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NUPIC CLOSEOUT COVER PAGE

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NUPIC JOINT AUDIT OF:

Supplier Name: U.S.T. & D. Inc.
Pittsburgh, PA

Supplier Number 2495

NUPIC Audit Number 17662

Lead Utility: Exelon (EXL)

Audit Date 06/19/00 thru 07/07/00

ETHANY Date Prepared April 11, 2001

A/13

Exelon Generation
1411 Opus Place
Downers Grove, IL 60515-5701

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Exelon
Nuclear

February 22, 2001
SES-01-23

Mr. Martin Edwards
Quality Assurance Manager
U. S. Tool & Die Incorporated
200 Braddock Avenue
Pittsburgh, PA 15145

Subject: Closure of Exelon Audit SR-2000-257, NUPIC/DSQG Audit of UST&D

References: 1. Exelon letter SES-00-138, Shirani to Edwards dated 10/19/00
2. Entergy letter ADM-QH01-029, Gillenwater to Mitchell dated 2/21/01

Dear Mr. Edwards:

The purpose of this letter is to provide notification that Exelon Nuclear has closed the nine findings resulting from audit SR-2000-257 and considers this audit closed.

In Reference 1, Exelon accepted the UST&D response to the findings resulting from audit SR-2000-257, but left the findings open pending verification of corrective actions. This verification was performed by the HUG Project Quality Assurance Representative (PQAR) during surveillance activities conducted from December 2, 2000 through February 15, 2001. The PQAR verification is documented in Reference 2. Exelon has reviewed the PQAR verification and concurs with the recommendation to close the findings.

Please direct any questions or comments regarding this transmittal to Stan Mitchell at 630-663-5763.

Prepared by:

Approved by:

Signature on file

Signature on file

Stanley W. Mitchell
Supplier Evaluation Services
Manager

Russell A. Bastyr
Supplier Evaluation Services

CC: Audit File SR-2000-257
Duplicate Storage File
N. Leech
J. Reiss
M. Soler (Holtec International)



Entergy Nuclear Northeast
Entergy Nuclear Operations, Inc.
P.O. Box 5029
White Plains, NY 10601-5029
Tel 914 272-3500

February 21, 2000
ADM-QH01-029

Mr. Stan Mitchell
Exelon Nuclear
1411 Opus Place
Downers Grove, IL 60515

Subject: HUG Project Quality Assurance Representative (PQAR) Verification of Corrective Actions associated with the NUPIC and DSQG Audit SR-2000-257 conducted on June 19-23, and July 5-7, 2001, at U.S. Tool & Die (UST&D), Inc. Pittsburgh, PA facility.

Reference: ComEd Letter SES-00-138, dated October 19, 2000

Dear Mr. Mitchell:

The UST&D corrective actions related to the findings that had been identified during Audit SR-2000-257 were verified during surveillance of shop activities at UST&D. These surveillance activities were conducted from December 2, 2000, through February 15, 2001. The summary of these surveillance activities is attached.

Based on the satisfactory results from the documentation reviews and verifications, it is recommended that SR-2000-257-09 be closed.

Sincerely,

Original signed by M. Mul for

Roger Gillenwater
Project Quality Control Representative

CC: H. Robinson, HUG members

Summary of Corrective Action Verification

1. Audit Finding SR-2000-257-01

This finding identified that the authorities and duties of the UST&D Organization, as shown in the current Organization Chart were not consistent with Revision 3 of the UST&D Quality Assurance Manual.

The UST&D response to this finding identified the cause as the recent re-organization and failure to update Section 1 of the QA Manual during the revision to address the ASME Code 2000 Addenda review. The corrective actions were to revise the QA Manual to show the current organizational structure by 10/30/2000.

Revision 4 of the QA Manual was issued on 10/22/00. A review of Section 1 "Organization" of the QA Manual against the current UST&D organization indicates that the authorities and duties of the persons and organizations performing activities affecting quality have been established and documented. The Quality Director has posted a memo, dated 12/05/2000 delegating additional areas of responsibility and authorities for personnel within the Quality Department.

Based on the documents and organization review it is recommended that Finding SR-2000-257-01 be closed.

2. Audit Finding SR-2000-257-02

This finding identified several deficiencies associated with QA Records. Specifically:

1. A number of QA Records such as Material Analysis Reports, Certificate of Compliances/Conformances, and Non-conformance documents were found in the Quality Control Inspector office being stored on a bookshelf and not in a fire safe cabinet.
2. Section 17 "QA Records" of the QA Manual including QCP 17.1 does not address lost or damaged records. No procedure exists for records, which are transmitted off site for storage.
3. The QA Records in the document control area were in fire safe cabinets, but were not indexed. There are no procedures established for the distribution and identification of QA Records.

UST&D's response committed to:

- Storing all of the identified QA Records in fire safe cabinets.
- Revising QCP 17.1 to address damaged records and transmittal to an outside storage source.
- Revising the QA Manual Section 17, paragraph 17.5.A.3 to reflect the current method of indexing in-process QA records.

The practice of putting in-process QA Records on a bookshelf in the QC Inspectors office has been discontinued. During this surveillance period there have been numerous walk through of the QC Inspector and QA Engineer offices. No QA Records were noted to be left out and unattended in the QC Inspector office. Quality documents such as CMTRs, Certificates of Conformance/Compliances were in the open and in-process of being reviewed for acceptance. Once these documents have been accepted they become QA Records and are filed in fire-safe cabinets. Records that were reviewed and found to be in fire-safe cabinets during this verification include calibration records, and material receipt records including CMTRs. Personnel qualification records and vendor files are stored in steel cabinets in what is designated as fire-safe room.

Reviewed QCP17.1, Revision 5. Paragraphs 6.3 and 6.4 now address steps for transferring records to a permanent out storage area. UST&D utilizes Iron Mountain for the out side record storage. Paragraph 5.3 addresses lost or damaged QA Records.

Summary of Corrective Action Verification

QA Manual Section 17 and QCP 17.1 provide an index with the distribution and storage life of various QA Records. As stated in the UST&D response, all lifetime records are transmitted to the owner at time of product shipment.

Based on the documents reviewed it is recommended that SR-2000-257-02 be closed.

3. Audit Finding SR-2000-257-03

This finding was closed during the course of the audit. No surveillance activities have been performed concerning this finding.

4. Audit Finding SR-2000-257-04

This finding identified several problems associated with training records of Quality Control personnel to the requirements of QCP 2.3 "Training" Revision 4, Section 3.3A "New Hire Orientation" requires that personnel be provided with a general overview of the QA Program. UST&D's documentation revealed that only one individual had documented evidence of having been provided with this training. After reviewing additional training records, the Training Director found similar forms being used or no supporting documentation existing. Procedures need to establish the mandatory and consistent requirement on the maintenance of training records.

UST&D took exception to part of this in that the finding incorrectly stated that only one individual had documented training. It should have read that all QC Inspectors had the documented training and that only one of them showed no evidence of training via written documents. In this one case the inspector had been hired and trained by the previous supervisor, documented and the documentation was subsequently misplaced.

The Corrective Action for the misplaced individual's Training Record was to recreate the training record. The Training Record for Thomas Cvetkovitch was reviewed. This was in the inactive file, as he is no longer employed at UST&D. The training record had evidence of the QA Indoctrination. As UST&D has downsized in the number of inspection personnel there have been no recent new-hires so the "New Hire Orientation of new employees was not reviewed for the current procedure. QCP 2.3 Revision 5 was reviewed for the current requirements for documenting training. The procedure clarified the requirement by stating that the information would be documented on a specified or similar form but must contain at a minimum the following information: the subject matter, the date and duration of the training, attendees and job titles, and the instructors name. Personnel qualification records have been reviewed for a number of the QC Personnel during various surveillances. These include James McLain, Jeffery Thomas, Michael Mangan, Dennis Buccigrossi, James Connors, Forrest J. Clester, and Paul Krebs. All of the training records were consistent with the requirements of QCP 2.3 and 2.5.

Based on the review of the UST&D procedures and listed training records it is recommended that SR-2000-257-04 be closed.

Summary of Corrective Action Verification

5. Audit Finding SR-2000-257-05

This finding identified a deficiency in the control and issuance of weld filler material. Specifically in that UST&D had overlooked the monthly temperature checks on their rod and flux ovens as required by QCP 9.2A. "Control and Issuance of SMAW and SAW Weld Filler Metal and Flux". This problem appeared to be caused by the failure to identify these ovens when UST&D had transferred items needing calibration to a new tracking base. UST&D had reviewed the rod usage from the two affected ovens from the last calibration in February 11, 2000 till checked again on June 22, 2000. As the oven thermometers were still in calibration at time of recalibration it was determined that the rod used was acceptable. The action to prevent recurrence was to add the ovens to the current calibration system. The record of monthly checks on Ovens # 16 and 17, along with the master calibration records were reviewed for the monthly checks. This period covered June 2000 through February 2001. Based on the review of the calibration records for Ovens #16 and 17, it is recommended that SR-2000-257-05 be closed.

6. Audit Finding SR-2000-257-06

This finding identified nine deficiencies related to special processes.

1. WPS 230 had a verification requirement for ferrite level checks of the weld, which is not being performed.

The Weld Engineer and QA reviewer identified the cause of the deficiency as a lack of attention to detail. The proposed corrective action was to revise WPS 230 to eliminate the ferrite level checks on the weld. UST&D meets the ferrite level requirements by purchasing weld wire with required ferrite level. WPS 230 was revised on 6/30/00. The procedure was not implemented until approved by Holtec International on 1/10/01. WPS 230, Revision 1 was reviewed and found that the ferrite level check was omitted. PQR 1094 was issued to qualify the revised WPS 230. The checklists for receipt inspection of weld wire include the required ferrite level check.

2. WPS 204 is in error. The WPS permits welding both with and without a subsequent PWHT. The Weld Engineer and QA reviewer identified the cause of the deficiency as a lack of attention to detail. The proposed corrective action was to revise WPS 204 to eliminate the allowance to weld without a subsequent PWHT. WPS 204 was revised on 6/30/00. The procedure was not implemented until approved by Holtec International on 1/10/01. WPS 204 Revision 3 was reviewed and found that the requirement for a post weld PWHT has been removed.

3. WPS 230 and 231 need the proper qualification (after the fact).

The cause of the deficiency was identified as the utilization of a plunger type side bend fixture in lieu of a wrap-around bend fixture, which led to ambiguity in interpretation of the test results. WPS 230 and 231 were both retested in accordance with ASME Section IX to provide the end use customers the added assurance that the welding procedures were technically adequate. PQRs 1091, 1092, and 1094 all dated 6/29/00 were reviewed. All three are applicable to WPS231 and WPS 83. And 1094 was applicable to WPS 230. Holtec International on 1/10/01 approved the WPSs and PQRs.

4. NCR 9925-171 permitted "welding-at-risk" without a qualified and approved WPS. This was in violation of the UST&D QA Manual Section 9.0.

This was not considered a non-conformance as UST&D had performed a "Conditional Release" using NCR 9925-171, for the welding procedure specifications. The conditional release is permitted by Section 15 of the QA Manual. In this case the performance of the PQR testing was being performed concurrently with the welding of one unit. Both WPS 230 and 231 were approved along with their associated PQRs 1075, 1077, and 1078.

5. The multiple pass weld joint data sheets are ambiguous and do not provide adequate information to determine whether or not welders have welded beyond their qualified thickness range.

Summary of Corrective Action Verification

The cause of this deficiency was identified as lack of communication. The welders involved did not understand the importance of documentation as it pertains to objective evidence of compliance to requirements.

