**Specification for a Specialist Cleaning Services for the UK Stem Cell Bank Cleanroom Facility.**

The UKSCB requires a specialist cleaning contractor to provide cleaning services for its GMP Cleanroom Suite. The suite is licenced under the HTA Human Tissue (Quality and Safety for Human Application) Regulations 2007 for the production of starting materials for human therapies and is required to comply with the microbiological and particulate standards set out in EU GMP (Annex 1). Compliance is maintained through the HEPA filtered air supply, cleanroom practices and particularly through the strict cleaning regime set out in UKSCB Standard Operating Procedures.

The suite comprises the areas set out in Appendix 1 of this specification. Cleaning requirements are set out Appendix 2.

The contract will run for 3 years in the first instance, with a possibility of two 1 year extensions. Only contractors with prior experience of cleaning GMP-compliant cleanrooms will be considered. The contract is for labour only; the UKSCB will provide all cleaning materials and cleanroom clothing. UKSCB will supply cleaning equipment (contractors may use their own cleaning mops provided that these will work with the biocide wipes used by the UKSCB). The disinfectants to be used to clean the UKSCB are detailed in Appendix 2. Contractors must be willing to work to UKSCB Standard Operating Procedures and comply with UKSCB Gowning and Cleanroom Entry and Exit procedures. Current SOPs are detailed in Appendix 3.

The contract should be priced on a per week basis for cleaning (i.e. those areas specified in Appendix 1) with a separate price for options ranging from cleaning of 1 cleanroom (including pass throughs) & associated change 3 area, to all 5 cleanrooms (including pass throughs), associated change 3 areas. Change areas 1 & 2, the cleanroom corridor, and lobby should be included in all price options. A site visit for potential contractors may be arranged following which a detailed proposal dealing with all the issues raised in the specification should be submitted.

The specification is as follows:

