When summary data are presented, it might also be helpful to have more detailed data available. Laboratory and organizational leadership might want to review the quality cost information to ensure the data collected are appropriate and the calculations are accurate. Involving these individuals in the design of the COQ program can preclude the need for excessive analysis of data during management review.

Graphs and charts can help communicate aggregate quality cost data. Trending the data can help assess performance over time. There are several ways to stratify data for trending. Example graphical presentations of quality cost data are provided in Appendixes C2 to C4. Laboratories should choose graphs for trending and management review that are appropriate to the complexity of their COQ program and the audience's understanding of COQ.

Appendix C2 depicts a simple method of trending the monthly cost of good quality, COPQ, total quality costs, and their relationships.

Appendix C3 stratifies the monthly total quality costs into prevention, appraisal, and internal and external failure costs and their relationships.

Appendix C4 stratifies year-to-year total quality costs into measurable and intangible costs and their relationships. This type of graph might be most appropriate for communicating total quality cost data to the financial function, because its focus might be on measurable costs affecting the budget.

The laboratory might be concerned about how failure cost reports will be interpreted by others in the organization and whether there will be personal ramifications from this information. Leaders should be reminded of the well-known quality truth that more than 85% of problems are due to organizational and laboratory systems and processes, not directly caused by individuals. Laboratories should consider and communicate failure costs as OFIs that will support the organization's mission and financial status. Research has found that up to a third of health care expenditures are related to process failures and waste.[45] When laboratories share their failure costs as a model, it can encourage other health care services to track and report their respective information as well. The results can generate organization-wide improvement in quality, patient safety, and cost.

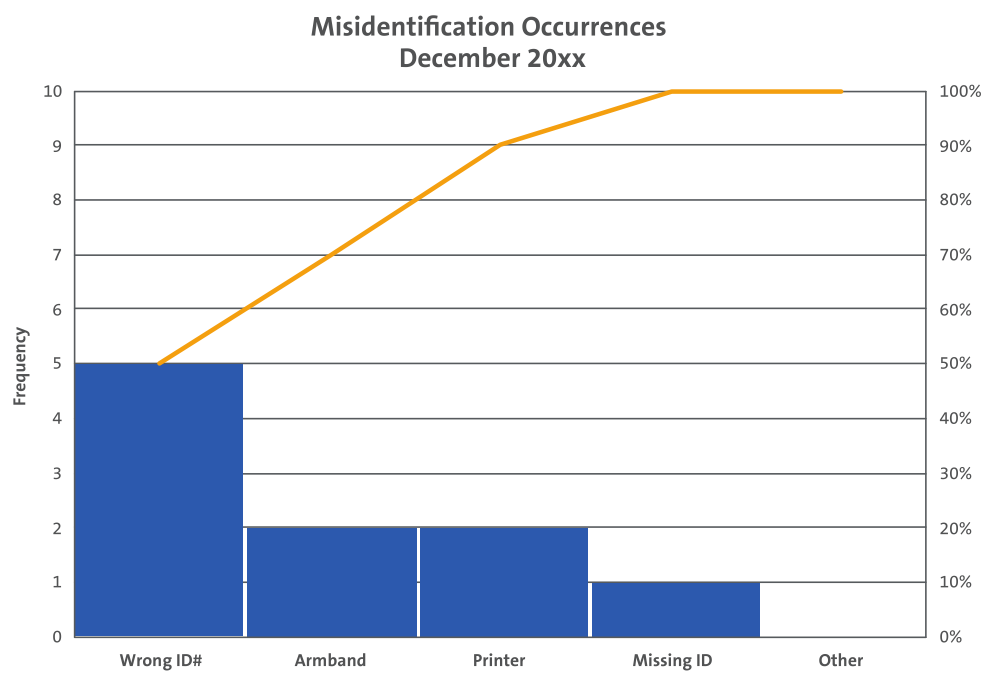
5.3.3 Identifying and Prioritizing Opportunities for Improvement

When aggregate quality cost data are compiled and the information is presented during management review, identifying the NCEs and/or unfavorable trends that cause the largest financial loss for the laboratory becomes possible. Occurrences commonly associated with the highest failure costs are:

- Individual NCEs that have high failure costs
- Frequently occurring NCEs that have relatively low failure costs per instance
- Moderately occurring NCEs that have moderate failure costs per instance

NCEs that have the highest failure cost and the highest patient safety risk should be prioritized for correction first, with a lower priority given to lower-cost and lower–patient safety risk NCEs.

