package supplier inspections was not credited

as on-site inspection time for the individuals. Currently, regional inspectors receive credit only for participating in inspections which are the responsibility of the Regions. Since the container supplier inspections are the responsibility of Headquarters, the regional inspectors may hesitate to participate in further inspections. It is desirable to resolve this discrepancy in order that the valuable resources available in the regional offices could be fully utilized.

2.6 Refine the Draft Inspection Guide

Prior to the pilot inspections, a draft Inspection Guide was developed by Idaho National Engineering Laboratory under contract. The draft guide was to serve as a field manual to reflect the requirements of the Code of Federal Regulations in terms of readily formulated questions suitable for field use. The draft guide has served as a valuable tool in the inspections; it has been especially helpful in assuring a comprehensive inspection which addressed the entire spectrum of the QA program. However, the draft guide has not been revised to reflect the lessons learned in the pilot program. Improvements could be implemented, for example, by eliminating a sub-tier of subject matter classifications in the guide, by reducing the size of the document, and by eliminating certain redundancies.

2.7 Inspection of Other Containers

Since the pilot inspection of suppliers of containers fabricated under NRC certificates of compliance found a large number of nonconformances, inspection of other container suppliers such as NRC certified overpacks, or storage containers should also be considered. The inspection expertise developed in the Transportation Branch could be utilized in these related areas. Such an inspection effort could be started with a few exploratory inspections and, as warranted by the findings, be either terminated or continued.

2.8 Inspection Fees

For safety inspections the NRC usually charges an inspection fee to the licensees. No inspection fees have been charged for the six inspections in Phase One, because these inspections were pilot inspections designed to determine the need for safety inspections in the package supplier industry. As part of the safety inspection program a determination must be made concerning fees for inspections.

Phase Two Implementation Plan
Container Supplier Inspection Program

Objective: To continue inspections of the Quality Assurance Program holders in the container supplier industry with emphasis on the areas of nonconformance which were identified in FY89; perform follow-up inspections and special inspections as needed. This effort is a continuation of the activities initiated and accomplished in Phase One.

Expected Products:

1. Routine Inspections

A series of six inspections will be conducted utilizing the inspection methodology and inspection guide developed in Phase One. The inspections will be conducted with a team of 2 to 4 inspectors. Each inspection is expected to include one week of preparation, about 3 to 4 days on site (plus travel), and 2 weeks of close-out documentation. Contractor support will be utilized when (1) NRC staff is unavailable for a full team, or (2) special skills (e.g. radiography) is needed. The tentative schedule for the inspections is shown in Figure 2.

2. Special Inspections

A number of special inspections are anticipated. The special inspections will focus on one or more specific activities of the certificate holder in contrast to the routine inspections which cover the entire QA program. A need for a special inspection has been identified at Pacific Nuclear Systems, Inc. in Carlsbad, NM to examine radiography of welds and to review the corrective actions taken by the certificate holder in response to the results of an earlier inspection. Two follow-up inspections have also been scheduled in FY 90 in relation to the reinstatement of QA programs previously withdrawn by NRC.

3. Implement Regulatory Changes

SGTB will initiate NMSS activities to address the regulatory issues which are discussed in Enclosure 1. These activities are aimed to clarify and possibly strengthen the NRC's enforcement posture for transportation QA program holders.

4. Inspector Training

The training requirements for transportation container supplier inspections will be formalized and maintenance of a training journal for the SGTB staff will be initiated.

5. Regional Support

Clarify the role of region-based inspectors in the container supplier inspection program.

TENTATIVE TRANSPORTATION PACKAGE SUPPLIER INSPECTION SCHEDULE (FY 90)

Supplier	Inspection Dates
Routine Inspections	
1 Nuclear Assurance Corp. Norcross, GA	11/13-17/89
2 Nuclear Assurance Corp. Spain	12/11-15/89
3 General Electric Co. Pleasanton, CA	1/15-19/90
4 Transnuclear, Inc. White Plains, NY	5/21-25/90
5 Babcock & Wilcox Co. Lynchburg, VA	7/23-27/90
6 Combustion Engineering Windsor, CT	8/20-24/90
Special Inspections	
1 SPEC St. Rose, LA	12/4-8/89
2 Pacific Nuclear Systems (TRUPACT-II) Carlsbad, NM	2/5-9/90
3 Industrial Nuclear St. Leandro, CA	3/12-16/90

FIGURE 2

6. Refine the Draft Inspection Guide

The draft Inspection Guide developed in Phase One will be revised on the basis of the lessons learned in the pilot inspections and will be issued as final.

Resource Requirements

SGTB Staff resources:

6 routine inspections (3 persons, 2 weeks)		36 wks
Special insp. at TRUPACT & follow-up		6 wks
Special insp's (estimated 3 insp's)		6 wks
Inspection documentation		72 wks
Corrective action follow-up		30 wks
Regulatory activities		8 wks
Training: staff attendance 3 persons, 3 weeks		9 wks
program formalization, Manual Chpt. change		6 wks
Contract monitoring		4 wks
	Total:	189 wks

Contractor Support Needs:

participate in 6 insp. (3 weeks each)		18 wks
radiography support: Carlsbad, NM		4 wks
NAC, Spain		4 wks
other special skill support		8 wks
training program development and administration		6 wks
	Total:	40 wks