NHS Aseptic Services Accreditations Group

NHS Pharmacy Education & Development Group UK

Nationally Recognised Framework for Accreditation of Pre and In-Process Checking within Technical Services

4th Edition: August 2016

NHS PEDG Pharmacy Technician and Support Staff (pre and post qualification) Group

Contents

1. Introduction

1.1 Welcome to the nationally recognised Framework for the accreditation of Pre and In-Process Checking within Technical Services.

1.2 This document provides details of training and assessment processes covering the pre and in-process checking function within technical services. This includes licensed and unlicensed technical services units, and also Quality Assurance/Quality Control, Aseptics, Production and Radiopharmacy and checking of outsourced products.

1.3 This Framework supports personnel within technical services who wish to become accredited checkers and is designed to give guidance and direction to training providers and educational supervisors who will be involved in the training, mentoring and assessment of candidates throughout the process.

1.4 This Framework was developed by a Working Group that has members from several professional areas of pharmacy: these include:

- NHS Pharmaceutical Quality Assurance Committee,
- NHS Pharmaceutical Production Committee,
- NHS Aseptic Services Accreditations Group (ASAG),
- NHS Pharmacy Education and Development Group (PEDG)
- NHS Pharmaceutical Technical Specialists Education and Training Group (TSET).

1.5 The framework has been reviewed and updated by the NHS PEDG Pharmacy Technician and Support Staff Group in consultation with the NHS ASAG.

1.6 This Framework is designed to cover pre and in-process checking functions in aseptic preparation services. The principles may be applicable to pre and in-process checking in other technical services areas (see 1.2).

1.7 The Framework is designed around a set of principles that can provide the foundation of any accreditation system designed for technical services, licensed or unlicensed.

1.8 Throughout the document the term "*Accountable Pharmacist*" is used. It is acknowledged that in licensed units the named Quality Controller on the licence will have responsibilities equal to the Accountable Pharmacist in an unlicensed unit.

1.9 Key issues that must be considered in any accreditation systems are:

- Accredited checking will only work within a robust system as a whole, incorporating premises, quality management systems, training and management, all of which are subject to external audit; under EL(97) 52 or equivalent, or MHRA

- In unlicensed aseptic preparation units the Accountable Pharmacist remains professionally responsible for the total operation but can delegate the pre or in-process check to the accredited person when all parameters are satisfied
- The Accountable Pharmacist remains responsible for the service and may select which product groups are suitable for accredited checking and which are not. This should be agreed locally
- The Accountable Pharmacist is professionally accountable for the operation of the process according to GMP principles and is responsible for ensuring there is supervision by a suitably trained and experienced person
- All practice will adhere to the GPhC Standards of Conduct, Ethics and Performance or the individual's equivalent regulatory body standards
- Personnel in technical services must complete a training and competency assessment programme in technical services prior to undertaking any tasks or checking functions in this area; it is recommended that a training and competency assessment for accredited checking is operated through a standardised approach
- The training programme incorporates clear entry criteria, teaching of underpinning knowledge base and assessment of competence
- The accreditation should specify:
    a) The scope within which the persons may operate, including types of products
    b) The elements of checking that are accredited (e.g. pre and in-process)
- Ongoing practice is required in order to maintain accreditation
- The application of accredited checking in technical services should be sanctioned under local clinical governance arrangements.

Scope

1.10 Pre and in-process checking forms an important part of the overall product approval process of aseptically prepared products[1].

1.11 *Pre-checks* are defined as the accuracy checks undertaken on starting materials, disposables, worksheets and labels before the product is prepared. *In-process checks* are those carried out during the preparation process including the accuracy checking

[1] Alison M Beaney D Prof, MSc, FRPharmS *Quality Assurance of Aseptic Preparation Services: Standards Part A | Fifth edition*; Chapter 14 Product Approval (Royal Pharmaceutical Society 2016) http://www.rpharms.com/support-pdfs/rps---qaaps-standards-document.pdf

of volumes. Further information may be found in NHSTSET aseptic processing chapter on accuracy checking[2].

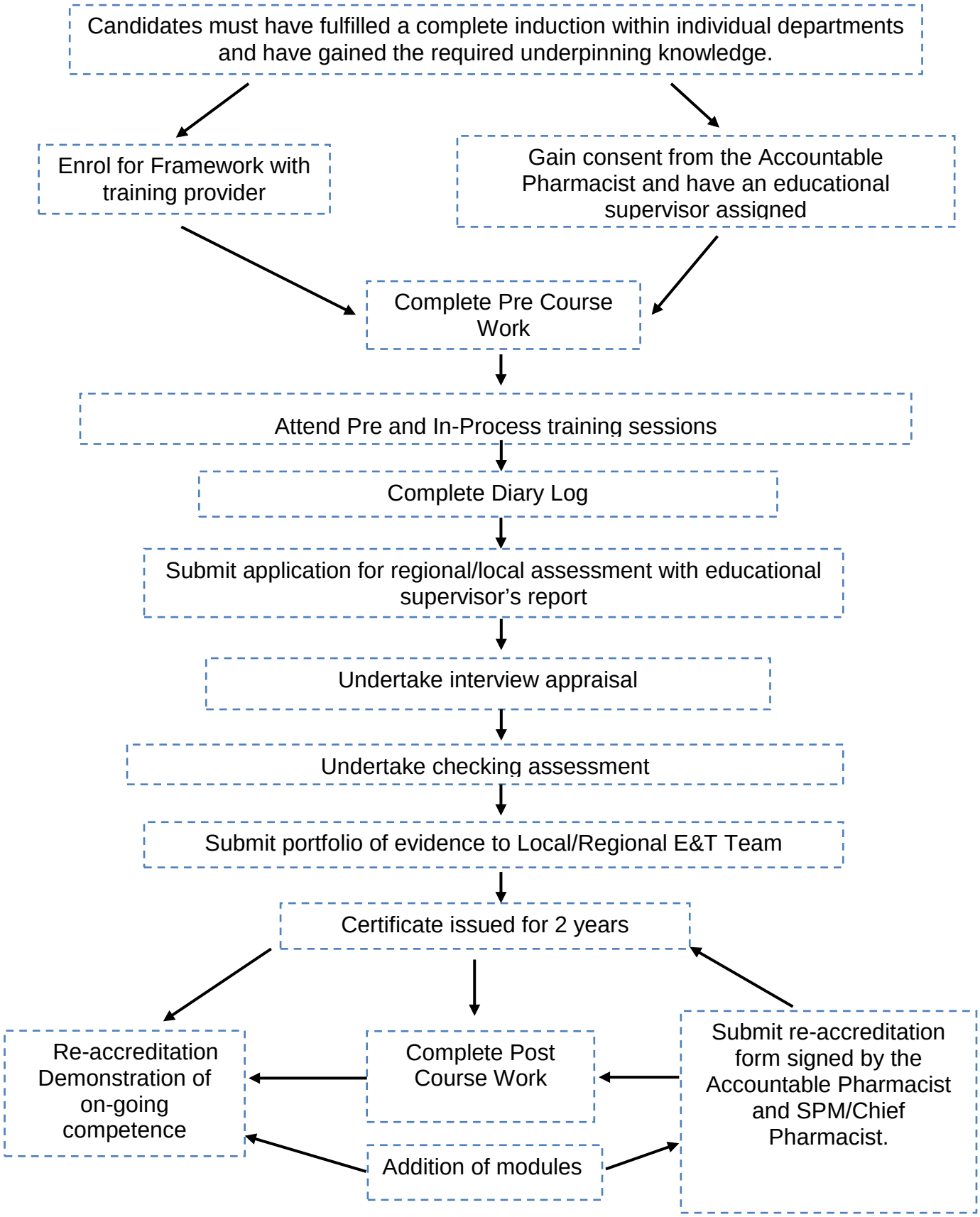
1.12 This Framework has been developed as best practice guidance to promote robust checking systems in technical services throughout the NHS as well as developing a safe and portable skill mix in line with government policy to ensure the patient receives a product suitable for its intended use.

