NHS Working Group for development of training and accreditation of checking activity carried out in aseptic services.

Nationally Recognised Framework for Accreditation of Final Accuracy checking within Aseptic Services

Contents page

Scope

Welcome to the nationally recognised Accreditation Framework for Final Accuracy Checking.

The *final accuracy check* must be carried out by a competent person, not necessarily a pharmacist. Under current statutory limitations the preparation and release of products prepared under Section 10 Exemption to the Medicines Act, ie in an unlicensed unit, is the responsibility of the *Responsible* or *Authorised Pharmacist*.

This Framework has been developed as best practice guidance to promote robust checking systems in aseptic 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.

Note: In the future there will be a framework for release of aseptic products.

1. Introduction

This document provides details of a training and assessment process covering the final accuracy checking function within aseptic services, including radiopharmacy. This Framework is aimed at personnel within aseptic services who wish to become accredited to final accuracy check products. It is designed to give guidance and direction to *work-based assessors* who will be involved in the mentoring of candidates through their assessment process.

This Framework has been developed by a Working Group that has members from several professional areas of pharmacy: the NHS Pharmaceutical Quality Assurance Committee, NHS Pharmaceutical Production Committee, NHS Pharmaceutical Aseptic Services Group, NHS Pharmacy Education and Development Committee, Pharmaceutical Aseptic Specialist Education and Training Group, pharmacists and pharmacy technicians. It is endorsed by the NHS Education and Development and Technical Services Education and Training (TSET).

This Framework is designed to cover the final accuracy checking function in aseptic preparation services. The principles may be applicable to final accuracy checking in other technical services. Additional work has been undertaken looking at other checking functions within aseptic services areas (eg pre and in-process checking).

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

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

The first time a term defined in the glossary is used it is italicised.

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

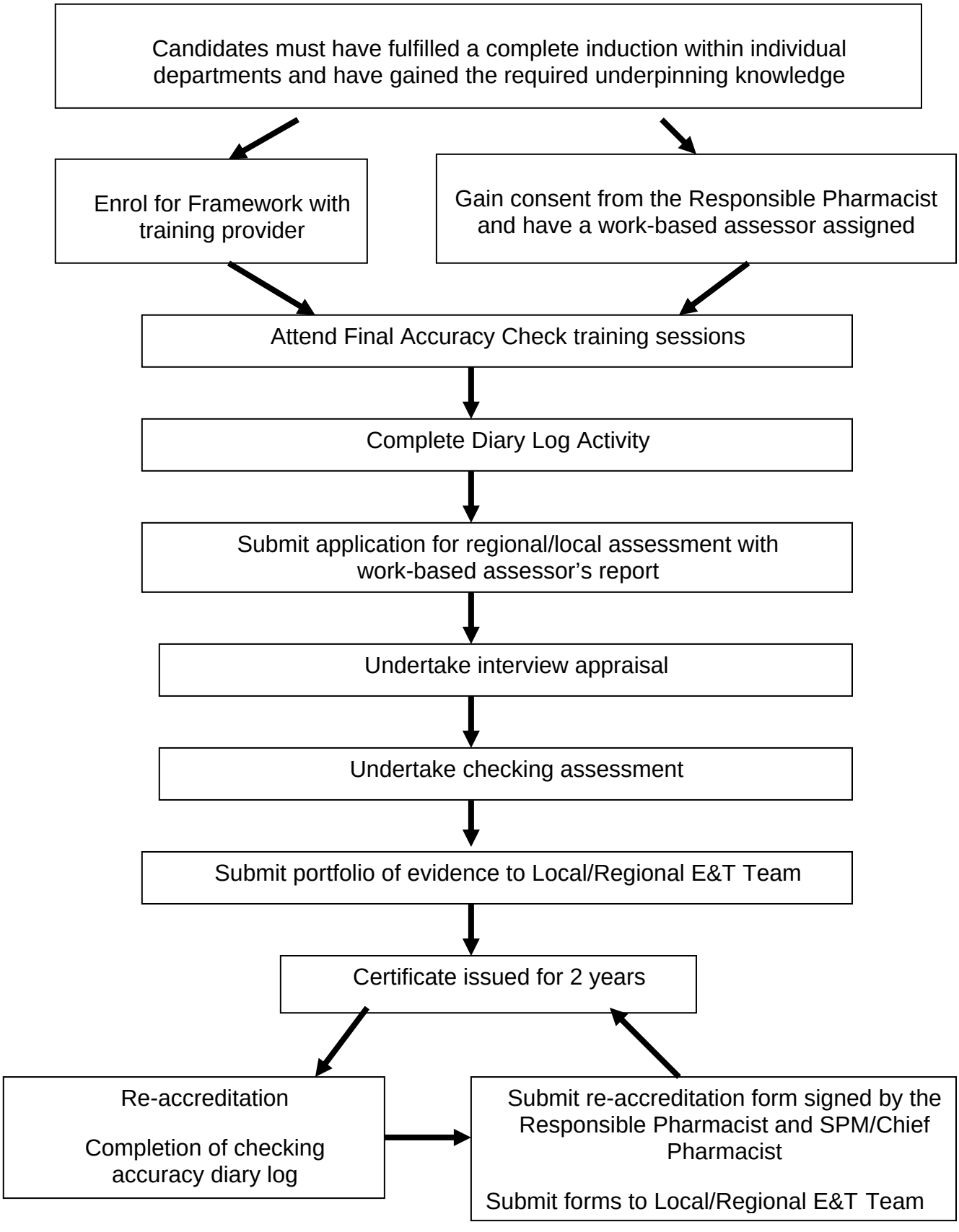
- Accredited checking will only work within a robust system as a whole, incorporating premises, quality management systems, training and

