NI Centre for
Pharmacy Learning
& Development

Pre and In-process Checking Accredited Programme (PIP)

N. Ireland

Contents page

1. Introduction

Welcome to the Nationally Recognised Framework for the accreditation of Pre and In-Process (PIP) 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 also Quality Assurance / Quality Control, Aseptics, Production and Radiopharmacy and checking of outsourced products. This programme is aimed at pharmacy technicians within technical services who wish to become accredited checkers and is designed to give guidance and direction to training providers and Educational Supervisors who will be involved in the training, mentoring and assessment of candidates through 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)
- NHS Pharmacy Education and Development Group (PEDG)
- Pharmaceutical Technical Specialist Education and Training group (TSET).

This programme is designed to cover pre and in-process checking functions in aseptic services; however, the principles may be applicable to pre and in-process checking in other technical services. The programme is designed around a set of principles that are all encompassing of the Pre and In-process National Framework and can provide the foundation of any accreditation system designed for technical services, licensed or unlicensed.

Contact at NICPLD

If you have any queries regarding this or any training programmes offered for pharmacy technicians through NICPLD, please contact:

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

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

- In unlicensed aseptic preparation units, the Accountable Pharmacist remains professionally responsible for the total operation but can delegate the pre or in-process check to the accredited person when all parameters are satisfied.

- The Accountable Pharmacist remains responsible for the service and may select which product groups are suitable for accredited checking and which are not. This should be agreed locally.

- The Accountable Pharmacist is professionally accountable for the operation of the process according to good manufacturing practice (GMP) principles and is responsible for ensuring there is supervision by a suitably trained and experienced person.

- All practice will adhere to the GPhC Standards of Conduct, Ethics and Performance or the individual's equivalent regulatory body standards.

- Personnel in technical services must complete a training and competency assessment programme in technical services prior to undertaking any tasks or checking functions in this area; it is recommended that a training and competency assessment for accredited checking is operated through a standardised approach.

- The training programme incorporates clear entry criteria, and assessment of competence.

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

- Ongoing practice is required in order to maintain accreditation.

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

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 equal to the Accountable Pharmacist in an unlicensed unit.

1. Introduction

Scope

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

1.2 *Pre-checks* are defined as the accuracy checks undertaken on starting materials, disposables, worksheets and labels before the product is prepared. *In-process checks* are those carried out during the preparation process including the accuracy checking of volumes. 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 the "Nationally recognised Competency Framework for Pharmacists and Pharmacy Technicians: The assessment of product approval (Release) in Aseptic services under Section 10 exemption"[3].

[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) https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Quality%20Assurance%20of%20Aseptic%20Preparation%20Services%20%28QAAPS%29/rps---qaaps-standards-document.pdf

[2] www.tset.org.uk

[3] http://www.nhspedc.nhs.uk/NRCF%20-%20PAAP.htm

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.
- Encourage best practice.
- Develop technical services personnel in areas of continuing professional practice and accountability within pharmacy services.
- Encourage the further development of effective communication skills.
- Support appropriate skill-mix within the pharmacy departments.
- Reduce overall error rates.

3. Learning Outcomes

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

- State the reasons why a nationally recognised Framework for pre and in-process checking has been developed.
- Describe the legal requirements for aseptic preparation of medicinal products.
- State the laws and guidance relating to the aseptic preparation of medicinal products.
- Describe the legal implications of pre and in-process checking in Technical Services.
- Undertake pre and in-process checks of aseptically prepared items within the specified parameters set locally.
- List the stages of the pre and in-process course and explain how the assessment documentation should be used.
- Develop a robust checking method in line with approved Standard Operating Procedures (SOPs) that will be applicable in the workplace.
- Discuss the impact of aseptic preparation / checking errors on patient safety and product quality.
- List different factors that contribute to errors and suggest methods to overcome them.
- Demonstrate communication skills required when informing others about errors made.
- Demonstrate ability to recognise their own limitations and make appropriate referrals.

4. Entry Criteria

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

- Be a qualified pharmacy technician registered with NICPLD.
- Be recommended and supported by the Lead Technical Services Pharmacist to undertake the accredited programme.
- Have a minimum of six months' 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 PIP checking Pharmacy technician) describes the application of the programme to accredited staff moving to a post in another Trust.
- Have demonstrated the ability to aseptically dispense/manufacture accurately 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 attended or intends to attend an appropriate mentoring training workshop and who has been deemed suitable for the role by the Senior Pharmacy Manager. They ideally should be a qualified and registered pharmacist with at least 3 years post-registration experience or a pharmacy technician with 2 years' experience as a PIP checker.

