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Commercial Grade Dedication

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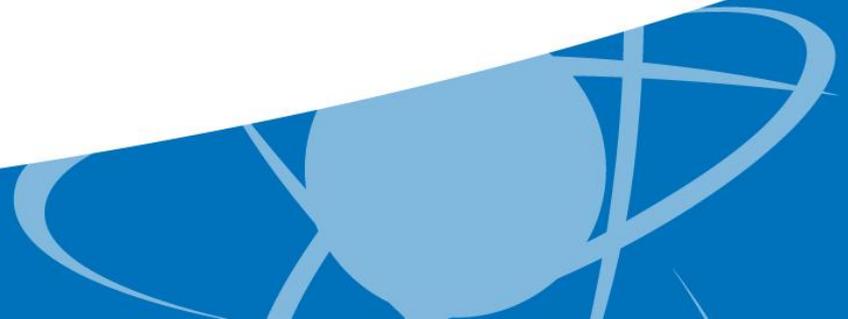
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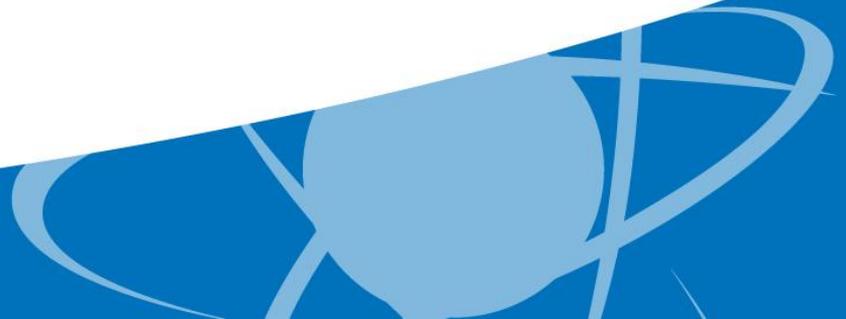
Overview

- IP 38703 & IP 43004 Guidance
- Commercial-Grade Surveys
- Traceability
- Sampling
- Questions
- Quiz



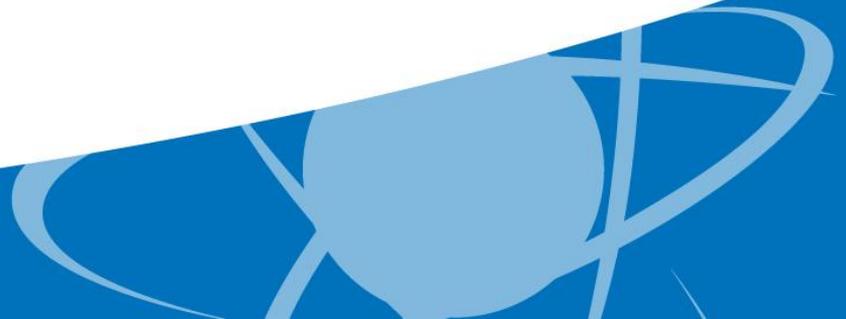
IP 38703

- Inspection Procedure 38703, “Commercial Grade Dedication”
 - Reactive and programmatic inspection requirements and guidance for licensee inspections
 - Program and Procedures
 - Dedication Package Reviews
 - Appendices give guidance on:
 - Critical characteristic selection and verification
 - Traceability
 - Sampling
 - Commercial Grade Surveys
 - CMTRs and CoCs



IP 43004

- IP 43004, “Inspection of Commercial-Grade Dedication Programs”
 - Inspection requirements and guidance for vendor (dedicating entity) inspections
 - Technical evaluations and Like -for -Like replacements
 - Method 1-4 acceptance
 - 4 Acceptance Methods provide guidance on:
 - Critical characteristic selection and verification
 - Traceability
 - Sampling
 - Commercial Grade Surveys
 - CMTRs and CoCs



Commercial-Grade Survey



- “Activities conducted by the purchaser or its agent to verify that a supplier of commercial-grade items controls, through quality activities, some or all of the critical characteristics of the designated commercial-grade items to be purchased. The verification can be used as a method to accept those characteristics. The commercial grade survey should include verification of the supplementary documentation and the effective implementation of the commercial-grade quality program.” – IP 43004



