

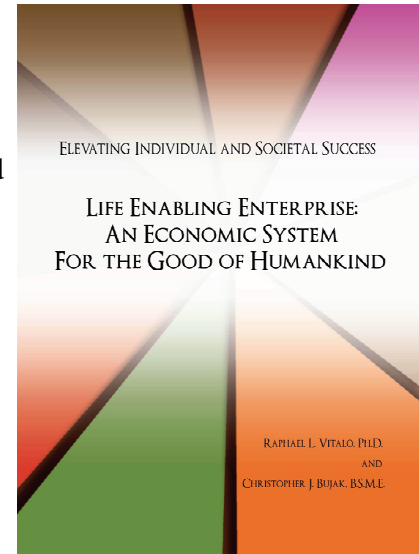
Introduction

Every commercial organization requires the effective execution of the human tasks that generate its success. But the successful performance of any task is not a given. When you observe a performance that falls short of success—what should you do?

If you ascribe to the view that people’s ability to perform the tasks of commerce is an expression of their inherited make up and will—then you would detect which of these two elements was the cause of nonperformance. If the issue were giftedness, then you would simply replace the person with another who is ‘more gifted.’ If the deficiency reflected a lack of will, then you might choose to prod greater investment of effort on the person’s part. Such a model need not address issues related to developing the capabilities of contributors so that they accomplish their work more effectively. Indeed, you might simply choose to replace the failing person with someone who shows promise of greater ‘merit’ (giftedness plus will) and save the resource expenditure required to ‘motivate’ better performance.

On the other hand, if you assume that people’s effectiveness is a function of both personal and nonpersonal factors, any of which may be alterable, then you need a way to detect which factor is impeding success so that you may remove or remedy it. Consider, for example, Karl, a worker who performs Job J. This work occurs at a particular work site (W). It uses a prescribed work process that generates an output to satisfy a certain specification. The process requires specific inputs that are transformed using machines, tools, and the decisions and actions of Karl. Recognize that in almost all cooperative enterprises, most of these factors are not under Karl’s control (e.g., the output specification; the process used; and the input resources, tools, and machines used). Any of these elements can undermine Karl’s success. If in fact one or more of these factors was defective in some way, then replacing Karl as your simple solution to improving effectiveness or pressing Karl to “do better” would be ineffective in correcting the organization’s performance problem.

This paper accepts the second assumption. It assumes that people’s performance is a function of multiple factors, some personal and some not. Following Gilbert (1978), we define human performance as both the results produced and the behavior used to produce those results. Given our view that performance is a function of multiple factors, a solution to a performance problem must uncover and correct the factor(s) that are its cause. This paper offers a simple approach to completing a cause analysis based on the application of Vital Enterprises’ (VE’s) Human Performance Model (HPM) (Vitalo, 2022). It also provides a case example you can use to test your understanding of how to use it



Finding the Root Cause of a Failed Task

To uncover the cause of a failed task, investigate three groups of factors: the Person, the Work Process implemented, and the Work Setting within which work was done. These three sets of factors model were derived from the work of Gilbert (1996) and augmented by the addition of causes uncovered by W.E. Deming’s (1982) observations of failed outcomes in a work context and the author’s learning from his own work in the area of Human Performance Improvement. Whether an individual undertakes a task alone or cooperatively with others, that person’s execution and outcome will be an interactive

consequence of the adequacy of these three groups of factors. Exhibit 1 briefly introduces these three groups of factors. Exhibit 2, page 3, lists examples of the factors within each group.

Exhibit 1. Examples of Causes for a Performance Problem		
Person	Work Process	Work Setting
The person doing the task lacks the motivation, competencies, capacity, focus, or personal judgment required to do the work correctly.	As designed, the prescribed method for doing the task can not accomplish the it at the required level of success.	The setting fails to provide the means needed for the process to be correctly implemented.
Example <ul style="list-style-type: none"> ■ Not skilled in using required machinery or tools. ■ Does not know the work process. ■ Not motivated to work with the diligence required to do the task correctly. ■ Lacks the strength or stamina or other physical capability to perform the task as specified. ■ Distracted by personal issues. ■ Takes on more responsibilities than he can or needs to handle. 	Example <ul style="list-style-type: none"> ■ Minimum cycle time for each operation is too long, no matter who performs the work. ■ Sequence of operations re-exposes materials to contamination causing an unacceptable level of product impurities. ■ Operation A overlaps with B causing the worker to repeatedly shift attention, thus provoking errors. 	Example <ul style="list-style-type: none"> ■ Machinery not maintained; breakdowns cause delays. ■ Raw materials frequently do not meet specifications. ■ Packaging provides products to the loading dock too late to ship when scheduled. ■ Information about customer requirements not given to the worker but later used to judge his or her performance.

