1 Purpose

This Guideline provides guidance on the qualification requirements to be applied to the Information Technology infrastructure. The establishment and maintenance of a qualified infrastructure for any regulated company is fundamental to meeting current business and regulatory requirements in respect of systems stability, reliability and security.

2 Scope and Applicability

This guideline applies to all business functions and contracted third parties who install, operate, manage or maintain the infrastructure. The requirement for qualification applies to all components of the infrastructure. This is necessary because of the interconnectivity of the network (a fundamental design requirement) and possible (unwanted) interactions that might ensue without conformance to the minimum standards contained in this Guideline.

The following infrastructure elements are covered by this guideline:

- Local and wide area networks (e.g. data transmission cabling, hubs, routers, bridges and switches, etc.).
- Servers and mainframe computers (and their operating systems and supporting software products).
- Clients (and their operating systems).
- Peripheral equipment (e.g. networked printers and storage devices)
- Electrical power supply and heating, ventilating and air conditioning equipment for server rooms and data centers.
- Server rooms and data centers.
- Infrastructure monitoring, management and maintenance systems.
- Middleware or enabling software., e.g. Oracle, SQL etc.)

3 Definitions

3.1 Installation Qualification

Documented verification that all physical aspects of a facility or system, which affect product quality, adhere to the approved specification and are correctly installed.

3.2 Operational Qualification

Documented verification that all functional aspects of a facility or system, which affect product quality, perform as intended throughout all anticipated operating ranges.

3.3 Change Request

This is a collective name for a ôRequest for Changeô form.

4.1 Infrastructure Owner

A person, or persons, who is/are óaccountableô for the provision, operation, and management of the infrastructure. This position could have a business wide remit or a local accountability for the infrastructure present on the site. Ultimate accountability for the status of the application lies with the System Owner, and this includes the relevant infrastructure.

4.2 Infrastructure Manager

A person, or persons, who is/are delegated by the Infrastructure Owner to be responsible for the day-to-day management of the infrastructure. A third party may perform this role.

4.3 Network Manager

A person, or persons, who is/are delegated by the Infrastructure Manager to be responsible for the day-to-day operation of network components, e.g. data transmission equipment, cabling, routers, switches and hubs, etc. A third party may perform this role.

4.4 IS Quality Manager

The IS Quality Manager assures that the IS unit operates a documented quality management system and processes to implement the company IS Quality Policy and Principles.

4.5 Functional Quality Assurance

Functional Quality Assurance will assure that regulated processes and supporting IS and IT systems remain compliant. For further guidance, please refer to óRoles

4.6 IS Security Manager

The IS Security Manager will advise on all aspects about the security of the infrastructure.

5 Guideline

5.1 Company Quality, Compliance and Security Standards

The standards applied to the management of the infrastructure must meet IS Quality, Compliance and Security policies and standards and the requirements of regulatory agencies (health, financial, etc.).

5.2 Infrastructure Life cycle

For infrastructure development a life cycle model must be used. To maintain the logical order, the deliverables from each stage of the life cycle must be approved before the next stage is commenced. A stage in the life cycle is

5.3.2 Development Environments

In the special case of áthrash and crashô environments, e.g. ósandboxesô and other development regions of the infrastructure, the interactions, if any, between the development region and the wider infrastructure (if a connection exists between the two regions) must be formally assessed for any security and compliance risks and qualification process must be followed.

5.3.3 Qualification Documentation

Adequate documentation is an essential part of the qualification and infrastructure management processes and all deliverables must be documented. Lack of adequate records will cause costly delays, errors and in some cases possible unwanted actions from regulators.

The documented evidence that is necessary to demonstrate qualification of infrastructure components can be seen in table 1 below. Each deliverable may be a separate document or combined for routine and simple changes and may cover one component which itself may be representative of a class of components.

Qualification of common and routine changes may be covered by a pre-determined change procedure and the qualification deliverables documented on the change request documentation.

5.3.3.1 Qualification Deliverables Flow

The illustration ñQualification Deliverable Flowò describes the order in which the deliverables should be produced from planning to completed qualification.

- Work on the Qualification Plan may start after the feasibility and/or initiating stage is finished.

- Work on Requirements specification also starts at this point, butthe RS must be completed prior to, or at the latest in parallel with the QP.

- For the actual planning of the qualification work to take place (writing the Test Plan), Functional Specifications, Technical Specifications and Design Specifications are to be completed, so that the correct acceptance criteria can be entered into the Test Plan.
- Input documents to the QP as well as documents created after completion of the QP are to be appropriately signed, dated and approved. After completion of a QP, tests are to be performed signed and dated. Version control must be used for all documents. All changes must be traceable. All documents, including test results, should be easily made available. These documents will also be used during an audit or inspection

5.3.3.2 Deliverables Description

Figure: Deliverables Description

Table 1 - Qualification Deliverables

Deliverable	Scope of Deliverable
Qualification Plan (QP)	The Qualification Plan outlines what information; documentation and processes will be produced or updated. This must include the scope of the activity and what elements need to be qualified based on a risk assessment. It is important to define which middleware components, if any, will be included. For small changes, a separate document is not required and the planning information may be contained in another document. For larger and more complex changes, a separate document will be required. Local procedures should be consulted for specific guidance.
Inventory Records (Asset Register)	The inventory must identify both hardware and associated software components (e.g. operating system).
Requirements Specification	Requirements must be documented so that the component can be properly specified, procured, installed and tested.
Technical Specifications	The technical specifications must include information about the functional, technical, and architectural and design aspects of the component.
Configuration Records	Each component with configurable items must have its configuration documented sufficiently to allow the component to be installed and operated correctly and to be maintained or replaced as required. Critical relationships, if they exist between different components, should also be documented.
Installation Qualification (IQ) Protocol	The IQ protocol confirms that each critical component, or representative sample of a common class of components, has been procured, installed and connected according to the installation instructions.
Operational Qualification (OQ) Protocol	The OQ protocol confirms that the correctly installed component operates according to requirements and includes testing of the operating system if this is necessary for the proper functioning of the hardware.
Traceability Matrix	The traceability matrix enables tests and test results to be correlated and traced back to their controlling specification.
Test Report	The test report is a summary of testing completed and make mention of any deviations, test failures or constraints and corrections. The test report may be combined with the IQ and OQ protocols.
Qualification Report	The results of the qualification work must be summarised and reported, either as a separate document, or combined with the change control documentation, for example.

