COMPUTER SYSTEM VENDOR QUALIFICATION AND MANAGEMENT

1. PURPOSE

The purpose of this procedure is to describe the requirements and process for the qualification and management of vendors who provide system software, application software, computer hardware, support services, or software development or integration services as required by VAL003.

2. SCOPE

This procedure applies to the qualification and management of all vendors who provide system software, application software, computer hardware, support services, or software development or integration services. Once a vendor is identified as a possible provider of products and services, the vendor must be qualified before an order is placed.

3. REFERENCE DOCUMENTS

[Note to the purchaser of this document: The policy documents, procedures, and templates referenced here are available at www.BPAconsultants.com and www.ComplianceOnline.com]

3.1.   ANSI/AAMI/IEC 62304:2006. Medical Device Software – Software Life Cycle Processes. Association for the Advancement of Medical Instrumentation, American National Standards.

3.2.   ISO 9001:2000. Quality Management Systems – Requirements. 2000

3.3.   MIS007 - Problem tracking and resolution

3.4.   RISK006 – Computer System Risk Evaluation for Determining Risk Mitigations, Validation Activities, and the Extent of Testing

3.5.   VAL003 – Validation of Computer Systems Used in Production and Quality Systems

3.6.   VAL008 - The Computer System Vendor Audit Checklist

3.7.   VAL009 - Creation, Validation, and Use of Spreadsheets Used in Conjunction with Quality Records

3.8.   VAL017 - Validation of Applications Created with Database Packages

4. DEFINITIONS

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4.1. <u>AVL:</u> Approved Vendor List

4.2. <u>Custom software development</u>: The development of a program(s) or application(s) that is not available for purchase "off-the-shelf." The program(s) or application(s) are designed and developed specifically to our company's requirements. Custom software can be developed by internal or contract programmers.

4.3. <u>Industry leadership:</u> Established market presence that is indicative of a quality product, such as market share or installed base in regulated industries

4.4. <u>Integration services</u>: Services provided to integrate two or more applications/computer systems such that information or commands are passed from one to the other. Integration services can be provided by internal developers or external service providers.

4.5. <u>Support Services:</u> Services provided by an outside firm, often the developer of the software, to troubleshoot and repair defects.

5. RESPONSIBILITIES

5.1. <u>QA:</u> Quality Assurance is responsible for the vendor qualification process, including gathering required information, conducting on-site audits as appropriate, reviewing the information and reaching a decision to approve, conditionally approve, or disqualify the vendor, managing supplier performance, conducting annual reviews, preparing the Vendor Qualification report, and maintaining the Approved Vendor List.

5.2. <u>IT:</u> Information Technology maintains records on the quality of products and services received from vendors, and interfaces with vendors to get problems/defects fixed. IT assists in obtaining the information from vendors to qualify them, provides input to the qualification and requalification processes, and assists in performing on-site audits of vendors.

5.3. <u>Purchasing:</u> Purchasing may assist in obtaining the information from vendors to qualify them.

6. METHOD

6.1. The purpose of the qualification is to evaluate the vendor's quality system in order to determine if its products and services are/will be produced with sufficient quality to provide the reliability and performance needed.

6.2. QA determines the criteria for the qualification of the vendor.

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6.2.1. The following table provides guidelines on requirements for qualifying different types of vendors whose products and services have various levels of associated risk. Ultimately, QA and IT have to be satisfied that enough evidence has been obtained to determine if the vendor is qualified to provide the products and/or services in question.

6.2.1.1. Classify the risk associated with the products and/or services to be obtained from the vendor as High, Moderate, or Low (see RISK006 for how to determine risk levels).

6.2.1.2. Follow the table below for determining the acceptance criteria based on the type of product or service. When the value "O" (for options) appears in the table, the vendor can be qualified if it meets any one of the options marked with "O." The value of "R" means that it, and all other criteria marked "R" for that type of product, have to be met by the vendor.