The Quality Mindset: Driving Excellence in Clinical Departments

[1]Lisa Finney, [1]Tiffany Jourdan

[1]Nevada Donor Network, Las Vegas, Nevada, USA

Background:

Accurate documentation and traceability are critical components of compliant tissue banking operations. Within the Tissue Services department, two documentation processes, freezer storage tracking and sterilization sheet management were identified as recurring sources of discrepancies and documentation-related nonconformances. These issues created traceability challenges and required multiple Corrective and Preventive Actions (CAPAs). Recognizing the need for sustainable improvement, the Tissue Services department partnered with Quality Regulatory Affairs (QRA) to evaluate processes, identify root causes, and implement system-based solutions to strengthen compliance and reduce errors.

Methods:

Freezer documentation historically relied on paper logs maintained on individual freezers to track local storage. This system resulted in incomplete entries, misplaced documentation, and multiple log pages when tissue was relocated. In 2023, more than 50 documentation discrepancies were identified, prompting a transition to electronic storage tracking within iTransplant. To support the change, Tissue Services implemented monthly internal freezer audits using a standardized audit form to verify tissue location and documentation accuracy. QRA provided additional oversight through routine freezer audits, initially conducted monthly and later transitioned to quarterly. Audit findings were jointly reviewed to identify trends, guide staff training, and inform SOP updates and corrective actions

Sterilization documentation was also evaluated due to recurring issues including missing sterilization stickers, absent biological indicator (BI) information, and illegible run receipts. Collaboration with hospital Sterile Processing leadership led to updates to the departmental sterilization reference guide, improved communication pathways, and workflow modifications. Technicians retrieving instruments now perform the first documentation review, followed by a secondary supervisory review to ensure completeness and address discrepancies with Sterile Processing. Weekly supervisory monitoring was implemented to track trends and ensure timely resolution.

Results:

Implementation of electronic freezer tracking and structured audit practices significantly reduced documentation discrepancies and improved traceability. The revised sterilization sheet workflow resulted in consistently complete and legible documentation, with errors significantly reduced within the first two months. Year-to-date quality reviews have identified no findings related to sterilization documentation or freezer documentation (Figures P0001-1 and P0001-2, respectively).

Conclusion:

Collaboration between Tissue Services and QRA played a critical role in reducing documentation-related nonconformances within the clinical department. Through electronic tracking, structured audit practices, standardized workflows, and cross-department communication, the department strengthened compliance, improved traceability, and fostered a culture of continuous quality improvement.

Keywords: Biological Indicator (BI), sterile processing, tissue documentation, tissue traceability, quality reviews. Quality internal audits, process improvement

Clinical Trial Registry: N/A

Data Disposition: N/A

Disclosures: I have no relevant relationships or conflicts of interest

Competing Interests: The authors declare no competing interest

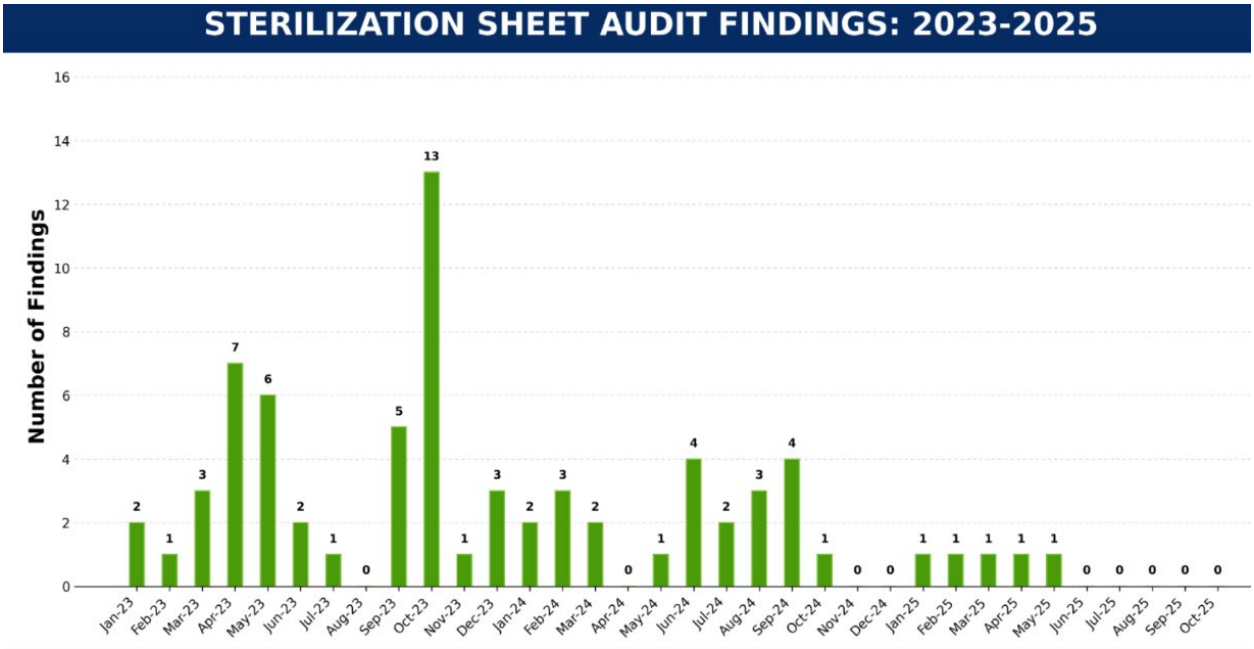
Ethical Approval: This study did not involve human participants, their data or biological material.

