

## Fluke Europe Policy Statement Regarding Reasonable Audit Access

This policy applies to Fluke ISO 9001 registered and ISO/IEC 17025 Accredited sites in Europe. The Fluke calibration laboratories Quality Management System (QMS) is based on the international standard ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." Laboratories have been assessed for accreditation by the different accrediting bodies.

Fluke Corporation is ISO 9001 registered through Dekra and BSI in Europe. Our Quality Management System is based on the ISO 9001 standard and all the principles of ISO 9001 are in place. Fluke Corporation's philosophy, management, and personnel fully support quality concepts.

Calibration Laboratory	ISO 9001 (Dekra/BSI)	ISO/IEC 17025 (DAkkS/RVA/UKAS)
Certificates and Scopes of Accreditation: <a href="https://eu.flukecal.com/support/accreditations">https://eu.flukecal.com/support/accreditations</a>		
Fluke Deutschland GmbH. –	Dekra Cert. No:	DAkks Lab Code:
Cologne, North Rhine-Westphalia, DE	2193682	D-K-15123-01-00
ISO 17025 Contact:	Michel Bremmers   r	nichel.bremmers@fluke.com   +4-9-221-947-7454
ISO 9001 Contact	Olaf Klaube   <u>o</u>	o.klaube@fluke.com   +4-97-684-800-9415
Fluke Process Instruments GmbH	Dekra Cert. No:	DAkks Lab Code:
Blankenburger, Berlin, DE	51199781/7	D-K-K18085-01-00
ISO 17025 Contact:	Juergen Filzhuth   jue	ergen.filzhuth@fluke.com   +4-93-047-800-8801
ISO 9001 Contact	Martin Berlin   martin.b	erlin@fluke.com   +4-93-047-800-8563
Fluke Nederland B.V.	Dekra Cert. No:	RVA Lab Code:
Eindhoven, N.B., Netherlands	89221	K 013
ISO 17025 Contact:	Ronald Dekkers	ronald.dekkers@fluke.com   +3-14-026-75723
ISO 9001 Contact	Olaf Klaube   <u>o</u>	o.klaube@fluke.com   +4-97-684-800-9415
Fluke Precision Measurement Ltd.	BSI Cert. No	UKAS Lab Code:
Norwich, Norfolk, UK	FM29700	0183
ISO 17025 Contact:	Paul Bunyan   p	aul.bunyan@fluke.com
ISO 9001 Contact:	Keith Breeze   ke	eith.breeze@fluke.com   +44-160-325-6672
Fluke (UK) Limited	N1 / A	UKAS Lab Code:
Norwich, Norfolk, UK	N/A	0775
ISO 17025 Contact:	Tom Harper   t	com.harper@fluke.com   +3-140-267-5189
Fluke (UK) Limited – Comark	N/A	UKAS Lab Code:
Northampton, UK		0451
ISO 17025 Contact:	Michael Hall   <u>n</u>	nichael.hall@fluke.com   +44-160-459-4202

## **Quality Management System Audits**

As a supplier of calibration and test equipment to thousands of organizations around the world, it becomes important that we manage the many requests we receive for these audits. We ask you, therefore, to please note the following regarding on-site audits:

- 1. A signed nondisclosure agreement (NDA) must be on file with Fluke Legal prior to scheduling any onsite audits.
- 2. The audit must be scheduled with Fluke Corporation through the applicable laboratory quality manager at least thirty days in advance. The date and time will be at the convenience of both companies.
- 3. The auditor must provide to Fluke Corporation information concerning the standard to be used in the audit. (Having an advance copy of any survey sheets assists in preparing the correct documents for the audit and saves time for both companies).
- 4. If the end-user of the equipment performs the audit, the audit may last up to one-half day (4 hours, one person) without charge. Any audit requiring more than one-half day or additional auditors must be approved by Fluke Corporation in writing and may be subject to an additional per person fee of up to €1,300 EUR per day.
- 5. Due to strict compliance with Federal export laws, Fluke Corporation is required to restrict access to certain areas and technologies.

## **Witness of Calibration Activities**

- 1. A signed nondisclosure agreement (NDA) must be on file with Fluke Legal prior to scheduling any onsite visits.
- 2. The activity must be scheduled with Fluke Corporation at least thirty days in advance. The date and time will be at the convenience of both companies.
- 3. Witnessing activities must be approved by Fluke Corporation in writing and may be subject to an additional per person fee of up to €1,300 EUR per day.
- 4. Due to strict compliance with Federal export laws, Fluke Corporation is required to restrict access to certain areas and technologies.



## **Traceability Paper Audits**

- 1. The International Vocabulary of Basic and General Terms, in Metrology (VIM), defines metrological traceability as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".
- 2. ISO/IEC 17025 notes that a calibration certificate accredited under ISO/IEC 17025 and bearing the accreditation body symbol is sufficient evidence of traceability of the calibration data reported.
- 3. Many government regulations, commercial contracts, and accrediting bodies require regulated or accredited organizations or contractors to verify that the measurements they make are "traceable". To support the claim of traceability, records are kept which document that measuring equipment has been calibrated by laboratories or testing facilities whose measurements are part of this "unbroken chain."
- 4. The only true and absolute method of "proving" an unbroken chain of traceability is to physically audit and view each calibration event's record for every instrument in the chain of traceability until ending with the actual viewing of the certificates which relates to the SI. This process is very labor intensive.
- 5. To maintain ISO registration and ISO/IEC 17025 accreditation, assessments are performed by recognized accrediting bodies. It is the responsibility of assessors to collect and evaluate objective evidence of traceability during the audit process.
- 6. Our calibration documentation provided to your organization contains appropriate statements of traceability. If your organization still requires a traceability paper audit to be performed such activities may be subject to an hourly rate up to €130 EUR per hour, with a 1-hour minimum charge. Fluke will provide documentation that sufficiently demonstrates traceability while preserving confidentiality requirements.

Sincerely,

Jeff C. Gust

**Chief Corporate Metrologist** 

FCM 7001.2 Revision: 001