NI Centre for
Pharmacy Learning
& Development

Pre and In-process Checking (PIPC) Accredited Programme

N. Ireland

Contents page

1. Introduction

Welcome to the nationally recognised Framework for the accreditation of Pre and In-Process (PIPC) 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 technical services units, and Quality Assurance / Quality Control, Aseptics, Production and Radiopharmacy. This programme 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.

The National Framework has been developed by a working group that has members (pharmacists and pharmacy technicians) from several professional areas of pharmacy:

- NHS Pharmaceutical Quality Assurance Committee
- NHS Pharmaceutical Production Committee
- NHS Aseptic Services Accreditation Group (ASAG). For ASAG TOR and further information see :- Nationally Recognised Framework for Accreditation of Pre and In-Process Checking within Aseptic Services (sps.nhs.uk)
- 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[1] is a NHS Working Group for development of checking activity conducted in technical services areas.

This programme is designed to cover pre and in-process checking functions in aseptic preparation services; however, the principles may be applicable to pre and in-process checking in other technical services areas. The programme is designed around a set of principles that would be the foundation of any accreditation system designed for pharmacy technical services, licensed or unlicensed.

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

- Accredited checking will only work within a robust system, 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 delegate the pre or in-process check to the accredited person when all parameters are satisfied.
  - **Unlicensed=operation under the Section 10 exemption of The Medicines Act*

- 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 good manufacturing practice (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 or the individual's equivalent regulatory body standards.

- 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; it is recommended that a training and competency assessment for accredited checking is operated through a standardised approach, aligned with the National framework.

- The training programme incorporates clear entry criteria, *teaching of underpinning knowledge base* and assessment of competence.

- The accreditation should specify:
  a) The scope within which the persons may operate, including types of products.
  b) The elements of checking that are accredited (e.g. pre and in-process).

- Ongoing practice is required to maintain accreditation. See section 7.10.

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

N.B. 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.

1. Introduction

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

1.2 *Pre-process checks* are defined as the accuracy checks undertaken on starting materials and components, worksheets and labels before the product is prepared.
In-process checks are those conducted during the preparation process including the identity of the ingredient, accuracy checking of volumes and that the prescribed process has been followed.
Further information may be found in TSET aseptic processing chapter on accuracy checking[2].

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

1.4 Details of the training and assessment processes covering the product approval function/role can be found in "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 service

Scope

1.5 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.

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

[2] www.tset.org.uk

[3] Nationally Recognised Framework for Accreditation of Pre and In-Process Checking within Aseptic Services (sps.nhs.uk)

2. Aims

2.1 The programme aims to:

- Provide personnel working within technical services with the skills and knowledge to be able to confidently and competently undertake pre and in-process checks within specified local parameters to ensure patient safety and product quality.

- 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 the pharmacy departments.

- Reduce overall error rates.

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

3. Learning Outcomes

3.1 By the end of the programme 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 service.
- Develop and apply a robust checking method in line with approved Standard Operating Procedures (SOPs) that will be applicable in the workplace.
- Have working knowledge of the programme structure and when and how to use the programme documentation.
- Understand varied 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.

4. Entry Requirements

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

- Be a qualified pharmacy technician registered with NICPLD.
- Be recommended and supported by the Accountable Pharmacist to undertake the accredited programme.
- Have a minimum of three months' (depending on previous experience) aseptic preparation/licensed manufacturing experience in their current aseptic unit within the 12 months prior to commencing this programme. Section 6.12 (Change of Work Base for a PIPC checking pharmacy technician) describes the application of the programme to accredited staff moving to a post in another Trust.
- Have demonstrated knowledge of aseptic preparation process according to locally approved Standard Operating Procedures (SOPs).
- Have demonstrated a good working knowledge of locally approved SOPs to the Accountable Pharmacist or Educational Supervisor.
- Have an allocated work based Educational Supervisor who has been deemed suitable for the role by the Accountable Pharmacist. This individual should have recent experience of mentoring staff. They should have undertaken or intend to undertake the Pre and In-Process accuracy checking ES Induction eLearning and they ideally should be a qualified and registered pharmacist with at least 2 years post registration experience in pharmacy technical services or an accredited pre and in-process checking pharmacy technician with 2 years' post-graduation experience in pharmacy technical services.

