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Validation Final Report for

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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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Provide a list of the documents referenced in the Validation Final Report. Do not include the deliverables from the validation process; they will be listed in Section 5, Analysis of Validation Results. Examples of what to include in the Reference section are:

Example:

- 2.1 VAL003, Validation of Off-the-Shelf Computer Systems
- 2.2 VAL004, Requirements for Computer System Requirements, Validation Plans, Protocols and Reports
- 2.3 Risk Assessment of the EDMS System
- 2.4 Your Company Infrastructure Qualification Final Report
- 2.5

3. Summary of the Validation Approach

Instructions:

Provide a summary of the validation approach as presented in the Validation Plan.

Example:

The selection, purchase, implementation, and validation of the EDMS system followed the process defined in VAL003. The deliverables that are considered part of the validation record, and their approval, are reviewed in the subsequent section.

A prospective validation was conducted on the EDMS system as purchased. The ability to generate the reports, and use the approval routes that were developed by the manufacturer, were included in the validation. The EDMS application includes tools to create different approval routes using configuration tools, and to create reports. These tools were not included in the validation, however three approval routes were created and documented in "Workflow Configurations for the EDMS System." These three approval routes were included in the validation. All routes and reports created in the future using the EDMS tools will have to be created and implemented following the Change Control procedure.

The validation testing included an IQ, OQ, and PQ.

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The installation qualification confirmed that all installed hardware and software for the EDMS system met specifications. The IQ indicates that the EDMS System was properly installed. No variances occurred.

- Operational Qualification

Eleven variances were identified during the execution of the OQ tests. A Variance Form was completed for each variance. All variances were resolved during the execution of the OQ.

- Four variances were protocol errors.
- Three variances were the result of errors made by the person executing the protocol.
- Two variances were the result of errors in the setup of the users' profiles that were used during the execution of the OQ.
- One of the patches that was installed to fix a bug inadvertently set the auto document numbering scheme back to the vendor's default setting. (The patch was installed after the autonumbering had been set.) As a result, some documents were assigned surprising numbers. The document number configuration had to be reset to the company's scheme. The tests were repeated, and the proper numbers were assigned.
- One of the workflows was incorrectly designed. After it was corrected, the workflow worked as intended.

All of the acceptance criteria for the OQ were met.

5.3 Performance Qualification

The PQ was executed.

- Tests were made of the high-risk items, and the system met all acceptance criteria.
- Trouble reports were monitored.
 - During the first 6 weeks of use, no trouble reports were opened for critical software failures.