Person

This group of factors relates to the make up of the person performing the process used to produce a specified outcome. Factors within this group include the performer's competence, capacity, motivation, self-efficacy, and freedom from distraction. Collectively, they constitute elements of an individual's personal capital—the wherewithal each person brings to accomplishing a task and producing a desired outcome.

Competence refers to the person's possession of the knowledge and skills needed to perform the process correctly at the level of proficiency required for success. It also includes one's demonstration of those "other personal characteristics" needed for success. These are sometimes referred to as *traits*. One example is "cooperativeness," especially if the task being done requires multiple people coordinating their efforts.

Capacity refers to the person's capability to handle the physical, emotional-interpersonal, and intellectual demands of the work. Physically, does the person possess the strength, endurance, flexibility, or other physical fitness qualities needed to do the work? With regard to the emotional-interpersonal sphere, is the person able to sustain the number and complexity of relationships required to coordinate the work as expected? Intellectually, can he or she manage the multitasking or concurrent processing demands of the process being implemented?

Motivation refers to both the level of effort a person applies and the sustainment of that effort until his or her work is completed.

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Self-efficacy refers to performer's judgment about his or her abilities (Bandura, 1982). That judgment may be accurate or inaccurate. If accurate, it may be positive or negative. When accurate and positive, one's sense of self-efficacy enhances success. When one's sense of self-efficacy is inaccurate and positive, it undermines success by leading to misjudgments about one's capabilities. When it is negative, it leads to

Exhibit 2. Factors That Help or Hinder Success

Person(s)

- Competencies (Knowledge, skills, abilities, and other personal characteristics (KSAOs) and the proficiency levels required of each for task success)
- Capacity (Physical, emotional-Interpersonal, Intellectual)
- Motivation
 - Level of effort applied to doing a task
 - Sustainment of effort until the task is completed.
- Self-efficacy (Accuracy, Positive/Negative)
- Freedom from distractions that compromise performance (self-doubt, stress, illness, etc.)

Work Process

- Prescribed method exists
- Prescribed method is effective
- Documentation of Method is:
 - Complete
 - Correctly documented
 - Current
 - Understandable for average performer
 - Inclusive of think and do steps
 - Contains metrics and a method for gauging progress and results
 - Available to performer

Work Setting

- Resources
 - Adequacy of workspace, utilities, tools, equipment, and other materials required for successful task performance
 - Quality of inputs and logistics
 - Availability of coaching from an expert and other performance support resources (e.g., job aides, technical manuals)
 - Lack of task-required information (e.g., customer requirements, quantity to produce)
- Expectation/Feedback
 - Completeness of assignment information provided (e.g., task, objective, product, process, schedule, performance criteria that the worker must satisfy)
 - Adequacy of achievement information provided (e.g., timeliness, accuracy, and feedback addresses both approach and results)
- Incentives
 - Correctness and sufficiency of recognition or rewards for correct performance
 - Presence of recognition or rewards for incorrect performance
 - Sufficiency of consequence for incorrect performance
 - Alignment of rewards and consequences to measures of tasks performance
 - Appropriateness of incentives given the perspective of the performer
- Coordination
 - Adequacy of execution of interrelated tasks by others (timeliness, correctness, consistency)
 - Alignment of perspectives among all involves decision makers as to directions

hesitant investment of effort and uncertainty in decision making. It also retards future learning because it renders one reluctant to undertake new activities.

Distractedness refers to the hindrance a person experiences in focusing on a task due to some life stressor (e.g., social conflict, illness of a loved one, debt). It hinders the expression of a person's capabilities.

Work Process

This group of factors refers to characteristics of the process a person uses to produce an outcome. The method prescribed by the performer's employer may not be effective. It is not capable of generating the result the performer is expected to produce even if the person implements it exactly as prescribed. If the process is effective, it may or may not be documented. Without documentation, what does a performer use to ensure he or she is doing the process correctly? Even if a method is documented, that documentation may not be complete, correct, current, understandable by the average performer, or available to him or her. It may not contain both "do" and "think" steps. "Do steps" tell a person what action to take. "Think steps" guide a person in doing them correctly and in verifying that each step the person completes is done correctly. The documentation also may not contain metrics and guidance for gauging progress and results. This leaves the performer guessing about how he or she got the results that were expected.

Work Setting

This group of factors relates to the context within which a performer completes his or her work. Four types of work setting factors affect the outcome of human performance. These are (1) resources, (2) coordination, (3) expectations/feedback, and (4) incentives.

