documents it is not necessary to generate a separate document.

3.2.5 Critical Items

Items which have been assessed to impact on product quality, safety and efficacy or otherwise present an unacceptable hazard if the equipment or its protective system should fail, and where failure or malfunction could lead to danger to life, significant harm to any person or to the environment.

3.2.6 Engineering (may also be known as maintenance management)

A dedicated Engineering department responsible for establishing and/or maintaining a system of planned preventative maintenance and for delivering or coordinating the required calibration and maintenance activities. Alternatively, depending upon organization structure these responsibilities may be carried by appropriately nominated persons within the 'line' function rather than by a dedicated engineering function.

3.2.7 FMEA

Failure modes effect analysis.

3.2.8 Maintenance (EN 13306)

Combination of all technical, administrative and managerial actions during the life cycle of an item intended to retain it in, or restore it to, a state in which it can perform the required function (EN 13306, 2.1).

3.2.9 National standard (ISPE: GAMP)

Standard recognized by a national decision to serve, in a county, as the basis for assigning values to other standards of the quantity concerned.

3.2.10 Process Owner

A nominated person with responsibility for the operation of a specified process.

3.2.11 RCM

Reliability centered maintenance.

3.2.12 Test equipment (ISPE: GAMP)

Instrument or device used to calibrate other instruments, which is traceable back to accepted national standards. The test equipment should have precision, accuracy, and repeatability that is higher than that of the instrument being calibrated.

3.2.13 Traceability (ISPE: GAMP)

Property of the result of a measurement or the value of a standard whereby it can

5.6 Item Labeling and status

Inventory equipment items must be uniquely identified or labeled to facilitate the execution of the calibration and maintenance program. Where appropriate this may require the labeling of constituent parts of a unit (for example multiple thermocouples within an autoclave may need to be uniquely identifiable to prevent ambiguity).

Procedures must require that the status of the item be easily verified before its use. The use of stickers indicating the status/expiry date or required re-calibration date is acceptable. Alternative systems (records, databases, status boards) are acceptable as

long as they are designed to ensure that items which are 'out of calibration' are easily identified to prevent use. Integrity sealing of critical instruments should be performed where appropriate. Items which require repair or are 'out of service' awaiting scheduled maintenance should be clearly identified to prevent their use.

5.7 Use of Contractors for calibration and maintenance

Local procedures will define the approach to management of calibration and maintenance performed by external contractors and calibration service suppliers, including requirements for contracts/service level agreements/shared SOPs. This will include a list of company approved providers, specified means of assessing the competence of the provider and the scheduling of site calibration checks pre and post transportation to an external calibration lab (eg for calibrations requiring adjustment of units which are sealed by the manufacturer).

Procedures will also describe the provision of calibration and maintenance records or certificates by external contractors. This will include review of work performed to verify that it has been completed to an acceptable standard, and approval by the company indicating that the appropriate acceptance criteria have been met.

5.8 Calibration and maintenance records

Records will be kept of all calibration and maintenance performed including both scheduled work and also that arising from breakdown. Information will be sufficiently detailed to enable the implications of GMP non- conformances to be investigated (e.g Traceability of batches involved etc).

Local procedures must ensure that the current versions of relevant reference documents are used.

The calibration and maintenance records shall include the following information:

- unique identity of the item
- the date the calibration/adjustment/maintenance was performed.
- as-found readings, status or performance
- the As-left readings, status or performance
- identification of maintenance, spare parts or test equipment and standards used
- identification of the procedure used
- signature of person performing calibration/maintenance following any

