Log# TXX-5048
File# 10130
IR 86-01
86-01

TEXAS UTILITIES GENERATING COMPANY

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October 13, 1986

WILLIAM G. COUNSIL
EXECUTIVE VICE PRESIDENT

Mr. Eric H. Johnson Director
Division of Reactor Safety and Projects
U. S. Nuclear Regulatory Commission
611 Ryan Plaza Drive, Suite 1000
Arlington, Texas 76012

SUBJECT: COMANCHE PEAK STEAM ELECTRIC STATION (CPSES)
DOCKET NOS. 50-445 AND 50-446
RESPONSE TO NRC NOTICE OF VIOLATION AND NOTICE OF DEVIATION
INSPECTION REPORT NOS.: 50-445/86-01 AND 50-446/86-01

Dear Mr. Johnson:

We have reviewed your letter dated August 29, 1986, concerning the inspection conducted by Mr. T.F. Westerman and other members of the Region IV Comanche Peak Group during the period November 1, 1985, through January 31, 1986. This inspection covered activities authorized by NRC Construction Permits CPPR-126 and CPPR-127 for Comanche Peak Steam Electric Station Units 1 and 2. Attached to your letter was a Notice of Violation and Notice of Deviation.

We requested and received a two week extension in providing our response during a telephone conversation on September 29, 1986.

We hereby respond to the Notice of Violation and Notice of Deviation in the attachment to this letter.

Very truly yours,

W. G. Counsil

RSB/gj
Attachments

c-Region IV (Original + 1 Copy)

Director, Inspection & Enforcement (15 copies)
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Mr. V.S. Noonan
Mr. D.L. Kelley

IE01

IC-249/86

NOTICE OF VIOLATION
ITEMS A.1 THROUGH A.6 (445/8601-V-12 AND 446/8601-V-03)

A. Criterion XV of Appendix B to 10 CFR Part 50 requires that measures be established to prevent the inadvertent use of nonconforming items, and that these measures include procedures for identification, documentation, segregation, disposition, and notification to affected organizations. It further requires that nonconforming items be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

Section 15.0 of Revision 5 to the TUGCo Quality Assurance Plan (QAP) states, in part, "The identification, documentation, segregation, and disposition of nonconforming materials, parts, or components is outlined in written procedures...." A nonconformance report is used to document deficiencies unless another method is prescribed by a specific procedure/instruction. Nonconformance reports . . . are made available to TUGCo for evaluation ....(and) TUGCo QA assures that periodic evaluations of these reports are forwarded to TUGCo management identifying trends adverse to quality."

Section 3.9 of Revision 3 to the TUGCo Operations Administrative Control and Quality Assurance Plan states, in part, "Material, parts and components which are determined to be nonconforming, shall be identified and reported. Nonconformance reports shall be prepared which identify and describe the nonconformance, the disposition of the nonconformance, and the . . . acceptability of the item after the disposition has been completed . . . ."

Contrary to the above, established procedures for handling of nonconforming materials, parts, or components were not effectively implemented as evidenced by the following observed conditions:

1. Deviation Reports (DRs) generated by ERC to document nonconforming conditions did not, in all cases, result in the initiation of nonconformance reports (NCRs) by the TUGCo QA/QC Coordinator as required by Revision 1 to Procedure CP-QP-16.3 dated August 28, 1985.

2. The TUGCO QA/QC Coordinator failed to initiate NCRs as required by Revision 1 to Procedure CP-QP-16.3 dated August 28, 1985, for numerous ERC identified out-of-scope observations which were subsequently repaired or reworked.

3. Nonconforming items identified by the TUGCo QC Inspection Process Control Group, and subsequently reworked and repaired, were not documented on NCRs as required by Revision 9 of Procedure STA-405 dated November 11, 1985, but rather on three-part office memos.

4. A large number of nonconforming items have not been physically identified with signs, barriers, or hold tags as required by Revision 25 of Procedure CP-QAP-16.1 dated August 17, 1985.

NOTICE OF VIOLATION
ITEMS A.1 THROUGH A.6 (445/8601-V-12 AND 446/8601-V-03)-CONT'D

5. Deficiency Notifications (DNs), as required by Revision 4 of Procedure N61-1 dated December 10, 1985, are to be used only for documenting deficient conditions identified during repair or replacement of mechanical components previously accepted by TUGCo. However, numerous instances have been identified where DNs have also been used to improperly document nonconformances and effect the issuance of work requests and work orders.