4.2 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 the collection of additional evidence and competency assessment.

5. Guidance for educational supervisors

5.1 Educational Supervision, for the purposes of this programme 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, using 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 understand the range of learning and assessment to be undertaken and support opportunities for learning in the workplace. They should collaborate 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.

- The Educational Supervisor must fulfil the following criteria 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 NICPLD in accordance with local arrangements, prior to undertaking the role.

- Educational Supervisors must meet the required Educational Supervisor training requirements for this programme.

- The Educational Supervisor should have a job description that reflects the responsibility to undertake the sign off of the trainee's portfolio and practice.

5. Guidance for Educational Supervisors

5.2 Educational Supervisors should attend induction 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.
- Have a working knowledge of this Framework.

6. Stakeholder Responsibilities

6.1 Responsibility of NICPLD

During the course of the programme, NICPLD, The Trust, the Educational Supervisor and the Trainee all have defined responsibilities to ensure that a supportive learning environment is provided for the trainee and to facilitate the completion of the accredited programme.

NICPLD is the training provider responsible for managing PIPC for pharmacy technicians in N. Ireland. The role of NICPLD is to support the Trainees, Educational Supervisors and all individuals involved in the delivery and completion of the programme. NICPLD is therefore responsible for:

- Regularly reviewing and updating the programme to ensure that the standards of the National Framework for the assessment of skills are met.
- Advertising and promoting PIPC to pharmacy technicians and Trusts.
- Accepting applications and facilitating places on the programme.
- Developing induction and expert training relating to the development of the key skills.
- Providing guidance to Educational Supervisors and Trainees regarding queries throughout the modules of the programme.
- Facilitating the final appraisal process, including the review of portfolios and final interviews.
- Supporting individuals who fail to meet the criteria and offering guidance.
- Issuing certificates of accreditation to Trainees who successfully complete the programme.
- Providing a tool for reaccreditation.
- Maintaining a database of all accredited individuals.

6.2 Responsibility of the Trust Pharmacy Manager (Employer)

The Trust Pharmacy Manager has overall responsibility for the quality of the pharmacy services provided within the Trust. It is their role to ensure that anyone involved in the delivery or implementation of this programme has the required resources and support to successfully complete the accreditation. To facilitate this, the Trust Pharmacy Manager or another nominated, and suitably experienced individual must:

- Ensure there is an accountable pharmacist in post responsible for the operational delivery of the service.
- Ensure that the learning agreement (**PIP 2**) is read, agreed, and signed as appropriate.
- Make available and implement SOPs outlining the roles and responsibilities of the pharmacy technician in delivering a service.
- Inform those staff whose work may be affected by the implementation of this programme.
- Ensure allocation of appropriate time to complete the programme.
- Ensure the extension to the individual's role is documented in their current job description to ensure that they are covered under vicarious liability of the employing organisation following accreditation.
- Appoint an appropriate Educational Supervisor to support the trainee.

6.3 Responsibility of the Educational Supervisor

The Educational Supervisor must

- Undertake or have undertaken the NICPLD pre and in-process checking (PIPC) ES induction eLearning.

- Complete a learning agreement (**PIP 2**) with the trainee prior to the start of the programme.

- Be familiar with the National Framework.

- 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 the 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.

- Ensure all documentation is submitted to NICPLD for final assessment and prepare trainee for the final appraisal assessment.

- Liaise with NICPLD to ensure the trainee completes the programme within the agreed timescale.

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

6.4 Responsibility of the Trainee

Pharmacy technicians are responsible for their own professional actions and must practice in accordance with their Trust's Standard Operating Procedures (SOPs) and the N. Ireland Clinical Pharmacy Standards. They should consult the current versions of the Medicines Ethics and Practice Guide (July 2023) and the PSNI Code (March 2016) for guidance relating to professional conduct. The role of the pharmacy technician is to provide support to the pharmacist and to ensure the patient receives care which is safe and effective.

