Commercial Grade Dedication
Frequently Asked Questions and Answers

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1. How are items controlled under an Appendix B-compliant quality assurance (QA) program without doing commercial grade dedication?

- Neither option is a shortcut.
- The types of quality activities should be very similar, although the approach to acceptance criteria may be different.

Control under Appendix B-compliant QA program without dedication	Control under Appendix B-compliant QA program with dedication
Based on known product / item design requirements (for example, a design document that includes acceptance criteria)	Based on critical characteristics necessary for safety function(s) or if known, design function(s) (for example, determining safety function, postulating failure modes, and identifying characteristics necessary to preclude the failures

1. How are items controlled under an Appendix B-compliant quality assurance (QA) program without doing commercial grade dedication?

Control under Appendix B-compliant QA program without dedication	Control under Appendix B-compliant QA program with dedication
Activities may not all be addressed in a single technical evaluation	Acceptance activities are addressed in a single commercial grade dedication technical evaluation
Basis for acceptance activities and criteria must be documented and retrievable	Basis for acceptance activities and criteria must be documented in the dedication technical evaluation
Quality activities are typically performed in accordance with procedures and processes such as: • Procurement specification • Examination of products upon delivery. • In-process manufacturing controls • Statistical process control • Functional tests • Source evaluation and selection • Objective evidence of supplier's quality • Inspection at the source	Quality activities are typically performed in accordance with the dedication technical evaluation and acceptance plan such as: • Method 1 – Special tests & inspections • Method 2 – Commercial grade survey • Method 3 – Source verification • Method 4 – Supplier/Item performance history

1. How are items controlled under an Appendix B-compliant quality assurance (QA) program without doing commercial grade dedication?

- What if a documented basis for controlling the item under an Appendix B-compliant QA program without dedication is not available?

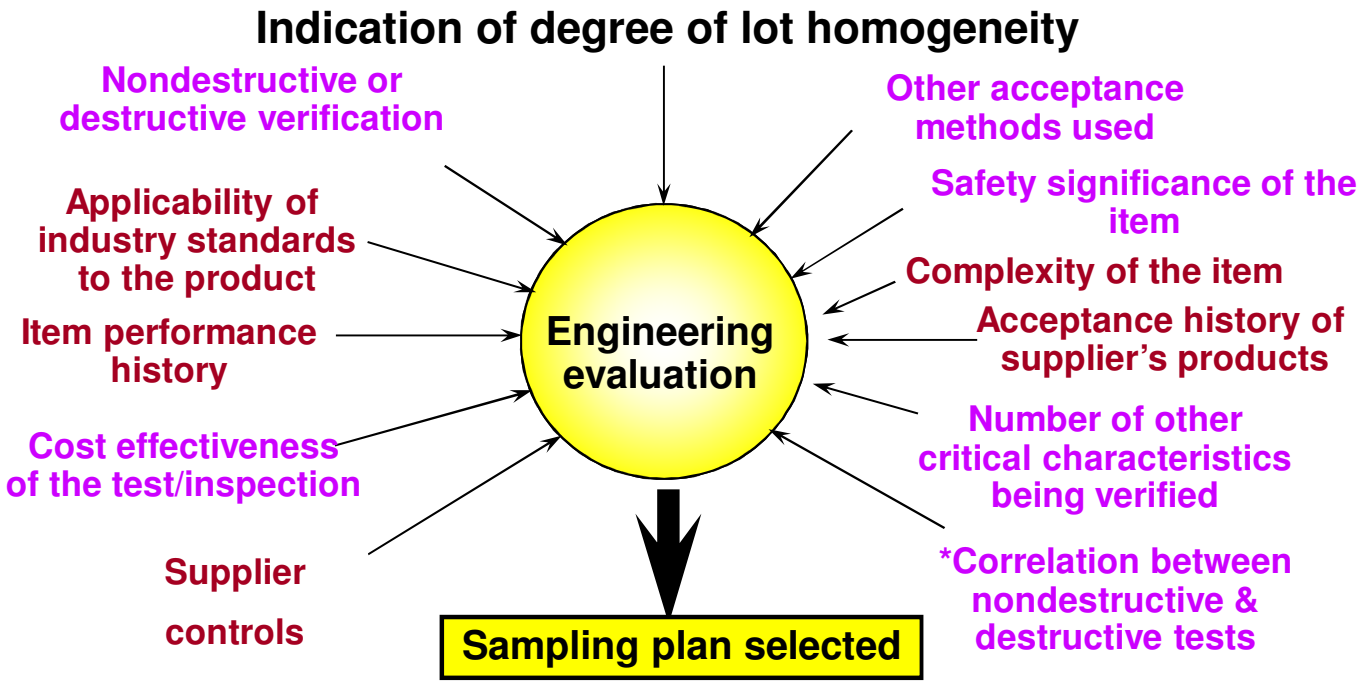
Item / Part	Characteristic important to function	Why is it important?	How is it verified?	Source document for acceptance criteria	Acceptance criteria