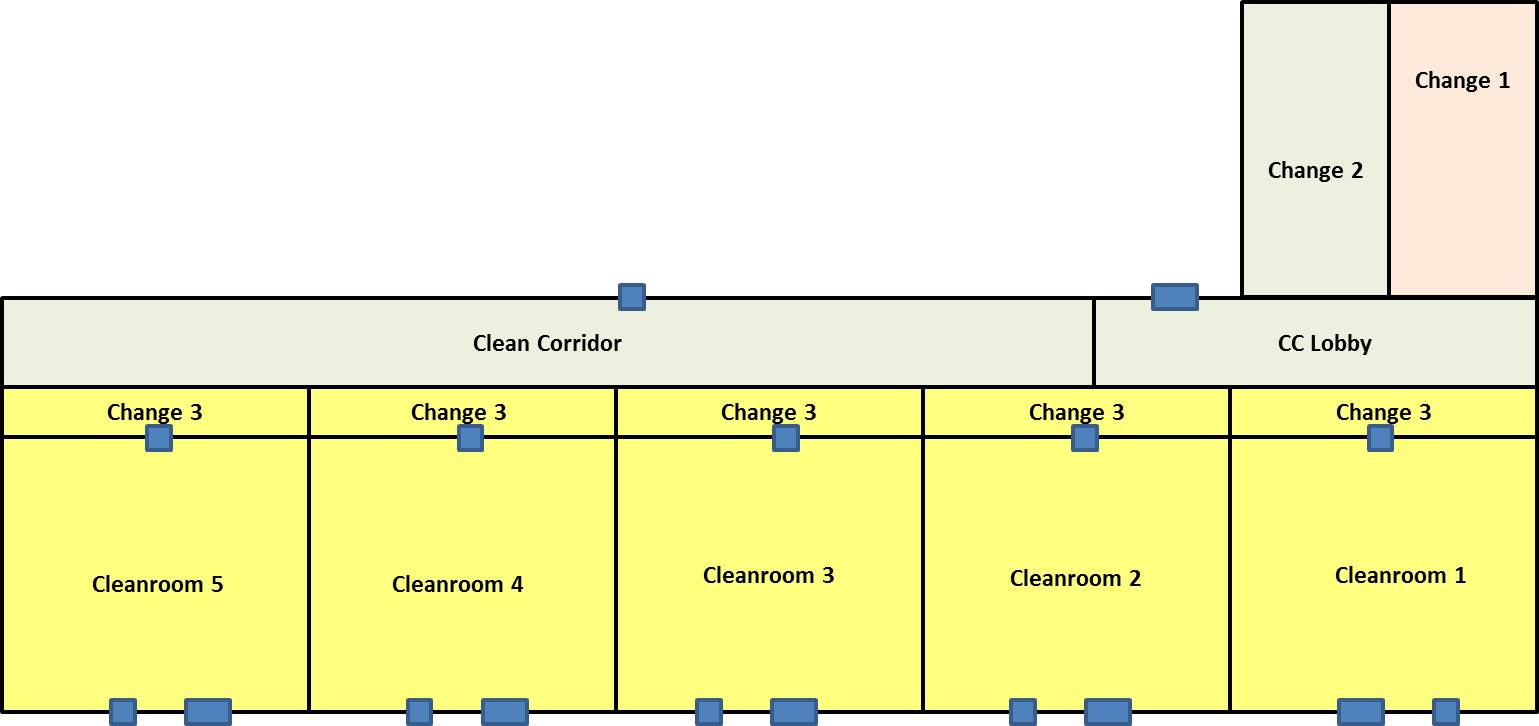
|  |  |  |
| --- | --- | --- |
| **General Specification**  *NB: Tendering companies must indicate whether or not they are able to comply with each Mandatory requirement* | | |
| Service Provider must demonstrate prior experience of cleaning contracts in a GMP (or equivalent) cleanrooms | | Mandatory  Companies must provide documentary evidence of existing or previous contracts for cleaning GMP (or equivalent) cleanrooms preferably pharma or HTA licenced establishments   * No prior experience – exclude * ≤ 5 current contracts additional 5 points * 6-10 current contracts additional 10 points * ≥11 current contracts additional 15 points * Additional 10 points if any contracts are for GMP or HTA licensed premises |
| Service Provider must sign a Service Level Agreement (SLA) & third-party agreement detailing client and service provider’s responsibilities prior to start of contract | | Mandatory |
| Service provider must be willing to undertake the UKSCB/NIBSC QA qualification process prior to the contract being awarded | | Mandatory |
| Staff employed by the Service Provider, working in UKSCB cleanrooms, must show evidence of formal training in working in a GMP (or equivalent) cleanroom environment | | Mandatory  Companies must specify the type of training and the number of trained staff available |
| Service Provider and their staff must work to all current versions UKSCB Standard Operating Procedures related to the cleanroom facility. If the SOP’s are update during the contract, the service provider will be supplied with updated versions of SOPs as required. | | Mandatory |
| Service Provider and their staff must undergo training in UKSCB procedures prior to start of contract and at intervals specified in the SLA/TPA. | | Mandatory |
| The service provider and their staff must be willing to participate in unscheduled spot checks on the quality of their work. These records will be retained by the UKSCB | | Mandatory |
| Only Service Provider’s staff who have undertaken training in UKSCB procedures may work in the UKSCB cleanroom facility | | Mandatory |
| Any events/anomalies occurring during cleaning must be reported immediately to the UKSCB Production Manager | | Mandatory |
| All staff employed by the Service Provider on the UKSCB cleanroom facility contract must be named and undergo NIBSC security checks prior to start of the contract | | Mandatory |
| Service provider must be willing to agree to a set of KPIs (Key performance indicators) in addition to the contact to be set at the contract stage. | | Mandatory |
| **Functional Specification** | | |
| The Service Provider must provide continuous coverage over the period of the contract, see annex 2 for cleaning requirements and example schedule. | Mandatory  Companies must provide a Business Continuity Plan showing how they will ensure weekly cover | |
| Cleaning must take place on Monday afternoons, except on Bank Holidays when cleaning will be done on a Tuesday. In exceptional circumstances, UKSCB may request this cleaning on the bank holiday Monday and this will need to be accommodated. | Mandatory | |
| The Service Provider must deploy sufficient cleaning staff to ensure that the facility is cleaned within the normal working day | Mandatory  Companies must indicate in the tender the minimum number of trained staff they intend to commit on a regular basis | |
| The Service provider must be able to assign the same trained staff to cleaning the UKSCB facility each week | Mandatory | |
| The Service Provider must be able to provide sufficient staff cover to take into account sickness and other leave so as to maintain the minimum number of on-site cleaning staff | Mandatory  Companies must indicate in their tender how they intend to comply with this requirement | |
| The Service Provider must be willing to work with the UKSCB production team in investigation of environmental monitoring warning / limit breaches including participating in any corrective / preventative actions that may arise from an investigation. | Mandatory | |
| On arrive at the UKSCB Cleaners must register their attendance with a member of staff from the UKSCB, and on completion of work the required paperwork must be handed to a member of staff of the UKSCB for sign off prior to the cleaners leaving site. | Mandatory | |
| Service Providers’ tenders must show the tender price for cleaning the cleanroom corridor and lobby, change 1 and change 2 areas plus the options of cleaning from just 1 cleanroom and associated change (3) area to all 5 cleanrooms and associated change (3) areas (Appendix 1), over the number of cleans required (Appendix 2). | Mandatory  Companies must show the cost of cleaning options on a per clean basis | |

