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

Gabriela Cruz Nieves
Master in Manufacturing Competitiveness
Advisor: Dr. Rafael Nieves, PharmD.
Polytechnic University of Puerto Rico
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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 pharmaceutical environmental monitoring. The existing practice required a single-sample zero count with an absolute zero acceptance criterion performed before every sampling point, leading to excessive failures, unnecessary equipment downtime, and increased maintenance costs without improving performance. Historical zero count failure data and maintenance records were analyzed to assess the impact of this approach. Manufacturer calibration guidelines, which define zero count verification as a 10-sample run with acceptance based on the last six samples meeting zero count criteria, served as the technical basis for revising both acceptance criteria and testing frequency. The revised methodology implemented one zero count per sampling session, with additional tests conducted only under predefined trigger conditions. Results showed a substantial reduction in failures, improved equipment availability, and decreased maintenance interventions, demonstrating greater reliability and operational efficiency.*

Keywords *— Environmental monitoring, manufacturer calibration guidelines, particle counting equipment, zero count verification*

PROBLEM

Non-viable particle counting equipment is routinely used in pharmaceutical environmental monitoring to verify cleanroom and utility conditions. As part of standard practice, a zero-count test is performed to confirm instrument cleanliness and electronic stability prior to sampling. However, the current operational practice requires a single-sample zero count with an acceptance criterion of an absolute zero particle count performed before every sampling point.

This approach exceeds manufacturer-recommended practices and has resulted in excessive zero count failures, frequent equipment interruptions, and unnecessary downtime. Repeating a highly restrictive zero count test multiple times during a monitoring session increases the probability of false failures without providing additional insight into instrument performance or sampling quality.

Manufacturer calibration guidelines specify that zero count verification should be performed using a 10-sample zero count run, with acceptance based on the last six samples meeting zero count criteria, and do not require repeated zero count verification prior to each sampling point. The current practice of performing multiple zero count tests using an absolute zero acceptance criterion represents a misapplication of zero count methodology and contributes to operational inefficiencies.

Therefore, a need exists to modify both the zero count acceptance criteria and the frequency of zero count execution. Aligning zero count verification with manufacturer-recommended methodology by performing a single zero count per sampling session—supported by appropriate acceptance criteria and defined re-test triggers—is expected to reduce false failures, improve equipment reliability, and enhance efficiency in environmental monitoring operations.

Research Description

This research evaluates and modifies the zero-count verification process used in non-viable

particle counting equipment for pharmaceutical environmental monitoring. Currently, zero count verification is performed before every sampling point using a single-sample run with an absolute zero acceptance criterion. This approach has led to excessive zero count failures and unnecessary equipment downtime.

The study will review historical zero count failure data to quantify the impact of repeated single-sample zero count testing. Manufacturer calibration guidelines, which define zero count verification as a 10-sample run with acceptance based on the last six samples, will be used as the technical basis for modifying the zero count acceptance criteria.

In addition to revising acceptance criteria, the research will evaluate the feasibility of performing a single zero count per sampling session or monitoring route, rather than before each sampling point. Additional zero count tests will be defined only under specific conditions, such as instrument restart, configuration changes, or abnormal performance indicators.

The revised zero count methodology will be implemented in a controlled manner. Equipment performance will be monitored to assess improvements in zero count stability, reductions in failure occurrences, and impacts on maintenance frequency. The economic effect of the revised process will be evaluated through comparison of equipment downtime and repair service costs before and after implementation.

Research Objectives

The objectives of this research are:

1. To evaluate the impact of performing single-sample, absolute-zero acceptance tests before every sampling point on zero count failure frequency and equipment downtime.
2. To align zero count acceptance criteria with manufacturer calibration guidelines requiring a 10-sample zero count run with acceptance based on the last six samples.
3. To assess the effectiveness of performing a single zero count per sampling session, supported by defined re-test conditions, in reducing excessive zero count failures.
4. To evaluate the impact of the revised zero count methodology on equipment reliability, maintenance frequency, and operational efficiency.

Research Contributions

Optimization of Zero Count Verification Strategy. This research demonstrates a transition from repetitive single-sample zero count testing to a manufacturer-aligned verification strategy that includes a single zero count per sampling session using defined acceptance criteria.