Survey Process

- Verification of Controls
 - Survey specific to CGIs being purchased
 - Controls of specific CCs should be identified in survey plan
 - Vendor's program/procedures controlling these CCs should be reviewed
 - Observation of actual implementation of these controls in the manufacture of items identical or similar to the items being purchased
- Vendor's Program/Procedures
 - Vendor must have documented program or procedures
 - POs must invoke these programs/procedures and revision
 - Vendor should certify compliance with the purchase order requirements

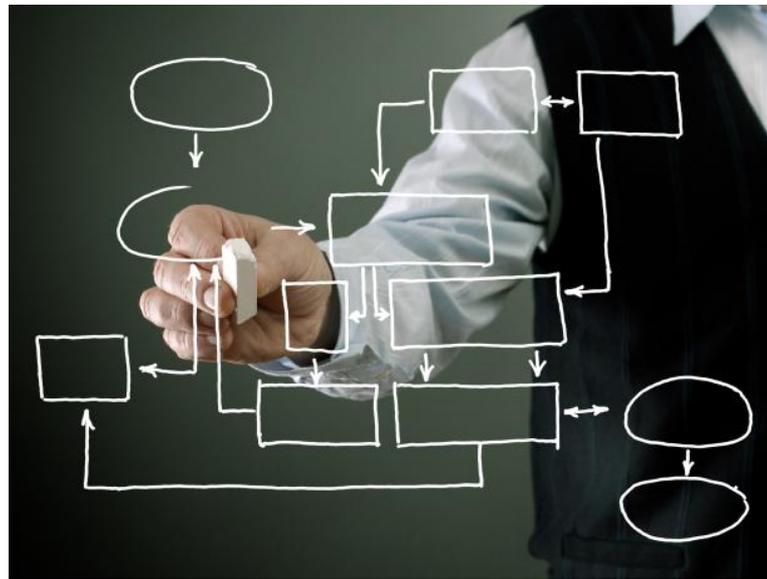


Survey Process

- Documentation
 - Identification of the item(s) being surveyed, identification of the CCs of controlled, identification of the controls (program/procedure and revision), and a description of the verification activities and results.
 - CCs that are not adequately controlled should be addressed by contractually requiring the vendor to institute additional controls or by utilizing other verification and acceptance methods
- Frequency
 - Ensures process controls applicable to procured item's CCs continue to be effectively implemented
 - Considers item complexity, procurement frequency, receipt inspection, performance history, and changes in vendor controls
 - NTE Appendix B audit frequency

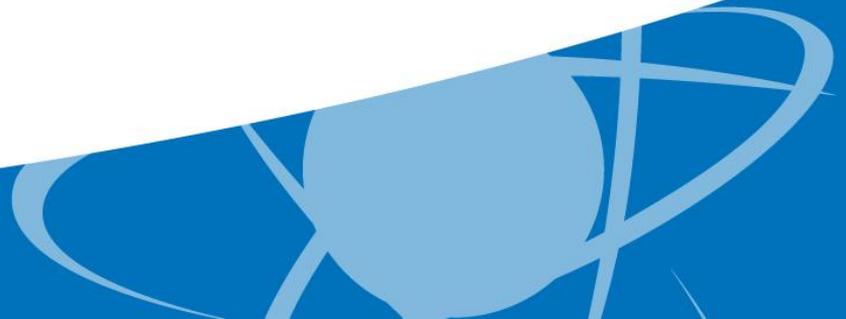
Traceability

- The ability to verify the history, location, or application of an item by means of recorded identification. – IP 38703



Traceability

- If acceptance is based entirely or partially on a certification by the manufacturer, the traceability must extend to the manufacturer. Survey or by other means that the manufacturer has established adequate traceability controls and that these controls are effectively implemented.
- If distributors are included in the supply chain, the activities of these organizations may need to be surveyed to ensure that traceability and proper storage conditions are maintained.



Sampling

- Potential method to verify a Critical Characteristic on a representative number of CGIs rather than 100% of the population



Sampling

- “Sampling plans for testing should be used in accordance with **nationally recognized industry standards**, and should have an **adequate documented technical basis**. This technical basis includes **homogeneity**, **complexity** of the item, **lot/batch control** for items, **heat traceability** for materials, and **adequacy of the vendor’s controls** as confirmed by a survey.
 - IP 43004



Sampling

- “Sampling plans utilized to select items for special test(s), inspection(s), and/or analysis shall have an **adequate technical basis** based on **established standards** that consider **lot traceability, homogeneity**, and the **complexity** of the item.” – NQA-1-2008
- “Sampling plans utilized to select items for special test(s), inspection(s) and/or analyses shall be based upon **standard statistical methods with supporting engineering justification** and shall consider **lot/batch traceability, homogeneity**, and the **complexity** of the item.” – NQA-1a-2009

