SQAD-1 REQUIREMENTS FOR SAFETY RELATED (ASME AND NON-ASME) ITEMS OR SERVICES

1.1 QA PROGRAM:

Items or services supplied under the PO/ Contract shall be subject to the requirements of an Exelon approved quality assurance program, which meets the requirements of 10CFR50 Appendix 'B' and any additional specific quality criterion as required by the PO/ Contract. The supplier providing the items or services as Nuclear Safety Related shall utilize the latest Exelon approved QA program that satisfies the applicable portions of ASME NQA-1 and the ANSI N45.2 Standards not covered by NQA-1 or the applicable ANSI N45.2 series of standards for previously accepted non-ASME quality assurance programs. When required by the PO/Contract, pressure retaining material or components supplied under this PO/Contract shall be subject to the requirements of the Exelon approved quality assurance program which meets the requirements of the ASME B&PV Code Section III, NCA-3800 or NCA-4000 as applicable.

1.2 RIGHT OF ACCESS:

Exelon, its agents or assigns, shall have the right to inspect and evaluate your facilities and activities at any time during the procurement process, from initiation of a request for quote through final payment. This right shall extend to sub-tier suppliers and will be coordinated through your firm. Inspections, surveillances, tests or audits performed by Exelon or its agents shall in no way relieve you or your sub-tiers of any responsibilities under the PO/Contract.

1.3 CONTROL OF SUB-TIER SUPPLIER:

Your firm shall be responsible for assuring that all sub-tier suppliers implement a QA program commensurate with the items supplied or services rendered. When a sub-tier supplier is used, all applicable technical and quality requirements imposed in the Exelon PO, Contract, Change Orders and Amendments shall be transmitted to the sub-tier supplier, whether the sub-tier is specifically identified in the procurement document or not. Your firm shall either maintain documentation of the vendor audit and acceptance of sub-tiers' QA programs or use only Exelon QA approved suppliers.

1.4 SUBSTITUTION:

Vendor shall identify to Exelon potential differences from established and field tested product lines. Potential differences can include material changes, configuration changes, changes in fabrication processes (e.g. 3-D Printing), etc.

Written approval by means of an Exelon PO change order or contract amendment is required prior to the substitution of items that are covered by the PO/Contract.

1.5 DEDICATION OF COMMERCIAL GRADE ITEMS:

1.5.1 The requirements of this section apply to items procured as commercial grade, which are dedicated by the supplier and provided to Exelon as nuclear safety related items (QL-1). This includes items provided as dedicated parts as well as items which are part of a safety related component that are needed for the component to perform its safety related function. The requirements of this section apply to items meeting the definition of Commercial Grade Item (CGI) contained in 10CFR Part 21.

1.5.2 The supplier's written Quality Assurance Program shall include following controls for dedicating commercial grade items for safety related use.

A. Requirements shall be established and documented to assure that the purchased item will perform its intended safety function. (requirements may include material specifications, dimensions, etc.). Qualified personnel shall establish requirements in the supplier's quality or engineering organization.

B. Applicable requirements shall be included in the procurement document to the sub-tier.

C. One or more of the following methods shall be identified and implemented to assure that the item ordered meets the established requirements:

(1) A Certificate of Compliance or other documentation from the supplier attesting to the fact that specified requirements has been met (this is only acceptable where the sub-tier has been audited, or where there is some other method validating the sub-tier's certification process).

(2) Inspections and/or tests upon receipt, during the manufacturing process, or upon completion of the manufacturing process. Inspections and/or tests shall reasonably assure that established requirements are verified and that the item will meet its intended safety function.

(3) Documented source surveillance or inspection performed by qualified personnel. Such source surveillance/inspection shall encompass those manufacturing and assembly steps and/or inspections or tests which assure that the item will perform its intended safety function (or meet the specified requirements).

(4) Sub-tier supplier history of supplying acceptable items. The supplier/item performance history method shall not be used as the only method of acceptance unless the historical record is based on

industry-wide performance data that is directly applicable to the item has intended function.
Some forms of acceptable supplier/item performance data of historical performance may be compiled utilizing monitored performance of the item, industry product tests, certification to national codes and standards (non-nuclear specific), and other industry records or data bases. Such performance data must be evaluated and results documented to describe the basis for such acceptance.

Note: Any sub-tier organization that performs any of the dedication activities for a commercial grade item shall have a Quality Assurance program that implements the applicable requirements of 10CFR50 Appendix B.

1.6 RECORDS

1.6.1 All records/drawings shall reference or be traceable to the Exelon PO/Contract. Records of inspection or test shall, as a minimum:

A. Identify the inspector or data recorder
B. The type of observation
C. The results
D. The acceptability
E. The action taken in connection with any discrepancies noted
F. Identify the affected drawings

1.6.2 Records shall be produced and retained in a manner which is consistent with applicable codes, standards, specifications and contract requirements. These records shall be maintained in facilities that provide a suitable environment to prevent loss through deterioration, pilferage, or mishandling. Records/drawings shall be of sufficient quality to be microfilmed and to be reproduced legibly from microfilm.

1.6.3 All records/drawings, including those from sub-tier suppliers, shall be dated, and bear the title and signature of the qualified individual who is attesting to the authenticity of the record content**.**

1.6.4 Documentation that is not required to be submitted to Exelon shall be retained by the supplier for the period that is consistent with the supplier's record/drawing retention requirements. QA records/drawings shall not be destroyed without prior written permission from Exelon.

1.6.5 Quality assurance records maintained by a supplier shall be accessible to Exelon for the life of the items involved, or until turnover of these records to Exelon at the end of the required retention period.

1.7 NONCONFORMANCE REPORTING

1.7.1 Items and services, which do not conform to Exelon PO/Contract requirements, shall be documented on the Supplier Deviation Notice (SDN) system and forwarded to the Exelon procurement agent. The SDN shall include a recommended corrective action together with adequate information for Exelon evaluation. This documentation shall be forwarded to the Exelon procurement agent. As minimum, the following type of nonconformance must be submitted for Exelon evaluation:

A. Technical or material requirements are violated.
B. Requirements in supplier documents which have been approved by the purchaser are violated.
C. Nonconformances that would affect the quality of the item and the function of its safety-related features. In cases where the supplier cannot make this determination, the nonconformance shall be submitted to Exelon. All Non-conformances, which have been dispositioned by the supplier as "Use as-is" or "Repair", require Exelon approval if they meet any of the following conditions:
    - The supplier has violated a technical or material requirement, or
    - The supplier has violated a requirement in supplier documents, which have been approved by the Company, or
    - The supplier cannot correct the nonconformance by continuation of the original manufacturing process or by rework, or
    - The item does not conform to the original procurement requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.
    - Company disposition of supplier recommendations.
    - Verification of disposition for nonconformances.
    - Maintenance of records for supplier nonconformances

1.7.2 The supplier shall not furnish or deliver any item or service to Exelon until all Supplier Deviation Notices associated with the item or service has been dispositioned and incorporated into the PO/Contract via Change order or Amendment.

1.8 MARKING IDENTIFICATION

Items furnished shall be marked in accordance with PO/Contract requirements and/or Codes, Standards or Specifications referenced in the PO/Contract. Marking shall be directly traceable to certifications required by PO/Contract. If no marking requirements are identified, the items shall be marked according to the supplier's QA program which has been approved by Exelon's Supplier Evaluation Services.

1.9 CALIBRATIONS

Calibrations shall be performed against standards having accuracy at least four times the requirements of the equipment being calibrated. When this accuracy ratio cannot be attained, the range and/or point of calibration affected shall be identified along with the accuracy ratio used or the uncertainty of the measurement process.