Project Timeline and Schedule

The project timeline was developed to align with the Fall 2025 and Winter 2026 academic terms, with final submission scheduled for February 2026. Figure 1 presents the Gantt chart outlining the sequence and duration of key project activities, including planning, data collection, methodology development, implementation, monitoring, analysis, and final reporting. The schedule reflects a logical progression from planning and analysis to implementation and evaluation, ensuring sufficient time for post-implementation monitoring and results interpretation.

1. Reduction of unnecessary testing and failures - By reducing the frequency of zero count execution and correcting acceptance logic, the study demonstrates measurable reductions in false zero count failures and associated equipment interruptions.
2. Improvement of monitoring efficiency and equipment reliability - The revised zero count process improves monitoring efficiency by reducing operator burden, sampling delays, and unnecessary maintenance actions while maintaining reliable instrument performance.
3. Practical framework for process improvement - The study provides a structured, data-driven framework for optimizing zero count practices that can be applied to similar monitoring

operations and equipment optimization initiatives.

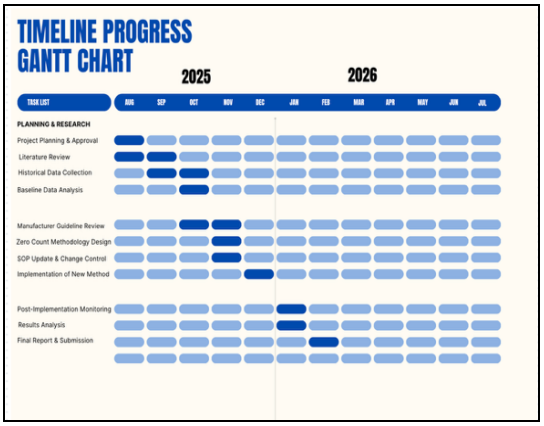

Figure 1
Project Gantt Chart (August 2025 – February 2026)

LITERATURE REVIEW

To establish the regulatory and technical foundation for optimizing zero-count verification practices, this chapter reviews the role of environmental monitoring in pharmaceutical manufacturing, the purpose of zero count testing, and the impact of acceptance criteria and verification frequency on equipment reliability and operational efficiency.

Environmental Monitoring in Pharmaceutical Manufacturing

Environmental monitoring is a fundamental component of contamination control in pharmaceutical manufacturing, providing objective data to verify that cleanrooms and critical utilities operate within established cleanliness limits. Non-viable particle monitoring is widely used to assess airborne particulate levels in classified areas and utilities that may impact product quality. Regulatory and industry standards emphasize the importance of reliable monitoring systems to support consistent manufacturing conditions and early detection of potential contamination risks, consistent with international quality frameworks such as ISO standards [1].

Particle counting equipment used for environmental monitoring must be properly calibrated and verified prior to use to ensure accurate and meaningful results. Routine verification activities, such as zero count testing, are intended to confirm baseline instrument performance rather than serve as indicators of environmental compliance, as emphasized in manufacturer best practice guidance [2].

Purpose and Interpretation of Zero Count Testing

Zero count testing is performed to verify the cleanliness of the particle counter's internal flow path and to detect excessive electronic noise that could result in false high particle counts. Manufacturer guidance indicates that zero count testing is a verification tool, not a direct measurement of environmental cleanliness [2].

Several studies emphasize that zero count results should be interpreted within defined acceptance limits rather than as an absolute zero requirement. Initial samples in a zero-count run may be influenced by stabilization effects or residual particles, which do not necessarily indicate contamination or instrument failure [2]. In addition, inlet contamination has been shown to affect optical particle counter accuracy, reinforcing the importance of appropriate verification methodologies [3].

Manufacturer Calibration Methodologies for Zero Count Verification

Manufacturer calibration practices for optical particle counters commonly define zero count verification as a multi-sample process designed to account for stabilization and normal variability. A typical approach involves a 10-sample run, with acceptance determined by the last six samples meeting zero count criteria [2].

