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December 16, 1999

1CAN129905

U. S. Nuclear Regulatory Commission
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Subject: Arkansas Nuclear One - Unit 1
Docket No. 50-313
License No. DPR-51
Request For Enforcement Discretion

Gentlemen:

This letter documents Entergy Operation's formal request for enforcement discretion from the requirements of Technical Specification 3.0.3 and is a followup to the verbal request made at 1730 CST on December 15, 1999. This specification stipulates that when a Limiting Condition for Operation is not met, except as provided in the associated Action requirements, within one hour action shall be initiated to place the unit in an operating condition in which the Specification does not apply.

During a review of eddy current test data, it was determined that a defective tube in the "A" Once Through Steam Generator (OTSG) was not repaired as required by Technical Specification 4.18.5.b during the last ANO-1 refueling outage (1R15). The defective tube cannot be repaired with the unit at power.

Technical Specification 3.1.1.2 requires that two steam generators be operable whenever reactor coolant average temperature is above 280° F. Since a defective tube in the "A" OTSG was not repaired as required by Specification 4.18.5.b, the affected OTSG was declared inoperable. Because there is no specific action statement associated with Technical Specification 3.1.1.2, Technical Specification 3.0.3 was determined to be applicable. Technical Specification 3.0.3 was entered at approximately 1446 CST on December 15, 1999.

Evaluation of the condition has determined that the tube is structurally capable of withstanding normal or accident conditions without failure or leakage that would result in exceeding accident analysis assumptions. Therefore, this enforcement discretion is requested in order to allow sufficient time for submittal and NRC review and approval of an exigent Technical Specification change request for a one time exception to the requirements of Technical Specification 4.18.5.b. This exception will allow one tube with axial indications in the upper roll transition area with a potential through-wall depth of greater than the plugging limit to remain in service for the remainder of cycle 16. A markup of the proposed Technical Specification change is attached.

PPR ADDA 0500 0313

ADD1

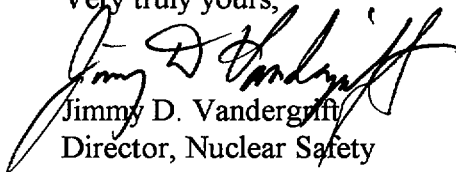
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This enforcement discretion request was prepared in accordance with NRC Administrative Letter 95-05, Revision 2 "Revision to Staff Guidance for Implementing NRC Policy on Notification of Enforcement Discretion." The details supporting the issuance of the enforcement discretion are attached.

The attached request was reviewed and approved by the ANO Plant Safety Committee at approximately 1604 CST on December 15, 1999.

Verbal approval of this enforcement discretion request was received at 1836 CST on December 15, 1999.

Very truly yours,



Jimmy D. Vandergift
Director, Nuclear Safety

JDV/rhs
Enclosure

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REQUEST FOR ENFORCEMENT DISCRETION REGARDING ONCE THROUGH STEAM GENERATOR SURVEILLANCE

Technical Specifications (TSs) Requiring Enforcement Discretion

The inservice inspection of the ANO-1 OTSGs is conducted in accordance with ANO-1 Technical Specification 4.18. Specification 4.18.2 states: *“Inservice inspection of steam generator tubing shall include non-destructive examination by eddy-current testing or other equivalent techniques.”* Specification 4.18.5.b notes: *“The steam generator shall be determined operable after completing the corresponding actions (plug, reroll, or sleeve all tubes exceeding the plugging limit and all tubes containing non-TEC through-wall cracks) required by Table 4.18-2.”* Table 4.18-2 specifies the expansion criteria for sampling of the steam generator tubes and requires “defective” tubes to be plugged, rerolled, or sleeved. Specification 4.18.5.a.6 defines Defect as follows: *“an imperfection of such severity that it exceeds the plugging limit except where the imperfection has been spanned by the installation of a sleeve. A tube containing a defect in its pressure boundary is defective.”* Plugging Limit is defined in specification 4.18.5.a.7 as follows: *“the imperfection depth at or beyond 40% of the nominal tube wall thickness for which the tube shall be sleeved, rerolled, or removed from service because it may become unserviceable prior to the next inspection.”*

The Bases for Specification 4.18 states: *“The surveillance requirements for inspection of the steam generator tubes ensure that the structural integrity of this portion of the RCS will be maintained. The program for inservice inspection of steam generator tubes is based on a modification of Regulatory Guide 1.83, Revision 1.”*

Failure to repair a tube with a flaw that potentially exceeds the plugging limit constitutes a failure to comply with the surveillance requirements of the ANO-1 Technical Specifications. There is no specific action statement associated with failure to comply with the surveillance requirements; however, the surveillance specification implies that operability of the OTSGs cannot be demonstrated without the performance of a valid surveillance.

