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

NHS ASEPTIC SERVICES ACCREDITATIONS GROUP

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CHAPTER 1 INTRODUCTION

Welcome to the nationally recognised Framework for the accreditation of Pre and In-Process Checking within Technical Services. 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 aseptic units, and Radiopharmacy.

This Framework is aimed at 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 trainees throughout the process.

This Framework was originally 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 Committee
- NHS Pharmaceutical Technical Specialists Education and Training Group (TSET).

The framework has been reviewed and updated by the NHS Aseptic Services Accreditations Group (ASAG). ASAG is a NHS Working Group for development of checking activity carried out in technical services areas

ASAG TERMS OF REFERENCE

Background

The working group formed in response to Chief Pharmacists requesting increased development and training (especially around checking activity) for all individuals working within technical services areas of pharmacy.

The group's aim is to develop robust checking systems NHS wide in technical services, develop a safe and portable skill mix in line with government policy.

The working group has members from several professional areas of pharmacy, National Pharmaceutical Quality Assurance Committee, Pharmaceutical Aseptic Services Group, National Pharmacy Education and Development Committee, Technical Services Manager, Pharmaceutical Technical Specialist Education and Training Group, Pharmacy Technician and Education & Training.

ASAG AIMS

- To retain oversight of the NHS wide picture with reference to schemes and accreditations already in place covering checking activity and the standards of these schemes, and their alignment with the national schemes.
- To develop and maintain a national framework with robust standards for NHS technical services units who wish to develop training in checking activity and to robustly develop their staff in these areas
- To advise the NHS on the development of such training accreditations covering checking activity in technical services areas.
- To reduce error rates in technical services areas.
- Promote skill mix and the correct use of existing staff.
- Enable retention of staff and also ensure provision of transferable qualifications
- To review course content and documentation for training modules

in the field of checking in Technical Services to ensure that the standards of the national framework are maintained particularly in the area of final product approval.

ASAG OBJECTIVES

To access error-reporting data and analyse error rates of checking activity carried out post 'local' accreditations in NHS units and to be able to compare different staff groups and those who have accredited through different training systems

To develop and maintain standards of competency covering staff in technical services completing accreditations around checking activity.

To feed back to all national groups

ASAG REPORTING

To provide publicly available (via the SPS website) framework documents for units to use and on which local training programmes can be built.

Members of national groups will report to their specific groups at each national meeting held.

FRAMEWORK AIMS

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.

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

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 similar or equivalent to the Accountable Pharmacist in an unlicensed unit.

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 Accountable Pharmacist remains professionally responsible for the total operation but can leave 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.

In an unlicensed unit all practice will adhere to the GPhC Standards of Conduct, Ethics and Performance

** Unlicensed = operation under the Section 10 exemption of The Medicines Act 1968*

Within a licensed unit the standards of the regulatory body (MHRA) must be adhered to. Personnel must complete a training and competency assessment programme in technical services prior to undertaking any tasks or checking functions in this area. The

training and competency assessment for accredited checking is operated through a standardised approach aligned with this Framework.

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 (e.g. Pre and in-process)

Ongoing practice is required in order to maintain accreditation (see Chapter 16)

The application of accredited checking in technical services should be sanctioned under local clinical governance arrangements.

SCOPE OF FRAMEWORK

Pre-process checks are defined as the accuracy checks undertaken on worksheets and labels, starting materials and components, before the product is prepared.

In-process checks are those carried out during the preparation process including the identity of the ingredient accuracy checking of volumes and that the prescribed process has been followed.

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.
Pre and in-process checking forms an important part of the overall product approval process of aseptically prepared products (QAAPS-5th-Edition, 2016). Completion of a nationally recognised Pre and In-process Checking accreditation is an entry requirement for Pharmacy Technicians enrolling on to the Product Approval Accreditation Programme