1.13 Details of the training and assessment processes covering the product approval function/role can be found in the 'Nationally Recognised Competency Framework for Pharmacists and Pharmacy Technicians: The Assessment of Product Approval (Release) in Aseptic Services under Section 10 exemption'[3].

[2] www.tset.org.uk

[3] http://www.nhspedc.nhs.uk/Docs/NRCF%20-%20PAAP/Product%20Approval%20National%20Framework%20FINAL%20April%2016%20v1.1.pdf

Suggested Framework Structure



Definitions

1.14 These terms relate solely to the body of this document. Although some terms have been taken from national guidance, there may also be variations in definitions according to regional and national documentation.

Accountable Pharmacist	Accountable Pharmacist is professionally accountable for the operation of the process according to GMP principles and is responsible for ensuring there is supervision by a suitably trained and experienced person
Appropriate persons	Staff who have been identified as suitably trained and qualified to give guidance and make decisions regarding the assessment process
Assessment period	The period during which assessments are carried out. This must be preceded by an adequate period of supervised training
Candidate	Person undertaking the training and assessment
Chief Pharmacist (CP)	Generally responsible for the strategic development and management of medicines use and pharmacy services within an organisation. This encompasses patient safety, effective medicine use, medicines optimisation, safe and secure handling of medicines, procurement and medicines quality
Clinical Governance	The system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care.
Clinical screening	Clinical assessment of a patient's prescribed medicines for safety, efficacy and compliance with local and/or national guidelines
Continuing Professional Development (CPD)	An ongoing process of reflection and learning focussing on an individual's area of practice to maintain currency and occupational competence
Competency	An ability to consistently successfully perform a task or activity to an agreed standard
Educational Supervisor	A suitably experienced pharmacy technician or pharmacist responsible for support of the candidate and facilitation of their training (See pages 11 – 12).
Pharmacy technician	A person who holds the appropriate General Pharmaceutical

	Council (GPhC) recognised pharmacy technician qualifications in the UK, and is registered with the GPhC Throughout the document, where the term 'pharmacy technician' is used, the framework assumes the definition 'registered pharmacy technician' (where registration is a requirement)
Pharmacist	A person who holds an appropriate university degree and is qualified and licensed to prepare and dispense medicines and who is registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society Northern Ireland (PSNI)
Pre-process checks	the accuracy checks undertaken on starting materials, disposables, worksheets and labels before the product is prepared
In process checks	The accuracy checks carried out during the preparation process including the accuracy checking of volumes
Pre and In process Checker (PIPC)	An individual whose current training and qualifications are assessed and accredited by the training provider as meeting the defined competencies for their role in pre and in process checking (i.e. is occupationally competent)
Practice-based	Learning based in actual situations related to professional practice
Reaccreditation	Recognition of revalidation of practice, to demonstrate that required standards of competence continue to be met
Reflective practice	The process of reviewing a specific task or day-to-day practice, identifying successes and weaknesses, and planning and taking action to address areas for development
Registered pharmacy technician	A pharmacy technician who is registered with the relevant regulatory body (where registration is a requirement), for example, in Great Britain registration is with the General Pharmaceutical Council (GPhC)
Senior Pharmacy Manager (SPM)	See Chief Pharmacist (NB: In some organisations the title, SPM, may not refer to chief pharmacist)
Standard Operating Procedures (SOPs)	Approved written step-by step instructions on how a task or process should be carried out

Supervised practice period	A period of training under the direct supervision of a suitably trained/qualified person e.g. pharmacy technician, pharmacist, educational supervisor
Training Provider	An organisation responsible for the programme, including delivery of training, assessment and accreditation

2. Aims

2.1 The Framework aims to:

- provide personnel working within technical services with the skills and knowledge to be able to confidently and competently undertake pre and in-process checks within specified local parameters to ensure patient safety and product quality
- encourage best practice
- develop technical services personnel in areas of continuing professional practice and accountability within pharmacy services
- encourage the further development of effective communication skills
- support appropriate skill-mix within pharmacy departments
- reduce overall error rates.

