DEFICIENCY SEVERITY MATRIX for EL(97)52 AUDITS

3 Minimising Risk with Injectable Medicines

Deviation from Standard –		
Complies / Negligible		**Severity Score (S)**
Current Injectables Medicines Policy (3.1.1) Organisational policies and SOPs for all items listed in 4.1.3, and associated roles and responsibilities (4.1.3)	**Complies / Non compliant***	
Risk assessments for the sites of preparation for all injectable medicines (3.1.2)	**Complies / Non compliant***	
No vial sharing for single use vials outside pharmacy (13.1.11)	**Complies / Non compliant***	
Location of preparation appropriate, with pharmacy involvement (level of risk determined by NPSA 2007)(3.1.3) System for communicating decisions on location of preparation – aseptic units / clinical areas (3.3.2)	**Complies / Non compliant***	
Current high risk (minimum) list of NPSA 'red' injectables (3.1.4)	**Complies / Non compliant***	
Risk assessment for new injectables e.g. D &T (3.1.5)	**Complies / Non compliant***	
Pharmacy strategy to reduce risk for all injectables (pharmacy prepared, out sourced, clinical areas) (3.2.1)	**Complies / Non compliant***	
Appropriate pharmacy catalogue (prepared and outsourced) available in clinical areas (3.2.2)	**Complies / Non compliant***	
Robust arrangements to specify the quality of outsourced aseptic products (3.2.3)	**Complies / Non compliant***	
Additions to PN only in pharmacy (3.2.4)	**Complies / Non compliant***	
Arrangements for PN out of hours satisfactory (3.2.5)	**Complies / Non compliant***	

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3 Minimising Risk with Injectable Medicines continued

Arrangements for intrathecal chemotherapy comply with national guidance (see separate aide memoire) (3.2.6, 3.2.7)	**Complies** / **Non compliant***	
Vinca alkaloids labelled 'Fatal if given by any other route' (8.8.5)	**Complies** / **Non compliant***	
Intrathecal products labelled 'For intrathecal use only' (8.8.6)	**Complies** / **Non compliant***	
Handling of concentrated potassium complies with NPSA 2002 Alert and R-T-A products provided if possible (3.2.8)	**Complies** / **Non compliant***	
Preparation uses closed systems only (3.2.9) Ampoules only ever used for single withdrawal immediately after opening (13.1.9)	**Complies** / **Non compliant***	
Shortest practical expiry allocated to all products (maximum 7 days) (3.2.10)	**Complies** / **Non compliant***	
Residual risks recognised e.g. risk register (3.3.1)	**Complies** / **Non compliant***	
System for communicating heightened risks e.g. initiating contingency (3.3.3)	**Complies** / **Non compliant***	
All risks regularly reviewed e.g. risk register (3.4.1)	**Complies** / **Non compliant***	
System to review errors and incident organisation-wide and respond (3.4.2)	**Complies** / **Non compliant***	
System to learn from external events and respond to national alerts (3.4.3)	**Complies** / **Non compliant***	

4 Prescribing, Clinical Pharmacy and Aseptic Services Verification

Deviation from Standard –		
Complies / Negligible		**Severity Score (S)**
Prescription signed by approved prescriber (4.1.1)	**Complies / Non compliant***	
Current approved list of non-medical prescribers (4.1.2)	**Complies / Non compliant***	
Access to references e.g. BNF, Medusa , for all staff involved in prescribing and verification (4.1.4)	**Complies / Non compliant***	
Specialist references available for paediatrics and neonates, e.g. BNF for children (4.1.5)	**Complies / Non compliant***	
Chemotherapy regimes authorised by MDT, consultant or follow a CT protocol (4.1.6) Documentation includes details listed in 4.1.6.1 (4.1.6.1) Procedure for recording deviations from algorithms (4.1.6.2) Documentation control system for regimens (4.1.6.3)	**Complies / Non compliant***	
Conditions for supply of diagnostic radiopharmaceuticals against Nuclear Medicine requests comply with conditions listed in (4.1.7.1)	**Complies / Non compliant***	
Pharmacist verifying Nuclear Medicines request familiar with procedure (4.1.7.2)	**Complies / Non compliant***	
Protocol states clearly use of adjuncts (4.1.7.3)	**Complies / Non compliant***	
Clinical trials protocols authorised. Activities comply with CT legislation (4.1.8)	**Complies / Non compliant***	
All prescriptions (generated manually or electronically) clear, unambiguous, accurate (4.1.9)	**Complies / Non compliant***	
Standardised prescription format for each product type (4.1.10) Trust approved for paper or electronic prescriptions	**Complies / Non compliant***	
Computerised systems for prescribing or dose calculations fully validated. Roles and responsibilities, security and audit trails clear (4.1.11.a,b,c)	**Complies / Non compliant***	

4 Prescribing, Clinical Pharmacy and Aseptic Services Verification continued

Suitable arrangements and responsibilities documented for clinical pharmacy and aseptic service verification (4.2.1, 4.2.2) Clinical pharmacy verification of the original prescription covers all items listed in 4.3.1 (procedure is in place) (4.3.1) Patient details and dose checks for worksheets linked to electronic prescribing should be verified initially (8.7.4)	**Complies** / **Non compliant***	
Additional check carried out for chemotherapy (4.3.2)	**Complies** / **Non compliant***	
Suitable arrangements for checking full blood counts and monitoring toxicities (4.3.3)	**Complies** / **Non compliant***	
Additional checks carried out for PN (4.3.4)	**Complies** / **Non compliant***	
Maximum glucose concentration/osmolarity for use peripherally agreed. For greater concentrations of glucose, PN is labelled for central line only (8.8.4)	**Complies** / **Non compliant***	
London & SE Multidisciplinary team for PN5	**Complies** / **Non compliant***	
Any modifications to prescription are suitably verified and recorded (4.3.5)	**Complies** / **Non compliant***	
Additional checks carried out for radiopharmaceuticals (4.3.6)	**Complies** / **Non compliant***	
Robust systems if original prescription not present during preparations (4.3.7)	**Complies** / **Non compliant***	
Authorised Pharmacists carries out aseptic services verification and ensures clinical verification product is correct for intended route (4.4.1, 4.4.2)	**Complies** / **Non compliant***	
Prescription verification recorded on worksheet (4.4.3)	**Complies** / **Non compliant***	

