MIL-HDBK-516C CHANGE NOTICE No. 516CN-7

AIRWORTHINESS BOARD DETERMINATION
MIL-HDBK-516C CHANGE NOTICE

1. DATE (YYYYMMDD) 20191204

2. AFLCMC/EZ POINT OF CONTACT
David Karr

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4. BOARD SECRETARIAT
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6. SUMMARY OF AIRWORTHINESS BOARD DETERMINATION / MIL-HDBK-516C CHANGE
(See attached Airworthiness Board charts for more information)

MIL-HDBK-516C Section 4.4 Manufacturing and Quality

Change impacts:

- Deleted 4.4.1-3
- Modified Criteria, Standards and Methods of Compliance - 4.4.4, 4.4.5
- Modified Criteria and Standards – 4.4.6

7. TAA SIGNATURE

THOMAS M. FISCHER, SES
Director, Engineering and Technical Management/Services
USAF Technical Airworthiness Authority

8. ORGANIZATION

AFLCMC/EN-EZ
USAF Airworthiness Change Notice Board

Manufacturing and Quality (4.4)

4 December 2019

David Karr
AFLCMC/EZSM
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Provide this image of a page with a table showing changes to a document, along with a list of key points:

**Change Notice (CN) Overview**

- **Title**: Manufacturing and Quality
- **Date Proposed**: 15 Mar 2018
- **POC**: David Karr, AFLCMC/EZSM, 937-255-7450
- **Revision To**: CN Proposal Revises MIL-HDBK-516C

<table>
<thead>
<tr>
<th>Paragraph(s) Impacted</th>
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<tbody>
<tr>
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<td>4.4.5</td>
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<td>4.4.6</td>
<td>Criterion Standard Method of Compliance</td>
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</tbody>
</table>
### 4.4 Manufacturing and quality

#### 4.4.1 Key characteristics
Criterion: Verify that key product characteristics (including critical characteristics) have been identified.

#### 4.4.2 Critical processes
Criterion: Verify that all critical process capabilities exist to meet key product characteristic requirements (including critical characteristics).

#### 4.4.3 Critical process controls
Criterion: Verify that all critical process controls exist to assure key product characteristic requirements (including critical characteristics) are met.

#### 4.4.4 Quality system
Criterion: Verify that the as-built configuration matches the as-designed configuration.

#### 4.4.5 Nondestructive inspections
Criterion: Verify that nondestructive inspection (NDI) processes have been validated to assure conforming parts.

#### 4.4.6 Control of Safety-Related Articles
Criterion: Verify that safety-related items (Critical Safety Items, flight critical components, and components containing critical characteristics that impact safety) conform to their approved design.

#### 4.4.4 Quality system
Criterion: Verify that the quality system ensures that each air system conforms to its approved design and is in a condition for safe operation.

#### 4.4.5 Nondestructive inspections
Criterion: Verify that nondestructive inspection (NDI) processes have been validated to assure conforming parts.

#### 4.4.6 Control of Safety-Related Items
• Often a source of confusion for program offices
  – Unclear wording and intent
  – Unclear division of content between the three criteria/standards

• Too narrow of a focus on parts that are covered (Only CSIs/flight critical hardware)

• Too narrow of a focus on specific methods for controlling quality (Only key/critical characteristics)

• Revised 4.4.6 will be broader, both in terms of parts affected and quality controls, while still covering the primary intent of these three criteria (key/critical characteristics and process controls)
• 4.4.4 (Quality System): Improve consistency with FAA Production Certification criteria

  – DoD already accepts FAA Production Certifications
  – Better understood and recognized by industry
  – More specific vs. top level, subjective Standards (“effective,” “sufficient,” etc.)
  – Clearer focus on specific elements of the quality system
  – More consistent approach for compliance reviews
Revision of 4.4.4 (Quality System)

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Current Language

• 4.4.4 Quality system.
  • **Criterion:** Verify that the as-built configuration matches the as-designed configuration.
  • **Standard:** The quality system is effective in assuring conformance to product design and realization, including production allowances and tolerances. The quality system addresses defect prevention and achieving stable, capable processes. The quality system employs methods sufficient for conducting root cause analyses and implementing effective corrective actions.
  • **Method of Compliance:** Compliance is determined by inspection of the Quality System's policies, processes and procedures and examples of Material Review Board records.

