Syllabus for National Frameworks for Accuracy Checking in Pharmacy

ACPT – Pre and In-Process Checking within Aseptic Services

AIMS:

The scope of this specification is to define the underpinning knowledge and skills requirements to enable the Accuracy Checking Trainee to carry out the final accuracy check of dispensed items and/or aseptically prepared items that have been clinically approved by a registered Pharmacist for dispensing/ preparation and annotated, according to Standard Operating Procedures.

The full accuracy checking syllabus aims to provide:

- A sound understanding of the knowledge and skills required to perform the final dispensing accuracy of any prescription previously screened/approved by a Pharmacist.
- Development of the individual's professional awareness of pharmacy practice
- Development and application of effective communication skills
- Understanding of the a professional interaction between pharmacy technicians, pharmacists, patients, colleagues and health care professionals
- Ability to critically evaluate the appropriateness of different approaches to solving problems.

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

Common understanding and practice across all checking frameworks includes

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

8. Collection of evidence for portfolio assessment and reflective learning

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

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

Acknowledgements:

- NHS Pharmacy Education & Development Committee ACPT/PIPC Task & Finish Group. Nationally Agreed Frameworks for Final Accuracy Checking of Dispensed Items , Pre and In-Process Checking within Aseptic Services
  http://www.nhspedc.nhs.uk/

- PETO: Pharmacy Education & Training Office. Northern Sector Course for Technician Checking of Dispensed Items
  http://www.newcastle-hospitals.org.uk/services/pharmacy_education-and-training.aspx

- Health Education North West/ Preston's College: BTEC Professional Development Certificate in Dispensing Technician Checking, BTEC Professional Diploma in Final Accuracy Checking within Technical Services

- South West Medicines Information & Training
  http://www.swmit.nhs.uk/

- Yorkshire & Humber Pharmacy Development Unit /University of Huddersfield Accuracy Checking for Pharmacy
  https://www.ewin.nhs.uk/groups/medslearning-resources/activity

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UNIT 1: ROLES, RESPONSIBILITIES AND PROTOCOLS

Rationale:

This unit provides participants with the opportunity to develop the understanding required in the role of Accuracy Checkers. It allows candidates to explore the issues surrounding Accuracy Checking personnel in the role and enhance understanding of their significance in the process of dispensing of medicines or medicinal products.

Learning Outcomes:

On completion of this unit, the participant will be able to:

- Describe the legal and ethical requirements for dispensing of medicines and medicinal products
- Outline the role of the Accuracy Checker in the dispensing of medicines within their own pharmacy organisation.
- Identify and discuss responsibility and accountability issues around the Accuracy Checkers role within the pharmacy organisation.
- Differentiate between the Pharmacist's Prescription clinical/validation check (also known as pharmaceutical assessment) and the Accuracy check
- Identify and use the local standard operating procedures for dispensing and accuracy checking, and the RPSGB guidelines for SOPs.
- Identify possible benefits and limitations of the Accuracy Checkers role and possible barriers you may encounter within Pharmacy

Element 1.1 - Law and Ethics relating to Accuracy Checking

- Current legislation and Code of ethics for Pharmacists and Technicians
- Standard Operating Procedures
- The components of the Clinical Check / Prescription Validation
- Accuracy check
- Accountability, Responsibility and delegation
- Liability and Vicarious liability
- Raising concerns

Element 1.2 – The Role of Key Personnel in Dispensing

- The role of the Accuracy Checker
- The role of the Pharmacist
- The role of the Dispenser
- The role of the Organisation and lines of accountability.
- Checking stages within the workflow process

Element 1.3 – The range of activity within the remit of Accuracy Checkers

To be identified from:

- Organisational policy in relation to medicines
- Pharmacy managers
- Pharmacy protocols
- Knowledge of range of dispensed items within candidate's Pharmacy
- Exceptions to the range of drugs permitted to be checked by the Accuracy Checker (agreed locally).

Element 1.4 – Professional Development

- The Accuracy Checkers role
- The candidate's own role within Pharmacy and the identification of possible barriers to success
- Time management
- Reflection on learning outcomes

UNIT 2: GOOD DISPENSING PRACTICE

Rationale:

This unit provides participants with the opportunity to develop the knowledge and skills, which will be required in the role of Accuracy Checker. It allows candidates to make an assessment of the prescriptions/orders and received in the pharmacy and their dispensing requirements and review legal aspects of the process. This unit will also cover the physical process of dispensing, including types of prescription, and reviewing the suitability of labeling and packaging of the final product.