During the production of Hi-Trac PWRP 6000-1, The following weld operations were partially observed in process and the SADS was reviewed to verify that all of the welders were qualified for the weld, and that the weld was per the appropriate WPS with correct weld wire.

Weld 11.1, 11.2, WPS 239: Weld 12, WPS 211: Weld 13.1, 13.2, 13.3, 13.4, WPS 239: Weld 15, WPS 211 & 239: Weld 16, WPS 239.

6. The information in the Data Sheets recorded by the welders is out-of-sequence (i.e. buttering after depositing 308), on the wrong Data Sheet (i.e. full thickness trunnion weld removed, and subsequently welded using the new joint detail), not consistent in the description of the weld pass (i.e. Lost Count), etc. It has taken meetings between up to 6 UST&D personnel to decipher the information.

The cause of this deficiency was identified as lack of communication. The welders involved did not understand the importance of documentation as it pertains to objective evidence of compliance to requirements.

No problems were noted in the documentation reviewed as noted in Item 5.

7. The Data Sheets do not reference NCRs, Rework, Repairs, etc. making it extremely difficult to recreate the work activities (i.e. how many trunnions were removed from the Hatch Casks). Again, it took numerous UST&D personnel to decipher the data.

UST&D took exception to item 7, as there are no requirements to list NCRs on the PWRPs. The UST&D program requires that a NCR be initiated after the 3rd reject of the weld. The weld repair would be performed on a rework PWRP that is numbered with the NCR number. This rework PWRP would become part of the document package.

8. Data Sheets for Hatch Unit 2 indicates the use of E81T1-Ni-1 for a seal weld. UST&D cannot determine what this weld was. Welding with E81T1-Ni-1 should be limited to Weld 66 (identified by NCR, not in Weld 30). It appears that there was 308 deposited directly onto carbon steel – the old 309 had been completely removed during the machining!

The cause of this deficiency was identified as lack of communication. The welders involved did not understand the importance of documentation as it pertains to objective evidence of compliance to requirements.

9. Most trunnion welds indicate a number of final cover passes were deposited with 308. Where is the verification that the 308 did not encroach upon the carbon steel surface of the overpack (if the machining was at the referenced dimensions). What assurances can be given that 308 did not contact carbon steel. UST&D took exception to item 9, saying there was no deficiency as the welding operation was planned and executed to ensure no 308 material encroachments onto carbon steel material surfaces. Procedures where this is applicable such as WPS 230 include the requirement that a layer of 309 material be present prior to the deposition of 308 onto carbon steel. Additionally, these are hold and witness points for verification prior to the welding of 308 material.

10. UST&D has used the NCR for applications where it is not intended to be used (i.e. welding "at risk"). The NCR process is more appropriately used when errors are discovered in the fabrication process – not to justify continuing fabrication activities driven by schedule.

UST&D took exception to item 10 as the UST&D Quality Program uses the NCR system to control nonconformance, potential nonconformance and as a vehicle to control manufacturing operations to

Summary of Corrective Action Verification

ensure that all issues are addressed and satisfactorily resolved. As stated in item 4, the UST&D Quality Program allows the use of a "Conditional Release" through the NCR program.

11. The existing system of documentation is ineffective in maintaining an accurate work history. On multiple occasions, in order to recreate the fabrication sequence, welders, machinists and foremen had to be interviewed. The fabrication records do not stand-alone. In addition, the welders have filled out the documentation incorrectly. This has led to misleading information in the records. And finally, there is no reasonable system that ties the original fabrication records to any NCRs and/or repairs. The system is unwieldy and needs to be reworked.

UST&D took partial exception by stating that the existing system of documentation meets all of the applicable requirements. The root cause of the documentation issues was the lack of communication on the importance of records as objective evidence. In discussions with the welding personnel they all acknowledge the importance of documentation process. UST&D regularly posts on the bulletin board any problems noted to a particular welder.

Based on the procedures and other welding related documentation reviewed it is recommended that SR-2000-257-06 be closed.

7. Audit Finding SR-2000-257-07

This finding identified five conditions associated with the UST&D External audit program.

1. "Pennoyer Dodge Co." was the provider of safety-related thread gauges to UST&D was not listed on the Controlled AVL.

UST&D revised QCP 12.1, Revision 7, which now has the requirement in Paragraph 4.6 and 4.6.1, that all M&TE, new or otherwise will be calibrated prior to use. UST&D or a qualified calibration facility will perform this calibration. Cal-Tec Labs Inc. has calibrated the thread gages identified during this audit. Cal-Tec was audited on 5/09/00 for Calibration Services. The calibration records were reviewed to verify calibration by Cal-Tec for the following Thread gauges: TG-013, TG-029, TG-024, TG-021, TG-022, TG-020, TG-026, TG-028, and TG-005.

2. The controlled AVL dated 22 June 2000 had the audit date for vendor "Dunkirk Industries, Inc.", as 4/21/2000. This was past the 60 day before/beyond the three year established frequency for the audit. UST&D took exception to this deficiency. QCP 7.2 states that audits shall be scheduled and performed no later than 60 days from the expiration date for vendors with open purchase orders. There were no open purchase orders with Dunkirk Industries. The audit of Dunkirk was performed on 6/20/00. The UST&D AVL dated 12/07/00 was reviewed for the last audit date and audit due dates. Two suppliers were noted to have audit dates that were in the 60-day window. Consolidated Power Supply was last audited on 10/28/97, and Energy & Process was last audited on 10/21/97. These two suppliers were audited on 12/4/00 and 12/5/00 by Dan Bowling. The audit report had not been issued at time of this review. The audit plan and checklist was reviewed for scope and objective evidence. Any not applicable were justified. No problems were noted on these suppliers. Dunkirk Industries is currently on the AVL Inactive list.

3. The UST&D AVL shows a next audit due date for vendors Hamill Manufacturing and Harmony Machine for 7/11/00 and 7/2/00 respectfully. There is no documented evidence of audit planning or scheduling available.

The UST&D response stated that no purchases had come from these two suppliers that were in the 60 day window. Harmony Machine was removed from the AVL for non-usage. Hamill Manufacturing was audited on 8/30/00 and is currently listed as inactive on the AVL.

Summary of Corrective Action Verification

4. The UST&D external audit of "Industrial Testing Lab" was not comprehensive and did not obtain sufficient objective evidence in the checklist.

UST&D reevaluated the audit that had been performed on Industrial Testing Lab and concurred that the areas of Control of Special Processes, Non-conformances, Corrective Action, and Test Control was not as comprehensive as might be desired. The final report did reflect evaluation in these areas.

Additionally, the listing on the AVL was modified to add the restriction that "Additional audit activities will be required on the next order. No new orders have been noted to date.

5. The audit of International Tube was not comprehensive and did not contain sufficient objective evidence. In addition the design section of the audit was marked not applicable with any justification. Additionally the audit team concluded that the Lead Auditor of these audits did not address all of the applicable criteria and the audit checklists did not include adequate objective evidence.

The UST&D response identified International tube as a material supplier with an ISO 9002 program and did not have a design program. Holtec International is responsible as the design owner. The audit checklists associated with the Consolidated Power Supply and Energy and Process were reviewed for sufficient objective evidence. Both of these checklists had design as not applicable as the scope was limited to material supply.

Based on the review of the UST&D response, their AVL and selected audits it is recommended that SR-2000-257-07 be closed.

8. Audit Finding SR-2000-257-08

This audit finding identified several non-conformances related to missed hold and inspection points and that the corrective action appeared insufficient.

This issue had been self identified by UST&D and corrective actions were in process at the time of the audit. The President of UST&D had issued a memo to all employees, a memo to management personnel, and a memo to the United Steel Workers organization establishing the company position on this issue and setting forth the disciplinary actions which will occur for future violations. Other actions included increased surveillance activities by Quality Control to detect violations in this area.

The various project NCR logs were reviewed for this type non-conformance after the 7/14/00 date. NCR 9925-241 dated 11/13/00 was noted. This was the only NCR initiated for a missed inspection point.

UST&D CAR 103 was initiated as a result of this item. This condition was investigated and appropriate corrective actions taken. The CAR was closed on 1/15/01. Several of the notification memos and e-mails are posted in the shop and office areas. These stress the importance of customer notification.

Discussions with craft and quality personnel indicate that they are aware of the issue and take it serious.

The QC inspectors perform periodic surveillances on in-process PWRPs to assure that all steps are documented. Copies of completed PWRP surveillance checklists were reviewed with no problems noted.

Based on the documentation reviewed it is recommended that SR-2000-257-08 be closed.

Summary of Corrective Action Verification

9. Audit Finding SR-2000-257-09

This finding identified two problems in the test control area.

1. UST&D did not initiate an NCR when a pressure test was performed using a gauge that was known to be out of calibration.

The initial UST&D response was that if the gauge came back showing the results to be in error than an NCR would have been appropriate. UST&D acknowledged that they erred in this matter and that a NCR should have been initiated to do a risk release on the gauge prior to the test. The gauge in question was sent for calibration after the test and found to be accurate. No other actions were taken.

2. An examination of a Pneumatic Test Record for a HI-STAR 100 Overpack identified the following deficiencies:

- UST&D did not satisfy the performance test requirements for the Pneumatic Test requirements for the HI-STAR 100 Overpack.
- UST&D did not establish the pneumatic test acceptance criterion of zero leakage as measured by the 0-600 psi gauge in the Pneumatic Test Instructions 9905-00-112, dated 5/16/00 or any other approved instructions or documents.
- The results of the pneumatic test that were documented on the HI-STAR 100 Overpack Pneumatic Test Report had not been reviewed and approved by responsible UST&D personnel.

A review of the test procedure for the pneumatic test indicates that the acceptance criteria is zero leakage. The tests for the HI-STAR 100: S/N 007 and 008 were witnessed by the Project Quality Control representatives (PQCRs). The test criteria recognized during both tests were that the test pressure would be held for 10 minutes with no reduction in pressure or zero leakage. The instructions (9905-00-112) provided to the test personnel were to provide instructions on the performance of the tests. The actual acceptance criteria were contained in the customer purchase specification HSP-105. 9905-00-0160 was revised on 11 August 2000 to show the zero leakage as the test acceptance criteria. Future test instructions will contain the acceptance criteria.

The following test instructions have been reviewed for the acceptance criteria. These include: CSP 0040-1, 9905-00-0160, CSP 0040-5, and CSP 0040-3. All of these had the appropriate review and acceptance signatures.

Commonwealth Edison Company
1411 Opus Place
Downers Grove, IL 60515-5701



October 19, 2000
SES-00-138

Mr. Martin Edwards
Quality Assurance Manager
U.S. Tool & Die Incorporated
200 Braddock Avenue
Pittsburgh, PA 15145

Subject: ComEd Follow-up response to your response (Ref. No.1) as a result of NUPIC and DSQG Audit, SR-2000-257 of U.S. Tool & Die (UST&D), Inc., Pittsburgh, PA Facility on June 19-23 and July 5-7, 2000

Reference: 1) UST&D Letter No. 00-0184 From V. Martin Edwards to Oscar Shirani, dated September 05, 2000


Dear Mr. Edwards:

I have reviewed your response as stated in the above Reference No. 1. You have provided the evidence of your corrective action and have indicated that some of the actions to be completed in future date. Your response to the Nine (9) Audit Findings sounds reasonable. However, the subject findings except the Finding No. SR-2000-257-03, which was closed during the audit, remains OPEN pending our verification of your completed corrective actions. Our newly elected Resident Inspector at UST&D, Mr. Roger Gillenwater will perform the follow-up of your corrective action and generate a response which will be concurred by me. Our follow-up will cover all your completed corrective action with a more rigor emphasis on your Special Processes and corrective action program which was determined to be ineffective by the audit team on June 19-23 and July 5-7, 2000.

