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Briefing Note

Deficiency Severity Audits Performed Under EL(97)52 and Quality Assurance Auditor's Expectations

Introduction

This is an audit system developed by Pharmaceutical Quality Assurance during 2008 and first issued for use in January 2009. The system will be continually reviewed and improved through application. Comments are therefore important and welcomed and should be communicated to the Regional Pharmaceutical Quality Assurance team.

The EL(97)52 audits of unlicensed aseptic facilities performed are not *per se* risk assessment audits. The deficiencies identified already exist. They are likely to persist unless found by unit staff or determined by another internal / external audit or inspection and followed by subsequent action taken to remove or reduce them.

The deficiencies in the EL(97)52 audit are assigned a level of severity. These levels of severity cannot be directly compared with those assigned in the Trusts own risk assessment procedures.

The Deficiency Severity Matrix

The severity of deficiencies found will be determined using the Deficiency Severity Matrix constructed with format based on National Patient Safety Agency's publication 'A risk matrix for risk managers – January 2008. When the matrix was first constructed where possible deficiency severities were referenced to NHS guidance and standards which in turn had their origins in the MHRA's 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors' (commonly known as the 'Orange Guide'). The matrix also reflects EL(97)52 auditors's experience and further developed areas where no NHS guidance previously existed, for example, PN compounders.

In the summer of 2016 a new edition of the 'Quality Assurance of Aseptic Preparation Service' was published by the Royal Pharmaceutical Society. Part A of the 5th edition is also titled 'Standards' and the text clearly lays these out; they are now expanded and more comprehensive. The Deficiency Severity Matrix has been thoroughly revised to align it with these standards and makes reference to the standards when reporting any deficiency found.

Within the Deficiency Severity Matrix deficiencies are assigned a numerical value with an associated colour: 1 dark yellow – minor, 2 yellow – moderate, 3 amber – major and 4 red – critical. Compliance is not scored. It is not possible for the matrix to describe every deficiency that the auditor may encounter nor will some deficiencies found fit exactly those described in the matrix. The auditor will determine the 'best fit' for the deficiency in the matrix but also consider any local mitigation that may increase or reduce the severity from the score assigned. It is anticipated that the consistency between auditors will be improved using this approach.
During the audit 'Audit Record Sheets' are used to assist the auditor to cover the categories in the detail required. Deficiencies found are marked with an asterisk and then later scored using the Deficiency

Severity Matrix. In the summary scores are replaced by their associated colours. This is to assist managers less familiar with pharmaceutical aseptic units to focus on what deficiencies may represent higher risks to their patients and the organisation.

It is intended that future development work will see the scores being used for benchmarking purposes between subsequent site audits or between sites.

Audit Frequency

The scope and detail examined within the EL(97)52 audits has increased since they were first started in 1995 and this audit system reflects this. It is now therefore unlikely that auditors will be able to cover all categories in sufficient depth but will work on a risk assessment basis determined during the audit. The audit report therefore reflects observations and discussions that took place during the audit and any subsequent confirmation of detail within the draft audit report between the auditor and trust. Categories not audited will be looked at first during the subsequent audit following review of the previous action plan. It is therefore likely that within the 12 to 18 month EL(97) audit frequency that sites will now be visited twice.

For issues around the facilities not declared by the trust and not examined by the auditor should the trust assume a satisfactory state of affaires.

Quality Assurance Auditor's Post Audit Expectations

National reporting requires the auditor to determine an 'Overall Risk Assessment to Patient Safety' of High, Significant or Low. The Deficiency Severity Matrix will assist consistency between auditors in making this decision.

The determination of risk from individual deficiencies, groups of deficiencies or the whole report lies with the trust audited and its senior pharmacy staff. The auditor cannot, on the audit day, fully appreciate the organisation of the aseptic unit, trust, staff, budgetary constraints, service development, etc. Risk assessment will be reported through local trust systems.

The trust's response to an EL(97)52 audit is, for this new audit system, no different to the replaced system and that is an action plan that addresses the deficiencies identified and includes a timescale for completion. It is advised that the detailed 'Summary of Recommendations & Actions to Address Individual Deficiencies' that appears as
Appendix 2 be copied and used as the action plan. The auditor will concur with the action plan and sign off the audit as complete providing actions are considered appropriate and timely.

The frequency of re-audit will reflect the number of deficiencies found and the overall risk assessment.

The new audit system describes deficiency action times:

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

The criticism most often encountered is that the expected action period for 'Major' deficiencies of three months cannot be achieved. For deficiencies such as obsolete facilities or isolators it is accepted by the auditor that replacement is impossible in such a tight timescale. To build a new unit may take years from

inception to completion of work on site and a replacement isolator could have a lead time of up to twelve months once an order is placed. However the importance of a deficiency set at this level is that the trust must start to address the deficiency and, if appropriate, start additional control measures to reduce risk. These measures are perfectly acceptable to the auditor and if put into place will reduce the severity of the deficiency in subsequent audits until the deficiency is resolved completely.

The practice of elevating the severity of a deficiency from a previous audit should a subsequent audit show that it not been addressed has also received comment. This is the practice adopted by MHRA during GMP inspections and is in the authority of EL(97)52 auditors also should it be necessary. 'Minor' deficiencies require action within twelve months and most are relatively simple to resolve; action within that period must be carried out. Many cases of patient harms stem from a number of relatively minor deficiencies aligning at a particular time and under exceptionall circumstances. To address 'Minor' deficiencies within their action timescales will perhaps break this potential alignment.

Martin Knowles
Director Pharmaceutical Quality Assurance 29 August 2016

Glossary:

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

References:

1. Beaney, A. M., Editor, Quality Assurance of Aseptic Preparation Services: Standards 5th Ed., Royal Pharmaceutical Society, London, 2016.
2. Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2016, MHRA.
3. Midcalf, B., Phillips, W. M., Neiger, J.S., Coles, T. J., Editors, Pharmaceutical Isolators, Pharmaceutical Press, London. 2004, ISBN 0-85369-573-3
4. A risk matrix for risk managers – January 2008, National Patient Safety Agency