



MARLOW OFFSHORE GERMANY GMBH & CO. KG

ISO 9001:2015

Control of Calibrated Equipment

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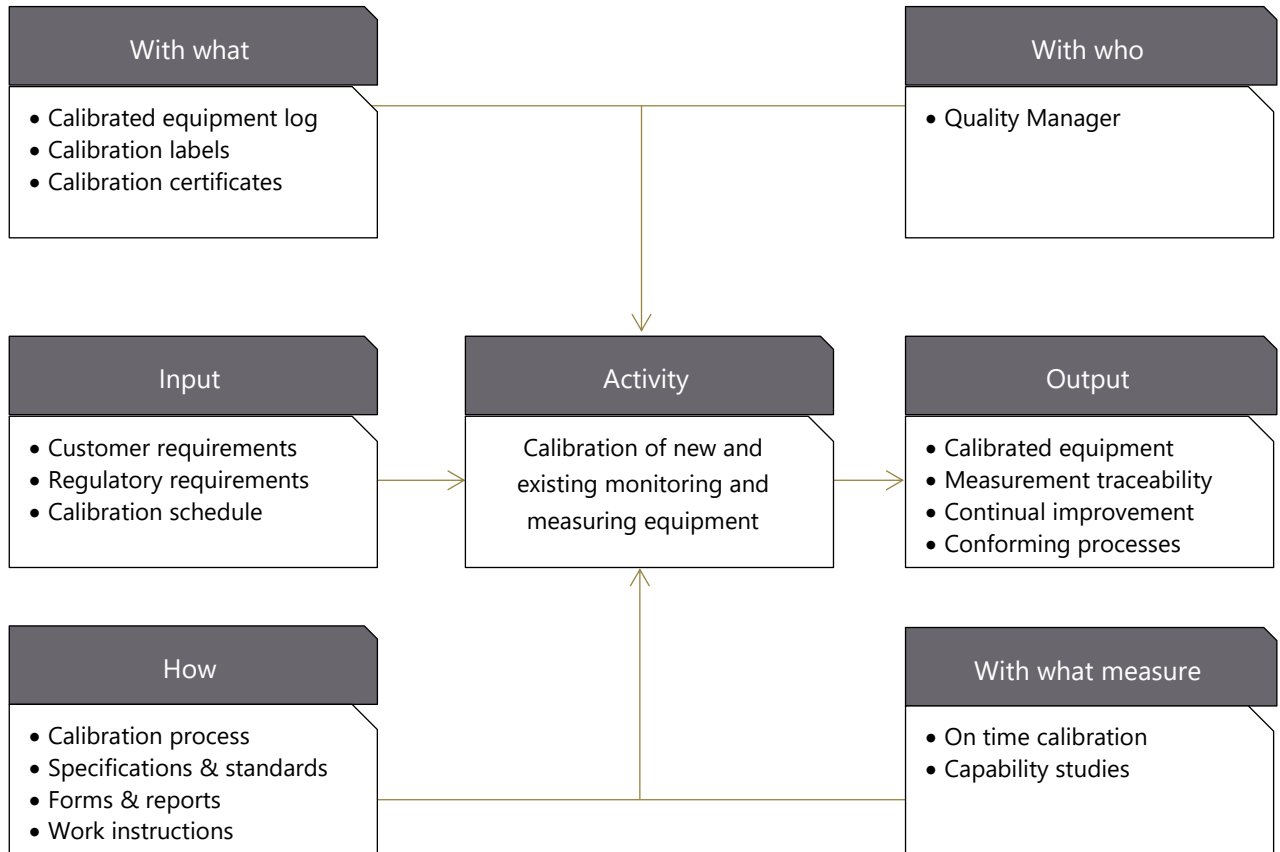
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1 Control of Calibrated Equipment

1.1 Introduction & Purpose

The purpose of this procedure is to define Marlow Offshore Germany GmbH & Co. KG responsibilities and activities in order to ensure that all inspection and test equipment used for product, service and process verification is controlled and calibrated against nationally traceable standards at specified intervals and that such devices are available to ensure continuity of measurement capability.