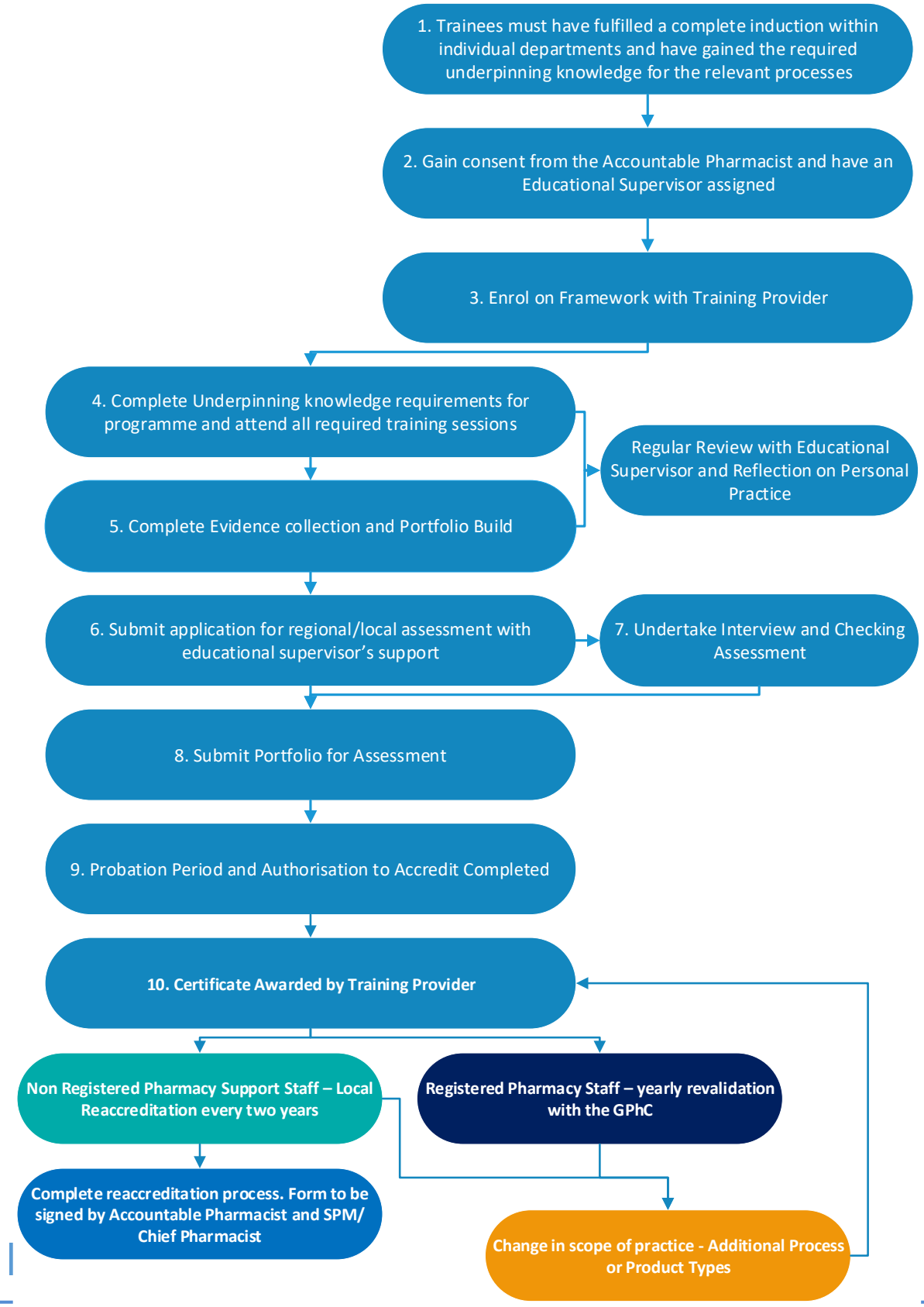
Details of the training and assessment processes covering the product approval function/role can be found in the 'Nationally Recognised Competency Framework for Pharmacists and Pharmacy Technicians: The Assessment of Product Approval (Release) in Aseptic Services under Section 10 exemption'. This framework applies to the aseptic preparation of the following product types:

- Centralised Intravenous Additive (CIVA)
- Parenteral Nutrition (PN)
- Cytotoxics,
- Other Aseptically Prepared Products
- Radiopharmacy in technical services

With suitable additional training this can be extended to cover final product approval of Clinical Trials under Paragraph 37 of the Clinical Trials Regulations where the medicines used are licensed products (but not for novel IMPs).

Accreditation in other specialities will require additional evidence collection and competency assessment.

CHAPTER 2 SUGGESTED PIPC FRAMEWORK



CHAPTER 3 DEFINITIONS

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

The pharmacist responsible for all aspects of the services within an aseptic preparation unit. The duties of the Accountable Pharmacist include the approval of all systems of work and documentation used in the unit. This person is also an Authorised Pharmacist.

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.

TRAINEE

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 PHARMACY VERIFICATION

The process of verifying against the prescription that the product is clinically appropriate for the particular patient.

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

Responsible for overall supervision and management of a specified trainee's educational progress during the programme.

PHARMACY TECHNICIAN

A person who is registered with the General Pharmaceutical Council (GPhC) as a Pharmacy Technician or who holds the appropriate and recognised Pharmacy Technician qualifications in Northern Ireland (where registration is not currently 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).

PHARMACY SUPPORT WORKER

All pharmacy staff except Pharmacists and Pharmacy Technicians

PREPROCESS CHECKS

Pre-process checks are defined as the accuracy checks undertaken on worksheets and labels and starting materials and components, before the product is prepared.

IN PROCESS CHECKS

In-process checks are those carried out during the preparation process including the identity of the ingredient accuracy checking of volumes and that the prescribed process has been followed.

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

Demonstrate that required standards of competence continue to be met. For the purposes of this framework reaccreditation applies to non-registered Pharmacy Support Worker.

REFLECTIVE PRACTICE

The process of critically analysing a specific task, day-to-day practice, learning or an error or incident, identifying successes and weaknesses of personal practice, and planning and taking action to address areas for development and improvement.

REVALIDATION

Revalidation is the process of providing evidence to your governing body of how you to keep your professional skills and knowledge up to date, how you provide the safe and effective care patients and the public expect, as set out in the standards for pharmacy professionals. For the purposes of this framework revalidation is applicable to Pharmacy Technicians and Pharmacists.

ROOT CAUSE ANALYSIS (RCA)

Root cause analysis (RCA) is a systematic process for identifying the "root causes" of errors and incidents and identifying an approach for responding to them and finding a way to prevent them from re-occurring.

SENIOR PHARMACY MANAGER (SPM)

See Chief Pharmacist definition.

STANDARD OPERATING PROCEDURES (SOPS)

Standard operating procedures are detailed written documents formally approved by the Accountable Pharmacist. They describe the operations to be carried out, the precautions to be taken and the measures to be applied that are directly or indirectly related to the preparation and supply of the product. They give directions for performing certain operations, e.g. cleaning, changing, environmental monitoring and equipment operation, to ensure that they are performed to a consistent standard.

SUPERVISED PRACTICE PERIOD

A period of training under the direct supervision of a person deemed suitably trained/qualified by the Accountable Pharmacist.

TRAINING PROVIDER

An organisation responsible for delivery of training programme, assessment and accreditation process and quality assurance of training materials.

