

## Standard Operating Procedure for Undertaking and Reporting EL(97)52 Audits

For use in NHS Hospital Pharmacy Aseptic Units

8th Edition

January 2018

Written by the Audit Subgroup of NHSPQAC

Published by the NHS Pharmaceutical Quality Assurance Committee

Endorsed and supported by:



**Background to EL(97)52 Audits**

During 1994 two children died in Manchester Children’s Hospital as a result of receiving contaminated intra-venous feeding fluids prepared by the Pharmacy Department. The preparations were made under Section 10 exemption (to the 1968 Medicines Act) and therefore did not require a manufacturer’s “Specials” licence from the (then) Medicines Control Agency (MCA). The granting of such a licence follows stringent inspection of the applicant’s site and regular inspections thereafter.

An investigation by the MCA during 1995 showed serious deficiencies in many aspects of the aseptic (sterile) facilities and procedures adopted by the Pharmacy that led to microbiological contamination of the feeds from the sink located in the preparation room.

A subsequent investigation throughout the United Kingdom performed by the MCA on behalf of Ministers found that an estimated 60% of NHS hospitals had failings in their aseptic services that would present a risk to patient safety. The NHS was then required to perform under EL(96)95 an internal audit of all hospitals preparing products under Section 10 arrangements. A report published in 1996 showed figures that agreed with the MCA.

During 1997 EL(97)52 was issued which required external audit at an interval of 12 to 18 months of all hospital pharmacy departments preparing injections under Section 10 exemption. Audits were to be carried out by Regional Quality Assurance Specialists with reports made to Hospital Chief Executives and to those commissioning health services. They were also to involve the Regional Offices (for Regional Pharmaceutical Advisors and performance managers).

Reorganisation of the NHS has led to a new reporting process issued in 2013 by NHS England. This is now outlined in Appendix 1.

**Procedure**

##### 1. Liability and Record Keeping

* Circumstances may arise whereby the EL(97)52 audit process and outcome may be scrutinised by those in or outside of the NHS. Internally this may be where hospital pharmacy senior managers are required to justify their decisions and actions. External scrutiny may be as a result of performance management, civil or criminal action against the hospital where the unlicensed aseptic unit is located or as a request under the Freedom of Information Act.
* Auditors trained to perform EL(97)52 audits must therefore retain sufficient documentation detailing the audit process for each individual site visited. It is recommended that this should comprise as a minimum:
  + Copies of all correspondence (letters and e-mails) between the auditor and the hospital.
  + Notes, signed and dated, of any relevant telephone discussions between the auditor and the hospital.
  + Auditor’s notes used to write draft report.
  + Draft report / draft summary of results sent to hospital and returned comments.
  + Final audit report, summary of results, covering letter (including distribution list), etc.
  + Any correspondence received as a result of the audit.
  + Approved action plan
    - Archived documentation must be retained in a way that is easily accessible by other auditors. This is of particular importance when sites are audited by different auditors who need to find and understand what has been done before at the site.
    - A list of trained auditors is maintained by the NHS Pharmaceutical Quality Assurance Committee.
    - Key documents should be maintained electronically as the archive record.

##### 2. Organisation and Preparation

##### Each audit team should maintain a local list of sites to be audited including details of ‘specialities’ (such as radiopharmacy, paediatrics, oncology, etc.)

* Each audit team should setthe local audit programme. The audit frequency (maximum intervals) is defined as not more than 18 months. Where all aspects cannot be covered in a single audit it will be necessary to return after 12 months to cover remaining areas. Although normally programmed there may be situations / exceptional circumstances where short-notice audits become necessary (based on intelligence received) or where the audit period is reduced (a ‘critical’ or high number of ‘majors’ assigned).
* The auditor must contact the Accountable Pharmacist to agree suitable dates. A minimum of two weeks’ notice should be given. The auditor should be flexible regarding the actual dates whilst aware of the possibility of delaying tactics being used, for example, the continued changing of dates by the hospital.
* The auditor should check the contact details (address, telephone numbers, e-mail addresses) of the Accountable Pharmacist, senior pharmacy manager and any other staff required to be involved which may include those of externally contracted QA/QC. He/she should also confirm the name and address of the Chief Executive
* The auditor must confirmthe agreed time and date of the audit in writing to the Accountable Pharmacist , the senior pharmacy manager and other officers according to local requirements (see Appendix 2 for a template letter). If a colleague is to accompany the auditor for training or as a co-auditor then this detail must be included. A pre-audit questionnaire (see Appendix 3) should be sent for the Accountable Pharmacist to complete and return prior to the audit.
* Review previous audit reports and action plans submitted in response to identify areas to focus on.
* Review the returned pre-audit questionnaire and any intelligence held about the site and other data requested from the site, if considered, necessary such as environmental monitoring and trending data.

Notes: The scope and detail examined within the EL(97)52 audits has increased since they started in 1995. It is now possible that auditors will not be able to cover all categories in sufficient depth but will work on a risk assessment basis determined during preparation for the audit and during the audit itself. Based on risk, the auditor should focus on those deficiencies determined during the previous audit and any categories not previously fully covered.