Literature on sensor optimization and verification supports the use of repeated measurements and stabilized acceptance criteria rather than single-point checks. Multi-sample verification improves confidence in baseline instrument performance while reducing false failure events [4].

Impact of Overly Restrictive Acceptance Criteria on Equipment Performance

The use of overly restrictive acceptance criteria, such as requiring an absolute zero particle count from a single sample, significantly increases the probability of false failures. Reliability engineering literature demonstrates that frequent checks under strict limits increase failure events caused by normal variability rather than true equipment issues [5].

Repeated zero count testing before every sampling point amplifies this effect, leading to unnecessary equipment interruptions, increased handling, and additional maintenance interventions. Excessive verification activities reduce overall system availability without improving performance [4], [5].

Optimization of Verification Frequency in Monitoring Systems

Process optimization literature emphasizes balancing verification frequency with operational efficiency. Verification should ensure reliable performance while avoiding unnecessary repetition that adds no technical value. Trigger-based verification approaches are widely used in instrumentation management to ensure checks are performed when risk increases rather than at fixed, overly frequent intervals [4].

Applying this principle to particle counting equipment suggests that performing a single zero count per sampling session, supplemented by clearly defined re-test triggers, provides adequate verification while reducing false failures and downtime [2].

Relationship Between Zero Count Practices and Operational Efficiency

Maintenance literature consistently identifies false alarms and unnecessary failures as major contributors to equipment downtime and increased service costs. In particle counting systems, excessive zero count failures can result in repeated service calls, recalibration, and loss of monitoring capacity [5].

Aligning acceptance criteria and execution frequency with manufacturer-recommended methodologies supports stable equipment operation and reduces unnecessary interventions. Minimizing false failures improves equipment availability and enhances overall efficiency in environmental monitoring programs [2], [4].

Summary of Literature Review

The literature supports the conclusion that zero-count testing is a baseline verification activity that should be performed using manufacturer-recommended methodologies and interpreted within defined acceptance criteria [2]. Single-sample absolute zero requirements and excessive testing frequency are not supported by reliability principles and contribute to increased false failures and operational inefficiencies [4], [5].

Therefore, aligning zero count acceptance criteria with manufacturer calibration guidance and reducing zero count frequency to a single test per sampling session, supplemented by trigger-based re-testing, represents a technically sound and data-supported approach to improving equipment reliability and monitoring efficiency. This literature foundation directly supports the objectives and methodology of the present research.

METHODOLOGY

This chapter describes the methodology used to evaluate and modify the zero-count verification process for non-viable particle counting equipment used in pharmaceutical environmental monitoring. Environmental monitoring programs operate under strict contamination control expectations consistent with international quality frameworks such as ISO standards [1]. The study focuses on correcting two key issues identified in current practice: (1) the use of a single-sample zero count with an absolute zero acceptance criterion, and (2) the execution of zero count testing before every sampling point.

The methodology aligns operational zero count practices with manufacturer calibration guidance, which defines zero count verification as a multi-

sample process using a 10-sample run with acceptance based on the last six samples meeting zero count criteria [2]. Additionally, the study evaluates the effectiveness of performing a single zero count per sampling session, supplemented by defined re-test conditions, rather than repeated testing at each sampling point, consistent with sensor optimization principles [4].

Research Design

This research employs a quantitative, retrospective, and comparative design. Historical environmental monitoring and maintenance data are analyzed to establish baseline performance under the current zero count practice. A revised zero count methodology aligned with manufacturer guidelines is then implemented, and post-implementation performance is evaluated.

The study compares two operational states:

Current State:

- Single-sample zero count.
- Acceptance criterion of absolute zero.
- Zero count performed before every sampling point.

Proposed State:

- One zero count per sampling session
- 10-sample zero count run
- Acceptance based on the last six samples meeting zero count criteria [2]
- Additional zero counts performed only under predefined trigger conditions [4]

Equipment and Scope

The study includes six non-viable particle counting units routinely used for environmental monitoring. These units are used for monitoring ISO-classified cleanrooms and compressed gas systems.

The scope of the study is limited to:

- Zero count verification methodology.
- Equipment performance related to zero count failures.
- Equipment downtime and maintenance service events.