5 Management

Deviation from Standard –		
Complies / Negligible		Severity Score (S)
Appropriate organisational Structure indicates clearly responsibilities and accountability of each member of staff (5.1.1) All accredited product approvers accountable directly to Accountable Pharmacist and in job descriptions (5.1.13) Where delegated product approval, management structure complies with national competency framework (5.1.14) All staff professionally accountable to Accountable Pharmacist (5.1.3) Accountable Pharmacist directly responsible to Chief Pharmacist (CP) (5.1.4) Accountable Pharmacist has title and responsibilities in their job description (9.1.2) Quality Management (QA) duties in job descriptions (8.1.4)	**Complies / Non compliant***	
Aseptic unit is managed by Accountable Pharmacist (AcP) who implements QA system (5.1.2)	**Complies / Non compliant***	
System for capturing staff suggestions for improvements and implementing regulatory changes (5.1.5)	**Complies / Non compliant***	
Supervision by an Authorised Pharmacist, including out of hours (5.1.6)	**Complies / Non compliant***	
Accountable Pharmacist authorises SOPs. Deviations approved and documented (5.1.8)	**Complies / Non compliant***	
Chief Pharmacist has effective governance arrangements for all injectable medicines (pharmacy, clinical areas, outsourced) (5.1.10)	**Complies / Non compliant***	
Chief Pharmacist responsibility for adequate resourcing documented in a policy (5.1.11)	**Complies / Non compliant***	

5 Management continued

Policy for aseptic preparation present. If delegated product approval, has board-level agreement (5.1.12)	**Complies** / **Non compliant***	
Regular quality management meetings. Chief Pharmacist aware PQS functioning correctly (5.2.4)	**Complies** / **Non compliant***	
PQS reviewed and Chief Pharmacist takes a risk management approach if quality is reduced (5.2.5)	**Complies** / **Non compliant***	
Culture of continuous quality improvement, e.g. learning from errors (5.2.6)	**Complies** / **Non compliant***	
Accountable Pharmacist authorises SOPs for product preparation. (If no evaluated data, patient-based decision made on clinical need and risks.) (5.2.7)	**Complies** / **Non compliant***	
Authorised Pharmacist risk-benefit decision for non-catalogue requests (5.2.8)	**Complies** / **Non compliant***	
Rationale for non-catalogue preparation recorded and AP informed (5.2.9)	**Complies** / **Non compliant***	
CP ensures QA system and off-site testing regularly reviewed (5.3.4)	**Complies** / **Non compliant***	
CP ensures regulatory compliance, e.g. for trials (5.3.5)	**Complies** / **Non compliant***	
Detailed contingency plan available (5.4.1)	**Complies** / **Non compliant***	
Current and effective capacity plan implemented (5.5.1)	**Complies** / **Non compliant***	
CP ensures capacity plan accepted outside pharmacy e.g. by Board (5.5.2)	**Complies** / **Non compliant***	
Workload figures regularly reviewed against capacity plan and action taken if necessary (5.5.3)	**Complies** / **Non compliant***	
Capacity plan ensures adequate resourcing, timely action if needed, and is comprehensive (includes QA and outsourcing workload) (5.5.4)	**Complies** / **Non compliant***	
Capacity plan reviewed at least annually and change control used if needed (5.5.5)	**Complies** / **Non compliant***	
London & SE Networking at all levels can be demonstrated both internally and externally	**Complies** / **Non compliant***	

6 Formulation, Stability and Shelf Life

Deviation from Standard –		
Complies / Negligible		**Severity Score (S)**
National (yellow-covered) standards used for stability studies (6.1.1)	**Complies / Non compliant***	
End of shelf-life testing used to provide additional assurance (6.1.2)	**Complies / Non compliant***	
Authorised Pharmacist ensures stability information valid and relevant (6.2.1) (Responsibility may be with the Accountable Pharmacist)	**Complies / Non compliant***	
References available and applicability carefully assessed, e.g. brands (6.2.2)	**Complies / Non compliant***	
PN stability assessed by matrix approach (6.2.3)	**Complies / Non compliant***	
Computerised systems used for stability calculations are validated (6.2.4)	**Complies / Non compliant***	
Stability data and stability assessments held on file (6.2.5) Controlled system for stability data (paper or electronic) (6.9.1)	**Complies / Non compliant***	
Documented risk assessment if no stability data (exceptional only) (6.2.6)	**Complies / Non compliant***	
Stability data obtained if (above) become routine products (6.2.7)	**Complies / Non compliant***	
Data interpreted and specifically applies, e.g. brands, concentrations (6.3.1) Extrapolation and interpolation used appropriately. (No extrapolation for biopharmaceuticals.) (6.3.2, 6.3.3) Identical practices used for biopharmaceuticals if expiry beyond SmPC (6.3.4) Degradation products considered for shelf-life (6.3.5)	**Complies / Non compliant***	
Factors which may impact on stability are considered, including nature of container, particularly for biopharmaceuticals (6.4)	**Complies / Non compliant***	

6 Formulation, Stability and Shelf Life continued

Integrity of final container assessed up to shelf-life (6.6.1)	**Complies** / **Non compliant***	
In-house integrity data or national data assessed as applicable is available (6.6.2)	**Complies** / **Non compliant***	
Infusion bags not spiked ahead of the time of their use in clinical areas (6.6.3)	**Complies** / **Non compliant***	
Expiry period based on all information available (microbiological and physio-chemical) (6.7.1)	**Complies** / **Non compliant***	
For biopharmaceuticals external data considered alongside in-house data (6.7.2)	**Complies** / **Non compliant***	
Expiry period reassessed if new data available (6.7.3)	**Complies** / **Non compliant***	
Maximum 7 day expiry (6.7.4)	**Complies** / **Non compliant***	
Starting materials and key components subject to formal change control (6.8)	**Complies** / **Non compliant***	
Data and assessments referenced on worksheets (6.9.2)	**Complies** / **Non compliant***	
Problems with products or patient adverse reactions investigated (6.10)	**Complies** / **Non compliant***	

7 Facilities and Equipment

Deviation from Standard –		
Complies / Negligible		Severity Score (S)
Design of new or refurbished facilities and equipment complies with the principles listed in section 7.1 (see standards) (7.1) London & SE Finishes and condition of facilities satisfactory London & SE Note: Will apply also to existing facilities with mitigation with design and age.	**Complies** / **Non compliant***	
Gaseous biodecontamination considered for new units/isolators (12.4.1)	**Complies** / **Non compliant***	
Validation included in Validation Master Plan that is authorised and subject to deviation and change control systems (7.1.3, 7.1.4)	**Complies** / **Non compliant***	
Clean rooms and clean air devices normally run continuously with no setback (7.2.1)	**Complies** / **Non compliant***	
Critical equipment including AHUs have been commissioned and have PPM are re-qualified and are operated according to SOPs (7.2.3)	**Complies** / **Non compliant***	
London & SE Workstation clean-up time validated.	**Complies** / **Non compliant***	
Technical Agreements (TA) for PPM of all critical equipment (11.10.1)	**Complies** / **Non compliant***	
Loss of environmental control subject to CAPA (7.2.4)	**Complies** / **Non compliant***	
Reports from visits reviewed, assessed against the TA and accepted by Accountable Pharmacist (7.2.6) (11.10.2)	**Complies** / **Non compliant***	
Access controlled and permit to work in place and appropriately signed off (7.2.7, 7.2.8) Normal operation confirmed after any maintenance (7.2.5)	**Complies** / **Non compliant***	

