- The URS is to be developed / prepared by the project team coordinating the project and approved by the end user, QA and Validation.

It is the responsibility of the project leader to ensure the document is prepared as per these guidelines.

The system owner is responsible to ensure that the system is validated.

The Validation / Technical Services group is responsible for validating the computerized system and coordinating validation support.

All FRS documents are to be approved by the user group and Quality Assurance representatives.

4.0 PROCEDURE

5.1 URS Development Guidelines

The following guidelines are to be followed to develop the required URS document:

5.1.1 The document must be issued a unique document number and must be version controlled.

5.1.2 The URS must express the required user requirements and not the methods or solutions to implement the required functions.

5.1.3 The URS should refer to and interpret the relevant GxP regulations. This is to assist the project team and suppliers to deliver a compliant system meeting GxP requirements. Each requirement statement is to be uniquely referenced to aid traceability.

5.1.4 Requirements should not be duplicated or contradicted throughout the document.

5.1.5 Each requirement should be testable or verifiable in some way.
Note: The URS requirement should be linked to the final PQ (Performance Qualification) protocol for the system, which tests the system in its operating environment, including the associated procedures.

5.1.6 The URS should distinguish between essential requirements (musts) and non essential requirements (wants). These requirements should be clear priorities within the URS document.

5.1.7 The URS should refer to and interpret the relevant GxP regulations. This is to assist the project team and suppliers to deliver a compliant system meeting GxP requirements.

5.2 URS Document Content

The URS must include each of the sections and sub sections below. If no requirements have been specified then section should include the statement “Not applicable to this URS” and include a brief reason for this omission.

5.2.1 **Cover Sheet**
The cover of the document needs to include:

- Layout: the physical layout of the plant or other work place may have an impact on the system, such as long distance links or space limitations.

- Physical conditions (e.g. dirty, dusty, or clean environment).

5.2.4.4 **Constraints**

This sub-section must define the constraints on the specification of the system. It needs to cover the following:

- Timescales and milestones: as appropriate.

- Compatibility: this shall take into account any existing systems or hardware and any user company strategy or policy.

- Availability: this will state reliability requirements and define any maximum allowable periods for maintenance or other downtime.

- Procedural constraints: such as statutory obligations, legal issues, working methods and user skill levels.

- Maintenance: including ease of maintenance, expansion capability, likely enhancements, expected lifetime and long term support.

5.2.5 **Life Cycle**

This Section is to define any requirements concerning the validation life cycle. It needs to contain the following sub-sections:

5.2.5.1 Development (e.g. minimum standards to be met by supplier's test methodology, procedures for project management and Quality Assurance, mandatory design methods).

5.2.5.2 Testing (e.g. special testing requirements, test data, load testing and required simulations).

5.2.5.3 Delivery: this sub-section shall define what deliverables are required. It should address the following:

5.2.5.4 How deliverable items are to be identified.

5.2.5.5 In what form deliverables are to be supplied (e.g. format and media).

5.2.5.6 Documents: what the supplier is expected to deliver (e.g. functional specification, testing specifications).

5.2.5.7 Data to be prepared or converted.

5.2.5.8 Tools.

5.2.5.9 Training courses.

- Functions which are configurable and any limits within which the configuration can take place.

- Traceability to specific requirements in the User Requirements Specification.

5.4.4.2 Data

This Section needs to define the data on which the system is to work. The following aspects need to be addressed:

- Definition: the data to be defined in a hierarchical manner with complex objects being built up from simpler objects (e.g. files of records; complex types defined in terms of simple types). Critical parameters should be highlighted.

- Access (e.g. which sub-systems need read or write access to each data item, access method, speed and update time, read / write interlocks).

- Data capacity, retention time, and details of data archiving.

- Data integrity and security.

5.4.4.3 Interfaces Section

This Section is to define any system interfaces, defining how the system or sub-system interact, what they each provide, and what they require. For GxP regulated systems, the security of the interfaces is of critical importance. This Section needs to contain the following sub-sections:

- Interface with users: this is to be defined in terms of roles; e.g. operator, administrator, clerk, or system manager. Topics to consider include facilities available, types of peripherals, general format of display and reports, error handling and reporting, and security.

- Interface with equipment, such as sensors and plant equipment.

- Interface with other systems: this needs to cover the nature of the interaction and the methods and rules governing the interaction.

Topics to consider for both equipment and system interfaces are listed below:

- Data transmitted and received

- Data type, format, ranges, and meaning of values

- Timing

