



NATF 1550 04
 (Relates to SOP No. NATS QAD 0189)
Quality Technical Agreement
SNBTS Blood Donor Centre,
Raigmore, Inverness



Contract Acceptor / Supplier	Contract Giver / Customer
National Services Scotland Facilities Management (NSS FM) with its principal office at Gyle Square 1 South Gyle Crescent, Edinburgh, EH12 9EB ("Contract Acceptor")	The Common Services Agency acting through its strategic business unit commonly known as the Scottish National Blood Transfusion Service, with its principal office at The Jack Copland Centre, 52 Research Avenue North, Edinburgh, EH14 4BE, ("Contract Giver")
individually a "Party" and together the "Parties."	
This Agreement is effective from the last date of signature of this Quality Technical Agreement ("Effective Date")	
Review Date: Three years from effective date.	

Summary of Changes	
Version	Changes/Justification
01	New Document



Quality Technical Agreement

Section A

Background

This is a quality technical agreement (the "Technical Agreement") between the Contract Acceptors/ Service Providers and Contract Giver /Customer which describes the roles and responsibilities of the involved Parties in relation to the supply of services to **SNBTS Blood Donor Centre, Raigmore, Inverness** as listed in Section C to this Technical Agreement. The aim of this Technical Agreement is to define the general conditions to be applied by the Contract Acceptor for the services supplied. This Technical Agreement further defines the key principles of co-operation between the Parties with respect to quality issues related to the services supplied.

This agreement involves two Parties as listed above and applies to the activities carried out by NSS Facilities for SNBTS, both being Directorates of the Common Services Agency.

In the event there is a conflict between the Technical Agreement and the Memorandum of Understanding (MoU) between NSS Facilities and SNBTS, the MoU will take precedence in all non-quality related matters unless otherwise stated in the MoU while the Technical Agreement will take precedence in all quality related matters. This Technical Agreement shall be effective at the time of the last approval signature of all parties and will remain in effect until either it or the MoU is terminated subject to the terms of the MoU.

Where the Contract Acceptor is authorized in writing by the Contract Giver to use Permitted Subcontractors these are listed in Section D. Any reference to responsibilities of the Contract Acceptor herein is to read as applying to the Permitted Subcontractor for any activities the Permitted Subcontractor performs on behalf of the Contract Acceptor. Accordingly, the Contract Acceptor is responsible for putting in place appropriate management systems and contractual agreements with said Permitted Subcontractors to ensure the responsibilities are met to the satisfaction of the Contract Giver.

Changes to this Technical Agreement:

Any changes to the information contained in the Technical Agreement must be approved in writing by the Parties in advance. Thereafter such changes can be implemented by approving a new revision of this agreement.

Ending the Technical Agreement:

This Technical Agreement shall remain effective until terminated as set out above. However, the termination of the Technical Agreement shall not relieve either Party of its obligations regarding safe storage of data, documents and materials associated with activities described herein.



Quality Technical Agreement

Quality Agreement Responsibility Table

Responsibilities	NSS FM Contract Acceptor	SNBTS Contract Giver
The primary quality contacts for each party are as detailed in Section B to this agreement		
Compliance		
Conform to the requirements of Good Practice Guidelines for Blood establishments required to comply with Directive 2005/62/EC, Good Distribution Practice Guidelines (2013/C/343/01) and requirements of EU GMP Eudralex EU GMP Volume IV, Part 1, Chapter 3 Premises and Equipment, and/or other quality criteria defined in the scope of this agreement.	X	X
Mutually agree upon specifications for the services which are the subject of this agreement.	X	X
Changes to the agreed upon specifications must be mutually agreed upon and communicated in writing between the parties to this agreement	X	X
Provide goods/products/services that conform to the mutually agreed upon specifications.	X	
Upon request, disclose to the Contract Giver recent regulatory agency or accreditation or industry standards body inspections and findings pertaining to the subject of this Technical Agreement.	X	
Notify promptly, and in any event within 10 working days if, in the course of an inspection, any findings are made related to the quality of any services being the subject of this Technical Agreement.	X	X
Shall have a quality agreement with third parties used in connection with the subject of this Technical Agreement which could be viewed during an audit.	X	
Documentation and Records		
Records & reports generated from services provided will be completed in ink in accordance with	X	



