

Objective

To document the cleanroom cleaning requirements within CMT for prospective contractors of this service.

Changes in this version

Updated prior to tender exercise to reflect current requirements

Requirements

1. Introduction

The Cellular and Molecular Therapies (CMT) function is a Specialist Services department forming part of NHS Blood and Transplant (NHSBT) Therapeutic Services. The laboratories process, store and distribute human cell based products and gene therapies for transplantation and other therapies.

CMT consists of seven laboratories based within NHSBT facilities at Barnsley, Birmingham, Filton (Bristol), Liverpool, Oxford and Southampton. Currently, these laboratories require scheduled and adhoc deep cleans of their clean rooms, with frequencies detailed in Appendix 1.

Each laboratory operates clean room facilities in accordance with EUGMP (Annex 1) requirements and is licensed by the Human Tissue Authority (HTA) in accordance with the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Joint Accreditation Committee – ISCT and EBMT (JACIE). The activities of the NHSBT CMT stem cell processing laboratories involve processing, testing, storage and distribution of human progenitor cells for autologous and/or allogeneic transplantation. Liverpool, Barnsley, CBC, Birmingham and Filton laboratories are also regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) for cell and gene therapy medicinal product manufacture. A high level of hygiene and cleanliness is essential to preventing contamination and maintaining the sterility of these products.

2. Purpose and Scope

This specification details the deep cleaning process that NHSBT requires the Supplier to carry out on each of its CMT Cleanrooms. Periodic, specialist deep cleaning is required, supplemental to in-house cleaning and disinfection regimes to ensure that the interior of the CMT Cleanrooms are maintained in a sufficient state of cleanliness in order to achieve ISO14644/ EUGMP standards as required by the regulatory authorities. The deep cleaning detailed in this specification covers the interior of the CMT Cleanrooms only.

3. Quality

The quality of the cleaning service is significant to the effective running of NHSBT operations and its compliance with the standards expected by MHRA, HTA and JACIE. It is imperative therefore that the following specification standards for this service are consistently achieved.

- 3.1. The Supplier will be expected to have Quality Management System BSI (EN) ISO 9001 or equivalent.
- 3.2. The Supplier shall be expected to use equipment/tools/products designed and suitable for specific use in ISO 14644/EUGMP standard cleanrooms to perform the tasks effectively, safely and efficiently.
- 3.3. The Supplier shall provide all equipment and cleaning solutions and maintain all equipment for use in the provision of this service in a safe, serviceable and clean condition.
- 3.4. The Supplier shall ensure that all cleaning equipment is clearly identified and that correct segregation during use is maintained at all times.
- 3.5. Product details shall be supplied to and agreed with NHSBT. All disinfectants used by the Supplier need to be validated to demonstrate effectiveness and demonstrate neutralisation with the plates used. Validation data must be shared and agreed with NHSBT.

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- 3.6. Where the supplier provides their own validation data to support effectiveness and neutralisation, this will be reviewed by NHSBT for suitability prior to contract award.

4. Scheduling of Cleaning

- 4.1. The Deep Cleaning process will occur approximately either every 6 months or annually for each site according to a schedule in Appendix 1 and as agreed with each Local manager.
- 4.2. There may also be a requirement to arrange ad hoc deep cleaning, for example following revalidation, within 5 working days. The Supplier will provide NHSBT with a contact number (or numbers) to facilitate the scheduling of Deep Cleaning procedures.
- 4.3. The Supplier MUST make all reasonable attempts to meet the requested date and time that NHSBT makes. Failing this, a mutually convenient time will be agreed between NHSBT and the Supplier.
- 4.4. The Supplier shall allocate sufficient staff and resources to ensure, unless otherwise agreed, that the cleaning process for site takes no more than eight hours per day. NHSBT shall approve the maximum number of people allowed to be working in the cleanrooms at any one time. This will be approved by the local manager.
- 4.5. The Supplier will be expected to provide a maximum of 3 working days response time for requests to undertake cleaning under exceptional /emergency situations.