The cooperation and assistance extended to the audit team by UST&D personnel during the audit is greatly appreciated.


Please refer questions to Oscar Shirani, ComEd Supplier Evaluation Services (SES), at Tel. No.: 630-663-5873.

Prepared By:


Oscar B. Shirani, PE
Audit Team Leader

Date: 10/19/00

Approved By:


Russell Bastyr
Supplier Evaluation Services Manager

Date: 10/20/00

cc: Audit File SR-2000-257
Duplicate File
NUPIC Members



UST&D

U.S. Tool & Die, Inc.

September 05, 2000
00-0184

Mr. Oscar Shirani, PE
ComEd/Supplier Evaluation Services
1411 Opus Place, Suite 250
Downers Grove, IL 60515-5701

Dear Mr Shirani:

This letter forwards UST&D's response to the Nine Findings and Three Observations noted on ComEd/NUPIC and DSQG Audit Report SR-2000-257 dated 4 August 2000. The response addresses the causes, corrective actions taken, or to be taken, actions to prevent recurrence, and expected completion dates.

UST&D understands that under the NUPIC guidelines, the classification of an audit discovery as a finding, observation, or recommendation is the prerogative of the lead utility. UST&D goes on record as considering many of the findings documented during the audit as observations when applied to universally recognized classifications of audit discoveries.

If you have any questions concerning UST&D's response to your Audit Report please feel free to contact me.

Sincerely,

UST&D, Inc.

V. Martin Edwards
Director Quality Assurance

Cc:
President and CEO UST&D, Inc.
Executive Vice-President UST&D, Inc.
President and CEO, Holtec International

ENCLOSURE TO UST&D LETTER 00-0184
UST&D RESPONSE TO COMED/NUPIC/DCOG AUDIT NO. SR-2000-257

A. AUDIT FINDING RESPONSES:

1. Audit Finding SR-2000-257-01

Requirement:

In Section I – Organization of 10CFR50 – Appendix B, the statement is written, “The authority and duties of persons and organizations performing activities shall be clearly established and delineated in writing.”

Discrepancy:

Contrary to the above requirements, the authority and duties of the U.S. Tool & Die Organization, as shown in the current Organization Chart, are not consistent with the identified positions and/or authority and responsibilities as depicted in Revision 3 of the Q.A. Manual.

Cause of Deficiency:

This deficiency was due to recent (May 2000) changes in the organization. The Q.A. Director had planned on revising section 1.0 of the manual when revising other sections based upon review of the 2000 Addenda of ASME Code.

Proposed Corrective Action:

Section 1.0 of the Quality Assurance Manual will be revised to reflect the changes in the organization identified during the audit as well as additional organizational changes made since the audit. The revised Organizational Chart will be reflected in Revision 4 of the Q. A. Manual.

Actions to prevent recurrence:

The accuracy of the Organization Chart will be reviewed during the annual Q.A. Program review and assessment scheduled for January of each year.

Expected completion date:

Revision 4 of the Q.A. Manual is expected to be issued by 31 October 2000.

2. Audit Finding SR -2000-257-02

Requirement:

QCP 17.1 establishes the measures necessary for the storage, protection and retention of quality records. It also addresses lifetime and & non-permanent QA Records.

QA Manual Section 17.3.B.1 States in part that records will be indexed and temporarily filed in the Quality Control Department using one hour rated fire safe file cabinets.

ANSI N45.2.9-1974, Section 3.2 States "The Quality Assurance Records shall be listed in an index"; "Shall be distributed and handled in accordance with written procedures"; "Shall provide sufficient information to permit identification between the record and the items, or activity to which it applies".

QA Manual, Section 17.5.C.1 specifies that records transmitted to a permanent storage facility is handled in accordance with a written procedure.

Discrepancy:

Contrary to the above requirements the following conditions were found:

1. A number of QA Records such as the Material Analysis Reports, Certificate of Compliances/Conformances, and Non-conformance documents were found in the Quality Control Inspector office being stored on a bookshelf and not in a fire safe cabinet.
2. Section 17 "QA Records" of the QA Manual including QCP 17.1 does not address lost or damaged records. No procedure exists for records, which are transmitted off site for storage.
3. The QA Records in the document control area were in fire safe cabinets, but were not indexed. There are no procedures established for the distribution and identification or classification of QA Records.

Cause of Deficiency:

1. This deficiency had been previously identified by Holtec as finding # 2000-E05-4 during a Holtec audit in April 2000. UST&D had committed to obtain fireproof cabinets and resolve this issue by August 1, 2000. Holtec accepted UST&D's response to this issue. UST&D was in the process of moving the records into fire-safe cabinets when the NUPIC/DCQG audit was being conducted. UST&D self-identified this issue to the auditor and provided objective evidence of the fact. UST&D has moved the in-process records in question into fire safe cabinets and completed the corrective actions required by Holtec's audit finding.
2. Quality Control Procedure for QA Records -QCP 17.1, Paragraph 4.3 addresses missing, incomplete, and records that contain erroneous information. The paragraph however failed to address "damaged" records, even though the resolution of this type item would be identical. Section 17 of the QA Manual, paragraph 17.3.B.2 states that lifetime quality records are transmitted to the owner at the time of product shipment. As

such, UST&D only retains non-permanent quality records. Although Section 17 of the QA Manual addresses the use of an outside vendor for records storage, the procedure for transferring these records had not been added to QCP 17.1 as needed.

3. The QA records in the document control area are in-process quality records and are indexed by Project number and type of record. UST&D interpreted the requirement in ANSI N45.2.9, Paragraph 3.2.2 to apply to Code Stamped items. Review of non-code records indicates that the requirement was not applied as required by UST&D's QA Program.

Proposed Corrective Action:

1. All QA records identified by Holtec's audit report and additional QA records identified during UST&D's review of other records affected have been temporarily stored in fire safe cabinets.
2. The Quality Assurance Manual Section 17 and the Quality Control Procedure 17.1 will be revised to address the issue of damaged records, transmittal of QA records to the outside storage source, and provide more detail on record corrections. Additionally, ANSI N45.2.9 will be reviewed and any missing requirements will be incorporated.
3. The Quality Assurance Manual Section 17, paragraph 17.3.A.3 and Quality Control Procedure 17.1 will be revised to reflect the current method of indexing in-process QA records and storage requirements per ANSI N45.2.9.

Actions to prevent recurrence:

1. All QA records will be maintained and distributed in accordance with ANSI N45.2.9.
2. UST&D will review and comply with subsequent NRC approved revisions of NQA-1 and any sister specifications concerning records.

Expected completion date:

Completion of all immediate corrective actions is expected to be complete by 31 October 2000.

3. **Audit Finding SR -2000-257-03**

This Finding was closed during the course of the audit.

4. **Audit Finding SR -2000-257-04**

Requirement:

UST&D Procedure No. QCP 2.3 "Training" Rev. 4 dated 3/6/95 establishes the requirements for specifying, conducting and documenting training of personnel. Section 3.3A "New Hire Orientation" requires that personnel be provided with a general overview on the requirements of the QA Manual. QA Manual Section 2.0, Rev. 2 dated 4/22/98 states that the training records will be maintained and filed by the QA Manager.

Discrepancy:

Contrary to the above requirements, the following conditions were found:

UST&D's documentation revealed that only one individual had documented evidence of having been provided with the training. However, the form on which this training was documented on is not addressed in the procedure. After further review of some additional training records, the Training Director found similar examples of different forms being used or no supporting documentation existing. Procedures need to establish the mandatory and consistent requirements of training and provide requirements on the maintenance of the training records.

Cause of Deficiency:

The audit report incorrectly stated that only one individual had documented training. To be accurate, all QC inspectors had the documented training and only one of them showed no evidence of training via written documents. This inspector began employment on 12/27/99 during the first week of the interim QA Managers duties. The training with the QC Inspector involved had been conducted by his supervisor and documented. The documentation was misplaced.

In response to the question of different training forms being used, the QCP on training (QCP 2.3) states that training will be documented on the attached Training Record or other similar form. The procedure continues by clarifying that the training record used will provide, as a minimum, the subject matter, date and duration of training, attendees and job titles, and instructor name. Additionally, the procedure addresses the review, maintenance and filing of training records.

Proposed Corrective Action:

The training record in question was re-created to reflect the actual dates of training and signed by the inspector and supervisor. Review of all QC Certification and training records was conducted. No additional documentation discrepancies were discovered.

Actions to prevent recurrence:

To better clarify the training documentation requirements; QC Procedure 2.3 was revised to ensure consistent requirements on documentation and maintenance.

Expected completion date:

Index revision number 17 to the QC Procedure is scheduled for issue by 29 September 2000. This revision will transmit QCP 2.3 Revision 5.

An additional issue was brought to UST&D's attention by the audit team leader after the final audit report had been issued. Specifically, the eye exam frequency for an inspector was questioned. UST&D's Quality Program Manual, Section 2.7.E requires that each inspector receive a yearly eye examination. The inspector in question satisfactorily completed an eye examination on 23 March 1999 and again on 23 March 2000. In practice, UST&D schedules inspectors for eye examination at an optometrist office on the morning of their anniversary date. The inspectors are required to report to work with a completed Visual Eye Examination Record. This record documents that the inspector has satisfactorily passed the exam, and is signed by the attending Optometrist. In this case the inspector passed the exam. UST&D believes that this practice complies with the requirement for a yearly eye examination and as determined during the audit, no deficiency exists.

5. Audit Finding SR -2000-257-05

Requirement:

Quality Control Procedure (QCP) 9.2A, "Control and Issuance of SMAW and SAW Weld Filler Metal and Flux," Revision 2, Paragraph 7.1 requires monthly oven temperature checks of the rod and flux ovens using a calibrated thermometer.

Discrepancy:

Contrary to the above requirement, the last monthly check of rod ovens No. 16 and 17 were performed on February 11, 2000. The temperature checks were approximately three months overdue. It appeared that when UST&D transferred items requiring calibration to a new tracking database, the two ovens were inadvertently not added to the new database.

Note: UST&D took immediate corrective action. Temperature checks of the two ovens were made without adjusting the temperature setting. The as-found temperatures of the ovens were acceptable. Filler metal issuance from the two ovens was reviewed. The filler metal issue records for the rods in the oven revealed that no rod was issued from Oven No. 16 since December 21, 1999 and approximately 60 rods were issued from Oven No. 17.

Cause of Deficiency:

The Rod ovens in question were inadvertently missed during the transfer of calibration recall records from the manual recall log to the calibration-computerized database in January of 2000.

Proposed Corrective Action:

Both Ovens were re-calibrated using a calibrated thermometer. Both were in compliance with QCP 9.2A requirements without any adjustments required. The Ovens were immediately added into the computer database calibration program for future recall and are checked on a monthly basis.

Actions to prevent recurrence:

All Ovens were reviewed and determined to be in calibration and present in the computerized recall system. The ASME Section IX oven weld material was inventoried. Additional investigation into use of the 60 rods revealed that only one heat of rod (UST&D MIC# WC-052) had been used on Southern Nuclear and Commonwealth Edison Projects. As the ovens were within temperature requirements without adjustments upon re-calibration, there is no affect on past product.

Expected completion date:

Complete

6. **Audit Finding SR -2000-257-06**

Requirement:

Quality Assurance Program Manual, Section 9.0, Revision 2 states that the special processes (such as welding, heat treating, and NDE) are controlled by qualified personnel to the acceptance criteria of the applicable Codes, Standards, and/or Specifications. All welding will be performed in accordance with ASME Section III and Section IX and UST&D procedures. All Welding Procedure Specifications (WPS) will be written and qualified in accordance with ASME Section IX and III of the Code as applicable. The WPS lists each essential and supplementary essential variables for each process. The actual value of each essential and supplementary essential variable used is recorded on the Procedure Qualification Record (PQR).

