

RECORDS · RETENTION

How long to keep temperature records

UK and Ireland, by setting

Wholesale, manufacturing, blood, tissues and cells, vaccines, pathology and care: how long each record must be kept, when the clock starts, and the legal basis, with a link to every source.

23 settings

Every figure sourced

Checked 19 October 2026

WHAT THIS IS

A summary to help you find the official requirement. Follow the source, your quality agreements and your Responsible Person or inspector.

THE ONE RULE

Where a unit holds products from more than one regime, keep its temperature records for the longest period that applies.

How long each record must be kept

Each period applies to its own records, so these are differences between regimes, not contradictions. Where one unit stores products from more than one regime, see our recommendation on page 8.

01 Wholesale (GDP), GB and Northern Ireland

Law (guidelines made binding by HMR reg 43(1))

HOW LONG

At least 5 years, or longer if national legislation says so

RECORD

All GDP documentation: procedures, records and data, including storage and transport temperature records. Backups of computerised system data are covered separately in chapter 3.3.1.

CLOCK STARTS

Not stated

BASIS: EU GDP Guidelines 2013/C 343/01, chapter 4.2 ('Documents should be retained for the period stated in national legislation but at least five years') and 3.3.1 (backups at least five years). Human Medicines Regulations 2012 reg 43(1) makes compliance a licence condition: in GB via reg C17, in NI via the Commission guidelines. [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013XC1123\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013XC1123(01))

Compliance is mandatory for wholesale dealer's licence holders under HMR 2012 reg 43(1).

02 Wholesale (GDP), Ireland

Law

HOW LONG

At least 5 years

RECORD

Transaction records for each medicinal product received or dispatched; all GDP documentation, including temperature records, under the EU GDP Guidelines

CLOCK STARTS

Not stated

BASIS: S.I. No. 538/2007, Schedule 2, para 8(1) (transaction records kept available for inspection 'for a period of not less than five years') and para 13 (must comply with the Commission GDP guidelines, which set at least 5 years in chapter 4.2) <https://www.irishstatutebook.ie/eli/2007/si/538/made/en/print>

The HPRA GDP guide (IA-G0046 v8, chapter 4) adds that superseded master copies of procedures should be kept for at least 5 years. The HPRA temperature guide (IA-G0011 v3) sets no retention period of its own. Neither HPRA guide gives a 15-year figure for GDP.

03 Manufacturing (GMP), UK and Ireland

Guidance

HOW LONG

Batch documentation: 1 year after batch expiry or at least 5 years after QP certification, whichever is longer. Critical raw data supporting the MA: while the authorisation remains in force.

RECORD

Batch documentation, plus critical raw data (e.g. validation or stability) that supports the marketing authorisation

CLOCK STARTS

Batch documentation: after the batch's expiry (1 year) or from QP certification (5 years), whichever ends later. Critical raw data: for as long as the marketing authorisation is in force.

BASIS: EU GMP Guide (EudraLex Volume 4), Part I, chapter 4, paragraphs 4.11 (batch documentation) and 4.12 (other documentation). Applied in GB through the MHRA's adoption of the EU GMP Guide. https://health.ec.europa.eu/system/files/2016-11/chapter4_01-2011_en_0.pdf

Compliance is a condition of a manufacturing licence. For investigational medicinal products, batch documentation is kept at least 5 years after the last clinical trial using the batch ends. 4.11 notes longer periods may apply to specific products such as ATMPs (see the ATMP row: 30 years for traceability data).

04 Active substance (API) manufacture (GMP Part II), UK and Ireland

Guidance

HOW LONG

At least 1 year after the batch's expiry date. For APIs with retest dates: at least 3 years after the batch is completely distributed.

RECORD

Batch production, control and distribution records for APIs and intermediates, including records of critical storage conditions (Part II 10.10) and calibration records (5.32)

CLOCK STARTS

Expiry-dated APIs: the batch's expiry date. Retest-dated APIs: when the batch is completely distributed.