**Appendix 1**

**Floor Plan UK Stem Cell Bank**

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**Floor Plan UKSCB Cleanrooms**



N.B. Pass-through shown in blue

**Areas covered by contract cleaning tender**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Item | Area | EU GMP Grade | Dimensions L x W x H  (m) | Floor Area (m2) |
| 1 | Change 1 | D | 5 x 2.5 x 2.7 | 12.5 |
| 2 | Change 2 | C | 5 x 2.5 x 2.7 | 12.5 |
| 3 | Clean Corridor (lobby) + pass-through | C | 7.5 x 1.5 x 2.7 | 11.25 |
| 4 | Clean Corridor + pass-through | C | 18 x 1.5 x 2.7 | 27.0 |
| 5 | *Cleanroom 1 including 2 MSC’s + Change 3 + pass-through hatches (3 total)* | *B*  *(A in MSC)* | *5.5 x 5 x 2.7* | *27.5* |
| 6 | *Cleanroom 2 including 2 MSC’s + Change 3 + pass-through hatches (3 total)* | *B*  *(A in MSC)* | 5.5 x 5 x 2.7 | 27.5 |
| 7 | *Cleanroom 3 including 2 MSC’s + Change 3 + pass-through hatches (3 total)* | *B*  *(A in MSC)* | 5.5 x 5 x 2.7 | 27.5 |
| 8 | *Cleanroom 4 including 2 MSC’s + Change 3 + pass-through hatches (3 total)* | *B*  *(A in MSC)* | 5.5 x 5 x 2.7 | 27.5 |
| 9 | *Cleanroom 5 including 2 MSC’s + Change 3 + pass-through hatches (3 total)* | *B*  *(A in MSC)* | *5.5 x 5 x 2.7* | *27.5* |
| 10 | **Total Floor Area (Core)** | | | **145** |

**Appendix 2**

**Disinfectants that will be in use from Jan 2021 by UKSCB (supplied):**

|  |  |  |
| --- | --- | --- |
| **Biocidal Agent** | **Type** | **Current Supplier** |
| 70% IPA | Klerwipe 70/30 IPA mop wipe | Cleanroom Shop |
| Low Residue Peroxide | Klerwipe Sporicidal Low Residue Peroxide mop wipe | Cleanroom Shop |
| Low Residue Quat | Klerwipe Low Residue Quat mop wipe | Cleanroom Shop |
| Sporicidal enhanced peroxide | Klerwipe sporicidal enhanced peroxide mop wipe | Cleanroom Shop |
| Active Chlorine (Will be used as required if persistent contamination is found) | TBC | Cleanroom Shop |

**Contractors Cleanroom Clothing Requirements (supplied)**

|  |  |
| --- | --- |
| Cat III Type 5/6 coverall with hood (Tyvek or similar) | Sterile gloves (2 pair) |
| Mop Cap | Overshoes |
| Masks |  |

**Cleaning Requirements 2021:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Cleaning type** | **Number cleans p.a.** | **Cleaning Agent** | **Areas** |
| Weekly Clean | **33** | 70% IPA | Surfaces, Equipment, Class II MSCs, Pass-through hatches |
| Alternating Low Residue Peroxide & Low Residue Quat **followed** by 70% IPA | Floors |
| Monthly deep Clean (every 4 weeks) | **10** | 70% IPA | Surfaces, Equipment, Class II MSCs. Pass-through Hatches |
| Alternating Low Residue Peroxide & Low Residue Quat **followed** by 70% IPA | Floors, Walls |
| Post Shutdown deep clean | **2** | 70% IPA | Surfaces, Equipment, Class II MSCs. Pass-through Hatches, inside cupboards, fridges and freezer |
| Sporicidal enhanced peroxide, **followed** by 70% IPA | Floors, Walls |