Proposed Language

• 4.4.4 Quality System
  • **Criterion:** Verify that the quality system ensures that each air system conforms to its approved design and is in a condition for safe operation.
  • **Standard:** The quality system addresses procedures for:
    – Design data control
    – Document control
    – Supplier control
    – Manufacturing process control
    – Inspection and testing
    – Inspection, measuring, and test equipment control
    – Inspection and test status
    – Nonconforming product and article control
    – **Counterfeit parts control**
    – Corrective and preventive actions
    – Handling and storage
    – Control of quality records
    – Internal audits
    – In-service feedback
    – Corrective actions for quality escapes
    – Issuing authorized release documents
  • **Method of Compliance:** Compliance is determined by inspection of the program Quality Plan or Quality Manual and examples of inspection and test records and Material Review Board records

**Proposed Criterion and Standard wording taken directly from FAR 21.137, Production Certificates – Quality System Criteria**

**Added References:** FAR 21.137, FAA Advisory Circular 21-43A, AS9100

**Distribution Statement A: Approved for Public Release (Case #88ABW-2020-0064)**
• 4.4.5 (NDI):
  – Eliminate overlap with other standards
  – Focus on process vs. specific technical requirements
  – Improve consistency with FAA quality system/NDI guidance (AC 21-43A, paragraph 2.7.4, Nondestructive Testing)
– **5.3.3 Stress and Strain Design Controls**
  - Critical castings receive 100% NDI

– **5.4.1 Damage Tolerance**
  - For embedded defects, the initial flaw size assumption is based on an assessment of the capability of the non-destructive inspections procedure.

– **5.4.3 Durability and Damage Tolerance Control Processes**
  - Complete nondestructive inspection requirements, process control requirements, and quality control requirements for maintenance, fatigue/fracture critical parts is established and approved by the procuring agency. This task includes the plan for certifying and monitoring subcontractor, vendor, and supplier controls.
  - The durability and damage tolerance control process includes any special nondestructive inspection demonstration programs conducted to satisfy the durability and/or damage tolerance requirements.

– **7.2.3.3 Damage Tolerance (Propulsion)**
  - Requirements for NDI flaw sizes/probabilities of detection, subjecting safety and mission critical parts to NDI

– **16.1.8 Maintenance Manuals – NDI**
  - Requirements for NDI techniques for continued airworthiness
Revision of 4.4.5 (NDI)

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**Current Language**

- 4.4.5 Nondestructive inspections.
- **Criterion:** Verify that nondestructive inspection (NDI) processes have been validated to assure conforming parts.
- **Standard:** Nondestructive inspection (NDI) methods and equipment have been qualified to suitable standards and meet the requirements of the applicable specification and application. The specification being used ensures any non-conformance adversely affecting the part will be detected. Accept and reject criteria for safety and flight critical hardware are based on validated models and data.
- **Method of Compliance:** Compliance is determined by inspection of NDI process, selection criteria, operator certification and method validation documentation. For new applications of specifications, test and inspection data confirms the inspection method is valid for the application.

**Proposed Language**

- 4.4.5 Nondestructive inspections
- **Criterion:** Verify that nondestructive inspection (NDI) processes have been validated to assure conforming parts.
- **Standard:** Nondestructive testing procedures address acceptance and rejection criteria. Adequate test pieces with known defects are available to nondestructive inspection (NDI) personnel. Procedures address the certification, recertification, and decertification of nondestructive testing personnel.
- **Method of Compliance:** Compliance is determined by inspection of NDI procedures and operator certification processes.

- Taken from FAA AC 21-43A, paragraph 2.7.4, Nondestructive Testing
- Not covered by current 516C Standard

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Covered by 5.4.3
Covered by 5.4.1 and 7.2.3.3
Covered by 5.4.3

Distribution Statement A: Approved for Public Release (Case #88ABW-2020-0064)
• 4.4.6 (Safety-Related Items):
  – Eliminate non-value-added and confusing criteria (4.4.1, 4.4.2, 4.4.3)
  – Broader focus for the parts covered and the potential methods of quality controls
  – Include the intent of 4.4.1, 4.4.2, 4.4.3 in their coverage of CSIs
Revision of 4.4.6 (Safety-Related Items)