Technical Specification 3.1.1.2 requires that two OTSGs be operable whenever reactor coolant average temperature is above 280° F. Since the defective tube in the “A” OTSG was not repaired as required by Specification 4.18.5.b, the affected OTSG must be considered inoperable. Because there is no specific action statement associated with Technical Specification 3.1.1.2, Technical Specification 3.0.3 was determined to be applicable.

Circumstances Surrounding Situation / Apparent Root Cause / Need For Prompt Action / Relevant Historical Information

During the 1R15 outage, an Alternate Repair Criteria (ARC) was implemented for indications located at the tube ends. Part of the requirements for determining the postulated accident induced leakage at the end of the cycle is a determination of the number of flaws at the tube end. To

perform this portion of the evaluation, a conservative assumption with respect to the number of axial tube end cracks was made for tubes containing multiple indications until detailed analysis could be performed. During this review, it was discovered that a non-repairable code was given to an indication at the upper roll transition (URT) of tube 110/60 in the "A" OTSG. Per the ANO-1 eddy current analysis guidelines, confirmed indications at the URT require a repairable code. Tubes containing indications are subsequently rerolled or plugged. In a review of the resolution analysis compare sheet for tube 110/60, it was observed that calls were made in two different locations: one at the tube end which received a correct non-repairable code, and one at the URT. The URT indication was given the correct repairable code by both primary and secondary production analysis but at an incorrect location. Both the primary and secondary resolution analysts agreed on the repairable classification and kept it at the incorrect location. During the independent oversight process, the reviewing analyst corrected the location of the flaw from "UTE-3" to "UTE-1"; however, the code was improperly changed to a non-repairable code. The basis for changing the classification from repairable to non-repairable is not known but appears to have been made in error. A reevaluation of Tube 110/60 data confirmed the original classification of repairable. As a result of this error, tube 110/60 was left in service with an indication that exceeded the Technical Specifications plugging limit.

Safety Basis For Request

The OTSG upper roll areas have been inspected three times (1R13, 1R14, and 1R15) with indications being detected in the roll transition each time. The indications were detected with the 0.115" pancake coil and/or the plus-point coil. The URT data was collected at an axial pull speed of 0.1 inch/sec, the rotational speed was 300 RPM, and the axial and circumferential digitization rate was 30 samples per inch. The helical pitch was 0.020 inches/revolution ($0.1 \text{ inch/sec} \div 300 \text{ RPM}) * 60 \text{ min}$. There have been several OTSG tubes pulled that confirmed that the degradation mechanism is Primary Water Stress Corrosion Cracking (PWSCC) with an axial orientation as a result of the residual stress fields. Examination of a tube pulled during 1R13 that exhibited a roll transition indication confirmed the existence of this degradation mechanism at ANO.

The approach used for evaluating the leakage integrity of the upper roll transition flaws is to conservatively estimate the number of flaws which may leak at accident conditions at the end of cycle. A depth distribution and flaw profile is used to determine which flaws could leak and to characterize the potential leakage through those flaws. From this the total potential leakage at accident conditions is calculated for this mechanism. The number and size distribution of upper roll transition flaws is expected to be the same at the end of cycle 16 as the previous cycle. Thus, the potential accident induced primary-to-secondary leakage will remain below 1 gpm.

There has been no evidence of leakage through an upper roll transition flaw in the operating history of ANO-1. A "bubble" test was performed at the end of cycle 14 with no leakage being identified from this degradation mechanism. This test consisted of pressurizing the secondary side of the OTSG with a gas and monitoring the primary side for leakage. The current operating leakage is approximately minimum detectable.