7 Facilities and Equipment continued

Unidirectional air flow cabinets (UAFC) and isolators appropriately sited (7.3.1, 7.3.2)	**Complies** / **Non compliant***	
Change rooms suitable design (7.3.3-7.3.5)	**Complies** / **Non compliant***	
Support rooms suitable design (7.3.7, 7.3.8)	**Complies** / **Non compliant***	
Materials transferred via dedicated hatches of suitable design (7.3.8-7.3.11)	**Complies** / **Non compliant***	
Additional considerations taken into account for specialist clean-room applications, e.g. ATMPs, blood labelling, cyclotrons (7.4.1-7.4.5)	**Complies** / **Non compliant***	
QC facilities physically separated from aseptic preparation and under suitable managerial control (7.5.1)	**Complies** / **Non compliant***	
UAFCs suitably sited and used to prevent disruption to airflow (7.6.1)	**Complies** / **Non compliant***	
Isolators suitably designed for products prepared, for both operator and product protection (7.6.2)	**Complies** / **Non compliant***	
Impact of equipment, e.g. auto-compounders, dose calibrators, on air flow is assessed (7.6.3.1)	**Complies** / **Non compliant***	
Suitable clothing and changing process (7.7.1-7.7.7) Entry and exit of personnel, gowning and gloving procedures acceptable (10.1.1.1 to 10.1.1.4)	**Complies** / **Non compliant***	
Clean room garments reviewed and subject to validated laundering (7.7.8)	**Complies** / **Non compliant***	
SOP details suitable changing frequency for garments (7.7.9, 7.7.10)	**Complies** / **Non compliant***	

7. 2 Facilities and Equipment Parenteral Nutrition Compounders

Deviation from Standard –		
Complies / Negligible		Severity Score (S)
Adequate Validation Master Plan, Installation and Operational Qualifications including draft SOPs	**Complies** / **Non compliant***	
Risk Assessment of general and local operational characteristics and health and safety issues including summary of all the critical control points	**Complies** / **Non compliant***	
Change Control for newly installed compounders	**Complies** / **Non compliant***	
Adequate Performance qualification including calibration and cleaning Final version of SOPs	**Complies** / **Non compliant***	
Robust IT protection and procedures including adequate back up systems and secure interface	**Complies** / **Non compliant***	
Adequate training and competency assessment records for all aspects including high level operations	**Complies** / **Non compliant***	
Manufacturer's recommendations followed for all operational aspects	**Complies** / **Non compliant***	
PPM schedule or manufacturer's support package	**Complies** / **Non compliant***	
Impact of auto-compounders on air flow is assessed (7.6.3.1)	**Complies** / **Non compliant***	
Controlled use of bar code identification system. Controls in place where bar code labels are printed and applied3	**Complies** / **Non compliant***	
Adequate control of source solutions drawn into syringes and connected to compounder	**Complies** / **Non compliant***	

7. 2 Facilities and Equipment Parenteral Nutrition Compounders continued

Documented evidence of critical checks and controls including set up and in process checks Correct starting material connected to correct line. Volume delivery check (10.1.4.4) Independent check on the required volume for each solution (10.1.4.4) These checks should be independent of set-up and may be either a second operator or automated verification e.g. barcode linking). Replenishment of starting solutions throughput the process should be similarly verified (10.1.4.4)	**Complies** / **Non compliant***	
Process and operator validations	**Complies** / **Non compliant***	
Sterility testing and accuracy testing ongoing	**Complies** / **Non compliant***	
Validated use of peripheral equipment e.g. scales	**Complies** / **Non compliant***	
Release specification based on documented evidence of satisfactory preparation All printed reports available for checking and final release3	**Complies** / **Non compliant***	
Controlled use of tubing and consumables associated with the compounder Tubing clamped before removal (10.1.3.19)	**Complies** / **Non compliant***	
Details of remaining manual additions (10.1.4.4) SOP for manual additions to part prepared bags and the attachment of lipid phase via lines and filters	**Complies** / **Non compliant***	
Reconciliation of starting solutions at the end of the session (10.1.4.4) Reconciliation of starting materials to ensure the correct quantity and strength Reconciliation of components3	**Complies** / **Non compliant***	

8 Pharmaceutical Quality System

Deviation from Standard –		
Complies / Negligible		Severity Score (S)
Robust PQS fully documented, e.g. in a quality manual (8.1.1, 8.1.2) PQS fully documented and effectiveness monitored (5.2.1)	**Complies** / **Non compliant***	
PQS adequately resourced (8.1.3)	**Complies** / **Non compliant***	
SOPs for product initiation, regular preparation, product discontinuation (8.2.1.1)	**Complies** / **Non compliant***	
SOP for documentation control covering, e.g. approval, archiving (8.2.2.1)	**Complies** / **Non compliant***	
Comprehensive and current VMP, including computerised systems (8.2.4)	**Complies** / **Non compliant***	
Suitable system for deviation management, including trending (8.2.5.1) Quality indicators, e.g. complaints etc recorded, investigated and trended (5.2.3)	**Complies** / **Non compliant***	
Appropriate level of investigation of deviations, e.g. RCA, CAPA (8.2.5.2)	**Complies** / **Non compliant***	
Suitable change control (CC) system, including impact assessment on product quality (8.2.6.1) Implementation of changes tracked and reviewed (8.2.6.2) Formal system for assessment of any proposed change (10.3.7)	**Complies** / **Non compliant***	
Periodic management review of PQS (8.2.7.1)	**Complies** / **Non compliant***	
Robust arrangements to specify the quality of outsourced aseptic products (3.2.3) Suitable TAs for any outsourcing (8.2.9.1)	**Complies** / **Non compliant***	
Sufficient resource to monitor TAs (products and services) (8.2.9.2)	**Complies** / **Non compliant***	
Comprehensive internal audit programme undertaken (8.2.10)	**Complies** / **Non compliant***	

