

20-MINUTE COMPLIANCE CHECK

# Temperature compliance report

Harrowfield General Hospital (example)

ISO 15189

BSQR

HTA

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**PREPARED FOR**

Dr Helen Achterberg  
Harrowfield General Hospital (example)

**SCOPE**

Pathology laboratory, Blood bank and ward blood fridges,  
Mortuary

**PREPARED BY**

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JTF Wireless · 19 October 2026

**BASIS**

What you told us on the call. We have not inspected your  
records.

SUMMARY

# Your theatre blood fridge and mortuary need clearer out-of-hours coverage and records.

55%

overall, across 20 questions answered

12

gaps to close

3

regimes covered by one set of answers

Your overall score is 55%. Core processes are in place, but the theatre blood fridge has a local-only alarm, while the mortuary has no out-of-hours call-out. These are immediate questions to resolve ahead of UKAS surveillance.

The gaps span the blood bank, pathology lab and mortuary. Switchboard calls the on-call biomedical scientist, but it is worth checking which alerts reach that route and what happens if a call is missed. Closing those gaps and keeping a continuous mortuary record would make it easier to respond promptly and establish what happened overnight or at weekends.

## Your top three risks

- 1. Theatre fridge alerts stay local Not met
- 2. Out-of-hours response differs by department Not met
- 3. Mortuary records miss unattended periods Not met

YOUR SCORE

By section

| SECTION                      |                        | SCORE | MET | PARTLY | NOT MET | NOT KNOWN |
|------------------------------|------------------------|-------|-----|--------|---------|-----------|
| Records and review           | <div><div></div></div> | 30%   | 0   | 3      | 1       | 1         |
| Alarms and out of hours      | <div><div></div></div> | 36%   | 2   | 1      | 4       | 0         |
| Calibration and traceability | <div><div></div></div> | 75%   | 1   | 1      | 0       | 0         |
| Excursions and CAPA          | <div><div></div></div> | 100%  | 2   | 0      | 0       | 0         |
| Data integrity               | <div><div></div></div> | 50%   | 0   | 1      | 0       | 0         |
| Training                     | <div><div></div></div> | 100%  | 1   | 0      | 0       | 0         |
| Documentation                | <div><div></div></div> | 100%  | 2   | 0      | 0       | 0         |

By regime

Each answer counts for every regime it applies to, so you were asked each question once.

| REGIME                                                           |                        | SCORE | QUESTIONS |
|------------------------------------------------------------------|------------------------|-------|-----------|
| ISO 15189<br>Medical laboratories (UKAS ISO 15189:2022)          | <div><div></div></div> | 71%   | 17        |
| BSQR<br>Blood and blood components (hospital blood bank)         | <div><div></div></div> | 77%   | 15        |
| HTA<br>Human tissue and cells (mortuary, tissue banks, research) | <div><div></div></div> | 45%   | 10        |

## Why they matter

### Theatre fridge alerts stay local Not met

The theatre blood fridge has a local alarm only, although the cold chain to the ward remains part of the blood bank's responsibility. Check how its alert and response compare with the main blood bank, especially when the theatre is unstaffed.

BSQR Schedule, Part 4, 1.1 and 2: Storage temperatures per component; transport maintaining integrity.  
BSQR Regulation 9(1)(h): Storage and distribution meet Part 4.

### Out-of-hours response differs by department Not met

Switchboard calls the on-call biomedical scientist, but the mortuary has no out-of-hours call-out. You need to know which alerts reach someone, who takes over if they are not acknowledged, and whether the mortuary has any response route.

Mortuary: Not met, No out-of-hours alarm

HTA Post-mortem standard PFE2(e): HTA guidance: units in areas not permanently staffed should have a remote alarm to alert staff out of hours.

### Mortuary records miss unattended periods Not met

Mortuary min/max readings are taken on weekdays only, so an overnight or weekend change may not be discovered until the next check. Without a continuous record, you cannot establish how long a unit was out of range when deciding what action to take.

Mortuary: Not met, Min/max read on weekdays only

HTA Post-mortem standard PFE2(f): Fridge and freezer temperatures monitored regularly, so trends and the extent of any variation can be seen.