5. Deep Clean Procedure

All areas must be cleaned using materials and methods validated in accordance with ISO EUGMP standards for the effective removal of viable and non-viable contamination in cleanrooms, summarised below

- 5.1. All areas will be given a deep clean following the same procedure. Cleaning must progress:

a) In the direction of the clean air flow thereby following the sequence:

- Ceilings
- Walls
- Surfaces
- Floors

b) From the highest EUGMP grade B rooms to the lower Grade C and D grade changing rooms.

The cleaning system and components must be appropriate for use in GMP grade B and ISO 14644 level standard cleanrooms.

- 5.2. All floors must be hoovered using a HEPA filtered Cleanroom Vacuum.
- 5.3. Ceilings, walls and floors must be mopped with sterile disinfectant solution on a cleanroom compatible mop head using a pattern suitable for use in GMP Grade cleanrooms e.g. a straight line pattern with an overlap between strokes. Light fittings, smoke detectors, sprinklers and other irregular surfaces are to be cleaned with a wiper impregnated with the disinfectant. Surfaces must then be left to dry. All solutions must be used once per area.
- 5.4. Walls must be cleaned from top to bottom.
- 5.5. All other vertical and horizontal surfaces (including the tops and sides of the cabinets and vertical laminar flow hoods) are to be cleaned with cleanroom compatible wipers impregnated with disinfectant. Wipers must be changed frequently and disinfectant left to dry.

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- 5.6. External surfaces of all equipment located in the cleanroom.
 - 5.7. Equipment must be moved to enable cleaning of all surfaces & floors. The supplier must discuss the movement of sensitive items of equipment with the lab manager. The lab manager will inform the supplier of any sensitive items of equipment in advance of the clean and will provide assistance from NHST staff, if required.
 - 5.8. All vertical and horizontal surfaces (including ceilings) must be rinsed with sterile de-ionised water ensuring all surfaces are dry before proceeding.
 - 5.9. All vertical and horizontal surfaces (including ceilings) must be sprayed using appropriate sterile alcohol solutions ensuring all surfaces are dry before proceeding.
 - 5.10. All floors must be cleaned using sterile disinfectant using a pattern suitable for GMP Grade cleanrooms e.g. a straight line pattern with an overlap between strokes. Cleaning must start at the end of the room furthest from the exit and work towards the exit with a new mop head being used for each area. Disinfectant must be left to dry and then rinsed with sterile water.
 - 5.11. Operators must be gowned up in sterile cleanroom suits, hoods, overboots, masks, and gloves and gloves must be changed at each point as per NHSBT gowning procedures.
 - 5.12. All processes must to be confirmed prior to commencement of clean down.
 - 5.13. All clean room wipes must be lint free and all consumables sterile. Any equipment or mops are to be re-used they must be subject to a validated cleaning and sterilisation process. A range of suitable cleanroom disinfectants generally comprise of biguanides, quaternary ammonium compounds and amphoteric agents and must be used according to manufacturer's recommendations.
 - 5.14. A written report must be received including batch numbers, expiry dates of consumables used and details on equipment used. The report must be received by NHSBT within 21 days of the deep clean.
 - 5.15. All sites will require a validation of the cleaning process post clean, this will require the supplier to perform particle counts in each room at locations agreed with the local manager. Surface environmental monitoring also must be performed at locations agreed with the local manager. These plates must then be incubated and read by a UKAS accredited laboratory. Surface environmental monitoring will also be performed in each room by NHSBT, after cleaning to ensure that an acceptable level of cleanliness has been achieved.