8 Pharmaceutical Quality System continued

System for complaints (8.2.11.1)	**Complies** / **Non compliant***	
Complaints have timely close out and are reviewed (8.2.11.2)	**Complies** / **Non compliant***	
Comprehensive independently approved documentation process (8.3.1)	**Complies** / **Non compliant***	
Document controls in place (8.3.2)	**Complies** / **Non compliant***	
Worksheets and labels have standardised style for product type (8.3.3) London & SE Note: Where worksheets cannot be produced from an e-prescribing system e.g. multiple dilutions check if a second system is in use.	**Complies** / **Non compliant***	
Documents regularly reviewed. Superseded documents clearly identified and archived. Draft documents identified (8.3.4, 8.3.5)	**Complies** / **Non compliant***	
SOPs clearly written and include those listed in 8.4 SOPs for all equipment in use for aseptic processing (10.3.9)	**Complies** / **Non compliant***	
Individual worksheet from approved master (8.5.1)	**Complies** / **Non compliant***	
Worksheet enables traceability of starting materials and appropriate components (8.5.2)	**Complies** / **Non compliant***	
Completed worksheets appropriately retained (8.5.3) London & SE Note: Apply to all records	**Complies** / **Non compliant***	
Worksheets suitably designed and include items listed in 8.5.4 (8.5.4)	**Complies** / **Non compliant***	
London & SE Worksheets correctly completed SOP must include independent calculation check and method to be used1	**Complies** / **Non compliant***	
Clear differentiation of paediatric worksheets (8.5.5)	**Complies** / **Non compliant***	
Operation, cleaning, maintenance and fault logs for all facilities and equipment (8.6.1)	**Complies** / **Non compliant***	

8 Pharmaceutical Quality System continued

Planned deviation/temporary change control used for any products made outside SOPs (8.6.2)	**Complies** / **Non compliant***	
Records and trending of errors, near misses and investigations (8.6.3)	**Complies** / **Non compliant***	
Errors recorded via national reporting schemes (PASG/UKRG), trended and investigated (14.12)	**Complies** / **Non compliant***	
Units participate in national error monitoring schemes (PASG/UKRG) (8.6.4)	**Complies** / **Non compliant***	
Risk analysis, trending and CAPA in use (8.6.5)	**Complies** / **Non compliant***	
Record of Authorised Pharmacist supervising each session (8.6.6)	**Complies** / **Non compliant***	
Computerised systems (CS) have restricted access (8.7.1)	**Complies** / **Non compliant***	
CS used for document control, fully validated and as accurate as paper system (8.7.2)	**Complies** / **Non compliant***	
Back-ups for computer held masters and fall-back system (8.7.3) Moved from below Back-up of critical CS, tested periodically (8.7.8)	**Complies** / **Non compliant***	
Updates or changes to CS via change control only (8.7.5)	**Complies** / **Non compliant***	
Revalidation of critical CS (8.7.6)	**Complies** / **Non compliant***	
Purely electronically-held records available for life of document (8.7.7)	**Complies** / **Non compliant***	
Labels clear, unambiguous, no overtyping (8.8.2)	**Complies** / **Non compliant***	
Labels include all items listed in 8.8.3 (8.8.3) Labels comply with legal and professional requirements (8.8.1)	**Complies** / **Non compliant***	
Maximum glucose concentration/osmolarity for use peripherally agreed. Greater concentrations, PN is labelled for central line only (8.8.4)	**Complies** / **Non compliant***	

9 Personnel Training and Competency Assessment

Deviation from Standard –		
Complies / Negligible		Severity Score (S)
Service managed by Accountable Pharmacist (AcP) with appropriate knowledge and experience (9.1.1)	**Complies** / **Non compliant***	
Accountable Pharmacist assured facilities and systems suitable each day (9.1.3)	**Complies** / **Non compliant***	
Deputy for Accountable Pharmacist trained, limits agreed and responsibilities clear (9.1.4)	**Complies** / **Non compliant***	
Any accredited product approvers trained, limits agreed and responsibilities clear (9.1.5)	**Complies** / **Non compliant***	
Radiopharmacy preparation staff are 'adequately' trained as in IR(ME)R (9.1.6)	**Complies** / **Non compliant***	
Simplified training for visitors, engineers, etc. (9.1.7)	**Complies** / **Non compliant***	
SOP for acceptable hygiene expected (9.2.1)	**Complies** / **Non compliant***	
Reporting of skin lesions, infections etc (9.2.2)	**Complies** / **Non compliant***	
Management of tattoos, piercings, religious clothing etc (9.2.3, 9.2.4)	**Complies** / **Non compliant***	
No watches, jewellery, cosmetics, false nails etc in unit (9.2.5, 9.2.6)	**Complies** / **Non compliant***	
All staff trained and assessed as competent for their role (9.3.1)	**Complies** / **Non compliant***	
Approved current training programme, documented completion and system for evaluation (9.3.2) Individual training records, available and acceptable (9.3.3) Current approved training programme and completion documented (8.2.8.1) System for evaluation of training programme (8.2.8.2)	**Complies** / **Non compliant***	
Staff preparing or supplying aseptic products competent and understand responsibilities(5.1.9)	**Complies** / **Non compliant***	
Competency assessment and sign off of initial training (9.4.1)	**Complies** / **Non compliant***	

9 Personnel Training and Competency Assessment continued

Competency regularly reassessed. Retraining where necessary (9.4.2) Effectiveness of additional training checked and rechecked after a further time interval (9.4.3)	**Complies** / **Non compliant***	
Regular testing of operator technique with broth and observation (9.4.4) Operator validations up-to-date and cover range of techniques and clean air devices in use (10.2.2)	**Complies** / **Non compliant***	
Initial competency requires three successful Universal tests. Reassessment six-monthly minimum (9.4.5)	**Complies** / **Non compliant***	
Hand hygiene acceptable (12.8.1) Effective hand sanitisation agent and techniques and effectiveness assessed (12.8.2, 12.8.3)	**Complies** / **Non compliant***	
Competency assessment for calculations (9.4.6) and worksheet accuracy	**Complies** / **Non compliant***	
Commitment to a staff development programme. (Use should be made of the TSET portal) (9.4.9)	**Complies** / **Non compliant***	