A Pareto chart illustrating failure costs in decreasing order, such as Figure 11, is an effective method for helping prioritize OFIs identified from the NCE data. The laboratory needs to use caution when interpreting the data, because in some instances, the most expensive problem might not be the most important to correct. For example, recurring instances of a less costly problem that affects patient safety, laboratory results, or customer or patient satisfaction (eg, hemolyzed specimens collected by nonlaboratorians) might be more urgent to resolve than a single instance of a more expensive instrument problem. Effective means to prioritize failure costs include linking the problems to the laboratory's or organization's strategic goals and objectives or to the severity of outcomes.



Abbreviation: ID, identification.

Figure 11. Example Pareto Chart (see CLSI document QMS06[46]). This chart shows typical laboratory failure cost types in decreasing order.

5.4 Acting on Opportunities for Improvement

After the laboratory has identified and selected an OFI, it should document and analyze the surrounding process. Improvement models and tools are used to redesign the process. Subsequently, a risk assessment can be applied to ensure the solutions will improve the process and not introduce new failure costs. Finally, the laboratory should determine the means to monitor the effectiveness of the new process before finalizing the revised documents, training personnel, and implementing the new process. Figure 12 depicts a standardized workflow for acting on OFIs that can increase the likelihood of success.

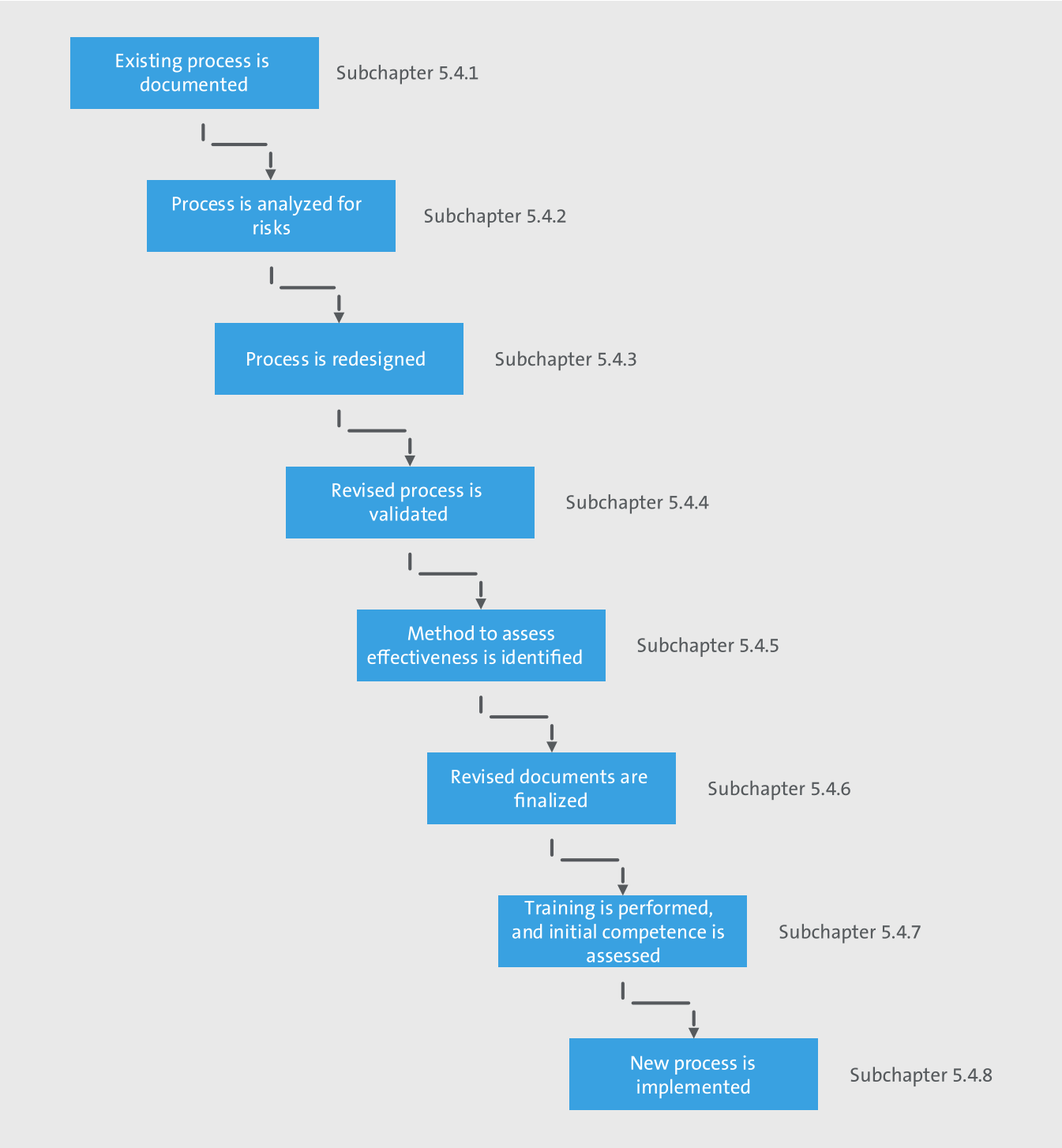


Figure 12. Workflow for Acting on OFIs

5.4.1 Existing Process Is Documented

A process should be systematically reviewed by those who perform it, so they can fully understand how it is really being done. A common mistake is the process being documented or described by the supervisor of the personnel who perform it. Personnel insight (in particular, into how the process should be done) is valuable because only the personnel who perform the process can accurately describe how it is really being carried out. The most reliable means to determine how the process truly happens is to watch more than one laboratorian perform it on more than one occasion, which enables objective observation of any variation and personal deviations. Observing the process is a valuable opportunity for supervisors to learn new information about challenges they did not know existed. The process can be documented using flow charts, process maps, or value stream maps, as described in CLSI document QMS02.[47]

