SERVICE LEVEL AGREEMENT: XXXXXX

TECHNICAL AGREEMENT
BETWEEN
XXXXXX ROYAL HOSPITAL ASEPTIC SERVICES DEPARTMENT
AND
CONTRACTOR

PHARMACY DEPARTMENT

xxxxxxx ROYAL NHS FOUNDATION TRUST

xxxxxxx

xxxxxxx

xxx xxx

REVISION No.	**-**	**2.0**
DATE OF ISUE	**-**	
DATE OF REVIEW	**-**	
SUPERSEDES	**-**	**1.0**
ISSUED BY	**-**	
APPROVED BY	**-**	

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1. Document Revision History

Revision	Details	Author	Date Superseded
1	New Document	J Scott	May 2019
2	Previous version out of date	A Laborit	N/A

2. Approval

The following Technical Agreement is made between:

The Contract Giver (CG):xxxxx Royal Hospital Aseptic Services department,

and

The Contract Acceptor (CA): xxxxxxxxxxxxxxxxxxxxx

Agreed on behalf of the CG:

Name:
Title: Aseptic Services Manager
Signature:
Date:

Name:
Title:
Signature:
Date:

Agreed on behalf of the CA:

Name:
Title: Technical Services Manager
Signature:
Date:

Name:
Title:
Signature:
Date:

This contract is supplemental to any financial agreements and any subsequent agreements between the two parties and will last for the duration of the agreement. The technical agreement shall be reviewed every two years or earlier if requested by either party. This Technical Agreement shall be effective as of the date of the final signature and shall remain in effect until review or termination.

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3. Scope:

This agreement defines the roles and responsibilities between the CG and CA relating to the planned and reactive maintenance of key plant and equipment within the Aseptic Services Unit as specified in the schedule in Appendix 1.

4. Services and terms of agreement:

4.1 The CA will perform maintenance, including reactive and Planned Preventative Maintenance (PPM), of all of the CG's assets, including the Air Handling Units (AHUs), workstations, clean room suites, intercoms and alarm systems in accordance with the relevant in-house procedures (copies will be made available by the CG when required) and regulations (EU GMP).

4.2 Each party must inform the other of any changes in working practices which may affect the operation of this agreement.

5. Staff and Training:

5.1 The CA shall issue a list of current staff; able to service the Aseptic unit at the time of this agreement, to the CG and ensure this is kept up to date (a log of staff approved to work in the aseptic unit is included in Appendix 3).

5.2 All work carried out by the CA should be performed by appropriately qualified and trained personnel. The CA must ensure that works are only completed by approved, trained personnel (see Appendix 3).

5.3 All CA staff must receive training from the CG in the principles of GMP, gowning, handwashing and transfer before performing work within the unit.

5.4 All CA staff must receive annual re- training from the CG in the principles of GMP.

5.5 CG must provide all CA staff with the appropriate training documentation. This must be completed by the CA and returned to the CG.

5.6 All CA staff must read SOPs AS1, AS2, AS3, AS133, AS204, AS138, AS4, AS145, AS104 and AS227. This must be recorded on the training documentation.

5.7 Non-trained staff are permitted to work in the unclassified areas within the aseptic suite.

5.8 The CA shall notify the CG before sending any new members of staff to perform work so arrangements can be made for training.

5.9 The CA will arrange for maintenance to be carried out by their engineers or suitable sub-contractors which must have been agreed with the CG beforehand; see Appendix 2 for list of approved sub-contractors.

5.10 The CA will supervise any works carried out by sub-contractors.

6. Permit to Work:

6.1 All CA staff must report to either: The Aseptic Services Manager, Aseptic Services Deputy or another designated senior member of staff upon arrival into the unit and before commencing works.

6.2 The CA shall obtain appropriate authorisation through the Planned Preventative Maintenance (PPM) record or works request form which act as the ‘permit to work’ before carrying out any work within the unit.

6.3 All details of the work completed should be recorded on the PPM record or works request form and returned to CG management upon completion.

6.4 CA must ensure that sub-contractors do not enter the unit unless an appropriate permit to work has been completed by aseptic staff.

6.5 CA must ensure that subcontractors record all the details of the works carried out on the PPM record or permit to work forms.

7. Planned maintenance:

7.1 PPM will be carried out by the CA in accordance with the PPM schedule in Appendix 1. Any deviations from the schedule must be notified to the CG.

7.2 Frequency of PPM should be in accordance with departmental procedures and Appendix 1.

7.3 The CG will ensure that all equipment and plant is made available to the CA at the times specified in the testing schedule in Appendix 1.

7.4 The CG management will complete a PPM record form, which acts as a ‘permit to work’, in accordance with SOP AS121 and provide to CA personnel upon arrival.

7.5 The CG management must give authorisation for the engineer to proceed, by signing the PPM form, before any works can commence.

7.6 CA personnel will complete the relevant sections of the PPM record form and will not commence work until authorisation to proceed has been given.

7.7 CA personnel will perform each part of the job description as required for the item being serviced and as per the PPM schedule in Appendix 1.

7.8 If the planned maintenance task is not able to be completed or any follow up work is needed this will be raised as a reactive works request.

8. Reactive Maintenance:

8.1 When reactive maintenance is required the CG will make a works request via the CA Helpdesk (xxxxxxx).

8.2 The CG will complete the works request form, which acts as the 'permit to work', as per in-house SOP xxxxx.

8.3 CG management must give authorisation for the engineer to proceed, by signing the works request form, before any works can commence.

8.4 CA personnel will record details of any work carried out in the relevant section of the works request form.

8.5 The CA should respond to a reactive maintenance request within 2 hours for all issues deemed urgent by the CG.

8.6 The CA should respond to a reactive maintenance request within an agreed length of time for issues deemed to be less urgent by the CG.

9. Review of work undertaken:

9.1 Upon completion of any work within the unit CA staff must report to either: The Aseptic Services Manager, Aseptic Services Deputy or another designated senior member of staff.

9.1 CG management will check that the equipment/plant serviced is in satisfactory working order upon completion of the work undertaken and that all documentation has been completed before signing the asset/unit back into use using the PPM record form or works request form.

9.2 CG management will review the work carried out including any relevant results, and take appropriate action.

9.3 The CA shall be responsible for the sending of any results and/or reports of completed work, including calibration certificates, to the CG.

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10. Complaints:

10.1 The CG will relay any feedback to the CA via the formal customer complaints system.

10.2 The CG will collaborate with the CA during the investigation of any complaints.

11. Changes to the schedule:

11.1 Both parties may jointly agree to omit any part of the service, or provide additional services, or vary temporarily or permanently any part of the service by mutual joint consent.

11.2 The CG must give the CA reasonable notice to request a second party audit.

12. Appendices:

Appendix No.	Title
1	PPM Schedule
2	Approved sub-contractors
3	Approved log of staff

APPENDIX 1:Contractor PPM SCHEDULE

APPENDIX 2: APPROVED SUB-CONTRACTORS

Sub-contractors which have been approved to carry out work within Xxxx (Hospital) Royal Aseptic Unit on behalf of Contractor:

- CONTRACTOR
- Acquisition Systems Ltd (Pharmagraph)
- Protec
- Direct security Ltd
- Universal Cooling

APPENDIX 3: APPROVED LOG OF STAFF AUTHORISED TO UNDERTAKE JOBS IN THE CLEANROOMS

CA staff must sign the log below after undertaking training and when authorised/request by the CG.

Only member of staff whose signature is included below are authorised to undertake jobs within the aseptic unit.

Name	Signature	Initial