# THE TRAINING OF AUDITORS TO UNDERTAKE AUDITS OF UNLICENSED ASEPTIC DISPENSING IN NHS HOSPITALS

**2nd Edition**

**June 2011**

**Published by the NHS Pharmaceutical Quality Assurance Committee**

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## 1. Background

Following the deaths of two children from the administration of microbiologically contaminated intravenous nutrition fluids prepared in an NHS hospital pharmacy in 1994, an investigation by the Department of Health and the Medicines Control Agency (now the Medicines and Healthcare Products Regulatory Agency) was undertaken into, and the adherence with, published standards of good manufacturing practice within the NHS. Following on from this in 1997 an Executive Letter (EL(97)52 - 22nd August 1997) was issued by the Chief Pharmacist and the Medical Director of the NHS Executive which required the regular assessment and inspection of hospital pharmacies undertaking aseptic dispensing that did not hold manufacturing licences from the (then) MCA for this activity. The aim of EL(97)52 was to ensure that aseptic dispensing in unlicensed NHS units complied with current NHS national standards and that this was maintained.

EL(97)52 mandated that Regional Quality Assurance Specialists should undertake these audit at least every 18 months and that the results of these inspections be made known to Trust Chief Executives and to those commissioning health services, so that standards are maintained. These audit inspections continue to be undertaken by Regional Quality Assurance Specialists. However, given the passage of time since this audit requirement was put in place new EL auditors have had to be trained to continue this function. This document describes the nationally agreed standards for the training and ongoing accreditation of EL auditors.

## 2. Training

As noted in "Quality audits and their application to hospital pharmacy technical services" (NHS Pharmaceutical Quality Assurance Committee 1999) a good auditor will have the following qualities:

- Academic qualifications
- Training
- Background and experience
- Personal and professional skills and attributes

### 2.1 Academic Qualifications

The knowledge and awareness of current national standards and best practices in the various disciplines of aseptic dispensing operations to be audited are of paramount importance. However, formal academic qualifications undoubtedly contribute to an auditor's perceived credibility and provide reassurance to the auditor of the validity of his/her opinions.

Completion to at least diploma level of the Pharmaceutical Technology and Quality Assurance course is regarded as a highly desirable qualification for new auditors although other post-graduate qualifications and experience may be considered as suitable. Additional credentials (such as ISO 9000 Lead Auditor) may be seen as

desirable.

### 2.2 Training

Auditors must keep up to date with current standards of good manufacturing practice along with developments (technological, clinical and regulatory) in the field through the application of continuous professional development (CPD). Auditor CPD can involve a combination of the following activities (not an exhaustive list):

- Reading current literature, journals etc.
- Involvement in specialist interest groups and attendance at conferences, symposia etc.
- Awareness of collated deficiencies and non-conformances from MHRA inspection reports.
- Attendance at joint audit visits (especially MHRA inspections of licensed NHS sites).
- Attendance at NHS Pharmacy Quality Assurance Committee annual audit training days

Auditors must be familiar with, and follow, the nationally agreed standard operating procedure (SOP) for undertaking EL audits. Other recognised training schemes for conducting audits include ISO 9000 Lead Auditor training and the Institute of Quality Assurance auditor registration.

### 2.3 Experience/Background

In addition to the qualifications and training described above, the ability to critique a process, operation or a whole service also comes from hands on experience and exposure to best practice. Whilst it is entirely feasible to undertake an audit with the aid of a detailed checklist, an EL auditor should be able to provide additional scrutiny in terms of risk assessment and risk management. Therefore, a minimum of at least 5 years experience (preferably in a quality assurance role) in a NHS aseptic unit preparing cytotoxics, total parenteral nutrition, Central IV Additive Services products or radiopharmaceuticals is deemed to be essential. Work experience in a licensed unit(s) undertaking some (if not all) of these activities is desirable.