Environmental classification limits, viable monitoring, and particle count action levels are outside the scope of this research.

Data Collection

To support a comparative evaluation of the current and revised zero count methodologies, data was collected across two distinct phases: baseline performance under existing practices and post-implementation performance following the revised approach.

Historical Data (Baseline)

Historical data from a defined period prior to implementation will be collected, including:

- Zero count failure records.
- Frequency of zero count execution.
- Equipment out-of-service events related to zero count failures.
- Maintenance service requests and associated downtime.

This data represents performance under the current one-sample, absolute-zero methodology, which can contribute to excessive downtime and unnecessary maintenance interventions [5].

Post-Implementation Data

Following implementation of the revised zero count methodology, equivalent data will be collected, including:

- Zero count pass/fail outcomes using the 10-sample acceptance logic [2].
- Number of zero count executions per sampling session.
- Equipment downtime related to zero count verification.
- Maintenance service events and repair frequency.

Revised Zero Count Methodology

The revised zero count process is based on manufacturer calibration guidelines and consists of the following steps:

1. Zero Count Execution: A single zero count test is performed at the start of each sampling

session using a 10-sample run, as recommended in particle counter best practices [2].

2. Acceptance Criteria: The zero-count test is considered acceptable if the last six samples of the run meet zero count criteria [2].
3. Sampling Session Definition: A sampling session is defined as a continuous monitoring route performed without instrument shutdown, configuration change, or extended interruption.
4. Re-Test Triggers: Additional zero-count tests are performed only when one or more of the following conditions occur:
    - Instrument power cycle.
    - Change in inlet tubing, probe, or filter.
    - Instrument drop or physical disturbance.
    - Abnormal instrument behavior or unexpected readings.
    - Extended pause between sampling activities.

These trigger conditions are supported by evidence that contamination or inlet disturbances can affect particle counter performance and verification outcomes [3].

Data Analysis

Data analysis focuses on comparing baseline and post-implementation performance using the following metrics:

- Zero count failure rate
- Number of zero count executions per sampling session
- Frequency of equipment out-of-service events
- Maintenance service request frequency
- Equipment downtime duration

Descriptive statistics will be used to evaluate trends and differences between the two operational states. Results will be presented using tables and comparative summaries to highlight performance improvements, consistent with reliability-focused monitoring approaches [4], [5].

Economic Impact Evaluation

The economic impact of the revised zero count methodology will be evaluated by comparing maintenance service costs and downtime-related impacts before and after implementation. Cost reduction will be estimated based on:

- Decreased frequency of service events.
- Reduced equipment downtime.
- Reduced labor associated with repeated zero-count execution.

Reducing downtime through optimized verification practices aligns with reliability and root-cause-based maintenance improvement frameworks [5].

Expected Outcomes

The revised methodology is expected to:

- Reduce false zero count failures
- Improve equipment availability and reliability
- Decrease unnecessary maintenance interventions
- Improve efficiency of environmental monitoring operations

These outcomes support broader sensor optimization and verification efficiency principles in complex monitoring systems [4].

RESULTS AND DISCUSSION

Historical data analysis revealed that the previous zero count methodology—consisting of a single-sample zero count with an absolute zero acceptance criterion performed before every sampling point—resulted in a high frequency of zero count failures. Each zero-count failure typically required maintenance intervention, with an average cost of approximately $1,500 per machine.

A critical operational event highlighted the severity of this issue when, out of 10 particle counting units, only 2 units remained available for use due to multiple zero count failures occurring during routine environmental monitoring. This situation significantly impacted monitoring

capacity and increased reliance on maintenance services.

Following implementation of the revised zero count methodology—consisting of a single zero count per sampling session using a 10-sample run with acceptance based on the last six samples, along with defined re-test triggers—equipment performance improved substantially. Post-implementation data showed a significant reduction in zero count failures, with only one zero count failure recorded during the evaluation period.

Importantly, the single post-implementation failure was confirmed to be caused by internal contamination, indicating a valid failure condition rather than a false failure related to acceptance criteria or test frequency.