BASIS: EU GMP Guide (EudraLex Volume 4), Part II (ICH Q7), paragraph 6.13. Applied in GB through the MHRA's adoption of the EU GMP Guide. https://health.ec.europa.eu/document/download/bd537ccf-9271-4230-bca1-2d8cb655fd83_en?filename=2014-08_gmp_part1.pdf

Part II also requires controls against gaps in electronic data (5.43) and a back-up system where a breakdown could permanently lose records (5.48).

05 Investigational medicinal products (clinical trial supply), GB and Northern Ireland

Law

HOW LONG

At least 5 years after the completion or formal discontinuation of the last clinical trial in which the batch was used

RECORD

Batch documentation for each IMP batch, including the storage and shipping records that support its certification; product specification file

CLOCK STARTS

When the last clinical trial using the batch is completed or formally discontinued.

BASIS: GB: Commission Directive 2003/94/EC, Article 9(1), as referenced by the Medicines for Human Use (Clinical Trials) Regulations 2004, Schedule 7 (as amended by SI 2025/538, in force 28 April 2026). Northern Ireland: Commission Delegated Regulation (EU) 2017/1569, Article 8(3). <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32003L0094>

IMP samples are kept for at least 2 years after the last trial ends (2017/1569, Article 11). The MHRA says separate GB guidelines for IMPs, reflecting the 2010 Annex 13, will be published.

06 Clinical trials (trial master file and essential records), UK

Law

HOW LONG

At least 25 years after the trial ends, for trials applied for on or after 28 April 2026. Trials under the old rules: at least 5 years.

RECORD

The trial master file and essential records, which typically include IMP shipment and site storage temperature records

CLOCK STARTS

After the end of the trial.

BASIS: Medicines for Human Use (Clinical Trials) Regulations 2004, regulation 31A, as amended by SI 2025/538 (in force 28 April 2026) <https://www.gov.uk/government/publications/clinical-trials-for-medicines-archiving-and-retention-of-clinical-trial-records>

An RP or QP at a clinical-supply depot should check whether its temperature records form part of a sponsor's essential records; if so, the 25 years applies to them, not the 5-year IMP batch period above.

07 Advanced therapy medicinal products (ATMPs)

Law

HOW LONG

At least 30 years after the product's expiry date, or longer if the marketing authorisation requires

RECORD

Traceability data for each ATMP and its starting and raw materials, including all substances coming into contact with the cells or tissues

CLOCK STARTS

After the product's expiry date.

BASIS: Regulation (EC) No 1394/2007, Article 15 (traceability), retained in GB law; GMP 4.11 notes that ATMPs may need longer periods than other batch documentation <https://www.legislation.gov.uk/eur/2007/1394/article/15>

The 30 years covers traceability data. Whether storage temperature records must be kept as long depends on what they support; many ATMP sites keep them with the traceability data.

08 Blood establishments, UK

Law

HOW LONG

At least 15 years

RECORD

Records of donor testing and of activity data (donor and donation totals, hospital blood banks supplied, components produced, recalls, serious adverse events and reactions) and donor information and eligibility records; separately, records of serious adverse events

CLOCK STARTS

Not stated

BASIS: Blood Safety and Quality Regulations 2005 (SI 2005/50), reg 7(4) (records 'for a minimum period of 15 years') and reg 7(1)(g) (serious adverse events, at least 15 years) <https://www.legislation.gov.uk/uksi/2005/50/regulation/7>

The 15-year rule covers the record types listed in reg 7. It is not a general rule for all blood establishment documents, and the regulation does not name temperature logs.

09 Blood traceability, UK blood establishments

Law

HOW LONG

Not less than 30 years

RECORD

Label information for each unit and all other records needed for full traceability of blood and blood components

CLOCK STARTS

Not stated

BASIS: Blood Safety and Quality Regulations 2005 (SI 2005/50), reg 8(2) and (3), read with Directive 2002/98/EC Article 14(3) and Directive 2005/61/EC Article 4 (traceability data at least 30 years) <https://www.legislation.gov.uk/uksi/2005/50/regulation/8>

Directive 2002/98/EC Article 13 sets the 15-year period for other blood establishment records (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002L0098>).