**Proposed Cleaning Schedule 2021**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Week Beginning** | **Type of clean** | **Disinfectant to be used**  **Followed by 70% IPA** |  | **Week Beginning** | **Type of clean** | **Disinfectant to be used**  **Followed by 70% IPA** |
| **2nd Jan – 7th  Feb 2021 - Not required, Winter shutdown** | | |  | 05-Jul | Weekly | Peroxide |
| 08-Feb | Post shutdown Deep clean | Sporicidal  enhanced peroxide |  | 12-Jul | Weekly | Peroxide |
| 15-Feb | Monthly | Peroxide |  | 19-Jul | Monthly | Quat |
| 22-Feb | Weekly | Peroxide |  | 26-Jul | Weekly | Quat |
| 01-Mar | Weekly | Peroxide |  | 02-Aug | Weekly | Quat |
| 08-Mar | Weekly | Peroxide |  | 09-Aug | Weekly | Quat |
| 15-Mar | Monthly | Quat |  | 16-Aug | Monthly | Peroxide |
| 22-Mar | Weekly | Quat |  | 23-Aug | Weekly | Peroxide |
| 29-Mar | Weekly | Quat |  | 30-Aug | Weekly | Peroxide |
| 05-Apr | Weekly | Quat |  | 06-Sep | Weekly | Peroxide |
| 12-Apr | Monthly | Peroxide |  | 13-Sep | Monthly | Quat |
| 19-Apr | Weekly | Peroxide |  | 20-Sep | Weekly | Quat |
| 26-Apr | Weekly | Peroxide |  | 27-Sep | Weekly | Quat |
| 03-May | Weekly | Peroxide |  | 04-Oct | Weekly | Quat |
| 10-May | Monthly | Quat |  | 11-Oct | Monthly | Peroxide |
| 17-May | Weekly | Quat |  | 18-Oct | Weekly | Peroxide |
| 24-May | Weekly | Quat |  | 25-Oct | Weekly | Peroxide |
| 31-May | Weekly | Quat |  | 01-Nov | Weekly | Peroxide |
| **7th - 14 June 2021 Not required, Summer shutdown** | | |  | 08-Nov | Monthly | Quat |
|  | 15-Nov | Weekly | Quat |
| 21-Jun | Post shutdown Deep clean | Sporicidal  enhanced peroxide |  | 22-Nov | Weekly | Quat |
| 28-Jun | Monthly | Peroxide |  | 29-Nov | Weekly | Quat |
| 05-Jul | Weekly | Peroxide |  | **6th – 27th December - Not required, Winter shutdown** | | |

**Appendix 3**

**Example of Current Cleaning SOP (Note: this procedure is currently under review due to implementation of new cleaning reagents and regime.)**

**UK STEM CELL BANK**

Standard Operating Procedure

Title: **CLEANING OF UKSCB CLEANROOMS**

**Purpose:**

To ensure that cleanrooms in UKSCB are cleaned to a consistent standard and that work surfaces and other critical areas are cleaned in the correct manner.

**Definitions:**

* Dedicated cleanroom garments – Cleanroom garments worn only within the UKSCB suite
* Dedicated cleanroom shoes – Shoes worn only within the UKSCB suite.
* 70% IPA – Sterile 70% isopropyl alcohol.

**Items required:**

* Cleanroom wipes & 70% IPA (Product code: Ecolab 3078480) or 70% IPA impregnated wipes (Product code: Ecolab 3079350)
* Disinfectants – Klercide A, B & D mopwipes (Product codes: Ecolab 3079280, 3079300, and 3079220 respectively).
* Mopwipe mop
* Autoclave bags and tape
* Incineration (Cin) bin
* Cleanroom/facility logbooks

**Applicable Documents:**

* Bench-Top Centrifuges and Microfuges. SCB/SOP/061. SN 5194
* CO2 & Multi-Gas Incubators. SCB/SOP/060. SN 5193
* Daily Cleaning Record. SCB/FRM/117. SN 7289
* Preparation for work in a Class II MSC. SCB/SOP/012. SN 1536
* Use and Maintenance of Nalgene (Mr Frosty) 1°C Freezing Containers. SCB/SOP/111. SN 6404

*NOTE:* It is important to be mindful of the potential physical impact that cleaning can have and to speak to your line manager if you have any concerns regarding your fitness for such duties. Where possible, vary tasks so that strenuous or repetitive actions are mixed with other activities, or share these tasks with another trained member of staff. Take regular breaks if required. For the safety cabinets, clean must be performed without lifting the base out but by moving sections to one side. Two operators required to lift the base completely out of cabinet. Refer to Manual handling Risk Assessment MH/00166.

