The Validation Project Plan is to be developed / prepared by a validation representative and must be approved at minimum by the Validation Manager, the end user of the system and the Quality Assurance Manager or their delegates. The following personnel are required to provide input to this document:

- Personnel who understand the process or activity.
- Individuals who are involved with the design and implementation of the System (including Vendors).

It is the responsibility of the Validation Project Plan author to ensure the document is prepared as per these guidelines.

5.0 PROCEDURE

5.1 Preparation of a Validation Projects Plan

The document shall be set out in the following format. Other sections may be included which are individual requirements for a specific project.

- Each VPP is to be issued with a unique number according to validation documentation procedure.
- The first page of the document should provide the name(s), signature, date and position of the personnel involved in the preparation of the document and approval.
- Approval of the VPP is to be given by personnel nominated by the Validation Steering Committee.
- Second page must contain The Table of Contents and any other sections as necessary.
- The following Sections 5.1.1 to 5.1.13 of this procedure detail the contents for each of the sections as listed in the Table of Contents. References to existing documents should be made wherever possible to eliminate duplication of information.

5.1.1 Purpose / Scope

These sections shall provide a description of the purpose of the VPP, system under validation and its purpose and which areas of the System are (and are not) to be validated and why. The purpose and scope will make reference to the site at which the project is going to take place and the final location and specific function of the validated system.

5.1.2 References

Provide a list of all the codes, policies, procedures and standards the Validation Project Plan is to comply with. Identify documents that may be considered pertinent to the development of the Validation Plan.

5.1.3 Responsibilities and Authorities

Provide the names of the key personnel involved in the Validation effort stating their responsibilities, authorities and position within the company. Vendor representatives should also be included at this stage.

5.1.4 Signature List

5.2.3 **Responsibilities and Authorities**

Provide the names of the key personnel involved in the Validation effort stating their responsibilities and position within the company. Vendor representatives should also be included at this stage if required. Define the function of the Steering Validation Committee within the project.

5.2.4 **Signature List**

A list of all personnel involved in the activities of the validation project is recommended.

5.2.5 **System Overview**

This section will provide a brief description of the System (include if the System was purchased and a description of the Vendor), referencing URS, FRS, DSS, User Manuals or any other related documentation for detailed descriptions. Extracts from these documents can be included, however duplication of information should be minimized as much as possible.

5.2.5.1 **System Block Diagram –** if appropriate a diagram or flow chart of the overall System should be included here**.**

5.2.5.2 **Hardware Description -** a brief description or list of the hardware, peripherals and interfaces required to operate the System is to be included.

5.2.5.3 **Software Description -** a brief description of the databases, files, language and development standards used, name and version numbers of the application software, operating system and supporting software.

5.2.6 **Validation**

5.2.6.1 **Validation Status**

Detail the current validation status of the system if applicable. Should any work be complete or underway, it should be referenced in the VPP.

5.2.6.2 **Validation Environment**

The validation environment should be defined in the Validation Project Plan and its validation status document.

5.2.6.3 **Validation Category**

Document the category and category requirements (hardware and software).

5.2.6.4 **Validation Testing**

The level of validation testing will depend on the category of hardware and software to be validated and will be defined in the Validation Project Plan. Validation testing may include acceptance testing (module / integration / site acceptance testing) and/or qualification testing (IQ/OQ/PQ) - refer to SOP **VAL-110** *Computer Validation Guideline*. If validation testing is performed in a validation environment, it must be comparable to the live environment. A validation environment must be validated.

5.2.6.5 **Validation Deliverables**

- Who requires training? e.g. Users, MIS, Vendor, etc.
- Who will conduct the training? e.g. Vendor
- At what stage is the training required? e.g. at IQ, OQ, PQ stage, etc.
- How will the training be conducted? e.g. User Manuals, approved procedures, etc.

Refer to and make reference to the applicable training SOP adopted during the validation study.

5.2.14 **Documentation**

This section should list all the documentation which will be retained, archived and updated for the System. The list should include as applicable:

System Development Documentation: URS, FRS, DSS, Validation Project Plans, Protocols and Reports, Audit Reports, Source Codes, User Documentation, Standard Operating Procedures, Maintenance records (hardware and software).

Indicate who is responsible for each document, where it will be kept and for what time period. For large scale projects a document matrix may be generated at the completion of the project, however this document should not be considered necessary for operation of the system.

5.2.15 **System Decommissioning**

If the new system is replacing one currently in use in production, refer to SOP **VAL-110** *Computer Validation Guideline*, the VPP should address the requirements of phase-out of the existing system. A separate decommissioning plan may need to be prepared to address the following as a minimum:

- The data generated, stored and calculated by the retiring system may have to be archived, transferred, or disposed of. The procedure for this should be documented and the required time the archived data is to be stored.
- Will the archived data need to be retrieved in the future? The software programs of the retiring system may have to be archived.
- Documentation related to the retiring system may need to be archived for the same period of time as the data.

5.2.16 **Amendment List**

An Amendment List must be included in the document.