6. Monitoring

- 6.1. The Deep Cleaning process is considered very important as it affects NHSBT'S licence to operate. Therefore, following the identification of a failure by the Supplier to achieve the required cleaning standards the situation must be corrected with a re-clean of affected areas within 3 working days at no additional cost to NHSBT.
- 6.2. Any recurring failure by the Supplier to achieve the standards identified in the Contract documentation shall lead to a financial review that could involve reductions in the contract price. In severe cases NHSBT reserves the right to terminate the contract.
- 6.3. The Supplier shall monitor the efficacy of the cleaning service and be able to provide documentary evidence that they have achieved the required quality. The supplier will be required to submit associated reports to the local managers.
- 6.4. Independent audit teams looking at a specific function's clinical and operational issues (e.g. internal audit, Quality Department) may augment monitoring undertaken by the Supplier and the

Local Managers. The Supplier must provide a channel for the rapid resolution of any concerns over the provision of the service. This will involve communication with NHSBT Local Managers.

- 6.5. NHSBT shall, at all times, reserve the right to observe, inspect and satisfy itself with respect to the adequacy of the procedures carried out. To carry out sample checks upon such procedures or otherwise to audit the Supplier's performance in the provision of the services in accordance with the Service Terms and the Service Specification Arrangements as NHSBT may consider appropriate. The Supplier shall provide the NHSBT with all assistance, co-operation, access, documentation, records and other information as may be reasonably necessary for NHSBT to exercise such right.
- 6.6. The Supplier shall comply with all reasonable requests of NHSBT to improve, alter or repeat any of its quality assurance or fault reporting systems or procedures
- 6.7. In order to provide an audit trail for the cleaning process, the Supplier will provide the local manager with a completed and signed checklist of the work carried out during the cleaning process. The design and content of this document will have to be agreed with NHSBT.
- 6.8. The supplier shall ensure that any complaints shall be handled quickly and effectively ensuring NHSBT's complaint procedure guidelines are adhered to.

7. Penalties for Poor Performance

- 7.1. As a result of either a poor report and/or an unsolicited complaint, corrective action must be implemented within 48 hours. Failure to comply with this requirement shall result in the following actions:
 - Failure to address complaints or poor reports within one month – letter to be sent to Contract Officer detailing that invoice payment will be delayed until the matter has been successfully resolved
 - 3 letters of noncompliance as above – delay of invoice payment plus NHSBT reserves the right to terminate contract

8. Health & Safety, Legislation and Policy Documents

- 8.1. NHSBT has a number of policies and procedures that the Supplier shall be required to adhere to. These are available upon request. Particular attention and adherence must be given to NHSBT policy on confidentiality.
- 8.2. The Supplier shall comply with all Health and Safety legislation, British and EU Standards, Department of Health guidelines and requirements, Technical Memoranda, SAB's and Hazard Notices. This is to include all current legislation and documents as well as all such future directives.
- 8.3. The Supplier shall ensure that their employees are fully trained and aware of the risks relating to handling of clinical waste.
- 8.4. The Supplier shall be responsible for the removal of all waste generated during the cleaning from NHSBT premises.
- 8.5. The supplier must ensure that they have undertaken detailed Control of Substances Hazardous to Health (CoSHH) risk assessments for all of the cleaning products and processes that they conduct on NHSBT sites. Their employees must be fully trained in these and any precautions identified as necessary in the assessment. Copies of any COSHH risk assessments should be provided to NHSBT on request.

- 8.6. The Supplier shall be aware of NHSBT's security policies and procedures. Access arrangements shall be agreed before undertaking the cleaning procedure for each.