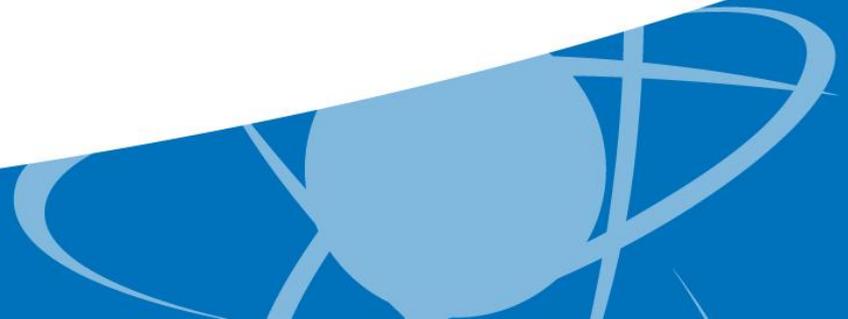


Sampling

- **Established Heat Traceability (Materials)**
 - Required chemical analysis and destructive testing may be performed on **one piece** of metallic material per heat
 - May be applied to containers of nonmetallic materials (e.g. lubricants, adhesives) from a single mix/batch
 - Each metallic piece must be identified by heat number and each container of nonmetallic material by mix or batch number
- **Established Lot/Batch Control (Items)**
 - Lot/batch = units of product of a single type, grade, class, size, and composition, manufactured under essentially the same conditions and at essentially the same time
 - Survey of lot/batch controls
 - Satisfactory performance history and the results of receipt inspection/testing
 - Sampling prescribed by standard statistical methods that are based on homogeneous product lots
 - Sample plans should be identified and should provide for the verification of the critical characteristics with a confidence level consistent with the item's importance to safety
- **Material and Items with No Lot Batch/Control**
 - Sampling plans needed on an individual, item-specific basis
 - Must ensure high level of assurance of item's suitability for service
 - Each item may need to be tested

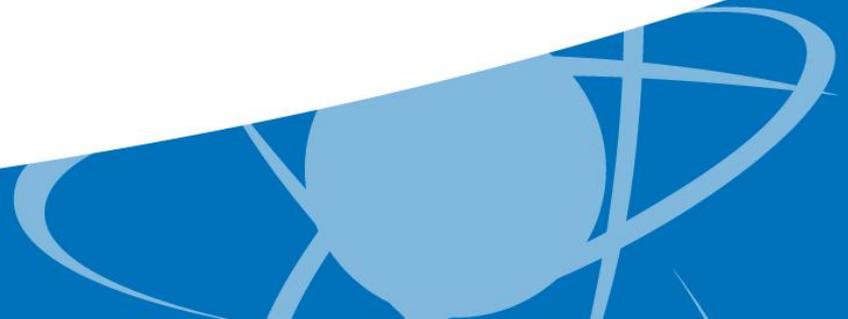
Sampling

- Item sampling considerations (EPRI TR-017218-R1)
 - CG manufacturer's lot/batch controls
 - Random sample
 - Lot acceptance
 - Documentation



EPRI TR-017218-R1

- EPRI TR Guidance for sampling plans
 - Reduced
 - Normal
 - Tightened
- Destructive testing guidance
- Staff has not endorsed TR-017218



