

**GUIDANCE ON THE DEFINITION OF SUPERVISION AS
APPLIED TO SECTION 10 ASEPTIC PREPARATION
ACTIVITIES**

1st Edition

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ACKNOWLEDGEMENT

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INTRODUCTION

The NHS Aseptic Services Accreditation Working Group, working closely with the South West Product Approval Accreditation Programme have developed and published this definition of Supervision as it can be applied to Section 10 Aseptic Preparation Activities.

This definition has been considered by the NHS Pharmaceutical Quality Assurance Committee and the Pharmaceutical Aseptic Services Group and agreed by both of these bodies.

The definition underpinned the South West Product Approval Programme which completed its pilot stages in 2013 and has formally been launched as an approved programme.

The NHS Aseptic Services Accreditation Working Group focuses on working with members of the SW Product Approval Accreditation Programme to develop a national framework to support the wider roll out of this initiative.

It must be noted that the definition of supervision cannot be considered in isolation and **must be fully supported by a framework that gives the same levels of resource, governance and oversight that has been incorporated into the South West Programme. Frameworks must be agreed by the NHS Aseptic Accreditations Working Group.**

It was also acknowledged that this definition would have a very significant effect on the Product Approval Chapter of the Quality Assurance of Aseptic Preparation Services standards. The fourth edition of the book is currently being reviewed and so it was decided to prioritise the update of the product approval chapter to reflect the new definition of supervision as applied to Section 10 activities.

The text of the revised chapter is included as an appendix to this document to provide context, but will in time be incorporated into the fifth edition of the standards.

Proposed framework for the definition of supervision as applied to Section 10 aseptic preparation activities

1. The concept of supervision as applied to The Medicines Act 1968 Section 10¹ aseptic preparation activities is complex and multi factorial.
2. The Accountable Pharmacist is defined as “The pharmacist responsible for all aspects of the 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.”
3. Currently an Authorised Pharmacist is defined as “The person designated in writing by the Accountable Pharmacist to supervise the aseptic process and release the product for use.”²
4. This framework seeks to describe the elements of the systems that organisations must ensure are in place at all times to provide an adequate level of supervision for Section 10 preparation activities when an Authorised Pharmacist does not personally carry out the product approval stage of the process.
5. In order to achieve an acceptable level of supervision it is necessary to describe the requirements in three levels. These may be defined as:
 - Organisational Level requirements
 - Day to Day Operational Level requirements
 - Individual Product Level requirements

Organisational Level Requirements

Chief Pharmacist

6. The Chief Pharmacist is defined as “The pharmacist responsible for the pharmacy service within a corporate body.”²
7. The Chief Pharmacist holds ultimate responsibility for the adequate resourcing of the aseptic preparation service to ensure that it meets the defined national standards.²
8. This needs to be formally documented in a Trust policy (such as the Medicines Policy).
9. The Chief Pharmacist is also responsible for ensuring that a policy on Section 10 aseptic preparation is in place and that where this allows delegated

¹The Medicines Act, 1968 (as amended) Section 10

²Beane, A. M., Editor, (2006) Quality Assurance of Aseptic Preparation Services, 4th Ed., London, Pharmaceutical Press, London, ISBN0-85369-615-2

product approval, this has specific formal organisational Board level agreement.

Accountable Pharmacist

10. The Accountable Pharmacist together with the Chief Pharmacist must ensure that an effective and comprehensive Pharmaceutical Quality System is in place within the unit. This must be confirmed by EL(97)52³ audit findings.
11. The Accountable Pharmacist must ensure that robust systems are in place to train, assess competence and authorise individuals to carry out the product approval process. For Pharmacy Technicians and Pharmacists new to the role, these systems must comply with the National Accreditation Framework requirements.
12. There should be an appropriate reporting structure so that all accredited product approvers are accountable directly to the Accountable Pharmacist for this activity and that this is reflected in their job description.

Chief Pharmacist and Accountable Pharmacist

13. The Chief Pharmacist and Accountable Pharmacist must agree a suitable management structure within the unit to ensure that the requirements of this framework are met at all times the unit is operational.

Day to Day Operational Level Requirements

Authorised Pharmacist

14. The Authorised Pharmacist must approve the unit for the preparation of items on a daily basis and ensure that any open quality exceptions are communicated to accredited product approvers.

³Department of Health (1997) Executive Letter (97)52 Aseptic Dispensing in NHS Hospitals. London, NHS Executive

15. If they cannot approve the unit for use then the issue must immediately be referred to the Accountable Pharmacist. The authorisation to use the unit should be signed each day by all accredited product approvers to show that they have acknowledged any ongoing or outstanding deviations within the unit and that available staffing and skill mix are appropriate for the anticipated level of preparation activity and that all scheduled monitoring and cleaning activities have been undertaken. (Beaney Section 14.5²)
16. The tasks described above must be completed by the Authorised Pharmacist at the start of each day.
The Authorised Pharmacist must as an absolute minimum be physically present within the unit for a sufficient period of the time at the start and end of each working day to discharge their professional responsibility.
17. There must be a formal review of the day's activities by the Authorised Pharmacist at the end of the working day. This must include as a minimum:
- A review of all batch documents of products released by accredited product approvers during the day
 - A review of any deviations
 - A review of all daily monitoring logs for the unit.

The Accountable Pharmacist must ensure that the above are completed appropriately on a daily basis.