## COVERAGE

# Each answer, under every regime it counts for

| QUESTION                                                                                                                                                                             | ISO 15189 | BSQR      | HTA       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-----------|-----------|
| How are temperatures recorded: continuously, including nights and weekends, or at manual checks only?                                                                                | Met       | Met       | Not met   |
| Is every temperature-controlled unit and area listed, with its acceptable range and an ID that matches its sensor?                                                                   | Partly    | Partly    | Partly    |
| Are the rooms where analysers, reagents and samples sit monitored, not just the fridges?                                                                                             | Partly    | .         | .         |
| How long are temperature records kept, is that the longest period any rule or customer agreement asks for, and how quickly can you pull up a given week?                             | Not known | Not known | Not known |
| Are the records reviewed and signed off at a set frequency, showing who reviewed them, when, and whether any issue was found?                                                        | Partly    | Partly    | Partly    |
| Does every unit have alarm limits set just inside its range, so a named person is told before the stock goes out?                                                                    | Met       | Met       | Met       |
| Who is alerted out of hours, how, and what happens if they do not acknowledge in time?                                                                                               | Met       | Met       | Not met   |
| For each alarm, is there a record of who acknowledged it, when, and what they did?                                                                                                   | Met       | Met       | Met       |
| Are the alarms tested end to end, from the sensor at its set points to the person on call and the escalation, on a set cycle and after changes, with each test recorded?             | Partly    | .         | Partly    |
| Do the alarm limits allow for each sensor's measurement uncertainty, taken from its calibration certificate, under a documented decision rule?                                       | Not met   | .         | .         |
| Is every monitoring sensor calibrated at least yearly by an accredited service, traceable to national standards, across the range it is used over and on the whole measuring system? | Met       | Met       | .         |
| Is each calibration certificate matched to its sensor's serial number, reviewed against your own acceptance criteria and signed off by you, with due dates tracked?                  | Partly    | .         | .         |
| When a calibration result is outside your acceptance criterion, is the effect on readings since the last good calibration assessed and recorded?                                     | Not asked | .         | .         |
| For each excursion, is the impact assessed from the start, peak and duration, and the decision on the stock recorded by the right person with the evidence they used?                | Met       | Met       | .         |

|                                                                                                                                                      |           |           |           |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-----------|-----------|
| Is there a written procedure for an excursion: what to do first, who is told, who decides about the stock, what to record?                           | Met       | Met       | Met       |
| Are causes trended and corrective and preventive actions (CAPA) tracked to close, so the same failure does not repeat?                               | Not asked | .         | .         |
| If a unit fails or the power goes, where does the stock go, when is it moved, and is the back-up capacity agreed in advance?                         | .         | .         | Not asked |
| Are storage conditions held and recorded on every delivery, with calibrated loggers, and are transport excursions reported and investigated?         | .         | Not asked | .         |
| Does each person have their own login, can only authorised people change data or settings, and does the system keep an audit trail that is reviewed? | Not asked | .         | .         |
| Has the monitoring system been validated for its use, and is there a written description of it?                                                      | Partly    | Partly    | .         |
| Are the people who record readings and respond to alarms trained for it, with the training recorded?                                                 | Met       | Met       | .         |
| Are monitoring, alarm, calibration and excursion procedures written down, version-controlled and current?                                            | Met       | Met       | .         |
| Are satellite and ward blood fridges under the same monitoring, alarms and response as the main blood bank?                                          | .         | Not met   | .         |
| Are mortuary fridges and tissue freezers (including liquid nitrogen) monitored, alarmed out of hours and acted on?                                   | .         | .         | Not met   |
| Can every blood unit be traced from the bank to its final destination, including ward and theatre fridges, with its fate confirmed?                  | .         | Met       | .         |
| Is the HTA licence current for the storage you do, and is the Designated Individual aware of how storage is monitored?                               | .         | .         | Not asked |