3. Learning Outcomes

3.1 By the end of the Framework the candidate will be able to:

- undertake pre and in-process checks within the specified parameters set locally
- describe the legal implications of pre and in-process checking in technical services
- develop a robust checking method in line with approved *Standard Operating Procedures* (SOPs) that will be applicable in the workplace
- list different factors that contribute to errors and suggest methods to overcome them
- demonstrate communication skills required when informing others about errors made
- demonstrate ability to recognise their own limitations and make appropriate referrals.

4. Entry Criteria

4.1 In order to meet the normal minimum entry requirements, the candidate must have:

- a recommendation and support from the Senior Pharmacy Manager/Chief Pharmacist or Designated Deputy to undertake an accreditation scheme based on the Nationally Recognised Framework for the Accreditation of Pre and In-Process Checking within Technical Services
- a minimum of six months aseptic preparation experience in current aseptic unit within the 12 months prior to commencing this Framework. Section 18.1 describes the application of the framework to accredited staff moving to a post in another trust
- demonstrated ability to aseptically prepare products accurately, according to locally approved SOPs
- an allocated educational supervisor who has completed the appropriate training and been deemed suitable for the role by the SPM/CP
- demonstrated a good working knowledge of locally approved SOPs to the Accountable Pharmacist or educational supervisor.

4.2 The unit must be able to offer an appropriate workload to enable the candidate the opportunity to complete accreditation within at least one *product type*, e.g. Centralised Intravenous Additive (CIVA), Parenteral Nutrition (PN), Cytotoxics, Aseptic Preparation, and Radiopharmacy in technical services. Accreditation in other specialities will require additional evidence collection and competency assessment.

5. Registration for this Framework

5.1 Candidates wishing to register for the Framework should complete the agreed application process according to local guidelines.

Pre-scheme preparation

5.2 Prior to attending the first study day, candidates must have completed a full in-house induction programme for their base unit and the pre course work, outlined by the Training Provider.

5.3 Confirmation of this must be included with the nomination form to the *training provider* prior to attending the training days. The educational supervisor should countersign both forms.

5.4 Candidates must have access to the current national guidance and other publications listed in the references section.

5.5 Pre course work study guides should be made available to give the candidate an appropriate foundation to the learning outcomes.

5.6 Candidates may be required to undertake a calculation assessment prior to starting the assessment to confirm a basic level of mathematical understanding. This requirement would be decided between the Accountable Pharmacist and the candidate.

6. Guidance for Educational Supervisors

Registration as an Educational Supervisor

6.1 The educational supervisor must fulfil the following criteria:

- be the Accountable Pharmacist for the unit, or a delegated person, e.g. accredited to undertake pre and in process checking in technical services with at least two years post registration experience in pharmacy technical services, including technical services
- be able to meet regularly with the candidate
- ideally be working in the technical services team to ensure maximum support
- Additionally it is preferable that the educational supervisor has experience of mentoring staff.

6.2 All new educational supervisors must register with the training provider in accordance with local arrangements, prior to undertaking the role.

6.3 Pharmacists or pharmacy technicians fulfilling the above criteria should submit a completed framework registration form and brief curriculum vitae (as per local agreement).

6.4 New educational supervisors must meet the regional educational supervisor training requirements (where applicable).

6.5 Regional study days for educational supervisors should ensure they are able to meet the following learning outcomes:

- describe the principles of the Nationally Recognised Framework for the accreditation of Pre and In-Process Checking within Technical Services
- describe the legal framework and implications of pre and in-process checking in technical services
- discuss and define the term “clinical screen/check”
- define the role of the educational supervisor
- discuss the need for locally agreed aseptic preparation procedures
- define the process of work-based assessments, accreditation assessment and re-accreditation process
- discuss and describe the use of all scheme paperwork
- facilitate the use of the scheme documentation and accuracy checking logs in the workplace prior to and during the assessment period.
- explain the process for the development and approval of SOPs and impact of any changes
- be aware of other suitable training resources to facilitate this Framework.

6.6 Educational supervisors must have a working knowledge of this Framework.

Role of the Educational Supervisor

6.7 The educational supervisor is required to offer support, guidance and feedback to the candidate whilst they undertake the practice activity, to facilitate the local implementation of this Framework and carry out formative appraisals in the workplace.

6.8 It is recommended that the educational supervisor is given time within work to support their candidates.

6.9 The educational supervisor is responsible for numbering / issuing each page of the assessment documentation and signing each blank page before issuing to the candidate.

6.10 The educational supervisor should complete the candidate review and the summary of activity (example can be found in Appendix 3). This may be based on comments from other colleagues who have worked closely with the candidate during the practice activity. The assessment panel will review this information, as appropriate.

6.11 All documentation including the nomination forms must be submitted to the training provider prior to final assessment.

6.12 Where appropriate, the educational supervisors must plan the probationary period in line with regional requirements.

6.13 The educational supervisor should have a job description that reflects the responsibility to undertake the signing off of the candidate's portfolio and practice.

7. The Role of the Senior Pharmacy Manager/Chief Pharmacist or Designated Deputy

7.1 The Chief Pharmacist / Senior Pharmacy Manager or designated deputy must ensure that:

- approved and current SOPs are in place and that the candidate is familiar with and works competently within these
- the extension to the individual's role is documented in their current job description to ensure that they are covered by the vicarious liability of the employing organisation following accreditation
- support mechanisms are in place for the candidates.

8. Study Sessions

8.1 Candidates are required to attend all training sessions prior to undertaking the worked based checking activity.

Learning outcomes

8.2 By the end of the framework the candidate should be able to:

- state the reasons why a nationally recognised Framework for pre and in-process checking has been developed
- list the stages of the pre and in-process course and explain how the assessment documentation should be used
- describe the legal requirements for aseptic preparation of medicinal products
- state the laws and guidance relating to the aseptic preparation of medicinal products
- discuss the legal and ethical implications of accredited checking
- discuss the impact of aseptic preparation/checking errors on patient safety and product quality
- demonstrate communication skills required in the process of pre and in-process accuracy checking
- explain the necessity of referral to colleagues in the pre and in-process accuracy check
- perform the pre and in-process accuracy check of aseptically prepared items.