9. Contract Period

- 9.1. Subject to the provisions of the 'terms of offer', this agreement shall remain in force for a period of 4 years from the Service Commencement Date. With an option to extend for a further two, one year periods.
- 9.2. In the event that the Supplier does not commence the operation of the services on the 'Service Commencement date', the Contract Period will nonetheless begin on the Service Commencement Date and NHSBT shall not be obliged to grant any extension of the Contract Period to the Supplier.
- 9.3. This Agreement shall commence on the Service Commencement Date and shall continue, subject to these Conditions of Contract, until midnight at the end of the Contract Period.
- 9.4. It is likely that changes to the delivery of service will occur during the contract period. To ensure further service development or future compliance with new legislation/directives, NHSBT and the Supplier will work together to co-ordinate action plans, identify resources and, if necessary, detail variations to this agreement.
- 9.5. The Supplier shall, during the Contract Period provide, in accordance with the terms of the Agreement such cleanroom Deep Cleaning services as may be required by NHSBT. The Supplier shall not deviate from the terms of the Agreement without the written consent of the Local Managers.
- 9.6. The Supplier shall provide all employees, equipment, transport, materials and consumables for the provision of the service to the Contract Standard.
- 9.7. It shall be the duty of the Supplier to provide the services to a standard, which is, in all respects, to the satisfaction of the Monitoring Managers.
- 9.8. The Supplier shall be aware of NHSBT's security policies and procedures. Access arrangements shall be agreed before undertaking the cleaning procedure for each.
- 9.9. NHSBT shall reserve the right to add/remove any sites for cleaning.

10. Employees

- 10.1. The Supplier shall ensure that each person employed by the Supplier who may have occasion to be upon NHSBT premises in connection with the provision of the Services is at all times properly and sufficiently trained and instructed with regard to NHSBT rules and procedures concerning conduct while on NHSBT premises, health & safety at work, fire precautions, pest control, security and confidentiality.
- 10.2. The Supplier's employees engaged in and about the provision of the services shall be managed and directed by the Supplier's supervisory staff but, shall obey all reasonable instruction given to them by NHSBT's own supervisory staff, in which the immediate safety or medical needs of any employee, patient or visitor may be involved.
- 10.3. The Supplier shall ensure that their employees carry out their duties and behave while on NHSBT premises in an orderly and quiet manner, be practicable, having regard to the nature of the duties performed by them.

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- 10.4. The Supplier shall ensure that their employees carry out their duties and behave while on NHSBT premises in such a way as to cause no unreasonable or unnecessary disruption to the routines and procedures of NHSBT employees.
 - 10.5. The Supplier shall require their employees at all times while on NHSBT premises to be properly and presentably dressed in an appropriate uniform or work-wear.
 - 10.6. The Supplier shall provide and shall require their employees to carry on them at all times, when on NHSBT premises, an identification card in such form as may be agreed with or, in default of agreement, specified by the local NHSBT office.
 - 10.7. The Supplier shall provide at their cost and ensure that their employees wear specialised sterile cleanroom protective clothing for the cleaning process. The supplier shall also ensure that the health and hygiene of their employees is at an acceptable level for class 100 cleanroom operation.
 - 10.8. The Supplier must satisfy the requirements of the Rehabilitation of Offenders Act 1974.
 - 10.9. The Supplier and their employees shall not disclose any information concerning NHSBT, NHSBT's customers, patients or employees to any third party.
 - 10.10. The Supplier shall provide sufficient administrative support for this contract to ensure that NHSBT staff will be able to make telephone contact with the company during normal office hours.

11. Compliance with NHSBT and Other Procedures

11.1. The Supplier will during and throughout the Contract Period:-

- Comply with all material requirements of the Health and Safety at Work Act 1974 and of any other acts, regulations or orders having the force of law pertaining to the health and safety of employees.
- Comply in relation to its employees with all the policies and procedures of NHSBT in relation to NHSBT employees concerning occupational health, health and safety at work and similar matters as may be in force from time to time.
- Comply with all the policies and procedures of NHSBT in force from time to time concerning infection control and the handling of any major incidents.
- Comply with NHSBT's complaints procedure.

11.2. The Supplier shall ensure that it shall be at liberty to make available and shall make available to NHSBT at any time in case of emergency and otherwise within twenty one (21) Business Days such information as NHSBT may reasonably require (including without limitation such information as to the health of any of the Supplier's employees) to enable NHSBT to verify that the obligations of the Supplier under this Clause are being complied with.

11.3. The supplier will be required to sign a Quality and Technical Agreement detailing the respective tasks and responsibilities of both parties before commencement of the contract.