Learning Outcomes:

On completion of this unit, the participant will be able to:

- State the laws and guidance relating to the dispensing of medicines and medicinal products
- Interpret prescriptions and assess the dispensing of the drug/product
- Identify the criteria which indicate the suitability of the packaging of the drug/product
- Demonstrate knowledge of legal requirements and the appropriateness of the labelling of the drug/product in relation to the labelling policy.
- Demonstrate knowledge of the appropriate documentation necessary for the dispensing of a prescription.

Element 2.1 – Policies in Relation to Prescribed Medicines

- Prescription validation
- In patient/non-stock medicines
- Out patient medicines
- Discharge medicines
- One-stop dispensing
- Ward Stock
- Extemporaneously dispensed medicines
- Controlled drugs
- Clinical trial medicines
- Medicines prescribed on FP10, FP10D, FP10P, etc.
- Medicines prescribed on private prescriptions

Element 2.2 – Review the Dispensing Process

- Legal requirements
- The local process of dispensing and the RPSGB SOP guidelines
- Labelling requirements
- Safe and effective dispensing
- Patient details

- Directions and warnings
- The suitability of containers/packaging
- Completion of legal documentation

Element 2.3. – Professional Development

- Reflection on achievement of learning outcomes

UNIT 3: CHECKING OF PRESCRIPTIONS

Rationale:

This unit provides participants with the opportunity to develop the knowledge and understanding, which will be required in the role of Accuracy Checker. It allows candidates to develop safe systems of checking (see Appendix 1) and explore the issues surrounding the checking of prescriptions.

Learning Outcomes:

On completion of this unit, the participant will understand:

- The function of the clinical check/prescription validation
- The process of labelling and dispensing by a dispenser
- The criteria for the suitability of labelling of the final product
- The process of the final accuracy/technical check of dispensed items
- The significance of the correct quality and quantity of the prescribed drug/product
- Why the completion of the documentation is important in a Pharmacy organisation
- Their own limitations within the checking process and when to make appropriate referrals

Element 3.1 – Reading and Interpreting Prescriptions

- Problems in reading prescriptions/orders in a Pharmacy
- The interpretation of prescriptions/orders
- Ambiguous prescriptions and how to deal with them

Element 3.2 – The Accuracy/Technical Check

- The process of accuracy checking
- Good practice guidelines – see local SOPs and RPSGB guidelines
- Understand checking consistency
- Significance and consequence of distractions and interruptions
- Criteria for referral to the dispenser
- Criteria for referral to the Pharmacist (prescription validation)

Element 3.3. – Continuing Professional Development

- Consider own limitations
- Identification of personal strategies for the checking process
- Reflection on achievement of learning outcomes

UNIT 4: COMMUNICATION SKILLS

Rationale:

This unit provides the candidate with an opportunity to understand the range of skills required to be able to communicate effectively as an Accuracy Checker.

The physical, verbal and social aspects of communication will be explored through group work, exercises and the use of visual aids.

Learning Outcomes:

On completion of this unit, the candidate will be able to:

- Employ effective communications skills with healthcare staff and patients
- Identify when to refer, and to whom
- Outline the need for confidentiality and describe how they will maintain confidentiality
- Describe their level of authority
- Provide others with feedback (both positive and negative)

Element 4.1 - Assumptions / perceptions

Describe how assumptions can be made about a situation or an individual and how this affects communications

- Assumptions
- Visual differences
- Emotional differences
- Personal preferences

Element 4.2 - Verbal and non-verbal communications

Verbal communications

Describe and employ the different types of questions used when communicating

- Open questions
- Closed questions
- The difference they can make

Non-verbal communications

Describe and employ how non-verbal actions can be used to impair and improve communications

- Body language
- Non-verbal sounds
- Physical contact

Barriers to communication

Identify how different barriers can prevent communication and employ strategies to overcome these

- Environmental
- Physical
- Verbal
- Cultural
- Emotional
- Special needs
- Language etc.