management, all of which are subject to external audit under EL(97)52 or equivalent or by the MHRA;

- In unlicensed aseptic preparation units the Responsible Pharmacist remains professionally responsible for the total operation but can leave the final accuracy check to the accredited person when all parameters are satisfied;
- The Responsible 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 Responsible 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 RPSGB Code of Ethics and Standards[(2)];
- Personnel in aseptic services must complete a training and competency assessment programme in aseptic 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 is to specify:
  - The scope within which the persons may operate, including types of products;
  - The elements of checking that are accredited (eg final accuracy);
- Ongoing practice is required in order to maintain accreditation;
- The application of accredited checking in aseptic services should be sanctioned under local clinical governance arrangements.

Final Accuracy Checking

2 Example Framework Structure



3 Aims of the Competency Assessment

The Framework aims to:

- provide personnel working within aseptic services with the skills and knowledge to be able to confidently and competently undertake final accuracy checks within specified local parameters to ensure patient safety and product quality;
- encourage best practice;
- develop aseptic 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.

4 Learning Outcomes

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

- undertake final accuracy checks within the specified parameters set locally;
- describe the legal implications of final accuracy checking in aseptic 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.

5 Entry Criteria

5.1 Minimum Entry Requirements

Pharmacy technicians undergoing accreditation must have:

- BTEC/ NVQ level 3 in Pharmaceutical Sciences or equivalent qualification accepted by RPSGB for registration;
- 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 Final Accuracy Checking within Aseptic Services;
- the recommendation and support of the Responsible Pharmacist;
- a minimum of two years aseptic preparation experience with at least 6 months in their current unit within the 12 months prior to commencing this Framework. Section 12.1 describes the application of the framework to accredited staff moving to a post in another Trust;
- demonstrated ability to work in accordance with locally approved SOPs;
- an allocated work-based assessor who has attended an appropriate mentoring training day;
- be able to demonstrate a detailed knowledge of
  - the processes being undertaken
  - locally approved SOPs

to the Responsible Pharmacist or work-based assessor;
- be able to demonstrate an understanding of the legal framework in which final accuracy checking in aseptic Aseptic services is carried out and of the concept of personal responsibility.

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*, eg Centralised Intravenous Additive (CIVA), Parenteral Nutrition (PN), Cytotoxics, Aseptic Preparation, Radiopharmacy in technical services. Accreditation in other specialities will require additional evidence collection and competency assessment.

6 Registration for this Framework

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

6.1 Pre-scheme preparation

6.1.1 Prior to attending the first study day, candidates must have completed the full in-house induction programme for their base unit.

Confirmation of this must be included with the nomination form to the *Framework leader* prior to attending the training days. The work-based Assessor should countersign both forms.

