Completing Self Inspection Audits in the Pharmacy Aseptic Unit (AU)-The Tallaght Experience

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INTRODUCTION

H/PICs are national Irish guidelines of professional practice developed by pharmacists working in aseptic compounding units. Chapter 9 advises that 'a self -audit programme should be established and conducted in an independent and detailed way by designated, trained, competent people'[1]. In order to adhere to these guidelines a self-audit of the premises and equipment section (Chapter 3) of the H/PICs was completed. This section was selected as the aseptic unit (AU) was built in 1998 and guidelines have changed since this time.

OBJECTIVES

To complete a self-audit against chapter 3 of the H/PICs guideline.

To implement changes where possible.

To escalate issues to the hospital's executive management team (EMT) where required.

METHODS

Training courses specifically geared for personnel working in pharmacy AUs were sourced and attended. Skilled auditors within the hospital setting were identified and these auditors were shadowed. This in turn led to the further training with this core group of experts.

An audit checklist was designed using a combination of templates presented at training courses. (See table 1)

An audit was completed in March 2015.

Non conformances (NC) were graded and actions required were detailed.

Corrective and preventative actions (CAPA) were put in place where possible. (See table 2)

Major/critical NCs not corrected in the pharmacy were escalated to the EMT for their support.

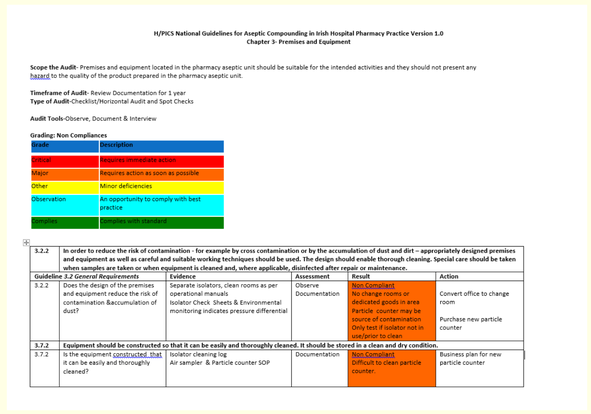
Unresolved NCs were escalated to hospital group level and placed on the Dublin Midlands Hospital Group risk register.

RESULTS

Training courses enabled the author to acquire the skills to complete this self audit. Identifying and linking in with skilled auditors in the laboratory enabled local support.

RESULTS (continued)

A checklist for the premises and equipment section of the H/PICs was prepared (see table 1). The statement, taken from the guideline was converted into individual questions. Using this template an audit was completed. The evidence to support compliance was documented. The type of assessment completed was listed. The result indicated the level of compliance with the guideline and it was graded according to the key in table 1. The scoring system applied was discussed with an audit inspector from Northern Ireland at a follow up training day. The proposed actions were detailed.



H/PICS National Guidelines for Aseptic Compounding in Irish Hospital Pharmacy Practice Version 1.0
Chapter 3- Premises and Equipment

Scope the Audit- Premises and equipment located in the pharmacy aseptic unit should be suitable for the intended activities and they should not present any hazard to the quality of the product prepared in the pharmacy aseptic unit.

Timeframe of Audit- Review Documentation for 1 year
Type of Audit-Checklist/Horizontal Audit and Spot Checks

Audit Tools-Observe, Document & Interview

Grading: Non Compliances

Grade	Description
Critical	Requires immediate action
Major	Requires action as soon as possible
Other	Minor deficiencies
Observation	An opportunity to comply with best practice
Complies	Complies with standard

3.2.2	In order to reduce the risk of contamination - for example by cross contamination or by the accumulation of dust and dirt – appropriately designed premises and equipment as well as careful and suitable working techniques should be used. The design should enable thorough cleaning. Special care should be taken when samples are taken or when equipment is cleaned and, where applicable, disinfected after repair or maintenance.				
Guideline 3.2 General Requirements		Evidence	Assessment	Result	Action
3.2.2	Does the design of the premises and equipment reduce the risk of contamination &accumulation of dust?	Separate isolators, clean rooms as per operational manuals Isolator Check Sheets & Environmental monitoring indicates pressure differential	Observe Documentation	Non Compliant No change rooms or dedicated goods in area Particle counter may be source of contamination Only test if isolator not in use/prior to clean	Convert office to change room Purchase new particle counter
3.7.2	Equipment should be constructed so that it can be easily and thoroughly cleaned. It should be stored in a clean and dry condition.				
3.7.2	Is the equipment constructed that it can be easily and thoroughly cleaned?	Isolator cleaning log Air sampler & Particle counter SOP	Documentation	Non Compliant Difficult to clean particle counter	Business plan for new particle counter

