## DEDICATION ISSUES IDENTIFIED DURING NUPIC AUDITS

NUPIC Vendor Conference – June 13, 2018 Cleveland, Ohio

John Simmons – Luminant Consulting Auditor Marc Tannenbaum – EPRI Technical Executive

### DEDICATION ISSUES IDENTIFIED DURING NUPIC AUDITS

- Audit findings for 25 of 37 audits performed in the past 12 months identified issues with commercial grade item dedication and/or use of accreditation
- Deficient programmatic areas include:
  - Inadequate procedural guidance
  - Inadequate implementation
  - Lack of documented basis for engineering judgement

### DEDICATION ISSUES IDENTIFIED DURING NUPIC AUDITS

- Could your dedication program be in jeopardy of not meeting regulatory requirements/industry guidance?
- Let's test our knowledge with

## DEDICATION JEOPARDY

Safety Function	Critical Characteristics	Acceptance Methods	Accreditation
100	100	100	100
100	100	100	100
100	100	100	100
200	200	200	200

#### SAFETY FUNCTION 1 - 100

## True or False?

A technical evaluation identifying safety function, critical characteristics and acceptance methods is *not* required for dedication of commercial grade services

Answer

## SAFETY FUNCTION 1 - 100 False

Technical evaluations consisting of the safety function(s), critical characteristics and method(s) used to verify the critical characteristics are required for the dedication of commercial grade items and services which have or could affect a safety related function.

EPRI 3002002982 Section 3.2

#### SAFETY FUNCTION 2 - 100

## True or False?

Effects of failure modes on safety function(s) may be considered in the technical evaluation for the selection of the critical characteristics

## SAFETY FUNCTION 2 - 100 True

Understanding how an item might fail in its application helps determine the characteristics of the item that are necessary to avoid failure. The failure modes and effects analysis is particularly useful when access to the decision-making process that led to the design and production of an item is not available to the dedicating entity.

EPRI 3002002982 Section Step 5.4 & 5.4.1

#### SAFETY FUNCTION 3 - 100

## True or False?

Functioning during and after seismic events and in harsh environmental conditions is only considered a safety function when the item has an active function during design basis events Answer

# SAFETY FUNCTION 3 - 100

An item may have safety functions during normal operating conditions and additional safety functions during design basis events for which it is qualified such as during seismic events and in extreme environmental conditions. These additional safety functions associated with the qualification of the item can exist regardless of the item having an active and/or Game passive function.

EPRI 3002002982, Step 5.3 and Section 6.6

#### SAFETY FUNCTION 4 - 200

Answer

#### True or False?

Identification of safety function or failure modes is not necessary if the dedicating entity has access to the design information and the design parameters and allowables become the critical characteristics and acceptance criteria

# SAFETY FUNCTION 4 - 200

Where the dedicating entity is the OEM or has access to the design information for the item being dedicated, identification of safety function or failure modes is not required, but the design parameters become the critical characteristics. Should a design parameter not be verified, technical justification is required.

NQA-1a-2009 Subpart 2.14, Section 401 EPRI 3002002982 Step 3.4



#### CRITICAL CHARACTERISTICS 1 -100

## True or False?

Critical characteristics are selected for all safety functions and documented with supporting basis

## CRITICAL CHARACTERISTICS 1 -100 True

Critical characteristics are selected to provide reasonable assurance that the item will be able to perform each intended safety function. Documentation should clearly identify each critical characteristic and contain sufficient detail to clearly identify the relationship between the critical characteristics and the associated safety function(s).

EPRI 3002002982 Step 5.5.3 and 5.5.4

## CRITICAL CHARACTERISTICS 2 -100 True or False?

Critical characteristics consisting of dimensions and configuration are adequate for dedication of radial ball bearings if the technical evaluation identifies fatigue as a failure mode



## CRITICAL CHARACTERISTICS 2 -100 False

Critical characteristics should be documented in enough detail to clearly establish how they relate to the ability of the item to perform its safety-related function(s) and not succumb to failure modes. Verification of dimensions and configuration does not provide reasonable assurance that the bearing will not succumb to the failure mode of fatigue.

EPRI 3002002982 Step 5.5.4

## CRITICAL CHARACTERISTICS 3 -100 True or False?

Answer

"+/- 10%" is an acceptable tolerance for electrical values such as contact resistance when based on undocumented performance history

# CRITICAL CHARACTERISTICS 3 -100 False

Acceptance criteria must be objective (not subjective) and quantitative. Document technical basis for the value specified and the tolerances. Undocumented performance history does not provide sufficient technical basis for acceptance criteria/tolerances established based on engineering judgement.