The repairable call in tube 110/60 consisted of two separate URT axial flaws. They were both sized at a maximum depth of 97% through wall (TW) with lengths of 0.05 inch and 0.04 inch. The average depth of these flaws were 74% and 59% respectively. The potential accident induced leakage resulting from two axial flaws of this length, assuming 100% TW for their entire length, is negligible. This is a small fraction of the allowable end-of-cycle 16 leakage typically calculated for PWSCC at roll transitions. Therefore, the postulated accident induced leak rate contribution at the end-of-cycle 16 from URT PWSCC is negligibly affected.

The leak rate calculation is taken from the Opcon leaker module which is based on PICEP freespan data. The results were benchmarked against Framatome Technologies Inc. (FTI) freespan leak rate results with a good relationship. This estimate is determined to be conservative based on the indications being located in the tubesheet.

Additional calculations were performed considering flaw growth over the remainder of cycle 16. An EPRI study reveals a maximum growth rate value of 0.03 in/EFY for PWSCC. This value is based on 15 points from standard roll transition plants. Therefore, a growth rate of 0.043 for cycle 16 (1.43 EFY) is used for the PWSCC flaws. The estimated leak rate value for a 0.1 inch (0.05 inch + 0.043 inch growth) flaw is 0.0026 gpm assuming 100% TW over the entire length. For two flaws of similar size, the leakage will be 0.0052 gpm. Assuming the flaws grow over the entire length of the transition, the resulting leak rate would still be bounded by the accident analysis assumptions.

The axial sizing is considered bounding based on a BWOOG project performed earlier this year. This project compared the performance of the plus-point sizing to the destructive exam results and out of 21 samples, 19 were oversized. Considering the axial extent to be 100% TW is conservative when estimating the leakage.

In 1996, to support ANO's study of intergranular attack defects, burst testing of pre-defected tubes was completed by FTI. The burst testing consisted of nine tubes containing through-wall drilled holes up to 0.5 inches in diameter and one tube containing no defects placed within a simulated tubesheet. Nine of the specimens burst at pressures $\geq 10,941$ psig. Each tube burst outside the tubesheet within the non-defected portion of the tubes. One tube reached a pressure of 9,577 psig but did not burst due to bladder leakage. These test results indicate that the tubesheet provides sufficient support to preclude tube rupture within the tubesheet.

Primary-to-secondary leakage through the flaws in the tube, should it begin to leak during a postulated main steam line break, would be negligible. Therefore, the potential leakage sources would remain within the level assumed in the accident analysis. Allowing this tube to remain in service will have no significant impact on offsite or operator doses during an accident.

Conditional core damage probability is the increase in core damage frequency due to a given condition other than that assumed for the base Probabilistic Risk Assessment (PRA). The PRA assumed that the tube integrity is such that no OTSG tube rupture would be induced due to transient conditions. The limiting licensing basis transient that could most adversely affect the tubes by creating a high differential pressure across the tubes is a Main Steam Line Break

(MSLB) accident. This accident could produce a tube differential pressure of up to 2500 psid. The tube sample burst pressures were well above pressures which would be seen in a limiting MSLB accident. Thus, the likelihood of tubes rupturing is not increased as a result of leaving a tube in service containing a flaw in the UTS. This situation has been qualitatively assessed and the conditional core damage probability for this condition is estimated to be inconsequential.

The limiting licensing basis accident with respect to dose consequences from induced tube leakage is the MSLB accident. This accident analysis assumes a total leakage of 1 gpm with 1% failed fuel in the core. However, OTSG tube leakage is procedurally limited to 0.069 gpm (100 gpd) during normal operation.

The subject flaws do not represent a structural or leakage concern. Therefore, continued operation with axial flaws in tubing contained within the tubesheet does not pose a concern relative to the health and safety of the public.

Engineering Evaluation and Basis For No Significant Hazard Consideration

An evaluation of the proposed enforcement discretion request has been performed in accordance with 10CFR50.91(a)(1) regarding no significant hazards consideration using the standards in 10CFR50.92(c). A discussion of those standards as they relate to this request follows:

Criterion 1 - Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated.

The OTSGs are used to remove heat from the reactor coolant system during normal operation and during accident conditions. The OTSG tubing forms a substantial portion of the reactor coolant pressure boundary. A OTSG tube failure is a violation of the reactor coolant pressure boundary and is a specific accident analyzed in the ANO-1 Safety Analysis Report.

