

Do You Spot a Problem?

Use of spot inspections as a tool to reduce compliance risks year-round

Background

Quality Management performs Operational System Audits once per year in each laboratory department including Accessioning, Red Cell Serology, Viral Marker, and Nucleic Acid Testing. Compliance issues can arise during the time span between annual audits and possibly go unnoticed until an outside inspecting agency arrives or until the time of the next Operational Audit. In an ever changing industry, spot inspections which are performed monthly and are unannounced are a sound way to increase staff awareness of regulations and internal Standard Operating Procedures (SOPs). Spot inspections are also an effective tool for continuous monitoring of known risk areas.

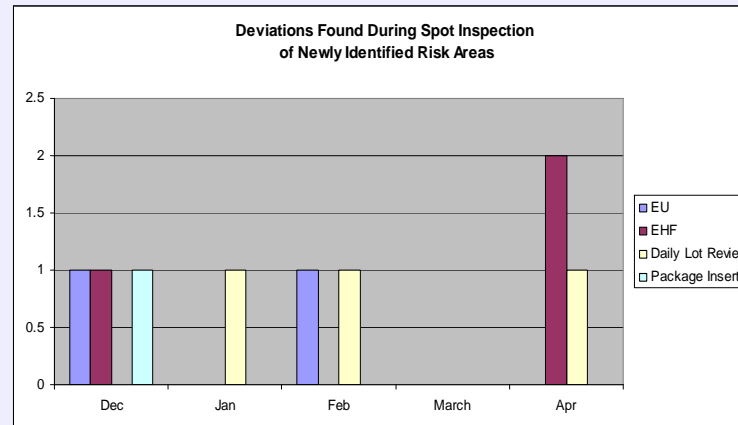
Methods

Deviation data for 2007 was analyzed to discern recurring problem areas that could easily be audited during a spot inspection. European Union (EU) requirements were also analyzed to identify common findings by the agency. The collective data was then utilized to determine which areas and processes within the operation would benefit from additional focus. Data revealed the Spot Inspection checklist should include review of Equipment History Folders, Daily Lot Review Checklists, package insert version, and EU cleanliness standards. An excerpt of the Spot Inspection Checklist is shown below.

Item to Review	Y/N/NA	Finding/Immediate Corrective Action/Comments	Event #	Performed by:	
				EC	Date
Verify: <ul style="list-style-type: none"> • Work surfaces clean, free of dust, and in good condition • No reagents stored on floor • Areas under counters and behind equipment are dust free • No personal items such as toys/pictures are present • Biohazard waste containers are kept closed when not in use 					
Review one Equipment History Folder for the following: <ul style="list-style-type: none"> • DTS 5030 • Randomly select one month's PM/QC documentation for review • PIRs – review 3 randomly selected PIRs 					

Results

The addition of these items on the Spot Inspection Checklist has proven effective in that 9 deviations in these areas were discovered in the 5 months following implementation of the new checklist. Because the same Spot Inspection Checklist is used in all departments, spot inspections are also effective in quickly identifying problems affecting multiple departments simultaneously.



Conclusion

The performance of spot inspections continuously brings to the forefront non-compliances that might otherwise not be regularly detected. By including new regulations on the checklist, those regulations are reinforced with the staff and the overall compliance of the operation is improved. Revising the Spot Inspection Checklist periodically to include newly identified risk areas maximizes the effectiveness of the spot inspection.

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