5.4.2 Process Is Analyzed for Risks

The laboratory analyzes the process to identify the elements that contribute to failures and their likely root causes—an important activity in reducing the cost of NCEs. Analyzing the existing process will reveal risks such as inconsistencies, redundancies, unnecessary delays, dead ends, bottlenecks, and inherent waste. The process analysis team should include personnel who contribute to process inputs, those who work in the process, and those who receive the process outcome. This team can use tools such as affinity diagrams, cause-and-effect diagrams, five whys, and gap analyses (see CLSI document QMS18[48]).

The process analysis team creates a revised process and uses a failure modes and effects analysis tool to identify the points where controls and other preventive actions can be inserted to avoid failures. This tool enables the analysis team and laboratory leaders to evaluate the frequency, severity, ease of detection, and costs associated with each failure type and to prioritize improvement initiatives based on this information (see CLSI document QMS11[49]). **NOTE:** Adding appraisal activities such as inspections and checks to the revised process increases both work and cost. In addition, when additional appraisal activity is needed before the process is completed, a longer TAT often occurs. Therefore, appraisal activities should be inserted only when the process activity has a high risk of a severe occurrence and it is not possible to apply a less expensive prevention activity instead.

5.4.3 Process Is Redesigned

After analyzing the process, the laboratory drafts the future-state (ie, desired) process that will mitigate or eliminate elements that contribute to failures. This is a good time to question old assumptions and evaluate new possibilities that could help create a process that produces outputs that are correct the first time, every time. For processes that need a rapid TAT, the laboratory should critically review any handoffs or workarounds to determine whether they are truly necessary.