6. Failure to initiate required NCRs impacts on the validity of the monthly trend analysis report required by Revision 1 of Procedure QI-QP-17.0-1. The report is required to contain potentially adverse trends, which are based on the number of NCRs issued during the report period.

RESPONSE TO ITEMS A.1 THROUGH A.6

1. Reason for Violation

Item 1 - The requirements of CP-QP-16.3 were not implemented for DRs generated when the component identified fell under the scope of ASME Section XI program.

Item 2 - CP-QP-16.3 R1 required an evaluation to be done on out-of-scope observations to determine whether they warrant the issuance of an NCR. There have been instances where the evaluation did not require the issuance of an NCR when in fact an NCR should have been issued.

Item 3 - TUGCO QC Inspection Process Control Group, used IPC-3 which did not require that an NCR be issued when the inspectors noted a deficiency that was out-of-scope from the inspector's checklist. Instead, 3-part memos were used to notify personnel of deficiencies in order to effect corrections.

Item 4 - We do not agree with the alleged violation because QP-QAP-16.1 R25 did not require the application of a hold tag in all cases. The items were being controlled since whether or not hold tags were placed on the items, further processing of the items was controlled through work package holds. However, a revision to CP-QAP-16.1 has been made which now requires the placing of hold tags on nonconforming items where practicable regardless of the stage of component processing. If a hold tag is not placed, the initiator must provide a brief justification on the NCR.

Item 5 - This violation resulted from deviating from the requirements contained within N61-1 dated 12/10/85. In several instances, DRs were received from ERC (that were associated with the N61-1 program) and TUGCo incorrectly used DNs to process these DRs.

RESPONSE TO ITEMS A.1 THROUGH A.6 CONT'D

Item 6 - We disagree with this violation. Quality Instruction QI-QP-17.0-1 "Preparation and Distribution of Trend Reports" contains criteria for the identification of Potential Adverse Trends (PAT) during the monthly NCR trend results evaluation. Since the objective of the Trend Program is the timely identification of activities which may require corrective action, NCRs initiated per CP-QP-16.3 "Processing CPRT Deviation Reports/Out of Scope Observations" are excluded from the Trend Program due to the inability to clearly identify current program weaknesses based on analysis of deficiencies not related to present conditions or requirements. In order to clearly exclude these NCRs from trending, these NCR numbers are suffixed with an "X" and do not have a specific Trend Code applied. Trend Reports provided for management review therefore contain evaluation results pertinent to ongoing construction and inspection/testing activities.

The CPRT Program Plan describes methods used by CPRT to develop, approve and document corrective action for deviations or deficiencies identified by CPRT. Methods used include identification of adverse trends through the evaluation of related observations and/or deviations. For these items, CPRT provides reports of adverse trends or areas requiring TUGCo management review and action as appropriate.

2. Corrective Action Taken

Item 1 - A review of DRs received was conducted and NCRs were issued for all DRs not previously documented on NCRs.

Item 2 - CP-QP-16.3 R2 now requires that all out-of-scope observations be documented on NCRs regardless of the described condition. All out-of-scope observations have been reviewed to determine if NCRs were issued for them. NCRO have now been issued for all out-of-scope observations.

Item 3 - NCR E-86-200637 R3 was generated to disposition all items listed on the 3-part memos.

Item 5 - Per CP-QP-16.3 R2, DNs may no longer be used to process DRs. NCRs are used to document deficiencies regardless of the stage of component processing. All previous DRs have been addressed as noted in Item 1 above.

RESPONSE TO ITEMS A.1 THROUGH A.6 CONT'D

3. Action to Prevent Recurrence

Item 1 - CP-QP-16.3 Rev. 3 was revised to delete the reference to N61.1. This revision unequivocally requires that all DRs received be documented in accordance with CP-QP-16.0 "Nonconformances" or CP-QAP-16.1 "Control of Nonconforming Items".

Items 2 - Same as corrective action noted above.

Item 3 - The Inspection Process Control Program was replaced by the Inspection Surveillance Program, which requires NCRs to be generated on all deficiencies noted.

Item 5 - Same as corrective action noted above.

4. Date of Full Compliance:

Item 1 - CPSES is currently in full compliance.

