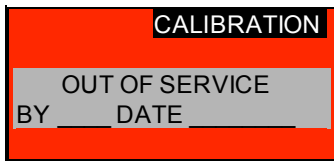


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Refer also to attachments, 2 available labels

### 5.17 Review, Archiving and Auditing

Review and archiving of calibration records and support data are to be carried out by the Calibration, Metrologist, or other qualified Maintenance associates. Calibration documents are to be completed, accurate, traceable, and completed on time. The Quality Assurance approves the calibration records.

Archiving of documents is carried out centralized under the responsibility of the calibration department.

The calibration program will be audited by Quality Assurance at least once every 12 months for accuracy completeness, and compliance to written procedures in the frame of the internal self-inspection program.

### 5.17 Change of Calibration Frequency

Frequency of calibration will be re-evaluated using stability, purpose, and degree of use as the primary criteria for a change in calibration frequency. Calibration frequencies may be adjusted based on the results of previous calibrations, provided such actions will not adversely effect the accuracy of the system being calibrated. This does not apply to calibration standards. A decision to change the calibration interval must be related to responsible management and be approved by the Quality Assurance department.

## 6. Definitions

*Accuracy:* The degree to which a measured value agrees with the true value, agreement of measured value to a standard.

*Calibration:* Comparison between two instruments or devices, one of which is a standard of known accuracy, to detect and to correlate or adjust any variation in the accuracy of the instrument being calibrated.

*Calibration Schedule:* A report that provides advance notice sufficient to schedule and perform calibrations prior to the next due date.

*Critical Instruments:* Those instruments whose measurements cause decisions on processes or systems which affect or determine the efficacy, purity, quality, or safety of product.

*Frequency of Calibration:* A calibration frequency/interval will be specified in the individual calibration document based on stability, purpose and degree of usage. The duration of time of which a calibration is considered to be acceptable.

*Measuring and Test Equipment:* Devices used to perform a calibration from which no measurements are directly recorded.

*NIST:* National Institute of Standards and Technology.