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

5. Stakeholder Responsibilities

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

5.1 Responsibility of NICPLD

NICPLD is the training provider responsible for managing PIP for pharmacy technicians in N. Ireland. The role of NICPLD is to support the candidates, 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 PIP 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 candidates 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 candidates who successfully complete the programme.
- Providing a tool for reaccreditation.
- Maintaining a database of all accredited individuals.

5.2 Responsibility of the Trust Pharmacy Manager

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 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.
- Appoint an appropriate Educational Supervisor to support the candidate.

5.3 Responsibility of the Educational Supervisor

The Educational Supervisor is an individual who is nominated and appropriately trained to be responsible for the overall supervision and management of a candidate's progress throughout this programme. The Educational Supervisor should facilitate the local implementation of the programme by providing support, guidance and feedback to the candidate and is also responsible for assessing the candidate's performance.

Each Educational Supervisor must:

- Complete a learning agreement (**PIP 2**) prior to the start of the programme.
- Provide the support and guidance required to complete the pre-course and in-practice activities.
- Meet regularly with the candidate to provide support, ensure development of underpinning competence and skills and offer guidance.
- Observe the candidate in practical situations and assess the candidate's performance objectively against the programme standards.
- Complete all documents or records required for the programme and ensure that the candidate's portfolio is completed prior to submission.
- Prepare candidates for the final appraisal.
- Liaise with NICPLD to ensure the candidate completes the programme within the agreed timescales.

5.4 Responsibility of the Candidate

Pharmacy technicians are responsible for their own professional actions and must practice in accordance with their Trust's SOPs and the N. Ireland Clinical Pharmacy Standards. They should consult the current versions of the Medicines Ethics and Practice Guide (July 2016) the PSNI Code (March 2016) and the GPhC Standards for Pharmacy professionals (May 2017) 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 candidate to:

- Complete a 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.
- Complete the programme within the agreed timescales.

6. 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
- Workshop
- In-house interviews
- 1000 item log of PIP checks
- 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)

6.1 Pre-course work

Pharmacy Technicians wishing to register for this PIP programme must complete the application form (**PIP 1**) and once they have received confirmation of a place, commence the pre-course work BEFORE the workshop date.

The pre-course work includes:

- Completing the online aseptic course which is offered on the NICPLD website for pharmacists and deemed appropriate for pharmacy technicians.
- 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.

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

6.2 Workshop

Candidates are required to attend a one-day workshop at NICPLD and on completion of this workshop should be able to:

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

6.3 In-house Interviews

During the course of the programme, candidates are required to have two in-house interviews with their Educational Supervisor. The first interview will take place prior to commencing their log of pre and in-process aseptic checks (**PIP 5**), whilst the second interview will take place once approximately 500 of the PIP checks have been undertaken (**PIP 8**).

The purpose of these interviews is to ensure that the candidate is supported and that they continue to make progress against the required competencies.

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

6.4 1000 item log of PIP checks

- Candidates must undertake the collection of 1000 accuracy checks and record their evidence in their portfolio. A single item, such as a parenteral nutrition bag will represent more than one check – please refer to Appendix 3 for worked examples.
- The candidate will only check the work of others and must have played no part in the aseptic dispensing/manufacturing or labelling of any items that they check.
- The prescription/order must be pre-screened/approved prior to the dispensing/manufacturing process by a pharmacist and annotated according to local procedures.
- The checking sessions should cover a breadth of product types to reflect current practice within the practice base. The breadth of items to be checked should be determined by the Educational Supervisor and candidate prior to beginning the log.
- Candidates must use the log provided by NICPLD (**PIP 3**) to record their 1000 item log of PIP checks.
- Educational Supervisors or appropriate witnesses should record their signature when they complete the double check of the PIP check. 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 candidate's portfolio. Please note that the log should be completed with no errors. If an error is missed, candidates should complete (**PIP 7**) and contact NICPLD.
- The candidate will check items under normal working conditions. The collection of evidence will span a minimum of 3 months to a maximum of 12 months from commencement of training. Candidates 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 candidate makes a serious error and needs to restart their log, then they should still complete their 1000 checks within the original 12-month period.