10 Hospital blood banks, UK

Law

HOW LONG

Traceability data: not less than 30 years.
Serious adverse event records: at least 15 years.

RECORD

Traceability data (Part 6 of the Schedule, as it applies to the blood bank) from receipt of each unit; records of serious adverse events

CLOCK STARTS

Not stated

BASIS: Blood Safety and Quality Regulations 2005 (SI 2005/50), reg 9(1)(e) and reg 9(1)(f) <https://www.legislation.gov.uk/uksi/2005/50/regulation/9>

The regulation does not set a period for temperature charts. See the RCPATH row for the 15-year recommendation on blood bank fridge and freezer charts.

11 Blood facilities (wards, theatres, clinics), UK

Law

HOW LONG

Not less than 30 years

RECORD

Traceability data held by facilities where blood is delivered or transfused (Part 6, Section B of the Schedule)

CLOCK STARTS

Not stated

BASIS: BSQR 2005 reg 12A(1)(a) and reg 12B(1)(a) <https://www.legislation.gov.uk/uksi/2005/50>

The regulations do not name temperature charts for facilities; the 30 years covers traceability data.

12 Blood bank refrigerators and freezers (transfusion laboratories), UK

Guidance

HOW LONG

15 years

RECORD

Refrigerator and freezer temperature charts for blood stored for transfusion

CLOCK STARTS

Not stated

BASIS: RCPATH and IBMS, The retention and storage of pathological records and specimens, 6th edition (October 2025), section 6.1.5 ('These should be kept for 15 years') and section 4.20, which refers to the BSQR 2005 as the appropriate standard <https://www.rcpath.org/static/049ea966-df5c-4a9f-9353ba24a69bb808/bd7ed2ba-8e77-4a2d-8c3ae7e74f3aaaa0/g031-The-retention-and-storage-of-pathological-records-and-specimens.pdf>

The figure is RCPATH's. The BSQR text itself sets 15 years for specific records (reg 7, reg 9(1)(f)) and does not name temperature charts. This is UK guidance; Irish law sets no period for fridge charts.

13 Blood establishments and hospital blood banks, Ireland

Law

HOW LONG

Blood establishment records: at least 15 years. Traceability data (blood establishments and hospital blood banks): not less than 30 years.

RECORD

Blood establishment records of donor testing, activity data and donor information; traceability records (blood establishments, to the point of delivery to a hospital); hospital blood bank traceability data from receipt; facilities where blood is delivered or transfused (Schedule 1 data)

CLOCK STARTS

Not stated

BASIS: S.I. No. 360/2005, reg 9(4) (15 years), reg 10(2) (30 years, blood establishments) and reg 11(e) (30 years, hospital blood banks); S.I. No. 547/2006, reg 10 <https://www.irishstatutebook.ie/eli/2005/si/360/made/en/print>

The regulations name the IMB, now the HPRA. From 7 August 2027 the EU SoHo Regulation (EU) 2024/1938 repeals Directives 2002/98/EC and 2004/23/EC; its Article 42(6) keeps traceability data for at least 30 years from distribution, disposal or export (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1938>).

14 Tissues and cells for human application (HTA licensed), UK

Guidance

HOW LONG

Critical records and raw data: at least 10 years after expiry, clinical use or disposal, kept in original format. Traceability data: at least 30 years after clinical use.

RECORD

All records critical to tissue and cell safety and quality, including raw data such as original temperature monitoring records; separately, data needed for traceability from donor to recipient

CLOCK STARTS

Critical records and raw data: after expiry, clinical use or disposal. Traceability data: after clinical use.