Element 4.3 – Giving Feedback

- Understanding the position of others
- Being clear and factual
- Using tact and discretion
- Techniques e.g.: sandwich technique
- Requesting rectification of errors

Element 4.4. - The Handling of Conflict

Employ strategies to avoid or reconcile communication difficulties

- Verbal/non verbal
- Emotional
- Perception
- Understanding the position of others
- Problems that may occur.
- Resolving Conflict
- Identification and avoidance of possible difficult situations, using appropriate communication skills.
- Be able to implement appropriate behaviour using skills highlighted in Element 1 & 2

Element 4.5 – Personal Development

- Identification of personal communication strategies
- Reflection on learning outcomes.

UNIT 5. RISK MANAGEMENT AND PATIENT SAFETY

Rationale:

This unit provides candidates with the opportunity to develop the knowledge and understanding, which will be required in the role of Accuracy Checker. It allows candidates to explore the issues surrounding the identification of errors and methods for dealing with and reporting errors, including formal documentation.

Learning Outcomes:

On completion of the unit, the candidate should be able to:

- Describe how errors occur within dispensed prescriptions/orders
- Describe the consequences of dispensing/checking errors
- Employ strategies to enable the successful development of error reduction
- Contribute to risk management strategies in the dispensary, including effective workflow
- Accurately identify different types of errors
- Identify communication issues around potential errors/near misses.

Element 5.1 – Errors in Dispensing

- Clinical Governance and risk management
- Nature and types of errors
  - Human error
  - System error
- Causes of errors
  - Environmental
  - Internal/External conversation
  - Similar names
  - Similar packaging
  - Abbreviations
  - Calculations
  - Rushing
- Error detection
- Operational protocols and procedures for dealing with errors
- Awareness of common errors
- Awareness of recent errors

Element 5.2 – Dealing with Errors

- Good practice guidance, e.g. local and RPSGB
- Errors detected within pharmacy
- Errors leaving pharmacy
- Error rectification
- Error/incident reporting (national, regional, in-house)
- Analysis of errors/incidents
- Communicating awareness of a near-miss

Element 5.3. – Professional Development

- Reflection on achievement of learning outcomes
- Reflection on personal experience of making an error.
- Reflection on giving feedback of an error.

UNIT 6. CHECKING PRACTICE WITHIN TECHNICAL SERVICES

This unit provides participants with the opportunity to develop the knowledge and skills, which will be required in the role of Accuracy Checker within Technical Services; this may be within Pre and in-process, Final Accuracy Checking of products or in the Final Product Approval stages (see Appendix 2). It allows candidates to make an assessment of the prescriptions/orders received within pharmacy technical services and their preparation/ dispensing requirements and review legal and regulatory aspects of the process. This unit will also cover the physical process of working within controlled areas, including types of cleanroom/workstation, environmental control of processing areas, reviewing the suitability of labelling and packaging of the final product. Knowledge and Skills may be mapped to nationally recognised standards (see Appendix 3 & 4)

Learning Outcomes:

On completion of the unit, the candidate should be able to:

- Describe the overarching principles of aseptic preparation and the application of Good Manufacturing Practice
- Understand how different Aseptic products are processed alongside the local procedures, regulatory and legal considerations
- Understand Error Reduction strategies and Identify Errors within process

Element 6.1 – Overarching principles of aseptic preparation

- Demonstrate an appropriate level of knowledge of Good Manufacturing Practice in aseptic preparation
- Demonstrate an appropriate level of knowledge of Quality Assurance in aseptic preparation.
- Demonstrate knowledge of principles and processes in aseptic preparation.
- Demonstrate knowledge of the facilities, environment and maintenance in aseptic preparation.

Element 6.2 – Processing Aseptic products; local procedures, regulatory and legal considerations

- Demonstrate an understanding of the main types of aseptic products in terms of their technical characteristics and clinical use and risks.
  i. CIVAS
  ii. Parenteral nutrition
  iii. Cytotoxics
  iv. Others; Eye drops, "Biologicals"

Element 6.3 – Understand Error Reduction strategies and Identifying Errors

- Demonstrate a thorough knowledge of the sources of human errors in aseptic presentation and steps that can be taken to identify them.
- Demonstrate a thorough knowledge of the sources of system error in aseptic preparation and steps that can be taken to identify them.

