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Briefing Note

Deficiency Severity Matrix for EL(97)52 Audits – Background and Development to 2015

Background

With the formation of NHS London in 2006 came new arrangements for performance. The Director of Pharmaceutical Quality Assurance was informed by NHS London (now NHS England London after re-organisation) that the nationally used EL(97)52 Audit Summary of Results report was no longer 'fit for purpose'. The recipients, the majority with little or no knowledge or experience of aseptic preparation, would not understand the report and be able to take the appropriate action necessary. The audit documentation should be updated with the recommendation that the National Patient Safety Agency's (NPSA) publication 'A risk matrix for risk managers' January 2008[1] be used.

The NPSA's paper tabulates Consequence scores (severity levels) with descriptors and Likelihood scores. In terms of aseptic audits the descriptors are examples of deficiencies found and a risk scoring is obtained by multiplying the Consequence score by the Likelihood (of it happening again) score. The deficiencies found during EL audits are there already in the facilities, documentation, aseptic processing, etc.; they are not likely to happen, they are already happening. Work proceeded to construct a matrix based on severity levels only with no Likelihood scoring component.

The NHS Pharmaceutical Quality Assurance Committee's standard EL(97)52 report form 'Inspection of Unlicensed Aseptic Preparation – Summary of Results' (Annex 1) was reviewed for the following reasons:

- The format was dated and did not align with current NHS performance reporting i.e. unfamiliar to those outside of pharmacy
- For each audit category deficiencies had to be summarised and a result of Critical, Major, Other (minor) or Satisfactory assigned. Important detail is therefore lost from those recipients of just the 'Summary of Results' form and not the full audit report.
- The auditor is required, based on experience, to provide a further summary in the form of an 'Overall risk assessment' of High, Significant or Low from the fourteen categories audited. This, as a worse case, can mean a Critical (immediate action) in the body of the Summary be reported as an overall risk at Significant hence loosing impact and the Critical remaining in place for a number of audits.

The construction of the Matrix proved time consuming and took around a year to the first draft. The layout (see sample below) is based on the NPSA work.

2 Prescription Validation (a)

0	1	2	3	4
Complies / Negligible	**Minor**	**Moderate**	**Major**	**Critical**
All prescriptions signed by approved prescriber	Missing signatures No approved lists of prescribers	No authorised prescriber signature until after preparation Unknown visiting prescriber e.g. from cancer network	No verification until after preparation Prescriber not authorised to prescribe the therapy e.g. house officer prescribing chemotherapy(4)	Preparation administered without prescriber signature Prescriber not authorised to prescribe the therapy e.g. an intrathecal cytotoxic and not on appropriate register (4)

In the Deficiency Severity Matrix the audit categories appear as section titles and compliance statements are on the left hand side of the table. These compliance statements have their origins in the NHSPQA Committee's Audit Aide Memoire which, in turn, is based on the chapters of the NHS Pharmaceutical Quality Assurance Committee's 2006 publication 'Quality Assurance of Aseptic Preparation Services'[2]. This publication is widely recognised as the standard for NHS unlicensed aseptic services. It is used in the NHS alongside the Rules and Guidance for Pharmaceutical Manufacturers and Distributors (the 'Orange Guide')[3].

The body of the Matrix was constructed using the NHSPQA's 'Pharmacy Quality Audit Guidelines (PQAGs)'[4-15]; the introduction to these documents states 'Pharmacy Quality Audit Guidelines are published by the NHS Pharmaceutical QA Committee as aids to auditors and to assist in the application of uniform standards and in the spreading of best practice through the audit process. There are 13 PQAGs dealing with subjects such as Product Release and Internal Audit and examples of deficiencies are given and graded at Critical, Major and Other. These deficiencies and their gradings were entered into the Matrix as 'reference points' and then, from the auditors experience, and using previous audits across London and South East non-compliance statements above and below the reference points were entered. Where applicable, examples of deficiencies from MHRA inspections were also employed. The national audit scheme does not have a Moderate deficiency as used by NPSA and so a decision was made whether Others were Minor or Moderate.