Some training providers may elect to deliver the units of knowledge as co-taught across cohorts from different Accuracy Checking Frameworks, whereas others may deliver as separate courses. This document aims to facilitate either delivery option.
NB: for in-process checking in either dispensaries or technical services, providers may elect to use those units relevant to scope of practice.

Common understanding and practice across all checking frameworks includes:

1. Patient safety, error theory, identifying problems and preventing errors
2. Work flow and safe systems
3. Regulation and legal frameworks
4. Communication
5. Developing a checking process
6. Dealing with errors

7. Personal and professional responsibilities
8. Collection of evidence for portfolio assessment and reflective learning

Suggestions for additional teaching (see Unit 6) for Technical Services are:

- Legislation, Regulation, GMP (Good Manufacturing Practice 'orange guide')
- Design of aseptic premises and equipment
- Working within the different controlled areas/ workstations
- Aseptic products types

Details of the full Syllabus for National Frameworks for Accuracy Checking in Pharmacy can be found within the attached document (or see www.nhspedc.nhs.uk)

Accuracy Checking
K&S Syllabus_PIPC_Te

The training provider may deliver the knowledge and understanding as defined within the syllabus, and/or may use available resources, such as the NHS TSET Aseptic Processing online trainings as pre course or course work. See www.tset.org.uk.

9. Work-based Activities

Documented Evidence of Competence

Overview

9.1 Candidates must undertake the collection of 1000 accuracy checks across a range of product types and record their evidence in a portfolio. The percentage of pre and in process checks and product types will be decided at the discretion of the Accountable Pharmacist. NB: a single item, such as a PN bag will represent more than one check. A worked example is included in Appendix 2.

9.2 All evidence collected must be included in the portfolio for review and discussion as part of the summative assessment. The portfolio forms part of the assessment.

9.3 The portfolio consists of three elements:

- a diary log of 1000 accuracy checks
- documented reports of dispensing/checking errors found and missed and associated reflection
- a minimum of 2 appraisals/reviews of the candidate by the educational supervisor.

9.4 The purpose of the portfolio is to:

- document the checking that has been undertaken
- ensure that a breadth of experience relevant to scope of practice has been covered
- highlight areas where further training is required
- provide evidence of reflection on any errors identified and/or missed.

9.5 The awarded certificate will reflect the types of checks and product types that the candidate has completed.

9.6 Evidence must be collected in line with local agreements. This will either be between the final study day and the final assessment or a candidate may apply for the practical assessment at any stage of the course, once they have completed the study sessions. The candidate must have agreement from their course lead, educational supervisor and SPM if they wish to undertake the practical assessment before portfolio completion.

Accuracy Checking Logs

9.7 The candidate must carry out 1000 pre and/or in-process accuracy checks on aseptically prepared items. NB: The prescription must be pre-screened/approved prior to the preparation process according to local procedure.

9.8 The checking evidence must be documented using the training provider approved checking log form (example can be found within Appendix 3). These forms must be numbered and issued by the educational supervisor.

9.9 Correction fluid/tape must not be used on the log sheets.

9.10 The Accountable Pharmacist and/or educational supervisor will decide with the candidate how the pre and in-process checks will be divided over the range of product types for the 1000 checks.

9.11 The checking sessions should cover a breadth of items within the product type to reflect the candidate's scope of practice and current practice within the practice base unit.

9.12 The candidate and the *checker* must sign each item checked on the log so it is clear that each item has been checked correctly. Bracketing of items for signing is not allowed as this can lead to errors being made.

9.13 The candidate will only check the work of others and must have played no part in the aseptic preparation or labelling of any items they check.

9.14 Evidence must be provided to show that the candidate can consistently (over a period of time) work to all of the assessment criteria. Candidates must complete the programme within a maximum of 12 months from the final day of theoretical training.

9.15 If a candidate does not complete within 12 months, the training provider must be consulted and a course of action decided upon on a case by case basis. Normal practice will be for the candidate to re-start the scheme, including all training sessions.

9.16 If a candidate makes a serious error and needs to restart then they should still complete their 1000 checks in the original 12 months. Should an extension need to be considered then the training provider must be contacted to discuss further.

10. Errors

10.1 The portfolio should contain documented reports of any dispensing/checking errors that have occurred during the assessment period (see Appendix 1 for error reporting categories).

10.2 Whilst completing the 1000 checks the following scope for error will apply:

- 1st attempt - 1 error = Period of reflection and 250 additional checks
- 2nd error within additional 250 checks = Period of reflection and restart 1000 checks.

10.3 The portfolio should contain a report of any aseptic preparation errors not detected by the candidate, which have occurred during the checking assessment. Candidate reflection and outcomes should be documented and included in the portfolio.

10.4 If a candidate fails to detect an error in something which was incorrectly validated by a pharmacist, then this will not be classified as an error on behalf of the candidate. However, any validation error detected by the candidate should be referred back to the validating pharmacist.

10.5 The department must have a mechanism for reporting and reviewing errors and should submit error data to the National Aseptic Error Reporting Scheme[4] – see Appendix1. It is important that all persons involved in the accreditation process are aware of the classification of the potential outcome of errors.

10.6 Any candidate who fails on their second full attempt (following a complete restart) must inform their educational supervisor who will then inform the training provider as soon as possible.

10.7 If a candidate is unsuccessful in their second attempt at their 1000 checks then they will be expected to:

- undergo re-training in checking
- carry out 250 checks successfully and pass another practical test before attempting a final 1000 checks

NB: The 250 checks would not count towards the next 1000 checks.

10.8 If a candidate is unsuccessful at this third and final attempt it would suggest that the candidate is not ready to progress. Further preparation/manufacturing experience is recommended before re-applying to start the course.

[4] National Error Reporting Scheme. Pharmaceutical Aseptic Services Group.
http://www.civas.co.uk

Errors in other areas of practice

10.9 Whilst this framework concentrates on the accuracy and error rates of the pre and in process checking process, it is important to note that individuals have a responsibility to maintain their accuracy in all other areas of their practice. As a result, should a trainee make sufficient numbers of preparation errors to trigger local review procedures, the training provider should be consulted and a decision made on the appropriate course of action regarding continuation on the PIPC scheme.