BASIS: HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment (January 2021), glossary ('Raw data'), paragraph 76 (10 years) and paragraphs 95 and 175 (30 years). The 30-year rule comes from Directive 2004/23/EC Article 8, applied by the Human Tissue (Quality and Safety for Human Application) Regulations 2007, Schedule 2. <https://www.hta.gov.uk/sites/default/files/2021-06/HTA%20guide%20to%20Quality%20and%20Safety%20Assurance%20for%20Human%20Tissue%20and%20Cells%20for%20Patient%20Treatment%20-%20Jan%202021.pdf>

The guide is issued under HTA directions that licence holders must follow. The clock runs from expiry, clinical use or disposal, not from when the record was made. After 10 years, raw data may be kept in consolidated form for traceability.

15 Other HTA sectors (post mortem, research, anatomy, public display, organ donation), UK

Guidance

HOW LONG

No fixed period except organ donation and transplantation (30 years from organ retrieval). Research and anatomy: at least until the tissue is disposed of (research also: used up or will never be used again). Post mortem: HTA points to its Code of Practice B and endorses the RCPATH guidance.

RECORD

Traceability records

CLOCK STARTS

Organ donation: from the date the organ was retrieved. Research, anatomy and public display: records are kept until the tissue is disposed of (no fixed period).

BASIS: HTA Record retention FAQs (updated 3 October 2025): 'With the exception of the Human Application and Organ Donation and Transplantation sectors, the HTA is not prescriptive about the length of time for which traceability records should be retained.' <https://www.hta.gov.uk/guidance-professionals/guidance-sector/public-display/record-retention-faqs>

The same FAQ says that for HTA-licensed NHS trusts, all records created under the Human Tissue Act 2004 are kept for 30 years, under the NHS records management code. The HTA sets no temperature-record period for these sectors.

16 Tissues and cells for human application, Ireland

Law

HOW LONG

Critical records and raw data, including storage temperature records: at least 10 years after expiry, clinical use or disposal. Traceability data: not less than 30 years after clinical use.

RECORD

Records needed for identification and full traceability of each tissue or cell donation and unit, including products that come into contact with them; donor records needed for full traceability; all records, including raw data such as storage temperature records, critical to the safety and quality of the tissues and cells

CLOCK STARTS

Critical records and raw data: after expiry, clinical use or disposal. Traceability data: after clinical use (donor records: after clinical use or the expiry date).

BASIS: S.I. No. 158/2006 reg 14(4) and Annex 1.4.4; S.I. No. 598/2007 reg 21, Sch 1 Part D para 7 and Part E para 7. <https://www.irishstatutebook.ie/eli/2007/si/598/made/en/print>

S.I. No. 598/2007 requires storage temperatures to be monitored and recorded and kept for at least 10 years after expiry, clinical use or disposal. From 7 August 2027 the EU SoHo Regulation (EU) 2024/1938 applies.

17 Vaccine storage (GP practices, pharmacies, clinics), UK

Guidance

HOW LONG

At least 1 year, and long enough to cover the full storage history of any product in the fridge. The Green Book says 5 years will generally cover this.

RECORD

Vaccine refrigerator temperature records

CLOCK STARTS

Not stated

BASIS: UKHSA, Immunisation against infectious disease (the Green Book), chapter 3: 'The records should be readily accessible, be retained for at least one year, and cover the full storage history of any products contained in the fridge... retaining records for five years will generally enable the full storage history of the vaccines be accounted for.' <https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3>

The Green Book gives the reason: manufacturer shelf lives can be up to four years or longer.

18 Pharmacy medicines storage (hospital and community), England

Guidance

HOW LONG

Storage temperature records and vaccine temperature logs: at least 5 years. Vaccine refrigerator maintenance logs: 11 years.