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Corresponding Author: Tiffany Jourdan

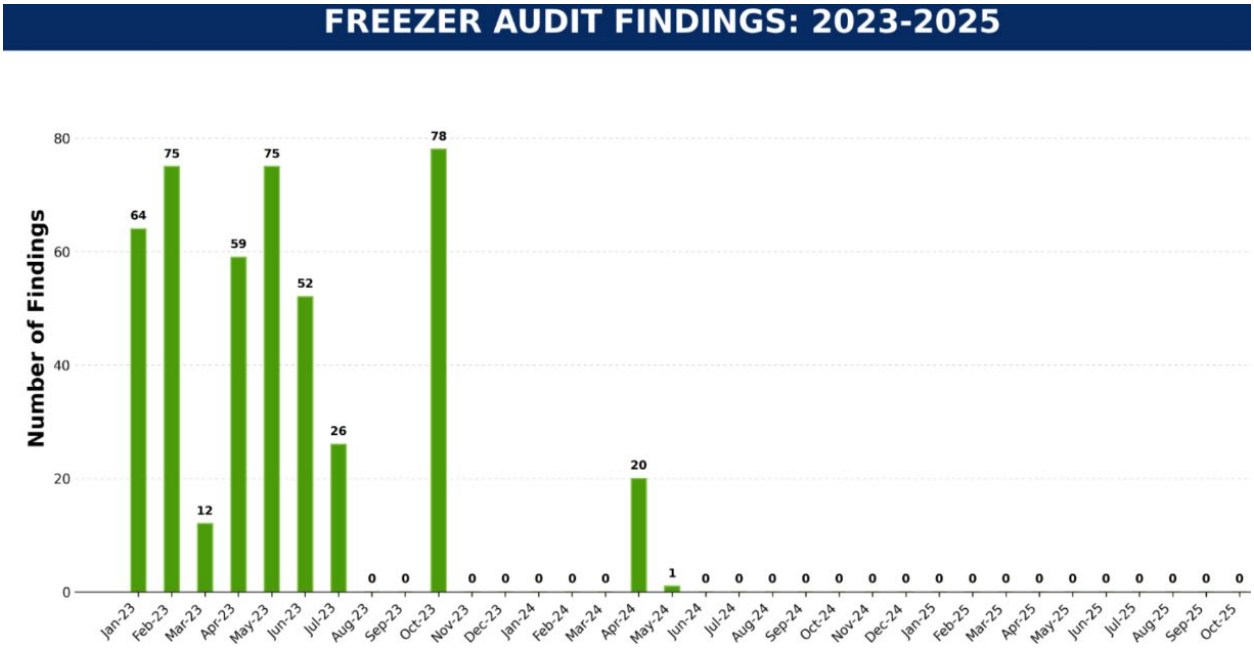
Figures:

P0001-1 – Sterilization Sheet Audit Findings



Sterilization sheet audits were performed starting in 2023, graph shows audits findings identified from 2023-2025.

P0001-2 – Freezer Audit Findings



Freezer audits were performed starting in 2023, graph shows audits findings identified from 2023-2025.