The purpose of the periodic surveillance performed on the OTSGs in accordance with ANO-1 Technical Specification 4.18 is to ensure that the structural integrity of this portion of the RCS will be maintained. The technical specification plugging limit of 40% of the nominal tube wall thickness requires tubes to be repaired or removed from service because the tube may become unserviceable prior to the next inspection. Unserviceable is defined in the Technical Specifications as the condition of a tube if it leaks or contains a defect large enough to affect its structural integrity in the event of an operating basis earthquake, a loss of coolant accident, or a steam line break. Of these accidents, the most severe condition with respect to axial cracking within the UTS is the MSLB. During this event the differential pressure across the tube could be as high as 2500 psid. The rupture of a tube during this event could permit the flow of reactor coolant into the secondary system thus bypassing the containment.

From testing performed on simulated flaws within the tubesheet, it has been shown that the axial indications within the upper tubesheet left in service during cycle 16 do not represent structurally significant flaws which would increase the probability of a tube failure beyond that currently assumed in the ANO-1 Safety Analysis Report.

Burst tests were conducted on tubing with simulated flaws within the tubesheet. In these tests, through-wall holes of varying sizes up to 0.5 inch in diameter were drilled in test specimens. The flawed specimen tubes were then inserted into a simulated tubesheet and pressurized. In all cases the tube burst away from the flaw in that portion of tube that was outside the tubesheet. The size of these simulated flaws bound the indication left in service within the upper tubesheet during 1R15. These tests demonstrate for flaws similar to the axial indication in the ANO-1 upper tubesheet that the tubes will not fail at this location under accident conditions.

The dose consequences of a MSLB accident are analyzed in the ANO-1 accident analysis. This analysis assumes a 1 gpm OTSG tube leak and that the unit has been operating with 1% defective fuel. The postulated accident induced leak rate contribution at the EOC from these indications is negligible.

Therefore, the requested enforcement discretion which will allow continued operation with axial flaws within the UTS does not result in a significant increase in the probability or consequences of an accident previously evaluated for ANO-1.

Criterion 2 - Does Not Create the Possibility of a New or Different Kind of Accident from any Previously Evaluated.

The OTSGs are passive components. The intent of the Technical Specification surveillance requirements is being met by this change in that adequate structural and leakage integrity will be maintained. The proposed change introduces no new modes of plant operation.

Therefore, the requested enforcement discretion does not create the possibility of a new or different kind of accident from any previously evaluated.

Criterion 3 - Does Not Involve a Significant Reduction in the Margin of Safety.

The ANO-1 Technical Specification Bases specify that the surveillance requirements (which includes the plugging limits) ensure the structural integrity of this portion of the RCS pressure boundary. The Technical Specification plugging limit of 40% of the nominal tube wall thickness requires tubes to be repaired or removed from service because the tube may become unserviceable prior to the next inspection. Unserviceable is defined in the Technical Specifications as the condition of a tube if it leaks or contains a defect large enough to affect its structural integrity in the event of an operating basis earthquake, a loss of coolant accident, or a MSLB. Of these accidents, the most severe condition with respect to flaws within the UTS is the MSLB.

Testing of simulated through-wall flaws of up to 0.5 inch in diameter within a tubesheet showed that the tubes always failed outside of the tubesheet. Thus the structural requirement of the bases of the surveillance specification is satisfied considering this request for enforcement discretion.

Leakage under accident conditions would be limited due to the small size of the flaws and would be low enough to ensure offsite dose limits are not exceeded.

Therefore, the requested enforcement discretion does not involve a significant reduction in the margin of safety.

Environmental Impact Evaluation

10 CFR 51.22(c) provides criteria for and identification of licensing and regulatory actions eligible for categorical exclusion from performing an environmental assessment. Per 10 CFR 51.22(c)(9), a proposed amendment to an operating license for a facility requires no environmental assessment if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant hazards consideration, (2) result in a significant change in the types or significant increase in the amounts of any effluents that may be released off-site, or (3) result in a significant increase in individual or cumulative occupational radiation exposure. Entergy Operations, Inc. has reviewed the proposed changes to the ANO-1 operating license and has determined that they meet the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the proposed license amendment. The basis for this determination is as follows:

1. The proposed enforcement discretion does not involve a significant hazards consideration as described previously in the evaluation.
2. As discussed in the significant hazards evaluation, this change does not result in a significant change or significant increase in the radiological doses for any Design Basis Accident. The proposed enforcement discretion does not result in a significant change in the types or a significant increase in the amounts of any effluents that may be released off-site.
3. The proposed enforcement discretion does not result in a significant increase to the individual or cumulative occupational radiation exposure because leakage would be limited due to the small size of the flaws.

