CONSOLIDATED POWER SUPPLY
NUCLEAR CERTIFIED PRODUCTS

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Subject: Reply to Notices of Nonconformance; NRC Inspection Report No. 99901263/2010-201

Nonconformance 99901263/2010-201-01

Criterion V, "Instructions, Procedures, and Drawings," of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that "activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

Contrary to the above, as of November 19, 2010:

A. CPS failed to adequately prescribe its commercial-grade dedication process by appropriate procedures. Specifically, CPS failed to properly identify certain dimensional verifications on as-shipped items in dedication plans.

B. In addition, CPS failed to document the identification of critical characteristics when dedication was performed in conjunction with American Society of Mechanical Engineers (ASME) Code material upgrades.

Reason for the Noncompliance

A. Commercial Grade Dedication Plans do not always list the customer's final dimensions ***as*** a Critical Characteristic; instead, (such as when purchasing items with oversized dimensions to accommodate removal of test samples) the Dedication Plan lists CPS dimensions as the Critical Characteristic rather than the customer's final dimensions. This insures the appropriate sizes are received that will accommodate CPS testing, and then provide for the dimensions required by the customer. The customer's requirements for final dimensions are reflected on the CPS Sales Order, and are subsequently verified by a CPS Inspector and documented on a Final Inspection Report which becomes a part of the overall Dedication Package. The Sales Order reflects the customer's requirements for configuration and final dimensions, but does not go as far as labeling these attributes as Critical Characteristics. CPS acknowledges that this approach places the CPS-assigned dimensions into the Dedication scenario as Critical Characteristics, and excludes the customer's final dimensions from the Dedication process as Critical Characteristics by addressing them at Final Inspection. It should be noted that while not being specifically labeled as "Critical Characteristics", the customer's final dimensional requirements *are* being verified and documented in all cases prior to shipment.

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B. In the utilization of unqualified source material in accordance with NCA3855.5, all inspection and test requirements of the material specification and the specific material requirements of ASME Section III are being performed as required by NCA-3855.5. A chemical analysis is being performed on each piece, and all other requirements of the material specification are being performed on each piece, unless CPS exercises the "alternative" of NCA-3855.5 which still requires chemical analysis of each piece, but allows "all other requirements" of the material specification to be performed on each Heat and Lot provided the additional specified requirements are satisfied. In the verification of the material specification requirements and the specific Section III material requirements, CPS failed to label these attributes *as* "Critical Characteristics" and, instead, had referred to them as "material specification and Code requirements." Dedication Plans were not used during this process, as they were not considered to be applicable to Code Upgrade. CPS had interpreted NCA-3855.5 Code requirements as being equivalent to Commercial Grade Dedication. This interpretation was based on NRC Information Notice 86-21 which recognizes the holding of an ASME N, RA, NPT or NV Certificate of Authorization, or Quality System Certificate as evidence that the holder of the Certificate has a documented QA program *that meets the requirements of 10CFR 50 Appendix B*. CPS assumed the NRC's recognition of these accreditations did not exclude Utilization of Unqualified Source Material as adequate to satisfy Commercial Grade Dedication. While CPS considered Utilization of Unqualified Source Material to be acceptable for Dedication, a dedicated item could not be used for ASME Code applications. In order to preclude the inadvertent use of a Dedicated item in a Utilization of Unqualified Source Material scenario, Procedure SP-716 includes the statement: *"Although similar in nature, this procedure does not include the Dedication of Commercial Grade Items for non-Code safety related use. However, Material qualified under this procedure may be used to fill non-Code safety related orders". Additionally,* Dedication Plans were not being used in the implementation of SP-716 because the process being used was based on NCA-3855.5 which does not specify a requirement for the use of Dedication Plans.

Steps That Have Been Taken and the Results Achieved / Corrective Steps That Will Be Taken to Avoid Noncompliance

Procedure SP-716 "Utilization of Unqualified Source Material" will be revised to include Commercial Grade Dedication such that the procedure merges and satisfies both sets of requirements, including the identification of Critical Characteristics, sample sizes, etc.

A new Dedication Plan format will be developed to implement the changes in procedure SP-716. These Dedication Plans will merge the requirements of the recognized EPRI sampling plans with the requirements of NCA-3855.5, with the most stringent of the requirements being utilized in the Plan.

Relative to the customer's final dimensions, each Dedication Plan (whether ASME Code Upgrade related, or non Code Safety Related) will include the customer's final dimensions as Critical Characteristics. This will be accomplished by including the requirements directly in the Dedication Plan or, alternatively, by indicating in the Plan that the customer's final dimensions are considered Critical Characteristics and, by reference, indicating where these requirements and acceptance criteria can be located (typically on the applicable Sales Order).

Both Procedures SP-716 "Utilization of Unqualified Source Material" and SP-701 "Dedication of Commercial Grade Items" will be revised to incorporate the above changes.

