

CHECKLIST · MEDICAL LABORATORIES

What UKAS assessors look for on temperature, under ISO 15189:2022

A summary for lab quality managers. It isn't UKAS guidance: your assessor's view is the one that counts.

1 Know every unit

ISO 15189:2022, 6.3 Facilities and environmental conditions; 6.6 Reagents and consumables

- ☐ List every temperature-dependent unit: fridges, freezers, incubators, water baths, the rooms where analysers and reagents sit, and sample transport.
- ☐ Record each unit's acceptable range, taken from the manufacturer's instructions or the method.
- ☐ Give each unit a unique ID that matches its records and its sensor.

2 Record and review

ISO 15189:2022, 6.3

- ☐ Monitor each unit at a defined frequency. Continuous monitoring covers nights and weekends.
- ☐ Keep the records retrievable for your retention period.
- ☐ Show that someone reviewed the records and signed them off, with the reviewer and the date.

3 Alarms and response

ISO 15189:2022, 6.3; 8.7 Nonconformities and corrective actions

- ☐ Set alarm limits for each unit, and document who is alerted, including out of hours.
- ☐ Record every alarm: the time, who responded and what they did.
- ☐ Treat an excursion as a nonconformity. Assess its effect on samples and reagents, and record the corrective action.
- ☐ Test the alarms, and keep the test record.

4 Calibration and traceability

ISO 15189:2022, 6.5 Equipment calibration and metrological traceability

- ☐ Calibrate the monitoring sensors with traceability to national standards. A certificate from a UKAS-accredited ISO/IEC 17025 calibration laboratory shows this.
- ☐ Match each certificate to the sensor's serial number, and check that it's in date.
- ☐ Track due dates, and record what you did when a sensor was found out of tolerance.

5 Measurement uncertainty

ISO 15189:2022, 7.3.4; UKAS LAB 48

- ☐ Know the uncertainty of each monitoring sensor. It's on the calibration certificate.
- ☐ Document your decision rule. For example, set the alarm inside the limit by the uncertainty, so a +8 °C limit alarms earlier.
[Our guide works through an example.](#)

6 Walk-in rooms and large stores

- ☐ ISO 15189 doesn't name mapping. For a walk-in cold room, a mapping study is the usual evidence that the probe represents the whole space.

7 Blood storage

- ☐ Blood and blood components also fall under the [Blood Safety and Quality Regulations 2005](#), which the MHRA inspects.

Have ready for the assessor

- the unit list with its ranges;
- 12 months of records, with the review sign-offs;
- the alarm log and responses;
- the alarm tests;
- calibration certificates matched to the sensors;
- the decision rule.

Sources

ISO 15189:2022 [iso.org/standard/76677.html](https://www.iso.org/standard/76677.html)

UKAS: Medical laboratory accreditation [ukas.com/accreditation/standards/medical-laboratory-accreditation](https://www.ukas.com/accreditation/standards/medical-laboratory-accreditation)

UKAS LAB 48: Decision rules and statements of conformity [ukas.com](https://www.ukas.com) (PDF)

Blood Safety and Quality Regulations 2005 [legislation.gov.uk/uksi/2005/50](https://www.legislation.gov.uk/uksi/2005/50)

This checklist summarises the published documents. It is not an audit or legal advice. "12 months of records" is a sensible preparation window, not a requirement of the standard.

NEXT STEP

Want us to go through it with your records?

A 20-minute call with a JTF specialist, and a written report on where you stand.

[Book a 20-minute check](#)

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