Items 2 - CPSES is currently in compliance with CP-QP-16.3.

Item 3 - CPSES is currently in compliance with the Inspection Surveillance Program.

Item 5 - CPSES is currently in compliance with the CP-QP-16.3.

NOTICE OF VIOLATION
ITEM B (445/8601-V-14 AND 446/8601-V-04)

B. Criterion V of Appendix B to 10 CFR Part 50, as implemented by Section 5.0, Revision 3, dated July 31, 1984, of the TUGCO QAP, requires that activities affecting quality shall be prescribed by and accomplished in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances.

Paragraph 6.15.1(t) of Gibbs and Hill Electrical Erection Specification 2323-ES-100, Revision 2, dated October 15, 1980, requires: (1) that field tests shall be performed by the Contractor on all cable reels in accordance with the manufacturer's recommendations, and (2) that the owner will witness these tests.

Contrary to the above, the specified field tests of cable reels were neither prescribed by implementing procedures nor performed.

RESPONSE TO ITEM B

It is our opinion that the conditions described in this Notice of Violation item are not a violation. None of the manufacturers that have supplied cable reels to CPSES have recommended that any field tests be run on cable reels.

CPSES procurement documents invoke and reference all applicable specifications and/or testing which is required of our manufacturers. The required certification/documentation is transferred to CPSES with the shipment of cable and is reviewed for acceptability by receiving inspection and quality control. Site procedures invoke additional acceptance testing of the individual conductors and cables after installation. These tests are more stringent than testing in the bulk reel form.

The requirements in paragraph 6.15.1(t) of electrical erection specification 2323-ES-100 are meaningless because no cable reel field tests have been recommended and are redundant because all necessary testing is already being accomplished by the manufacturer.

In order to eliminate this redundancy in the specification, the paragraph in question was removed from the specification by design change DCA-24088 issued January 24, 1986.

NOTICE OF DEVIATION
ITEM A (445/8601-D-04)

A. FSAR Section 10.4.9.1 states that the Auxiliary Feedwater (AFW) System is capable of supplying the minimum required flow to at least two steam generators against a back pressure equivalent to the accumulation pressure of the lowest set main steam safety valve plus the system frictional and static losses.

FSAR Table 14.2-2, Sheet 51, Test Method No. 3 commits the applicant to verify through preoperational testing that the hydraulic performance of each AFW pump meets design requirements and is within limits assumed in the appropriate accident analysis.

In deviation from the above, preoperational tests 1CP-PT-37-01, "Auxiliary Feedwater System (Motor Driven Pumps)," and 1CP-PT-37-03, "Auxiliary Feedwater System (Turbine Driven Pumps)," failed to test the AFW pumps against a back pressure determined using main steam safety valve accumulation pressure, but instead incorrectly used the safety valve set pressure. This amounts to a less conservative 36 psi reduction in the back pressure during this test. Consequently, the pump capacity data recorded in the above completed test packages are incorrect for the maximum back pressure test.

RESPONSE TO ITEM A

CPSES Engineering is still evaluating the Notice of Deviation, the tests and requirements for the Auxiliary Feedwater Pumps. We intend to provide a complete response by November 3, 1986.

NOTICE OF DEVIATION
ITEM B.1 (445/8601-D-17)

B. Section 4 of Revision 3 to CPRT Procedure CPP-009 states, in part, "Qualified QA/QC Review Team personnel perform field inspections of specific hardware items and reviews of appropriate documents in accordance with approved instructions ..."

In deviation from the above, the following example was noted where field reinspections were not performed in accordance with approved instructions:

1. Attribute 1.f in Section 5.2.6.2 of Quality Instruction (QI) QI-025, Revision 1, which states, in part, "All lines with operating temperatures below 200°F may be installed with a minimum of one inch clearance, including insulation, with respect to other piping," was signed off as acceptable by the ERC inspector for Verification Package No. I-M-LBCO-038. However, independent inspection showed an existing clearance of 0.75 inch between spool piece 2Q2 of drawing BRP-CS-1-SB-060 and the inspected line at a point 12 inches above sleeve 3.

RESPONSE TO ITEM B.1

1. Reason for Deviation

ERC investigation confirmed the stated condition. A 0.75-inch clearance existed between spool piece No. 2Q2 on Drawing BRP-CS-SB-060 at a point 12 inches above sleeve No. 3 on the inspected line. The ERC inspector accepted this attribute when in fact a minimum 1-inch clearance was required.