5.4.4 Revised Process Is Validated

The laboratory validates the new or changed process in a pilot study to reveal likely failures and enable easier adjustments before full-scale implementation. Pilot studies should be conducted using only the minimum number of process cycles needed to achieve actionable information. Depending on the process, many pilot studies can occur over several hours or days. When a potential failure is identified, the process should be reanalyzed and any improvements validated before implementation (see CLSI document QMS18[48]).

5.4.5 Method to Assess Effectiveness Is Identified

Before implementing any countermeasures or improvement initiatives, the laboratory should identify the methods it will use to monitor and evaluate the effectiveness of the new or revised process. The laboratory should define the intended process outcomes and identify monitors that clearly demonstrate the success or improvement needs of the revised process, while also supporting effective communication with its partners in the improvement project.

5.4.6 Revised Documents Are Finalized

When the process is ready for implementation, the laboratory approves and finalizes applicable process, procedure, and form documents in the document control system (see CLSI document QMS02[47]). Well-written procedures are clear and unambiguous. In addition to text, charts can enhance understanding and compliance. A well-documented process reduces the amount of time and cost to train personnel on the new or revised process.

5.4.7 Training Is Performed and Initial Competence Is Assessed

The last prevention activity is effective training and initial competence assessment of all personnel involved in the new or revised process (see CLSI document QMS03[23]). To improve the likelihood of success, management should communicate expectations and provide additional support to personnel during the transition to the new process.

5.4.8 New Process Is Implemented

Time and resources are needed to act on OFIs and implement a new process. However, when done in a deliberate, strategic way, this prevention cost can have lasting effects. The effectiveness of the new process will be monitored, and the information will be used to communicate shared benefits with stakeholders and drive future improvement initiatives.

5.5 Monitoring and Evaluating Effectiveness of the Cost of Quality Program

After implementing any improvement project, including the COQ program, the laboratory should monitor and evaluate outcomes to ensure the change was successful and to identify additional OFIs. As the laboratory gains experience with having a COQ focus, it can implement a more comprehensive process to monitor and evaluate the effectiveness of changes. Ideally, the laboratory should identify a few quality indicators that can be easily monitored and displayed to encourage personnel comprehension and involvement. However, selecting too many indicators can be overwhelming for personnel and difficult to manage. Subchapters 5.5.1 to 5.5.4 discuss options that can be used individually or in combination to monitor and evaluate the effectiveness of the laboratory's COQ program.

5.5.1 Internal Audit

After implementing the COQ program, the laboratory can conduct a scheduled internal audit of all or relevant parts of any improved process, including review of related documents and records and any reported NCEs. An audit is an effective means to determine whether changes and current practices are efficient (see CLSI document QMS15[31]).

5.5.2 Quality Indicators

The laboratory can use quality indicators to assess the current performance of the COQ program (see CLSI document QMS12[27]). During management review of quality indicator data and information, trends are analyzed and opportunities are identified for preventive action or continual improvement. The laboratory might choose to create indicators based on the type of quality cost, eg, prevention, appraisal, internal and external failures (see Appendixes A1 and A2). A simple worksheet (see Appendix C1) or a variety of graphs (see Appendixes C2 to C4) can be used to provide a high-level overview of the COQ program's performance.

An indicator threshold helps identify unacceptable performance and need for additional improvement. For each quality indicator, the laboratory should determine a conservative threshold (based on past performance) that can be supported by action and adjust the threshold accordingly as the program evolves over time.

5.5.3 Nonconforming Events

In addition to ongoing monitoring, laboratory personnel should report problems through the laboratory's NCE management program so they can be trended and analyzed (see CLSI document QMS11[49]). NCE information can also be included in COQ program reporting, so as to alert personnel to the COPQ.

5.5.4 Benchmarking

Owing to the immense variability in operations among different laboratories, even when a standardized tool is used, it is difficult to find appropriate published benchmarks to compare interlaboratory performance.[50] The laboratory should establish internal thresholds and targets, with the goal of continual improvement over time.

5.6 Critical Success Factors and Tips

Several factors are critical to the success of a laboratory COQ program.