CHAPTER 4 AIMS

This 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 checking within specified local parameters to ensure patient safety and product quality.

- Develop technical services personnel in areas of best practice continuing professional development and personal and professional responsibility and accountability within pharmacy services.

- Encourage the further development of effective communication skills

- Support appropriate skill-mix within pharmacy departments.

- Reduce overall error rates.

- Prepare Pharmacy Technicians for entry onto the Product Approval Accreditation Programme (PAAP).

CHAPTER 5 LEARNING OUTCOMES

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

- undertake Pre and/or in-process checks within the specified parameters set locally
- describe the legal implications of Pre and in-process checking in technical services
- develop and apply a robust checking method in line with approved *Standard Operating Procedures* (SOPs) that will be applicable in the workplace
- understand various and different factors that contribute to errors
- understand and apply root cause analysis methods and outcomes
- demonstrate the communication skills required when undertaking the checking role and when informing others about errors made
- demonstrate the ability to recognise their own limitations and make appropriate interventions and referrals
- demonstrate ability to critically analyse their own performance
- describe the legal and professional responsibilities and accountability associated with the PIPC role

CHAPTER 6 ENTRY CRITERIA AND REGISTRATION ON THE FRAMEWORK

ENTRY CRITERIA

In order to meet the minimum entry requirements, the trainee must have:

- A recommendation and support from the Senior Pharmacy Manager/Chief Pharmacist or Designated Deputy to undertake an accreditation programme based on the Nationally Recognised Framework for the Accreditation of Pre and In-Process Checking within Technical Services.
- A minimum of three to six months (depending on previous experience) aseptic preparation experience in current aseptic unit within the 12 months prior to commencing this Framework. Chapter 18 describes the application of the framework to accredited staff moving to a post in another trust.
- Demonstrated knowledge of aseptic preparation process according to locally approved SOPs.
- An allocated educational supervisor who has completed the appropriate training and been deemed suitable for the role by the Accountable Pharmacist.
- Demonstrated a good working knowledge of locally approved SOPs to the Accountable Pharmacist or educational supervisor.

The unit must be able to offer an appropriate workload to enable the trainee the opportunity to complete accreditation within at least one *product type*, e.g. Centralised Intravenous Additive (CIVA), Parenteral Nutrition (PN), Cytotoxics, Other Aseptically Prepared Products, and Radiopharmacy in technical services.

Accreditation in other specialities will require additional evidence collection and competency assessment.

REGISTRATION ON THE FRAMEWORK

Trainees wishing to register for the Framework should complete the agreed application process according to local guidelines and training provider requirements.

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PROGRAMME PREPARATION

Prior to commencing evidence collection, trainees must have completed a full in-house induction programme for their base unit and the underpinning knowledge requirements, outlined by the Training Provider.

All staff should receive training and be assessed as competent for the range of activities they will perform in their role, as outlined in recognised competency frameworks such as those from NHS TSET, RPS, Skills for Health etc. Training should provide staff with at least: „

- an appropriate knowledge of current EU GMP (EC 2015) „
- a knowledge of local practices, including health and safety „
- a knowledge of pharmaceutical microbiology
- a working knowledge of the department, products and services provided (QAAPS-5th-Edition. (2016). *Royal Pharmaceutial Society.)*

Trainees must also demonstrate competency to perform calculations correctly for the tasks being undertaken

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

Underpinning knowledge resources should be made available to give the trainee an appropriate foundation in order to meet the learning outcomes.

CHAPTER 8 GUIDANCE FOR EDUCATIONAL SUPERVISORS

Educational Supervision, for the purposes of this Framework involves overall supervision and management of a specified trainee's educational progress during the programme.

Educational Supervisors are responsible for ensuring that trainees are making the necessary practice-based and educational progress, through the use of appraisals and review meetings. The ability to effectively review a trainee's entire portfolio will also be necessary. This will require a holistic approach, rather than assessing single pieces of evidence.

The Educational Supervisor is responsible for the trainee's educational agreement and learning plan. This will include formal assessment and sign off.

The Educational Supervisor should have an understanding of the range of learning and assessment to be undertaken and support opportunities for learning in the workplace. Work collaboratively with colleagues to monitor and support the trainee's progression and foster learner autonomy. They should also be able to identify and support trainees in difficulty, including interfacing with employment performance management procedures.

EDUCATIONAL SUPERVISOR CRITERIA

The educational supervisor must fulfil the following criteria in order to undertake the role:

- Be the Accountable Pharmacist for the unit, or a person delegated by the Accountable Pharmacist as being suitably trained and qualified. This person must have recent experience in technical services and mentoring staff. If a Pharmacy Technician, be accredited to undertake Pre and in-process checking in technical services with at least two years post registration experience in pharmacy technical services.
- Be able to meet regularly with the trainee
- Be given time within work to support their trainees.
- 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.
- All new Educational Supervisors must register with the training provider in accordance with local arrangements, prior to undertaking the role.
- Educational Supervisors must meet the regional Educational Supervisor training requirements (where applicable).
- The Educational Supervisor should have a job description that reflects the responsibility to undertake the signing off of the trainee's portfolio and practice.

Educational Supervisors should attend regional study days when available and 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 Pharmacy Verification" and "Aseptic Services Verification"
- 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 revalidation and reaccreditation process
- discuss and describe the use of all programme paperwork

- facilitate the use of the programme 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
- also have a working knowledge of this Framework

CHAPTER 9 ROLES AND RESPONSIBILITIES

ROLE OF THE CHIEF PHARMACIST

The Chief Pharmacist must ensure that:

- There is an Accountable Pharmacist in post responsible for the operational delivery of the service.
- Ensure that the Learning Agreement is read, agreed and signed.
- The extension to the trainee'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 Trainee, Educational Supervisor and Accountable Pharmacist.