Resource factors include the workspace, machines and tools, raw materials, supervision and other performance-support aids, and all other wherewithal a setting must supply to support the correct execution of a work process as specified in the design of that process.

Coordination addresses the impact on a performer's success that others have whose work affects that of the performer. Coordination factors include the adequacy of execution by others of interrelated tasks (timeliness, correctness, consistency) and the alignment of perspectives of the people who direct (not support) task performance. If multiple decision makers direct a worker in conflicting ways, no performer can succeed.

Expectations/Feedback factors address the adequacy of information about what a performer is expected to do and produce and how well he or she is doing in satisfying those expectations. These factors include the completeness of assignment information provided to the performer (e.g., task, objective, product, process, schedule, performance criteria that the worker must satisfy) and the adequacy of the achievement information provided (e.g., feedback on both approach and results, correctness of feedback, and timeliness of feedback).

Incentives factors affect one's motivation to do work. Factors in this category address whether (1) the incentives offered have motivational value from the performer's perspective¹ and are aligned with the organization's performance expectations and (2) the setting consistently recognizes and rewards good performance and points out poor performance. It supports the correction of poor performance and provides consequences if it is not corrected.

¹ For example, extrinsically motivated people find inducements of pay, awards, and other positive or negative consequences motivating, but intrinsically motivated people do not. They find factual information about their progress and results energizing and material rewards only when the reward is directly generated by their own performance. In contrast, they respond negatively to motivators that are controlled externally (Cerasoli, Nicklin, and Ford, 2014; Deci, Koestner, and Ryan, 1999).

Approach

1. Document the performance gap.

Tip: A performance gap is a difference between how a task was completed versus how it was expected to be completed and what result was achieved versus what the expected. Be complete in documenting the gap. Identify the task on which performance was problematic, the target for success the person had to meet (approach and results), and what was observed. Also identify its impact on the business. Record your findings.

2. Understand the possible causes for a performance problem.

Tip: Study the three groups of factors that affect human performance as described above. Imagine examples of each from your own experience. Check those against the examples in Exhibits 1 and 2.

3. Decide if the performance gap is due to a Work Process issue.

Tip: Ask and answer each of the following questions. Also ask whether your interviewees have observed any other Work Process issue that hinders performance. Gather the information you need from the workers and their supervisors. Confirm the information you receive by reviewing the process's documentation and observing the work itself. Document your findings.

- a. Is there a written description of the process the worker is expected to implement? (If answer is "No," then the lack of a documented standardized work process is a contributor to the observed performance problem.)
- b. Is the documentation complete and understandable to the average worker? If answer is "No," then the documentation of the work process is a contributor to the observed performance problem.)
- c. Is the documentation available to workers? If answer is "No," then the lack of availability of the documentation is a contributor to the observed performance problem.)
- d. Has anyone been able to satisfy task expectations consistently using the prescribed approach? (If answer is "No," then the work process's design is a contributor to the observed performance problem.)
- e. Do many workers fail to meet expectations on more than one occasion when using the prescribed approach? (If answer is "Yes," then the work process's design is a contributor to the observed performance problem.)²
- f. Do performers meet expectations but only by using work-arounds to avoid problems that occur when using the prescribed approach? (If answer is "Yes," then the work process's design is a contributor to the observed performance problem.)

4. Decide if the gap is due to how the work setting supports performance.

Tip: Every work setting must support task execution; otherwise, it undermines correct performance. Below are the most common types of support workers need to succeed in meeting expectations. Gather the information you need to assess the adequacy with which each of these identified needs were met. Also ask whether your interviewees have observed any other Work Setting issue that hinders performance. Record each deficiency in Work Setting support as a contributor to the observed performance problem.

Expectations/Feedback

- Incomplete assignment information (e.g., task, objective, product, process, schedule, performance criteria that the worker must satisfy)
- Inadequate achievement information (e.g., late, inaccurate, feedback does not address both approach and results)

² Otherwise, your Selection and Training processes are at fault for failing to provide people capable of doing the work as designed.

Incentives

- Lack of recognition or reward for correct performance
- No acknowledgment or consequence for incorrect performance
- Presence of recognition or rewards for incorrect performance
- Rewards and consequences are not aligned with measures of tasks performance
- Inappropriateness of incentives given the perspective of the performer

Resources

- Lack of task-required information (e.g., customer requirements, quantity to produce, model to produce)
- Poor input materials; missing tools, equipment, forms, or other materials required for the task
- Problematic logistics
- Work space inadequate to accommodate operations

Coordination

- Poor execution by other individuals or organizations whose actions affect the successful execution of the work process (timeliness, correctness, consistency)
- Lack of alignment of perspectives among decision makers who affect performance

5. Decide if the gap is due to the worker's capacity, competence, or motivation or to a physical or to distraction caused by a physical, psychological, or social problem.