**Procedure:**

1. Determine type of cleaning required.
   1. Pre-processing clean is carried out at the start of each working session by following steps 1.2.1-1.2.2 and is recorded on form SN 7289 (Daily Cleaning Record).
   2. Post-processing clean is carried out at the end of each working session by following steps 1.2.1-1.2.5 and is recorded on form SN 7289.
      1. Remove as much equipment as possible from the class II safety cabinet, then clean the work surface with 70% IPA wipes.
      2. Clean all other work surfaces and microscopes with 70% IPA wipes.
      3. Discard all disposable plasticware, used wipes etc into a cin bin or autoclave bag, as appropriate.
      4. Close all filled autoclave bags and cin bins with autoclave tape, following local disposal procedures.
      5. Transfer items for disposal to large pass-through for transfer out of the UKSCB.
   3. Post-campaign clean must be performed at the end of a banking campaign by following steps 1.3.1-1.3.2 and recorded on form SN 7289 (Daily Cleaning Record).
      1. Remove as much equipment as possible from the class II safety cabinet, then clean the work surface with 70% IPA wipes. Different cleaning reagents might be required upon discovery of contaminated cell banks.
      2. Clean the incubator, centrifuge, microfuge and Mr Frosty(s) that were used during the campaign according to SN 5193 (CO2 & Multi-Gas Incubators) SN 5194 (Bench-Top Centrifuges and Microfuges) and SN 6404 (Use and Maintenance of Nalgene (Mr Frosty) 1°C Freezing Containers SN 6404).
   4. Monthly (deep) clean must be performed by cleaning contractors or by trained UKSCB staff as per cleaning schedule in Table 1, at the end of a production run, prior to recertification of the cleanrooms, or following any maintenance work requiring large amounts of equipment not normally used in the UKSCB. Record cleaning products used during the monthly (deep) clean on the designated logbook assigned outside cleanroom facility.
   5. Weekly clean must be performed in all other circumstances by cleaning contractors or by trained UKSCB staff. Record cleaning products used during the weekly clean on the designated logbook assigned outside cleanroom facility. Please see Table 1 for cleaning schedule.
   6. Re-opening clean must be performed by cleaning contractors or by trained UKSCB staff post Planned Preventative Maintenance (PPM) of cleanroom suite (refer to Table 1). The Re-opening clean includes deep cleaning of the room surfaces and equipment and cleaning inside cupboards, fridges and freezers. Record cleaning products used during the re-opening clean on the designated logbook assigned outside cleanroom facility.
   7. Deep cleaning (6 stage cleaning) must be performed by cleaning contractors, prior recertification of the cleanroom suit. Records of the cleaning products used during the deep cleaning can be found in the Cleanroom certification folder.
2. For weekly & monthly (deep) cleans, collect mop & appropriate Klercide mopwipes.
   1. Klercide A & D wipes are used for weekly cleans on a rotational basis. (See Table 1 and 2)
   2. Klercide B (sporocidal) wipes are used for monthly (deep) and re-opening cleans. (See Table 1 and 2)
3. In the UKSCB cleanroom suite, rooms must be cleaned in the following order:
   1. Laboratories & associated pass-throughs (Hatches)
   2. Change 3 areas
   3. Clean corridor & associated pass-throughs (Hatches)
   4. Change 2 area
   5. Change1 area
4. Clean the walls [monthly (deep) and re-opening clean only].
   1. Move all equipment away from the walls to allow access for cleaning.
   2. Use the mop & Klercide mopwipes to clean the walls. Allow the walls to be exposed to the disinfectant for the recommended contact time (please see table 2). Following the recommended contact time listed in table 2.
   3. Remove biocide residues with 70% IPA mopwipes (product code: 3079350). It is essential that residues are removed so cleaning remains effective (microbes do not build up within the residue) and rusting does not occur.
   4. Discard all used wipes to autoclave bag.
5. Clean the class II cabinet with 70% IPA.
   1. Lift the cabinet front to allow access inside the cabinet.
   2. Clean the inside of the cabinet with 70% IPA wipes.
   3. Ensure that the inside of the cabinet front is cleaned.
   4. Discard all used wipes to autoclave bag.
6. Clean all work surfaces.
   1. Clean all surfaces with 70% IPA wipes.
   2. Clean all surfaces, including legs and undersides of benches, intercoms, microscopes and door handles.
   3. Ensure that, where practicable, equipment standing on benches is lifted and the area beneath the equipment is cleaned.
   4. Clean around doors and inner surfaces of all equipment.
   5. Allow to air dry.
   6. Discard all used wipes to autoclave bag.
7. Clean the floor.
   1. Move equipment, where practicable, to allow access for mopping the total floor area with the exception of refrigerators and freezers which require moving for cleaning once a year (after winter shutdown).
   2. Use the mop & disinfectant wipes to clean the floor. Allow the floor to be exposed to the disinfectant for the recommended contact time (please see table 2). Following the recommended contact time listed in table 2.
   3. Remove biocide residues with 70% IPA mopwipes (product code: 3079350). It is essential that residues are removed so cleaning remains effective (microbes do not build up within the residue) and rusting does not occur.
   4. Discard all used wipes to autoclave bag.
8. Repeat steps 4 to 7 for all areas to be cleaned.
9. Personnel can now exit the UKSCB cleanroom suite and remove clean room suits.
   1. Discard used gloves, mobcaps, masks etc into autoclave bag. Close bag with autoclave tape, and discard using following local disposal procedures.
   2. Place used clean room suits in the designated laundry locker.
10. Remove any items for discard from the cleanroom & clean corridor pass-throughs, and then clean all surfaces of the pass-through with 70% IPA wipes.
11. On leaving the UKSCB cleanroom suite, cleaning contractors or trained UKSCB staff must record details of cleaning in designated logbook. Production Manager and Quality Co-ordinator shall review logbook upon completion.