EPRI 3002002982 Step 5.7.4

#### CRITICAL CHARACTERISTICS 4 -200

Answer

#### True or False?

Critical characteristics consisting of dimensions and visual comparison of configuration and material with the original seismically qualified test specimen is adequate for providing reasonable assurance that that the replacement item being dedicated will maintain its original seismic qualification

## CRITICAL CHARACTERISTICS 4 -200 False

Visual comparison of material with the original test specimen does not provide reasonable assurance that the material has not changed since the original seismic qualification test.

EPRI 3002002982 Section 6.6

### ACCEPTANCE METHODS 1 - 100

## True or False?

Results of multiple dimensions measured in thousandths for dedication of items using Method 1 should document the actual values measured Answer

# ACCEPTANCE METHODS 1 - 100 True

Actual values should be recorded when calibrated measuring and test equipment (M&TE) is required instead of an acceptversus-reject determination.

3002002982 Step 5.10

# ACCEPTANCE METHODS 2 - 100 True or False?

Critical characteristics are not required to perform commercial grade surveys



# ACCEPTANCE METHODS 2 - 100 Faise

The purpose of the commercial grade survey is to assess the adequacy of the documented controls for verifying critical characteristics to provide reasonable assurance that the item/service will perform its intended safety function.

3002002982 Section 8.1.2

#### ACCEPTANCE METHODS 3 - 100

Answer

#### True or False?

Programmatic controls typically evaluated during audits may be identified as critical characteristics for evaluation during commercial grade survey of items? Examples:

- Design Control
- Procurement Control
- Inspection/Test Control
- Material Control

## ACCEPTANCE METHODS 3 - 100 False

Critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Reference to programmatic controls alone typically does not provide the specific characteristics important to the safety function of the dedicated item. Identifying the specific physical and/or performance critical characteristic should ensure that the survey evaluates the controls for the proper characteristics.

3002002982 Section 6.1.1 and 8.1.2

#### ACCEPTANCE METHODS 4 - 100

Answer

### True or False?

When utilizing sampling based on EPRI TR-017218-R1 to verify critical characteristics, it is acceptable for the dedicating entity's procedure to contain the dedication plans (Reduced, Normal, and Tightened) and refer to the EPRI guideline for criteria on selection of sample plans

## ACCEPTANCE METHODS 4 - 200 False

The guidance contained in the EPRI guideline should be incorporated in the dedicating entity's procedures identifying how they will implement the guidance under their QA program requirements for selection of one or more sample plans to verify critical characteristics. Documented basis for selection of sample plans is contained in the Technical Evaluation.

10CFR50 App. B Criterion V and EPRI 3002002982 Section 7.4

#### ACCREDITED LABORATORIES 1 - 100

## True or False?

A documented technical evaluation identifying safety function and critical characteristics is required for commercial calibration and testing services accepted based on accreditation Answer

# ACCREDITED LABORATORIES 1 - 100

Regardless of the method of acceptance, these services are procured from commercial suppliers which will be used in safety related applications. These services require commercial grade dedication and therefore require a documented technical evaluation identifying safety function and critical characteristics.

NEI 14-05A Rev. 0 Section 3.2

## ACCREDITED LABORATORIES 2 - 100

### True or False?

The requirements specified in the NRC Arizona Public Service Safety Evaluation Report allowing use of accreditation to accept commercial calibration services applies to any calibration laboratory that holds accreditation by an accrediting body recognized by the ILAC MRA

Answer

# ACCREDITED LABORATORIES 2 - 100

The NRC APS Safety Evaluation Report provides conditions for use of accreditations issued by NVLAP and A2LA only. NRC subsequently recognized ACLASS, IAS, L-A-B, and Perry Johnson as acceptable accreditations which may be used in conjunction with the requirements specified in the APS SER for accepting commercial calibration services.

NRC APS SER dated 9/28/05 ML052710224

## ACCREDITED LABORATORIES 3 - 100

## True or False?

Laboratory documentation for calibration and testing services must certify the calibration/test services were performed in accordance with the laboratory's ISO/IEC-17025:2005 program and has been performed within their scope of accreditation Answer

# ACCREDITED LABORATORIES 3 - 100

The laboratory's documentation is required to certify that:

- The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2005 program, and has been performed within their scope of accreditation, and
- The purchase order's requirements are met.

NEI 14-05A Rev. 0 Section 1.3

#### ACCREDITED LABORATORIES 4 - 200

### True or False?

Critical characteristics for calibration services accepted based on accreditation include a documented review of the accreditation to verify the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, Answer ranges, and uncertainties

# ACCREDITED LABORATORIES 4 - 200 False

Review of the accreditation is an action/step that must be performed for utilization of accreditation as the acceptance method to verify critical characteristics. The critical characteristics for calibration services remain the same no matter the acceptance method selected and include critical controls such as: (examples only)

- Traceability of standards
- Calibration procedures
- Environmental Controls
- Accuracy of standards
- Personnel qualifications

NEI 14-05A Rev. 0 Section 1.3 and 6.1



### TEAM 1

TEAM 2

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