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

Candidates must have familiarised themselves with their local SOPs.

7 Study sessions

Study sessions

Candidates are required to attend all training sessions prior to undertaking the work-based checking activity.

Learning outcomes

By the end of the scheme the candidate should be able to:
- state the reasons why a nationally recognised Framework for final accuracy checking has been developed;
- list the stages of the final accuracy checking 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;
- discuss the concept of personal responsibility;
- demonstrate communication skills required in the process of final accuracy checking;
- explain the necessity of referral to colleagues in the final accuracy checking process;
- perform the final accuracy checking of aseptically prepared items.

8 Practice Activities

Overview

Candidates must undertake the collection of final accuracy checks for 100 items of each product type and record the evidence. A single item, such as a PN bag, or CIVA product will represent one final accuracy check.

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.

The portfolio consists of two elements:

- a diary log of 100 final accuracy checks in a single product type;
- appraisal of the candidate by the work-based assessor.

The purpose of the portfolio is to:

- document the checking that has been undertaken;
- ensure that a breadth of experience has been covered (see 7.2);
- highlight areas where further training is required.

8.1.5 Evidence must be collected between the final study day and the final assessment.

Diary Log

The candidate must carry out 100 final accuracy checks on aseptically prepared or manufactured items. The prescription must have been pre-screened/approved prior to the preparation process according to local procedure.

The checking evidence must be documented using the Framework Leader approved diary log form (Appendix 1). These forms must be numbered and issued by the work-based assessor.

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

The checking sessions should cover a breadth of items within the product type to reflect current practice within the practice base.

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.

The Responsible Pharmacist and/or work-based assessor will decide with the candidate how the final accuracy checks will be divided over the 100 checks for each product type.

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.

The candidate will check items under normal working conditions, the collection of evidence will span a minimum of 1 month to a maximum of 12 months from commencement of training. If not completed within 12 months the Framework Leader must be consulted. A suitable course of action decided upon on a case by case basis.

Error reports

The candidate must not miss any errors during the collection of 100 final accuracy checks. This is due to the relatively low incidence of errors in aseptic preparation activities and the critical consequences to patient safety.

The portfolio should also contain a report of any aseptic preparation errors not detected by the candidate, which have occurred during the checking practice activity.

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.

The department must have a mechanism for reporting and reviewing errors and should submit error data to the National Aseptic Error Reporting Scheme[(1)]. It is important that all persons involved in the accreditation process are aware of the classification of the potential outcome of errors.

7.3.5 No candidate will be allowed more than two attempts in total at completing the collection of 100 final accuracy checks without retraining. Before retraining the work-based assessor/ Responsible Pharmacist should review the candidate's suitability for the role.

Candidate review

In association with the practice activity, the candidate's progress must be reviewed by the work-based assessor at regular intervals and on a minimum of two occasions. The portfolio should be reviewed at this stage.

Candidates must be counselled after any checking error has occurred and a period of reflection is recommended.

At the completion of the practice activity of 100 checks, a review must occur by the Framework Leader. A sample form is included in Appendix 1.

9 Notes for the work-based assessor

Registration as a work-based assessor

The work-based assessor must:

- be the Responsible Pharmacist for the unit or a person currently accredited to undertake final accuracy checking in aseptic services for a minimum of one year;
- be able to meet regularly with the candidate.

Additionally it is preferable that the assessor has experience of mentoring staff.

All new work-based assessors must register with the Framework Leader in accordance with local arrangements, prior to undertaking the role.

Regional study days for work-based assessors should ensure they are able to meet the following learning outcomes:

- define principles of the checking Framework;
- describe the legal and ethical Framework of accredited checking;
- discuss the concept of personal responsibility and liability;
- describe the Nationally Recognised Framework for Final Accuracy Checking Accreditation within Aseptic Services;
- define the role of the work-based assessor;
- discuss the need for locally agreed aseptic preparation procedures;
- define the process of work-based assessments, accreditation assessment and re-accreditation process;
- be familiar with the practice activity documentation;
- understand 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;
- to be able to use the assessment documentation.

Work-based assessors must have a working knowledge of this Framework.

Role

The work-based assessor 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.

It is recommended that the work-based assessor is given time within work to support their candidates.