6.5 Errors

6.5.1 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).

6.5.2 Whilst completing the 1000 checks the following scope for errors not detected by the candidate will apply:

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

6.5.3 The portfolio should contain a report of any aseptic preparation errors not detected by the candidate, (**PIP7**). during the checking assessment. Candidate reflection and outcomes should be documented and included in the portfolio.

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

6.5.5 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 the potential outcome of errors.

6.5.6 Any candidate who fails on their second full attempt (following a complete restart) at their 1000 checks must inform their Educational Supervisor who will then inform NICPLD as soon as possible.

6.5.7 If a candidate is unsuccessful in their second full attempt (following a complete restart) at their 1000 checks then they will be expected to:

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

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

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

6.6 Final Appraisal

6.6.1 Final appraisal panel

On completion of the 1000 item PIP log of checks, candidates should apply to NICPLD for their final appraisal. The final appraisal panel requires a minimum of two individuals and should consist of any of the following:

- A suitably trained member of NICPLD staff.
- A lead aseptic Pharmacist for the unit or designated deputy.
- A current PIP checker (if appropriate).
- A work based Educational Supervisor.

6.6.2 Appraisal process

This appraisal is a three stage process and includes:

Stage 1: A practical checking assessment - A simulated test at the candidate's base comprising of 20 aseptically dispensed items. The items included should reflect the range of products made in the unit and contain 6-8 deliberate errors. The candidate must detect each of these errors. The time allowed to complete this assessment should be appropriate to the type of checks being undertaken.
Candidates who are not successful at the checking assessment must collect a further 100 checks at work base, with no errors, and re-apply for the next available practical assessment. If candidates make an error whilst collecting their 100 checks they must notify NICPLD. Candidates 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 candidate's portfolio which should include:

- required information about the Candidate, e.g. CV/Job description.
- confirmation of completion of pre-course work.
- satisfactory diary log of 1000 checked PIP items.
- 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 candidate.
- confirmation of satisfactory completion of practical checking assessment.

Stage 3: A final interview (**PIP 9**) which provides an opportunity for the candidate to demonstrate their understanding of the aseptic process. It also allows the candidate to reflect on their progress throughout the programme and allows the panel to assess their overall performance. This interview must be undertaken within eight weeks of completion of evidence collection.
Educational Supervisors of candidates who do not satisfactorily meet the portfolio and/or final interview assessment requirements should contact NICPLD for further guidance.

Candidates who fail to pass the simulated test will be allowed a second attempt when they have completed a further log of 100 PIP checks, with no errors. Candidates who fail a second attempt must seek permission from their Trust to apply to re-start the programme.

6.7 Appeals

NICPLD will treat all candidates fairly, equally and with respect in relation to any assessment. If a candidate 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 candidate has given notice of their intent.

2. On receipt of notification of an appeal NICPLD will 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.

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

3. The appeals panel will meet within 30 working days of receipt of the 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 5 working days.
The decision will be final.

6.8 Probation

Following successful completion of the final appraisal, candidates will be required to undertake a probation period. This should be for a period of two weeks or ten working days depending on the number of hours usually worked by the candidate. During this probation period, candidates should:

- comply with the required double PIP checks at the start of probation, and then should decrease everyday so that at the midpoint of the probation period approximately 50% of the PIP checks should be completed by a witness pharmacist or pharmacy technician with the appropriate qualification and experience. The extent of re-checking should then rapidly decline so that in the final 3-4 days, the candidate assumes full responsibility for the checking of items.
- ensure that all PIP checks during the probation period are 100% accurate and contain no errors.
- re-start their probation period if an error is detected by the pharmacist or pharmacy technician so that they complete a full two weeks or ten days of PIP checking with no errors.

6.9 Accreditation

On completion of probation candidates must submit their completion record (**PIP 12**) to NICPLD. Successful candidates will receive an accreditation certificate. This certificate is valid for two years from the date of accreditation and it is the responsibility of the candidate to ensure they are reaccredited before their certificate of accreditation expires.

6.9.1 Competence range post-accreditation

Once accredited, pharmacy technicians are able to expand their areas of PIP competence. This will require submitting a log of 250 PIP checks which have been double-checked and is evidence of their new practice area. They are also required to submit a supporting statement from their Educational Supervisor to confirm this new practice area has been agreed as suitable for the department and the PIP checker.