ROLE OF ACCOUNTABLE PHARMACIST

The Accountable must ensure that:

- All local policies and procedures regarding technical services processes are in place and up to date.
- Establish clear departmental guidelines/written procedures for the roles and responsibilities of the trainee prior to the trainee embarking on the framework.
- Ensure that all staff whose work may be affected by the implementation of the programme are fully informed of the process
- Identify the appropriate product types for the trainee to accredit with
- Ensure a documented outline of the checking procedure for each product/process type is available for the trainee prior to evidence collection
- Identify an appropriate Educational Supervisor to support the trainee through the training and assessment period

ROLE OF THE EDUCATIONAL SUPERVISOR

The Educational Supervisor is required to offer support, guidance and feedback to the trainee whilst they undertake the practice activity, to facilitate the local implementation of this Framework and carry out formative performance reviews in the workplace.

The educational supervisor is responsible for controlling the issue of assessment documentation. In accordance with MHRA 'GXP' Data Integrity requirements (Medicines & Healthcare products 'GXP' Data Integrity Guidance and Definitions, 2018) The Educational Supervisor should complete the trainee's performance reviews and the Summary of Achievements. This may be based on feedback from other colleagues who have worked closely with the trainee during the practice activity. The final assessment panel will review this information, as appropriate.

All documentation must be submitted to the training provider or an appropriate quality assured process be in place for final assessment.

Where appropriate, the Educational Supervisors must plan the trainee's probationary period in line with the training provider's requirements.

CHAPTER 9 STUDY SESSIONS

Trainees must attend/undertake all required training sessions/self-directed learning prior to commencing the worked based checking activity.

Trainees will also be required to undertake a calculation assessment prior to starting the evidence collection to confirm a basic level of mathematical understanding.

STUDY SESSION LEARNING OUTCOMES

Study session should provide the trainee with the following skills and learning outcomes:

- Be able to undertake Pre and/or in-process checking within the specified parameters set locally.
- Describe the legal implications of Pre and in-process checking in technical services.
- Develop and apply a robust checking method in line with approved Standard Operating Procedures (SOPs) that will be applicable in the workplace.
- Understand different factors that contribute to errors.
- Understand and apply root cause analysis methods and outcomes.
- Demonstrate the communication skills required when undertaking the checking role and when informing others about errors made.
- Demonstrate the ability to recognise their own limitations and make appropriate interventions and referrals.
- Demonstrate ability to critically analyse and reflect on own performance.
- Describe the legal and professional responsibilities and accountability associated with the PIPC role

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.

Common understanding and practice across all checking frameworks includes:

- Patient safety, error theory, identifying problems and preventing errors, root cause analysis
- Work flow and safe systems of work
- Regulation and legal frameworks
- Communication
- Developing a checking process
- Dealing with errors
- Personal and professional responsibility and accountability
- Collection of evidence for portfolio assessment and reflective learning

Suggestions for additional teaching for Technical Services are:

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

CHAPTER 10 WORK-BASED ACTIVITIES

OVERVIEW

In order to successfully complete the programme, trainees must accurately check a fixed number of products per product type covering a range of stages in the preparation process, these include:

- Documentation (worksheets and labels) Pre-process checks

  and/or

- Assembly Pre-process checks

  and/or

- In-process checks

Each product will count as 'one' but the trainee will carry out multiple checks per product as per local policy.

PORTFOLIO OF EVIDENCE

All evidence collected must be included in the trainee's portfolio for review and discussion as part of the summative assessment.

The portfolio should consist of the following elements:

- Evidence that the required underpinning knowledge has been completed and understood.
- A checking log providing evidence of 100 accurately checked products per product type (60 products for PN) covering a range of stages in the preparation process. For each Pre-process stage the trainee wishes to be accredited to undertake, e.g. Pre-process documentation checks, a minimum of 25 products of that type (20 for PN) and a minimum of 50 products for in-process stage must have been accurately checked during that stage.
- Documented reports of dispensing/checking errors found and missed and associated reflection.
- A minimum of 3 performance reviews of the trainee by the Educational Supervisor.

The purpose of the portfolio is to:

- document that consistent accuracy checking 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 learning and any errors identified and/or missed

The awarded certificate will reflect the type of process and product type(s) that the trainee has completed checking evidence for and included in the portfolio.

Evidence must be collected in line with local agreements. This will be between completion of, or attendance at the initial study sessions and the final assessment.

ACCURACY CHECKING EVIDENCE

The trainee must carry out accuracy checks on a minimum of 100 aseptically prepared products per product type (60 for PN). See Appendix 2 for example of checking log.

For each stage in the process the trainee wishes to be accredited to undertake, e.g. Pre-process documentation checks, a minimum number of products of that product type must have been accurately checked during that stage. (See table below for examples)

Product Types	Pre-process Documentation Checks (worksheets & labels)	Pre-process Assembly Checks	In-process Checks (volume)	Total number of products checked
CIVAs, Cytotoxic, MABs, Other Aseptic Product	Minimum of 25 products	Minimum of 25 products	Minimum of 50 products	Minimum of 100 products in total
PN	20 products	20 products	20 products	Minimum of 60 products in total

When checking each product type at each process stage, the trainee will need to undertake multiple checks. **It is the responsibility of the Accountable Pharmacist to identify and document the checks to be undertaken for each product type prior to the trainee commencing their checking evidence.** See appendix 3 for examples of typical checks per product/process.

