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Briefing Note

Deficiency Severity Matrix for EL(97)52 Audits 2016 – 2017 Update

1. Background

The audit system developed and first issued for use in 2009 has provided, through several update versions a stable and useful tool for both auditors and sites audited under EL97(52). Both parties know what is expected of each other i.e. there are no audit surprises. However the NHS has once again been through a number of re-organisations that have changed the NHS recipients of the audit reports also updates to key documentation used as the foundation for EL(97)52 audits. This briefing note serves to describe these changes and how the audit system has been updated to reflect them.

2. NHS Organisation in 2016 - 2017 (with Particular Reference to Pharmaceutical Quality Assurance)

2.1 Administration of the NHS now sits within NHS England and the geography is divided into four NHS Regions: NHS England North, NHS England Midlands and East of England, NHS England South and NHS England London. The latter reflects the size, population number, diversity and health requirements of London as a major city.

It is worth noting that these 'new' Regions are not co-terminus with the NHS geographies of previous re-organisations or even new organisations such as Health Education England. This presents a minor problem as many of the regional Quality Assurance services retain responsibilities for previous regional geographies. Perhaps the most complex of these is Regional Pharmaceutical Quality Assurance, London and South East originally covering what was 'North East Thames', 'North West Thames', 'South East Thames', 'South West Thames', South Central. In the current NHS organisation the geographies we cover are now known as NHS England London and two thirds of NHS England South (South East Coast, Wessex and Thames Valley).

Only NHS England London currently retains a Chief Pharmacist.

2.2 'London and South East developed 'Specialist Pharmacy Services encompassing overarching Quality Assurance, Medicines Information, Procurement and primary and secondary clinical pharmacy services in the late 1980's as a means of protecting those services, deemed to be valuable, from loss through NHS re-organisation.

In a similar way the formation of the current structure of the Specialist Pharmacy Service has protected these valuable services in England.

3. Publication of the 5th Edition (2016) of the Quality Assurance of Aseptic Preparation Services: Standards Handbook (Ed. Alison M Beaney D Prof, MSc, FRPharmS)

The Deficiency Severity Matrix was developed from the standards published in the 4th Edition, 2006 and subsequently updated from a number of publications and reports in the intervening period such as:

- GMP Q & A for Manufacturing Specials (MS) license holders
- 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
- 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
- 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

There were some concerns that we were seen to be writing 'new standards' by including guidance and recommendations from the above documents in the Matrix and deficiencies identified could only be reported as 'Comments' before publication of a 5th Edition where they would be incorporated as standards. The recommendations made in the 'Toft' Report are intended to prevent a similar incident of patient harm being repeated. The decision was made that these recommendations should be included in the Matrix and given a realistic severity rating to ensure sites responded appropriately should they be identified through audit. The 5th Edition has now developed new standards to address the causes of many of the errors made and deficiencies found in the last 10 years. In addition, there are now plans to allow the timely inclusion of additional standards should it become necessary.

4. Deficiency Severity Matrix for EL(97)52 Audits January 2017 Update

A comprehensive review and rewriting of the Matrix and supporting documentation has taken place over the last 6 months to produce a new comprehensive audit tool for both EL(97)52 auditors and Trust pharmacy staff:

Key points:

- All the standards contained within the 5th Edition are incorporated into the Matrix
- The Audit Aide Memoire written for EL(97)52 auditors against the 5th Edition states these standards. Aide Memoire standard texts have been reviewed and in some cases modified to improve clarity.
- The 5th Edition of the Quality Assurance of Aseptic Preparation Services: Standards Handbook 2016 is a comprehensive publication and some standards are applicable for more than one chapter. Where standards appear more than once a decision has been made where it is believed, that the auditor would wish to examine it in the audit. This avoids returning to the same issue for a second time during the audit.
- The entries against each standard in the 4th Edition, 2015 issue of the Deficiency Severity Matrix have been matched with the standards in the 5th Edition.
- There are more standards in the 5th Edition than the 4th and additionally some 4th Edition standards have been split into separate components. There are consequently now areas of the Matrix with no severity entries. It is not intended to invent deficiencies to fill the Matrix. Deficiencies against these standards found during audits will be assessed for severity by the Regional Quality Assurance team and entered into the Matrix. The Matrix will then be re-issued at regular intervals.
- In recent years auditors have found it increasingly difficult to cover, in sufficient detail, all aspects of an EL(97)52 audit in a one day site visit. Therefore a second visit to the same site has been common practice to ensure all aspects of the audit are covered. Areas to examine first are decided by considering the local risks in the audit opening session. The increase in standards to cover will make even this approach more of a challenge. There is no option to increase the number of auditors or the audit days on site.