RECORD

Medicine storage temperature records: fridge and ambient readings, excursions, monitoring system downloads and calibration records; vaccine temperature logs; vaccine refrigerator maintenance logs

CLOCK STARTS

Not stated

BASIS: NHS Specialist Pharmacy Service, stock management, waste and recall records in pharmacy (citing the GDP guidelines and the Green Book); the 11 years for maintenance logs is SPS citing the NHS England Records Management Code of Practice <https://sps.nhs.uk/articles/stock-handling-waste-and-recall-records-in-pharmacy/>

SPS advice, not law. It is the main NHS pharmacy reference for these periods. The 11-year figure comes from the [NHS England Records Management Code of Practice](<https://transform.england.nhs.uk/information-governance/guidance/records-management-code/>), which SPS cites.

19 Pathology laboratories and mortuaries, UK

Guidance

HOW LONG

Temperature records: primary traces at least 2 months if regularly summarised; summarised or untranscribed records 5 years for reagents, short-term specimens, mortuary fridges and research or QC storage; lifetime of the equipment for long-term (biobank) freezers; as long as the oldest sample for forensic freezers. IQC records: at least 5 years. Maintenance and service logs: lifetime of the instrument plus at least 4 years.

RECORD

Refrigerator and freezer temperature records; internal quality control records; equipment maintenance and service logs

CLOCK STARTS

Mostly not stated. Maintenance and service logs: after the instrument's lifetime ends. Forensic freezers: as long as the oldest sample is held.

BASIS: RCPATH and IBMS, The retention and storage of pathological records and specimens, 6th edition (October 2025), sections 4.17, 4.20, 4.21 and 4.22 <https://www.rcpath.org/static/049ea966-df5c-4a9f-9353ba24a69bb808/bd7ed2ba-8e77-4a2d-8c3ae7e74f3aaaa0/g031-The-retention-and-storage-of-pathological-records-and-specimens.pdf>

The 6th edition replaces the 5th (2015). Blood transfusion fridge and freezer charts are 15 years (see the blood bank row). Accreditation records: RCPATH gives at least 8 years or 2 ISO 15189:2022 assessment cycles (ISO 15189 itself sets no retention period).

20 Care homes, England

Guidance

HOW LONG

No period set

RECORD

Medicines fridge and storage temperature records

CLOCK STARTS

Not applicable (no period set)

BASIS: NICE SC1 (Managing medicines in care homes) and the CQC guidance on storing medicines in fridges in care homes both require temperature records but give no retention period <https://www.nice.org.uk/guidance/sc1/chapter/Recommendations>

CQC page checked: <https://www.cqc.org.uk/guidance-regulation/adult-social-care/medicines-information-adult-social-care-services/storing-medicines-fridges-care-homes>. Where a care home holds vaccines, the Green Book row applies.

21 Food (BRCGS Food Safety certified sites)

Guidance

HOW LONG

A defined period that takes account of legal and customer requirements and the product's shelf life (including any consumer extension such as freezing, where the label allows it); at minimum the shelf life plus 12 months.

RECORD

Quality and food safety records, including temperature records

CLOCK STARTS

Not stated (the minimum is tied to the product's shelf life)

BASIS: BRCGS Global Standard for Food Safety, Issue 9, clause 3.3.2 (paraphrased) <https://www.brcgs.com/documents-resources/food-safety-issue-9-standard/>

BRCGS Storage and Distribution Issue 4 (3.1.3.1): reflecting shelf life and customer or legal requirements, never less than 1 year.

22 Storage and transport of time and temperature sensitive products (WHO model guidance, for reference)

Guidance

HOW LONG

Temperature records: at least 1 year after the end of the stored product's shelf life, or as long as national legislation requires. Records generally: the minimum under local legislation, but not less than 3 years.

RECORD

Temperature (and humidity) records for each storage environment; records in general

CLOCK STARTS

Temperature records: after the end of the stored product's shelf life. Records generally: not stated.

BASIS: WHO Technical Report Series 961 (2011), Annex 9, clauses 9.3.1 and 9.2.3 <https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstorageandtransport>

International model guidance, not UK or Irish law. National rules take precedence.