11. Reflective Practice

11.1 Whenever a candidate is required to reflect on an error they have made or failed to identify, the following points should be considered, documented and reviewed by the educational supervisor:

- Description of error
- Corrective actions taken
- Root cause of the dispensing/preparation error
- Root cause of the candidate missing the error
- Potential outcome and impact of the error to the patient.

12. Candidate Reviews

12.1 In association with the assessment period, the candidate's progress must be reviewed at regular intervals and on a minimum of two occasions. The portfolio should be reviewed at this stage.

12.2 Candidates must be supported after any checking error has occurred and a period of reflection is recommended. Candidates must document their reflection and include this, along with details of the error, within their portfolio.

12.3 At the completion of the collection of 1000 accurately checked items, a summative review must occur.

13. Continuing Professional Development (CPD)

13.1 Whilst it is not a requirement of the National Framework for candidates to formally record their experiences as CPD entries, it is recognised that there will be many opportunities for learning and CPD along the course of the scheme. Candidates should be encouraged to document these experiences as CPD records where appropriate.

13.2 Following successful completion of the framework, as part of the CPD process, it is good practice for individuals to keep a record of any errors they have made/missed and any near misses that they may have been involved in.

14. Assessment

The competency-based assessment

14.1 The competency-based assessment will assess performance and will be in four parts:

a) A practical checking assessment consisting of 10 aseptically prepared items
b) Review of the portfolio
c) Evidence of understanding of the aseptic process and the role that pre and in process checks play in Quality Assurance
d) Evidence that the required underpinning knowledge has been completed.

Practical Checking Assessment

14.2 This assessment must be arranged and completed at the base unit or at a regional base.

14.3 The simulated checking of aseptically prepared items against test documents is intended to test the skills and application of knowledge. Candidates will check 10 items over a range of products made in the unit or sample products from a regional base. The assessment will contain 6-8 deliberate errors. The time allowed to complete this assessment should be appropriate to the types of checks being undertaken. The candidate must detect each of these errors. It may be more appropriate to carry out this test before the candidate begins the 1000 check log to ensure that they can identify errors.

14.4 Candidates who are not successful at the checking assessment must collect a further 100 checks at work base, with no errors, and re-apply for the next available practical assessment. If candidates make an error whilst collecting their 100 checks they must notify the training provider. Candidates should undergo further training in checking before carrying out a final attempt at the practical assessment.

14.5 Candidates are allowed a total of two attempts of the practical assessment. Failure on the second attempt would suggest that they are not ready to proceed and further preparation/manufacturing experience would be recommended.

Admission to the Assessment

14.6 Candidates who have completed the assessment period listed in the scheme requirements are eligible to sit the practical assessment providing they have been nominated by their Senior Pharmacy Manager/Chief Pharmacist or a designated deputy and the educational supervisor.

14.7 Candidates may apply for the practical and/or oral assessment at any stage of the course, once they have completed the study sessions. The candidate must have

agreement from their course lead, educational supervisor and SPM/CP if they wish to attend before portfolio completion.

14.8 In certain circumstances any qualified practising pharmacy technician who considers his/her knowledge to be sufficient due to previous experience or completion of another framework may apply to register directly with the training provider for an assessment. Any pharmacy technician in this category must still meet the framework's entry criteria.

Evidence of understanding

14.9 The evidence of understanding of the aseptic process is assessed by an interview/appraisal, and a review of a portfolio.

14.10 The assessment is intended to measure achievement of the learning outcomes; these can be assessed by means of an interview, portfolio review, educational supervisor's final report, and the checking assessment.

14.11 This final assessment should be undertaken within eight weeks of completion of the evidence collection.

14.12 Candidates must meet the criteria set for the portfolio, practical assessment and in the interview.

14.13 If candidates do not satisfactorily meet the portfolio and/or oral assessment requirements the educational supervisor will contact the Accountable Pharmacist and/or training provider and decide on an appropriate course of action.

14.14 Candidates will be permitted to re-sit the assessment on one further occasion, a total of two attempts. There may be a recommendation or a requirement to undertake relevant remedial work prior to registration for the next assessment. Candidates are permitted to re-sit individual parts of the assessment.

14.15 Error reporting should be completed when any error is made. This should be a formal process of documenting and reflecting with the Accountable Pharmacist.

Assessment Panel

14.16 In some cases it may be appropriate to assess evidence of understanding and acceptance of associated responsibility via an interview. If an interview is not held then all evidence of these aspects must also be provided in the portfolio.

14.17 The interview will be conducted by an assessment panel, ideally with three people but could be a minimum of two, and will consist of any of the following:

- a member of Regional Pharmacy Education & Training team or training provider
- a Senior Pharmacy Manager/Chief Pharmacist
- a Technical Services Manager

- a currently accredited PIPC
- a current PIPC educational supervisor.

Portfolio Review

14.18 The portfolio must contain:

- confirmation of completion of underpinning knowledge requirement
- information about the candidate e.g. Job description / summary of role
- satisfactory evidence of a minimum of 1000 accurately final checked items
- details of all checking errors detected and missed and associated reflection
- educational supervisors review of performance/appraisals – on a minimum of two occasions and after a serious error
- Confirmation of satisfactory assessment of practical test.

14.19 Candidates must not make any errors in the accuracy checking assessment.

14.20 Candidates must meet criteria (within permitted error rate) set for the portfolio and in the interview.

14.21 Candidates will be permitted to re-sit individual parts of the summative assessment on one further occasion, provided the requirement to undertake relevant remedial work prior to registration for the next assessment is met.

14.22 Candidates who register directly for an assessment based on the recognition of their prior learning and skills, and who fail, will not be permitted another attempt until they have participated in the full training programme.

15. Probationary Period

15.1 Following satisfactory completion, the candidate and/or educational supervisor may feel that the candidate may benefit from a probationary period.