10 Aseptic Processing

Deviation from Standard –		
Complies / Negligible		Severity Score (S)
London & SE A separate room or space in a quiet environment for the preparation of worksheets; minimum interruptions allowed1	**Complies** / **Non compliant***	
Appropriate disposal of waste (10.1.1) Waste disposal avoids cross-contamination and risks to staff (10.1.4.5)	**Complies** / **Non compliant***	
Choice of clean air device risk-based (10.1.2.1)	**Complies** / **Non compliant***	
Vials used in preference to ampoules (10.1.2.3)	**Complies** / **Non compliant***	
Use of sharps minimised. No manual re-sheathing. Risk assessment if re-sheathing used (10.1.2.4)	**Complies** / **Non compliant***	
Processes use minimum manipulations (summary available) (10.1.3.1)	**Complies** / **Non compliant***	
London & SE Preparation activities requiring pooling of solutions are risk assessed and will reduce the risk to the finished product when compared to a non pooling method of preparation 4	**Complies** / **Non compliant***	

10 Aseptic Processing continued

London & SE Comprehensive SOPs for all key elements and staff are aware of them London & SE Principles of good aseptic technique adhered to. All operators are mindful of the patient and severities of inappropriate behavior (by auditor observation) Strips of components separated before transfer into critical zone (10.1.3.4) Starting materials allowed to dry before manipulation (10.1.3.5) Critical zone uncluttered. No storage. Positioning to avoid obstruction of air flow (10.1.3.6) Operators don't reach over product (10.1.3.7) No touch of critical surfaces (10.1.3.8) Over-wrapped items peeled open in air stream. Paper-backed items not torn (10.1.3.9) Re-sheathing aid used if re-sheathing justified (10.1.3.10) 70% alcohol used to wipe vial bungs and ampoule necks (10.1.3.11) Ampoules opened in air stream (10.1.3.12) Filter used for glass ampoules (10.1.3.13) Ampoules used for immediate single withdrawal (10.1.3.14) Pressure equalisation used for vials (10.2.3.15) Additive port of bags in airstream for additions (10.1.3.16) Appropriate gauges of needles used (10.1.3.17) Needles inserted in centre of additive port (10.1.3.18) Tubing clamped before removal (10.1.3.19) Work surface and gloves sanitised between products or on contact (10.1.3.20) Spills wiped immediately, then glove change and cleaning (10.1.3.21)	**Complies** / **Non compliant***	

10 Aseptic Processing continued

Processes designed to avoid mix-up (10.1.4.1)	**Complies** / **Non compliant***	
Pre- and in-process checks appropriate and recorded (10.1.4.2)	**Complies** / **Non compliant***	
Vial sharing only on a campaign basis with appropriate in-process checking. (10.1.4.3) Any vial sharing is risk assessed and done on a campaign basis (13.1.10) London & SE Worksheets reflect the campaign process (No sharing of ingredients unless accurate reconciliation assured	**Complies** / **Non compliant***	
Aseptic process appropriately validated; Facility and equipment validation, process validation and operator validation (10.2) Process validations done initially and 6 monthly (minimum) (11.3.5)	**Complies** / **Non compliant***	
Process validations are worst case and cover range of processes in use (10.2.1)	**Complies** / **Non compliant***	
Comprehensive SOPs for all key elements and manipulative steps (10.3.1)	**Complies** / **Non compliant***	
Aseptic processing only uses validated staff (10.3.2)	**Complies** / **Non compliant***	
Staff understand all relevant SOPs before work in unit.10.3.4	**Complies** / **Non compliant***	
Pre- and in-process checks only by accredited staff (10.3.5)	**Complies** / **Non compliant***	
All staff aware of consequences of deviations and report errors and deviations to supervising pharmacist (10.3.6)	**Complies** / **Non compliant***	
Techniques to minimise RSI in use and staff trained to recognise symptoms (10.3.8)	**Complies** / **Non compliant***	

11 Monitoring

Deviation from Standard –		
Complies / Negligible		Severity Score (S)
Monitoring and testing programme complies with Tables 11.1, 11.2.1, 11.2.2, 11.2.3, 11.2.4 (11.1.1)	**Complies / Non compliant***	
Action and alerts level appropriately set (11.1.2) Action limits for microbiology comply with Table 11.3 (11.4.2)	**Complies / Non compliant***	
A monthly and annual review of trends and types of micro-organisms made. Trend data available for each workstation, operator, disinfectant transfer personnel and for each clean room (11.1.2) Alert limits reassessed during annual review (11.4.1) London & SE Review of organisms detected with those previously found	**Complies / Non compliant***	
Validity of result checked if action level exceeded and out-of-specification raised if appropriate (11.4.3) London & SE Written reports satisfactorily filed and actions noted	**Complies / Non compliant***	
Monitoring equipment calibrated annually. (11.2.1) Equipment used in testing serviced annually (11.5.1)	**Complies / Non compliant***	
Storage temperature of media monitored (11.2.1)	**Complies / Non compliant***	
Evidence to demonstrate media fit for purpose (positive control) (11.2..2)	**Complies / Non compliant***	
Media residues removed after sampling (11.2.3)	**Complies / Non compliant***	
Plates labeled and bagged/wrapped soon after exposure (11.2.4)	**Complies / Non compliant***	
Negative control plate used weekly (11.2.5)	**Complies / Non compliant***	
Incubation within 7 days of exposure (11.2.6)	**Complies / Non compliant***	
Liquid media fertility tested after use (11.2.7)	**Complies / Non compliant***	

11 Monitoring continued

Record of checks of equipment functionality available daily/sessionally (11.3.1) Operation, cleaning, maintenance and fault logs for all facilities and equipment (8.6.1) London & SE e.g. pressure and airflow logs, leak testing, alarm functions, glove changing, cleaning logs, temperature logs	**Complies** / **Non compliant***	
Sessional monitoring of critical zone with settle plates and finger dabs with satisfactory results 11.3.2)	**Complies** / **Non compliant***	
Settle plates exposed for full session (max 4 hours) (11.3.3)	**Complies** / **Non compliant***	
Surface monitoring results trended and linked to cleaning (12.1.14)	**Complies** / **Non compliant***	
Rooms and isolator hatches monitored weekly. Plates correctly exposed (11.3.4)	**Complies** / **Non compliant***	
Any growth in a gaseous biodecontamination isolator identified to species level and urgently investigated (11.4.4)	**Complies** / **Non compliant***	
Routine identification of contaminants to genus level. Routine species I.D. for grade A and where action limits exceeded. (11.4.5) London & SE By trained competent staff in an audited laboratory Incubation temp TSA / SDA dual temp incubation	**Complies** / **Non compliant***	
In-use testing carried out for viables and no-viables (11.5.2)	**Complies** / **Non compliant***	
DOP test on all HEPA supply filters (11.5.3)	**Complies** / **Non compliant***	
Senior staff understand design of unit eg ventilation (11.6.1)	**Complies** / **Non compliant***	
Sterility test programme (1/workstation/week). Failures identified to species (strain) level and investigated. (End of sessions (EOS) broth test can be alternative) (11.7.1, 11.7.2)	**Complies** / **Non compliant***	
Investigation/CAPA for EOS fail (11.7.3)	**Complies** / **Non compliant***	