The intention is that the completed Matrix remains a relevant document and is to be reviewed and updated annually. This was first done 2012 and all subsequent years by considering 10 audits with associated deficiencies from each of the audit team with these deficiencies, where relevant, entered into the Matrix.

In 2013, with recognition that 'Quality Assurance of Aseptic Preparation Services'[1] is now 7 years old and the MHRA has published in draft 'GMP Q & A for Manufacturing Specials (MS) license holders[16]'which are equally applicable to unlicensed NHS sites the Matrix was again reviewed to include this important document. Also considered in the 2013 review for inclusion in the Matrix are recommendations from 'Improving Practice and Reducing Risk in the Provision of Parenteral Nutrition for Neonates and Children, A Report from the Paediatric Chief Pharmacists Group[17], Report of the Mid

Staffordshire NHS Foundation Trust Public Inquiry[18] and the Independent review of the circumstances surrounding a serious untoward incident that occurred in the Aseptic Manufacturing Unit, Royal Surrey County Hospital, Professor Brian Toft, October 2012.

The 2013 Matrix review also considered duplication within the original NHSPQA Committee's Audit Aide Memoire. As this was based on the chapters of the publication, some repetition has occurred. For example, many categories cover aspects of documentation. These lines can be reviewed and consolidated into 'Documentation'

Work Alongside the Matrix

In recent years the technical skills of more senior pharmacy staff has reduced. It was therefore decided that alongside the Matrix development that the entire EL(97)52 audit process be documented and made available. The intention being that no part of the EL audit process should come as a surprise to staff in those pharmacy departments being audited and that they could complete their role in the audit cycle.

A list of the current documents is in Annex 2 and the complete documents on:

Future Work

During Matrix development the word 'risk' was carefully avoided. Within the transitional period between use of the existing NHSPQA Committee audit system and the new Matrix system the message came back clearly from a number of audited sites that they would determine the risk locally for their Trust Risk Register based on our audit reports.

In the Matrix system we assign a time line for action to be taken for each severity level:

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

Each auditor will assess the deficiencies found and reflect the level of risk in the frequency they return to the site to review the previous audit report or re-audit. An action plan from the site will assist this decision. The outcomes from all draft audit reports are confirmed before sending to the Trust by peer review. (See also Briefing Note 012 'Deficiency Severity Audits Performed under EL(97)52 and Quality Assurance Auditor's Expectations')

Deficiencies found are traceable through the Matrix to published standards giving the auditor a foundation for the decision made and consistency between auditors. As the NHS re-organises it may be necessary to return and use overall 'risk' once again in our reports; this decision can only be based on the auditor's experience with discussion with the auditor's peers for consistency.

Martin Knowles
Director Pharmaceutical Quality Assurance 17 March 2017

Glossary:

EL(97)52	Executive Letter (97)52
GMP	Good Manufacturing Practice
MHRA	Medicines and Healthcare products Regulatory Agency
PN	Parenteral nutrition

Specialist Pharmacy Service

NHS

Annex 1

…… Region

INSPECTION OF NON-LICENSED ASEPTIC PREPARATION
SUMMARY OF RESULTS

HOSPITAL: **SITE & ACTIVITY:**

DATE OF AUDIT: **DATE OF PREVIOUS AUDIT:**

In accordance with EL(97)52, the aseptic unit at the above site was audited against the Quality Assurance of Aseptic Preparation Services Standards (NHS QC Committee 2001).

The findings are summarised below.