Discussion

The results demonstrate that the previous zero count methodology contributed to excessive false failures and unnecessary maintenance interventions. Performing a zero count before every sampling point using an absolute zero acceptance criterion increased the probability of failure due to normal variability and instrument stabilization effects, rather than actual equipment issues.

The incident in which only two out of ten particle counters remained available illustrates the operational risk associated with overly restrictive and repetitive zero count practices. Beyond the direct maintenance cost of approximately $1,500 per machine, this situation reduced equipment availability and constrained environmental monitoring operations.

In contrast, the revised methodology aligned with manufacturer calibration guidelines proved effective in distinguishing between false failures and legitimate equipment issues. The significant reduction in zero count failures, combined with the identification of a true contamination-related failure, indicates that the new approach maintains instrument verification integrity while eliminating unnecessary interruptions.

These findings confirm that optimizing both zero count acceptance criteria and execution frequency improves equipment reliability, reduces maintenance costs, and enhances overall monitoring efficiency. The revised methodology provides a balanced approach that supports reliable performance without excessive testing or misinterpretation of zero count results.

Process Update and Implementation

As part of the implementation of the revised zero count methodology, the environmental monitoring standard operating procedure (SOP) was formally updated to reflect the new zero count execution strategy. The revised SOP defines zero count verification as a single zero count per sampling session, using a 10-sample run with acceptance based on the last six samples, and specifies conditions under which additional zero count tests are required.

The change was formally documented through the site's change control process, ensuring that the updated methodology was reviewed, approved, and communicated prior to implementation. The change control documentation captured the rationale for the update, the comparison between the previous and revised zero count practices, and the expected operational benefits associated with the change.

Following SOP revision and implementation, operators were trained in the updated zero count procedure, including the revised acceptance criteria and defined re-test triggers. This ensured consistent execution of the new methodology across all particle counting units included in the study.

The successful implementation of the SOP update and change control documentation supported the sustained application of the revised zero count methodology and contributed to the observed reduction in zero count failures and maintenance interventions.

CONCLUSION

This study evaluated and modified the zero-count verification process used in non-viable particle counting equipment for pharmaceutical environmental monitoring. The project addressed

two key deficiencies in the existing practice: the use of a single-sample zero count with an absolute zero acceptance criterion and the execution of zero count testing before every sampling point. Both practices were found to contribute to excessive zero count failures, unnecessary equipment downtime, and increased maintenance costs.

Analysis of historical data confirmed that the previous zero count methodology resulted in frequent false failures that did not reflect actual equipment condition. The operational impact of this approach was demonstrated by an incident in which only two out of ten particle counting units were available due to zero count failures, significantly limiting monitoring capacity. Each failure required maintenance intervention at an average cost of approximately $1,500 per machine, highlighting the financial and operational burden associated with the existing process.

The revised zero count methodology, aligned with manufacturer calibration guidelines, introduced two critical improvements: (1) the adoption of a 10-sample zero count run with acceptance based on the last six samples, and (2) the reduction of zero count execution frequency to a single test per sampling session, supported by defined re-test triggers. Implementation of this approach resulted in a substantial reduction in zero count failures. Post-implementation data showed only one zero count failure, which was attributed to confirmed internal contamination, demonstrating that the revised methodology effectively distinguishes between false failures and legitimate equipment issues.

In addition to improving equipment performance, the revised zero count process was formally incorporated into the environmental monitoring SOP and documented through the site's change control process. This ensured consistent execution of the updated methodology and supported its sustained application. Operator training further contributed to reliable implementation and reduced variability in zero count verification practices.

Overall, the results demonstrate that aligning zero count acceptance criteria and execution frequency with manufacturer calibration guidance significantly improves equipment reliability, reduces unnecessary maintenance interventions, and enhances the efficiency of environmental monitoring operations. The findings confirm that excessive testing and overly restrictive acceptance criteria do not improve equipment verification and may instead introduce operational risk and inefficiency.

This study concludes that a standardized, manufacturer-aligned zero count methodology provides a more accurate and practical approach to instrument verification while supporting operational stability and cost reduction. The framework developed through this project can serve as a foundation for future optimization initiatives involving environmental monitoring equipment and verification practices.

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