If out of specification results occur following environmental monitoring of class II cabinets and surfaces, they can be cleaned again with the appropriate disinfectant and 70% IPA.

Note:

No cleaning activities are required during the period of summer shutdown, unless banking activities are scheduled. During summer shutdown, only operating rooms must be cleaned and monitored for microbiological contaminations.

**Table 1: Schedule for cleaning of UKSCB cleanroom facility 2020**

|  |  |  |
| --- | --- | --- |
| **Date** | **Type of clean** | **Biocide to be used** |
| **25th November 2019 – 26th January 2020 - Not required, Winter shutdown** | | |
| 27th January | Monthly (**Re-opening**) | B (Chlorine)+IPA |
| 3rd February | Weekly | D (Amine)+IPA |
| 10th February | Monthly (deep) | B (Chlorine)+IPA |
| 17th February | Weekly | A (Biguanide)+IPA |
| 24th February | Weekly | A (Biguanide)+IPA |
| 2nd March | Monthly (deep) | B (Chlorine)+IPA |
| 9th March | Weekly | D (Amine)+IPA |
| 16th March | Weekly | D (Amine)+IPA |
| 23th March | Weekly | D (Amine)+IPA |
| 30th March | Monthly (deep) | B (Chlorine)+IPA |
| 6th April | Weekly | A (Biguanide)+IPA |
| 14th April | Weekly (**Tuesday**) | A (Biguanide)+IPA |
| 20th April | Weekly | A (Biguanide)+IPA |
| 27th April | Monthly (deep) | B (Chlorine)+IPA |
| 4th May | Weekly | D (Amine)+IPA |
| 11th May | Weekly | D (Amine)+IPA |
| 18th May | Weekly | D (Amine)+IPA |
| **25th of May 2020 – 7th of June 2020- Not required, Summer shutdown** | | |
| 8th June | Monthly (**Re-opening**) | B (Chlorine)+IPA |
| 15th June | Weekly | A (Biguanide)+IPA |
| 22th June | Weekly | A (Biguanide)+IPA |
| 29th June | Weekly | A (Biguanide)+IPA |
| 6th July | Monthly (deep) | B (Chlorine)+IPA |
| 13th July | Weekly | D (Amine)+IPA |
| 20th July | Weekly | D (Amine)+IPA |
| 27th July | Weekly | D (Amine)+IPA |
| 3rd August | Monthly (deep) | B (Chlorine)+IPA |
| 10th August | Weekly | A (Biguanide)+IPA |
| 17th August | Weekly | A (Biguanide)+IPA |
| 24th August | Weekly | A (Biguanide)+IPA |
| 1st September | Monthly (**Tuesday**) | B (Chlorine)+IPA |
| 7th September | Weekly | D (Amine)+IPA |
| 14th September | Weekly | D (Amine)+IPA |
| 21th September | Weekly | D (Amine)+IPA |
| 28th September | Monthly (deep) | B (Chlorine)+IPA |
| 5th October | Weekly | A (Biguanide)+IPA |
| 12th October | Weekly | A (Biguanide)+IPA |
| 19st October | Weekly | A (Biguanide)+IPA |
| 26th October | Monthly (deep) | B (Chlorine)+IPA |
| 2nd November | Weekly | D (Amine)+IPA |
| 9th November | Weekly | D (Amine)+IPA |
| 16th November | Weekly | D (Amine)+IPA |
| **23rd November 2020- 6th January 2021- Not required, Winter Shutdown** | | |