###### 3. Performing the Audit

* Arrive on site in good time to start the audit at the agreed time.
* Requestan opening meeting with the Accountable Pharmacist. Attendance by the senior pharmacy manager, quality control manager, senior technician, etc. is dependent on local circumstances but generally expected.

**3.1** **At the Meeting:**

* Describethe purpose and process of the audit including the background to EL(97)52 audits (if necessary), the appraisal of activities against current guidelines and the importance of a hospital action plan in response to the audit. Describe the progress if staff present have not experienced an EL(97)52 audit in recent years or are new in post. Stress that the audit should be a learning exercise and an opportunity to share best practice and excellence.
* Statethe standards to be used.
* Summariseprevious audit findings where relevant and identify problem areas. Inform that the scope and detail examined within the EL(97)52 audits is very broad. It is therefore possible that the auditor process may not cover all categories to the same depth and that some aspects may receive less scrutiny based upon a risk assessment determined during the audit.
* Examine the progress since the previous audit by examining the site’s current action plan and comparing this with the audit’s deficiencies to ascertain those not closed out.
* Discuss any significant changes in workload / staffing / equipment.
* Discuss workload data submitted in pre-audit questionnaire and note any trends.
* Estimatethe timetable for the audit and state who should attend the closing session.

##### 3.2 The Audit Process

* Be aware that the identification of areas of increased risk may alter the structure of the day and under some circumstances may lead to all the categories or part of individual categories not being wholly covered.
* Walkabout, following processes from start to finish.
* Discuss issues throughout the audit.
* Praisewhere appropriate at the time.
* Keep focussed on categories.
* Encourage openness.
* Examine the errors / deviations register, adverse incident reports, and exception logs (as applicable).
* Check standard operating procedures.
* Talk to junior staff to assess level of understanding.
* Observe the unit working for example, staff disinfecting medicines and components and aseptic preparation in isolators and laminar flow cabinets.

##### Request, at the end of the audit, 10 to 15 minutes quiet time to marshal thoughts.

##### 3.3 At the closing meeting

* Thank people for their time.
* Summarise strengths as well as weaknesses.
* Inform how categories will be graded.
* Identify critical deficiencies requiring immediate attention.
* Suggest how to improve.
* Invite comments and questions.
* State when the draft report can be expected and when a response is required (10 working days from receipt of draft report for comments on accuracy and interpretation). State that once the report is finalised an action plan will be required within a further 10 working days.

* State the extent of the final report’s circulation.
* Indicate, based on the findings, the period before the next audit.

Note: Audit feedback must be such that there are no surprises when the hospital receives the draft audit. See Section 5 below on the resolution of disputed gradings of risk.

4. The follow-up

* Complete electronically the audit report from notes made during the audit and identify the deficiencies found stating the paragraph of the relevant section of the Quality Assurance of Aseptic Preparation Services standard.
  + Refer to the recommendations from the previous audit into the report and comment if the recommendation action is complete or comment if further action is necessary.
* Complete the Chief Pharmacist’s and hospital Chief Executive’s Letters and Audit Summary Report (see Appendix 4) taking into account the intended recipient (see Appendix 5 and 6 respectively). Reference each deficiency in the report, comment and make recommendations where appropriate. If no deficiencies are found within a category then report this as ‘Satisfactory’. The Audit Summary report should be used to note deficiencies only, any praise or commendation should be confined to the full report.
* The result column in the Audit Summary Report should be completed using the wording from the table below i.e. C,M,O, or S and colour coded such that;

|  |  |
| --- | --- |
| Result | Action |
| Critical | Deficiencies that require immediate action (within 24 hours) |
| Major | Deficiencies that require initial action within three months |
| Other/Minor | Deficiencies that require initial action within twelve months |
| Satisfactory | No action required |

|  |  |
| --- | --- |
|  | **Microsoft Colour** |
|  | Red |
|  | Light Orange |
|  | Yellow |

An overall risk assessment should be assigned and annotated at the top of the Audit Summary Report. The categories of overall risk are;

* **High**
* **Significant**
* **Low**
* Write the draft report and Audit Report Summary documentation within 20 working days of the audit unless the auditor identifies issues that will prevent this occurring.

In exceptional circumstances, where a critical deficiency has been found, then an e-mail confirming the critical deficiency should be received by the site within one working day and the full report in draft as soon as is possible afterwards. In such circumstances the Senior Pharmacy Manager/Hospital Chief Pharmacist must also be included these communications.

Note: Where a critical deficiency is considered the auditor must keep others within the audit team informed.

* If an overall risk rating of High Risk or a Critical deficiency is given then if possible pass the draft report on to another EL auditor (either within the local team or from another team) for peer review before sending to audited site. This review is informal and to cover report appearance, consistency of deficiency scoring and fairness.

Note: New and inexperienced team members will not peer review reports until they have been audit trained and completed at least 12 months in post.

* Send the draft report, summary report and any other promised information to the Accountable Pharmacist and hospital senior pharmacy manager inviting comments on factual accuracy.