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Responsibilities	NSS FM Contract Acceptor	SNBTS Contract Giver
GMP. All entries will be dated and signed at time of completion.		
Service reports will be both reviewed and acted upon in a timely manner	X	
Change Control		
Changes to the services will be evaluated and communicated based upon agreed criteria and timelines.	X	
Changes will be managed as appropriate through the SNBTS QMS change management process.	X	X



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Responsibilities	NSS Facilities Contract Acceptor	SNBTS Contract Giver
Non-Conformance		
Any non-conformance related to the service should be investigated. Where applicable this includes the identification of the root cause, a risk analysis of the actions taken for correction of the problem, prevention of future occurrence and the formal conclusion by SNBTS in conjunction with the service supplier where necessary. If an investigation reveals that there is an impact to the subject of this Technical Agreement, Contract Acceptor shall inform Contract Giver without unreasonable delay.	X	
Complaints		
Have a written procedure to investigate and document quality related complaints. A root cause analysis, actions taken for correction of the problem, prevention of future occurrence and the formal conclusion will be provided to the Contract Giver within a reasonable time after receipt of the complaint.	X	
Complaints made shall at least indicate the date and location of any service carried out and the complaint subject. The complaint shall be communicated to the Contract Acceptor within a reasonable time after receipt of the service.		X
The parties shall cooperate in the exchange of information required to effectively conduct an investigation.	X	X
Auditing		
Have the right to audit Contract Acceptor's facilities, systems and documentation, as they relate to the subject of this Technical Agreement, at mutually agreed upon times.		X
Allow Contract Giver to audit facilities, systems and documentation, as they relate to the subject of this Technical Agreement at mutually agreed upon times.	X	
If required, a confidentiality agreement will be executed within a reasonable period of time prior to the audit.	X	X
Contract Giver shall issue a confidential written audit report to the Contract Acceptor, which will include audit observations, within mutually agreed upon timelines.		X



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Responsibilities	NSS Facilities Contract Acceptor	SNBTS Contract Giver
Contract Acceptor shall issue responses within mutually agreed upon timelines to all observations in writing to Contract Giver Quality Assurance. Where the Contract Acceptor commits to a corrective action, a description and timeframe for completion will be included in the written response.	X	
Where applicable, agree upon requirements for auditing third parties used in association with the subject of this Technical Agreement.	X	X



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Section B

The Primary Quality Representatives for each Party:

	Contract Acceptor / Service Contract Acceptor	Contract Giver / Service Receiver
Name of Party	National Services Scotland Facilities Management (NSS FM) with its principal office at Gyle Square 1 South Gyle Crescent, Edinburgh, EH12 9EB	The Common Services Agency acting through its strategic business unit commonly known as the Scottish National Blood Transfusion Service, with its principal office at The Jack Copland Centre, 52 Research Avenue North, Edinburgh, EH14 4BE,
The name of the Primary Quality Representative for this contract & service:	Paul Donnelly	[QA Manager for the Site]
The Primary Quality Representative's email address:	[REDACTED]	[QA Manager for the Site]
The Primary Quality Representative's day time phone number (during working hours):	[REDACTED]	[QA Manager for the Site]
Communication of notifications in relation to this agreement to be sent to:	[REDACTED] and [REDACTED]	[REDACTED] and [REDACTED]



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Section C

**The services covered by this agreement at the
SNBTS Blood Donor Centre, Raigmore, Inverness**

Goods/products/services	Brief Description
Hard FM	
Mechanical and Electrical Services – C/PPM and Reactive	PAT testing only
Water Management	Water Sampling
Soft FM	



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Section D

List of Approved Relevant Third-Party Contractors working with the Contract Acceptor

Name and Address of Third Party	Service Provided
FES FM Ltd Forth House, Pirnhall Business Park, Stirling, FK7 8HW	PAT Testing only
Dalkia 1 Rutherglen Links, Rutherglen Links Business Park, Glasgow, G73 1DF	Water Sampling



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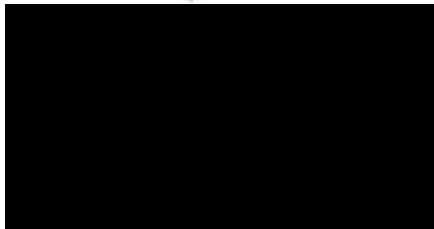
Quality Technical Agreement

Signed for and on behalf of Scottish National Blood Transfusion Service

[Docusign signature here]

[QA Manager for the Site]

Signed for and on behalf of NSS Facilities



Barrie Richardson,
Head of Estates & Facilities