**Table 2. Contact times for Klercide A, B and D Klerwipes**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Klerwipe** | **European standard and micro-organism activity** | **Contact time (time floor remains wet)** | **Contact time operators should use prior to removal of residue with 70% IPA** |
| Klercide A (Quat/Biguanide)  Product code: 3079280 | EN1276 Bactericidal | 5 min | 5 min |
| EN 1650 Yeasticidal | 5 min |
| Klercide B (Chlorine/Quat)  Product code: 3079300 | EN1276 Bactericidal | 5 min | 5 min |
| EN 1650 Yeasticidal | 15 min |
| EN 13704 Sporicidal | 60 min |
| Klercide D (Amine)  Product code: 3079220 | EN1276 Bactericidal | 5 min | 5 min |
| EN 1650 Yeasticidal | 15 min |

END

**UK STEM CELL BANK**

Standard Operating Procedure

Title: **CLEANROOM ENTRANCE and Exit PROCEDURE**

Purpose:

* To ensure that personnel carry out the correct entrance and exit procedure to gain access to the UK Stem Cell Bank cleanroom Facility.

Definitions:

* + “Modesty switch” – A switch that, when activated, prevents the doors to the change area being opened by other members of staff, whilst the staff member that operates the switch is using the change area.
* 70% IPA – Sterile 70% isopropyl alcohol.

Applicable documents:

* + SCB/MPD/019 – Cleaning Disinfection , Environmental Monitoring and Management of the Cleanrooms, Cleanroom Personnel and Materials [s/n 1578](http://waddell/scripts/WebObjects.dll/IVPro.woa/wa/Docfetch?db=NIBSC%20(view%20only)&id=1578)
  + SCB/SOP/028 – Instructions for Contractors and Visitors Working in the UKSCB Cleanrooms and Other Controlled Areas [s/n 1313](http://waddell/scripts/WebObjects.dll/IVPro.woa/wa/Docfetch?db=NIBSC%20(view%20only)&id=1313)

Items required:

* 70% IPA
* Skin disinfectant
* Tape for covering jewellery etc
* Supplies shelves
* Disposable mob hat
* Disposable Bouffant Cap/Beret
* Disposable face mask
* Dedicated cleanroom shoes or disposable overshoes
* Cleanroom undergarments/coveralls
* Disposable sterile gloves (several pairs for emergency and double gloving)
* Disposable Tyvek coveralls (for visitors)
* Sterile wipes
* Waste bag/bin
* Lockers for storage of clothing
* Laundry locker

Notes:

* UKSCB staff shall wear dedicated cleanroom garments in the UKSCB cleanrooms. Disposable Tyvek coveralls shall be provided for visitors and contractors entering the cleanrooms (refer to [s/n 1313](http://waddell/scripts/WebObjects.dll/IVPro.woa/wa/Docfetch?db=NIBSC%20(view%20only)&id=1313)).
* The entry, exit and gowning procedures are suspended during the winter shut-down for planned preventative maintenance (PPM) but remain in place during the summer period of PPM.
* Due to health and safety concerns open wounds are not permitted within the cleanroom. All open wounds, regardless of size or location should be safely dressed and covered.

**Cleanroom Garment Components**

Materials

* Durable, non-shedding material with particle retention properties
* Polyester material to prevent body temperature increase during physical activity or long periods of wear

Frequency of garment changing

* It is not required to change garment upon each entry
* In practise, a personalised garment must be change at least weekly.
* Change garment after weekly/monthly cleaning
* If for any reason, the sterility of the garment has been compromised, then change garment.

**Personal Hygiene**

Prior to entering the cleanrooms:

1. Discuss any condition that might lead to increased contamination or shedding of particulates with the Production Manager or deputy.
2. Wash hands and nails (No nail polish is allowed)
3. Ensure hair is tidy and long hair tied back
4. Ensure shoes are visually clean, removing any mud or water

**Entrance Procedure:**

1. Wash hands before entering the cleanroom facility and mark self as checked-in on the check-in / check-out board.
2. Enter change 1 from the viewing corridor.
3. Once the door has closed, you can activate the “modesty switch” located on the wall to the right of the door (optional).