# What the rules ask

| GAP                                                                                                                                                                                                                 | ANSWER    | REGULATION AND SOURCE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Are satellite and ward blood fridges under the same monitoring, alarms and response as the main blood bank?<br>You said: Theatre fridge has a local alarm only                                                      | Not met   | <b>BSQR Schedule, Part 4, 1.1 and 2:</b> Storage temperatures per component; transport maintaining integrity. <a href="#">Source</a><br><b>BSQR Regulation 9(1)(h):</b> Storage and distribution meet Part 4. <a href="#">Source</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Who is alerted out of hours, how, and what happens if they do not acknowledge in time?<br>You said: Switchboard calls the on-call biomedical scientist                                                              | Not met   | <b>HTA Post-mortem standard PFE2(e):</b> HTA guidance: units in areas not permanently staffed should have a remote alarm to alert staff out of hours. <a href="#">Source</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| How are temperatures recorded: continuously, including nights and weekends, or at manual checks only?                                                                                                               | Not met   | <b>HTA Post-mortem standard PFE2(f):</b> Fridge and freezer temperatures monitored regularly, so trends and the extent of any variation can be seen. <a href="#">Source</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Are mortuary fridges and tissue freezers (including liquid nitrogen) monitored, alarmed out of hours and acted on?<br>You said: Body store and freezer not alarmed out of hours                                     | Not met   | <b>HTA Post-mortem standard PFE2(a), (e), (f):</b> Bodies refrigerated at about 4 °C (freezers about -20 °C); units alarmed, alarms tested and temperatures monitored. <a href="#">Source</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Do the alarm limits allow for each sensor's measurement uncertainty, taken from its calibration certificate, under a documented decision rule?<br>You said: Alarm set at exactly 8.0 °C                             | Not met   | <b>ISO 15189 7.3.4 and UKAS LAB 48:</b> Measurement uncertainty evaluated; decision rules documented. <a href="#">Source</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Is every temperature-controlled unit and area listed, with its acceptable range and an ID that matches its sensor?<br>You said: Lab list current; mortuary units missing                                            | Partly    | <b>ISO 15189 6.3:</b> Facilities and environmental conditions suitable, monitored and recorded. <a href="#">Source</a><br><b>BSQR Schedule, Part 4, 1.1:</b> Storage conditions set per component (red cells +2 to +6 °C, platelets +20 to +24 °C). <a href="#">Source</a><br><b>HTA Post-mortem standard PFE2(e):</b> Staff know each fridge and freezer's acceptable range and alarm trigger points (guidance). <a href="#">Source</a>                                                                                                                                                                                                                                                                             |
| How long are temperature records kept, is that the longest period any rule or customer agreement asks for, and how quickly can you pull up a given week?<br>You said: Not sure chart recorder records meet 30 years | Not known | <b>BSQR Regulation 9(1)(e):</b> Traceability data kept readable for not less than 30 years. <a href="#">Source</a><br><b>BSQR RCPATH and IBMS record retention guidance (2025), 6.1.5:</b> Fridge and freezer temperature charts for blood stored for transfusion kept 15 years. <a href="#">Source</a><br><b>ISO 15189 8.4 and RCPATH and IBMS retention guidance (2025):</b> Records retained for a defined period; RCPATH and IBMS suggest 5 years for most fridge and freezer records. <a href="#">Source</a><br><b>HTA HTA record retention FAQs (2025):</b> Outside human application and organ donation the HTA sets no fixed period; for post mortem it endorses the RCPATH guidance. <a href="#">Source</a> |

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Are the records reviewed and signed off at a set frequency, showing who reviewed them, when, and whether any issue was found?

You said: Reviewed, sign-off not recorded in the blood bank

Partly

**ISO 15189 8.4:** Records kept, retrievable and controlled. [Source](#)

**BSQR Regulation 9(1)(d):** Operational procedures and records kept ready for inspection. [Source](#)

**HTA Post-mortem standard PFE2(f):** Monitoring lets the establishment identify trends and the extent of variations (guidance). [Source](#)

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Are the alarms tested end to end, from the sensor at its set points to the person on call and the escalation, on a set cycle and after changes, with each test recorded?

You said: Lab tests quarterly; blood bank not recorded

Partly

**HTA Post-mortem standard PFE2(e):** Alarms tested regularly at the upper and lower set points; tests include call-out procedures and are recorded. [Source](#)

**ISO 15189 6.4:** Equipment checked to show it works as intended. [Source](#)

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Has the monitoring system been validated for its use, and is there a written description of it?

You said: Lab system validated; blood bank chart recorders not

Partly

**BSQR Regulation 9(1)(c):** Relevant processes validated. [Source](#)

**ISO 15189 7.11:** Laboratory information systems validated before use. [Source](#)

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Is each calibration certificate matched to its sensor's serial number, reviewed against your own acceptance criteria and signed off by you, with due dates tracked?

