Optimization of Zero Count Parameter Settings to Improve Equipment Reliability and Reduce Maintenance Costs

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Abstract

The purpose of this research was to optimize the zero-count verification methodology used in non-viable **particle counting equipment** for **environmental monitoring** in pharmaceutical manufacturing. The existing practice required a single-sample zero count with an absolute zero acceptance criterion performed before every sampling point, resulting in excessive zero count failures, unnecessary equipment downtime, and increased maintenance costs without measurable improvement in equipment performance. Historical zero count failure data and maintenance records were analyzed to evaluate the impact of the existing methodology. **Manufacturer calibration** guidelines, which define zero count verification as a ten-sample run with acceptance based on the last six samples meeting zero count criteria, were used as the technical basis for revising both the acceptance criteria and the frequency of zero count execution. The revised methodology implemented a single zero count per sampling session, with additional zero count tests performed only under predefined trigger conditions. Results demonstrated a substantial reduction in zero count failures, improved equipment availability, and a significant decrease in maintenance interventions. These findings demonstrate that aligning zero count verification practices with **manufacturer calibration** guidance improves equipment reliability and operational efficiency in pharmaceutical **environmental monitoring** programs.

Key Terms — Environmental monitoring, manufacturer calibration guidelines, particle counting equipment, zero count verification

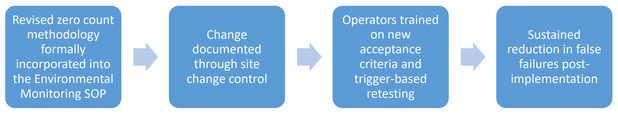
Problem Statement

This research evaluates and optimizes the zero-count verification process used in non-viable particle counters for pharmaceutical environmental monitoring. The current practice—performing a single-sample zero count with an absolute zero acceptance criterion before each sampling point—has resulted in frequent failures and unnecessary equipment downtime. Historical failure data were analyzed, and manufacturer calibration guidelines recommending a 10-sample run with acceptance based on the final six samples were used as the technical basis for revising acceptance criteria. The study also assessed the feasibility of performing a single zero count per monitoring session rather than before each sampling point. The revised methodology was implemented under controlled conditions, demonstrating improved zero-count stability, reduced failure rates, decreased maintenance frequency, and measurable cost savings related to equipment downtime and service repairs.

Methodology

A quantitative, retrospective comparison was conducted to optimize zero-count verification in non-viable particle counters used for pharmaceutical environmental monitoring. Baseline data were collected under the existing single-sample, absolute-zero method performed before each sampling point. A revised manufacturer-aligned approach was implemented using a 10-sample zero count with acceptance based on the last six samples and reduced testing to one per sampling session with defined re-test triggers. Performance was evaluated by comparing failure rates, equipment downtime, and maintenance impacts before and after implementation.

Process Implementation



Results and Discussion

DESIGN PHASE

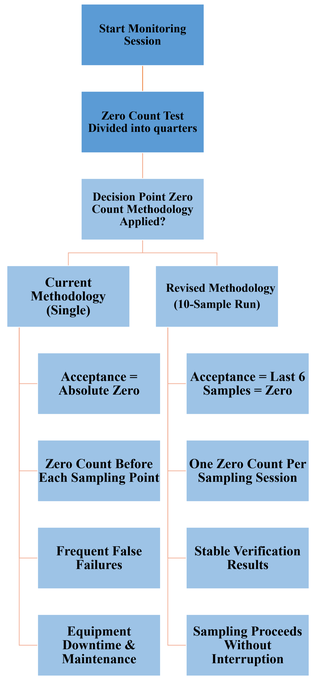


Figure 1: Comparison of current and revised zero count verification methodologies

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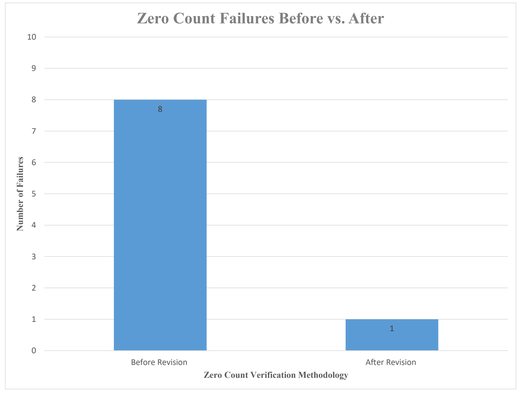

Figure 2: Units unavailable due to zero count failures before and after implementation of the revised methodology (8 vs. 1).