It is the responsibility of the Trainee to:

- Complete the learning agreement (**PIP 2**).
- Complete all pre-course activities and agree the scope of their role with their Educational Supervisor.
- Work within the Trust policies and procedures relating to the role they will be undertaking.
- Meet regularly with their allocated Educational Supervisor.
- Take responsibility for their own learning and development.
- Use constructive feedback from colleagues to further their self-development.
- Complete all documentation accurately and store within their programme portfolio.
- Liaise with educational supervisor to complete the programme within the agreed timescales.

7. Programme Overview

This programme is designed to cover pre and In-process checking functions in aseptic services and the core assessments of the programme are similar to other accredited programmes offered by NICPLD.

The programme consists of a number of elements including:

- Pre-course work
- eLearning induction and initial interview with NICPLD training Lead
- In-house interviews
- log of PIPC checks (including a fixed number of products per product type)
- Final appraisal
- Probation
- Accreditation
- Reaccreditation

Each of the elements of the course are discussed in more detail in this section. (See appendix 1 for summary)

7.1 Pre-course work

Pharmacy Technicians wishing to register for this PIPC programme must complete the application form (**PIP 1**) and Learning contract (PIP 2). Once they have received confirmation of a provisional place, they should commence the pre-course work.

The Pre-course work includes:

- Providing an up-to- date curriculum vitae (CV).
- Providing an up-to-date job description which details the extent of their role in Aseptic services.
- Undertake the NICPLD Open Learning course:- Accredited Programme: Pre and in-process accuracy checking.
- Complete the pre course error report practice with their educational supervisor.
- Undertake an induction session with the NICPLD learning lead and their Educational Supervisor. This will mark the start of their 12-month completion requirement.

All required pre-course documentation must be signed by the Educational Supervisor where appropriate and stored in the trainee's portfolio. The witness signatures should be included in the trainee's witness list (**PIP 4**) which should also be included in their portfolio.

7.2 Open Learning induction

Trainees are required to undertake the NICPLD Open Learning course: - Accredited Programme: Pre and in-process accuracy checking.

After completion they should be able to

- Have working knowledge of the programme structure and when and how to use the programme documentation.
- State the laws and guidance relating to the aseptic preparation of medicines products.
- Describe the legal and ethical implications of Pre and in-process checking in technical services.
- Discuss the impact of aseptic preparation/checking errors on patient safety and product quality.
- Understand various and varied factors that contribute to errors.
- Develop and apply a robust checking method in line with approved Standard Operating Procedures (SOPs) that will be applicable in the workplace.
- Demonstrate the ability to recognise their own limitations and make appropriate interventions and referrals.
- Describe the legal and professional responsibilities and accountability associated with the PIPC role.
- Demonstrate the communication skills required when undertaking the checking role and when informing others about errors made.
- Demonstrate ability to critically analyse their own performance.
- Undertake Pre and/or in-process checks within the specified parameters set locally.
- Understand and apply root cause analysis methods and outcomes.

7.3 In-house Interviews

During the course of the programme, Trainees are required to have three in-house performance interviews with their Educational Supervisor.

There will be an initial review session with the NICPLD programme lead prior to commencing the in-practice work.

The first in-house interview will take place prior to commencing the log of pre and in-process aseptic checks (**PIP 5**), whilst the second interview will take place approximately halfway through the agreed number of PIPC checks (**PIP 8**) the third interview will take place once the log of the PIPC checks is complete. (**PIP 9**)

If the trainee has a change in Educational Supervisor – the handover between Educational Supervisors should be documented during a regular 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. The purpose of these interviews is to ensure that the trainee is supported and that their performance is reviewed against the required competencies.

The in-house interviews should be recorded using (**PIP 5**) (**PIP 8**) and (**PIP 9**); these completed forms should be emailed to NICPLD, and the originals stored in the trainee's portfolio.