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Date Corrective Actions Will be Completed

February 28, 2011.

Nonconformance 99901263/2010-201-02

Criterion V of Appendix B of 10 CFR Part 50 states, in part, that "activities affecting quality shall be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

Contrary to the above, as of November 19, 2010, CPS failed to prescribe appropriate quantitative or qualitative acceptance criteria for determining that the calibration of the optical emission spectrometer had been appropriately accomplished for each element. Specifically, CPS failed to perform the required sample testing to calculate the acceptance criterion for each constituent and to include the calculated acceptance criteria in instructions, procedures, or drawings.

Reason for the Noncompliance

Cause was human error on the part of the present Laboratory Supervisor and present Quality Assurance Manager.

To address the NRC's 1993 finding of this nonconformance, the missing acceptance criteria had been added in Revision 7 to SP-202 Dated 12/93 by the previous CPS Laboratory Supervisor and Quality Assurance Manager. Subsequent to 1993, SP-202 has been revised numerous times for the purpose of adding new equipment, clarifying existing requirements, and making editorial corrections (during the NRC's 2010 Inspection, SP-202 was at Revision Level 34 Dated 11/09.)

Throughout the evolution of Procedure SP-202, the spectrometer in service during the NRC's 1993 visit has been replaced with a newer model, and a second spectrometer has been procured. SP-202 was revised to incorporate these two newer spectrometers as each was added to the CPS M&TE system. During the CPS investigation of cause for the NRC's finding of this nonconformance, it was found that SP-202 Revision 26 Dated 4/06 had been issued to make clarifications, and to remove reference to the spectrometer manufacturer's names as this was considered extraneous information. During the Revision 26 re-write of the paragraph addressing spectrometers, the acceptance criteria for standardization was inadvertently omitted by the present Laboratory Supervisor and Quality Assurance Manager.

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Corrective Steps That Have Been Taken and the Results Achieved

The two spectrometers operated by CPS (identified as QA-239 and QA-115) and affected by this noncompliance were removed from service on 11/22/2010.

Paragraph 4.14 of CPS Procedure SP-202,"Calibration and Maintenance of Measuring and Test Equipment", has been revised to include requirements for spectrometer standardization acceptance criteria. Results of pre- test QC checks will be considered acceptable if the observed values for the elements of interest fall within the certified values ± 2 calculated standard deviations. Results of interim and post- test QC checks will be considered acceptable if the observed values for the elements of interest fall within the certified values ± 3 calculated standard deviations. While a result of an interim QC check that falls outside ± 2 calculated standard deviations but within ± 3 calculated standard deviations is not cause for rejection of test results, the operator shall take the appropriate actions necessary to achieve an interim QC check that falls within the certified values ± 2 calculated standard deviations prior to proceeding with analysis of samples. In the event that an unacceptable QC check is observed, the operator shall discard test results obtained since the last acceptable QC check and perform the appropriate actions (such as instrument maintenance, standardization, etc.) to achieve an acceptable pre- test QC check prior to proceeding with analysis of samples.

All laboratory personnel have been trained to the requirements of the revised procedure, SP202, Revision 35. This training was performed on 12/13/2010 and 1/6/2011.
In accordance with SP202 Revision 35, acceptance criteria have been established for all methods utilized with spectrometer QA-239. These methods are identified as Fe-30MO, Fe-10MO, and Cu-10MO. Each of these methods has been verified to the established acceptance criteria. For each method, this verification consisted of five analyses (2- burn averages) on each of two days for a total of ten analyses of each standard. A review of past QC checks of each of these methods has been performed. These historical QC checks were found to be within the established acceptance criteria. Upon completion of these verifications and QC check reviews, spectrometer QA-239 was place back in service.

In accordance with SP202 Revision 35, acceptance criteria have been established for three of the six methods utilized with spectrometer QA-115. These methods are identified as CR-MO-01, 400SS_01, and PH-STEEL. Each of these methods has been verified to the established acceptance criteria. For each method, this verification consisted of five analyses (2- burn averages) on each of two days for a total of ten analyses of each standard. A review of past QC checks of each of these methods has been performed. These historical QC checks were found to be within the established acceptance criteria. During the week of 1/31/2011, QA-115 will be placed back in service and tagged as "Restricted Use" indicating it is acceptable for use only with methods CR-MO-01, 400SS_01, and PH-STEEL. In accordance with SP202 Revision 35, CPS laboratory personnel are currently working to establish acceptance criteria for the remaining three methods utilized with spectrometer QA-115. These methods are identified as NICKEL01, LOALLOY5, and 30431607. Verification of these methods will consist of five analyses (2-burn averages) on each of two days for a total of ten analyses of each standard. A review of historical QC checks of each of these methods will be performed to determine compliance with the established acceptance criteria. CPS estimates that establishment of acceptance criteria, verification, and historical QC check reviews for these three methods will be complete by 2/28/2011.