6.10 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 13**) made relating to PIP checking and document these according to their department error recording policy.
- reflect on any errors made and record, using **PIP 14**, 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 15**).
- 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 15**).

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.

6.11 Periods of absence

If a pharmacy technician is unable to work on a regular weekly basis as a PIP checker for a minimum of eight hours per month it is recommended that before re-commencing any PIP 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 PIP checks as described in the table below. (Documented on **PIP 3** with all PIP checks endorsed by their Educational Supervisor or other suitable witness).

Period of absence	*Required quantity of PIP checks*
< 6 months	100
6 – 12 months	200
13 – 24 months	500
≥ 24 months	Must restart the accreditation

Accredited PIP 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 PIP checking role for more than two years they must re-start the process.

6.12 Change of Work Base for a PIP checking Pharmacy Technician

Prior to a pharmacy technician moving from one Trust to another it is the responsibility of the technician to have their accreditation certificate validated by their Aseptic Lead Pharmacist before leaving their original Trust.

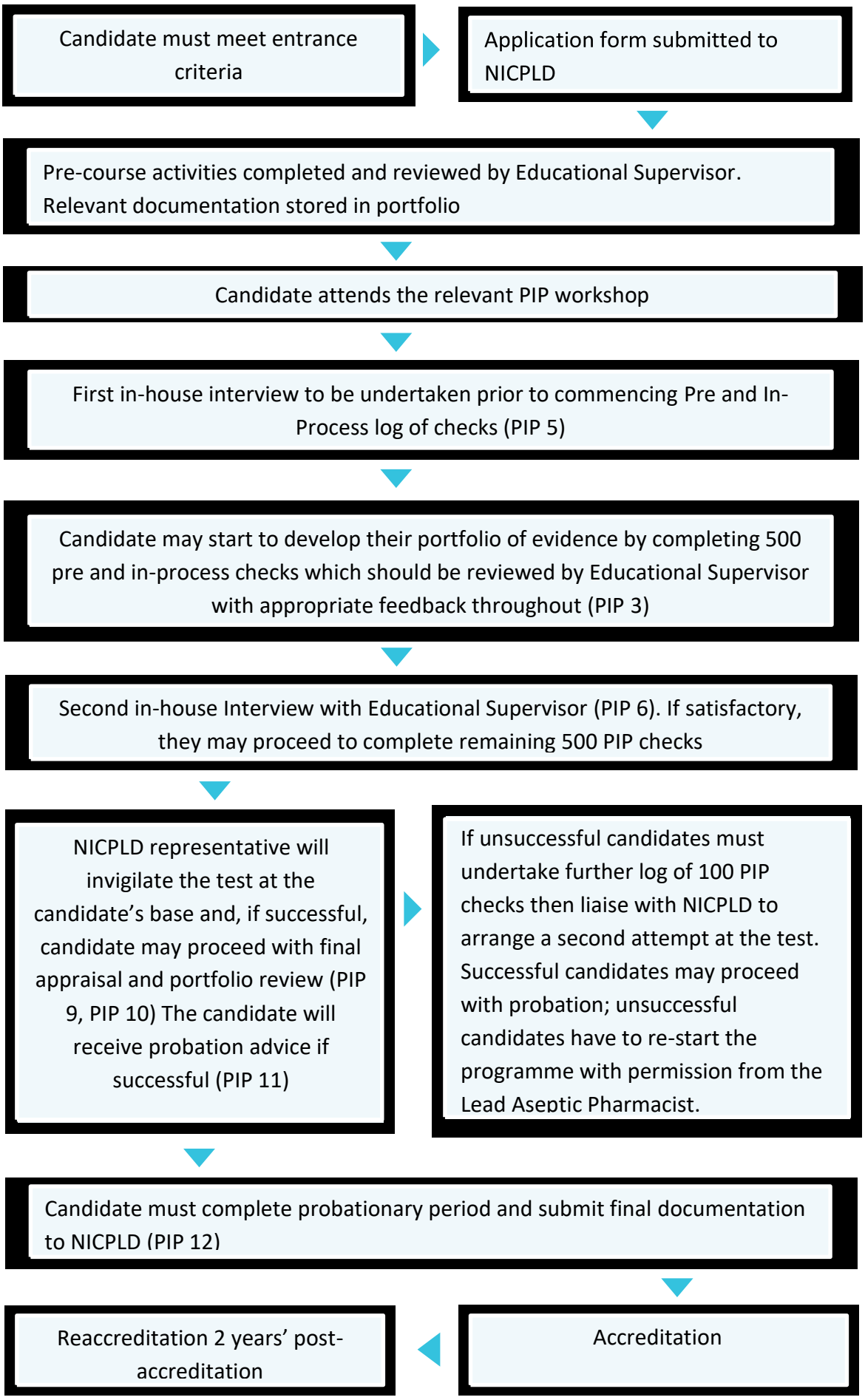
A pharmacy technician who transfers from a hospital in Great Britain will have to present their relevant certificates which must be endorsed by their Aseptic Lead Pharmacist or equivalent. It is the Aseptic Lead Pharmacist's decision at each Trust to agree with the pharmacy technician the amount of time required to re-train in their new and different environment. A three-month period of orientation at their new site would always be recommended.

