5.0 PROCEDURE

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

5.2 Each VPP is to be issued with a unique number.

5.3 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. The first page will also detail the name and version of the software / system being validated.

5.4 Approval of the VPP is to be given by personnel nominated by the Validation Steering Committee.

5.5 A table of contents should be included.

5.6 The following Sections 5.6.1 to 5.6.23 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.

5.6.1 Purpose And Scope

This section shall provide a description of the purpose of the VPP, the computer system under validation and its purpose and which areas / modules 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. The scope should detail the extent of the validation effort including boundaries, exceptions and detailed project scope. The scope should reference any applicable documentation that is used to justify omissions from the validation exercise.

5.6.2 References

Provide a list of all the codes, policies, procedures and standards the Validation Project Plan is to comply with. Identify the documents that are pertinent to the development of the VPP and where applicable, identify the version number.

5.6.3 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.

5.6.4 Signature List

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

5.6.6.11 **Validation Report**

This section should specify a Validation Report will be prepared at the conclusion of the Validation effort to summaries all the deliverables and activities against the Validation Plan. For large scale projects, separate IQ, OQ and PQ reports should be written and approved prior to commencing the next validation step.

The summary will include a list of all the documents, records, data, procedures, etc., to be reviewed and evaluated by the personnel approving the Validation Report.

Where appropriate, address traceability requirements for the documents delivered. For example, traceability of URS to FRS and Qualification Protocols. This can be achieved by a traceability matrix, where each URS requirement is referenced to an FRS requirement and a qualification test is referenced to the URS.

5.6.6.12 **Maintaining the Validated State**

This section should define the actions and procedures required to maintain the system in its validated state.

5.6.6.13 **Change Control**

Refer to and make reference to the applicable Change Control procedure adopted during the validation project and following implementation.

5.6.6.14 **System Standard Operating Procedures**

A number of procedures are to be developed (reference to be made to procedures already existing) to ensure the continued operation of the System in a secure environment that is maintained in a validated state throughout its lifecycle. This will depend on the complexity of the system and the required documents should be listed.

Examples:

- Change Control
- Security
- Backup and archiving
- Disaster Recovery
- Periodic review (Auditing) /on-going monitoring
- Prevention, detection and correction of errors
- Operational Standard Operating Procedures

Typically the procedures would be drafted at the IQ stage, finalized at the OQ stage and executed at PQ stage of the validation program.