7.4 Accuracy checks

- The trainee must conduct accuracy checks on a minimum of 100 aseptically prepared products per product type (60 for PN). See Appendix 2 for example of types of checks to be undertaken per process.
- 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 Appendix 2 for examples)
- The trainee will only check the work of others and must have played no part in the aseptic dispensing/manufacturing or labelling of any items they check.
- The prescription/order must be clinically verified prior to the dispensing/manufacturing process and annotated according to local procedures.
- The checking sessions should cover a breadth of product types to reflect the trainee's current scope of practice within the practice base. The processes and product types of the trainee will be covering should be determined by the Accountable Pharmacist and/or Educational Supervisor and trainee prior to beginning the log.
- Trainees must use the log form provided by NICPLD (**PIP 3**) to record their PIPC checks. These forms must be sequentially numbered and issued to the trainee by the Educational Supervisor to ensure an audit trail for the checking evidence.
- The trainee and the second checker should record their signatures on the log so it is clear that each item has been checked correctly N.B. The use of brackets to group items for signing is **NOT** allowed as it can lead to errors being made.
- All documentation of the log should be stored in the trainee's portfolio. Please note that the log should be completed with no errors. If an error is missed, trainees should complete (**PIP 7**) and contact NICPLD.
- The trainee will check items under normal working conditions. The collection of evidence will span to a maximum of 12 months from commencement of training. trainees who fail to complete their log within the twelve-month period should contact NICPLD.
- Correction fluid/tape must not be used on the log sheet. (**PIP 3**)
- If a trainee makes a serious error and needs to restart their log, then they should still complete their checks within the original 12-month training period.

7.5 Errors

7.5.1 The portfolio should contain documented reports of any dispensing/checking errors that have occurred during the assessment period (see Appendix 2 for error reporting categories).

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

- 1st attempt - 1 error = Period of reflection and 25 additional product checks of that type.
- 2nd error within additional 25 products = Period of reflection and restart 100 products of that type checks. (60 for PN).

7.5.3 The portfolio should contain a report of any aseptic preparation errors not detected by the trainee, (**PIP7**) which have occurred during the checking assessment. Trainees should be supported after any checking error and a period of re-reflection is recommended. Outcomes should be documented and included in the portfolio.

7.5.4 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 to the verifying pharmacist.

7.5.5 The department must have a mechanism for reporting and reviewing errors and should submit error data to the National Aseptic Error Reporting Scheme – see Appendix 2. It is important that all persons involved in the accreditation process are aware of the classification of and the potential outcome of errors.

7.5.6 Any trainee who fails on their second full attempt (following a complete restart) must inform their Educational Supervisor who will then inform NICPLD as soon as possible.

7.5.7 They will be expected to:

- undergo re-training in pre and in-process checking.
- Re apply to re-start the programme including all inductions with support of their Accountable Pharmacist and Senior pharmacy Manager.

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

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 enough 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.

7.6 Final Appraisal

7.6.1 Final appraisal panel

On completion of the PIPC log of checks, trainees should apply to NICPLD for their final appraisal interview. This will be facilitated by the NICPLD programme lead and will be virtual. The final appraisal panel requires a minimum of two individuals and should consist of any of the following:

- NICPLD programme Lead. (mandatory panel member)
- A lead aseptic Pharmacist for the unit or designated deputy.
- An Accountable Pharmacist.
- A Pre and in-Process trained educational supervisor or pharmacy technician with 2 years post accreditation experience.

7.6.2 Appraisal process

This appraisal is a three-stage process and includes:

Stage 1: A practical checking a simulated assessment arranged and completed at the trainee's base assessment - unit. comprising of 10 products over a range of types made in the unit or sample products from a regional base. This would typically include product types that the trainee has checked during their collection of evidence. The assessment will contain 6-8 deliberate errors. The trainee must detect **all** these intentional errors. The time allowed to complete this assessment should be appropriate to the type of checks being undertaken.
Trainees who are not successful at the checking assessment must collect a further 10 products of each agreed type at work base, with no errors, and re-apply for the next available practical assessment. If Trainees make an error whilst collecting their 10 products, they must notify NICPLD. Trainees should undergo further training in checking before conducting a final attempt at the practical assessment.