The defined checks per product type/process should be documented and included as part of the trainee's portfolio.

Each prescription must be clinically verified prior to the preparation process according to local procedure.

The checking evidence must be documented using the training provider's approved checking forms (see appendix 2). These forms must be sequentially numbered and issued to the trainee by the Educational Supervisor to ensure an audit trail for the checking evidence.

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

The Accountable Pharmacist and/or Educational Supervisor will decide which process and product types the trainee will be covering during the checking assessment period.

The checking assessment period should cover a breadth of items within the product type to reflect the trainee's scope of practice and current practice within the practice base unit.

The trainee and the *second checker* must sign each item recorded on the log so it is clear that each item has been checked correctly. **Bracketing of items for signing is not allowed**.

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

Evidence must be provided to show that the trainee can consistently (over a period of time) work to all of the assessment criteria. Trainees must complete the programme within a maximum of 12 months. The training provider will confirm when the 12 month training period starts.

If a trainee 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 trainee to re-start the programme, including all training sessions.

If a trainee needs to commence a second attempt at a product type the 12 month training period still applies. Should an extension need to be considered then the training provider must be contacted to discuss further.

CHAPTER 11 ERRORS

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).

Whilst completing the product checks the following scope for error will apply:

- **1st Attempt** at each product type - 1 error = Period of reflection and 25 additional products of that type.
- 2nd error within additional 25 products = Period of reflection and restart 100 products of that type.
- **2nd Attempt** at product type – if error occurs after restart of 100 products then the trainee will need to re-apply to re-start the programme and evidence collection for **all** product types.

Any trainee who fails on their 2nd attempt at any product type must inform their Educational Supervisor who will then inform the training provider as soon as possible.

If a trainee is unsuccessful in their 2nd attempt at their collecting 100 products of any type will be expected to:

- undergo re-training in checking
- re-apply to re-start the programme including all study sessions with support of their Accountable Pharmacist and SPM

If a trainee is unsuccessful after a full restart of the programme, it could suggest that the trainee is not ready to progress into a checking role. Further preparation/manufacturing experience is recommended before re-applying to start the programme again.

The portfolio should contain a report of any aseptic preparation errors not detected by the trainee, which have occurred during the checking assessment. Trainee reflection and outcomes should be documented and included in the portfolio on the approved paperwork.

If a trainee fails to detect an error in something which was incorrectly clinically verified by a pharmacist, then this will not be classified as an error on behalf of the trainee. However, any verification error detected by the trainee should be referred back to the verifying pharmacist.

The department must have a mechanism in place for reporting and reviewing errors and should submit error data to the National Aseptic Error Reporting Programme (National Aseptic Error Reporting Scheme, 2019) – see Appendix 1. It is important that all persons involved in the accreditation process are aware of the classification of and potential outcome of errors.

Trainees must be supported after any checking error has occurred and a period of reflection is recommended. Trainees must document their reflection and include this, along with details of the error, within their portfolio. (Learning from patient safety incidents, 2018)

ERRORS IN OTHER AREAS OF PRACTICE

Whilst this framework concentrates on the accuracy and error rates of the Pre and in process checking, 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 programme.

CHAPTER 12 REFLECTIVE PRACTICE AND CONTINUAL PROFESSIONAL DEVELOPMENT (CPD)

Trainees are expected to reflect on their practice and learning throughout their training period, this enables them to demonstrate insight by identifying actions to help their own development or improvement of practice, promoting greater insight and self-awareness. It also encourages the trainee to identify opportunities to improve quality and patient safety in their organisation.

Educational Supervisors are expected to encourage discussion with the trainee about their experiences and encourage the trainee to reflect on these prior to documenting. Educational Supervisors are also expected to judge reflective content and provide support to improve depth and breadth of reflection.

Trainees should be encouraged to document these experiences as CPD records where appropriate.

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.

REFLECTION ON LEARNING

Trainees should be provided with opportunity to reflect on the study session content and ongoing learning that occurs during their training period.

When reflecting the trainees should consider the following:

- Describe the experience or learning – this might be either a completely new experience or a reinterpretation of one that has occurred before
- Reflection – think about the experience noting anything they haven't experienced before
- Has the experience or learning caused the trainee to develop new ideas or concepts
- How they will apply what they have learnt to new situations

REFLECTING ON ERRORS

Whenever a trainee is required to reflect on an error they have made or failed to identify, the following points should be considered and documented. The Educational Supervisor should then discuss this reflection with the trainee:

- Description of error
- Corrective and preventative actions taken by the trainee and/or the person who identified the error, including review of checking process to identify gaps or changes needed
- Root cause of the dispensing/preparation error – the trainee should carry out a root cause analysis of the initial error
- Root cause of the trainee missing the error – the trainee should carry out a root cause analysis of the their own error
- Potential outcomes and impact of the error for the patient.

CHAPTER 13 TRAINEE PERFORMANCE REVIEWS

Alongside the assessment period, the trainee's progress and performance must be reviewed by the Educational Supervisor at regular intervals and on a minimum of three occasions. The trainee's portfolio should also be reviewed as part of the performance review.

Performance reviews are an opportunity to feedback to the trainee about their progress and performance. It is also an opportunity for the trainee to raise any issues or concerns they have as they progress through the PIPC programme.

Recommended review times are:

- Prior to commencement of the programme
- Before commencement of evidence collection
- If a trainee makes an error or has encountered a difficult situation
- If a trainee is not making progress in order to discuss an action plan
- Prior to final assessment
- If the trainee has a change in Educational Supervisor – the handover between Educational Supervisors should be documented during a regular review.