2. Corrective Action Taken

Deviation Report (DR) number I-M-LBCO-038-DR-1 was prepared on March 18, 1986, to document the existence of the pipe to pipe insulation clearance of 0.75-inch. Nonconformance Report (NCR) number M-25226N was generated as a result of the DR to disposition the above condition.

3. Action to Prevent Recurrence

In cases where inspector error was evident, the inspector and the lead inspector or population engineer discussed specifics to determine why the error occurred. Actions taken to address the error and preclude recurrence typically included one or more of the following, as necessary:

- Documented retraining of the inspector(s) to the pertinent Quality Instruction(s),
- Clarification or revision of the Quality Instruction.

At the discretion of the lead inspector, formal and informal group meetings were held to discuss inspector errors on a generic basis. These discussions allowed appropriate information to be disseminated to various cognizant ERC inspectors.

RESPONSE TO ITEM B.1 CONT'D

An Overview Inspection Program was implemented to reinspect a sample of each Inspector's work. Action is ongoing to analyze the results of the Overview Inspection Program, which includes pertinent inspector error data from other sources (i.e., NRC inspections, etc.).

4. Date of Full Compliance

Corrective action will be completed commensurate with the final disposition of nonconformance report M-25226N. Results of the Overview Inspection Program are scheduled to be completed by October 31, 1986.

NOTICE OF DEVIATION
ITEM B.2 (445/8601-D-20)

B. Section 4 of Revision 3 to CPRT Procedure CPP-009 states, in part, "Qualified QA/QC Review Team personnel perform field inspections of specific hardware items and reviews of appropriate documents in accordance with approved instructions ..."

In deviation from the above, the following example was noted where field reinspections were not performed in accordance with approved instructions:

2. Attribute 1.f in Section 5.2.6.3 of QI-025, Revision 1, which requires that all lines with operating temperatures less than 200°F be installed such that an air gap exists between the pipe, or pipe insulation, and other objects, was signed off as acceptable by the ERC inspector for Verification Package No. I-M-LBCO-144. However, independent inspection identified a portion of a pipe support in contact with the insulation of the inspected line at approximately 14 feet south of the 76° bend in the package.

RESPONSE TO ITEM B.2

1. Reason For Deviation

ERC investigation confirmed the trapeze hanger is touching the insulation on the inspected line. The ERC Inspector did not note this condition at the time of his original inspection.

2. Corrective Action Taken

Deviation Report (DR) number I-M-LBCO-144-DR-3 was prepared on March 14, 1986, to document the clearance deviation. Based in part on this DR, Nonconformance Report (NCR) number M-23475N R-1 was generated to disposition this condition.

3. Action to Prevent Recurrence

In cases where inspector error was evident, the inspector and the lead inspector or population engineer discussed specifics to determine why the error ocurred. Actions taken to address the error and preclude recurrence typically included one or more of the following, as necessary:

- Documented retraining of the inspector(s) to the pertinent Quality Instruction(s),
- Clarification or revision of the Quality Instruction.

At the discretion of the lead inspector, formal and informal group meetings were held to discuss inspectors error on a generic basis. These discussions allowed appropriate information to be disseminated to various cognizant ERC inspectors.

An Overview Inspection Program was implemented to reinspect a sample of each Inspector's work. Action is ongoing to analyze the results of the Overview Inspection Program which includes pertinent inspector error data from other sources (i.e., NRC inspections, etc.).

RESPONSE TO ITEM B.2 - CONT'D

4. Date of Full Compliance

Corrective action will be completed coincident with final disposition of NCR M-23475N R-1. Results of the Overview Inspection Program are scheduled to be completed by October 31, 1986.

NOTICE OF DEVIATION
ITEM B.3 (445/8601-D-19)

B. Section 4 of Revision 3 to CPRT Procedure CPP-009 states, in part, "Qualified QA/QC Review Team personnel perform field inspections of specific hardware items and reviews of appropriate documents in accordance with approved instructions ...."

