Specialist Pharmacy Service

NHS

Pharmaceutical Quality Assurance Service
London and South East

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

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.

Specialist Pharmacy Service

NHS

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 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
    - All documents sent to, or received from NHS England (London or South)

- Archived documentation must be retained in a way that is easily accessible by other auditors in the Regional QA Trust's file on the GSTT 'G' drive. 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. File title must be in the form 'year/month/day audit' e.g. 20170701 Audit

- A list of trained EL(97) 52 auditors within the NHS Pharmaceutical Quality Assurance Service is maintained by the NHSPQA Committee. Auditors within London and the South East are listed in document reference 003.

- Key documents should be maintained electronically as the archive record.

- Auditors are encouraged to now enter audit data straight onto laptops to both improve accuracy and reduce write up times.

2. Organisation and Preparation

- Maintain the local list of sites to be audited including details of 'specialities' (such as radiopharmacy, paediatrics, oncology, etc.)

- Set the local audit programme using the Excel spreadsheet. 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).

- 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.

- 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

- Confirm the agreed time and date of the audit by e-mail 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. If a pre-audit questionnaire (see Appendix 3) is to be used it 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 (if sent) 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, no later than 09.30, to start the audit.

- Request an 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:

- Describe the 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.

- State the standards to be used.

- Summarise previous 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 (if sent) and note any trends.

- Estimate the timetable for the audit and state who should attend the closing session.

3.2 The Audit Process

- Use the Audit Record Sheets (Document Number 004) as guidance as to what to cover in each category. If the standard is satisfactory mark the line as 'Complies' with relevant notes where possible of what evidence you requested and examined to reach this conclusion. If a deficiency is found then mark the line as 'Non Compliant*' and bullet point the observations / reasons below. This data can be recorded on a copy of the Audit Record Sheets (Document 004) or preferably directly onto the same sheets on a laptop. Mark with an asterisk (*) on the record sheets where deficiencies are found.

  Note: It is important that as much information is entered on the Audit Record Sheets 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

- 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.

- Walk about, following processes from start to finish.

- Discuss issues throughout the audit.

- Praise where 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 deficiencies will be graded and categories graded according to the most severe deficiency in each category. Action times are allocated against this table:

Deficiencies	Score	Action
Critical	4	Critical deficiencies that require immediate action (within 24 hours)
Major	3	Major deficiencies that require action within three months
Moderate	2	Moderate deficiencies that require action within six months
Minor	1	Minor deficiencies that need to be addressed within twelve months

- Identify critical deficiencies requiring immediate attention.
- Suggest how to improve.
- Invite comments and questions.
- State the overall level of risk (Low, Significant, High).
- 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.

4. The follow-up

- Complete electronically the **Audit Record Sheets** (Document Number 004) from notes made during the audit. Mark with an asterisk (*) on the record sheets where a deficiency has been found. The record sheets can be referenced to the Deficiency Severity Matrix compliance statements which are standards from Quality Assurance of Aseptic Preparation Services and best practice guidance from auditor's experience.
- Using the **Deficiency Severity Matrix** (Document Number 005), for each identified deficiency in the **Audit Record Sheets** (Document Number 004) work across the columns in same row to assess the severity of the deficiency to determine the severity score (S), which is the number (on the scale of 1 to 4) given at the top of the column. Although the specific deficiency may not be described or there may be local mitigation to increase or reduce the severity of the deficiency use the matrix to place the identified deficiency against a score. Enter the severity score in the Column S on the Audit Record Sheet. Critical 4, Major 3, Moderate 2, Minor 1.

  Notes:
  - Do not score compliance with standard.
  - When first developed it was envisaged that during audits only one deficiency would be found in each 'compliance statement'. In practice it has been found that numerous deficiencies may fall within one 'compliance statement'. The severity of these is scored separately allowing subsequent action plans to also

address them individually.