Trainees are allowed a total of two attempts at the practical assessment. Failure on the second attempt would suggest that they are not ready to proceed, and further experience would be recommended.

Stage 2: A review of the trainee's portfolio which should include:

- required information about the trainee, e.g. CV/Job description.
- confirmation of completion of pre-course work.
- 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 reflections.
- a minimum of two reviews documented after any error(s); these should be completed by the educational supervisor and trainee.
- confirmation of satisfactory completion of practical checking assessment.

Stage 3: A final interview (**PIP 10**) which provides an opportunity for the trainee to demonstrate their understanding of the aseptic process. It also allows the trainee to reflect on their progress throughout the programme and allow the panel to assess their overall performance. This interview must be undertaken within eight weeks of completion of evidence collection.
Educational Supervisors of trainees who do not satisfactorily meet the portfolio and/or final interview assessment requirements should contact NICPLD for further guidance.

Trainees will be allowed to re-sit the assessment on one further occasion - a total of two attempts. Trainees who fail a second attempt must seek permission from their Trust to apply to re-start the programme. There may be recommendation or a requirement to undertake remedial work prior to registration for the next assessment.

7.7 Appeals

NICPLD will treat all trainees fairly, equally and with respect in relation to any assessment. If a trainee is dissatisfied with the outcome of their final appraisal they must, within 5 working days, contact NICPLD and give notice of their dissatisfaction and of their intent to forward an appeal. The formal appeal procedure must then be followed:

1. All appeals against the conduct, adequacy or outcome of an assessment must be forwarded, in writing, to NICPLD within 10 working days after the trainee has given notice of their intent.

2. On receipt of notification of an appeal NICPLD will acknowledge receipt in writing and set a date for the appeal to be heard by an appeals panel. The appeals panel will consist of:

- A representative of NICPLD.
- An Aseptic Lead Pharmacist not otherwise involved in the appeal.
- A Pharmacy Technician not involved in the appeal.

3. The trainee will be offered the opportunity to be accompanied by another person (not involved in their accreditation) to help them present their case.

Written notification of the appeal.

4. The appeals panel will reach a decision and all involved parties will receive verbal notification of the outcome on the day of the appeal and written notification within 3 working days.

The appeals panel decision is final.

7.8 Probation

Following successful completion of the final appraisal, trainees will be required to undertake a probation period.

The probationary period recognises that up to its commencement, all the checks conducted 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, and then should decrease everyday so that at the midpoint of the probation period approximately 50% of the PIPC checks should be completed by a witness pharmacist or pharmacy technician with the appropriate qualification and experience. 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 or 10 working days depending on the number of hours usually worked by the trainee. However, to meet specific circumstances the Accountable Pharmacist, the Educational Supervisor or the trainee may extend this period after consultation with the education provider.

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.

7.9 Accreditation

On completion of probation trainees must submit their completion record (**PIP13**) to NICPLD. Successful trainees will receive an accreditation certificate. This certificate is valid for two years from the date of accreditation and it is the responsibility of the trainee to ensure they are reaccredited before their certificate of accreditation expires.

7.9.1 Competence range post-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.

7.10 Reaccreditation

It is the responsibility of all pharmacy technicians to gain reaccreditation before the expiry of their certificate.

All pharmacy technicians seeking to be reaccredited must:

- maintain an on-going log of any errors (**PIP 14**) made relating to PIPC checking and document these according to their department error recording policy.
- reflect on any errors made and record, using **PIP 15**, or if a learning need has been identified, using a CPD cycle. These reflections should be reviewed periodically by the Educational Supervisor to ensure they are within Trust error reporting limits.
- provide documentation to confirm the opportunity to work within the scope of the role on a regular basis, defined as at least two hours weekly (**PIP 16**).
- provide evidence of an appraisal which has reviewed their role over the last two years and include a summary of performance by the lead aseptic pharmacist (**PIP 16**).

