

COMMERCIAL-GRADE CALIBRATION SERVICES
NVLAP/A2LA

by

Richard McIntyre and Paul Prescott

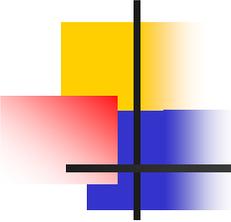
June 2005

NUPIC/Vendor Meeting

Scope of Review

- Suppliers of Commercial-Grade Calibration Services for Safety-Related Applications.
- 3rd Party Accreditation in Lieu of Supplier Audit, Commercial-Grade Survey, or In-Process Surveillance.
- Supplier Calibration Programs Accredited to ANSI/ISO/IEC 17025, “General Requirements for the Competence of Testing and Calibration Laboratories.”



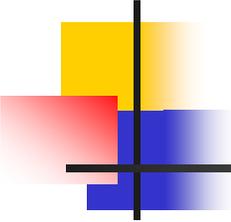


COMMERCIAL-GRADE CALIBRATION SERVICES

NVLAP

- NVLAP (National Voluntary Laboratory Accreditation Program) is a service of the National Institute of Standards and Technology
- NVLAP provides third-party accreditation to testing and calibration laboratories.
- NVLAP is in full conformance with the standards of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), including ISO/IEC 17025 and Guide 58.
- NVLAP identifies its accredited laboratories in a published directory and on the NVLAP web site (<http://ts.nist.gov>)



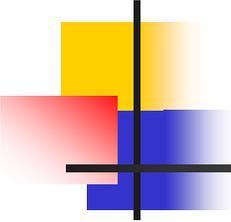


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Comparison of NVLAP to NUPIC Assessment Process

- Comparison of ISO/IEC 17025 with the NUPIC Checklist (NISTIR 6989 - on NVLAP web site)
- The report identifies the following issues:
 - 1.The calibration certificate/report shall include identification of the laboratory equipment/standards used. (NUPIC clause 14.1.c.7). 17025 does not require this.
 - 2.The calibration certificate/report shall include as-found and as-left data. (NUPIC clause 14.1.c.12). 17025 does not require this.
 - 3.Well defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of the measurement process. If such techniques are not used, the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance for each characteristic being calibrated. (NUPIC clause 4.1) 17025 requires an uncertainty analysis to support all measurement results.
- The report states that these issues can be addressed by adding language to utility purchase orders for commercial grade calibration services.





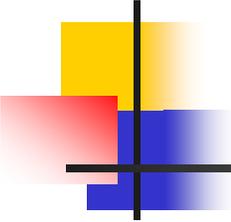
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Comparison of NVLAP to NUPIC Assessments

- NVLAP - Ruska Instrument Corporation (GE Infrastructure), Houston, Texas
 - Ruska is a manufacturer of precision laboratory instrumentation since 1944 offering primary pressure standards, transfer standards, and air data test sets. (NUPIC conducted a survey at Ruska on July 13-15, 2004)
 - NVLAP assessment - March 29-30, 2005

- NUPIC - Wilcoxon Research, Gaithersburg, Maryland
 - Wilcoxon is a manufacturer of vibration instrumentation equipment since 1960.
 - NUPIC survey - July 12-14, 2005



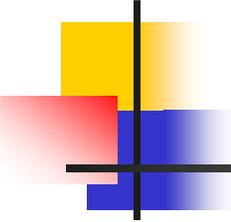


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RUSKA

- The structure of the assessment was similar to those conducted by U.S. utilities. The supplier provided the quality manual in advance of the assessment. The assessors provided an audit plan prior to the assessment, which outlined the assessment activities and items/records to be reviewed. An entrance meeting was conducted on March 29, 2005 with laboratory principles in attendance. The scope, assessment process and methods, and logistics, such as communications contacts and meeting times, were confirmed. A tour of the calibration facilities was conducted prior to the assessment.
- The assessment was performed in accordance to NVLAP Handbook 150, ANSI Z540:1994, and ISO 17025:2000. A standard checklist was used, which itemizes the specific requirements of NIST Handbook 150, Section 4, Management requirements for accreditation and Section 5, Technical requirements for accreditation.



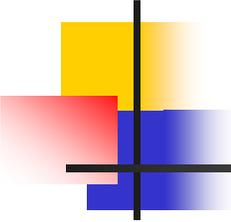


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RUSKA (continue)

- NVLAP assessment was conducted by two NVLAP assessors. The conduct of the assessment was observed by two NVLAP staff members and two NRC staff members.
- NVLAP Administrative Procedure (APM) 22.01 addresses the recruitment, evaluation, selection and training of personnel who perform on-site assessments. APM 22.02 addresses the process for monitoring and evaluating persons who serve as NVLAP assessors. The files for the two NVLAP assessors were reviewed and determined to be complete and in accordance with the administrative requirements.
- Each of the assessors were observed throughout the assessment. They were determined to be technically competent in the areas of assessment and very familiar with the quality program.
- The exit meeting was conducted on March 30, 2005 with the supplier principles in attendance. An interim assessment report was distributed at the exit meeting and each deficiency and comment was discussed with supplier management. The staff reviewed the interim report and also the final report and found the deficiencies and comments to be consistent with activities observed during the assessment.