An additional final overall performance review should take place at the end of the trainee's probation period. The purpose of the final review is to document the trainee's successful transition from trainee to Accredited Pre and In-process Checker, assess confidence levels and fully sign off the trainee with any closing comments from the Educational Supervisor about overall performance.

CHAPTER 14 SUMMATIVE ASSESSMENT

The Summative Assessment is designed to assess the trainee's accuracy skills, understanding of the PIPC role and overall performance during the PIPC programme. The summative assessment consists of three parts:

- A practical checking assessment of 10 products that include a range of errors (held regionally or locally depending on training provider requirements)
- Evidence of understanding of the aseptic process and the role that Pre and in process checks play in Quality Assurance through oral interview
- Portfolio assessment

ADMISSION TO THE ASSESSMENT

Trainees who have completed the assessment period listed in the programme 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.

Trainees may apply for the practical and/or oral assessment at any stage of the course, once they have completed the study sessions. However the trainee must have agreement from the training programme lead, Educational Supervisor and Accountable Pharmacist if they wish to attend before portfolio completion.

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.

Trainees 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.

PRACTICAL CHECKING ASSESSMENT

This assessment must be arranged and completed at the base unit or at a regional base (depending on training provider requirements).

The simulated checking of aseptically prepared items against test documents is intended to test the skills and application of knowledge gained during the PIPC programme.

Trainees will check 10 products over a range of types made in the unit or sample products from a regional base. This would usually include product types that the trainee has checked during their evidence collection.

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 trainee must detect **all** intentional errors in order to pass the assessment.

Trainees who do not successfully pass the checking assessment must collect a further 10 products of each agreed type at work base, with no errors, and re-apply for a second practical assessment.

If trainees make an error whilst collecting their 10 products they must notify the training provider. Trainees should undergo further training in checking before carrying out a final attempt at the practical assessment.

Trainees 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.

EVIDENCE OF UNDERSTANDING

The evidence of understanding of the aseptic process is assessed by a panel interview, and review of the portfolio.

The assessment is intended to measure achievement of the learning outcomes; these can be assessed by means of the interview, portfolio review and the checking assessment.

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

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

If trainees do not satisfactorily meet the portfolio and/or oral assessment requirements the Educational Supervisor will contact the Accountable Pharmacist and the training provider agree on an appropriate course of action.

Trainees 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. Trainees are permitted to re-sit individual parts of the assessment.

ASSESSMENT PANEL INTERVIEW

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
- an Accountable Pharmacist
- a current PIPC Educational Supervisor

PORTFOLIO REVIEW

The portfolio must contain:

- evidence of completion and understanding of underpinning knowledge requirements
- A checking log providing evidence of 100 accurately checked products per product type (60 products for PN) covering a range of stages in the preparation process. For each Pre-process stage the trainee wishes to be accredited to undertake, e.g. Pre-process documentation checks, a minimum of 25 products of that type (20 for PN) and a minimum of 50 products for in-process stage must have been accurately checked during that stage.
- details of all checking errors detected and missed and associated reflection
- additional checking evidence if required
- Educational Supervisors performance reviews, on a minimum of three occasions, plus after any serious error and the final performance review
- confirmation of summative assessment completion and authorisation to accredit from Accountable Pharmacist and SPM

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

CHAPTER 15 PROBATIONARY PERIOD

Following satisfactory completion of the summative assessment, it is recommended that the trainee undertake a probationary period.

The probationary period recognises that up to its commencement, all of the checks carried out by the trainee will have been subject to a further check by a qualified second person. At the commencement of the probationary period the trainee'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 trainee assumes full responsibility for the checking of products. The probationary period should last a minimum of two weeks. However, to meet specific circumstances the Accountable Pharmacist, the Educational Supervisor or the trainee may extend this period.

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 trainee should complete a root cause analysis (RCA) and reflection and discuss with the Educational Supervisor who should provide appropriate support for the trainee during this time.

An additional final overall performance review should take place at the end of the trainee's probation period. The purpose of the final review is for the Educational Supervisor to document the trainee's successful transition from trainee to Accredited Pre and In-process Checker, assess confidence levels and fully sign off the trainee with any closing comments about overall performance.

CHAPTER 16 CERTIFICATE OF ACCREDITATION AND EVIDENCE OF ONGOING COMPETENCE

On completion of the programme a certificate will be awarded to the trainee detailing the product types and process types that were successfully achieved during evidence collection.

The Senior Pharmacy Manager/Chief Pharmacist will be notified accreditation.

It is important to note that undertaking checking activities outside of the scope of practising outlined on the certificate will result in the individual being in breach of their job description and professional responsibilities.

EVIDENCE OF ON-GOING COMPETENCE

REGISTERED PHARMACY TECHNICIANS WHO HAVE SUCCESSFULLY COMPLETED THE PIPC PROGRAMME:

It is the professional responsibility of each accredited individual to keep a personal record of their on-going competence.

Ongoing fitness to practice in the PIPC role is for registered Pharmacy Technicians is assured through the registrant's professional responsibility to maintain their competence. This can be achieved via the annual revalidation cycle.