It is recommended that all staff undertake regular performance management reviews. 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.

7.11 Periods of absence

If a pharmacy technician is unable to work on a regular weekly basis as a PIPC checker for a minimum of eight hours per month it is recommended that before re-commencing any PIPC checks, they undertake a review of the SOPs and re-familiarise themselves with the process.

If the pharmacy technician is absent from this role for a longer period of time, it is recommended that they undertake the minimum quantity of double checked PIPC checks as described in the table below. (Documented on **PIP 3** with all PIPC checks endorsed by their Educational Supervisor or other suitable witness).

Period of absence	*Required quantity of PIPC checks*
< 6 months	Locally agreed
6 – 24 months	20 products for each product type and 5 products per process stage on accreditation certificate.
≥ 24 months	Must restart the accreditation

Accredited PIPC checking pharmacy technicians and their educational supervisors should conform to this guidance relating to periods of absence. If any pharmacy technician is absent from the PIPC checking role for more than two years they must re-start the process.

7.12 Change of Work Base for a PIPC checking Pharmacy Technician

This Framework is intended to enable skills to be recognised if staff move from one Trust to another. 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.

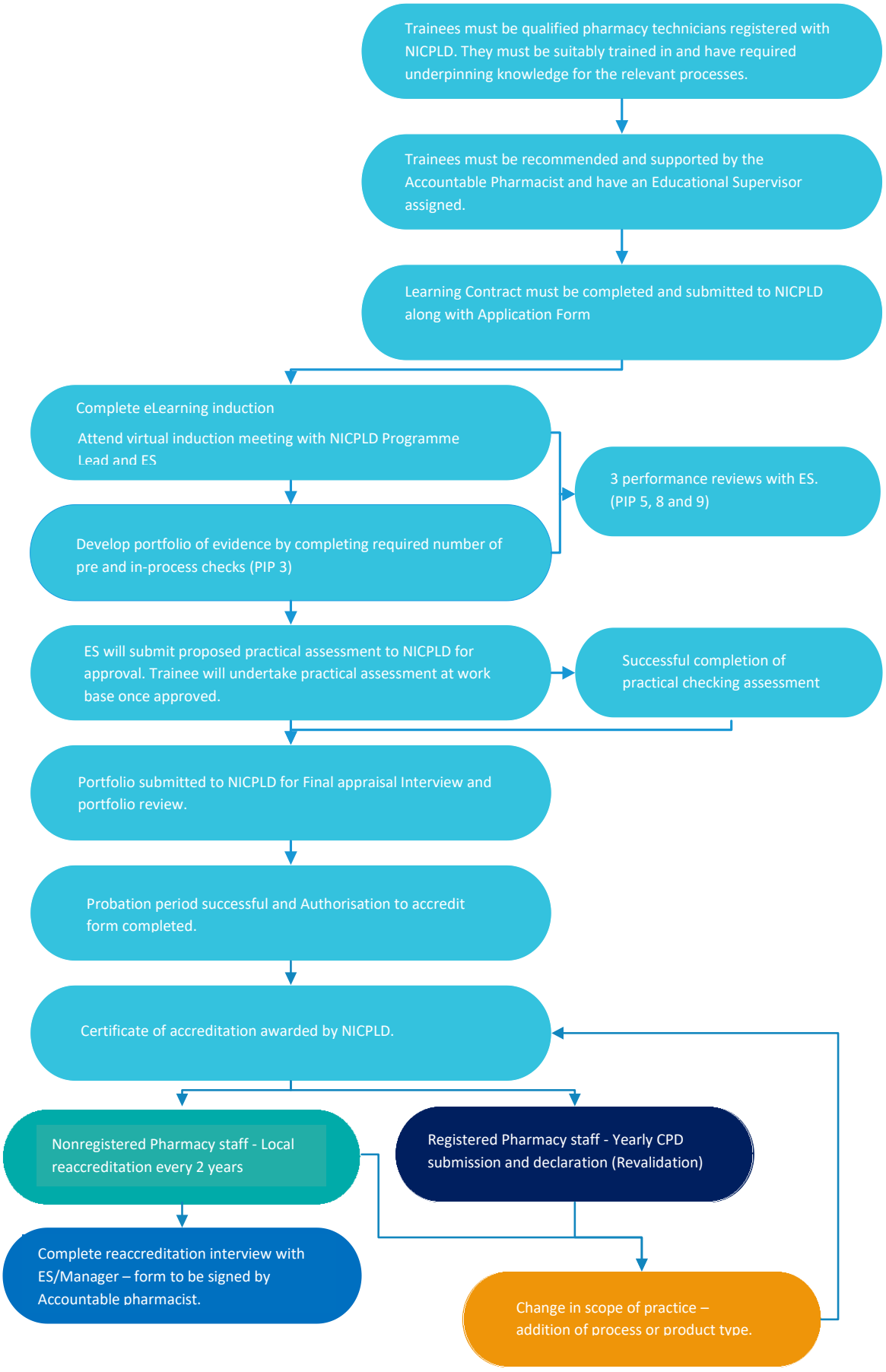
On completion of this process, they must inform the training provider to allow updating of records and inform the Accountable Pharmacist.

