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COMPUTER SYSTEM VENDOR AUDIT CHECKLIST

1. PURPOSE

The purpose of this work instruction is to provide an audit checklist for auditing computer system software as recommended in VAL007.

2. SCOPE

This work instruction applies to the audit of both commercial and custom software developers.

3. REFERENCE DOCUMENTS

- 3.1. ANSI/AAMI SW68:2001, Medical Device Software – Software Life Cycle Processes. Association for the Advancement of Medical Instrumentation, 2001.
- 3.2. IEEE 1012-1998, IEEE Standard for Software Verification and Validation Plans.
- 3.3. IEEE 12207.0-1996, IEEE/EIA Standard: Industry Implementation of International Standard ISO/IEC 12207:1995 Standard for Information Technology – Software Life Cycle Processes.
- 3.4. ISO 9001:2000, Quality Management Systems – Requirements
- 3.5. Stein, R. Timothy. *Computer System Risk Management and Validation Life Cycle*, Paton Press, 2006.
- 3.6. VAL007 – Computer System Vendor Qualification and Management

4. DEFINITIONS

- 4.1. None

5. RESPONSIBILITIES

- 5.1. Auditor: The auditor is responsible for completing the checklist based on the audit that is conducted.

6. METHOD

- 6.1. Complete the information on the first page after the Table of Contents. The audit number ought to be obtained from the individual who manages the auditing of vendors.

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COMPUTER SYSTEM VENDOR AUDIT CHECKLIST

- 6.7.1. If the checklist is modified, or if it is completed electronically, refresh the table of contents on page one of the checklist.

To create or refresh the table of contents in **Windows 2000** go to the Insert menu and select "Index and Tables." Select the middle tab, "Table of Contents." If the window in the middle of the screen does not show ONLY the style "Sec. Title #.0," click the "Options" button. Delete the numbers for all of the existing styles and put a "1" for style "Sec. Title #.0." Click "OK" to close the "Table of Content Options" window. Click OK on the "Table of Contents" window to create the Table of Contents. In **Windows 2003**, go to the Insert menu, References, and "Index and Tables." Click on "Options" and the Table of Contents Options window opens. In the "Available Styles" list remove all numbers for every style except put a 1 in the "Sec. Title #.0" option field. Click OK to close each window

7. QUALITY RECORDS

- 7.1. The audit checklist is filed as back-up data with the audit report, but in itself is not a quality record.

Record Name	Record Format	Record Owner	Storage Location	Filing Method
None				

(Note that the Record Owner is the function that keeps the records, and not the function that creates the record).

8. SUMMARY OF REVISION CHANGES AND JUSTIFICATION

- 8.1. The changes created in this revision, and their justifications are provided in the following table.

Changes	Justification
1. New document	An audit checklist is provided for auditing developers of commercial and custom developed software.

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COMPUTER SYSTEM VENDOR AUDIT CHECKLIST

Organization audited: _____ **Audit date:** _____

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Audit area: Software testing 23
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Audit information

Audit Number: _____

Audit Type:

- Regular Follow up to CA
 Recertification Special

Auditor Name	Auditor's Signature	Date

Audit area: Established quality system

Manager of Area: _____

Individuals interviewed: _____

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COMPUTER SYSTEM VENDOR AUDIT CHECKLIST

Organization audited: _____ **Audit date:** _____

Process, Activity, Document	Questions to Answer
Documented quality system	<input type="checkbox"/> Yes <input type="checkbox"/> No Is a documented quality system in place? <input type="checkbox"/> Yes <input type="checkbox"/> No Has that system been registered by a third party as complying with a quality system standard (e.g., ISO 9001)? Which standard?
Quality manual	<input type="checkbox"/> Yes <input type="checkbox"/> No Has a quality manual been prepared, approved and trained?
Responsibilities & authority	<input type="checkbox"/> Yes <input type="checkbox"/> No Has management defined the roles and responsibilities for quality? <input type="checkbox"/> Yes <input type="checkbox"/> No Has management given the functions responsible the independence and authority to act as necessary to ensure quality products?
Company Resources	<input type="checkbox"/> Yes <input type="checkbox"/> No Are the resources (including people, tools and infrastructure) in place to ensure a quality product?

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COMPUTER SYSTEM VENDOR AUDIT CHECKLIST

Organization audited: _____ **Audit date:** _____

Process, Activity, Document	Questions to Answer
Contract review	<input type="checkbox"/> Yes <input type="checkbox"/> No Are contracts reviewed to ensure that customer requirements are defined (including promises made to customers)? <input type="checkbox"/> Yes <input type="checkbox"/> No Are contracts reviewed to ensure that the customer's requirements can be met, and that promises made to the customer can be met?
Quality system internal audits	<input type="checkbox"/> Yes <input type="checkbox"/> No Are internal audits of the quality system performed by independent auditors? <input type="checkbox"/> Yes <input type="checkbox"/> No Are negative audit findings corrected? <input type="checkbox"/> Yes <input type="checkbox"/> No Is the correction verified?
Corrective action	<input type="checkbox"/> Yes <input type="checkbox"/> No Are quality issues tracked and resolved through a corrective-action system? <input type="checkbox"/> Yes <input type="checkbox"/> No Are corrective actions closed in a timely manner?

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COMPUTER SYSTEM VENDOR AUDIT CHECKLIST

Organization audited: _____ **Audit date:** _____

Process, Activity, Document	Questions to Answer
Training	<input type="checkbox"/> Yes <input type="checkbox"/> No Do training requirements exist for employees and/or job classes? <input type="checkbox"/> Yes <input type="checkbox"/> No Is training performed to the defined requirements? <input type="checkbox"/> Yes <input type="checkbox"/> No Are training records up to date?
Software development lifecycle	<input type="checkbox"/> Yes <input type="checkbox"/> No Has a software development methodology/lifecycle been documented? <input type="checkbox"/> Yes <input type="checkbox"/> No Has a software development methodology/lifecycle been implemented? <input type="checkbox"/> Yes <input type="checkbox"/> No Has a software development methodology/lifecycle been maintained?
Management reviews	<input type="checkbox"/> Yes <input type="checkbox"/> No Is the effectiveness of the quality management system reviewed by management on a periodic basis?