11 Monitoring continued

Planned programme of physical, chemical and microbiological analysis of the finished product as appropriate (11.8.1)	**Complies** / **Non compliant***	
Samples suitably obtained avoiding threat to the integrity of the finished product (11.8.2, 11.8.3)	**Complies** / **Non compliant***	
Accountable Pharmacist ensures testing laboratory understands pharmaceutical microbiology (11.8.4)	**Complies** / **Non compliant***	
TA with all external testing services and monitored (11.8.5)	**Complies** / **Non compliant***	
All sinks hand-wash stations and drains monitored for TVC (11.9)	**Complies** / **Non compliant***	

12 Cleaning, Sanitisation and Biodecontamination

Deviation from Standard –		
Complies / Negligible		Severity Score (S)
SOP and programme for sanitisation (12.1.1) London & SE Areas are clean by observation	**Complies / Non compliant***	
Cleaning and disinfecting agents approved, and more than one type used (12.1.2, 12.1.3)	**Complies / Non compliant***	
Cleaning and disinfecting agents sterile for Grades A and B. Sterile water used if needed (all grades) (12.1.4)	**Complies / Non compliant***	
Any in-use dilutions freshly prepared. Six monthly microbiological monitoring (minimum) (12.1.5)	**Complies / Non compliant***	
Wet cleaning with detergents used. Vacuum cleaners dedicated, with HEPAs (12.1.6)	**Complies / Non compliant***	
Sanitisation process considers factors in 12.1.7 (12.1.7)	**Complies / Non compliant***	
Sanitisation SOP includes factors in 12.1.8 (12.1.8)	**Complies / Non compliant***	
Sterile water used periodically to remove residues (12.1.9)	**Complies / Non compliant***	
Logs show agent(s) used and are checked before unit used (12.1.10)	**Complies / Non compliant***	
Staff cleaning are trained and competent (12.1.11)	**Complies / Non compliant***	
Continuity of cleaning staff. Monitored TA for contract cleaners (12.1.12)	**Complies / Non compliant***	
Microbiological and chemical testing programme for surfaces present and reviewed to test the effectiveness of cleaning (12.1.13)	**Complies / Non compliant***	
Surface monitoring of residues, e.g. cytotoxics (minimum annually) (12.1.15)	**Complies / Non compliant***	
All areas of facility regularly cleaned and, when necessary, disinfected (minimum frequency as in Table 12.1) (12.2.1)	**Complies / Non compliant***	
Appropriate dedicated cleaning equipment (12.2.2)	**Complies / Non compliant***	
Cleaning equipment stored separately (12.2.3)	**Complies / Non compliant***	
Facility cleaned cleanest to least clean (12.2.4)	**Complies / Non compliant***	

12 Cleaning, Sanitisation and Biodecontamination continued

Sterile disposable low-linting mops for Grade B (12.2.5)	**Complies** / **Non compliant***	
Sufficient agent delivered for effective cleaning (12.2.6)	**Complies** / **Non compliant***	
Adhesive flooring included in cleaning schedule (12.2.7)	**Complies** / **Non compliant***	
Clean air devices cleaned and disinfected before and after each session with sterile agents (12.3.1)	**Complies** / **Non compliant***	
Internal surfaces of clean air devices have (minimum) monthly clean with sporicide (12.3.2)	**Complies** / **Non compliant***	
All surfaces cleaned (minimum) quarterly to remove chemical residues (12.3.3)	**Complies** / **Non compliant***	
All equipment included in cleaning schedule (12.3.4)	**Complies** / **Non compliant***	
Biodecontamination cycles acceptable and physical cleaning carried out (12.4.2, 12.4.3)	**Complies** / **Non compliant***	
Validated SOP for transfer process (12.5.1)	**Complies** / **Non compliant***	
Sterile agents used in Grades A and B and last sanitisation stages of the transfer disinfection process (12.5.2)	**Complies** / **Non compliant***	
Contact time stated, validated and maintained in practice (12.5.3)	**Complies** / **Non compliant***	
Storage of paper and cardboard minimised in support room but products protected (12.5.4)	**Complies** / **Non compliant***	
Spray and wipe with sporicide before transfer to clean room (12.5.5) (10.1.3.3)	**Complies** / **Non compliant***	
Spray and wipe with disinfectant before transfer to working zone (12.5.6)	**Complies** / **Non compliant***	
Spraying during transfer disinfection is carried out into the transfer hatch it is not remote from the hatch (12.5.7)	**Complies** / **Non compliant***	
Justification for any circumstances not using a sporicide, e.g. radiopharmacy (12.5.8)	**Complies** / **Non compliant***	
All surfaces subjected to all steps, e.g. flip caps removed at start of process (12.5.9)	**Complies** / **Non compliant***	
Evidence available for effective contact time for sanitising agents (12.5.10)	**Complies** / **Non compliant***	

12 Cleaning, Sanitisation and Biodecontamination continued

Transfer SOP considers factors in 12.5.11, e.g. bioburden (12.5.11)	**Complies** / **Non compliant***	
Use made of triple- and double-wrapped packs. Consideration given to other methods of minimising transfer of bacteria and fugal spores (12.5.12) (10.1.2.2)	**Complies** / **Non compliant***	
Sterile/disinfected gloves worn for transfer (12.6.1)	**Complies** / **Non compliant***	
Routine supervision of transfer technique (12.6.2)	**Complies** / **Non compliant***	
Wipes impregnated, low-linting and sterile for last step (12.6.3, 12.6.4)	**Complies** / **Non compliant***	
Wiping technique satisfactory, e.g. fresh surface, attention to folds, septa etc (12.6.5, 12.6.6)	**Complies** / **Non compliant***	
Initial bioburden controlled and monitored (annually minimum) (12.6.7)	**Complies** / **Non compliant***	
Health and safety considered, e.g. sporicides (12.6.8)	**Complies** / **Non compliant***	
Trays appropriate design and washed and decontaminated regularly (12.7.1)	**Complies** / **Non compliant***	
Tray cleaning done outside unit (12.7.2) Trays dried and disinfected (not 'drained') (12.7.3) Tray cleaning validated (annually) (12.7.4)	**Complies** / **Non compliant***	
Hand washing facilities appropriately located and water regularly monitored (12.8.4, 12.8.5)	**Complies** / **Non compliant***	
Cleaning validation frequencies comply with Table 12.2 (12.9.1)	**Complies** / **Non compliant***	
Limits based on both microbiological and chemical residue analysis (12.9.2)	**Complies** / **Non compliant***	