7.13 Evaluation of the programme

The evaluation of this programme is a two-stage process:

- eLearning induction evaluation – the PIPC eLearning is evaluated by all participants using the standard NICPLD workshop evaluation form.
- Programme evaluation by experts – the programme is reviewed on a bi-annual basis by experts who engage in the delivery of the training. The recommendations of these individual will then be presented to the Regional Lead Aseptic Pharmacist group who will decide if any changes are needed due to changes in service or its requirements.

Appendix 1. Programme Structure



Appendix 2. 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 type 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 number 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 dug 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

The trainee must carry out accuracy checks on a minimum of 100 aseptically prepared products per product type (60 for PN). For each stage in the process the trainee wishes to be accredited to undertake, e.g. Pre-process worksheet 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 (critical 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

Appendix 2.1. Definition of a check: worked examples

The number of checks set by the accountable pharmacist should reflect the types of checks carried out and ensure that the trainee is able to demonstrate consistency and competency across the range.

Chemotherapy / Central Intravenous Additive (Individual)

- 1 check for worksheet
- 1 check for labels
- X checks for X number of ingredient products to be in completed product. If more than one of the same product, that is one item, e.g. 2 vials of Amikacin for one dose, is one item
- X critical volume checks. This would include ensuring that the correct starting material has been used and would not count as separate check.

For Parenteral Nutrition:

- 1 check for worksheet
- 1 check for labels
- X checks for X number of ingredient products to be in completed product
- X critical volume checks. This would include ensuring that the correct starting material has been used and would not count as a separate check.

Worked example:

In a Parenteral Nutrition solution where there was:

1 amino-acid container (e.g. Vamin 14)
1 bottle of lipid (e.g. Intralipid 10%)
2 bags of different strength glucose solution (e.g. Glucose 5%, Glucose 10%)
1 trace element via (e.g. Additrace®)
2 x ampoules of sodium chloride 30%
5 x ampoules of potassium chloride 15%
1 x vial of Solivito N®
1x Ampoule of Water for injection (to reconstitute Solivito N®)
Would count as:
1 worksheet, 1 label check, 9 ingredient checks, 9 critical volume checks and 2 reconciliation checks.