Upon successful completion of the PIPC programme, trainees must ensure that they maintain their standards and that their competency remains current. In order to demonstrate ongoing competence we recommend that Pharmacy Technicians accredited in in the PIPC programme;

- Have an up to date job description which outlines the activities that they are accredited to undertake
- Should regularly engage with the activities in which they are accredited in order to maintain competence and confidence. It is recommended that PIPCs undertake a minimum of 8 hours of accuracy checking activities per month
- Must always comply with their organisations governance requirements
- Should always follow local standard operating procedures and polices
- Should maintain a record of any errors that they make and subsequent reflections, document these according to their department error recording policy. Any error must be fully reflected upon. These logs must be reviewed and discussed periodically with Educational Supervisors or line managers.
- Should understand and follow systems for reporting, sharing and learning from errors
- Should complete GPhC revalidation entries annually that demonstrate that they are keeping up to date with current practice and legislative changes in their accredited role

NON-REGISTERED PHARMACY SUPPORT STAFF WHO HAVE SUCCESSFULLY COMPLETED THE PIPC PROGRAMME:

Non-registered Pharmacy Support Staff must ensure that they maintain their standards and that their competency remains current. The inclusion of the reaccreditation requirement is designed to ensure that accredited individuals remain active in the area of practice and have evidence of continued competence in this role.

In order to ensure that all accreditations/training files remain current reaccreditation is necessary at least every 2 years. Reaccreditation can be carried out more frequently than this according to local agreement.

For Non-registered Pharmacy Support Staff to remain "current" they must;

- Maintain a record of any errors that they make and subsequent reflections, document these according to their department error recording policy. These logs must be reviewed

and discussed periodically with Educational Supervisors or line managers.

- Have an up to date job description which outlines the activities that they are accredited to undertake
- Should regularly engage with the activities in which they are accredited in order to maintain competence and confidence. It is recommend that PIPCs undertake a minimum of 8 hours of accuracy checking activities per month
- Must always comply with their organisations governance requirements
- Should always follow local standard operating procedures and polices
- Should understand and follow systems for reporting, sharing and learning from errors
- Liaise with their Educational Supervisor/line manager to ensure they complete the reaccreditation process within the specified timeframe. The reaccreditation process should include;

    a reflective statement from the PIPC that consists of a minimum of 250 words, briefly describing the role that the PIPC has been undertaking since their last reaccreditation, how they feel about this role, and how they maintain their standards

    a supporting statement from the Senior Pharmacy Manager/Chief Pharmacist, Accountable Pharmacist and the Educational Supervisor that the PIPC is maintaining their checking competence by checking for a minimum of 8 hours per month

ONGOING COMPETENCE

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

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 or 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 take 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 statements and observed assessments must be completed during this supervision period. If there is a need, the line manager can extend the period with further support for the PIPC depending on the individual's progress.

CHAPTER 17 APPEALS

There must be a system in place to allow trainees to appeal against any decision or conduct of any assessment process associated with this Framework.

Below is an example of such an appeals procedure:

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

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 trainee 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 trainee 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

The appeals panel's decision is final.

CHAPTER 18 TRANSFER OF ACCREDITATION AND RECOGNITION OF PRIOR LEARNING (RPL)

STAFF MOVING BETWEEN ORGANISATIONS

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 products to reflect local practice within the same product type as previously accredited (minimum 20 products).

If the trainee 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 training provider to allow updating of records and inform the Accountable Pharmacist.

TRAINEES WHO HAVE COMPLETED ACCREDITATION USING OTHER TRAINING AND ASSESSMENT PROGRAMMES

In certain circumstances any trainee 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.

If the trainee 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 trainee should then successfully complete the checking assessment and demonstrate a working knowledge of their local practices and procedures.

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, the accredited 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.

During this probationary period the PIPC will become familiar with local policies, SOPs and complete an accuracy checking log of a suitable number of product types to reflect local practice (in the region of 20).

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

CHAPTER 19 SCOPE OF PRACTICE

ADDING PRODUCT TYPES OR PROCESS TYPES TO AN ACCREDITATION

PIPC certificates awarded will reflect the process and the product types that have been covered within the PIPCs portfolio of evidence. It is the responsibility of the accredited PIPC to only check within their scope of practice.

PIPCs wishing to extend their role into a previously non accredited area, either 'Pre-process documentation checking' 'Pre-process assembly checking' or 'in-process checking' or within a new product type can do this by adding additional product checks to their accreditation.

To become accredited for an additional **product type** the PIPC must complete checks on a minimum of 100 products of that type with a minimum of 25 products within each Pre-process stage and/or 50 within the in-process stage.

To become accredited for **additional processes** for an **existing product** on their certificate, the PIPC must complete a minimum of 25 products within each Pre-process stage and/or 50 within the in-process stage.

The number of checks completed for the initial and additional accreditation may be increased (but not decreased) by the Accountable Pharmacist to reflect training needs and workload.

CHAPTER 20 PERIODS OF ABSENCE OR EXPIRED CERTIFICATES

If accredited individuals have not checked for a period of time for any reason or their reaccreditation has expired (if they are non-registered pharmacy support staff) they must contact the training provider for the appropriate course of action. Suggested courses of action would be:

- Up to 6 months – to be locally agreed.
- Over 6 months – familiarise with SOPs and change control log and complete 20 products for each product type and a minimum of 5 products per process stage on accreditation certificate and a documented review should take place by an educational supervisor.