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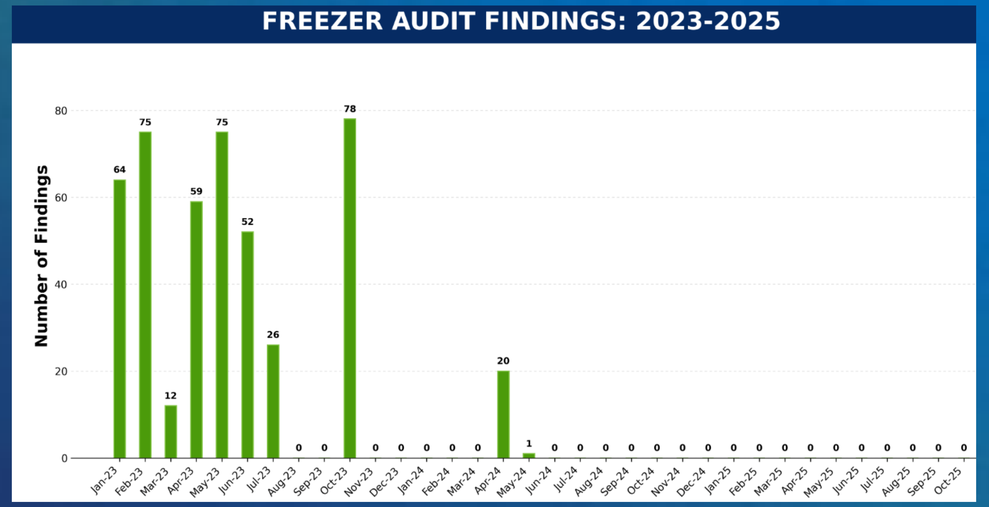
Authors: Lisa Finney, Director of Quality and Regulatory Affairs and
Tiffany Jourdan, Manager of Tissue Services

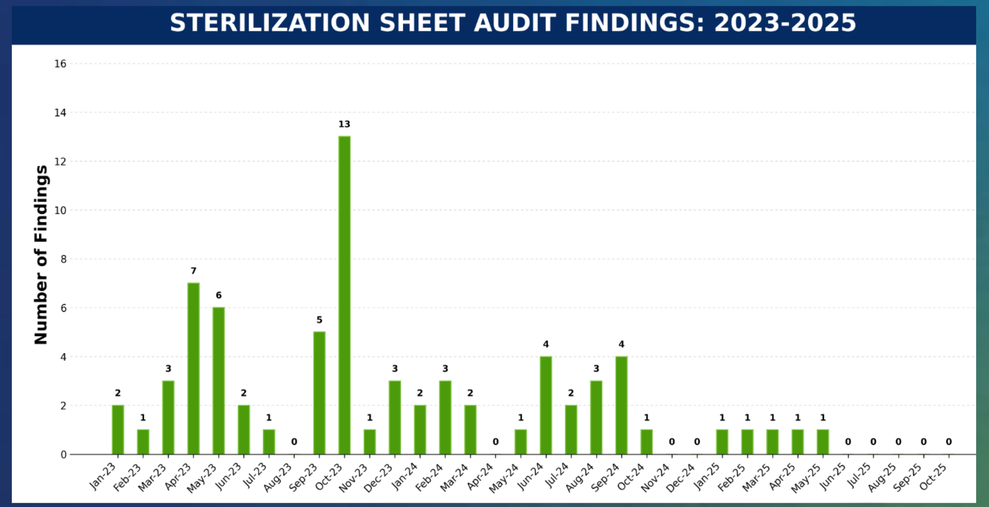
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Approach

Freezer documentation historically relied on paper logs maintained on individual freezers to track local storage. This system resulted in incomplete entries, misplaced documentation, and multiple log pages when tissue was relocated. In 2023, more than 50 documentation discrepancies were identified, prompting a transition to electronic storage tracking within iTransplant. To support the change, Tissue Services implemented monthly internal freezer audits using a standardized audit form to verify tissue location and documentation accuracy. QRA provided additional oversight through routine freezer audits, initially conducted monthly and later transitioned to quarterly. Audit findings were jointly reviewed to identify trends, guide staff training, and inform SOP updates and corrective actions. Sterilization documentation was also evaluated due to recurring issues including missing sterilization stickers, absent biological indicator (BI) information, and illegible run receipts. Collaboration with hospital Sterile Processing leadership led to updates to the departmental sterilization reference guide, improved communication pathways, and workflow modifications. Technicians retrieving instruments now perform the first documentation review, followed by a secondary supervisory review to ensure completeness and address discrepancies with Sterile Processing. Weekly supervisory monitoring was implemented to track trends and ensure timely resolution.





Outcome

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A **quality** mindset turns compliance into ***excellence***.

Conclusion

Collaboration between Tissue Services and QRA played a critical role in reducing documentation-related nonconformances within the clinical department. Through electronic tracking, structured audit practices, standardized workflows, and cross-department communication, the department strengthened compliance, improved traceability, and fostered a culture of continuous quality improvement.