CATEGORY	AUDIT RESULT	COMMENTS/ACTION REQUIRED
Risk Management	C M O S*	
Prescription Validation	C M O S	
Management	C M O S	
Formulation, Stability & Shelf Life	C M O S	
Facilities	C M O S	
Documentation	C M O S	
Personnel, training and competency assessment	C M O S	
Aseptic Processing	C M O S	
Monitoring	C M O S	
Cleaning	C M O S	
Starting Materials, components and other consumables	C M O S	
Product Approval	C M O S	
Storage & Distribution	C M O S	
Internal & External Audit	C M O S	

* C = Requires immediate action
M = Requires action as soon as possible
O = Minor deficiencies
S = Complies with standards

Overall risk assessment (to patient safety): HIGH/SIGNIFICANT/LOW

QA Specialist **DATE:**

Annex 2

Document number (xxx)	Document title
002	EL(97)52 Audit and Reporting Procedure
003	EL(97)52 Auditors trained / accredited to perform EL(97)52 audits
004	Audit record sheets
005	Deficiency severity matrix EL(97)52 audits
006	Executive's Letter and Audit Report Summary
008	Satisfaction Questionnaire
009	Audit Report Tracking Form
010	Briefing Note: Aseptic Service Audits Performed Under EL(97)52
012	Briefing Note: Deficiency Severity Audits Performed Under EL(97)52 and Quality Assurance Auditor's Expectations
017	Briefing Note: Deficiency Severity Matrix for EL(97)52 Audits – Background and Development

References:

1. A risk matrix for risk managers – National Patient safety Agency, January 2008
2. Beaney, A. M., Editor, Quality Assurance of Aseptic Preparation Services, 4th Ed., London, Pharmaceutical Press, London, 2006. ISBN0-85369-615-2
3. Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007, MHRA, Pharmaceutical Press, London. ISBN 978-0-85369-719-0
4. Pharmacy Quality Audit Guideline, NHS Pharmaceutical Quality Assurance Committee, PQAG 15 Risk Management, 3/2008
5. Pharmacy Quality Audit Guideline, NHS Pharmaceutical Quality Assurance Committee, PQAG 13 Prescription Verification 08/2007
6. Pharmacy Quality Audit Guideline, NHS Pharmaceutical Quality Assurance Committee, PQAG 10 Good Aseptic Technique 08/2007
7. Pharmacy Quality Audit Guideline, NHS Pharmaceutical Quality Assurance Committee, PQAG 9 Validation (Process and Operator) 08/2007
8. Pharmacy Quality Audit Guideline, NHS Pharmaceutical Quality Assurance Committee, PQAG 8 Maintenance and Technical Agreements 08/2007
9. Pharmacy Quality Audit Guideline, NHS Pharmaceutical Quality Assurance Committee, PQAG 7 Aseptic Facilities (Draft) 06/2008
10. Pharmacy Quality Audit Guideline, NHS Pharmaceutical Quality Assurance Committee, PQAG 6 Internal Audit 08/2007
11. Pharmacy Quality Audit Guideline, NHS Pharmaceutical Quality Assurance Committee, PQAG 5 Capacity Planning 08/2007
12. Pharmacy Quality Audit Guideline, NHS Pharmaceutical Quality Assurance Committee, PQAG 4 Training Manuals and Training Records 08/2007
13. Pharmacy Quality Audit Guideline, NHS Pharmaceutical Quality Assurance Committee, PQAG 3 Product Release 08/2007
14. Pharmacy Quality Audit Guideline, NHS Pharmaceutical Quality Assurance Committee, PQAG 1 Disinfection / Sanitation Prior to Transfer
15. Pharmacy Quality Audit Guideline, NHS Pharmaceutical Quality Assurance Committee, PQAG 14 Clean room Garment Laundering 8/2007
16. GMP Q & A for Manufacturing Specials (MS) license holders, MHRA, 2013 Note: This is currently a draft out for comment.
17. Improving Practice and Reducing Risk in the Provision of Parenteral Nutrition for Neonates and Children, A Report from the Paediatric Chief Pharmacists Group, November 2011,
18. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Chaired by Robert Francis QC, 2013, TSO, HC 898-I, HC 898-II, HC 898-III Note: Relevant pharmaceutical aspects only
19. Independent review of the circumstances surrounding a serious untoward incident that occurred in the Aseptic Manufacturing Unit, Royal Surrey County Hospital on Monday, 18 June 2012, Professor Brian Toft OBE, October 2012