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Records governance, archive risk and information governance in BTL / Clinical Biochemistry

1. For 2021/22 to 2025/26, the number of Q-Pulse audits, CAPAs, observations or equivalent records relating to records governance, retention, archive storage, document control, information asset management or data protection within Belfast Trust Laboratories, if held.

214 audits scheduled on Q-Pulse between 01/04/2021 to 31/03/2026

2. For those records, the number raised, closed, overdue and average time to closure, if held.

For Q-Pulse audits:

Number raised = 214 audits scheduled on Q-Pulse

Number closed = 179 closed with closed date on Q-Pulse

Number overdue = 27 past scheduled start date

Average time to closure = 158 days for those audits with a start date

Providing the same data for CAPA, observations or equivalent records is not readily available. To undertake this exercise would necessitate a manual interrogation of data which would involve a significant number of hours. This would exceed the costs limit specified in the FOI act.

We estimate that compliance with this element of the request for information would exceed the appropriate costs limit. Under Section 12 of the Freedom of Information 2000, the limit has been specified as £450 and represents the estimated cost of one or more persons spending 18 hours in determining whether we hold the information, locating, retrieving and extracting this information.

3. Any BHSCT or BTL policy/process describing how concerns about laboratory records retention, archive risk, public inquiries, GMGR/PRONI retention, RCPATH pathology records or Q-Pulse records governance should be escalated.

BHSCT and BTL Policies listed below:

<https://www.health-ni.gov.uk/articles/gmgr-disposal-schedule>

<https://www.health-ni.gov.uk/topics/good-management-good-records>

TP 08/08 - Adverse Incident Reporting and Management Policy (Awaiting Regional Review)

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HSCB SAI_Procedure Procedure for the Reporting and Follow up of Serious
Adverse Incidents November 2016 version 4
20230929_GuidanceDisclosingInformationSafely_BT_V1.1_Final
C-62 - Datixweb for incidents: user guidance for reporting, approving and
investigating incidents
C-73 Belfast Trust Laboratories (BTL) Risk register Process
C-208 - BTL H&S Manual - Risk Assessment & Incident Reporting
C-320 - Reporting of Medical Device Adverse Incidents & Near Misses
H-213 - LP - Incident/Reaction Investigation and Reporting by Haemovigilance
Practitioners
H-426 - QP - Management of Incidents and Informal User Complaints
H-2069 - LP - Procedure for Reporting and Management of Quality Incidents
HI-247 - QP - Reporting and Management of Nonconformities, Incidents and
Complaints
HI-472 - LI - H&I Quick Reference Guide for Datixweb Nonconformity / Incident
Reporting, Management and Trending
HI-833 - PD - NIBTS Procedure for reporting and management of quality incidents
TP-222 - Incident and Error Reporting
TP-2177 - Guidance on HTA Reportable Incidents (HTARIs) in the Post Mortem
Sector
TP 91/14 – Risk Register Production and Management Guidance
B-3549 – Clinical Biochemistry Risk Management Procedure
H-3526 – MP – Risk Management within Haematology & Blood Transfusion
HI-1116 – QP Risk Management in H&I
MP 304 003 – RMDS Risk Management
TP-2666 - Cellular Pathology Risk Management
TP 22/08 – Your Right to Raise a Concern (Whistleblowing) Policy
BHSCT/PPI (06) - Policy on the Data Protection and Protection of Personal
Information
TP 026/08 – Policy On the Data Protection and Protection of Personal Information
BHSCT/PPI (02) 2021 - Records Retention and Disposal Schedule
TP 60/10 – Policy for Processing Requests for Access to Patient/Client and
Personal Records
BHSCT/PPI (08) – Transportation of Records Policy
TP 78/11 – Decommissioning of Trust Owned and Leased Properties
TP 13/08 - Records Management Policy
TP 076/11 - Social Media Policy
TP 69/10 - Data Sharing Policy
Amended guidance on the recording of video conferencing
sessions using Trust approved applications v4.0
B-3111 – Clinical Biochemistry Records Retention and Disposal Schedule
M-257 – LI - Retention and Storage of Documents, Electronic and Paper Records
C-197 – The retention and storage of pathological records and specimens (6th
edition)
TP-467 - COSHH Assessment Processing & Disposal of Autopsy Tissue

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TP-2391 - General Risk Assessment Handling of Placental Tissue & Disposal of Waste Formalin (Mortuary)
B-3111 - Clinical Biochemistry Records Retention and Disposal Schedule
TP-1150 - General Risk Assessment Disposal of Waste from the Mortuary
TP-2609 - Manual Handling Risk Assessment Off site slide disposal
TP-2568 - Manual Handling Risk Assessment Cellular Pathology Stores and Waste Disposal
TP-2574 - Manual Handling Risk Assessment Cellular Pathology stores and waste disposal during lift failure
C-569 - Manual Handling RA - Removal and disposal of Domestic waste from the Kelvin building
H-2896 - COSHH - Laboratory Waste Disposal COSHH Assessment
HI-166 - COSHH - Disposal of Spleen & Lymphnode COSHH Risk Assessment
C-577 - General Risk Assessment - Waste Disposal
C-655 - Manual Handling Risk Assessment - Disposal of Waste into Secondary Waste Bins
B-509 - Metabolic Specimen Reception, Sample Receipt Processing and Disposal
I-470 - Risk Assessment on Disposal of Tritiated Thymidine Liquid waste down sink in room BI 3015 in Biochemistry
H-741 - Stem Cell Bank Disposal policy
C-214 Quality Manual
C-589 - Labs Assurance, Governance and Quality Group Terms of Reference
I-111 - Procedures for evaluating and improving quality processes in the Regional Immunology Laboratory
C-729 - Labs Ops – Governance Reporting Template
C-714 - Information Governance Bulletin Oct 2025 Issue 38
C-621 - Discipline Reporting Form for Labs Assurance, Governance & Quality Meeting
B-1045 - Clinical Biochemistry Governance and Quality Key Progress Indicators 1st April 2026 to 31st March 2027

4. Since 1 January 2023, how many records-governance, data-protection or information-governance incidents from BTL or Clinical Biochemistry were reported to the ICO, RQIA, DoH or another external body? Numbers only.

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5. Any anonymised lessons-learned, shared-learning or action-plan headings arising from such reports or incidents, if held.

Incident Reference	Lessons Learnt / Shared Learning
1	Person 1 instructions how to Report and escalate chart corrections for patient were passed to Person 2 and she informed relevant leads and staff for inclusion on safety briefs
2	Blank, investigation still ongoing

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- 3 All staff should ensure doors and windows are secured when leaving the building
- 4 Blank
- 5 Shared learning was shared with all staff and the importance to stop and check patient details.
- 6 Blank, investigation still ongoing