Element 6.4. Work in accordance with the relevant Legal, Regulatory and Professional Frameworks

- Demonstrate a thorough knowledge of relevant legislation and professional guidance.
- Demonstrate a thorough understanding of the professional responsibilities and accountabilities surrounding section 10 exempt aseptic preparation.
- Demonstrate a thorough understanding of pharmacist supervision of section 10 exempt aseptic preparation.
- Demonstrate an appropriate professional attitude/behaviours toward the role of (tick as appropriate):
    - Pre-process Check
    - In-Process Check
    - Final Accuracy Check
    - Product Approval
- Demonstrate competence and an appropriate level of confidence in carrying out product approval on aseptically prepared items.
- Demonstrate a clear understanding of their personal professional capabilities and scope of practice.

APPENDICES

Appendix 1: Common Considerations when Checking Prescriptions

Check and Read prescription,
Confirm all details are clear and prescription is complete
Check that the prescription has been endorsed and a clinical check has been made
Confirm a check has been made that there are no allergies

Check label, start at top left hand corner and work down:

Drug name form and strength,
Directions
Additional Warnings
Quantity issued on label
Cost Code
Patient name
Date
Batch number
Expiry Date
Ward
(Look for correct spellings, and make sure that there are no bits of additional information that you do not require.)

Check contents/product

Check is it the correct drug, form and strength,
Check quantity/volume
Check expiry date of bulk items

Patient information leaflets/additional information?

Think about the container; is it suitable for the patient/product?
Closure/packaging – Is it appropriate, is the Child resistant cap on securely, tamper-evident?
Do they need any additional items e.g. spoons, warning cards, specific instructions etc.

Ensure prescription is signed by dispenser and checker

Suggested method for check:
1. Prescription
2. Label
3. Contents/product
4. Container/leaflets/signatures/secondary packaging etc

You may want to use this as a prompt when you are checking. Read details out loud if this helps to make sure you read it!

If you are unsure about anything, do not check it! ASK!!

Appendix 2. Example of Technical Service Checking (Section 10 Exemp)

Process	**1(a) Pharmacist Clinical Validation** (Prescription or order)
Key: Red Shaded Areas – Registrant to check	
1.Clinical Validation Check	**1(b) Pharmacy Technician Technical ValidationCheck** legal/ procedural/ transcription formulation/calculations,correct worksheet/labels
2. Pre-Process set-up	2. Assembly Check (starting materials & disposables with worksheet and labels)
1. In-Process Checks	3. In-Process Checks (BN, expiries, reconciliation, calibration, equipment, volumes)
2. Self-Check (before, during and after preparation)	4. Self-Check (work-station, reconciliation, calculation, measurement product against worksheet against manipulations)
3. Preparation Checks	5. Preparation Checks (area clearance, product & volume checks, particle checking, mix check, product integrity/intact)
4. Labelling & Reconciliation Checks	6. Labelling & Reconciliation Checks (labels, consumables, residual volumes/product)
5. Cleanroom Supervisor Checks	7. Cleanroom Supervisor Checks (environmental, standards, documentation, processing, 2nd volume check)
6. **Product Approval Check**	**8. Final Accuracy Check – Accredited Pharmacy Technician/Pharmacist (finished product)**
7. Final Release	**9. Final Release - Pharmacist**

Appendix 3: National Occupational Standards – NOS Accuracy Checking (Skills for Health www.skillsforhealth.org.uk)

Skills for Health NOS	NHS KSF	NOS PDF
PHARM19 **Prepare aseptic products and carry out in-process checking** Updated: 29th Mar 2011, 11:23 This standard covers the preparation of aseptic products including preparing the environment, self and in-process checking. It covers aseptic preparation for both dispensing and manufacturing. Your practice will be consistent with your occupational role and carried out under the regulatory and ethical frameworks established in the context of current legislation. You will work at all times within Standard Operating Procedures that relate to the way in which a pharmacy service is provided in your place of work. Users of this standard will need to ensure that practice reflects up to date information and policies.Version No 1	**NHS KSFHWB102**	HFM: **B15.12**
PHARM23 **Check documentation, starting materials, components and other consumables for the production of aseptic products** Updated: 31st Mar 2011, 14:36 This standard covers the checking of documentation, starting materials, components and other consumables necessary for the production of aseptic products. It covers aseptic preparation for both dispensing and manufacturing. Your practice will be consistent with your occupational role and carried out under the regulatory and ethical frameworks established in the context of current legislation. You will work at all times within Standard Operating Procedures that relate to the way in which a pharmacy service is provided in your place of work. Users of this standard will need to ensure that practice reflects up to date information and policies.Version No 1	**NHS KSFHWB102**	HFM: **B15.11**
PHARM52 **Prepare and maintain the working environment for aseptic manufacture and dispensing of medicinal products in cleanrooms** Updated: 29th Jun 2011, 14:43 This standard relates to the preparation, maintenance and monitoring of the controlled environment used for manufacture and dispensing of medicinal products in cleanrooms. It	**NHS KSFHWB102**	HFM: **B15.4**

includes maintenance of and compliance with the Principles of Good Manufacturing Practice and associated guidance. Your practice will be consistent with your role and be carried out under the relevant regulatory and ethical frameworks. You will work at all times within local Standard Operating Procedures.Users of this standard will need to ensure that practice reflects up to date information and policies.Version No 2		