In deviation from the above, the following example was noted where field reinspections were not performed in accordance with approved instructions:

3. Attribute 1.d in Section 5.2.4 of QI-025, Revision 1, which states, in part, "Ensure that the actual piping dimensions are in agreement with those shown on the piping isometric ....," was signed off as acceptable by the ERC inspector on December 9, 1985, for Verification Package No. I-M-LBCO-144. However, field survey measurements taken by Brown & Root on December 6, 1985, in response to an ERC request, showed the distance from the end of the containment penetration at field weld 18-A to the working point of the 76^{0} bend as 10 feet 5 7/16 inches with respect to a distance (with a tolerance of +2 inches) indicated by the applicable Isometric Drawing BRP-CC-1-RB-046 of 10 feet 8 1/8 inches.

RESPONSE TO ITEM B.3

1. Reason for Deviation

An ERC investigation confirmed the stated condition. The difference between the Brown and Root field survey results and the dimension shown on the isometric drawing exceeds the +2 in. Tolerance. The ERC Inspector did not note this condition at the time of his original inspection.

2. Corrective Action Taken

Deviation Report (DR) I-M-LBCO-144 DR2 was prepared on March 14, 1986, to document the tolereance deviation. Based in part on this DR, Nonconformance Report (NCR) M-23475N R-1 was generated to disposition this condition.

3. Action to Prevent Recurrence

In cases where inspector error was evident, the inspector and the lead inspector or population engineer discussed specifics to determine why the error ocurred. Actions taken to address the error and preclude recurrence typically included one or more of the following, as necessary:

- Documented retraining of the inspector(s) to the pertinent Quality Instruction(s),
- Clarification or revision of the Quality Instruction.

At the discretion of the lead inspector, formal and informal group meetings were held to discuss inspector error on a generic basis. These discussions allowed appropriate information to be disseminated to various cognizant ERC inspectors.

RESPONSE TO ITEM B.3 CONT'D

An Overview Inspection Program was implemented to reinspect a sample of each Inspector's work. Action is ongoing to analyze the results of the Overview Inspection Program which includes pertinent inspector error data from other sources (i.e., NRC inspections, etc.).

4. Date of Full Compliance

Corrective action will be completed coincident with final disposition of NCR M-23475N R-1. Results of the Overview Inspection Program are scheduled to be completed by October 31, 1986.

NOTICE OF DEVIATION
ITEM B.4 (445/8601-D-13)

B. Section 4 of Revision 3 to CPRT Procedure CPP-009 states, in part, "Qualified QA/QC Review Team personnel perform field inspections of specific hardware items and reviews of appropriate documents in accordance with approved instructions..."

In deviation from the above, the following example was noted where field reinspections were not performed in accordance with approved instructions:

4. Paragraph 6 on page 34 of Attachment 6.17 of QI-058 requires (for vendor safety wiring of attachment bolts between the forward bracket assembly and the snubber assembly) that the inspector shall verify that the lockwire is not damaged. Independent inspection showed for Verification Package No. I-S-PS42-021 that the inspection checklist was accepted by the ERC inspector despite the presence of a broken lockwire on the snubber adaptor plate.

RESPONSE TO ITEM B.4

1. Reason For Deviation

Inspection for damaged lockwire was not included as an attribute on the QI-058 inspection checklist. However, Attachment 6.17 required that the inspector verify that the lockwire is not damaged. Therefore, the ERC inspector noted the broken lockwire as an out-of-scope observation in lieu of an in-scope deviation.

2. Corrective Action Taken

An out-of-scope observation (OOS) number 289 was generated on November 11, 1985. Subsequently, Nonconformance Report (NCR) M-234474 was prepared and dispositioned to replace the broken lockwire on the snubber adapter bolts. This action is addressed via TUGCO work request No. 7288.

In order to clarify inspection requirements, QI-037 and QI-058 are currently being revised to include the inspection of lockwire on snubber adaptor plate bolts. In addition, 36 Verification Packages from the PS7N population and 11 Verification Packages from the PS42 population have been reinspected, via a supplemental inspection instruction, to verify that lockwires are installed and not damaged. This supplemental instruction will be included in QI-037 and QI-058.

Further, a Hardware Validation Program (HVP) has been initiated based on Corrective Action Requests (CAR) 65x through 69x. These CARs will be dispositioned by TUGCO by performing a 100% reinspection of pipe supports. Many attributes will be examined including lockwire.