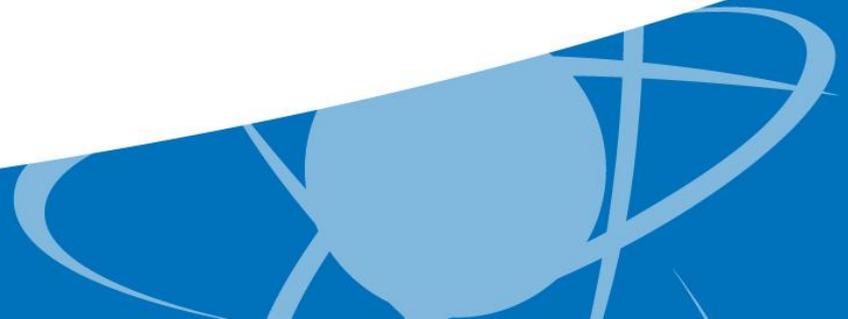
Questions



Situation Analysis

Question 1

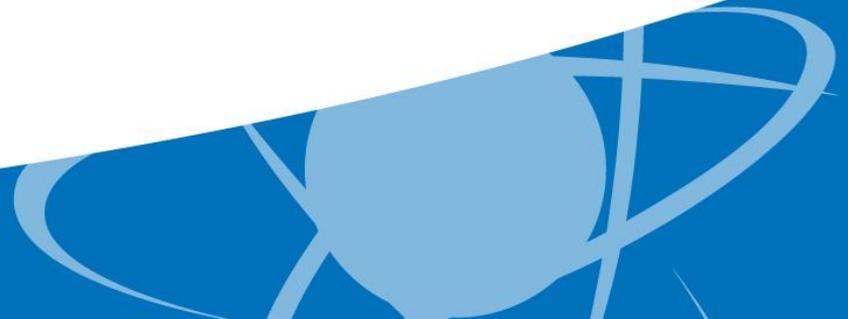
- Criteria VII and VIII of 10 CFR 50, Appendix B establish controls to assure the correct safety-related items are specified and accepted.
 - Are these controls also applicable to commercial grade items intended for safety-related use?



Situation Analysis

Answer 1:

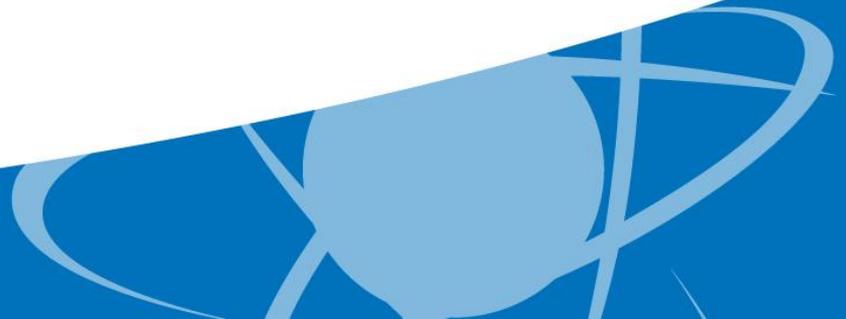
YES



Situation Analysis

Question 2

- Is there a nonconformance with Criterion VII, “Control of Purchased Material, Equipment, and Services” if traceability cannot be provided to the original equipment manufacturer due to changes in the manufacturers or unavailability of authorized distributors?



Situation Analysis

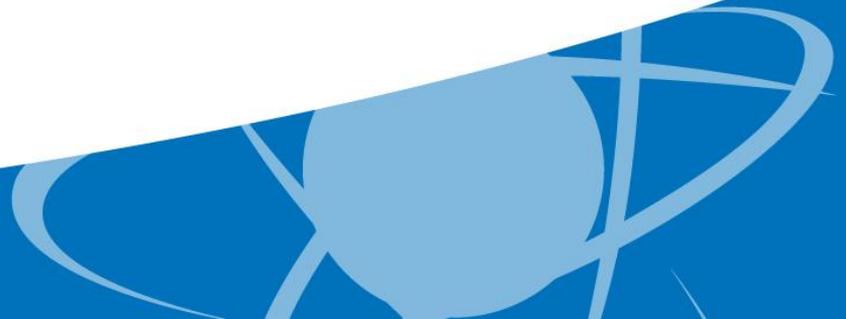
Answer 2

- **YES**
 - Criterion VII states, in part that, “Measures shall be established to **assure** that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, **conform to the procurement documents.**”

Situation Analysis

Question 3

- Can programmatic audit be used instead of a commercial-grade survey as part of dedicating a commercial grade item for safety-related use?

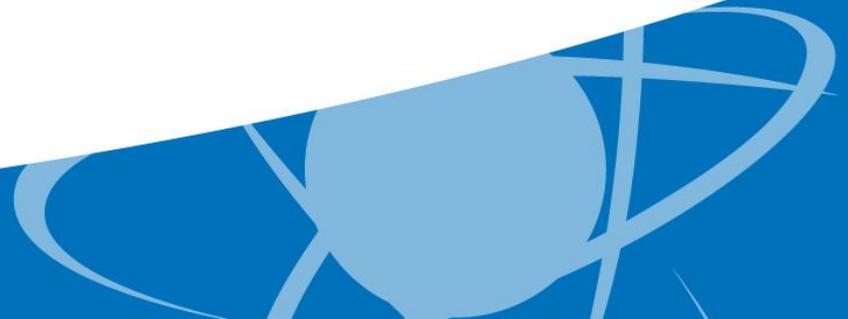


Situation Analysis

Answer 3

– NO

- Audits verify compliance with an Appendix B Quality Assurance Program
- Commercial Grade Surveys verify implementation of documented commercial quality controls of a critical characteristic