Appendix 4. Additional Guidance for Technical Services Checking Competencies – adapted from NHS TSET TPD Portal www.tpdportal.org

Competence no	TSET Level	Descriptor	(Associated skills and knowledge [ASKs])
6.1.10	3	Checks worksheet and or labels (legibility, , against original request, Exp, BN, calculations)	Can perform basic pharmaceutical calculations [S6.2] Knowledge of common errors [C4.2] Understand batch number sequence and allocation [S6.5] Understand expiry dates [S6.4] Understands the GMP principles or recording data on worksheets and documents [C9.1] Can identify deviation or problems [C4.10
6.2.4	1	Daily physical room checks (manometers/gauges) and log recording	Understands segregation and area clearance [C3.3]
6.2.6	2	Equipment physical checks (I.e. pressure decay and gauges) and log recording	Able to evaluate the quality of own and others' work and raises quality issues and related risks with the relevant people. [N3]
6.5.50	3	Equipment set-up check	Ability to appropriately use individual equipment and understand its function [C12.2] Understand the necessity for and process of equipment calibration [C12.7] Understands the GMP principles or recording data on worksheets and documents [C9.1] Able to evaluate the quality of own and others' work and raises quality issues and related risks with the relevant people. [N3] Knowledge of common errors [C4.2]

6.2.9	3	Checks correct choice, assembly and recording of raw materials and components	Understands the GMP principles or recording data on worksheets and documents [C9.1] Awareness of starting material QC and fitness for use [S6.8] Understand expiry dates [S6.4] Ability to identify a Batch Number and know its purpose [S6.5.1] Knowledge of common errors [C4.2] Ability to identify a potential defect [C4.13]
6.5.47	3	Volume check in syringes	Knowledge of common errors [C4.2] Understands the GMP principles or recording data on worksheets and documents [C9.1] Able to evaluate the quality of own and others' work and raises quality issues and related risks with the relevant people. [N3 Understand how to accurately measure using syringes [S6.1.2]
6.5.48	3	Check temperature of raw material or product within parameters before or during processing	Understand how to measure temperature accurately. [S6.33] Able to evaluate the quality of own and others' work and raises quality issues and related risks with the relevant people. [N3] Understands the GMP principles or recording data on worksheets and documents [C9.1]
6.5.49	3	Mix check between additions and before pack etc	Has comprehensive knowledge of specific product and the production process. [S6.13] Can identify out of specification results- As applicable to checking product. [S6.14] Able to evaluate the quality of own and others' work and raises quality issues and related risks with the relevant people. [N3] Understands the GMP principles or recording data on worksheets and documents [C9.1]

6.5.51	3	Compounding supervision	Able to evaluate the quality of own and others' work and raises quality issues and related risks with the relevant people. [N3] Can identify deviation or problems [C4.10]
6.5.52	3	Weight/tare check	Awareness of starting material QC and fitness for use [S6.8] Able to evaluate the quality of own and others' work and raises quality issues and related risks with the relevant people. [N3] Understands the GMP principles or recording data on worksheets and documents [C9.1] Ability to appropriately use individual equipment and understand its function [C12.2] Understands basic units of measurement and weight. [S6.1]
6.8.3	4	Documentation checks	Correct validated worksheet selected, Documented BN/Exp/Operator And I/P Checker IDs correctly, Completed workstation logs/checks
6.8.4	4	Reconciliation checks	Number components/labels,
6.8.5	4	Pre-labelling. Visual inspection of final product Identify and check in-process deviations	Prior to passing for final check – document any unusual events/deviations
6.8.6	4	Authorised and appropriate	Record outcome of discussions

Key:

NHS TSET Level:	**Suggested guidance**
1	Pre check
2	Pre check
3	In-Process Checks
4	In-Process Checks