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VALIDATION PLAN TEMPLATE FOR SINGLE SYSTEM VALIDATIONS – REPLACE WITH TITLE

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Note: 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.

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3.7 VAL019, Computer System Risk Evaluation for Determining the Rigor and Intensity of Validation Activities and Testing

3.8 Stein, R. Timothy. Computer System Risk Management and Validation Life Cycle, Paton Press, 2006.

Note: Do not list reference materials for the system such as system documentation, users' manuals, etc.

4. DEFINITIONS

Instructions

4.1 Include in the definitions only terms used in the Validation Plan that are not common knowledge, or that have a specific definition within the context of the validation plan.

5. RESPONSIBILITIES

Instructions and examples

List the major responsibilities for each functional area that is involved. Provide only a high-level summary. The responsibilities to approve documents that are part of the validation record are provided in Appendix III.

Include only each function's responsibilities regarding the validation; examples are provided below. Do not include additional responsibilities for the project.

5.1 The Validation Department is responsible for:

- 5.1.1. Project management of the validation.
- 5.1.2. Supporting IT in drafting, and reviewing and approving all IQ protocols.
- 5.1.3. Creating (drafting and dry-running) OQ, and PQ protocols.
- 5.1.4. Supporting Document Control in running the OQ tests.
- 5.1.5. Reviewing and approving all IQ and OQ completed protocols and reports.
- 5.1.6. Preparation of the PQ protocol, data collection and report preparation.
- 5.1.7. Preparing the validation final report.

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5.1.8. The collecting, organizing, reviewing, and filing of all documents that are part of the validation record.

5.2 System Owner

5.3 Additional user representatives, if any

5.4 IT

5.5 Project Manager

5.6 QA

6. SYSTEM DEFINITION AND DESCRIPTION

Instructions

Provide a high level description of the major elements of the system, so that the validation approach can be determined. You may reference a system description document or specification for more detailed information. System Specifications and IQs typically include more detailed listings of system components.

Provide a diagram in Appendix I of the major hardware components. Give the manufacturer and product name of the hardware. Provide a technical description of the major system components.

Also provide a list of the major software components in Appendix II; include the name, release level, and the manufacturer's name. Include all major programs/applications/tools that will be installed separately, such as:

- Database software
- The application
- Server hardware
- System software
- System tools for monitoring the use of the application

Example