Appendix 3. Error reporting categories

The following classification is based on the National Aseptic Error Reporting Scheme (Appendix 4 reference links - 5)

3.1 Licensed Status

A Made under MS License
B Made under Section 10
C Bought in and dispensed
D Clinical Trial

3.2 Product Name

A Cytotoxic adult
B Cytotoxic paediatric
C Parenteral nutrition – adult
D Parenteral nutrition – paediatric
E Monoclonal Antibody
F Other Aseptic Product

3.3 Error Type – Please include all errors.

A Prescription Error
B Worksheet Preparation Error
C Label Generation Error
D Labelling and Packaging Error
E Assembly Error
F Product Preparation Error
G Ancillary Item Error
H Product Approval / Checking Error
I Other – (must be qualified with details - please see the criteria in the "review and relaunch of the National Aseptic Error Reporting scheme (NAERS))" **www.pasg.nhs.uk**

3.4 Who Detected Error

A Accountable Pharmacist
B Pharmacy Technician
C Pharmacy support worker
D Student Pharmacy Technician
E Pre-registration Pharmacist
F Pharmacist
G Nurse
H Doctor
I Patient
J Other

3.5 When was Error Detected

A Prescription Verification check
B Worksheet and label check
C Check in preparation area
D In process check during preparation
E During labelling
F At final product check prior to release / approval
G At Product release / approval stage
H After release, prior to administration
I After release during or after administration
J Other (Must be qualified with details)

3.6 Who Made the Error

(From same list as "Who detected error" above). More than one person may be involved since one person may have compounded the error or missed a check.

3.7 Contributory Factors

There may be more than one.

A Staff Awareness of SOPs
B Staff New/ In Training
C Communication Breakdown
D Staff Knowledge
E Automaticity
F Facility/Equipment Fault
G Poor quality of Packaging and Labelling of starting materials
H Computer system Design
I Process design
J Poor Storage/Distribution Practices
K Workload Pressures
L Documentation Design
M Poor segregation
N Distraction
O Interruptions
P Deviation from the Process
Q Out of Hours Working
R Other – please see the criteria included in the "Review and relaunch of the National Aseptic Error Reporting Scheme (NAERS)" for details **www.pasg.nhs.uk**

3.8 Potential Outcome or Actual Outcome

If the error had not been identified 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 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[5]. Particular attention is drawn to section 1 of the executive summery – "purpose, scope and responsibilities" on page 25. The full text of the document can be accessed at http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=68464&type=full.

Appendix 4. Reference links

Learning from patient safety incidents. (2018, June). *NHS Improvement*. Retrieved from https://improvement.nhs.uk/resources/learning-from-patient-safety-incidents/

Assurance of aseptic preparation of medicines (March 2023) Assurance of aseptic preparation of medicines – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Medicines & Healthcare products 'GXP' Data Integrity Guidance and Definitions. (2018, March). MHRA. Retrieved from GOV.UK: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/687246/MHRA_GxP_data_integrity_guide_March_edited_Final.pdf

National Aseptic Error Reporting Scheme. (2019). NHS Pharmaceutical Aseptic Services Group. Retrieved from https://pasg.nhs.uk/national-aseptic-error-reporting-scheme

QAAPS-5th-Edition. (2016). Royal Pharmaceutical Society. Retrieved from rpharms.com: https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Quality%20Assurance%20of%20Aseptic%20Preparation%20Services%20%28QAAPS%29/r ps---qaaps-standards-document.pdf

General Pharmaceutical Council (GPhC). Minimum training requirements for dispensing/pharmacy assistants. Available at: http://www.pharmacyregulation.org/education/support-staff/dispensing-assistant

NHS Technical Specialist Education and Training (TSET). Technical Professional Development (TPD) Portal. Available at: www.tpdportal.org.uk

NHS Technical Specialist Education and Training (TSET) Aseptic Processing Program. Available at: www.tset.org.uk

Skills for Health National Occupational Standards. Available at: http://tools.skillsforhealth.org.uk/

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 5. Definitions

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 conducted. This must be preceded by an adequate period of supervised training.

Trainee
Person undertaking the training and assessment.

Chief Pharmacist
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
An ongoing process of reflection and learning focussing on an individual's area of practice to maintain currency and occupational competence.

Pharmacy support worker
All pharmacy staff except Pharmacists and Pharmacy technicians.

Pre-process 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 conducted 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 staff.

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.

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).

Root cause analysis
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 conducted, 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.