Discrepancy:

Contrary to the above requirements, the following conditions were found:

1. WPS 230 has a verification requirement for ferrite level checks of the weld which is not being performed / documented. This requirement should either be deleted from the WPS or a verification check should be added to the PWRP.
2. WPS 204 is in error. The WPS permits welding both with and without a subsequent PWHT. The supporting PQRs do not qualify welding without a subsequent PWHT. UST&D has stated the error is strictly typographical. UST&D needs to verify that all applications where this WPS was used have received a subsequent PWHT (i.e. there are not welds left in the as-welded condition. Also PQR 1006 contains a typo.

3. WPS 230 and 231 still need the proper qualification (after-the-fact).
4. NCR 9908-171 permitted "welding-at-risk" without a qualified and approved WPS. This is a violation of the UST&D QA Manual, Section 9.0.
5. The Multiple Pass Weld Joint Data Sheets are ambiguous and do not provide adequate information / documentation to determine whether or not welders have welded beyond their qualified thickness range. This documentation must be revised to provide adequate information to ensure welders are qualified for the thickness they are depositing in any given weld joint.
6. The information in the Data Sheets recorded by the welders is out-of-sequence (i.e. buttering after depositing 308), on the wrong data sheet (i.e. full thickness trunnion weld removed, and subsequently welded using the new joint detail), not consistent in the descriptions of the Weld Pass (i.e. Lost Count), etc. It has taken meetings between up to 6 UST&D personnel to decipher the information.
7. The Data Sheets do not reference and NCRs, Rework, Repairs, etc. making it extremely difficult to recreate the work activities (i.e. how many trunnions were removed from the Hatch casks). Again, it took numerous UST&D personnel to decipher the data.
8. Data Sheets for Hatch Unit 2 indicates of the use of E81T1-Ni-1 for a seal weld. UST&D cannot determine what this weld was. Welding with E81T1-Ni-1 should be limited to Weld 66 (identified by NCR, not in Weld 30. It appears that there was 308 deposited directly onto carbon steel – the old 309 had been completely removed during the machining!
9. Most trunnion welds indicate a number of final cover passes were deposited with 308. Where is the verification that the 308 did not encroach upon the carbon steel surface of the overpack (if the machining was at the referenced dimensions). What assurances can be given that 308 did not contact carbon steel.
10. UST&D has used the NCR for applications where it is not intended to be used (i.e. performing welding "at risk"). UST&D knowingly performed welding without an approved procedure. The NCR process is more appropriately used when errors are discovered in the fabrication process – not to justify continuing fabrication activities driven by schedule.
11. The existing system of documentation is ineffective in maintaining an accurate work history. On multiple occasions, in order to recreate the

fabrication sequence, welders, machinists and foremen had to be interviewed. The fabrication records do not stand-alone. In addition, the documentation has been filled out incorrectly by the welders. This has led to misleading information in the records. And finally, there is no reasonable system that ties the original fabrication records to any NCRs and/or repairs. The system is unwieldy and needs to be reworked.

Cause of Deficiency:

1. Lack of attention to detail by the Weld Engineer and QA reviewer.
2. Lack of attention to detail by the Weld Engineer and QA reviewer.
3. Utilization of plunger type side bend fixture in lieu to a wrap-around bend fixture let to ambiguity in interpretation of the test results.
4. No deficiency, this was a conditional release of the Weld Procedure Specifications in accordance with UST&D's QA Program.
5. Lack of communication. The welders involved did not understand the importance of documentation as it pertains to objective evidence of compliance with requirements.
6. Lack of communication. The welders involved did not understand the importance of documentation as it pertains to objective evidence of compliance with requirements.
7. No deficiency, there is no requirement to list NCRs on PWRP steps.
8. Lack of communication. The welders involved did not understand the importance of documentation as it pertains to objective evidence of compliance with requirements.
9. No deficiency existed. This operation was planned and executed to ensure no 308 material encroachments onto carbon steel material surfaces.
10. In UST&D's Quality Program the NCR system is used for nonconformance, potential nonconformance, and as a vehicle to control manufacturing operations to ensure that all issues are addressed and satisfactorily resolved. As such, the NCR for this application was appropriate.
11. The existing system of documentation meets all applicable requirements. The root cause of the documentation issues is the lack of communication on the importance of records as objective evidence.

Proposed Corrective Action:

1. WPS 230 has been revised to eliminate the ferrite level checks of the weld. UST&D meets the ferrite level requirements by purchasing weld wire with the required ferrite level as allowed by NB-2432.
2. WPS 204 has been revised to eliminate the allowance to weld without a subsequent PWHT. Review of weld records revealed that WPS 204 was not used to weld without a subsequent PWHT. Additionally, PQR 1006 has been revised to eliminate the typographical error.
3. WPS 230 and WPS 231 were retested in accordance with ASME Section IX to provide end use customers with the added assurance that the welding procedure was technically adequate. Both weld processes have successfully passed the requirements on several occasions. PQRs 1091, 1092, and 1094 document the retests.
4. UST&D QA Manual, Section 9.0 requires that all welding will be performed in accordance with ASME Section III and Section IX, and UST&D Procedures. UST&D Quality Control Procedure 15.1 "Control of Non-conformance Reports," allows the conditional release of the item which is non-conforming for further fabrication provided the conditions of release are satisfied prior to a predetermined point in manufacture. NCR 9908-171 disposition allowed for a conditional release of WPS 230 and 231 pending final results of PQR testing. The PQR testing was being performed concurrently with the welding on one unit. The practice of "risk releasing" is common practice in the nuclear fabrication industry. The customer and end users were informed of UST&D's intention at the time of risk release and the non-conformance was controlled by UST&D's quality program. Although the product being fabricated was not an ASME Code vessel, the Authorized Nuclear Inspector attested that had it been a Code stamped item, he would have accepted the welds prior to the officially qualified procedures. As such, this extraordinary situation was handled in an acceptable manner as determined by the ANI.
5. UST&D verified that all welders welding on the weld joint in question were qualified for unlimited weld deposit. All other multi-pass welds were reviewed by Quality Assurance and it was determined that no welders welded past their range of qualifications.
6. Interviews with the welders who deposited weld in the weld joints in question revealed that they had welded in the proper sequence; however, the paperwork was not completed in the sequence that the weld was deposited. The weld data sheets were recreated and each welder involved signed a document to attest that the recreated weld sign-off sheets were accurate under penalty of law. The welders in question were retrained on

the proper method of completing weld documentation, and received a warning that future instances of improperly completed weld documentation would result in additional disciplinary actions.

Note: UST&D QA Director corrective action follow-ups have revealed compliance in this area. Monitoring will continue.

7. The referencing of NCRs on specific Production Work Routing Plan (PWRP) steps is not a Code or UST&D requirement. UST&D's Quality Program controls the sequence of operations by requiring the PWRP operations stop while an NCR is open. PWRP sequenced operations may not proceed until an NCR has been closed or a conditional release is in place.
8. Again this was a case where the documentation did not reflect the actual sequence of welding. The E81T1-Ni-1 was used to seal between layers prior to the deposition of 309 material. The issue of 308 depositions on carbon steel was a factor when removing the old pocket trunnions. A layout was completed demonstrating that clearances did exist between the old and new welds. Additionally, UST&D Quality Control Inspectors in conjunction with the Southern Nuclear Resident Inspector verified that 309 Material was present in the boundaries of the weld joint prior to depositing 308 materials.
9. As stated above, the removal of the pocket trunnions were performed according to a layout and planned removal sequence. UST&D Quality Control and customer resident inspectors performed verification activities to ensure that 308 did not encroach upon the carbon steel surfaces.
10. 10CFR50, Appendix B, Section XV requires that "measures be established to control materials, parts, or components that do not conform to requirements in order to prevent their inadvertent use or installation. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures". UST&D Quality Control Procedure - QCP 15.1 is the procedure that provides this control.
As such, limited and highly controlled use of this technique can be rationalized if the safeguards of 10CFR50 can be met.
11. The existing system of documentation is effective in maintaining a work history that meets documentation requirements if properly complied with. This issue of weld documentation was addressed in item number six.

Actions to prevent recurrence:

1. The QA Director or designee will pay closer attention to detail during the review and approval of future WPS documents.
2. The QA Director or designee will pay closer attention to detail during the review and approval of WPS and PQR documents.
3. UST&D has evaluated all previous bend specimens for this bend-fixtured phenomenon and determined that the anomalous bend specimens are confined to extreme dissimilar metal weld qualifications. All future dissimilar PQRs will be bent using a wrap-around bend fixture. Furthermore, all labs performing test work will be required to submit test specimens within a week of test completion. UST&D will monitor this corrective action through follow-ups to Corrective Action Request Number 075, which was initiated to investigate and track this issue.
4. UST&D maintains that highly controlled and limited use "risk release" of a WPS prior to completion of all elements of a PQR qualification is within the allowances of 10CRF50, Appendix B and UST&D's Quality Program. Discussions with various ASME Section IX Code Committee members and our Authorized Nuclear Inspector reinforce this position.
5. Weld Engineering notified all welders of their qualification limitations to verify that they understood their responsibilities. The Weld Engineer will update this notification of weld qualification limitations monthly and transmitted to the welders. In addition, the Production Foreman have been tasked with ensuring that the welders understand their deposited depth limitations, if any, prior to assignment to a weld joint in which their depth limitations could be exceeded.
6. UST&D QA personnel will review all multi-pass weld sheets and take disciplinary action with welders who fail to comply with documentation requirements. This will be accomplished with the existing Production Work Routing Plan Random Audit Program.
7. The practice of recording the NCR number on the inspection PWRP step is not a UST&D requirement. The NCR lists the applicable PWRP to which it applies. This provides the traceability necessary to re-create work activities as NCRs are generated at UST&D inspection steps.
8. As discussed previously (item 8) of proposed corrective action, proper weld documentation was addressed and QA personnel will monitor corrective actions

9. Not applicable. This was an isolated rework due to removal of the previously installed pocket trunnions.
10. UST&D will continue to follow its approved Quality Program.
11. These issues were previously addressed under items 6 and 7.

Expected completion date:

All immediate corrective actions are complete. Monitoring and follow-up will be performed and tracked under UST&D Corrective Action Requests generated to document these issues.

7. Audit Finding SR -2000-257-07

Requirement:

UST&D Quality Assurance Program Manual Section 18.0 (Audit), Revision 2, dated 4/22/98 states "Quality Assurance Program Audits will be planned and scheduled to provide coverage of activities affecting quality. Audit personnel shall have the authority and organization freedom to conduct an effective and meaningful audit. Audits will be performed in accordance with established procedures with audit checklists developed to cover the selected elements of the quality program.

UST&D Quality Assurance Program Manual Section 7.0 (Control of Purchased Items and Services), Revision 2, dated 4/22/98 states "Vendors shall be evaluated and approved based on their capability to provide items and services in accordance with the requirements of the Code and/or design documents".

QCP 7.2 Rev 4, Section 4.2.3 states "Vendor audits shall be scheduled and performed no later than 60 days from the expiration date for vendors with open purchase orders".

NRC Letter dated September 11, 1992 provided clarification on requirements for manufacturers of equipment who provided calibration services. The NRC staff interpretation stated that the manufacturer is required to be audited if a customer accepts the calibration certification with the M&TE purchased.

Discrepancy:

Contrary to the above requirements, the following conditions were found:

1. Vendor "Pennoyer Dodge Co." who provided safety related thread gages to UST&D was not listed on the controlled AVL dated June 22, 2000 nor was it audited. The thread gages have been actually used in production.

