4. Complexity Assessment (GAMP Categorisation)

All Items can be categorised into one of following five categories. The GAMP category reflects the degree of novelty or complexity of an Item and will influence which validation activities are applicable.

4.1. Category 1 – Operating Systems (Compilers and System Configuration Files)

Specific validation of commercially available operating systems (and compilers), which are established in the market, is not required. The validation of the application software running on the operating system is considered to validate the operating system. Operating systems rely on system configuration files that can impact on system performance and data usage and therefore should be recorded.

Typical examples: Windows NT and Unix

4.2. Category 2 – Firmware (Standard Instruments, Micro controllers, Smart Instrumentation)

This category is essentially hardware with onboard firmware that cannot be programmed by users but can be configured to set up a run-time environment and process parameters. Custom firmware should be considered Category 5.

Typical examples: Printer, Barcode Reader, Check Weigher.

4.3. Category 3 – Standard Software Packages (Commercial Off-The-Shelf or COTS)

COTS packages are items that are exposed to high volume use in the marketplace, such that validation of the package itself is not required. COTS packages are not configured to define the business or manufacturing process, apart from establishing the run-time environment (e.g. network and printer connections). Process parameters may be input into the application. Supplier audits may be needed for highly critical or complex applications or where experience with the application is limited.

Typical examples: Excel, Word (documents, used as word processors),

Artwork Generation packages,

Statistical Analysis packages,

and Diagnostic tools,

4.4. Category 4 – Configurable Software Packages

These packages are also widely-used but provide the ability for significant tailoring of functionality to suit the specific requirements of a business or process. The package provides a number of standard modules, functions and interfaces which can be tuned, selected or assembled as required. The standard elements being configured would each typically contain significant operational depth and their configuration would be a high-level activity. (Some packages permit the development of fully customised modules. These developments should be managed as Category 5.) Category 4 packages normally require a vendor audit to be performed for critical and complex operations with emphasis on design qualification of the package (documented evidence of a quality approach to system development and structural testing). The outcome of the audit may dictate the testing approach required at the user site, and this should form the basis of a validation rationale.

Typical examples: SCADA,

Building Management System

Unsophisticated Excel spreadsheets, e.g. Particulates results, Cleaning criteria, Bio-burden graphs.

Autoclave Control System (as-standard from Original Equipment Manufacturer but utilising a configuration file of cycles)

Filter Integrity Test System