

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Calibration of equipment used in clinical trials
Date: Wednesday, March 11, 2020 11:30:40 AM
Attachments: [REDACTED]

Good morning -

Thank you for your email. FDA regulations regarding calibration can be found at 820.72 (Quality System Regulation). [CFR - Code of Federal Regulations Title 21](#) Please note - this email site is strictly for good clinical practices queries. You may search FDA's website for quality system questions.

You may also consult the Center for Devices (CDRH) at DICE@fda.hhs.gov

Kind regards,

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [REDACTED]
Sent: Wednesday, March 11, 2020 10:52 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Calibration of equipment used in clinical trials

Sir,

- 1.) If a clinical research site ensures yearly calibration of equipment (e.g. Weighing scale, centrifuges) is performed by an external vendor, and documented in a log stating equipment name, serial # and date of calibration - is this acceptable ? as there would be no calibration certificate as such except the log.
- 2.) If only a sticker is put on the instrument (which shows calibration status, date of calibration, and next calibration date), is this acceptable? as there are no calibration certificate available or given.

Thank you