12. Access and Security

- 12.1. NHSBT will provide access to the sites during the scheduled cleaning. NHSBT will be responsible for ensuring that the room(s) is unlocked prior to the start of the cleaning and is secured at the end of the process.
- 12.2. The Supplier will be responsible for security of the room during the cleaning process (if applicable).

13. Supply of Materials and Equipment

13.1. NHSBT will provide the following:

- Hot and cold running water
- Waste water disposal
- Mains electricity supply

13.2. All other materials and equipment shall be provided by the Supplier.

14. Business continuity

14.1. The Supplier shall be able to provide a Business Continuity Plan covering all aspects and locations of their business which impact on supply of the goods or services, and this plan should be reviewed, updated and tested or exercised at least every two years.

15. Equality & Diversity

15.1. Suppliers are required to comply with all UK and European statute law relating to Equality and Diversity. This covers all discriminatory issues due to race, religion, age, sex, sexual orientation and disability. Failure to comply in any area will result in exclusion from tendering.

16. Customer service/Account management

16.1. The Supplier must provide a dedicated Strategic Account Manager to act as a single point of contact for the purposes of the operation of the contract. The Supplier shall also appoint a reserve contact in the event of the nominated contact not being available. If required a named account team on the help desk will be provided. Regional and/or sector account management contacts will also be appointed where appropriate.

16.2. The Supplier must provide a nominated Account Manager, who shall take responsibility for the overall relationship with the NHSBT, including agreeing any individual requirements relating to invoicing, management information and preferred methods of communication. The Account Manager shall also act as a primary point of contact for the Member on issues relating to the arrangement.

17. Environmental considerations

17.1. NHSBT requires Suppliers to take responsibility for their impact on the Environment and where relevant society. Suppliers are required to demonstrate an Environmental Management System e.g. ISO14001 or an equivalent EMS. NHSBT may require the auditing of this system. Where an EMS does not exist Contractors will be required to demonstrate adequate management of their impact and where suitable may be required to develop an EMS system.

18. Contract Management

18.1. The Supplier shall attend meetings to review performance of the Supplier and services provided. Frequency of the meetings will be every 6 six (6) months unless agreed otherwise and at a nominated NHSBT premises or by telecom.

Meeting agenda's will include:

- review of key performance indicators
- agree and monitor status of actions to resolve and quality
- technical or contractual issues
- identify topics/areas to feed into the continuous improvement programme

Definitions

- **CMT** – Stem Cell Immunotherapies
- **NHSBT** – National Health Service Blood and Transplant
- **JACIE** – Joint Accreditation Committee- ISCT (International Society for Cellular Therapy) and EBMT (European Group for Blood and Bone Marrow Transplantation)
- **HEPA** – High Efficiency Particulate Air Filter
- **HTA** – Human Tissue Authority
- **MHRA** – Medicines and Healthcare Regulatory Agency
- **GMP** – Good Manufacturing Practice
- **SAB** – Safety Alert Bulletin
- **COSHH** – Control of Substances Hazardous to Health

Related Documents / References

- N/A

Appendix 1

NHSBT Site	Department	Grade of Cleanroom	No. of rooms	Floor area m2 (all areas are approximate)	Scheduled cleaning frequency
Barnsley	CMT Barnsley	B/C	2xB cleanrooms 2xC cleanrooms 10xC lobbies/corridors 4xD lobbies/corridors	48 82 140 26	6 months
Birmingham	Birmingham	B	2 x Cleanrooms Access lobbies & change area	67 30	6 months
Filton	CMT Filton	B	4 x cleanrooms Access corridor Access lobbies Change area	120 52 50 29	6 months
Filton	CBC	C/D	CNC areas 3 x C processing rooms 7 x D processing rooms D supporting areas	36 76 140 148	Annually
Liverpool	CMT Liverpool	B	Cleanrooms Change area	80 18	n/a <i>adhoc only</i>
Oxford	CMT Oxford	C	2 x Cleanroom Lobbies Change areas	20 8 13	6 months
Southampton	CMT Southampton	B	2 x Cleanrooms Change areas	40 14	6 months