23 Medical device manufacturers and importers (EU MDR), Ireland

Law

HOW LONG

At least 10 years; at least 15 years for implantable devices

RECORD

Manufacturers: technical documentation, EU declaration of conformity and any relevant certificates, with amendments and supplements. Importers: a copy of the EU declaration of conformity and any relevant certificates.

CLOCK STARTS

After the last device covered by the EU declaration of conformity has been placed on the market

BASIS: Regulation (EU) 2017/745, Article 10(8) (manufacturers: 'at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years') and Article 13(9) (importers keep copies 'for the period referred to in Article 10(8)') <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745>

This covers device documentation, not temperature records as such. It is included as an example of a longer period that sits beside GDP. GB and NI device rules were not checked here.

Ireland: quality agreements often ask for longer

In Ireland, many pharmaceutical companies require their distributors to keep temperature records for 15 years through quality agreements; GDP itself requires at least 5. If a customer asks for 15, that's a contractual requirement: build it into your retention settings. This is what we see in practice, not a regulatory figure, so it is a difference between contract and law rather than a contradiction. When a customer or auditor quotes 15 years, ask which clause they rely on: usually it is the quality or technical agreement, sometimes a group data integrity policy. Other laws can also set longer periods for other records; for example, the EU MDR keeps device technical documentation for at least 10 years after the last device is placed on the market (15 for implantable devices).

Mixed sites: keep the longest period that applies

Start from the risk

One fridge or freezer often holds stock covered by different rules. If the monitoring system deletes data after the shortest period, the records for the longest-lived obligation are lost, and that cannot be fixed afterwards.

What we recommend

Keep temperature records for the longest period that applies to anything stored in that unit, and set the monitoring system's retention to match.

Scale it to the risk

- A hospital fridge holding blood for transfusion: keep the fridge charts for at least 15 years (RCPATH; UK guidance, and Irish law sets no period for fridge charts). We recommend keeping calibration certificates and equipment records for the same 15 years, so the charts they support can be shown to be valid (the BSQR sets no period for either). The BSQR's 30 years applies to traceability data (which unit went to which patient), not to temperature charts or calibration certificates.
- A pharmacy or ward medicines fridge: at least 5 years (SPS, which draws on EU GDP), and longer for any stock whose storage history runs past that.
- A fridge or freezer holding tissues or cells for patient treatment: at least 10 years after expiry, clinical use or disposal, in original format (HTA).
- An Irish distributor under a customer quality agreement or group policy: the period in that agreement or policy, often 15 years.
- If you change monitoring supplier, make sure the export includes the audit trail and stays readable for your full retention period: [EU GMP Annex 11, clause 17](#) expects archived data to be checked for accessibility, readability and integrity, and the ability to retrieve it to be ensured and tested when systems change.

What to record

Write down, for each unit, what it stores, which rules apply, the period chosen and why, and confirm the monitoring system's retention setting matches. This is a JTF position, not a regulatory requirement.

WORKED EXAMPLE (ILLUSTRATIVE)

A hospital fridge that holds blood

A hospital transfusion laboratory has a blood bank fridge that also holds a few ward medicines. The medicines alone would need at least 5 years under SPS and EU GDP, but the blood brings in RCPATH's 15 years for the fridge charts and the BSQR's 30 years for traceability data. The BSQR's 30 years covers traceability data, not temperature charts, so the site sets 15 years for this fridge's temperature records and calibration certificates, keeps its transfusion traceability data for 30 years in the laboratory system, and sets the monitoring system to keep the temperature data, with its audit trail, for 15 years. It also records this decision in its SOP and checks once a year that the archived data still opens.

This is a summary to help you find and apply the official requirements. Follow the source, your local policy and quality agreements, and your Responsible Person or inspector. Sources last checked 19 October 2026. The online version, with links: jtfwireless.com/guidance/records-and-data-integrity#retention

THE 20-MINUTE COMPLIANCE CHECK

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