5.6.1 Use a Standardized Tool to Calculate Quality Costs

In order to uniformly list all costs in as much detail as possible, it is necessary to use a standardized tool to calculate quality costs. The laboratory can use an established tool or create its own. Training personnel before piloting the calculation tool will ensure that the cost information obtained is consistent and accurate.[50]

5.6.2 Gain Support Within the Organization

Successful implementation of a culture of quality and consideration for COQ in all workflows, processes, and decisions depends heavily on support within the organization, including laboratory leadership, managers, supervisors, and personnel. For laboratories in larger organizations, meeting with organizational leadership before implementing a COQ program provides the opportunity to obtain consensus on meaningful goals, objectives, and metrics and encourages support for the program.

The laboratory should establish and use data collection methods and tools to track and trend COQ performance, communicate regularly with personnel, and encourage participation and support for COQ projects.[50] Communication with leadership and personnel should explain, clearly and concisely, the need for and benefit of the COQ program. Laboratory leadership and personnel need to understand that the program's purpose is to improve quality and increase operational capacity, not to reduce personnel.

5.6.3 Calculate and Communicate Quality Costs

When calculating and discussing quality costs, the laboratory should use conservative financial estimates, taking into consideration to whom the data will be communicated. For example, when communication is directed to the organization's financial leader, it is helpful to understand where his or her focus is likely to be. The top three priorities for health care chief financial officers, in order of importance, are[51]:

- Reducing costs
- Managing changing payment models
- Improving performance management

Preferably, the measurable (direct and indirect) and intangible quality costs should be established in collaboration with and/or approved by the financial function and laboratory leadership. Although the financial leader might not be interested in intangible costs, estimating these costs could help laboratory leadership and personnel fully understand the effect of failures. In addition, the data could be used to gain support for improvement initiatives.

5.6.4 Ensure Continual Support

To ensure the COQ program is continually supported, laboratories can:

- **Ensure ongoing communication:** It is important to involve all members of the COQ program team and laboratory personnel in COQ projects. Sharing successes as they occur can help create and maintain a culture of quality.
- **Measure and display:** Posting COQ performance data and tracking information in a location accessible to all personnel so that they can see the improvements can help reinforce initiatives for COQ.
- **Educate stakeholders on financial benefit:** When COQ information is presented, it is important to use terms routinely used by the financial function and organizational and laboratory leadership, such as "cost savings" and "cost avoidance" (discussed in Subchapter 3.3.3). The laboratory should take care to use proper terminology that accurately communicates the effects of the COQ program.
  - **Cost savings** result from actions that can be directly tied to a reduction in spending. For example, changing to a lower-cost collection device results in cost savings for specimen collection.
  - **Cost avoidance** is incurred when an action is implemented that avoids future costs. For example, routine maintenance can ensure cost avoidance related to breakdowns, downtime, and potentially inaccurate results.
  - Cost savings or cost avoidance? When personnel time spent handling failures is reduced, the quality cost associated with personnel can be either a cost savings (ie, when personnel levels are reduced in the budget) or, more commonly, a cost avoidance (ie, when personnel have more time for other laboratory activities).
  - The laboratory representative can use the term "financial benefit" with stakeholders to discuss both types of costs without focusing solely on cost savings.

Stakeholders in a laboratory COQ program can include:

- Laboratory's leadership and personnel
- Organization's administration, leadership, and financial function
- Laboratory's external customers (eg, nursing, respiratory therapy, pharmacy, purchasing)

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Chapter 6

Transitioning to a Cost of Quality Culture

This chapter includes:

- Estimating failure costs from NCEs and quality indicator information
- Reporting results to others in the laboratory and organization
- Developing and communicating the COQ value proposition
- Justifying the laboratory COQ program

6 Transitioning to a Cost of Quality Culture

When a laboratory builds on a culture of continual improvement by adding the COQ perspective to all laboratory processes, the change to a COQ culture can be fairly simple, provided that quality costs are incorporated and used effectively. Components of an effective COQ culture include:

- Identifying existing prevention and appraisal activities
- Using failure costs to identify improvement projects
- Sharing gains by reporting results
- Educating others on COQ
- Communicating quality cost data in the organization
- Using COQ in purchasing decisions
- Developing and communicating the COQ value proposition
- Incorporating intangible costs
- Expanding the COQ program and scope

Subchapters 6.1 to 6.9 provide examples of logical approaches to making this transition.