The work-based assessor is responsible for numbering / issuing each page of the assessment documentation and signing each blank page before issuing to the candidate.

The work-based assessor should complete the candidate review and the summary of activity (Appendix 1). 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.

All documentation including the nomination forms must be submitted to the Framework Leader prior to final assessment as directed by local Framework co-ordinator.

Where appropriate, work-based assessors must plan the probationary period in line with regional requirements.

10 Chief Pharmacist / Senior Pharmacy Manager or Designated Deputy

The Chief Pharmacist / Senior Pharmacy Manager or Designated Deputy must ensure that:

- checking accreditation activity is covered by the vicarious liability of the employing organisation;
- approved and current SOPs are in place and that the candidate is familiar with and works competently within these;
- support mechanisms are in place for the candidates are available.

11 Assessment

The competency-based assessment

11.1.1 The competency-based assessment will assess performance and will be in three parts:

a) A checking assessment of 20 aseptically prepared items.

b) Review of the diary log.

c) Evidence of understanding of the aseptic process and the role final accuracy checks play in quality assurance.

11.1.2 This assessment must be arranged and completed at the base unit.

a) Checking assessment: 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 within the product type made in the unit, containing 3-5 deliberate errors. The time allowed to complete this assessment should be appropriate to the types of checks being undertaken, but would not normally be more than a maximum of 60 minutes. The candidate must detect each of these errors. It may be more appropriate to carry out this test before the candidate begins the 100 check log to ensure that they can identify errors.

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

b) Diary log: This should be a satisfactorily completed log of 100 checks, including all errors detected and not detected.

Candidates **must not make any errors** in the diary log to successfully complete this stage. If the candidate does not detect an error then they must restart the 100 checks.

If the candidate is unsuccessful in this second attempt then they will be expected to undergo re-training in checking, carry out a 50 check log successfully and pass another practical test before attempting a final 100 check log. The 50 checks would not count towards the 100 checks. If a candidate is unsuccessful at this 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.

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

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

11.1.3 This final assessment should be undertaken within eight weeks of completion of the diary log.

11.1.4 The portfolio must contain:

- Work-based assessor's report based on a minimum of two reviews and after any serious error.
- Information about the Candidate, eg CV/Job description.
- Evidence that the candidate understands the aseptic process and meets the learning outcomes.

11.1.5 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.

11.1.6 The optional interview will consist of an assessment panel of two of the following:

- a member of Regional Pharmacy E&T Team or Framework Leader;
- the Responsible Pharmacist for the unit or designated deputy;
- a currently accredited checker ;
- the work-based assessor.

11.1.7 Candidates must meet the criteria (with zero error rate) set for the portfolio and in the interview.

11.1.8 If candidates do not satisfactorily meet the portfolio and/or oral assessment requirements the work-based assessor will contact the Responsible Pharmacist and/or Framework Leader and decide on an appropriate course of action.

11.1.9 Candidates will be permitted to re-sit the assessment on a maximum of two occasions, 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.

11.1.10 Candidates referred to in category 12.1.2, who register directly for an assessment and who fail, will not be permitted another attempt until they have participated in the full training programme.

11.2 Optional probationary period

11.1.1 Following satisfactory completion, the candidate and/or work-based assessor may feel that the candidate may benefit from a probationary period.

11.1.2 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 work-based assessor. 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 work-based assessor or the candidate may extend this period.

11.1.3 If a checking error occurs during the probationary period, this should be recorded and reported to the local scheme co-ordinator. Any action taken should be in accordance with local error monitoring procedures. The work-based assessor should counsel the candidate during this time.

11.2 The award

11.2.1 Certificates will be awarded to all candidates who:

- submit a satisfactory portfolio of evidence;
- have a satisfactory work-based assessor's report;
- achieve a pass in the checking assessment;
- pass the evidence and portfolio review.

11.2.2 The certificate is valid for two years from the date of successful completion of the assessment, and states the areas of practice to which it applies.

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

11.2.4 The Chief Pharmacist / Senior Pharmacy Manager / Designated Deputy and Responsible Pharmacist will be notified of the results

12 Appeals

There should be a local system in place to allow candidates undertaking the accreditation programme to appeal against any decision or conduct of any assessment process associated with this Framework.