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Current Language

- **4.4.6 Control of Safety-Related Articles.**
- **Criterion:** Verify that safety-related items (Critical Safety Items, flight critical components, and components containing critical characteristics that impact safety) conform to approved design.
- **Standard:** The quality of safety-related items, whether furnished by the prime contractor, supplier, or sustainment organization, is controlled to ensure conformance with design. The manufacturers of the items have instituted manufacturing process controls, inspections, and testing procedures to ensure each safety-related product or part conforms to its approved design.
- **Method of Compliance:** For safety-related items, initial design conformance is verified by inspection of First Article Inspection reports, First Article Test reports, or other manufacturing records that prove design conformance. Controls for ensuring the quality of safety-related items are verified by inspecting manufacturing process control plans (including work instructions) and inspection and test procedures.

Proposed Language

- **4.4.6 Control of Safety-Related Items.**
- **Criterion:** Verify that safety-related items (Critical Safety Items, Flight Critical Items, Safety Critical Items, and Safety of Flight Items) conform to approved design.
- **Standard:** The quality of safety-related items, whether furnished by the prime contractor, supplier, or sustainment organization, is controlled to ensure conformance with design. The manufacturers of the items have identified Key Characteristics (including critical characteristics associated with CSIs), mapped them to corresponding critical manufacturing processes, and instituted critical manufacturing process controls, inspections, and testing procedures to ensure each safety-related product or part conforms to its approved design.
- **Method of Compliance:** For safety-related items, initial design conformance is verified by inspection of First Article Inspection reports, First Article Test reports, or other manufacturing records that prove design conformance. Controls for ensuring the quality of safety-related items are verified by inspecting manufacturing process control plans (including work instructions) and inspection and test procedures.
Specific Comments

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• **Organization:**
  – AFLCMC/EZFP, LPS (Propulsion) - Doug Black, Loren Lutz
  – NAVAIR (AIR 4.1.9 Mfg/QA) – Clint Osbourne

• **Comment:**
  – Disagreed with removing 4.4.1, 4.4.2, 4.4.3. – need key and critical characteristics for CSIs

• **Date Comments Received:**
  – May, August 2018

• **Response:**
  – Added key and critical characteristics to 4.4.6 Standard
Specific Comments

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• **Organization:**
  – Army Aviation & Missile Center, Aviation Engineering Directorate, Standards Office, Redstone Arsenal (Joseph Wathen)

• **Comment:**
  – Disagreed 4.4.6 being designated as AF only (since some content from 4.4.1, 4.4.2, 4.4.3. was moved to 4.4.6)

• **Date Comments Received:**
  – 12 April 2019

• **Response:**
  – Removed “AF Only” designation (was not intended anyway)
Recommendation

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<th>Organization</th>
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- **Recommendation:**
  - [x] Approve
  - [ ] Disapprove

- **Potential safety/design impact to currently fielded fleet:**
  - [ ]
  - [x]

Checking ‘Significant’ above will help TAA determine need to inform program offices of urgent safety/design issue

Distribution Statement A: Approved for Public Release (Case #88ABW-2020-0064)
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4.4.1 Verify that critical elements (key product characteristics) have been identified.  
Y  
No additional clarification required.  
KCs are documented on drawings and flowed throughout the supply chain.

4.4.2 Verify that all critical process capabilities exist to meet key product characteristic requirements.  
Y  
Key Characteristics have been mapped to Critical Processes. Process Capability Index (Cpk) has been determined for each Critical Process. Process control plans have been developed for all critical processes.  
Cpk is defined for all critical processes and associated process control plans exist.

4.4.3 Verify that all critical quality standards exist to meet key product characteristic requirements.  
Y  
Work instructions and inspection instructions exist for all critical manufacturing processes and they match design requirements. Planned manufacturing tolerances are within design tolerances. Product Acceptance Criteria have been defined.  
Compliance is determined by inspection, e.g. reviewing samples of work instructions, inspection instructions, and Acceptance Test Procedures to assure they match design requirements and result in conforming product. This may be accomplished during First Article Inspections, Physical Configuration Audits, etc.

4.4.4 Verify the safety of the as-built design and that production allowances and tolerances are within acceptable limits and assure conformance to design.  
Y  
A Quality System is in place to assure the as-built configuration matches the as-designed configuration.  
Compliance is determined by inspection, e.g. reviewing samples of work instructions, inspection instructions, and Acceptance Test Procedures to assure they match design requirements and result in conforming product. This may be accomplished during First Article Inspections, Physical Configuration Audits, etc.