Situation Analysis

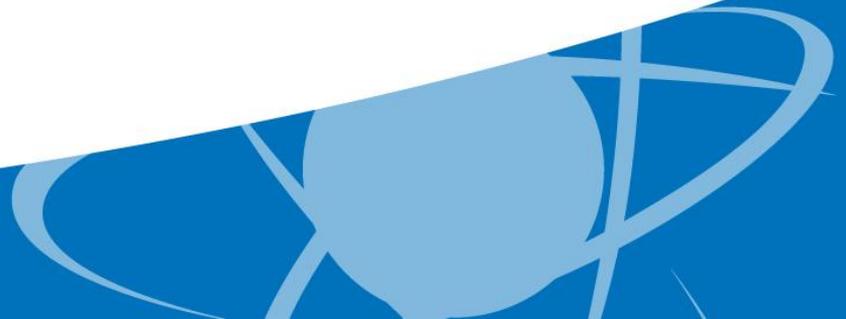
Acceptance Methods

Acceptance Method	Specific Utility Activities	Specific Supplier Activities
<p>Method 1</p> <p>Special Tests and Inspections</p>	<ul style="list-style-type: none"> ● Determine sample size. ● Determine post-installation testing requirements. ● Determine special receipt tests and inspections. ● Accept item via special receipt inspections. ● Accept item via post-installation testing. 	<ul style="list-style-type: none"> ● Furnish technical design information to enable utility to verify critical characteristics.
<p>Method 2</p> <p>Commercial Grade Survey of Supplier</p>	<ul style="list-style-type: none"> ● Conduct survey of CG program. ● Require the supplier to invoke the controls necessary to verify critical characteristics. ● Accept item based on supplier Certificate of Conformance verified by CG survey. 	<ul style="list-style-type: none"> ● Implement controls necessary to verify critical characteristics. ● Provide utility with a Certificate of Conformance (as requested).
<p>Method 3</p> <p>Source Verification</p>	<ul style="list-style-type: none"> ● Conduct source verification. ● Accept item based on documented source verification results. 	<ul style="list-style-type: none"> ● Implement item-specific design, fabrication, assembly, manufacturing, testing, or inspection controls substantiated by the source verification for a particular commercial grade item. ● Allow utility access to facilities to conduct source verification.
<p>Method 4</p> <p>Acceptable Supplier/Item Performance Record</p>	<ul style="list-style-type: none"> ● Establish documented performance record. ● Monitor performance of item. ● Confirm applicability of independent product test results, INPO NPRDS, commercial program audits/surveys conducted by industry groups, utilization of national codes and standards, supplier responses to CG program controls, results of periodic maintenance surveillance, results of successfully employing other acceptance methods. ● Accept item by issuing certification which is based on supplier/item performance record. 	<ul style="list-style-type: none"> ● Respond to CG Program Controls Questionnaire. (See Subsection 3.4.3, Item 3.e.) ● Ensure item complies with national codes and standards, if applicable.

Situation Analysis

Question 4

- Why do dedication programs and plans need a documented bases to substantiate the sampling plans for verifying critical characteristics?



Situation Analysis

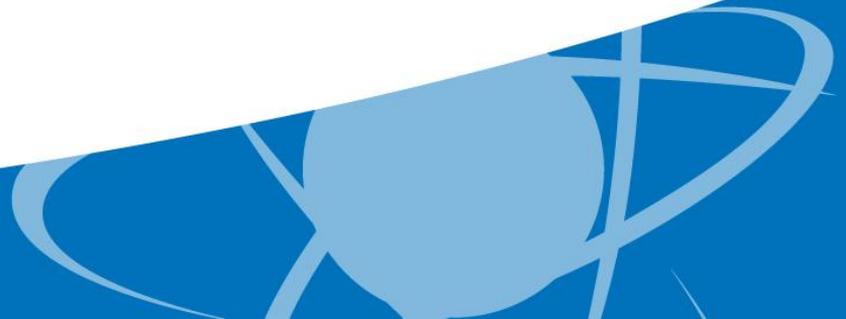
Answer 4

- To provide reasonable assurance that the dedicated items conform to the specification requirements.
 - Criterion III, “Design Control,” of Appendix B to 10 CFR Part 50, states, in part, that measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the SSCs.