13 Starting Materials, Components and Consumables

Deviation from Standard –		
Complies / Negligible		Severity Score (S)
Starting materials (SM) sterile and MA when available (13.1.1)	**Complies** / **Non compliant***	
Any unlicensed medicines have documented quality assessment (13.1.2)	**Complies** / **Non compliant***	
Unlicensed starting materials from appropriate licensed supplier (13.1.3)	**Complies** / **Non compliant***	
London & SE The chief Pharmacist (delegated senior manager - RQA interpretation) must ensure that the unit reviews range of materials stocked. If use of more than one strength or salt of the same electrolyte is justified, risk assessment needed2	**Complies** / **Non compliant***	
Systems for receipt include that SmPC or technical data not changed since previous receipt; invoke change control if required. (13.1.4)	**Complies** / **Non compliant***	
One session only for unpreserved starting materials and they remain in critical zone (13.1.5)	**Complies** / **Non compliant***	
Starting materials from same manufacturer if different strengths mixed in product (13.1.6)	**Complies** / **Non compliant***	
No non-sterile starting materials (13.1.7)	**Complies** / **Non compliant***	
Re-worked material assess as a starting material (13.1.8) London & SE If prepared in an unlicensed facility cannot be re-worked. If unlicensed product prepared in a licensed facility re-working will increase the number of manipulations	**Complies** / **Non compliant***	
Components pre-sterilised and either CE marked devices or documented assessment. Appropriate packaging (13.2.1)	**Complies** / **Non compliant***	
Filters pre-assembled, CE marked and sterile (13.2.2)	**Complies** / **Non compliant***	
Batch numbers of critical components are on worksheets (13.2.3)	**Complies** / **Non compliant***	
Audit trail for other components e.g. using logs to record batch numbers (13.2.4)	**Complies** / **Non compliant***	

13 Starting Materials, Components and Consumables continued

Local sterilisation of non-sterile consumables validated and monitored. TA and audit of sterilising site available (13.2.5)	**Complies** / **Non compliant***	
Filing systems not modified (13.2.6)	**Complies** / **Non compliant***	
All items appropriately stored to minimise bioburden and prevent damage (13.2.7)	**Complies** / **Non compliant***	
One working session only for sterile components (13.2.8)	**Complies** / **Non compliant***	
Components and consumables used in Grades A and B are sterile (13.2.9)	**Complies** / **Non compliant***	
No storage of paper-backed components in clean room after transfer sanitisation (13.2.10)	**Complies** / **Non compliant***	

14 Product Approval

Deviation from Standard –		
Complies / Negligible		Severity Score (S)
Formal recorded decision (product approval) by Accredited Product Approver (APA – includes Authorised Pharmacist (5.1.7) (14.1) Term Accredited Product Approver (APA) includes previously used 'Releasing Pharmacist'	**Complies / Non compliant***	
Robust systems for 'release' training. Non-pharmacist by Accredited Product Approver comply with national competency framework. List of APAs (14.2)	**Complies / Non compliant***	
Accountable Pharmacist ensures effective and comprehensive PQS in place (14.3)	**Complies / Non compliant***	
Accredited Product Approver directly accountable to Accountable Pharmacist and in their job descriptions (14.4)	**Complies / Non compliant***	
Accredited Product Approver or Authorised Pharmacist has not prepared the product (check out-of-hours supervision) (14.5)	**Complies / Non compliant***	
SOPs for final accuracy checking and release give roles and responsibilities (14.6)	**Complies / Non compliant***	
Authorised Pharmacist identifiable and contactable (14.7)	**Complies / Non compliant***	
Accredited Product Approvers authorised for product type involved, e.g. PN (I/T needs pharmacist on I/T register) (14.8)	**Complies / Non compliant***	
All who release are competent and comply with Code of Ethics (14.9)	**Complies / Non compliant***	
After preparation and before release the Accredited Product Approver completes all actions in 14.10 London & SE All actions are in the SOP Dose and patient details checked at Product Approval against the prescription (on the screen when necessary to ensure the most up to date prescription is used)	**Complies / Non compliant***	

14 Product Approval continued

Authorised Pharmacist makes release decision if unplanned deviation (14.11)	**Complies** / **Non compliant***	
Authorised Pharmacist aware of any errors and acts on them (14.13)	**Complies** / **Non compliant***	
SOP for failures. Investigated, CAPA and trending. Chief Pharmacist aware of adverse trends/major failures (14.14)	**Complies** / **Non compliant***	

15 Storage and Distribution

Deviation from Standard –		
Complies / Negligible		Severity Score (S)
Storage and distribution staff trained (documented) and aware of responsibilities, e.g. product integrity, supply, etc,(15.1.1)	**Complies** / **Non compliant***	
Product quality not compromised between release and use (15.1.2) London & SE Adequate facilities / space for safe and secure storage and distribution; organised and clean.	**Complies** / **Non compliant***	
Products needing specific handling and storage comply with legislation, e.g. COSHH, Radiation Regulations (15.2.1)	**Complies** / **Non compliant***	
Products refrigerated unless detrimental or suitably stored (15.2.2) Products stored in a refrigerator if this does not negatively impact on quality (6.5)	**Complies** / **Non compliant***	
All storage areas temperature mapped (15.2.3)	**Complies** / **Non compliant***	
All storage areas continually temperature monitored (2-8℃ fridges, ≤ 25℃ ambient (15.2.4)	**Complies** / **Non compliant***	
SOP for temperature monitoring includes action for out of specification temperatures. Actions recorded and trends monitored (15.2.5)	**Complies** / **Non compliant***	
Annual two-point (minimum) calibration of temperature monitoring equipment traceable to a recognised measurement standard (15.2.6)	**Complies** / **Non compliant***	
Validation of automatic temperature monitoring equipment (15.2.7)	**Complies** / **Non compliant***	
Product quality not impaired by repair, maintenance, calibration (15.2.8)	**Complies** / **Non compliant***	
Alarms appropriate limits and tested regularly. Authorised Pharmacist aware of any alarms (15.2.9)	**Complies** / **Non compliant***	
Knowledgeable decision made if storage temperature failure (15.2.10)	**Complies** / **Non compliant***	
Transit containers offer adequate protection (15.3.2)	**Complies** / **Non compliant***	