4.4.5 Verify that nondestructive inspection (NDI) accept/reject criteria have been validated.  
Y  
No additional clarification required.  
Compliance is determined by inspection, e.g. reviewing samples of work instructions, inspection instructions, and Acceptance Test Procedures to assure they match design requirements and result in conforming product. This may be accomplished during First Article Inspections, Physical Configuration Audits, etc.

- 516A: KCs, Cpk, etc. not tied to CSIs or Flight Critical hardware
- 2004-2005: Gebhard/Van Oss update 4.4.1 – 4.4.3 for 516B based on JACG Performance Based Product Definition Guide
  • Based on PBBE (Performance Based Business Environment) initiative
TACC Sec 4.4

4.4.1 Key characteristics.

Criterion: Verify that key product characteristics (including critical characteristics) have been identified.

Standard: Physical characteristics which are key to the successful function of critical safety items (CSIs) and flight critical components are defined and documented. Tolerance allowances for each characteristic and traceability through the design hierarchy are defined, and the effects of adverse tolerance accumulation at higher (e.g., above the CSI) levels of product assembly are analyzed and reflected in the design documentation.

Method of Compliance: Key product characteristic (including critical characteristics) and tolerance definitions are verified by inspection and analysis of program design documentation at the applicable levels of the product hierarchy. Manufacturing process controls for specific key product characteristics identified as Critical to Safety (CTS) and manufacturing process parameters necessary to achieve and maintain acceptable process indices are verified by inspection and analysis of manufacturing process control documentation for the applicable stages of manufacture and assembly.
4.4.2 Critical processes.

**Criterion:** Verify that all critical process capabilities exist to meet key product characteristic requirements (including critical characteristics).

**Standard:** All key characteristics (including critical characteristics) are mapped to corresponding critical processes. Critical process capabilities are characterized, process capability indices (Cpk) are calculated and acceptable limits established. Process control plans for critical processes are defined and implemented throughout the supply chain. For Army and Navy only, quality control procedures for critical processes are defined and implemented throughout the supply chain.

**Method of Compliance:** Critical process capabilities and control plans are verified by inspection of design documentation and process control documentation and if applicable, on-site audit documentation, throughout the supply chain.
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TACC Sec 4.4

Current Language

- 4.4.3 Critical process controls.
- **Criterion:** Verify that all critical process controls exist to assure key product characteristic requirements (including critical characteristics) are met.
- **Standard:** Work and inspection instructions are defined, documented and implemented for all critical manufacturing processes. A process capability index (Cpk) of at least 1.67 is maintained for processes Critical to Safety (CTS) or processes that produce Critical Safety Items (CSI). Quantitative product quality criteria (i.e., product acceptance criteria) are defined and used for product acceptance at all levels of the product hierarchy up to and including the air system level.
- **Method of Compliance:** Work and product inspection instructions, product acceptance criteria are verified by inspection. Cpk is verified by analysis and inspection of design documentation and manufacturing process capability data. Design conformance (i.e., “as built” configuration is in accordance with design requirements) is verified by first article inspections or first article tests, review of manufacturing process control data, and/or periodic hardware quality audits.

Proposed Language

- 4.4.3 Critical Process Control
- **Criterion:**
- **Standard:**

**Method of Compliance:**

Delete
• NDI coverage in other MIL-HDBK-516C sections:
  – 19.3.x Materials – NDI (Not used by Air Force)

  19.3.1 Defect characterization and detection.
  • Criterion: Verify that specific defect types, sizes, and locations critical to material integrity are characterized and assessed for probability of detection.
  • Standard/MoC: To be provided by the procuring agency

  19.3.2 NDI assessment criteria.
  • Criterion: Verify that NDI accept/reject criteria are validated and correlated with 'effects of defects' testing.
  • Standard/MoC: To be provided by the procuring agency

  19.3.3 NDI manuals.
  • Criterion: Verify that the nondestructive inspection manuals are developed and that each of the methods is valid.
  • Standard/MoC: To be provided by the procuring agency

  19.3.4 Inspection intervals.
  • Criterion: Verify that initial and recurring inspection intervals are defined where applicable.
  • Standard/MoC: To be provided by the procuring agency