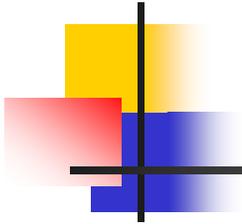


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Mutual Recognition Agreements

- The International Laboratory Accreditation Cooperation (ILAC) is the world's principal international forum for the development of laboratory accreditation practices and procedures, the promotion of laboratory accreditation as a trade facilitation tool, the assistance of accreditation systems, and the recognition of competent calibration and test facilities around the globe.
- There are two full ILAC members: Asia Pacific Laboratory Accreditation Cooperation (APLAC) and European Cooperation for Accreditation (EA).
- NVLAP is signatory to the APLAC MRA and, subsequently, a signatory to the ILAC MRA.
- The American Association for Laboratory Accreditation (A2LA) and the International Accreditation Service (ISA) are also signatories to the APLAC and ILAC.
- The staff is currently evaluating the acceptability of accrediting bodies recognized by NVLAP through an MRA.





COMMERCIAL-GRADE ITEM DEDICATION UPDATE

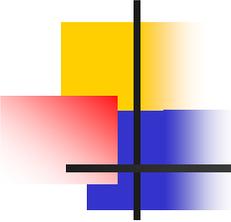
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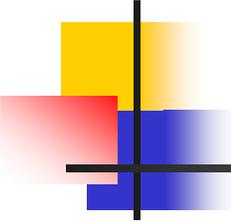


COMMERCIAL-GRADE ITEM DEDICATION

ANCIENT HISTORY

- NRC Inspection in the late 1980's identified common problems
- Pause for industry improvement
- NRC Assessments in the early 1990's
- Pilot inspections
- Numerous meetings with industry
- Public workshop in 1993
- NRC IP 38703 issued in November 1993
- Recent NUPIC Audits identified findings in Vendor CGI Dedication



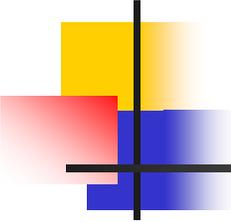


COMMERCIAL-GRADE ITEM DEDICATION

CGI DEDICATION GUIDANCE

- ANSI N 18.7-1976/R.G. 1.33 – “off the shelf” items may be similarly procured but care must be taken to assure at least equivalent performance
- EPRI NP-5652 – Guideline for the Utilization of CGIs in Nuclear Safety Related Applications (1988)
- Generic Letter 89-02 – conditionally endorsed EPRI NP-5652
- Generic Letter 91-05 – Announces pause in inspections/provides additional clarifications
- NUMARC Procurement Initiative--Basic Initiative – January 1, 1990
Comprehensive Initiative July 1, 1992
- Appendix A to IP 38703

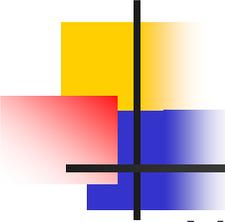




COMMERCIAL-GRADE ITEM DEDICATION

- 10CFR50 Appendix B – Applies to all safety related structures, systems, and components (Basic Components)
- Dedication-Process by which a CGI is designated for use as basic component. Process includes the identification and verification of critical characteristics





COMMERCIAL-GRADE ITEM DEDICATION

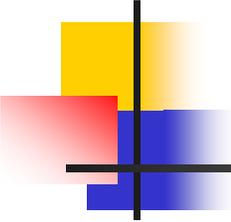
NRC STAFF VIEW ON COMMERCIAL GRADE ITEMS (CGIs)

- Determine Safety Function
 - Design basis, parts classification

- Engineering Evaluation to Identify Design/Performance Attributes Necessary to Perform Safety Function

- Procurement Activity to Confirm Engineering Evaluation
 - e.g., surveys, testing





COMMERCIAL-GRADE ITEM DEDICATION

QA ISSUES IN DEDICATION

- SELECTION OF CRITICAL CHARACTERISTICS
 - Safety function
 - Graded quality
 - Failure modes
 - Reasonable assurance
 - Engineering judgment

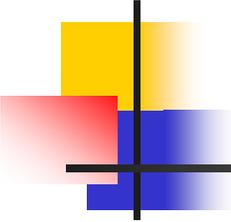
- TRACEABILITY
 - Items purchased thru distributors



QA ISSUES IN DEDICATION

- SAMPLING
 - established heat traceability (materials)
 - established lot/batch control (items)
 - Materials/items with no lot/batch control



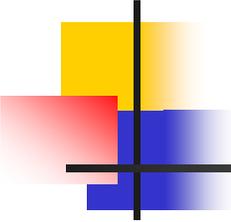


COMMERCIAL-GRADE ITEM DEDICATION

QA ISSUES IN DEDICATION

- COMMERCIAL GRADE SURVEYS
 - Verification of vendor controls
 - Identification of program/procedures
 - Documentation of survey results
 - Survey frequency