2. The controlled AVL, dated 22 June 2000 reflected the audit date for vendor "Dunkirk Industries, Inc." the provider of safety related tube bending services to be 4/21/2000 which is past due at the time of the audit, 6/22/00. This 60 days before/beyond the three-year established frequency of audits has also expired.
3. The next audit due date for Vendors "Hamill Manufacturing" and "Harmony Machine" for safety related machining services are reflected on the AVL as 7/11/2000 and 7/2/2000 respectively (a few days left from the date of the NUPIC/DSQG Audit), but there is no evidence of any audit planning and scheduling documentation.
4. The UST&D external audit of Vendor "Industrial Testing Lab" the provider of safety related material testing, NDE, metallography, and calibration was incomprehensive and contained insufficient objective evidence in the sections of the checklist.
5. The audit of vendor "International Tube" the provider of safety related Stainless Steel Tubes was also incomprehensive and contained insufficient objective evidence. In addition, the design section of International Tube was documented as "Not applicable" without any explanation stating who is taking the design responsibility for the purchased safety related tubes, in light of the fact that the purchase order was safety related and invoking the vendor's QA program and 10CFR Part 21

It was the conclusion of this audit team leader that the audits did not effectively address all the applicable 18 Criteria and the checklist did not adequately document sufficient objective evidence.

Cause of Deficiency:

1. UST&D NDT & Training Director purchased the M&TE from an unapproved source due to a lack of knowledge. The gauge was put into use by accepting the manufacturer's calibration because scheduling considerations dictated expediency, and UST&D was unaware of the NRC guidance on this subject.
2. There is no deficiency. UST&D Quality Control Procedure QCP-7.2 "Vendor Evaluation and Qualification," Paragraph 4.2.3 states that "Vendor Audits shall be scheduled and performed no later than 60 days from the expiration date for vendors with open purchase orders. In this case there was no open purchase order with Dunkirk Industries, Inc. It should be noted that the audit of Dunkirk had been planned and completed within the 60-day window despite the fact that there were not open orders.

3. There is no deficiency. As mentioned in number 2 above, there were no open purchase orders at Hamill Manufacturing. UST&D was aware that Hamill required auditing. However, due to limited use of Hamill Manufacturing and discussions with Project Managers, there was no plan to utilize Hamill Manufacturing for orders in the near future. As such, there would be no evidence of audit planning and scheduling documentation, and the requirements of QCP - 7.2 Paragraph 4.2.4 would apply once the 60-day window had passed.
4. UST&D QA Director's review of the subject audit and objective evidence indicated that the audit included a comprehensive quality systems evaluation. However, the compliance evaluation in the areas of Control of Special Processes, Non-conformances, Corrective Action, and Test Control were not as comprehensive as might be desired. The final report did reflect evaluation activity in these areas; however, the objective evidence on the audit checklist did not reflect examples of what was evaluated. Industrial Testing Lab (ITLS) is a proven supplier of services to both the Commercial and Naval nuclear industries. As such, the quality of services provided is not suspect. However, ITLS status on the approved vendor list will be restricted to require a focused audit on each order until which time the deficient sections of the evaluation are reperformed.

Note: NQA-1-1989 Section 7 states that "The procurement of items and services shall be controlled to assure conformance with specified requirements". This requirement continues by providing the Quality Program holder the prerogative to apply this control by a variety of methods. UST&D QA Program Manual Section 7.2.B states "Vendors shall be evaluated and approved based upon their capability to provide items and services in accordance with the requirements of the Code and/or design documents. UST&D utilizes methods of control in addition to quality audits, such as surveillances and 100% receipt inspection. Vendors are evaluated according to their capability to supply material or services to UST&D Purchase Order requirements. UST&D's expectations of a Vendor on orders is determined by the scope and complexity of the work contracted.

UST&D QA Program Manual Section 18.2.F states "Audits will be performed in accordance with established procedures with audit checklists developed to cover the selected elements of the quality program. It is UST&D's responsibility to determine the scope and depth of its vendor audits according to the planned utilization of the vendor's services. As such, audits that on the surface appear to be incomplete or lack adequate objective evidence, are in fact comprehensive as it relates to the planned use of the vendor.

5. International Tube's Quality Program audit was reviewed. International Tube has been removed from the AVL. International Tube has an ISO-9002 Quality Program. The design function was not reviewed during the subject Audit, since International Tube does not have design capabilities. International Tube was utilized by UST&D for tubing once, under Purchase Order 98-0490 (Project 9808 – GPU Tube Bundles). As explained during the audit, design services for Project 9808 was provided by Holtec International (reference UST&D Purchase Order 98-0972). Holtec International is an audited and approved supplier of design services and is listed on the UST&D AVL.

Proposed Corrective Action:

1. The gauges manufactured by Pennoyer Dodge Co. were calibrated by an audited and approved calibration laboratory. Additionally, a review of other gauges purchased previously on Purchase Order # 00-0297 determined that they also were in violation. An audited and approved calibration laboratory has also calibrated these gauges. There were no discrepancies noted between the Certificate of Calibration provided by Pennoyer Dodge Co. and the calibration laboratory on UST&D's Approved Vendor List.
2. None Required.
3. None Required.
4. The UST&D QA Director reviewed all audits for suppliers on the Approved Vendor List (AVL). After review, additional vendors were removed from the AVL due to inadequate audits, poor performance, or lack of use. The deficient elements of ITLS QA program will be evaluated for compliance at the next order placement.
5. International Tube was removed from the UST&D AVL, as this was a one-time procurement. International Tube will require re-auditing prior to being placed back on the AVL.

Actions to prevent recurrence:

1. UST&D Quality Control Procedure for Calibration (QCP-12.1) was revised to require that all M&TE, new or otherwise, be calibrated at UST&D or an approved calibration supplier listed on the Approved Vendor Listing prior to being placed into service.
2. N/A
3. N/A

4. N/A

5. A comprehensive review of UST&D's method for vendor evaluation and qualification was conducted. As a result of this review, the following actions will occur. Q.A. Program Manual Sections 7 and 18, and Quality Control Procedures 7.2 and 18.1 will be revised to document improved methods of vendor evaluation and qualification as well as to strengthen both internal and external audits. In addition, an auditor-training program is being developed to increase the skill base for both internal and external audits. Internal audit checklists are being revised to reflect the NUPIC/DSQC audit methodology.

Expected completion date:

Item No. 1 has been completed and Item No. 5 is scheduled for completion as a part of a complete rewrite and issue of the QA Manual and applicable QC Procedures. This action will be completed by 31 October 2000. All other items are not applicable.

8. **Audit Finding SR -2000-257-08**

Requirement:

UST&D Procedure QCP 14.1 Rev. 2, dated 3/18/98, Section 5.2.2 States "Operations may occur out of sequence listed provided no operation or inspection is bypassed or omitted and the intent of all hold points is maintained

UST&D CAR No. 68, was generated for bypassing the inspection (hold and witness points). The subject CAR was dispositioned on 5/11/2000 addressing the cause, corrective action, and action to prevent recurrence.

Discrepancy:

Contrary to the above requirements, the following conditions were found:

- NCR No. 9925-70 dated 6/5/00 addressed bypassing of the hold points and resulted in the issuance of CAR No. 071
- NCR No. 9925-74, dated 6/19/00 addressed bypassing of a witness point
- NCR No. 9925-80, dated 6/21/00 addressed bypassing of a inspection step
- NCR No. 9925-82, dated 6/22/00 addressed bypassing of a inspection step

Four NCRs are written after the dispositioning of CAR No. 068 which had identified bypassing of the witness points as isolated in nature. The above NCRs are reasonable indications that UST&D's Corrective Action Program is not effectively implemented.

Cause of Deficiency:

UST&D CAR No. 68 was issued on 5/9/00 to address what appeared to be an isolated incidence. However, on 6/5/00 the QA Director issued CAR No. 71 to

the President of UST&D after determining that this deficiency was recurring and involved operations at both UST&D production facilities. This Corrective Action Request was open and corrective actions were in progress during the audit. In the course of the first week of the audit (19-23 June 2000) the audit team was presented with additional instances of missing inspection steps and witness points by the ComEd resident inspector. The additional NCRs were initiated while the QA Director was facilitating the audit team and unable to immediately respond. Investigation into the cause of the bypassing of inspection/witness point (NCR 9925-74) revealed that it occurred when the Production Work Routing Plan (PWRP) was revised and the Project Manager failed to transfer the witness point to the revised PWRP. This resulted in the issuance of CAR 073 to the Project Manager. Investigation into the remainder of the NCRs revealed that lack of communications was the root cause of the deficiency. In these instances the outgoing shift foreman had failed to notify the incoming shift foreman, or a QC Inspector, that a PWRP step requiring an inspection had been completed, and that the following operation was an inspection point. This communication oversight occurred during weekend production. The need for a QC inspection/witness point was not communicated to the incoming supervisor and work proceeded. The oversights were a direct result of the lack of shift turnover communications.

Proposed Corrective Action:

This issue was self-identified by UST&D and corrective actions were in progress at the time of the audit. The UST&D Corrective Action Request remains open and is being handled by UST&D's QA Program. The President of UST&D had issued a memo to all employees, a memo to management personnel, and a memo to the United Steel Workers organization establishing the company position on this issue and setting forth the disciplinary actions which will occur for future violations. Meetings with the production workforce were conducted by Plant Managers to reinforce the President's directives. Additionally, actions are in place through time-keeping systems, ongoing worker readiness assessments, Random Production Work Routing Plan audits, and increased shop floor surveillance by Quality Control to detect violations and take the appropriate disciplinary action. All Production workers and managers have been re-trained in UST&D's documentation system, as well as, their responsibilities in quality record documentation and the intent of QC and customer inspection points. Production Management has implemented a formal shift turnover procedure to ensure that priorities are communicated between shifts. This will result in improved communications and eliminate the possibility that these operations are missed due to shift changes.

Actions to prevent recurrence:

Actions identified in UST&D President's response to CAR 071 are ongoing. The QA Director will monitor the corrective action's long-term results until he is confident that a cultural change has occurred. Although initial indications reveal the corrective actions have been successful, this issue will be monitored, and additional corrective actions requested if necessary.

Expected completion date

The immediate corrective actions are complete. Long-term corrective actions will continue. This issue remains open within UST&D's QA Program on Corrective Action Request # 071. It is considered closed within the context of this audit.

9. **Audit Finding SR -2000-257-09**

Requirement:

Quality Assurance Program Manual, Section 9.0, Rev. 2 states that all welding will be performed in accordance with ASME Section III and Section IX and UST&D's procedures. All Welding Procedure Specifications (WPS) will be written and qualified in accordance with ASME Section IX and Section III of the Code as applicable.

ASME NQA-1-1989 Edition, Supplement 11S-1 states "Test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied".

Discrepancy:

Contrary to the above requirements, the following conditions were found:

1. UST&D did not initiate an NCR when a pressure test was performed using a gauge that was out of calibration. Again, the test was performed with the gauge knowing it was not calibrated. Then the gauge was calibrated after the test was completed. No NCR was initiated for this chain of events, again demonstrating a lack of understanding of the NCR process.
2. The examination of one Pneumatic Test record for a Hi-Star 100 Overpack identified the following deficiencies:
 - UST&D did not satisfy the hydrostatic (pneumatic) test requirement of the Hi-Star 100 Overpack.
 - UST&D did not establish the pneumatic test acceptance criterion of zero leakage as measured by the 0-600 psi gauge in the Pneumatic Test Instructions 9905-00-112, dated 5/16/2000 or any approved instructions or documents.
 - The results of the pneumatic test that were documented on the Hi-Star 100 Overpack Pneumatic Test Report had not been reviewed and approved by responsible UST&D personnel.

