

Date: 05/09/2016

FREEDOM OF INFORMATION REQUEST FOI/012991 -

I wish to request your Aseptic unit's most recent EL (97)52 audit report.

Please see below

The unit is classed as low risk and must be audited between 12-18 months of the last. The next audit is due Nov 2016

QUALITY CONTROL NORTH WEST – QUALITY ASSURANCE

INSPECTION OF UNLICENSED ASEPTIC PREPARATION SUMMARY OF RESULTS

Region	West Midlands	Hospital Trust	The Dudley Group of Hospitals	Site	Russell's Hall
--------	---------------	----------------	-------------------------------	------	----------------

In accordance with EL(97)52 the aseptic unit at the site named below was audited against the Quality Assurance of Aseptic Preparation Services Standards (NHS QA Committee 2006). The findings are summarised below.

Date of audit	30 th June 2015	Overall risk assessment to patient safety	(Assigned risk in bold) High / Significant / Low
Date of previous audit	23 rd June 2014		
Date proposed for re audit	July 2016		

Deficiencies	Action
Critical	Critical deficiencies that require immediate action (within 24 hours)
Major	Major deficiencies that require action within three months
Other / Minor	Other / Minor deficiencies that need to be addressed within twelve months
Satisfactory	Complies with standards

Category	Audit Result	Summary of Comments / Action Required (see full report for details)
Minimising Risk with Injectable Medicines	Satisfactory	
Prescription Verification	Satisfactory	
Management	Other/Minor	Some capacity issues
Formulation, Stability & Shelf-Life	Satisfactory	
Facilities	Satisfactory	
Pharmaceutical Quality Systems	Satisfactory	
Personnel, Training & Competency Assessment	Satisfactory	
Aseptic Processing	Satisfactory	
Monitoring	Other/Minor	System for incident reporting requires review
Cleaning & Sanitisation	Other/Minor	Minor adherence issues
Starting Materials, Components & Consumables	Satisfactory	
Product Approval	Satisfactory	
Storage & Distribution	Satisfactory	
Internal & External Audit	Satisfactory	

Overall Comments:

The service is well managed and is performing to a high level. Service capacity is currently under review following a restructure and the service should be underpinned by a robust capacity plan.