2. Do all commercial grade items have to be dedicated prior to use in fabrication of a basic component?

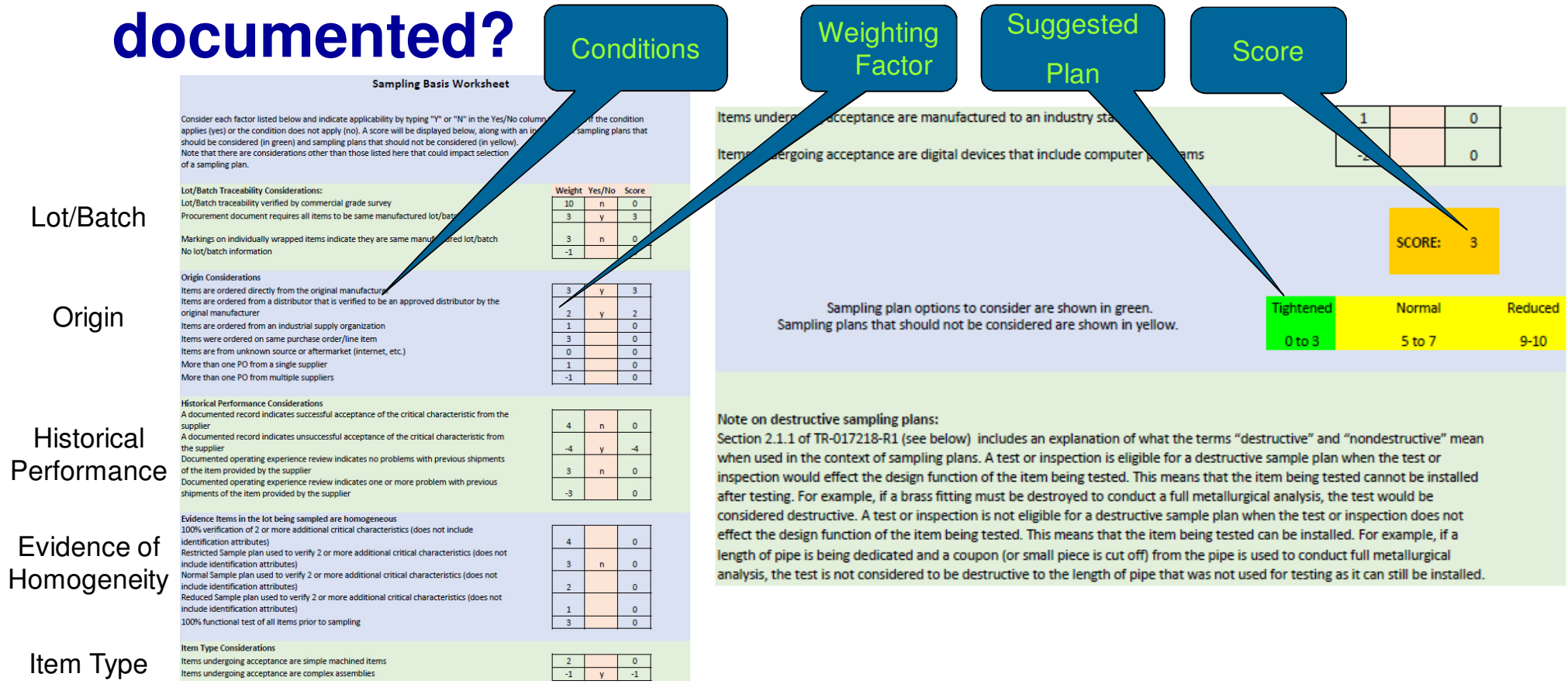
- No. However, the component must be controlled
  - Items can be controlled under the auspices of a 10CFR50, Appendix-B compliant QA program
    - QA activities verify the item meets design requirements
  - Items can be dedicated at the level of supply
    - Not always necessary to dedicate each part or material prior to assembly

3. Can the sampling plans on page 2-10 & 2-13 of EPRI NP 017218-R1 always be used?

- No. Use of sampling requires a documented technical basis



3a. How can the basis for use of sampling and selection of an appropriate sample plan be documented?



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4. When should the licensee review the supplier's dedication plan

- NRC IN 2011-01, Commercial-grade Dedication Issues Identified During NRC inspections

"In order to have an acceptable CGD program, the vendor must document the dedication process, from the selection of the CCs to the acceptance criteria and acceptance methods used to verify these CCs. Additionally, the purchaser or licensee should review and approve the CGD package before the dedication of the item. CGD is an engineering process that concludes with the reasonable assurance that a commercial-grade item to be used as a basic component will perform its intended safety function. Each step taken during the dedication process should be documented and auditable."

4. When should the licensee review the supplier's dedication plan?

- Information notice 2011-01 can be interpreted as conveying the expectation that the purchaser must review every dedication plan prior to dedication occurring
  - Review of every dedication plan is not the intent

- Purchasers should consider customer review of dedication plans in instances where:
  1. The dedicating entity is not familiar with end use
  2. Known problems exist with the dedication program
  3. Item is being dedicated for the first time and is very complex
  4. Item is being dedicated for the first time and has customer-specific requirements such as seismic or environmental qualification

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