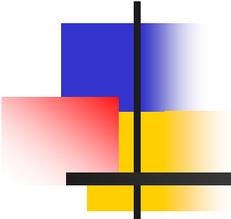
COMMERCIAL-GRADE ITEM DEDICATION

QA ISSUES IN DEDICATION

- ACCEPTANCE OF VENDOR CERTIFICATES
 - Verify through surveys, testing, other
 - Include distributor controls

- USE OF INDUSTRY GUIDANCE
 - Difference between NRC/EPRI definitions





REVISION OF QUALITY ASSURANCE STANDARD
REVIEW PLANS

by

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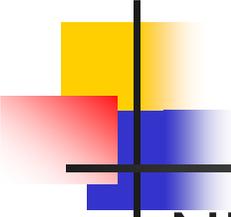
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CONSOLIDATION OF QUALITY ASSURANCE PROGRAM REQUIREMENTS

- SRP 17.1, “Quality Assurance During the Design and Construction Phases”
- SRP 17.2, “Quality Assurance During the Operations Phase”
- SRP 17.3 “Quality Assurance Program Description”



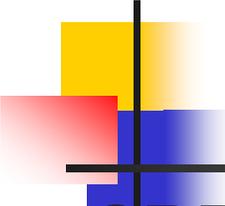


Revision of Quality Assurance Standard Review Plans

NEW SRP 17.1-3, “Quality Assurance Program Description”

- Will include the latest NRC-approved guidance
- NQA-1/1994
- Review of approvals via safety evaluation reports through the 50.54(a) process
- NMC and Exelon approved QATRS





Revision of Quality Assurance Standard Review Plans

SRP 17.1-3 would reference but not include details on:

- ANSI N45.2.1 - “Cleaning of Fluid Systems Associated Components During the Construction Phase of NPPs” (RG1.37)
- ANSI N45.2.2 - “Packaging, Shipping, Receiving, Storage, and Handling of Items for NPPs During Construction Phase” (RG 1.38)
- ANSI N45.2.3 – “Housingkeeping During the Construction Phase of NPPs” (RG 1.39)

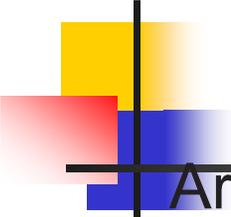


Revision of Quality Assurance Standard Review Plans

■ SRP 17.1-3 would reference, but not include details on (cont'd)

- ANSI N45.2.5, “Supplementary QA Requirements for Installation, Inspection, and Testing of Structural Steel During the Construction Phase of NPPs (RG 1.94)
- ANSI N45.2.8, “Supplementary QA Requirements for Installation, Inspection and Testing of Mechanical Equipment and Systems” (RG 1.116)



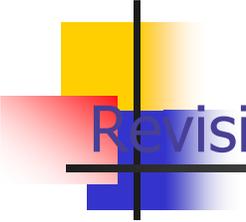


Revision of Quality Assurance Standard Review Plans

Areas under review of deletion/addition to SRP 17.1-3

- Qualification of NDE personnel (ASME Section III endorses SN-TC-1A and CP-189; ASME Section XI endorses CP-189)
- Requirements for computer software design, control, verification and validation (RG 1.168)
- Commercial Grade Dedication
- Graded Quality Assurance (RG 1.176)
- Electronic Records (RIS 2000-18)

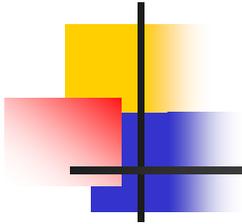




Revision of Quality Assurance Standard Review Plans Coverage of Commercial Grade Dedication

- NRC conditionally endorsed EPRI 5652 “Guideline for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications”
- Modified guidance from Generic Letters 89-02 and 91-05
 - Acceptance Method 2, Commercial Grade Survey of Supplier
 - Acceptance Method 4, Acceptable Supplier/Item Performance Record
 - Inspection Procedure 38703





NRC/NUPIC INTERACTIONS

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NRC/NUPIC Interactions

NRC Observations of NUPIC Audits

- NRC Observed NUPIC Audit at Enertech in April 2005
- NRC issued Trip Report Dated April 28, 2005 in ADAMS (ML051150089)
 - Comprehensive Performance Based Audit at Enertech
 - Identified Numerous Findings in Program Implementation
 - Team Leader Efficiently Managed the Large Audit Team



NRC/NUPIC Interactions

NRC Observations of NUPIC Audits (cont'd)

- Team Leader Established Effective Lines of Communications and Methods for Identifying the Many Findings.
- Commercial Grade Item Dedication Implementation was Lacking
- Areas of Improvement
 - Safety Significance of Findings
 - Technical Specialization
- NRC plans to Observe Westinghouse/Joint Utility Audit at ENSA in Spain
- NRC Staff Preparing for New Construction Supplier Inspections
- NRC/NUPIC Interface Protocol with NEI?