15.2 The probationary period recognises that up to its commencement, all of the checks carried out by the candidate will have been subject to a further check by the educational supervisor. At the commencement of the probationary period the candidate's checking should continue to be re-checked, but over two weeks the extent of the re-checking should rapidly decline so that in the final 3-4 days, the candidate assumes full responsibility for the checking of items. The probationary period should last a minimum of two weeks. However, to meet specific circumstances the assessment panel, the educational supervisor or the candidate may extend this period.

15.3 If a checking error occurs during the probationary period, this should be recorded and any action should be taken in accordance with local error monitoring procedures. The educational supervisor should provide appropriate support for the candidate during this time.

16. The Award

16.1 Certificates will be awarded to all candidates who:

- submit a successful portfolio of evidence
- submit a satisfactory educational supervisor report
- achieve a pass in the practical checking assessment
- pass the evidence and portfolio review

16.2 The certificate is valid for two years from the date of successful completion of the assessment.

16.3 Candidates will be informed whether they have achieved a pass or fail within an agreed period of the assessment.

16.4 The Senior Pharmacy Manager/Chief Pharmacist will be notified of the results.

17. Appeals

17.1 There should be a system in place to allow candidates to appeal against any decision or conduct of any assessment process associated with this framework. Below is an example of such an appeals procedure:

17.2 Any candidate who is dissatisfied with the conduct or adequacy of an assessment must give notice of their dissatisfaction and of their intention to forward an appeal to the Appeals Officer (Contact your training provider for details).

17.3 The notification must be given within 5 working days of their assessment or 5 working days of their receipt of the results.

17.4 The formal appeals procedure must then be followed:

- All appeals against the conduct, adequacy or outcome of an assessment must be forwarded in writing to the Appeals Officer within 10 working days of the candidate having given notice of their intention to appeal
- On receipt of an appeal, the Appeals Officer will:
    - acknowledge receipt in writing and set a date for the appeal within 10 working days
    - decide how and who will hear the appeal.
- The appeal panel will meet within 20 working days of the Appeals Officer receiving written notification of the appeal
- The candidate will be offered the opportunity to be accompanied by any person of their choice to help with the presentation of evidence
- The appeal panel will reach a decision on the day of hearing
- All involved parties will receive verbal notification of the decision on the day of the hearing and written notification within 3 working days

17.5 The appeals panel's decision is final.

18. Validity of award

Transfer and Recognition of Prior Learning (RPL)

Staff moving between Organisations

18.1 This Framework is intended to enable skills to be recognised if staff move from organisation to organisation. It is essential that when there are transfers between organisations or departments that the checker undergoes a period of probation of 3 months before re-assuming their accredited checking role in the new department. During this probationary period the checker must become familiar with local policies and procedures and complete a log of a suitable number of checks to reflect local practice within the same product type as previously accredited (minimum 100 checks).

18.2 If the candidate makes an error during the probationary period, further training should be provided in accordance with the local SOP.

18.3 On completion of this process they must inform the training provider to allow updating of records and inform the Accountable Pharmacist.

Candidates who have completed accreditation using other training and assessment programmes

18.4 In certain circumstances any candidate who considers their knowledge to be sufficient due to previous experience or by completion of another checking training and assessment programme may apply to register directly with the training provider for an assessment.

18.5 If the candidate meets the Framework's entry criteria, the training provider should review the evidence of previous experience/accreditation and assess how it maps to the National Framework. Consideration should be given to the assessments undertaken and the individual's experience in the role. If the training provider is satisfied that there is sufficient evidence to RPL, the candidate should then successfully complete the checking assessment and demonstrate a working knowledge of their local practices and procedures.

18.6 Accreditations awarded by training and assessment programmes that meet the standards of the Nationally Recognised PIPC Framework represent a transferable skill across organisations. The framework is recognised by all NHS regions in England, Wales and Northern Ireland. It is recommended that when there are transfers between organisations, departments/units or a satellite unit e.g. HIV, the final accuracy checker undergoes a period of probation of 3 months but this is only necessary if SOPs are significantly different or if the product types are different, before assuming their checking role.

18.7 During this probationary period the final accuracy checker will become familiar with local policies, SOPs and complete an accuracy checking log of a suitable number of final accuracy checked items to reflect local practice (in the region of 200).

18.8 On completion of this process please inform the training provider to allow updating of the candidate's records.

Adding product types to an accreditation

18.9 Candidates wishing to extend the role into a previously non accredited area (either pre or in process checks or within a new product type) can do this by adding additional checks to their accreditation. The numbers of checks required for these additions should be decided locally with the Accountable Pharmacist (minimum of 250 checks are recommended).

19. Periods of absence or expired certificates

19.1 If accredited individuals have not checked for a period of time for any reason or their certificate has expired they must contact the training provider for the appropriate course of action. Suggested courses of action would be:

- Up to 6 months – familiarise SOPs and complete 100 checks documented on the accuracy checking logs which are double checked
- 6 – 12 months - familiarise SOPs and complete 200 checks documented on the accuracy checking logs which are double checked
- 13 – 24 months - familiarise SOPs and complete 500 checks documented on the accuracy checking logs which are double checked
- Over 2 years the pharmacy technician will need to re-enter the scheme from the beginning.

20. Rotational Accuracy Checking Activity

20.1 If an individual undertakes accuracy checking activities across different practice areas (e.g. dispensary, technical services, ward-based etc.), it is recommended they should:

- complete the initial accuracy checking training framework for each practice area
- be aware of their individual organisation's requirement for reassessment (e.g. see recommendations for return to practice above) on return to each rotation
- comply with organisational requirements for revalidation against specific checking frameworks
- The maximum recommended length of time for period(s) of absence from either practice area (dispensary or technical services/other), before reassessment is **six months**
- On return to practice within dispensaries or technical services in the same organisation, the individual should
- Check for introduction of any new procedures/changes since last working session
- Undertake any reassessment/revalidation exercises, as required, in line with organisational procedures
- Receive signed approval to undertake checking activity from the Senior Pharmacy Manager/Accountable Pharmacist

21. Evidence of On-going Competence

21.1 It is the professional responsibility of each accredited individual to keep a personal record of their on-going competence. This evidence should be recorded at least every 2 years after the certificate is issued.