### 2.4 Personal and Professional Skills

It is likely that the EL auditor and the auditees will already know each other and that if the auditor has the attributes described above he/she will be well respected. A successful auditor should remain credible and sensible during audit inspections and should provide objective and unbiased assessment of risk. An EL auditor must be observant and vigilant. More often than not, it is the combination of a series of loosely linked deficiencies or problems that, combined, represent a significant risk. The auditor must remain focussed during the audit and not be distracted by irrelevant issues.

The auditor must remain pragmatic and sympathetic to local problems and not allow his or her demeanour to indicate otherwise. Being realistic to the problems encountered,

taking a common sense approach and being kind in expressing criticism will help rather than hinder the progression of the audit. Encouraging and praising achievements is of particular importance, given the local pressures the auditees may be under.

## 3. Report Writing

This is one of the key duties of an EL auditor. There is a nationally agreed format for EL reports and this must be adhered to. The requisite number of copies of the report and summary report must be sent to the appropriate personnel as detailed in the national SOP. The auditor should be able to write reports that are accurate and factual while avoiding repetition. The auditor should be able to keep such reports as simple and brief as possible whilst remaining comprehensive and unambiguous. The choice of tense and language used is important and EL auditors must be tactful and diplomatic. For example incompetence may be implied but direct naming and shaming is likely to be counter-productive.

The assessment and rating of risks identified during the audit process is of fundamental importance to the staff in the service being audited and the management of the Trust concerned. This will help prioritise the management of the risks identified and the risk reduction strategies to be pursued to improve patient safety. To some extent the rating of risk will be a subjective assessment by the report writer. To ameliorate this subjectivity and to provide a degree of national consistency in risk rating, trainee auditors should be familiar with the Pharmacy Quality Audit Guidelines published by the NHS Pharmaceutical QA Committee which outline situations commonly encountered during audit and assigns appropriate risk ratings.

## 4. Accreditation

### 4.1 Initial Accreditation

Each trainee auditor should be proposed for training by an existing EL auditor and should be assigned an existing EL auditor as a trainer and mentor to ensure uniformity in national standards of auditing. The accreditation of new EL auditors should follow a structured programme of development. Any additional training and experience required by the candidate should be provided prior to commencement of auditing duties, after an individual assessment of training needs. The trainee auditor should shadow an experienced EL auditor on a number of audits (this would normally be not less than 3 audits but should cover the range of facilities encountered in that area e.g. radiopharmacy). This should be followed by a period in which the trainee auditor leads the audit under the supervision of an experienced auditor (again normally at least 3). The trainee should be given the opportunity to shadow EL auditors during inspections of unlicensed units in a different region as well as audits of commercial suppliers and MHRA audits of licensed NHS units. As a final step, once an EL auditor is deemed capable of “flying solo” by the mentor, his or her reports should be subject to oversight and discussion with the mentor EL auditor prior to dispatch. As part of the formal accreditation process, all new auditors recommended by their mentor will be added to the register of accredited EL Auditors held by the Audit Sub-Committee on behalf of the NHS PQA Committee (subject to the final approval by the sub-committee).

### 4.2 Continued Accreditation

The maintenance of EL auditor registration will be subject to confirmation of appropriate CPD and ongoing experience of EL(97)52 audits. Participation in either the annual Auditor Training Day or in an observed audit involving an accredited EL auditor from a different region (e.g. a "cross border" audit) on at least a biannual basis and the performance of at least 1 EL(97)52 per annum as the lead or sole auditor will be required to maintain registered status.

## References


1. Aseptic Dispensing in NHS Hospital EL(97)52 22/8/97 NHS Executive Letter
2. Beaney A M. The Quality Assurance of Aseptic Preparations Services 4th Edition 2006
3. Quality audits and their application to hospital pharmacy technical services. NHS Pharmaceutical Quality Control Committee 1999
4. National EL 97(52) Audit Procedure NHS Pharmaceutical QA Committee SOP001 version 2, July 2007
5. Pharmacy Quality Audit Guidelines. NHS Pharmaceutical QA Committee (current versions).


| Document History | Issue date and reason for change |
|---|---|
| Version 1 September 2007 | NHSPQAC response to retirement of some existing auditors |
| Version 2 June 2011 | Updated to reflect requirements for ongoing accreditation |