CHAPTER 21 ROTATIONAL ACCURACY CHECKING ACTIVITY

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 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

CHAPTER 22 ACKNOWLEDGEMENTS

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Further information is available from the chairperson of the NHS Aseptic Services Accreditations Group (ASAG) Mark Santillo, Regional Quality Assurance Officer, South West

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Nationally Recognised Competency Framework for Pharmacists and Pharmacy Technicians:

The Assessment of Product Approval (Release) in Aseptic Services under Section 10 exemption v2.0 March 2019

APPENDIX 1 – ERROR REPORTING CATEGORIES AND POTENTIAL CONSEQUENCES OF ERRORS

The following classification is based on the National Aseptic Error Reporting Scheme (National Aseptic Error Reporting Scheme, 2019)

Licensed Status	Product Name	Error Type	Who Detected Error	When Was the Error Detected	Contributory Factors (There May Be More Than One)
A - Made under MS License	A - Adult Cytotoxic	A - Prescription Verification check	A - Accountable Pharmacist	A - Prescription Verification Check	Staff Awareness of Sops (A)
B - Made Under Section 10	B - Paediatric Cytotoxic	B - Worksheet and label check	B - Pharmacy Technician	B - Worksheet & Label Check	Staff New / In Training (B)
C - Bought in and Dispensed	C - Adult PN	C - Check in preparation area	C – Pharmacy Support Worker	C - In Preparation Area (Worksheet/Label/Tray Check)	Communication Breakdown (C)
D - Clinical Trial	D - Paediatric PN	D - In process check during preparation	D – Preregistration Pharmacy Technician	D - In Process Check During Preparation	Staff Knowledge (D)
	E - MAb	E - During labelling	E – Pre-Registration Pharmacist	E - During Labelling	Automaticity (E)
	F - Other Aseptic Product	F - At final product check prior to release / approval	F – Pharmacist	F - At Final Product Check Prior To Release / Approval	Facility / Equipment Fault (F)

		G - At Product release/ approval stage	G – Nurse	G - At Product Release / Approval Stage	Poor Quality of Packaging and Labelling of Starting Materials (G)
		H - After release, prior to administration	H - Doctor	H - After Release, Prior To Administration	Computer System Design (H)
		I - After release during or after administration	I - Patient	I - After Release During Or After Administration	Process Design (I)
		J - Other (must be qualified with details)	J - Other	J - Other (Must Be Qualified With Details)	Poor Storage / Distribution Practices (J)
					Workload Pressures (K)
					Documentation Design (L)
					Poor Segregation (M)
					Distraction (N)
					Interruptions (O)
					Deviation from Process (P)

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 Programme (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' (Learning from patient safety incidents, 2018). Particular attention is drawn to section 1 of the executive summary – 'Purpose, scope and responsibilities' on page 25.

APPENDIX 2 EXAMPLE OF EVIDENCE COLLECTION LOG

Trainee Full Name:					GPhC Number(if applicable):				Trust and Hospital:			
Date	Tick to indicate Process			Product Category	Licensed Status	Product Batch Number	Error type found by Candidate	Contributory Factors	Potential or Actual Outcome	Candidate's signature	Checker's signature	Errors missed by candidate
	Worksheet and/or Labels	Assembly	In Process check									
Total number of per process												

Page number ..... of ..... Signed by Accountable Pharmacist.....

APPENDIX 3 – EXAMPLES OF CHECKS TO BE UNDERTAKEN PER PROCESS

When checking each product type at each process stage, the trainee will need to undertake multiple checks.

It is the responsibility of the Accountable Pharmacist to identify and document the checks to be undertaken for each product and process type prior to the trainee commencing their checking evidence. Examples of typical types of checks expected for each process are detailed below.

Please note: this is not an exhaustive list; the checks documented for the trainee should reflect your current SOPs:

Pre Process – Documentation Checks	• Check prescription e.g. correct regimen, signatures from prescriber and pharmacist, legibility of information • Check all correct details are on prescription e.g. patients name, hospital number, ward, consultant, day of treatment etc. • Check details of dose modifications or protocol deviations • Check necessary blood results which correspond to dosing of drugs • Check the patient has go ahead for treatment • Check worksheet has all the correct information corresponding to the prescription e.g. patient details, number of doses • Check the worksheet has the written calculations recorded • Check the worksheet has the right handwritten information recorded on it • Check the worksheet has been processed for either a paediatric or adult patient • Check the labels correspond to the worksheet and batch number and expiry are correct • Check the correct amount of labels have been reconciled with the worksheet • Check the worksheet has been signed
Pre Process – Assembly Checks	• Correct drug/infusion bag/final container selected • Correct diluent selected (where relevant) e.g. Water for Injection, Sodium chloride 0.9% • Correct concentration of drug • Correct size and number of drug vials/ampoules/infusion bag according to volume required and number of doses • Batch numbers and expiry dates have been recorded for all products • Expiry dates of drug vials/ampoules/infusion bags are in date and do not expire prior to the treatment being administered

	• Necessary checks by Senior Technician/ Pharmacist performed and recorded • Appropriate number and size of syringes selected for the; number of doses, drug volume, volume to be removed from an infusion bag, reconstitution • Correct extra consumables have been included when required i.e. filter, filter needle, oral syringes, intrathecal consumables • Check overwraps are intact and items are undamaged e.g. no cracks, discolouration • Check worksheet has been signed by operator assembling the tray
In Process Checks	• Correct drug/infusion bag/final container selected • Correct diluent selected (where relevant) e.g. Water for Injection, Sodium chloride 0.9% • Correct concentration of drug • Correct size and number of drug vials/ampoules/infusion bag according to volume required and number of doses • Batch numbers and expiries have been recorded for all products • Expiries of drug vials/ampoules/infusion bags are in date and do not expire prior to date treatment is to be administered • Necessary checks by Senior Technician/ Pharmacist performed and recorded • Appropriate number and size of syringes selected for the; number of doses, drug volume, volume to be removed from an infusion bag, reconstitution • Correct extra consumables have been included when required i.e. filter, filter needle, oral syringes, intrathecal consumables • Check all items are intact and not damage e.g. no cracks, discolouration • Check the overage volume is correct • Check the correct drug volume has been drawn up • Check whether the drug needs to be diluted further, if so check the volume of diluent