Compensatory Measures

Extensive measures have been previously taken by ANO to enhance the operators' ability to detect and respond to OTSG tube leakage. Additionally, ANO has previously implemented more restrictive shutdown limits based upon primary-to-secondary leakage than those required by the Technical Specifications. Since these measures were already in place, no additional compensatory measures were determined necessary to address the surveillance deficiency. A summary of ANO-1's detection/monitoring capability, shutdown limits, operator guidance, and training is provided below.

The methodology for monitoring the secondary system for leakage includes the use of process monitors to check radiation levels in the condenser off-gas, N-16 gamma levels from the OTSGs, chemistry samples, and RCS mass balances to calculate leakage. Additionally ANO-1 has a procedural limit of 0.069 gpm (100 gpd) that is more conservative than the 0.104 gpm (150 gpd) limit allowed by Technical Specification 3.1.6.3.b.

Operations personnel trend information from the steam, condenser off-gas and OTSG process monitor systems to determine indication of an OTSG tube leak. Steam lines are monitored by radiation monitors and N-16 gamma detectors that provide chemists and operators with the capability of promptly detecting primary-to-secondary leakage.

The amount of N-16 present in the secondary system is influenced by the size of the leak, location, and the power level. ANO-1 utilizes scintillation type detectors as N-16 monitors. These monitors are normally selected to measure gross activity from the OTSGs but are selected to monitor N-16 in accordance with Abnormal Operating Procedure (AOP) guidance for small OTSG tube leaks. The monitors provide input to control room annunciators associated with OTSG tube leakage. These N-16 monitors have only a single point correlation of leakage to an N-16 reading based on 100% power level. Guidance is given in AOP 1203.023, "Small Steam Generator Tube Leaks" to correlate an N-16 reading of 1×10^4 CPM as being indicative of tube leakage of ≥ 0.1 gpm (150 gpd).

Additionally, ANO-1 installed high sensitivity N-16 detectors in January 1997 to enhance detection of small changes in primary-to-secondary tube leakage at various power levels. A modification was made to the plant computer to allow monitoring of both the original and newly installed N-16 monitors to provide a readily visible indication of changes in count rate due to changes in leakage. The plant computer input has an alarm that can be used to actuate a control room annunciator panel to alarm at a value set by operators. In November 1999, a software package was installed on the Plant Monitoring System (PMS) which further enhances OTSG tube leakage detection capability. The software uses the count rate supplied by the N-16 detectors and applies a equally weighted (upper and lower tube sheet) transport time. The readings are in gpm, gpd, and rate of change in gpm/hr and gpd/hr for each OTSG. PMS alarms have been established slightly above current values for each point. Also, a second alarm for each point has been set at entry level conditions for AOP 1203.023.

The condenser off-gas monitor is an in-line detector on the combined suction line of the condenser vacuum pumps. It is a gamma sensitive scintillation detector that provides a means to measure the gaseous activity levels released to the system vent. The monitor provides displays and an alarm in the control room to alert operators of a possible OTSG tube leak.

The main steam high range radiation monitors are Geiger-Mueller type detectors. These detectors provide input to the Safety Parameter Display System (SPDS) for display in the front of the control room.

The plant computer leak rate program provides operators the ability to validate indications of primary-to-secondary leakage by observing changes in the Reactor Coolant System (RCS) mass inventory. This program allows detection of changes in the make up tank level and determination of leak rate changes based on the time interval selected.

The SPDS is also available for use by operators. This system has a screen dedicated for use during suspected or actual primary-to-secondary leakage events. The "Steam Generator Tube Rupture" screen contains N-16 readings (from the original detectors), condenser off gas, RCS Avg. Temp (Loop A/B), OTSG Tube-to-Shell delta T (OTSG A/B) and T-Sat for the OTSGs. In addition, the SPDS graphics display is outlined in red and flashing when a parameter on the graphics display is in alarm.