- Severity scores are shared with site. They are to be used for benchmarking purposes only to show site improvement (or otherwise) between audits and also between sites when appropriate.

- Incorporate the recommendations from the previous audit into the report and in bold comment if the recommendation action is complete or comment if further action is necessary.

- Complete the **Summary of Recommendations and Actions to Address Individual Deficiencies** (document number 021) taking into account the intended recipient (See Section 5 Distribution of the Report). Number each deficiency, comment and make recommendations where appropriate. If no deficiencies are found within a category then report this as 'Satisfactory' or 'Not Assessed'. Select the appropriate colour for each deficiency. Complete the overall comments section

- Complete the **Audit Executive Summary of Results** (document number 006). An overall risk assessment of **high, significant or low** must be entered. This is based on the auditor's judgement. The audit result for each category will be based on the deficiency with the highest severity in that category. Comments will be based on those already made in the Summary of Deficiencies. If no deficiencies are found within a category then report this as 'Satisfactory' or 'Not Assessed'.

- 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 10 working days of the audit unless the auditor identifies issues that will prevent this occurring. Use template document 022.

  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.
  - Ideally the draft report will be passed to a team member's line manager. In reality with individuals working off site frequently it may be that the draft report is shared with whoever is around on the day it is completed or who can respond the quickest as not to delay the reports issue. It is acknowledged that this will only work if the team are experienced.
  - The peer review will also serve to inform the audit team of findings at other sites.

- Send electronically the draft report and **Audit Report Tracking Form** (Document Number 009), **Satisfaction Questionnaire** (Document number 008), supporting letter and any other promised information to the accountable pharmacist and Trust senior pharmacy manager inviting comments on factual accuracy within 10 working days

  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 within another 10 working days.

  - If the comments to the returned draft are not acceptable or require further comment this should be done before the report is finalised. Allow 15 working

days for a response. If NO response is received then use the draft report as the final version.

- 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.

- Allow a total of 20 working days for a response. 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 of the relevant NHS England Region Local Area Team (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. Distribution of the Report

- A pdf copy of the **Full Report** (document number 022 is the template), which includes the **Executive's Letter**, the **Audit Executive Summary of Results** and the **Summary of Recommendations & Actions to Address Individual Deficiencies** should be sent to the hospital Chief Pharmacist and Accountable Pharmacist by e-mail.
- A copy of the **Executive's Letter** and **Audit Executive Summary of Results** should be sent to the Trust Chief Executive by post.
- Refer to Appendix 1 when a high or significant risk has been issues
- A copy of the summary report should be sent to Martin Knowles for national collation and review/trending by the NHS Pharmaceutical Quality Assurance Committee Audit Sub Group. See Appendix 1 for additional distribution arrangements within England.

6. Records

- Each audit team shall keep a spreadsheet of hospital sites, dates audited, proposed date of next audit and the overall risk rating assigned. In England this list shall be

submitted to the Head of Specialist Pharmacy Service - NHS England annually at the end of each calendar year.

- 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.

- Notify the particular Pharmacy Quality Audit Guideline (PQAG) lead authors of any contentious issues (where appropriate) that arise in order that they are further considered. References to the PQAGs appear in the Deficiency Severity Matrix for EL(97)52 Audits.

Specialist Pharmacy Service

NHS

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

A copy of the Summary Audit report and a copy of the action plan in response to any individual critical findings and/or an overall risk assessment of High and Significant risk 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 the relevant Medical Director of the corresponding NHS England Region for consideration at the next Quality Surveillance Group Meeting.

Appendix 2 Template Letter Announcing an Audit

Template - Audit Confirmation Letter -

Appendix 3 Pre Audit Questionnaire

Pre-audit questionnaire 2016 -

Appendix 4 Template Audit Summary Report

Summary Template MK Draft vers 2E(2).c

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

Chief Pharmacist Template Letter.doc

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

Chief Executive Template Letter.doc