Situation Analysis

Question 5

- With respect to sampling practices for dedicating commercial grade items, what are some of the items that need to be verified to provide reasonable assurance that items received from suppliers conform to specific requirements?



Situation Analysis

Answer 5

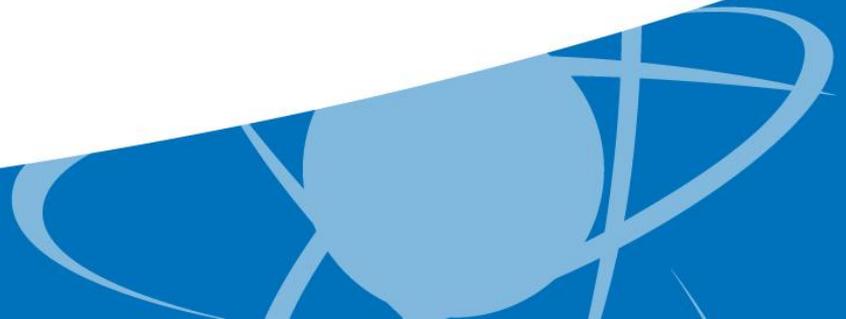
- Material Traceability
- Lot/batch Controls
- Ensure that procurement documents identify applicable programs / procedures to control identified critical characteristics



Situation Analysis

Question 6

- Does a vendor need to provide objective evidence that critical characteristics are controlled under the supplier's documented quality control program?



Situation Analysis

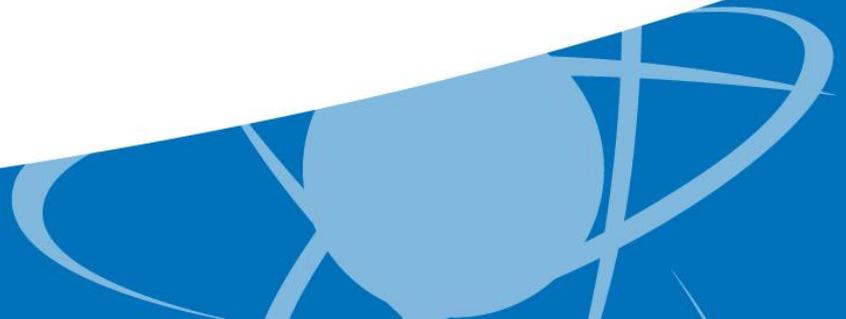
Answer 6

- **YES**
 - If a manufacturer's quality controls are credited to control a critical characteristic, these controls must be surveyed for similar items.
 - Criterion VII, states in part, that "These measures shall include provisions, as appropriate, for source evaluation and selection, **objective evidence of quality** furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source."

Situation Analysis

Question 7

- Are sampling plans required to be documented in a dedication package to support the verification of CCs?



Situation Analysis

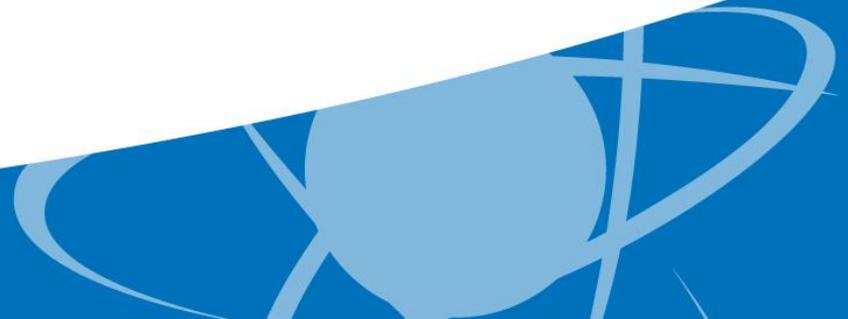
Answer 7

- Yes
 - Dedication procedures should provide generic documented technical basis for the acceptance criteria and selected sampling plans OR
 - requirement that such documentation be provided for a given circumstance

Situation Analysis

Question 8

- Can a single piece of metallic material be tested for chemical and physical properties if quality controls for heat number traceability have not been verified?



Situation Analysis

Answer 8

- No
 - If acceptance is based entirely or partially on a certification by the manufacturer, the traceability must extend to the manufacturer. Survey or by other means that the manufacturer has established adequate traceability controls and that these controls are effectively implemented.
 - If distributors are included in the supply chain, the activities of these organizations may need to be surveyed to ensure that traceability and proper storage conditions are maintained.