Configuration Management SOP

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Document Approval

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1 Introduction

1.1 Purpose
To provide a methodology for the management of software and related configuration items for a validated computer system.

1.2 Scope
Department/Section: IT Groups.
Configuration Management provides a basis for ensuring an orderly control of configuration elements produced by IT and an effective mechanism for incorporating software changes, both during development and operations.

1.3 Definition
Baseline - A point in time when all modifications to source and object are frozen and are under change control.

Element - Application programs, object files, source code files, documentation, data base structures, key parameter file information.

Environment - A collection of hardware, software, network communications and procedures that work together to provide a discrete type of computer service. There maybe one or more environments on a physical platform (e.g. test, pilot, production). An environment has unique features and characteristics that dictate how they are administered in similar, yet diverse manners. Examples of platforms are Windows 2003 Server, Linux, and Solaris.

Version Identifier - A version date or version number.

Software Categories – the following list provides a categorization of software referenced in this SOP:

- Category 1 - Operating Systems
- Category 2 - Standard Instruments, Micro Controllers, Smart Instrumentation
- Category 3 - Standard Software Packages
- Category 4 - Configurable Software Packages
- Category 5 - Application Specific or Custom Built Software
**Client** – the business system owner is typically the ‘line’ manager responsible for the business process where the computer system will be used.

**Validation Group** – the group responsible for ensuring that computer systems are implemented and maintained in a validated state.

**IT Group** – the group responsible for development, operation, and maintenance of computer systems.

### 1.4 Responsibility

Validation and the other disciplines listed within this SOP are responsible for ensuring this procedure is followed.

It is the responsibility of the IT groups to ensure that source code, object code and other software components are maintained under proper configuration control.

### 1.5 References

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### 2 Configuration Management Plan Contents - Procedure

The Configuration Management Plan must be prepared according to the general format requirements defined in SOP SOP_0102 “Documentation Standards.”

A Configuration Management Plan is developed for each unique computer system that would define for each application the specific process for controlling the application elements.

A software system that functionally provides configuration management should be employed. Where a suitable software product is not available, access security must be restricted to prevent write/update privilege on the test and production baseline libraries to members of the IT Group who are responsible for maintaining configuration control.
### 2.1 Configuration Management Plan Title
Give the configuration management plan a descriptive title that uniquely identifies the system.

### 2.2 Approval
At the beginning of the configuration management plan an approval section is required. This section will contain a table for signatures. The table of signatures must provide for the following information to be captured:

1. The department or function of the signatory;
2. The name of the signatory;
3. A space to record the signature, and;
4. A space to record the date of the signature.

The section must contain a statement informing the reviewer that signing this document infers that they have read, understood and agree with the contents of the plan.

Normally this information is collected on the approval page of the plan.

### 2.3 Environment identification
Describe the hardware including the model number, operating system version, and vendor. Also include change control product names and release numbers.

### 2.4 Application Configuration Items
Identify the specific type or group of configuration elements that comprise the application and are defined as requiring configuration control.

### 2.5 Baselines
Provide a description of the baselines (i.e. unit, system, production) from an environment perspective (hardware & software).

Provide a description of the tools necessary for managing/controlling the baseline.

Provide a description of the location of system configuration element (or libraries) for each baseline.
2.6 Version Identifier and Version Control

Control must be maintained over the various versions of configuration elements to ensure consistency and also to ensure that modifications are implemented appropriately. Each configuration element must be uniquely identified with a version number or version date before it is initially placed under change control in the test environment. Modifications to configuration elements can be approved and implemented between each baseline. A version will be incremented for configuration elements each time a modification is approved and placed under change control. The version number or version date will remain the same as the element moves from one baseline to another as long as the element has not been modified.

Describe the method and format of the version numbering of elements.

Describe how each element can be examined for its unique version number.