RESPONSE TO ITEM B.4 CONT'D

3. Action To Prevent Recurrence

In addition to the lockwire reinspections required by supplemental instructions to QI-037 and 058, inspection for lockwire on snubber adapter plate bolts is required by the ISAP VII.c Quality Instructions QI-019 and QI-029 under a separate attribute for safety wire.

TUGCO Operations has issued procedures governing housekeeping and inspection of plant systems, structures, components and equipment turned over to Operations. These procedures are QAI-001, "Plant Housekeeping and Equipment Inspection Plan", and STA-607, "Housekeeping Control". Part of this monthly inspection requires the visual inspection for loose, damaged, broken or missing parts/components on equipment.

4. Date of Full Compliance

Corrective action will be completed commensurate with the final disposition of CARs 65x through 69x. ERC reinspection concerning the aforementioned populations are complete. Revisions to QI-037 and QI-058 are scheduled to be completed by October 31, 1986.

NOTICE OF DEVIATION
ITEM C (445/8601-D-18)

C. Section 4.0 of CPRT Project Procedure CPP-008, Revision 1, requires that verification packages provide the information necessary to conduct reinspections and document the results. Section 5.1.1 of this procedure states, in part, "...Should an attribute appear on the generic checklist and not be applicable to the specific item, the engineer indicates "N/A" and provides reasonable justification for the entry."

In deviation from the above, the engineer incorrectly indicated "N/A" for attribute 1.e on the checklist for Verification Package No. I-M-LBCO-038. As a result, this attribute, dealing with assuring branch connections were in accordance with the piping isometric drawing, was not reinspected by ERC. Independent inspection identified that the attribute was applicable for Verification Package No. I-M-LBCO-038 as evidenced by the observation of the presence of a branch connection

RESPONSE TO ITEM C

1. Reason for Deviation

ERC investigation confirmed that attribute 1.e in the ERC inspection checklist had N/A incorrectly inserted by the QA/QC engineer, and thus was not inspected. This attribute addresses assuring that branch connections are in accordance with the piping isometric drawing. The existence of a branch connection was confirmed on the piping isometric drawing bill of material.

2. Corrective Action Taken

No corrective action has been planned for this deviation. The lack of reinspection of one branch connection will not affect the final conclusions drawn concerning branch connection installation. A statistically sufficient quantity of branch connections (approximately 115) have been inspected to permit the adequacy of branch connection installation to be determined.

3. Action to Prevent Recurrence

The QA/QC engineer was instructed to take added precautions when completing inspection checklists. Additionally, ERC inspectors have been instructed to correct a checklist when an error is found or return the list to the QA/QC engineer for correction. A memorandum dated May 28, 1986, confirmed the above instruction.

RESPONSE TO ITEM C CONT'D

In addition to the specific actions identified above, the following activities are ongoing on a generic basis to identify and correct inspection, engineering or program deficiencies to insure compliance with the Quality Assurance guidelines for the CPRT Program:

1) Surveillances are scheduled and performed routinely of CPRT activities per ERC-QA-15, "Performance of Project Surveillance". Specific elements of the surveillance practice are:

   - Monitoring ongoing work to determine what activities have been planned, what activities are in process, and what activities have been completed and accepted.
   - Verify the work is being accomplished in accordance with requirements.
   - Determining when independent inspections should be made and recommending conduct of those inspections.
   - Determining when direct observation of the work performance or overview of inspections and tests should be made and arranging for the conduct of those observations.
   - Performing and documenting observations or witnessing of inspections or tests performed by others.
   - Determining when special audits of quality assurance activities should be performed.
   - Initiating recommendations for corrective action based upon observations.

   These surveillances are performed through selected activities such as monitoring of direct observation of work activities, quality trends, etc. Surveillance activities and their results are recorded. If any deviations are identified, the appropriate organization within ERC is notified to correct the deviation and submit a report describing corrective action taken or proposed. All deviations are logged and tracked until closed.

2) Audits are performed per ERC-QA-18, "Administration of Quality Assurance Auditing". These audits verify the adequacy of the ERC Quality Assurance Program. Audit reports are prepared and if deviations from the Program Plan or Procedures are identified, the audited organization is notified to correct the deviation, review areas where similar deviations can occur and to initiate corrective action. All deviations are tracked until closed.

4. Date of Full Compliance

Quality Assurance surveillances and audits consist of an ongoing program.