Corrective Steps That Will Be Taken to Avoid Noncompliance

All laboratory personnel have been trained to the requirements of the revised procedure, SP202, Revision 35. This training was performed on 12/13/2010 and 1/6/2011. In accordance with SP202 Revision 35, Form 202K ("Spectrometer Acceptance Criteria Reference Sheet") will be utilized to document the established acceptance criteria for each method and check standard/verifier utilized. A completed Form 202K will be maintained with the Certificate of Analysis for each check standard/verifier utilized for QC checks.

Date Corrective Actions Will be Completed

February 28, 2011

Nonconformance 99901263/2010-201-03

Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 states in part that, "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected." CPS Standard Procedure (SP) SP-601, "Identification, Evaluation, and Reporting of Defects and Failure to Comply," Step 4.5, states in part that, "The QA Manager or the Assistant QA Manager shall review all Nonconformance Reports and Corrective Action Request forms to determine if a deviation or a failure to comply exists. Evidence of this review shall be documented on the applicable Nonconformance Report or Corrective Action (CPS Form 405 and 802 respectively)."

Contrary to the above as, of November 18, 2010, CPS failed to identify deviations as part of its corrective action process. Specifically, multiple examples of CPS Nonconformance reports failed to identify deviations despite describing nonconformances that departed from the technical requirements in the purchasers' procurement documents.

Reason for the Noncompliance

Based on our interpretation of the regulation, CPS was under the impression that checking "Yes" or "No" in the "10CFR21 Reportability Evaluation Required" box on Nonconformance Reports and Corrective Action forms satisfied requirements. CPS was unaware of a specific requirement for documenting the reason a nonconforming condition was *not* classified as a deviation. Contributing to a further misunderstanding of the requirements was the removal of the pertinent 21.21(a) requirements from CPS Procedure SP-601 "Identification, Evaluation, and Reporting of Defects and Failure to Comply." This information had been removed as corrective action required to resolve a finding issued during the 2009 NIAC audit of CPS. During that audit, CPS was advised that our 10CFR21 procedure was inappropriate in that it contained provisions for performing activities described in 21.21(a), and that CPS (as a supplier) could only perform the activities described in 21.21(b). On November 13, 2009 CPS implemented Revision 7 to procedure SP-601. This revision to the procedure addressed the audit finding by removing the 21.21(a) requirements, and by confining CPS to 21.21(b) activities.

Corrective Steps That Have Been Taken and the Results Achieved

The total number of Nonconformance Reports issued since November 13, 2009 (implementation date of SP-601 Rev. 7) is 493. This number encompasses applicable 2009 NCRs, all 2010 NCRs, and those written in 2011 up to January 27, 2011. Of the 493 NCRs, 144 were Safety Related. Based on the requirements of Revision 9 to CPS procedure SP-601 resulting from the NRC's Inspection, the QA Manager has re-evaluated the 493 NCRs, and corrections have been made to each NCR, as required, to bring each into compliance with the requirements conveyed during the NRC Inspection. Each NCR now clearly identifies whether the nonconformance is or is not a Deviation as defined in 10CFR21, and includes the basis for that conclusion. Furthermore, for those Deviations CPS *is* capable of evaluating and concludes there is no Defect or need to notify the NRC, the basis of that conclusion is also documented on each NCR.

During the QA Manager's re-evaluation, it was concluded that, based on the parameters conveyed by the NRC during their inspection, 75 of the 493 NCRs were Deviations as defined in 10CFR21. CPS evaluation concluded that none of these were Defects, and none were reportable to the NRC in accordance with 10CFR21; however, CPS was not capable of evaluating some of the Deviations and, in these instances, CPS informed the affected purchasers within the prescribed 5-business-day time frame to allow them to perform their own evaluations. The remainder of the NCRs were not Deviations, as they documented issues with commercial items. In these cases, a statement was added to each NCR that there was no Deviation under 10CFR21 because the item was commercial.

Corrective Steps That Will Be Taken to Avoid Noncompliance

Procedure SP-601 "Identification, Evaluation, and Reporting of Defects and Failure to Comply" was revised to accomplish the following:

1. Reinstate the requirements of Section 21.21(a) including evaluation and reporting timelines, report format/contents, and the communications requirements of section 21.5; and
2. Add the requirement for documenting the basis when it is concluded that a nonconforming condition does not constitute a Deviation or failure to comply as defined in 10CFR21.

Company personnel have been trained to the SP-601 changes.

Date Corrective Actions Will be Completed

Procedure SP-601 Revision 9 Dated 12/10 (with the 21.21(a) requirements reinstated) was implemented on December 13, 2010.

Training to the new SP-601 requirements was conducted between December 6 and December 29, 2010 and is complete.

Re-evaluation of CPS Nonconformance Reports issued on and after November 13, 2009 was completed on January 27, 2011.

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Respectfully submitted,

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