Cause of Deficiency:

1. It would have been appropriate to issue an NCR to document and control the potential that this situation would result in an actual non-conformance had the gauge not calibrated accurately after the test. The issuance of an

NCR with a "risk release" disposition would provide the levels of control required in this situation. In this case, UST&D was in error by not controlling this potential non-conformance through an NCR.

2. The Project Managers intent when creating the test instructions was to provide test personnel with instructions on how to perform the test. Acceptance of test results would be determined by applying the result to the customer procurement specification (HSP-105). Additionally, the test instructions that were released for production included the review and approval signature of the responsible UST&D personnel. The copy provided the audit team was a copy of the instruction prior to Project Management signature and release under the UST&D document control system. UST&D did satisfy the test requirement for the Hi-Star 100 Overpack as the test pressure end time exceeded the test pressure end time by 10 minutes and the recorded test pressure at the end of test did not change from the test pressure at the beginning of the test. This is documented on the HI-STAR 100 Overpack pneumatic test report. It is the documentation trail that led to this misunderstanding.

Proposed Corrective Action:

1. The gauge in question was calibrated and documented as accurate without adjustments when sent for calibration after the test. As such, the test results recorded are accurate and no product was affected. Since that example, UST&D has proceduralized the NCR Program as a vehicle to address issues where there is a potential for non-conformance.
2. The Pneumatic Test Instructions were revised and approved on 11 August 2000 (9905-00-0160) to document zero leakage as the test acceptance criteria. This revised instruction includes the appropriate acceptance criteria as specified in the procurement specification.

Actions to prevent recurrence:

1. UST&D has recently demonstrated that the use of the NCR Program to document and control potential non-conformances has been incorporated into the Quality Assurance Program. This level of control will continue to be exercised to ensure that all quality related issues are addressed and resolved to prevent non-conformances.
2. In the future, test instructions will include the acceptance criterion. This will provide a clear indication of the test acceptance without referring to other documents for verification.

Expected completion date:

The actions noted above are complete.

B. AUDIT RECOMMENDATION RESPONSES:

1. Audit Recommendation No. 1

Recommendation:

UST&D's procedures on procurement and vendor qualification may be revised to clarify the following:

- There are suppliers listed on the AVL that indicate surveillance required. These vendors can be used through performance of surveillance even through not audited. Use in this context is the method 3 of commercial grade dedication. The QA manual for QCP 7.2 does not discuss what is surveillance and under what conditions is it permitted in lieu of an initial or triennial audit.
- QCP 7.2 paragraph 4.2.4 uses the term "survey." Survey is also not defined in the procedure and not clear when a survey is performed.
- QA Manual Section 7, section 7.4.B.3.g and section 8.5 discuss procurement of material from "unqualified sources." This should be clarified to indicate whether this is commercial grade dedication.
- Note: UST&D does not have the capability to perform Commercial Grade Dedication due to the fact that this is design activity and it is outside of UST&D scope of work.

Response:

UST&D will revise Section 7 and 18 of the QA Program Manual as well as Quality Control Procedures 7.2 and 18.1 to address the issues needing clarification or improvement. Note: as addressed in finding # 7, UST&D does have the capability, through purchase orders to Holtec for design services, to perform commercial grade dedications.

2. Audit Recommendation No. 2

Recommendation:

While reviewing the NCR Log book for NCR 9911-62, neither columns for disposition nor closure status was filled for this NCR, however, the subject NCR was closed and filed in the logbook. Another example was the NCR logbook for Project 9925. NCR 9925-41 was closed and misfiled between NCR Nos. 9925-61 and 9925-63 and it was hard to find. This recommendation was made to pay attention to details in maintenance of the NCR Log Book and maintenance of consistency in filling out the appropriate blocks of the NCR.

The recommendation is also made that UST&D incorporate instruction into the NCR procedure that addresses the review of the NCR upon initiation and

disposition assignment for the necessity for issuance of a CAR so that it can be accomplished in a timely manner.

Response:

UST&D appreciates any suggestions or recommendations for improving the Quality Program and will take this recommendation under advisement. UST&D will determine the appropriate actions to address these issues.

3. Audit Recommendation No. 3

Recommendation:

The procedures that control the order entry process and procurement documents do not address PO exceptions very clearly. Quality Control Procedure (QCP) No. 3.1 Rev 5, section 4.5 states "In the event that the design/procurement specification review is unsatisfactory, the Project Engineer/Manager will submit comments of the Owner/Client for Resolution.

The audit team recommended to more clearly proceduralize the purchase order exceptions and documentation.

Response:

Quality Control Procedure for Design/Procurement Specification Review and Design Input Requirements – QCP 3.1 will be revised to clarify the actions to be taken when exceptions are taken during specification review.

ETHANY

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NUPIC CLOSEOUT FINAL PAGE

CLOSEOUT

NUPIC JOINT AUDIT OF:

Supplier Name: U.S.T. & D. Inc.
Pittsburgh, PA

Supplier Number 2495

NUPIC Audit Number 17662

Lead Utility: Exelon (EXL)

Audit Date 06/19/00thru 07/07/00

ETHANY Date Prepared April 11, 2001

ATTACHMENT – 2

**Evaluation Report – NRC Tracking No. 02-A-0005
Supporting Information for Detail #3**

Exelon Procedure MS-AA-200

Revision 1

Dated April 5, 2000

SUPPLIER QUALIFICATION ACTIVITIES

1. PURPOSE

1.1. Objective

- 1.1.1. This procedure describes the Supplier Evaluation Services (SES) process for the evaluation of suppliers, which includes audits, surveys, source surveillances, annual evaluations, and maintenance of the Approved Suppliers List (ASL).

1.2. Applicability

- 1.2.1. This procedure applies to Nuclear Generating Group personnel responsible for the oversight of supplier activities, including maintenance of the ASL.

2. TERMS AND DEFINITIONS

- 2.1. **Action Tracking (AT)** - A computer based commitment tracking system. Action Tracking is a PassPort integrated, on-line means of tracking events and ensuring that appropriate actions have been taken.
- 2.2. **Adverse Conditions** – Deficiencies, including nonconforming material, parts, or components; failures; malfunctions; deviations; hardware problems involving noncompliance with licensing commitments, specifications, or drawing requirements; abnormal occurrences; and non-hardware problems such as failure to comply with the operating license, technical specifications, licensing commitments, procedures, instructions, or regulations.
- 2.3. **Annual Evaluation** - An annual review of the supplier's internal and external performance indicators for the purpose of identifying performance trends.
- 2.4. **Approved Suppliers List (ASL)** - A listing of suppliers with acceptable quality assurance programs approved by ComEd which meet various qualification levels for providing nuclear Safety Related, Commercial Grade, Augmented Quality parts/materials, equipment, and services that are determined to be important to safety. ASL data are found in PassPort Panels Q160 and Q161 (OLE Field).
- 2.5. **Audit** – A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

- 2.6. **Commercial Grade Dedication Plan**- The document developed by Engineering that outlines the duties for source surveillance of components, equipment, or material to ensure compliance to procurement contract requirements. The Commercial Grade Dedication Process should be in accordance with EPRI Guideline – EPRI NP-5652 (NCIG-07)
- 2.7. **Commercial Grade Survey** - A documented activity to verify that a supplier of commercial grade items controls, through quality activities, the critical characteristics of specifically designated commercial grade items, as a method to accept these items for safety-related use.
- 2.8. **NUPIC** - The Nuclear Procurement Issues Committee (NUPIC) is a group of utilities which share supplier audits.
- 2.9. **Performance Based Supplier Audit (PBSA)** - An audit using methodology that evaluates processes or activities on the basis of their performance and allows subsequent conclusions about the products of the process or activity and the quality assurance program of the supplier audited.
- 2.10. **Problem Identification Form (PIF)** - Integrated Reporting Program input form.
- 2.11. **Source Inspection** - This term is used in contracts synonymously for source surveillance.
- 2.12. **Source Surveillance** - A review, observation, or surveillance by ComEd for the purpose of verifying that an action has been accomplished as specified at the location of material/equipment fabrication or manufacture.
- 2.13. **Supplier** - Any individual or organization that furnishes items or services to a procurement document. It includes the terms supplier, manufacturer, seller, contractor, distributor, subcontractor, fabricator, consultant, and sub-tier levels.

3. **RESPONSIBILITIES**

- 3.1. **Supplier Evaluation Services Manager** - Overall responsibility for supplier audits and surveys performed by Supplier Evaluation Services (SES).
 - 3.1.1. Responsible for the selection of qualified audit and survey team members and the approval of plans, checklists, and reports for all supplier audits and surveys. Provides direction to the audit and survey team to ensure the adequacy of the effort and the accuracy of the conclusions of audits and surveys
- 3.2. **Team Leader** - Responsible for the overall performance of the assigned supplier audit or survey. This includes preparation, planning, and verification of team qualifications, performance, reporting, follow-up and closure of deficiencies.
- 3.3. **Auditor** - Responsible for the performance of the assigned areas of supplier audits/surveys. This includes planning, performance, and report preparation.

- 3.4. **Supplier Evaluation Services Personnel** - Responsible for the overall coordination of assigned supplier audits and surveys. Additionally, SES will facilitate obtaining required reference material for audit/survey preparation meetings and the maintenance of ASL.
- 3.5. **Technical Specialist (TS)** - Responsible for development and evaluation of the technical audit/survey areas of interest and determining the technical acceptability of the product or service reviewed. Technical Specialists will be individuals who have the capabilities/practical understanding appropriate for the activity/process being evaluated. The Technical Specialist determines the critical characteristics or elements for the items supplied by the supplier and the processes affecting these characteristics or elements. The audit/survey team uses this information during the planning meeting and throughout the audit/survey.

4. **MAIN BODY**

4.1. **Approved Suppliers List**

- 4.1.1. SES maintains an ASL for procurements. It imposes a supplier quality program for the purchase of Safety-Related, ASME Safety-Related, Commercial Grade, and Augmented Quality equipment, materials, or services that are determined to be important to safety.
- 4.1.2. Maintenance
1. Suppliers shall be listed and maintained on the ASL based on review and acceptance of documented evidence of the supplier's conformance or capability to comply with necessary quality program requirements for the material, product, or service provided. This evidence may include all or part of the following:
 - A Nuclear Procurement Issues Committee (NUPIC) audit within the past three years that has been reviewed and accepted by ComEd.
 - Review of another nuclear utility's audit report performed within the past three years that has been reviewed and accepted by ComEd.
 - Verification that the supplier holds a current ASME Section III certificate for the material, product, or service. When using this option, an SES, NUPIC or utility audit of an ASME supplier's program is required. In addition, SES reviews and maintains the supplier's QA Manual. The ASME QA Manual review is documented on Attachment 4
 - Suppliers with an NRC approved 10CFR71 Subpart H, Quality Assurance Program, may be added to the ASL for the scope of work as approved by the NRC without a ComEd review of the program. The supplier must provide a copy of the NRC License prior to placement on the ASL.

2. Annual evaluations are utilized to support maintenance of suppliers on the ASL between audits in accordance with section 4.4 of this procedure.
3. The supplier's scope of approval identifies materials, products, or services a supplier is approved to furnish. This scope of approval is listed on the ASL. For Safety Related suppliers with ASME Certificates, the suppliers approved QA Manuals are listed on the ASL.

4.1.3. Changes to ASL

1. Addition or reinstatement of a supplier to the ASL must be requested in writing from the management of a procuring organization. This is done by the completion of a "Supplier Evaluation Request" form, as shown in Attachment 2.
2. Extension of the supplier's expiration date(s) or their deletion from the ASL will be made prior to the listed expiration date(s).
3. SES personnel make changes to the ASL. Changes to the ASL are reviewed and approved by the SES Manager.