6.1 Identifying Existing Prevention and Appraisal Activities

As mentioned in Subchapter 3.3, laboratory management should be able to identify prevention and appraisal costs in the laboratory's budget. Appendix A1 provides a starting point to match prevention and appraisal costs to the laboratory's budget.

6.2 Using Failure Costs to Identify Improvement Projects

Laboratories should begin by identifying a quality indicator(s) that affects patient care or safety and has been trending in a negative direction and determining the failure cost for that indicator for a period of time. Some common NCEs that occur in laboratories are also tracked as quality indicators, such as recollected blood specimens, failed instrument examinations, and corrected reports (see examples in Appendixes B5 and B8). NCEs can be sorted into categories by examination phase. For example, recollected blood specimens would be included in the preexamination phase, failed instrument examinations would be categorized in the examination phase, and corrected reports would be considered part of the postexamination phase. An overall TAT delay could be categorized into a fourth category that represents the total testing process.

The generic basic worksheet in Appendix B2 can help laboratories calculate the failure cost of an individual occurrence or estimate an average cost per occurrence. The worksheet in Appendix C1 provides a means to summarize the magnitude of failure costs for a defined time period. Basic failure cost information for both quality indicators and NCEs provides the laboratory with defensible data for identifying and prioritizing improvement projects and securing management approval and resources for necessary improvements.

6.3 Sharing Gains by Reporting Results

Regulatory agencies and accreditation organizations require laboratories to provide objective evidence of improvements made between external assessments. Laboratories are also generally required by their own organizations to regularly demonstrate improvements in laboratory processes, particularly those that relate to patient care and safety.[52] As a valuable addition to a standard continual improvement report, the laboratory can include data on failure cost estimates both before and after the improvement initiative. The laboratory's quality report (see Appendix C1) can track and monitor failure costs over time.

6.4 Educating Others on Cost of Quality

Educating personnel at every level of the organization, including the highest-level administrators and leaders, about the types of quality costs, using examples from their respective work processes, can strengthen a COQ culture. Organizational leadership should understand that, by reducing the prevention and appraisal activities that support good quality, "across-the-board" budget cuts can create the potential for higher failure costs. A significant increase in failure costs due to insufficient prevention activities could have a negative long-term effect on a laboratory's sustainability and reputation.

6.5 Communicating Quality Cost Data in the Organization

Prevention and appraisal costs should be included in the financial planning process to ensure the cost to maintain good quality is quantified and included in the budget. When budgets are challenged, as they often are by the financial function, these identified costs are more easily defended. When quality costs are communicated within an organization, the laboratory should consider:

- Which quality costs need to be measured?
- Who needs to know?
  - How often?
  - What level of detail is needed?
- How will the report be used? What is the expected response?
- How can the data be simplified and integrated into the budget process?

The laboratory should add failure cost data to the laboratory quality report it provides to the organization (see Appendix C1). Many health care organizations are challenged to contain costs. Therefore, objective evidence of wasted resources and a plan for containing the costs associated with them will most likely attract the administrator's attention.[53] Laboratory leadership should carefully consider how to discuss labor costs associated with failures. When there is a plan for reducing personnel levels, labor costs should be classified as cost savings or cost reduction. When personnel levels will not be reduced, labor costs should be communicated as cost avoidance (ie, increasing capacity without increasing personnel).

The laboratory should share failure cost data with its personnel. All laboratory personnel should recognize the financial consequences of ineffective processes, procedures, and personal choices (eg, overuse of supplies) and should also appreciate the positive effects of their quality improvement efforts on reducing failure costs. Personnel should understand that using the laboratory's limited financial resources to pay for failures could ultimately result in budget reductions for other needs such as technology improvements, continuing education, professional development, and/or pay increases.