6.13 Evaluation of the programme

The evaluation of this programme is a two stage process:

- Workshop evaluation – the PIP workshop 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 are involved 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. Error reporting categories

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

2.1 Licensed Status

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

2.2 Product Category

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

2.3 Error Type – Please include all errors

A Incorrect transcription
B Calculation error
C Incorrect drug
D Incorrect dose/strength
E Incorrect diluent/Infusion fluid
F Incorrect final volume
G Labelling error
H Incorrect expiry date
I Incorrect container, e.g. infusor, bag
J Other – please see the criteria in the "review and relaunch of the National Aseptic Error Reporting scheme (NAERS)" for details

2.4 Who Detected Error

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

2.5 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)

2.6 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.

2.7 Contributory Factors

There may be more than one

A Staff error
B Inadequate training
C Facility/equipment error
D Poor quality of starting materials used
E Inadequate computer system
F Process design
G Poor storage/distribution
H Staffing level below establishment
I Workload above planned capacity
J Poor segregation
K Distraction/interruptions
L Other – please see the criteria included in the "Review and relaunch of the National Aseptic Error Reporting Scheme (NAERS)" for details **www.pasg.nhs.uk**

2.8 Potential Outcome or Actual Outcome

If the error had not been identified before administration, there should be no actual outcome. Therefore, for the report, Responsible Persons should estimate the potential outcome if the error had not been spotted. If the medication has been administered to a patient, the actual outcome should be recorded.
Errors are to be classified according to the categories defined in the National Patient Safety Agency document entitled "Doing Less Harm." These may be defined as follows:

Descriptor	Actual or potential unintended or unexpected impact on patient
Catastrophic	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 3. Definition of a check: worked examples

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

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 4. Bibliography

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Appendix 5. Glossary of Terms

Accountable Pharmacist	Accountable pharmacist is professionally accountable for the operation of the process according to GMP principles and is responsible for ensuring there is supervision by a suitably trained and experienced person.
Candidate	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.
Competency	An ability to consistently successfully perform a task or activity to an agreed standard.
Educational Supervisor	A suitably experienced pharmacy technician or pharmacist responsible for support of the candidate and facilitation of their training.
GMP/QA	Good manufacturing practice / quality assurance.
Pharmacy technician	A person who holds the appropriate and recognised pharmacy technician qualifications in the UK.
Pre –process checks	The accuracy checks undertaken on starting materials, disposables, worksheets and labels before the product is prepared.
In- process checks	The accuracy checks carried out during the preparation process including the accuracy checking of volumes.
Pre and in process Checker (PIPC)	An individual whose current training and qualifications are assessed and accredited by the training provider as meeting the defined competencies for their role in pre and in-process checking (i.e. is occupationally competent).

Appendix 5. Glossary of Terms

PSNI	Pharmaceutical Society of Northern Ireland.
Practice-based	Learning based in actual situations related to professional practice.
Reaccreditation	Recognition of revalidation of practice, to demonstrate that required standards of competence continue to be met.
Reflective Practice	The process of reviewing a specific task or day-to-day practice, identifying successes and weaknesses, and planning and taking action to address areas for development.
RPS	The Royal Pharmaceutical Society.
Standard Operating Procedures (SOPs)	Approved written step-by-step instructions on how a task or process should be carried out.
Supervised Practice period	A period of training under the direct supervision of a suitably trained/qualified person e.g. pharmacy technician, pharmacist, Educational Supervisor.
Training provider	The organisation responsible for the programme i.e. NICPLD.

Appendix 6. References

Reference links

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