The Chemistry Department routinely analyzes and trends samples from the RCS and secondary water systems to identify and quantify primary-to-secondary leakage. Off-gas samples taken from the condenser vacuum pump discharge are analyzed for Argon-41 activity. Liquid condensate samples are analyzed for tritium to quantify activity levels in the secondary system. Argon-41 levels yield a better measure of instantaneous levels of primary-to-secondary leakage. Tritium levels in the secondary system increase linearly over time during a primary-to-secondary leak. A primary to secondary leak rate can also be determined from the tritium analysis. Secondary liquid samples are also routinely analyzed for fission product activity using gamma spectroscopy. An AOP directs special sampling by the Chemistry Department until primary-to-secondary leakage is reduced below 0.1 gpm or the reactor is tripped.

The Operations and Chemistry Departments utilize available information to detect changes in primary-to-secondary leakage and to initiate actions to place the unit in a safe condition. Procedures are provided such as Emergency Operating Procedure (EOP) 1202.06, "Steam Generator Tube Rupture," AOP 1203.023, "Small Steam Generator Tube Leaks," and the 1203.012 series for annunciator corrective actions are utilized when the monitors, indicators, trends, or annunciators exhibit changes indicative of the development of, or change in, primary-to-secondary leakage. The Operations Department uses these procedures to place the plant in a stable condition and to mitigate the consequences of an OTSG tube leak.

Finally, ANO maintains thorough training of licensed operators by using the plant simulator for primary-to-secondary tube leaks and ruptures. This insures familiarity with the symptoms and indications of this event to enable timely diagnosis and action for placing the unit in a safe condition.

Justification For Duration

Since the subject flaws do not represent a structural concern as they are located within the upper tubesheet area, and any potential primary to secondary leakage would be well within the allowable limits for the current cycle, ANO has concluded that the presence of these inservice upper roll transition area indications do not pose a concern relative to safe operation of the plant or the health and safety of the public. The basis for this conclusion is presented in the discussion above. The duration of the enforcement discretion will provide sufficient time for review and approval of an exigent Technical Specification change.

Plant Safety Committee (PSC) Review

This proposed enforcement discretion was reviewed and approved by the ANO PSC at approximately 1604 CST on December 15, 1999.

Criterion for Discretion Approval

Initiation of a plant shutdown and reducing the RCS temperature to below 280° F to perform the required action would increase the potential for a plant upset. Although this increased potential has not been quantified, it is considered by ANO to represent a greater risk than continuing to operate with the existing tube flaws for the remainder of the current cycle. Therefore, NOED criterion B.2.1.(a) is considered applicable to this request.

Followup License Amendment

A markup of the requested TS change is attached.

Severe Weather Or Other Natural Event Justification

This proposed enforcement discretion is not required because of any severe weather condition or any natural event.

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PROPOSED

TECHNICAL SPECIFICATION CHANGE

MARK-UP

- b. The steam generator shall be determined operable after completing the corresponding actions (plug, reroll, or sleeve all tubes exceeding the plugging limit and all tubes containing non-TEC through-wall cracks) required by Table 4.18-2.

Tube 110/60 in the "A" steam generator contains indications in the upper roll transition that exceed the plugging limit. Tube 110/60 may remain in service with these indications for the duration of cycle 16 without rendering the "A" steam generator inoperable.

4.18.6 Reports

Following each inservice inspection of steam generator tubes, the complete results of the inspection shall be reported to the NRC. This report, to be submitted within 90 days of inspection completion, shall include:

- a. Number and extent of tubes inspected;
- b. Location and percent of wall-thickness penetration for each indication of an imperfection;
- c. Identification of tubes plugged and tubes sleeved;
- d. Number of tubes repaired by rerolling and number of indications detected in the new roll area of the repaired tubes;
- e. Summary of the condition monitoring and operational assessment results when applying TEC alternate repair criteria; and
- f. Summary of the condition monitoring and the operational assessment results (including growth) when applying the upper tubesheet ODIGA alternate repair criteria.

This report shall be in addition to a Special Report (per Specification 6.12.5.d) required for the results of steam generator tube inspections which fall into Category C-3 as denoted in Table 4.18-2. The Commission shall be notified of the results of steam generator tube inspections which fall into Category C-3 prior to resumption of plant operation. The written Special Report shall provide a description of investigations conducted to determine cause of the tube degradation and corrective measures taken to prevent recurrence.