***Note:*** *The doors to the outer corridor and clean corridor cannot be opened until the “modesty switch” is deactivated, preventing other members of staff from entering the change area whilst it is in use.*

1. Remove street clothing/shoes and store in dedicated locker in change 1.
2. Remove jewellery, watches etc and place in locker. If the jewellery cannot be removed it must be covered with tape – prior agreement with Management required.
3. Collect any required items of cleanroom clothing from the supplies shelves. Wipe/spray the packaging with 70% IPA.
4. Dispense pumped skin disinfectant (e.g. Spirigel) onto one hand, then rub hands together, and up both arms to the elbow, until the disinfectant has been absorbed.
5. Put on a pair of non-sterile disposable gloves.
6. Remove a disposable mob hat from the supplies shelves.
7. Put on mob hat, ensuring that all hair is tucked inside the hat.
8. Step over the barrier in Change 1 into cleanroom shoes.
9. Spray gloved hands with 70% IPA.
10. Press the button to open the door & proceed through to change 2.
11. Clean the step-over barrier with 70% IPA wipes.
12. Remove a disposable face mask from the supplies shelves.
13. Put on face mask, ensuring that the nose and mouth are completely covered.
14. Remove the disposable Bouffant Cap/ Beret from the supplies shelves.
15. Put on Bouffant Cap/Beret over mob hat.
16. Spray gloved hands with 70% IPA.
17. Put on cleanroom coverall (or disposable Tyvek coverall)taking care not to let the garments touch the floor. The outside layer of the cleanroom garment should be touched to the minimum.
18. Stepping out of the first pair of cleanroom shoes from Change 1, step over the step-over bench into a pair of dedicated cleanroom shoes or disposable overshoes.
19. Remove the non-sterile disposable gloves that were donned earlier and place in the waste bin.
20. Take 1 pack of appropriately sized disposable sterile gloves from the supplies shelves. Open the pack and put on the pair of gloves.

***Note:*** *Double gloves must be worn for any cell banking procedures.*

1. Take additional pairs of appropriately sized disposable gloves from storage and transfer into the cleanroom.
2. Check garments in the full-length mirror in change 2, to ensure that all closures are correctly sealed, and that all garments have been donned correctly.
3. Once satisfied that all garments are in order, spray gloves with 70% IPA, deactivate the “modesty switch” located to the right of the door to the clean corridor (if activated), to enable the doors to the outer and clean corridor to be opened, and to indicate that the change area is free for use.
4. Proceed from change 2 to the clean corridor.

*Note: Access to cleanrooms 2 – 5 is through a restricted access door. Appropriately trained staff must swipe their security pass to open this door.*

1. Enter change 3 for the required cleanroom from the clean corridor.
2. Proceed from change 3 to the cleanroom.
3. Prior to commencing any banking work put on another pair of gloves.
4. Outer sterile gloves should be changed a minimum of once during the processing procedure.

**Exit Procedure:**

1. Enter change 3 from the cleanroom laboratory and proceed to the clean corridor.
2. Enter change 2 from the clean corridor.
3. Once the door has closed, the “modesty switch” located on the wall to the left of the door from the clean corridor may be activated (optional).

***Note:*** *The doors to the outer corridor and clean corridor cannot be opened until the “modesty switch” is pressed again, preventing other members of staff from entering the change area whilst it is in use.*

1. If carrying items for disposal/laundry, place these on the step-over bench.
2. Step out of cleanroom clothing and cleanroom shoes and over the step-over bench into another pair of cleanroom shoes from Change 1.
3. Remove one pair of disposable gloves, face mask, bouffant cap/beret, and discard into waste bag.
4. With the remaining pair of sterile disposable gloves and the mob hat still worn, remove cleanroom clothing and hang them in designated locker in change 2.
5. Collect any items for laundry.
6. Proceed through the door to change 1.
7. Place items for laundry onto the step-over.
8. Step out of cleanroom shoes and over the step-over bench, leaving the shoes behind.
9. Remove mob hat and disposable gloves, put on street clothing, jewellery, watches etc stored in designated locker in change 1.
10. Once satisfied that clothing etc is in order, de-activate the “modesty switch” located to the left of the door from change 1 to the viewing corridor (if activated), to enable the doors to the outer and clean corridor to be opened, and to indicate that the change area is free for use.
11. Proceed from change 1, taking any items of laundry for transfer to the laundry locker located in the viewing corridor. Mark self as checked-out on the check-in / check-out board.

**END**