Individual Product Level requirements

Authorised Pharmacist

18. The Authorised Pharmacist must carry out the Prescription Verification process for all items and ensure that a clinical check has been completed by a suitably qualified pharmacist.
19. The Authorised Pharmacist must approve each prescription either as being suitable for delegated product approval or as requiring approval by an Authorised Pharmacist only. This process must be fully described in a specific SOP. There may be some circumstances where in the event of certain planned deviations being in place, delegated product approval may still be possible. Any such decision must be as a result of formal, documented risk assessment of the planned deviation which has been approved by the Accountable Pharmacist.
20. The Authorised Pharmacist must be easily contactable and available for advice at any time during the working day.
21. The Authorised Pharmacist must be able to physically attend the unit immediately in the event of an urgent requirement.

22. Any items where there has been an unplanned deviation or non-conformance during the preparation process, where the product may still be deemed suitable for use must be referred to the Authorised Pharmacist.

Accredited Product Approver (Section 10 Releasing Officer)

23. The accredited product approver must meet all the requirements of the National Accreditation Framework and hold appropriate certification or other suitable evidence
24. The accredited product approver must only release those product types for which they have been accredited.
25. The accredited product approver must be registered with the General Pharmaceutical Council or Pharmaceutical Society of Northern Ireland (PSNI).

Definitions

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

Product Approval – Approval of the product as being suitable for issue to and administration to the patient. This must take place by an accredited product approver against all relevant documentation and the prescription and must include a visual and physical examination of the product.

APPENDIX 1

Text of Revised Product Approval Chapter for the 5th Edition the Quality Assurance of Aseptic Preparation Services (1)

Product approval

Units operate under a professional exemption (Section 10) to the UK Medicines Act which allows preparation of pharmaceuticals to be undertaken under the supervision of a pharmacist without the need for product and manufacturing licences to be held. Supervision, as applied to Section 10 aseptic preparation activities, has been defined by the NHS. This definition cannot be applied in isolation and must be fully supported

by the UK national framework for product approval (2), giving assurance of resource, governance and oversight in line with national requirements.

- (1) A formal recorded decision of product approval (release) should be taken by an accredited product approver before a product is released and after completion of all preparation and technical checking procedures.
- (2) The Accountable Pharmacist should ensure that robust systems are in place to train, assess and authorise individuals to carry out the product approval process. These systems should comply with the UK national framework for product approval (2) requirements.
- (3) The Accountable Pharmacist should ensure that an effective and comprehensive Pharmaceutical Quality System is in place within the unit (also see Chapter 8 - Pharmaceutical Quality Systems).
- (4) There should be an appropriate structure so that all accredited product approvers are accountable directly to the Accountable Pharmacist for this activity and that this is reflected in their job description.
- (5) The accredited product approver should not, other than in exceptional circumstances, be the person who prepared the product.

Note: Out of hours the requirements for supervision still apply.

- (6) There should be written procedures covering final accuracy checking and product approval (release). These processes may, or may not, be undertaken by the same person. Details of the roles and responsibilities of all the staff involved in these processes should be clearly defined.
- (7) The Authorised Pharmacist responsible for supervision should be identifiable and contactable at any point.
- (8) The accredited product approver should ensure that they are authorised to approve the specific product type for release, e.g. cytotoxics, parenteral nutrition etc.

NB: Intrathecal chemotherapy should only be approved for release by an Authorised Pharmacist named on the intrathecal chemotherapy register.

- (9) All those involved in the process of product approval should maintain the appropriate levels of competence and act in accordance with the GPhC code of professional ethics and standards. (3)
- (10) The accredited product approver should, before release:
 - carry out a visual inspection of the product (for particles, precipitation and integrity)
 - ensure that the product complies with the prescription and the appropriate specification, including labelling

- ensure that the product has been produced in accordance with approved and validated operators and procedures, and be aware of any deviations
 - be aware of recent microbiological and physical environmental results for the facilities
 - ensure that the daily monitoring records for the unit are satisfactory, e.g. pressure differentials, cleaning
 - be aware of the status of the unit and ensure the planned preventative maintenance programme is up to date
 - be aware of recent retrospective testing results for products
 - consider any prospective testing results, e.g. analytical testing, weight checks.
 - ensure that all necessary accuracy checks e.g.including in process checks and reconciliation of empty and part-used containers of components and starting materials has been carried out.
 - ensure any planned deviations have been approved by an authorised pharmacist.
- (11) In the case of any unplanned deviation, any decision to approve the product should be taken by an authorised pharmacist.
- (12) All errors detected should be recorded via the national aseptic error reporting scheme, trended and investigated to an appropriate level depending upon the severity.
- (13) The authorised pharmacist should be aware of, and act on, any errors detected and any interventions made both during the preparative stages and/or at the product approval stage. This is relevant even where the product is able to be released.
- (14) There should be a written procedure for dealing with preparations failing to meet the required standard. The investigation of these events should be fully documented and corrective and preventative actions implemented to an appropriate level. Trending of failures should be undertaken regularly and any adverse trends or major failures to comply with standards should be brought to the attention of the chief pharmacist.

Note: Definition of Accredited Product Approver.

An Authorised Pharmacist or a person who has been approved through a nationally recognised accreditation programme for product approval.

Reference

1 Quality Assurance of Aseptic Preparation Services, 5th Edition, A. Beaney, in press as of March 2014.

2. Nationally Recognised Competency Framework for Pharmacists and Pharmacy Technicians: Product Approval (Release) in Aseptic Services under Section 10 exemption

[NHS Aseptic Services Accreditations Working Group, in draft as of March 2014.](#)

3. Standards of conduct, ethics and performance, General Pharmaceutical Council, July 2012.