21.2 It is important to note that practising outside of a current certificate will result in the individual being in breach of their job description and professional responsibilities.

21.3 For individuals to remain "current" they must keep an on-going log of any checking errors made and document these according to their department error recording policy. Any error must be fully reflected upon and recorded. These logs must be reviewed and discussed periodically with educational supervisors or line managers.

21.4 Individuals must liaise with their educational supervisor/line manager to ensure they complete the reaccreditation process.

21.5 Individuals must submit a supporting statement from the Senior Pharmacy Manager/Chief Pharmacist, a designated deputy or the educational supervisor that they are maintaining their checking competence by checking for a minimum of 8 hours per month.

21.6 Guidance regarding reaccreditation and post course development must be available for all accredited checkers.

21.7 It is recommended that all staff undertake regular performance management reviews. Any serious error or series of minor errors should require a local review of the suitability of the individual to continue the role without further training. Below is a suggested course of action for when this situation arises:

- A**ny** accredited individual may be requested to undertake a period of further training and assessment/follow a probationary period following errors and/or near misses in their work.
- If an error is made the line manager should review the nature of the error and taking into account all the evidence and the individual's situation and then decide a course of action (this may include being suspended temporarily from the role).

- Depending on the level and number of errors made, managers and individuals may decide on a suitable period of supervision e.g. 1-3 months and then re-assess the situation.
- Reflective diary logs and observed assessments must be completed during this supervision period. If there is a need for more time, the line manager can extend the period with further support depending on the individual's progress.

22. Acknowledgements

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Further information is available from the **chairperson of the NHS PEDG Pharmacy Technician and Support Staff (pre and post qualification) Group or the NHS ASAG**.

2016 Review Working Group Members		
Geographical area	**Representative**	**Organisation**
Yorkshire & Humber	Gill Risby Chair of NHS PEDG (TSET)	Health Education England working across Yorkshire and the Humber.
South West	Ellen Williams (Task & Finish Group Lead)	South West Medicines Information & Training (SWMIT)
South	Joanne Palmer	University Hospital Southampton NHS Foundation Trust
Wales	Catherine Talbot Nichola Butler-Griffiths Michele.Sehrawat Paul Spark	Cardiff and Vale University Health Board

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24. Appendix 1 - Error Reporting Categories and Potential Consequences of Errors

The following classification is based on the National Aseptic Error Reporting Scheme (7)

24.1 **Licensed Status**

A Made under MS License

B Made under Section 10

C Bought in and dispensed

D Clinical Trial

24.2 **Product category**

A Cytotoxic adult

B Cytotoxic paediatric

C Parenteral nutrition – adult

D Parenteral nutrition – paediatric

E Monoclonal Antibody

F Other Aseptic Product

24.3 **Error type – Please include all errors**

A Incorrect transcription

B Calculation error

C Incorrect drug

D Incorrect dose/strength

E Incorrect diluent/Infusion fluid

F Incorrect final volume

G Labelling error

H Incorrect expiry date

I Incorrect container, e.g. infusor, bag

J Other – please see the criteria in the 'Review and relaunch of the National Aseptic Error Reporting Scheme (NAERS)' for details www.pasg.nhs.uk

24.4 **Who detected error**

A Accountable Pharmacist

B Technician

C Assistant

D Student Technician

E Pre Reg

F Nurse

G Doctor

H Patient

I Other

24.5 **When was error detected**

A Prescription Verification check

B Worksheet and label check

C Check in preparation area

D In process check during preparation

E During labelling

F At final product check prior to release / approval

G At Product release/ approval stage

H After release, prior to administration

I After release during or after administration

J Other (must be qualified with details)

24.6 **Who made the error**

As in, “Who detected error” above. More than one person may be involved since one person may have compounded the error or missed a check.

24.7 **Contributory factors**

There may be more than one

A Staff error

B Inadequate training

C Facility/equipment error

D Poor quality of starting materials used

E Inadequate computer system

F Process design

G Poor storage/distribution

H Staffing level below establishment

I Workload above planned capacity

J Poor segregation

K Distraction/interruptions

L Other – please see the criteria included in the 'Review and relaunch of the National Aseptic Error Reporting Scheme (NAERS)' for details **www.pasg.nhs.uk**

24.8 **Potential outcome or actual outcome**

If the error is spotted before administration, there should be no actual outcome. Therefore, for the report, Accountable Pharmacists should estimate the potential outcome if the error had not been spotted. If the medication has been administered to a patient, the actual outcome should be recorded.

Errors are to be classified according to the categories defined in the document 'Review and relaunch of the National Aseptic Error Reporting Scheme (NAERS)'. These may be defined as follows:

Descriptor	Actual or potential unintended or unexpected impact on patient
Catastrophic	Could have caused patient death
Major	Could have caused serious harm
Moderate	Potential to cause patient harm
Minor	Unlikely to cause patient harm
None	No potential for patient harm

Further detail on classification of errors can be found in the npsa document 'National Framework for Reporting and Learning from Serious Incidents Requiring Investigation'[5]. Particular attention is drawn to section 1 of the executive summary – 'Purpose, scope and responsibilities' on page 25. The full text of the document can be accessed at:

http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=68464&type=full

[5] National Framework for Reporting and Learning from Serious Incidents Requiring Investigation (2010) http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=68464&type=full

25. Appendix 2 - Definition of a Check: worked examples

25.1 Introduction

It should be noted that there have been no specific numbers attributed to each type of check in order to complete the accreditation. This is left to the discretion of the Accountable Pharmacist within the unit. However the numbers set should reflect the types of checks carried out and ensure that the candidate is able to demonstrate consistency and competency across the range.

25.2 Chemo / CIVA (individual)

1 check for worksheet

1 check for labels

x checks for x number of ingredient products to be in completed product. If more than one of the same product, that is one item, e.g. 2 vials Amikacin for one dose, is one item.

x critical volume checks. This would include ensuring that the correct starting material has been used and would not count as separate check.