4.1.4. ASL Quality Classifications

1. Q1 SAFETY RELATED
 - Indicates a program that meets the quality assurance criteria for nuclear power plants and fuel reprocessing plants.
 - A subset of Safety Related is ASME Section III indicates N, NA, NPT, MO, NV, and QSC. All procurements for ASME Code components and assemblies must be made from a supplier with a current ASME III Certificate. A material organization, manufacturer or supplier must have a current MO, N, NPT, NV, or QSC certificate as appropriate. An MO program is in accordance with NCA-3800; N, NA, NPT, NV and QSC programs are in accordance with NCA-4000.
2. Q-2 COMMERCIAL GRADE
 - Indicates a supplier that has been surveyed and will be used to support Method 2 of EPRI NCIG-07 for commercial grade dedication of parts. Commercial Grade may also include Calibration Services.
3. Q-3 AUGMENTED QUALITY
 - This indicates suppliers who are used to provide materials and services that are identified in Section 19 of the ComEd Quality Assurance Topical Report and determined to need this level of Quality. Program controls evaluated are for ComEd designated critical characteristics or augmented quality program requirements.

4.2. Supplier Evaluation Process

4.2.1. The supplier evaluation process verifies by examination of objective evidence that the supplier's documented quality program has been satisfactorily implemented; identifies adverse conditions (if applicable); and verifies adequacy of corrective actions for identified adverse conditions. This program applies to audit and survey activities conducted under ComEd and NUPIC guidelines and to audit and survey reports evaluated from other utilities.

4.2.2. Scheduling of Supplier Audits/Surveys

1. ComEd initiated audits/surveys of suppliers are normally scheduled on a triennial basis. ComEd led NUPIC audits are scheduled in accordance with NUPIC guidelines.
2. Additional audits/surveys are scheduled as necessary for one or more of the following conditions:
 - When, after award of a contract, it is appropriate to determine that the supplier is adequately performing the functions as defined in the contract quality assurance program requirements. This is considered when the item or service is:
 - Vital to plant safety; or
 - Difficult to verify quality characteristics after delivery; or
 - Complex in design, manufacture, and test.
 - When significant changes are made in functional areas of the supplier's QA program such as significant reorganization or major QA manual and procedure revisions.
 - When there is evidence that the reliable performance of safety-related or ASME safety-related items/activities is in jeopardy because of deficiencies or nonconformances in the supplier's QA program.
 - When a systematic independent assessment of program effectiveness, item quality, or both is considered necessary (e.g., input from a site regarding supplier performance).
 - When it is necessary to verify implementation of a supplier's complex or significant corrective actions.

4.2.3. Audit/Survey Scheduling & Planning Activities

1. An audit/survey schedule is maintained by SES. It lists the suppliers to be evaluated and the assigned audit team leader. The audit/survey schedule is reviewed every six months, per requirements of the QATR, to ensure that coverage is maintained current. The audit team leader is responsible for scheduling, planning, performing, reporting, and any follow-up activities associated with the supplier assignment. The audit team leader:

- Requests team members with specialized technical qualifications when required.
- Contacts supplier to discuss the proposed dates, contract information, status of contract work, and QA program.
- Communicates with Procurement Engineering and the Site Materials Organization for supplier performance issues that need to be included in the scope of the audit.
- Conducts team meetings to identify audit scope, contract requirements, and activities to be evaluated; and reviews pertinent policies, procedures, standards, regulatory requirements, previous audit/survey reports, contract documents, source surveillance and inspection reports, and any pertinent qualifications and evaluation information from outside ComEd (e.g., NUPIC evaluations and NRC inspections and bulletins).
- Develops an Audit/Survey Plan identifying the team members, the audit/survey dates, audit/survey checklist and the audit scope, as applicable.
- Submits the plan to the SES manager for Approval. (Approval of this plan by the SES Manager also documents the approval of the audit/survey checklist.)
- Distributes the plan to the Supplier
- Directs team members in planning, conducting, reporting, and follow-up activities.
- For commercial grade surveys, requests the cognizant Engineering Group or requisitioning organization to identify critical characteristics for the item(s) or services to be surveyed and requests a technical specialist when necessary.
- Documents Technical Specialist qualification, training and orientation regarding audit processes.

4.2.4. Conducting the Audit/Survey

1. During the audit/survey, the team leader:
 - Conducts an entrance meeting with supplier personnel at the supplier location to present the audit/survey scope, introduce team members, discuss audit/survey sequence, and establish channels of communication.
 - Resolves any problems or questions that may arise between team members and supplier personnel during the evaluation.
 - Keeps supplier management advised of progress and any actual or potential adverse conditions.

- Reviews all adverse conditions to determine if there may be some weaknesses that when grouped together, show a generic problem; documents these deviations on a draft Problem Identification Form.
 - Conducts an exit meeting with supplier management to present evaluation results before departing supplier's facility.
 - Instructs the supplier in preparing a corrective action response, if necessary.
 - Initiates a Problem Identification Form (PIF) to report any adverse condition. If the potentially adverse condition impacts ComEd plants, then the team leader shall take the following actions:
 - Promptly notify the Supplier Evaluation Services Manager or designee by telephone of the adverse condition and if possible, transmit a draft Problem Identification Form. The Supplier Evaluation Services Manager or designee informs appropriate management of potential adverse condition(s).
 - Initiates a memorandum to engineering to evaluate the impact of the finding on ComEd purchase orders and previous procurements. Places an appropriate restriction on the ASL including removal of the supplier from the ASL.
2. If conditions are noted during an evaluation that require a shipment hold or stop work be imposed on a supplier, then the team leader shall take the following actions:
- Notify the Nuclear Oversight Vice President, NGG Supply Manager and Site Supply Chain Managers.
 - Prepare a memorandum to the NGG Supply Manager and Site Supply Chain Managers, stating reasons for hold or stop work actions. Generate a PIF, in accordance with the Corrective Action Program (CAP) that describes the deficiency leading to the stop work order.
3. Team members are responsible for the following.
- Review assigned program areas with appropriate supplier personnel, examine objective evidence of conformance to requirements, and further investigate deficient areas to identify the apparent cause.
 - Record names of persons contacted during the audit/survey and where necessary identify by title, number, and revision those documents (procedures, drawings, purchase orders, etc.) examined during the evaluation.
 - Record objective evidence reviewed for inclusion in appropriate checklist section.
 - Discuss adverse conditions, comments, recommendations or suggestions for improving QA program(s) with team leader before exit meeting.

- Document each adverse condition on a PIF in accordance with the Corrective Action Program (CAP).
- If requested by the team leader, present results and comments to supplier management during the exit meeting.

4.2.5. The team leader issues the report, completed checklist, and required documentation with transmittal letter within 30 calendar days from the date of the exit meeting.

4.2.6. Evaluation of Supplier Corrective Action and Follow-Up Activities

1. The team leader or designee:
 - Evaluates the supplier's corrective action response. Initiates a letter to the supplier notifying them of the results of this evaluation. Updates Action Tracking (AT) Items as required.
 - Schedules follow-up visits, if applicable, to verify that suppliers have implemented corrective actions.
 - Examines sufficient objective evidence to verify implementation of corrective actions and documents evidence and closure of any AT Items.
 - Reviews completed AT items and, if acceptable, approves for closure.
 - Prepares a letter to the supplier stating that Corrective Action is acceptable, the adverse condition is now resolved, and the issue is closed. Attaches copies of any closed AT items with associated documents and forwards to the audit/survey file.
2. If an initial response is not received from the supplier within 30 days, the team leader or designee should:
 - Telephone the supplier's quality representative and determine status of the response and corrective actions.
 - If a response has not been sent, prepare a letter to the supplier stating that the corrective action response is delinquent and request that the response be provided within 10 working days.
 - If the supplier does not respond, an appropriate warning shall be placed on the ASL restricting purchase from the supplier until the response is received.

4.2.7. NUPIC/Utility Audits, Surveys and Follow-Ups

1. ComEd Participation:
 - The assigned ComEd team leader should contact the other team members and the supplier at least 90 days before the proposed audit/survey dates.
 - The audit/survey scope, duration, and areas of interest should be discussed and tentatively agreed upon as soon as possible. Obtain Engineering or others' input as necessary.

- The ComEd auditors should consider other NUPIC utility members' inputs concerning specific contracts or program problem areas for consideration during the audit/survey.
- The ComEd team member shall contact the audit team leader within 30 days of the proposed audit/survey date if contact has not already been established.
- Specific program areas and interests shall be discussed with the audit team leader.

Responsibilities, as noted in the NUPIC Joint Audit Procedure or NUPIC Joint Commercial Grade Item Survey Procedure, shall be addressed.

2. ComEd not Participating:

- When requested, provide input, using information from SES files, Engineering, or sites as appropriate, to the lead utility for suppliers due for requalification.
- When appropriate, a copy of the Performance Based Supplier Audit (PBSA) worksheet may be sent to the affected engineering organizations requesting technical input for NUPIC audits or surveys when deemed necessary for suppliers on the ComEd ASL. A letter may be sent to the lead utility to inform them that ComEd has considered PBSA input to this audit.

4.2.8. Evaluation of Other Audit/Survey Reports

- Audit and survey reports will be reviewed to determine if they can be used to maintain a supplier's qualification on the ASL.
- The reviewer will complete the ComEd NUPIC Joint/ Member, Audit/Survey Assessment Form as shown in Attachment 3 or the NUPIC Third Party Evaluation Form to document the review.
- The evaluation sheet shall be completed addressing scope of work, adverse conditions, and identification of any program areas not adequately addressed. The reviewer will use a ComEd audit/survey number to document the use of the report in SES's program and monitor the status of documented deviations.
- If conditional acceptance is noted, SES shall take appropriate action to limit the approval on the ASL or schedule a limited scope audit/survey to address those portions not covered by the audit/survey.
- All audit/survey documentation, including the report and evaluation sheet, shall be filled in the appropriate audit folder.
- If a NUPIC Third Party Evaluation is available, it should be used to verify the audit's acceptability and the above attributes. Any conclusions of the NUPIC Third Party should be evaluated to the requirements of the ComEd Quality Assurance Program. PIFs will be written for Technical Issues identified by the NUPIC Third Party Review. Warnings will be placed on the ASL based on the NUPIC Third Party Review.

4.2.9. Other Audit/Survey Deviations (Adverse Conditions) and Follow-Up

- During the evaluation of the report, the reviewer shall evaluate all adverse conditions to determine any noncompliances with ComEd requirements. Recommended methods for closure shall also be reviewed. These reviews shall also be documented on the evaluation sheet (Attachment 3).
- Adverse conditions that have technical impact to ComEd, shall be tracked by the same system used for ComEd generated Problem Identification Form (PIF). A ComEd PIF number shall be assigned to the deviation. SES personnel are responsible for acceptance and closure of each deviation report once it is identified as being applicable to ComEd.
- SES does not track adverse conditions judged not to have technical impact to ComEd.
- Documented follow-up activities shall be made part of the audit/survey file.
- Where follow-up or closure activities do not meet ComEd's technical requirements, Adverse Conditions will be followed-up upon and closed by SES.
- If a NUPIC Third Party Evaluation is used, any conclusions of the NUPIC Third Party should be evaluated to the requirements of the ComEd Quality Assurance Program. PIFs will be written for Technical Issues identified by the NUPIC Third Party Review. Supplier Restrictions will be placed on the ASL as warnings based on the NUPIC Third Party Review.