Note:

* If the comments to the returned draft are not acceptable or require further comment this should be done before the report is finalised.
* Finalise the report and return it as a pdf document by e-mail and request the Action Plan in response.
* Review the action plan. If it is not acceptable discuss issues further with the site. Confirm that reasonable time scales are quoted in the received action plan and the plan is not a ‘wish list’. The auditor should also recognise that some deficiencies may be outside the control of the Accountable Pharmacist / Chief Pharmacist. In this case risks should be minimised as far as is practicable, for example, by reducing expiry dates. Ask the hospital to adjust the action plan time scales if they are not appropriate to the deficiencies. If the action plan is acceptable inform the site.
* If NO response is received then use the draft report as the final version and note that no Action Plan was returned in all correspondence during the distribution of the report. In such circumstances the report should also be sent to the relevant Medical Director and Regional Pharmacist of the corresponding NHS England Region (in England) if applicable, even if the overall finding is low risk, for consideration at the next Quality Surveillance Group Meeting.

Note: It is important that as much information is entered in the final report as is reasonable in the available time to:

* Justify the decision reached
* Defend the decision reached if challenged at a later date (and not rely on memory – remember if it is not written down it does not exist!)
* Assist the peer reviewer to understand your decisions
* Assist other auditors visiting the site to understand your decisions and improve continuity

**5. Action to be taken in the event of a dispute**

In the event that the findings, deficiency ratings or overall risk assessment is disputed by the Chief Pharmacist and/or the Chief Executive of the hospital concerned the Audit Sub-Committee of the NHS Pharmaceutical Quality Assurance Committee shall be called upon to independently review all the evidence and judge whether the original findings and assessments were justified or not. In England the Head of Specialist Pharmacy Services will be notified that the audit has been disputed and is being investigated by the Audit Sub-Committee. If the author of the disputed audit report is a member of the Audit Sub-Committee then they shall not take part in the independent review process. The Audit Sub-Committee will be the sole arbiters of the complaint and may approach the auditor for further information if considered necessary. The committee’s decision shall be final and not subject to further appeal.

1. **Distribution of the Report**

A pdf copy of the full report, summary report, agreed Action Plan and covering letter should be sent to the hospital Chief Pharmacist copying in the Accountable Pharmacist. A copy of the Summary Audit report and covering letter should be sent the hospital Chief Executive. A copy of the summary report should be sent to Justine Scanlan (Head of Specialist Pharmacy Services) for national collation and review. See Appendix 1 for additional distribution arrangements within England.

#### Records

* Each audit team shall keep a spreadsheet of hospital sites, dates audited, proposed date of next audit and the overall risk rating assigned.
* Identify particular local deficiencies. These may be discussed at the local technical services network or chief pharmacist network meetings, the NHSPQA Committee meetings and also during the annual audit review day.
* Inform the Audit Sub Group if you participate in an accompanied audit visit with another member of the NHSPQA Committee or EL(97)52 trained / accredited auditor.
* Notifythe lead authors of the Quality Assurance of Aseptic Preparation Services and/or the relevant author of any applicable Pharmacy Quality Audit Guideline (PQAG) of any contentious issues (where appropriate) that arise in order that they are further considered in the next publication.

**Appendix 1 Distribution of EL(97)52 Audit Reports in England**

For audits with an overall rating of Low risk a copy of the summary report should be sent to Justine Scanlan (Head of Specialist Pharmacy Services) for national collation and review.

For audits with an overall risk assessment of High and Significant risk a copy of the Summary Audit report and a copy of the action plan in response along with a covering e-mail should be sent to the Head of Specialist Pharmacy Service - NHS England. Any overall risk ratings of Significant or High risk should also result in a copy of the Summary Audit report and action plan in response along with a covering e-mail being sent to both the relevant Medical Director and Regional Pharmacist of the corresponding NHS England Region for consideration at the next Quality Surveillance Group Meeting.

**Appendix 2 Template Letter Announcing an Audit**

****

**Appendix 3 Pre Audit Questionnaire**

****

**Appendix 4 Template Audit Summary Report**

****

**Appendix 5 Template Letter to a Hospital Chief Pharmacist (England)**

****

**Appendix 6 Template Letter to a Hospital Chief Executive (England)**



Version History:

|  |  |  |
| --- | --- | --- |
| Version Number | Date | Reason for Change |
| 1 | Pre 2010 | First version |
| 2 | Nov 2014 | Distribution of reports in England, updating summary report format, introduction of pre-audit questionnaire and template letters. |
| 3 | Feb 2016 | Changes to distribution of reports (England) to reflect changes in NHS England and introduction of annual summary reporting to head of SPS (England) |
| 4 | Apr 2016 | Corrections to template letters and clarification on timing of summary report submission (England) |
| 5 | Nov 2016 | Changes to Pre Audit Questionnaire (Version 7) |
| 6 | Aug 2017 | Changes to distribution of reports (England) at the request of Head of SPS and changes to template letters as a consequence. |
| 7 | Sep 2017 | Changes to distribution of reports (England) to include NHS England Regional Pharmacists |
| 8 | Jan 2018 | Changes to the timelines for report writing. Addition of a section on dispute resolution. Changes to Pre Audit Questionnaire (Version 8) |