

Standard Operating Procedure

Title: Equipment Specification and Qualification

This standard document covers Environmental, Health and Safety (EHS) requirements for the purchase, fabrication, installation, operation and modification of plant and equipment. It converts to a EHS Verification Report using hidden text.

2.11. Purchase Agreement

2.11.1. The commercial conditions that should be specified depend on the nature of the procurement. The factors to take into account include size of purchase cost, contract arrangement, e.g. fixed price contract, time and materials or design and construct contract, intellectual rights ownership, etc. The Supply Chain Procurement Manager should be included in the assessment of the conditions that are appropriate.

2.11.2. One of the ways that the commercial conditions can be covered is by the inclusion of a Purchase Agreement as part of the Order.

2.11.3. The Purchase Agreement covers terms of payment, timetable, performance warranties, intellectual property rights, confidentiality agreement, termination conditions. The Purchase Agreement should form part of the Tender documents so that the supplier can review it before they submit their tender.

3. Managing Supplier s Documentation

3.1. The normal expectation of this procedure is that suppliers will respond to buyer's requirements document with their own specifications and proposals (including those for testing). These should address the requirements outlined in the documents and identify in more detail how they will satisfy these requirements in the equipment the supplier will develop, and by the processes the supplier will operate to manage this development. The Project Manager is to ensure that each of the supplier's proposals are reviewed and approved by relevant personnel, prior to the supplier undertaking the proposed works. Relevant stakeholders for this review may include:

- Project Engineers, for mapping the sufficiency of the supplier's proposal against the in-house requirements.
- Electrical Engineers, for assessing Control Hardware and Software proposals.
- Quality Assurance Officers, for identifying areas of GMP impact and assessing Quality Management System procedures.
- Validation personnel, for evaluating Test Methods and Results.

3.2. Each reviewer should be clear as to his or her role within the review process and comfortable they have the necessary understanding to perform this task. Reviewers should mark-up documents with observations and record their name, date and signature on completion of the review.

3.3. Supplier documents are likely to require revision through the project. The Project Manager should ensure that each version is released in a controlled manner; identified with a unique version number and document status, (e.g. "for construction", etc.).

3.4. The supplier should have a procedure that identifies when version updates will be required and how they will be initiated. This would ideally include the production of "as-built" versions at completion of the project. A copy of each approved version is to be retained by the Project Manager, to demonstrate control of the development 'life-cycle'. Electronic copies of final versions should be filed.

3.5. Test documents, generated by the supplier or buyer's project teams, may be used to complement Validation documents and may limit the need for additional Validation testing. Such an approach requires the prior agreement of the Validation Manager and will mean that these test documents must meet the standards for Validation evidence.