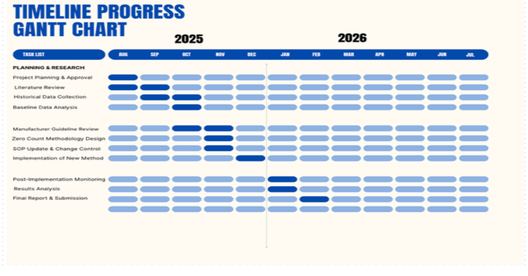

Figure 3: Project Timeline

Results and Discussion

Zero Count Failures caused 8 of 10 units to become unavailable under the previous methodology.

After implementing the revised manufacturer-aligned approach only one confirmed contamination related failure occurred.

Equipment availability improved substantially, reducing downtime and unnecessary maintenance events.

Maintenance cost avoidance was significant, with service interventions averaging $1,500 per unit.

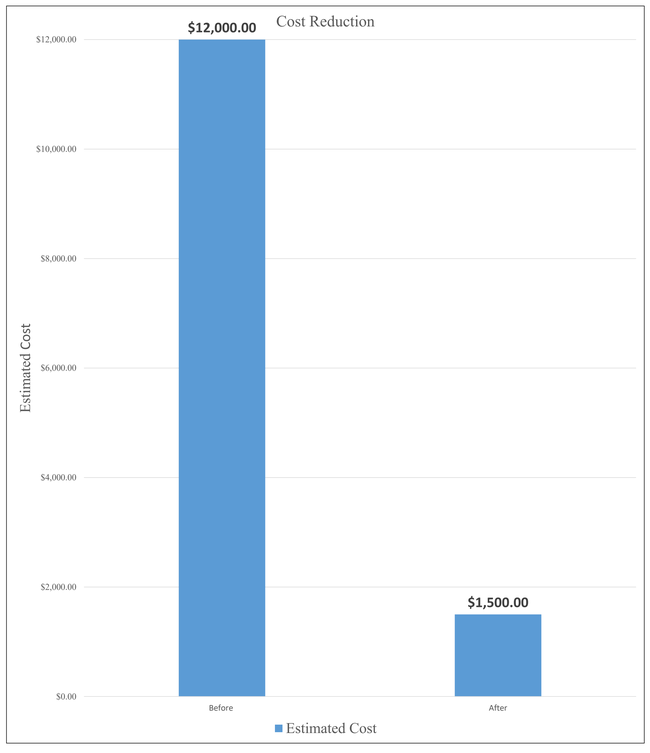

Figure 4: Estimate based on an average service intervention cost of ~$1,500 per unit. Total maintenance cost decreased from ~$12,000 (Before) to ~$1,500 (After), resulting in an estimated savings of approximately $10,500.

Conclusions

This study demonstrated that the previous zero-count practice—single-sample absolute-zero testing before every sampling point—generated excessive false failures, equipment downtime, and increased maintenance costs. Aligning zero-count verification with manufacturer calibration guidelines by implementing a 10-sample run once per sampling session significantly improved equipment reliability and availability. Post-implementation results showed a major reduction in failures, with only one confirmed contamination-related event recorded. Overall, the revised methodology provides a standardized, efficient, and cost-effective framework for improving environmental monitoring operations.

Acknowledgements

I would like to express my sincere gratitude to my advisor, **Rafael A. Nieves-Castro, PharmD**, for his guidance, mentorship, and continuous support throughout the development of this project. His expertise and constructive feedback were essential to the successful completion of this research. I would also like to acknowledge the **PAT Department** at my workplace for their collaboration, technical assistance, and support in providing the operational context and resources necessary for this study. Their commitment to continuous improvement greatly contributed to the implementation and impact of this work.

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