2 reconciliation checks (labels and ingredients)

25.3 For PN :

1 check for worksheet

1 check for labels

x checks for x number of ingredient products to be in completed product

x critical volume checks. This would include ensuring that the correct starting material has been used and would not count as separate check.

2 reconciliation checks

25.4 Worked example:

In a PN solution where there was:

1 amino-acid container (e.g. Vamin 14)

1 bottle of lipid (e.g. Intralipid 10%)

2 bags of different strength glucose solution (e.g. Glucose 5%, Glucose 10%)

1 trace element via (e.g. Additrace®)

2 x ampoules of sodium chloride 30%

5 x ampoules of potassium chloride 15%;

1 vial of Solivito N®

1 ampoule of Water for Injection (to reconstitute Solivito N®)

would count as:
1 worksheet, 1 label check, 9 ingredient checks, 9 critical volume checks and 2 reconciliation checks

26. Appendix 3 – Resources and sample paperwork

Pre and In Process Checking Scheme Application/Nomination Form

Course Dates:……

Applicant Details: Name Job Title Full Name and Address of Hospital Home Address Telephone Number (Emergency Use Only) Professional Qualification (eg BTEC, NVQ) Relevant Underpinning Knowledge
Candidate statement in support of application.(Why do you think you should undergo this training e.g. Experience, benefits and relevance to your post)
Educational Supervisor Details Name Job Title I am willing to mentor the candidate named above. Signed
Approval by Accountable Pharmacist I recommend this candidate for the Pre and In Process Checking Scheme and I also approve the Educational Supervisor named above Signed Date
Approval by Senior Pharmacy Manager/Chief Pharmacist I recommend this candidate for the Pre and In Process Checking Scheme and I also approve the Practice Supervisor named above Signed Date

The application form must be completed and returned to:

Pre and In Process Checking On-going feedback appraisal

Name .....

Points discussed

-
-
-
-
-

Action plan

-
-
-
-
-

Candidate comments on review of performance

Accountable Pharmacist/Educational Supervisor comments on review of performance

Signed by Candidate **Date**

Signed by Accountable Pharmacist **Date**

Pre and In Process checking Summary of Assessment

Candidate Name:……

Date Assessment started:	Date assessment Finished	Time taken to complete assessment	Did you record your assessment continuously?

Total number of pre process checks Total number of in process checks	Modules covered -

Points discussed:

Outcome of the assessment
The candidate has */ has not * demonstrated their ability to accurately check in process* and or pre process* systems. * Delete as applicable

Action Plan

Candidate comments on review of performance

Accountable Pharmacist/Educational Supervisor comments on review of performance

Next Assessment Date:

Candidate signature……Accountable Pharmacist signature……..Date……

Chief Pharmacist/Senior Pharmacy Manager Signature……Date……

Accuracy Assessment Diary Log form for technical services – pre process / in process checks (please circle)

Initials……**BD**…….Hospital code……**A**……..

Date	Product Category	Licensed status	Product Name / code, (refer to key)	Tray / Worksheet/ Label T/ W/ L	Error Type	Who detected the error	When was error detected	Contributory factors	***Potential or actual*** outcome	Trainees signature	Error type found	Checkers signature
25/5	**A**	**C**	**A**	**W**						**B Dowling**		A Pharmacist
25/5	**A**	**C**	**A**	**T**	**C**	**B**	**B**	**A**	**Major**	**B Dowling**		A Pharmacist
25/5	**C**	**C**	**B**	**T**						**B Dowling**		A Pharmacist
25/5	**C**	**C**	**B**	**T**						**B Dowling**		A Pharmacist
25/5	**C**	**C**	**B**	**T**						**B Dowling**		A Pharmacist
25/5	**C**	**C**	**B**	**T**	**A**	**B**	**B**	**A**	**None**	**B Dowling**		A Pharmacist
25/5	**E**	**C**	**C**	**L**	**H**	**B**	**A**	**B**	**Minor**	**B Dowling**		A Pharmacist
25/5	**E**	**C**	**D**	**W**						**B Dowling**		A Pharmacist
25/5	**E**	**C**	**E**	**L**						**B Dowling**		A Pharmacist
25/5	**A**	**C**	**F**	**L**						**B Dowling**		A Pharmacist

This sheet is page:……..of…….. Signed by Accountable Pharmacist:……

To successfully achieve the assessment you should make no errors

Code Descriptions Product category	**Licensed Status**	**Error Type**	**Who detected the error**
A. Made under MS License	A. Cytotoxic adult	A Incorrect transcription	A Pharmacist
B. Made under Section 10	B. Cytotoxic paediatric	B Calculation error	B Technician
C. Bought in and dispensed	C. Parenteral nutrition – adult	C Incorrect drug	C Assistant
D. Clinical Trial	D. Parenteral nutrition – paediatric	D Incorrect dose / strength	D Student Technician
	E. Monoclonal Antibody	E Incorrect diluent / infusion fluid	E Pre Reg
	F. Other Aseptic Product	F Incorrect final volume	F Nurse
		G Labelling error	G Doctor
		H Incorrect expiry	H Patient
		I Incorrect container e.g. infuser, bag	I Other
		J Other, please give details on attached sheet.	

When was the error detected	**Contributing Factors, there may be more than one.**	**Actual or potential outcome descriptor**	**Actual or Potential unintended or unexpected impact on patient**
A. Prescription Verification check	A staff error		
B. Worksheet and label check	B Inadequate training	Catastrophic *	Death
C. Check in preparation area	C Facility / equipment error	Major *	Major permanent harm
D. In process check during preparation	D Poor quality of starting materials used	Moderate *	Semi permanent harm (up to one year)
E. During labelling	E Inadequate computer system	Minor*	Non permanent harm (up to one month)
F. At final product check prior to release / approval	F Process design	None	No obvious harm
G. At Product release/ approval stage	G Poor storage / distribution		
H. After release, prior to administration	H Staffing level below establishment		
I. After release during or after administration	I Workload above planned capacity		
J. Other (must be qualified with details)	J Poor segregation		
	K Distraction. Interruptions		
	L Other		