1.1.1 Process Activity Map



1.1.2 References

Standard	Title	Description
BS EN ISO 9000:2015	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9001:2015	Quality management systems	Requirements
BS EN ISO 9004:2000	Quality management systems	Guidelines for performance improvements
BS EN ISO 19011:2011	Auditing management systems	Guidelines for auditing

1.1.3 Terms & Definitions

Term	ISO 9000:2015 Definition
Measuring equipment	Reference material necessary to realize a measurement process (3.11.5)
Metrological characteristic	characteristic (3.10.1) which can influence the results of measurement (3.11.4)
Metrological confirmation	Operations to ensure that measuring equipment (3.11.6) conforms to the requirements

1.2 Application & Scope

This procedure applies to all inspection and test equipment required for product and process verification. There must be confidence that equipment used to inspect or measure attributes of the design is calibrated to an acceptable level of accuracy.

The Quality Manager ensures that any devices which do not meet these criteria are isolated from use and recalibrated before being used. Devices used to calibrate equipment are traceable to a national or International standard unit of measurement. Each measurement instrument is traceable through its own calibration record which contains:

- Identification number;
- Manufacturer and model;
- Frequency of calibration;
- Reference standards used;
- Validation certificates and calibration findings;
- Details of actions taken in case of unsatisfactory results.

1.3 Responsibilities

The Quality Manager is required to:

- Select suitable equipment to perform the required measurements with accuracy and precision;
- Extend the control of inspection and test equipment to all approved suppliers where applicable;
- Ensure inspection and test equipment cannot be used if they are not registered and calibrated;
- Ensure inspection and test equipment is calibrated in a suitable environment;
- Control all measurement, calibration and maintenance activities.

All employees & Process Owners are required to:

- Check that inspection and test equipment is not damaged and is fit for purpose;
- Check the calibration status of inspection and test equipment prior to use.

1.4 Controlling Calibrated Equipment

1.1.1 Existing Devices

These steps are to be followed to control the calibration of existing in-house devices:

- Remove device from use before calibration due date;
- Determine whether calibration is to be done in-house or by an external supplier;
- Verify need for maintenance and undertake maintenance where required;
- Update device details on the controlled equipment log;
- Verify device performance and calibrate;
- Affix new calibration label;
- Update the calibration log;
- Issue device for use.

1.1.2 New Devices

These steps are to be followed to control the registering and calibration verification new devices:

- Assign device identification/asset number;
- Add device details to the controlled equipment log;
- Determine calibration frequency;
- Determine next calibration date;
- Verify device performance and calibrate;
- Affix **Calibration Label**;
- Update the device details to the calibration log;
- Issue device for use.

1.1.3 Calibration Frequency

Calibration frequency is determined by comparing the performance of the measuring equipment to:

- Equipment purpose;
- Manufacturer's specifications;
- Degree of usage;
- Equipment type;
- Stability/reliability.

1.1.4 Calibration Due Date

After the calibration frequency has been established; the specific calibration due date is established and documented.

- Attach the calibration label to the equipment;
- Update the calibration log;
- Ensure equipment is re-calibrated by the due date.

1.1.5 Calibration Label

Upon completion of calibration, satisfactory equipment is tagged with a calibration label indicating:

- Calibration date;
- Due date of the next inspection;
- Initials of the person performing the calibration.

For inspection and test equipment too small to affix a sticker, an alternative method of labelling will be used:

- String tag on equipment;
- Label affixed to container;
- Notation on calibration log.

1.1.6 Outsourced Calibration

A commercial laboratory will be used for calibration and repair that cannot be accomplished in-house.

- The calibration facility must comply with a nationally or internationally recognized calibration standards;
- The calibration facility will be evaluated by the Quality Manager;
- Calibration certificates will be required.

1.1.7 Software

Test software developed in house or purchased from commercial suppliers is validated before it is used for product verification.

- Standard software purchased from commercial sources is ordered with validation certificates;
- Software developed in-house is validated and approved in accordance with customer requirements;
- Software is re-validated at prescribed intervals or whenever a change from the original release is introduced.

1.1.8 Non-conforming Equipment

If confirmed that inspection and test equipment is out of calibration, the Quality Manager is required to:

- Remove suspect device from service;
- Investigate the validity of measurements for which the equipment was previously used;
- Assess the acceptance status of all affected products;
- Select appropriate corrective actions to mitigate the subsequent non-conforming product;
- Immediately inform the customer if the product has been shipped;
- Re-calibrate any inspection or test equipment that appears to give inaccurate readings.

1.1.9 Review

All monitoring and measurement equipment performance data is reviewed by the Quality Manager.

1.5 Forms & Records

All documentation and records generated by calibration process are retained and managed in accordance with the Control of Documented Information procedure.

Title & Description
Controlled Equipment Log
Calibration Log

1.6 Calibrated Equipment Process Map