You said: Certificates held centrally, not matched to serials

Partly

**ISO 15189 6.5:** Calibration status and traceability kept for each item. [Source](#)

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Are the rooms where analysers, reagents and samples sit monitored, not just the fridges?

You said: Reagent store monitored, analyser room not

Partly

**ISO 15189 6.3:** Environmental conditions monitored where they affect results. [Source](#)

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## What to do, in order

### Quick wins

1. List every blood bank, theatre and mortuary unit, its acceptable range, sensor ID and current alert route. Add the mortuary units missing from the existing list.
2. Trace a theatre fridge alarm from the local sounder through to the person expected to act. Record how this differs from the main blood bank response.
3. Write down the switchboard-to-on-call process, including what happens if the first call is missed. Record separately that the mortuary has no out-of-hours call-out.
4. Review recent mortuary min/max records and mark periods when no reading was taken. Agree and record how staff should investigate a reading outside range.
5. Match calibration certificates to sensor serial numbers and review alarm limits against the uncertainty shown on the certificates.

### Bigger changes

1. Plan continuous monitoring and remote alerts for the theatre fridge and mortuary units, with a documented acknowledgement and escalation process across departments.
2. Create continuous, retrievable records for nights and weekends, with a recorded review and sign-off process.
3. Arrange accredited calibration for every sensor and validate any shared monitoring and record system for its intended use.

6 questions were not covered this time; we will pick them up with you.

## If you want a hand closing the gaps

JTF can discuss monitoring across departments to address the theatre alert, mortuary coverage and gaps in records. JTF's own UKAS-accredited ISO 17025 calibration lab, number 10723, covers temperature calibration only.

JTF works with 25 NHS trusts, health boards and pathology networks.

### Next steps with us

If useful, we can arrange a follow-up call to walk through the theatre fridge alert route and the mortuary's out-of-hours arrangements before discussing a shared approach.

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## SOURCES

|                  |                                                                                                                                                                                                                                                                                         |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>ISO 15189</b> | ISO 15189:2022 Medical laboratories: requirements for quality and competence<br><a href="https://www.iso.org/standard/76677.html">https://www.iso.org/standard/76677.html</a>                                                                                                           |
| <b>ISO 15189</b> | UKAS: Medical laboratory accreditation<br><a href="https://www.ukas.com/accreditation/standards/medical-laboratory-accreditation/">https://www.ukas.com/accreditation/standards/medical-laboratory-accreditation/</a>                                                                   |
| <b>ISO 15189</b> | UKAS LAB 48: Decision rules and statements of conformity<br><a href="https://www.ukas.com/wp-content/uploads/2023/05/LAB-48-Decision-rules-and-statements-of-conformity.pdf">https://www.ukas.com/wp-content/uploads/2023/05/LAB-48-Decision-rules-and-statements-of-conformity.pdf</a> |
| <b>BSQR</b>      | The Blood Safety and Quality Regulations 2005<br><a href="https://www.legislation.gov.uk/uksi/2005/50/contents">https://www.legislation.gov.uk/uksi/2005/50/contents</a>                                                                                                                |
| <b>BSQR</b>      | BSQR 2005, regulation 9: hospital blood bank requirements<br><a href="https://www.legislation.gov.uk/uksi/2005/50/regulation/9">https://www.legislation.gov.uk/uksi/2005/50/regulation/9</a>                                                                                            |
| <b>BSQR</b>      | MHRA: Blood authorisations and safety reporting<br><a href="https://www.gov.uk/guidance/blood-authorisations-and-safety-reporting">https://www.gov.uk/guidance/blood-authorisations-and-safety-reporting</a>                                                                            |
| <b>HTA</b>       | Human Tissue Act 2004<br><a href="https://www.legislation.gov.uk/ukpga/2004/30/contents">https://www.legislation.gov.uk/ukpga/2004/30/contents</a>                                                                                                                                      |
| <b>HTA</b>       | Human Tissue Authority: codes of practice and licensing standards<br><a href="https://www.hta.gov.uk/">https://www.hta.gov.uk/</a>                                                                                                                                                      |

This report summarises what you told us against the published requirements above. It is not an audit or legal advice, and the source documents are what your inspector or auditor works from. Example report: the organisation, people and findings are illustrative.