Table 1-Completed Checklist-Chapter 3 Premises & Equipment H/PICS

There were 32 sections in this chapter and 15 NCs of various grades identified. 9 of these were rectified within pharmacy department resources. For example (see table 1) the particle counter used as part of the quality management system was in itself, a potential source of contamination. The device was old, difficult to clean and contained paper. This device was graded as a major NC under a number of statements. The corrective action (action taken to eliminate the cause) was to only use this equipment during downtime to avoid the contamination risks. The preventative action (action taken to eliminate the cause before it happens) was to source a new model which complied with the guideline. A business case was prepared and the product was purchased.

The results of the audit were presented to individual members of the EMT. NCs requiring financial support, for example purchasing closed systems, updating the current facility and increasing staffing levels were highlighted (see table 2).

RESULTS (continued)

Guideline No.	Risk	Non Conformance Grade	Corrective Action (CA) or Current Controls	Date completed by	Preventative Action (PA)	Action to date	Final Outcome
3.2.2 Are careful and suitable working techniques employed to reduce the risk of contamination?	Chemotherapy and Monoclonal antibodies (MABs) are prepared in the same isolator. Risk of cross contamination.	Major Non Compliance	Prepare MABs in separate isolator	11/05/15	Purchase a closed system which would prevent risk of cross contamination across all products. Cost €100,000 but system would pay for self due to associated vial savings.	Business case forwarded to EMT on 04/09/15.	Waiting final financial approval.
3.2.1 Is the capacity (staff and space) sufficient to enable a logical workflow?	AU designed in 1998 at that time preparing 200 items/month in 2016 preparing 1000 items/month.	Major Non Compliance	Maximise throughput by inputting process improvement tools. Outsource cost neutral products. Prioritise compounding over all other activities.	Ongoing	Upgrade the infrastructure of the AU to support the workload.	No capital funding available in 2016.	Placed on Dublin Midlands Hospital Group Risk Register
	AU capacity plan calculator indicates a staffing deficit of 1WTE pharmacist & 2 WTE technicians based on workload.				Increase staffing levels to support the workload.	Business case forwarded to EMT in December 2016, resubmitted with changes on 10/03/16.	Waiting final approval.
3.2.4 Are washing and cleaning activities a source of contamination?	Sink in change facility and next to preparation room. No dedicated cleaning area. Risks of contamination.	Critical	Monthly QC activities and SOPs in place which monitors the microbial activity in this location.	Ongoing	Upgrade AU to comply with guidelines.	No capital funding available in 2016.	Placed on Dublin Midlands Hospital Group Risk Register

Table 2 –Actions Taken in Response to NCs

There are major staffing deficits in the AU and a business case to rectify these shortages was prepared. This awaits final approval by the EMT.

The audit highlighted many deficiencies in the infrastructure of the AU. It was built in 1998 when activity was 200 item/month, it is now 1000. There are no change facilities (table 1) and there is a sink adjacent to the preparation room (table 2). These structural risks/constraints could not be remedied despite consultation with facilities and estates department. It is agreed that a new AU is needed, however this requires significant capital funding (>€2 million). This upgrade has been highlighted at hospital group level and with the NCCP. In the meantime the risks have been added to the Dublin Midlands Hospital Group risk register by the EMT detailing the controls currently in place.

CONCLUSION

Self-audit is an invaluable tool and aids compliance with H/PICs guidelines. It allows the identification of high risk activities. Grading NCs assists in the prioritisation of process improvement projects. Audit supports the feedback of performance against recognised guidelines to management. This has assisted in raising their awareness and gaining their support. It has resulted in positive changes for the AU and highlighted future needs.

REFERENCE

1. H/PICs National Guidelines for Aseptic Compounding in Irish Hospital Pharmacy Practice

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