13 Validity of the award

13.1 Staff Transfers

13.1.1 Staff moving between Trusts

This Framework is intended to enable skills to be recognised if staff move from Trust to Trust. It is essential that when there are transfers between Trusts 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 50 checks).

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

On completion of this process they must inform the Framework Leader to allow updating of records, and inform the Responsible Pharmacist.

13.1.2 Candidates who have completed accreditation using other frameworks

In certain circumstances any candidate who considers their knowledge to be sufficient due to previous experience or by completion of another checking Framework may apply to register directly with the Framework Leader for an assessment. Any such candidate must meet the Framework's entry criteria, successfully complete the checking assessment and provide evidence of existing knowledge.

13.2 Periods of absence

If Accredited Checkers have not checked for a period of 6 months or more for any reason e.g. maternity leave, long term sickness etc, or their certificate has expired they must contact the work-based assessor and agree an appropriate course of action.

14 Re-accreditation

14.1.1 For Accredited Checkers to remain "current" they must keep an ongoing log of any checking errors they have made and document these according to their department error recording policy. Any error must be reflected on and recorded with the staff members learning from this incident using the CPD cycle. These logs must be reviewed and discussed every 6 months with the Responsible Pharmacist.

14.1.2 It is recommended that all staff undertake regular performance management review. Any serious error or series of minor errors should require a review of the suitability of the individual to continue the role without further training.

14.1.3 Accredited checkers are responsible for their personal re-accreditation before their certificate expires.

14.1.4 Accredited checkers must liaise with their work-based assessors to ensure they complete the re accreditation process.

14.1.5 As a minimum, every two years the all Accredited Checkers must complete a re-accreditation assessment consisting of:

- 20 checks completed on assessment documentation and submit a supporting statement from the Responsible Pharmacist.

15 Error Reporting Categories and Potential Consequences of Errors

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

15.1 Licensed status

A Section 10, individual patient non-licensed

B Section 10, batch non-licensed

C Section 10, individual patient, licensed

D Section 10, batch licensed

E Licensed, individual patient

F Licensed, batch

15.2 Product category

A Cytotoxic adult

B Cytotoxic paediatric

C Parenteral nutrition – adult

D Parenteral nutrition – paediatric

E Other IV additive

F Other pre-filled syringes

G Other

15.3 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, eg infusor, bag

J Other

15.4 Who detected error

A Responsible Pharmacist
B Technician
C ATO
D Student Technician
E Pre Reg
F Nurse
G Doctor
H Patient
I Other

15.5 When was error detected

A First check in assembly area
B Operator check in preparation area
C During labelling
D Final check prior to release
E At release stage
F In clinical area prior to administration
G In clinical area during or after administration
H Other

15.6 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.

15.7 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

15.8 Potential outcome or actual outcome

If the error is spotted before administration, there should be no actual outcome. Therefore, for the report, Responsible 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 National Patient Safety Agency document entitled "Doing Less Harm." These may be defined as follows:

Descriptor	Actual or potential unintended or unexpected impact on patient
Catastrophic	Death
Major	Major permanent harm
Moderate	Semi permanent harm (up to one year)
Minor	Non permanent harm (up to one month)
None	No obvious harm

Further detail on classification of errors can be found in the Doing Less Harm document in Section 4 "Incident Grading and Stakeholder Reporting." Particular attention is drawn to Table 1 – Definitions for impact/consequence on page 25. The full text of the document can be accessed on the NPSA web site at www.npsa.org.uk/html/incidents.htm.

References and Bibliography

References

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

2. Medicines, Ethics and Practice 30 2007, RPSGB, ISBN 0-85369-680-2

Bibliography (as stated or Current Editions)

1. Pharmaceutical Isolators, Ed. B. Midcalf et al, Pharmaceutical Press (London), 2004

2. Aseptic Dispensing for NHS Patients, Department of Health, January 1995

3. Guidance to the NHS on the Licensing Requirements of the Medicines Act 1968, Medicines Control Agency, September 1992

4. MHRA: Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007, The Stationery Office, 2007

5. The Quality Assurance of Aseptic Preparation Services, 4th Edition, Ed A.M. Beaney Pharmaceutical Press (London), 2006

6. Medicines Act 1968

Appendix 1 Sample Documentation

Final Accuracy 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 eg Experience, benefits and relevance to your post)

Work-based Assessor Details

Name

Job Title

I am willing to mentor the candidate named above.