4.3. Source Surveillance

4.3.1. SES is responsible for source surveillance activities. These activities include:

- The review of ComEd issued purchase orders for which source surveillance has been included.
- Scheduling, performing/coordinating, and reporting of surveillance activities, as required.
- Issuing Quality Release(s) for items accepted during surveillance activities, as shown in Attachment 1.
- Follow up on supplier nonconformances resulting from surveillance activities.

4.3.2. Contract Review and Preparation for Source Surveillance

- Perform a review of the Purchase Order and other related Quality and Technical documents, including the CGD plan, as applicable, to determine appropriate Source Surveillance activities.
- Any contract document problem or deficiencies should be resolved with the NGG Procurement Manager.
- Prepare a letter notifying the supplier that a surveillance is required and/or is to be performed. If the purchase order requires source surveillance and provides information as to whom to contact for surveillance, a notification letter is not required.

4.3.3. Performing Source Surveillance

- Source surveillance is performed in accordance with the CGD plan and purchase order requirements. Required documentation furnished by the supplier should be reviewed for compliance with the contract for completeness and accuracy.
- Complete "ComEd Checklist and Quality Release" as shown in Attachment 1 for items determined to be acceptable for release on the contract. The supplier should include a copy of the completed Quality Release with the released items.
- If an interpretation is required during surveillance, to determine if a specification violation has occurred, the problem is referred to the responsible engineering department for resolution.
- The supplier should be notified of any deficiencies found during source surveillance activities. Program deficiencies are documented on a Problem Identification Form.
- Deviations from the requirements of the purchase order (or applicable codes and standards) will be reported on a supplier nonconformance report in accordance with contract requirements. Nonconforming item(s) should be verified to be properly marked or tagged and segregated from any conforming items.
- If it is determined that any nonconforming condition(s) has the potential to adversely affect a ComEd facility, then the following actions shall be taken:
 - Notify the Supplier Evaluation Services Manager. The affected site(s) shall be notified.
 - Prepare PIF (if applicable).

4.3.4. Reporting Source Surveillance Activities

- Prepare a surveillance report documenting the results of the surveillance.
- Surveillance reports shall be issued within 30 days from the surveillance completion date.

4.3.5. Waiving of Source Surveillance

- Prepare a checklist and Quality Release as shown in Attachment 1, and indicate those inspections that need to be performed by the supplier and site receiving inspection personnel and forward it to the supplier and site.

4.4. Annual Supplier Evaluations

- 4.4.1. Evaluations of supplier performance will be performed annually. Where applicable, this evaluation should take into account review of supplier's furnished documents, results of source surveillances, audits, receiving inspections, operating experience of identical or similar products furnished by the same supplier, and results of audits from other external sources.
- 4.4.2. PIFs will be generated to address suppliers found to have performance problems. The results of the review will be documented in a report and issued throughout the supply chain.

4.5. Qualification of Audit Personnel

- 4.5.1. Audit personnel are qualified in accordance with the guidelines of ANSI/ASME NQA-1 and the appropriate implementing procedures. An Orientation Checklist for personnel new to SES is provided in Attachment 5.
- 4.5.2. NUPIC Audit Team Members and Audit Team Leaders shall be qualified as required by the NUPIC Joint Audit Procedure.

5. DOCUMENTATION

5.1. QA Records

- 5.1.1. All SES QA records for suppliers are submitted and maintained for the life of the plant in the appropriate audit files and supplier folders. This includes:
- Changes to the ASL
 - Audits/surveys of suppliers and related correspondence
 - Source surveillance reports and Quality Releases
 - Annual evaluations of suppliers

6. REFERENCES

- 6.1. 10CFR50 Appendix B
- 6.2. ASME NQA-1, 1989 Edition, "Quality Assurance Program Requirements for Nuclear Facilities."
- 6.3. Regulatory Guide 1.28.
- 6.4. EPRI Report NP-5652: Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Applications (NCIG-07).

- 6.5. EPRI Report NP-6630, Guideline for Performance Based Audits of Suppliers (NCIG-16).
- 6.6. ASME Code Section III: NCA-3800 and NCA- 4000.
- 6.7. ANSI/ASME NQA-1 Basic Requirement 7, 18, and Supplements 7S-1, 18S-1.
- 6.8. ComEd NGG Procedure NSP-AP-4004, "Corrective Action Program Procedure"
- 6.9. ComEd Quality Assurance Topical Report.

7. **ATTACHMENTS**

- 7.1. Attachment 1 – ComEd Checklist and QUALITY Release Supplier Evaluation Services
- 7.2. Attachment 2 – Supplier Evaluation Request
- 7.3. Attachment 3 – Checklist for Evaluation of Third-Party audits/survey from external organization
- 7.4. Attachment 4 – Evaluation of ASME Safety Related Supplier's Quality Assurance Program
- 7.5. Attachment 5 – SES Orientation Checklist

ATTACHMENT 1
ComEd Checklist and QUALITY Release Supplier Evaluation Services
Page 1 of 1

Supplier _____ Supplier # _____

PO # _____ Release # _____ Date _____

Documents _____

Items Released by ComEd Supplier Evaluation Services Representative (Complete Identification)

ComEd SES Representative must mark all Boxes below. X = Surveillance Performed, V = Verification of Records, N = Not Applicable to this release, C = Contingent item requiring supplier's QA Representative clearance and signature prior to shipping.

Surveillance Activity Required:

Visual _____

Marking _____

Tagging _____

Quantity _____

Remarks: _____

The undersigned hereby certifies that the equipment and/or materials released meets all contractual requirements. All non-conformances, if any, are approved. (List the non-conformance nos. with status – if any – in the remarks section, and/or state that no non-conformance occurred.)

Supplier's QA Rep. _____ Title _____
Date _____

The ComEd SES Representative's approval for shipment of the above described equipment/ and or materials is subject to the provisions of the purchase order concerning surveillance and, not withstanding such approval the supplier is in no way released from complying with all provisions of the purchase order. ComEd Rep. _____ Title _____
_____ Date _____ Phone Number _____

ATTACHMENT 2
Supplier Evaluation Request
Page 1 of 1

TO: Supplier Evaluation Services

Location: Downers Grove (ETWII)

From: _____

Date: _____

Supplier: _____

Supplier Number _____

Address: _____

Telephone Number _____

Justification _____

Date for ASL addition (justification for less than 60 days) _____

Bid Title _____ Number _____ Date _____

Quality Level (circle one):

Safety Related/ ASME Safety/ Commercial Grade/ Augmented Quality

QA Program Requirements _____

Name of Technical Specialist to Participate on audit/survey team _____

Designated contact/phone number for question/clarifications that may arise during the audit/survey

Requesting Organization Manager (signature) _____ Date _____

NGG Procurement Manager. (signature) _____ Date _____

(SES Use Only)

Assigned to: _____

Supplier will be evaluated for addition to the ASL: ☐ Yes ☐ No

Remarks _____

Supplier Evaluation Services Manager Approval _____ Date _____

ATTACHMENT 3
Checklist for Evaluation of Third-Party
Audits/Survey from External Organization
Page 1 of 1

☐ AUDIT

☐ CGI SURVEY

1. Name, number and location of Supplier audited:

SES Auditor/Survey Report No. _____

Date of Audit _____

Date of Report _____

2. Name of company who performed the audit:

3. Title and revision of the audited QA program document:

4. Product or service audited:

Comments:

(Use attachments for additional comments.)

- | | YES | NO |
|--|-----|-----|
| 5. Is the product or service audited relevant to the scope of supplier qualification? | ___ | ___ |
| 6. Does the audit apply to the same facility which will provide the product or service? | ___ | ___ |
| 7. Does the audit report provide sufficient information to show that applicable elements of the Supplier's QA Program have been developed, documented and effectively implemented? | ___ | ___ |
| 8. Were any deficiencies written? Quantity ___ | ___ | ___ |
| a) Programmatic | ___ | ___ |
| b) Potential hardware/service impact | ___ | ___ |
| c) Procurement Engineering review required | ___ | ___ |
| 9. Is each page of the audit report legible and complete with signatures where applicable? | ___ | ___ |
| 10. Does the company submitting the report consider the supplier to be currently qualified? | ___ | ___ |
| 11. Does the audit reflect supplier's compliance with 10CFR Part 21 requirements? (if applicable) | ___ | ___ |
| 12. Is auditor(s) certification included with the audit report or at SDI and correct/current? | ___ | ___ |
| 13. Is audit notification letter and audit plan included with audit report? | ___ | ___ |
| 14. Does the audit address the attributes established by Procurement Engineering (PEG) via PBSA Worksheets/PBSA/CGI Summary Sheets? | ___ | ___ |
| 15. Can the audit be accepted in its entirety? | ___ | ___ |
| If not, describe actions required _____ | | |

Date: _____ Reviewed: _____

Date: _____ Approved: _____

ATTACHMENT 4
Evaluation of ASME Safety Related Supplier's Quality Assurance Program
Page 1 of 1

Supplier: _____

Location: _____

Projects: _____

REVISION TO BE EVALUATED

Description: _____

Control No.: _____

Latest Revision: _____

Date: _____

Evaluator comments: _____

THE ACCEPTABLE QUALITY ASSURANCE PROGRAM CONSISTS OF:

Evaluated by: _____

Date: ____/____/____

Accepted by: _____

Date: ____/____/____

ATTACHMENT 5
SES Orientation Checklist
Page 1 of 2

Name: _____

Reference Document Review

Review the current applicable edition of the following:

	<u>Training Method</u>	<u>Completion</u> <u>Initial/Date</u>
NCIG 07	Self Study	____/____
NCIG 11	Self Study	____/____
NCIG 16	Self Study	____/____
QA Manual	Self Study	____/____

II. Procedure Training

Participate in the following:

	<u>Training Method</u>	<u>Completion</u> <u>Initial/Date</u>
MS-AA-200 , "Supplier Qualification Activities	SME Discussion	____/____
NUPIC Procedures	SME Discussion	____/____
ISO 9000	SME Discussion	____/____
Codes and Standards Training	Formal Training	____/____

ATTACHMENT 5
SES Orientation Checklist
Page 2 of 2

III. Practical Factors

The SES Manager (or designee) shall, upon review of the individuals experience establish the necessary quantity of activities the trainee must be involved in.

Perform Review of _____ Supplier(s) SME Evaluation _____/_____

Programs

Perform _____ ASL updates SME Evaluation _____/_____

Qualifications/Certifications: (As assigned)

Lead Auditor _____/_____

Section Review

The trainee has demonstrated sufficient knowledge of the aforementioned sections to perform Supplier Evaluation Services general tasks.

_____/_____
SES Manager Date

ATTACHMENT – 2

**Evaluation Report – NRC Tracking No. 02-A-0005
Supporting Information for Detail #3**

Exelon letter dated December 13, 2000

December 13, 2000

Mr. Ross B. Landsman
U. S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532

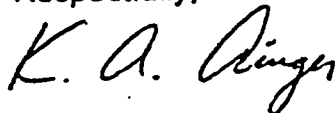
Subject: ComEd Supplier Evaluation Services Audit Report SR-2000-257

Dear Mr. Landsman:

In response to your request, attached is a copy of Commonwealth Edison (ComEd) Company Supplier Evaluation Services Audit Report SR-2000-257 dated August 4, 2000. This report documents an audit of U. S. Tool & Die, Inc. conducted under the auspices of the Nuclear Procurement Initiative Committee (NUPIC) and the Dry Storage Quality Group (DSQG). The member utilities of the NUPIC have agreed to contain the distribution of NUPIC audit reports to its members only. Accordingly, as we discussed on the telephone today, this report will not be made available for public inspection.

If you have any questions about this matter, please contact me at (630) 663-7350.

Respectfully,



K. A. Ainger
Licensing Manager,
Braidwood and Byron Stations