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
3.6. 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.
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.

<table>
<thead>
<tr>
<th>Record Name</th>
<th>Record Format</th>
<th>Record Owner</th>
<th>Storage Location</th>
<th>Filing Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(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.

<table>
<thead>
<tr>
<th>Changes</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. New document</td>
<td>An audit checklist is provided for auditing developers of commercial and custom developed software.</td>
</tr>
</tbody>
</table>
COMPUTER SYSTEM VENDOR AUDIT CHECKLIST

Organization audited: _________________________________ Audit date: _____________

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Audit information

Audit Number:

Audit Type: ☐ Regular ☐ Follow up to CA
☐ Recertification ☐ Special

<table>
<thead>
<tr>
<th>Auditor Name</th>
<th>Auditor’s Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Audit area: Established quality system

Manager of Area:

Individuals interviewed:

_________________________________________________

_________________________________________________
## COMPUTER SYSTEM VENDOR AUDIT CHECKLIST

**Organization audited:** ___________________________ **Audit date:** ____________

<table>
<thead>
<tr>
<th>Process, Activity, Document</th>
<th>Questions to Answer</th>
</tr>
</thead>
</table>
| Documented quality system   | ☐ Yes ☐ No  Is a documented quality system in place?  
☐ Yes ☐ 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              | ☐ Yes ☐ No  Has a quality manual been prepared, approved and trained? |
| Responsibilities & authority| ☐ Yes ☐ No  Has management defined the roles and responsibilities for quality?  
☐ Yes ☐ No  Has management given the functions responsible the independence and authority to act as necessary to ensure quality products? |
| Company Resources           | ☐ Yes ☐ No  Are the resources (including people, tools and infrastructure) in place to ensure a quality product? |
### COMPUTER SYSTEM VENDOR AUDIT CHECKLIST

Organization audited: _________________________________  Audit date: _____________

<table>
<thead>
<tr>
<th>Process, Activity, Document</th>
<th>Questions to Answer</th>
</tr>
</thead>
</table>
| Contract review             | Yes ☐ No ☐ Are contracts reviewed to ensure that customer requirements are defined (including promises made to customers)?  
                               | Yes ☐ 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 | Yes ☐ No ☐ Are internal audits of the quality system performed by independent auditors?  
                                   | Yes ☐ No ☐ Are negative audit findings corrected?  
                                   | Yes ☐ No ☐ Is the correction verified? |
| Corrective action           | Yes ☐ No ☐ Are quality issues tracked and resolved through a corrective-action system?  
                               | Yes ☐ No ☐ Are corrective actions closed in a timely manner? |
## COMPUTER SYSTEM VENDOR AUDIT CHECKLIST

**Organization audited:** _________________________________  **Audit date:** _____________

<table>
<thead>
<tr>
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<th>Questions to Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Training</strong></td>
<td>![Yes] ![No] Do training requirements exist for employees and/or job classes?  ![Yes] ![No] Is training performed to the defined requirements?  ![Yes] ![No] Are training records up to date?</td>
</tr>
<tr>
<td><strong>Software development lifecycle</strong></td>
<td>![Yes] ![No] Has a software development methodology/lifecycle been documented?  ![Yes] ![No] Has a software development methodology/lifecycle been implemented?  ![Yes] ![No] Has a software development methodology/lifecycle been maintained?</td>
</tr>
<tr>
<td><strong>Management reviews</strong></td>
<td>![Yes] ![No] Is the effectiveness of the quality management system reviewed by management on a periodic basis?</td>
</tr>
</tbody>
</table>