Signed

Approval by Responsible Pharmacist

I recommend this candidate for the Final Accuracy Checking Scheme and

I also approve the work-based assessor named above

Signed

Date

Approval by Senior Pharmacy Manager/Chief Pharmacist

I recommend this candidate for the Final Accuracy Checking Scheme and

I also approve the work-based assessor named above

Signed

Date

The application form must be completed and returned to: (Framework Leader)

Final Accuracy 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 checks	Product type covered:

Points discussed:

Outcome of the assessment

The candidate has */ has not * demonstrated their ability to accurately check in final accuracy systems.

*** Delete as applicable**

Action Plan

Candidate comments on review of performance

Responsible Pharmacist / work-based assessor comments on review of performance

Next Assessment Date:

Candidate signature…….. Date ……

Responsible Pharmacist / Work-based Assessor signature…….. Date……

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

Final Accuracy Checking

Ongoing feedback appraisal

Name .....

Points discussed

-
-
-
-
-

Action plan

-
-
-
-
-

Candidate comments on review of performance

Responsible Pharmacist / work-based assessor comments on review of performance

Signed by Candidate …… Date ……

Signed by Responsible Pharmacist / Work-based Assessor …… Date ……

Accuracy Assessment Diary Log form for aseptic services – final accuracy checks *(please circle)*

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

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

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

To successfully achieve the assessment you should make no error

Product category	Licensed Status	Error Type	Who detected the error
A Cytotoxic adult	A Section 10 individual patient non licensed unit	A Incorrect transcription	A Pharmacist
B Cytotoxic paediatric	B Section 10 batch non licensed unit	B Calculation error	B Technician
C Parenteral nutrition – adult	C Section 10 individual patient licensed unit	C Incorrect drug	C ATO
D Parenteral nutrition – paediatric	D Section 10 batch licensed unit	D Incorrect dose / strength	D Student Technician
E Other IV additive	E Licensed individual patient	E Incorrect diluent / infusion fluid	E Pre Reg
F Other pre filled syringes	F Licensed batch	F Incorrect final volume	F Nurse
G Other		G Labelling error	G Doctor
		H Incorrect expiry	H Patient
		I Incorrect container eg 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 staff error		
A First check in assembly area	B Inadequate training	Catastrophic *	Death
B Operator Check in preparation area	C Facility / equipment error	Major *	Major permanent harm
C During labelling	D Poor quality of starting materials used	Moderate *	Semi permanent harm (up to one year)
D Final Check prior to release	E Inadequate computer system	Minor*	Non permanent harm (up to one month)
E At release stage	F Process design	None	No obvious harm
F In clinical area prior to administration	G Poor storage / distribution		
G In clinical area during or after administration	H Staffing level below establishment		
H Other	I Workload above planned capacity		
	J Poor segregation		
	K Distraction. Interruptions		

Appendix 2 Glossary

Authorised Pharmacist – The person designated in writing by the Responsible Pharmacist to supervise the aseptic process and release the product for use.

Checker – The person who checks the accuracy of the work of the candidate and who is normally responsible for carrying out the checks themselves.

Chief Pharmacist – The Pharmacist responsible for the pharmacy services within a corporate body.

Final Accuracy Check – Checking all details of the product and production process against the worksheet. Note this is carried out prior to release of the product.

Framework Leader – The person responsible for the operation of the framework within the region.

Product Types – PN, CIVA, Cytotoxics, Non-Sterile, Aseptic Manufacturing, Terminally Sterilised

Responsible Pharmacist– The person responsible for all aspects of the services within an aseptic preparation unit. The duties of the Responsible Pharmacist include the approval of all systems of work and documentation used in the unit.

Standard Operating Procedures – These are detailed written documents formally approved by the Responsible Pharmacist and or Quality Controller. They describe the operations to be carried out, the precautions to be taken and the measures applied that are directly or indirectly related to the preparation and supply of the product. They give directions for performing certain operations to ensure they are performed to a consistent standard.

Work-based assessor – The person responsible for mentoring the framework candidates, administration of documentation and workplace review of candidate progress.

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