15 Storage and Distribution continued

Transit containers comply with appropriate regulations, e.g. radiopharmacy or chemotherapy (15.3.3)	**Complies** / **Non compliant***	
Compliance with all health and safety regulations, e.g. COSHH (15.3.4)	**Complies** / **Non compliant***	
Transit containers suitably labelled, e.g. identity, handling. Includes – source, emergency contacts for hazardous products (15.3.5, 15.3.6)	**Complies** / **Non compliant***	
Prevention of movement, e.g. syringe barrel and plunger (15.3.7)	**Complies** / **Non compliant***	
Cold/ambient chain assessed if appropriate (15.3.8) Distribution maintains product quality, security and integrity (15.3.1)	**Complies** / **Non compliant***	
Documented training of staff involved (15.3.9)	**Complies** / **Non compliant***	
Records of destination of products. (Additional system for CDs and radioactive products.) (15.3.10)	**Complies** / **Non compliant***	
Policy for returned/unused products, including outsourced and environmental factors(15.3.11) Returned/unused products clearly marked and segregated (15.2.11)	**Complies** / **Non compliant***	
Complaints recorded. Distinction between quality and service complaints (15.4.1)	**Complies** / **Non compliant***	
Specific person for complaints. Thorough investigation of cause (15.4.2)	**Complies** / **Non compliant***	
CAPA if necessary after complaint evaluation (15.4.3)	**Complies** / **Non compliant***	
Procedure for recall (covers own products, and starting materials or components used) (15.4.4)	**Complies** / **Non compliant***	
Annual testing of recall system (if no actual), and report produced (15.4.5) Recall SOPs tested annually (8.2.12.1)	**Complies** / **Non compliant***	

16 Internal and External Audit

Deviation from Standard –		
Complies / Negligible		Severity Score (S)
Chief Pharmacist and Regional QA (RQA) ensure regular external audits (5.3.2) Chief Pharmacist sends action plan to RQA on time and communicates major changes to RQA, e.g. staffing etc (5.3.3)	**Complies / Non compliant***	
Chief Pharmacist ensures regular internal audits carried out (5.3.1) Audit of all aseptic areas on a regular, planned basis (16.1) Detailed quality review of PQS (16.2) Audit programme documented and adhered to (16.3) Audits include review of capacity planning (16.4)	**Complies / Non compliant***	
Internal audit carried out by designated competent staff in independent way (16.5)	**Complies / Non compliant***	
Observations recorded with proposals for corrective actions (16.6)	**Complies / Non compliant***	
Suitable action plan, with timescales and persons responsible produced (16.7)	**Complies / Non compliant***	
SOP for management and review of action plan and the effectiveness of these procedures should be verified (16.8)	**Complies / Non compliant***	
Corrective actions reviewed (16.9)	**Complies / Non compliant***	
Chief Pharmacist ensures QA system and off-site testing regularly reviewed (5.3.4)	**Complies / Non compliant***	
Audit report submitted to senior management. Escalation procedures in place to communicate risks to hospital management (16.10) Response to external audit is realistic and timely (16.11)	**Complies / Non compliant***	
Subject to additional audit if preparing intrathecal chemotherapy (16.12)	**Complies / Non compliant***	

Deficiency Action Times

Deficiencies	Severity Score	Action
Critical	4	Critical deficiencies that require immediate action (within 24 hours)
Major	3	Major deficiencies that require action within three months
Moderate	2	Moderate deficiencies that require action within six months
Minor	1	Minor deficiencies that need to be addressed within twelve months

Notes:

- Audit categories e.g. 'Risk Management Arrangements', Internal and External Audit are chapter titles from Reference 1 below
- In the Matrix the 'Complies / Negligible' column is the compliance statement. Compliance statements have been developed from the audit aide-memoir written by Alison Beaney which is based on Reference 1
- The Matrix has been constructed using the references cited below and auditor's experience. Where a Pharmacy Quality Audit Guideline states a deficiency severity then this has been referenced in the Matrix

Abbreviations:

AHU	Air Handling Unit
ARSAC	Administration of Radioactive Substances Advisory Committee
BMS	Building Management System or Building Maintenance System
BNF	British National formulary
CE	*Conformité Européenne* (possible interpretation of the abbreviation) meets all the essential requirements of the relevant European Directive(s).
CIVAS	Centralised Intravenous Additive Service
CPD	Continued Professional Development
CT	Chemotherapy
DOP	Dispersed Oil
GAMP	Good Altermated Manufacturing Practice
GMP	Good Manufacturing Practice
HEPA filter	High Efficiency Particulate Air filter
HVAC	High Velocity Air Conditioning
IMS	Industrial Methylated Spirit
IP	Ingress Protection
IV	Intravenous
LAF	Laminar Air Flow
LAFC	Laminar Air Flow Cabinet
LFC	Laminar Flow Cabinet
MA	Marketing Authorisation
MHRA	Medicines and Healthcare products Regulatory Agency
PN	Parenteral Nutrition
NPSA	National Patient Safety Agency
PL	Product Licence
PPM	Planned Preventative Maintenance
PQAG	Pharmacy Quality Audit Guideline
QA	Quality Assurance
QE	Quality Exception
QER	Quality Exception Report
QC	Quality Control
SLA	Service Level Agreement
SOP	Standard Operating Procedure
TSE	Transmissible Spongiform Encephalopathies

References:

All standards are:

Beaney, Alison, M, D Prof, MSc, FRPharmS , Editor, Quality Assurance of Aseptic Preparation Services: Standards Handbook, 5th Ed. Royal Pharmaceutical Society 2016. ISBN0- 978-0-85711-307-8

unless otherwise stated. Alternative references will be from the documents listed below or from the London & SE audit team which will be stated in the document.

1 Professor Brian Toft OBE, Independent review of the circumstances surrounding a serious untoward incident that occurred in the Aseptic Manufacturing Unit, Royal Surrey County Hospital on Monday, 18th June 2012

2 Paediatric Chief Pharmacists Group. Improving Practice and Reducing Risk in the Provision of Parenteral Nutrition for Neonates & Children 11/2011

3 Good Manufacturing Practice Question and Answers for Manufacturing Specials (MS) Licence Holders, MHRA, 2013

4 Good Manufacturing Practice Question and Answers for Manufacturing Specials (MS) Licence Holders, MHRA, 2015

5 Report of the Mid Staffordshire NHS Foundation Trust Public Enquiry, Robert Francis QC, HC 947, February, 2013