Tip: Gather the information you need from job incumbents and their supervisors and by direct observation. Decide the answer to each question below. Document what you find.

Capacity

- Do the performers have the strength, flexibility, coordination, balance, stamina, or other physical fitness features required to perform the task to expectation?

Tip: If the answer is "No," then deficiencies in the workers' physical capabilities are a contributor to the observed performance problem. Physical barriers are dealt with by redesigning tasks to reduce their physical demands or augmenting the person's capabilities through physical training or the use of some type of work aid.

- Are performers able to manage the number and complexity of social relationships required to coordinate the task to expectation?

Tip: If the answer is no, then deficiencies in the workers' emotional-interpersonal capabilities are a contributor to the observed performance problem.

- Are performers able to manage the multitasking or concurrent processing demands the work requires, if such is required to complete the task to expectation?

Tip: If the answer is no, then deficiencies in the workers' intellectual capabilities are a contributor to the observed performance problem.

Competence/Motivation

- Assume the following is true: the work process is correctly designed; workers receive proper work setting support; they are free of personal distractions; and they have the capacity to do the task. Given these conditions, could these workers execute the work process to expectation if their lives depended on it?

Tip: If the answer is "No, they could not" then deficiencies in the person's knowledge, skills, or proficiency levels or other required personal characteristic are a contributor to the observed performance problem. Any gap due to a competency issue means that you have identified a learning need and

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possibly a problem with your Selection and Training functions. Document what competencies are insufficient.

If the answer is “Yes,” then the person’s level of motivation is a contributor to the observed performance problem. Identified that problem with Incentives (see Step 4, above), correct that problem first, and then recheck this item. If motivation issues continue, try other options such as providing the worker counseling or warning the employee of an adverse personnel action (demotion, termination) should performance not improve.

Personal Distractions/Misjudgement of Capabilities

- Are performers being distracted from their work by physical illness, psychological problems, social stresses either inside or outside work, or any other issue? If the answer is “Yes,” then personal distractions are a contributor to the observed performance problem.
- Did the performer choose to assume a responsibility he or she was not capable of handling? If “Yes,” then misjudgment of personal capabilities is a contributor to the observed perform.

6. Record the cause(s) for the performance gap.

Tip: Mark the cause(s) for each gap as “Work Process,” “Work Setting,” or “Person.” List all the contributing factors you detect within each cause group. Add details to each so that someone reading your findings can understand what is wrong and what the factual basis for your judgment is. Note, for example, what work process design features seem problematic, including the problem(s) each causes, its consequences, and how it can be detected; what work setting support is insufficient, how, how often it occurs; and what its consequences are; and what elements of worker capacity, competence, motivation, self-efficacy, or distract- edness contribute to the performance gap and what evidence confirms this finding.

Study the *Example of a Cause Analysis* (beginning on next page). As you read through the problem statement, imagine applying the cause analysis process just described.

References

- Bandura, A. (1982). Self-efficacy mechanism in human agency. *American Psychologist*, 37(2), 122-147. Retrieved 3/10/2020, from <https://pdfs.semanticscholar.org/8bee/c556fe7a650120544a99e9e063eb8fcd987b.pdf>
- Cerasoli, C. P., Nicklin, J. M., & Ford, M. T. (2014). Intrinsic motivation and extrinsic incentives jointly predict performance: A 40-year meta-analysis. *Psychological Bulletin*, 140(4), 980–1008.
- Deci, E. L., Koestner, R., & Ryan, R. M. (1999). A meta-analytic review of experiments examining the effects of extrinsic rewards on intrinsic motivation. *Psychological Bulletin*, 125(6), 627–668.
- Deming, W.E. (1982). *Out of crisis*. Cambridge, MA: Massachusetts Institute of Technology Center for Advanced Engineering Study.
- Gilbert, T.F. (1978). *Human competence*. New York: Mc Graw Hill.
- Peek, G. A. (2003). *The political writings of John Adams*. Indianapolis, IN: Hackett Publishing Company, Inc.
- Vitalo, R.L. (2022). The factors that determine human performance and its success. Vital Enterprises. Retrieved November 25, 2022, from https://www.vitalentusa.com/learn/hpm_model.ph

Case Example of a Cause Analysis

This example of a cause analysis takes place in a bio-chemical plant manufacturing sterile drug products.

Uncovering Performance Gaps

As part of the yearly training needs assessment, staff of the plant's Learning Organization collects information about gaps in performance—places where the results expected by the business are not realized. One stop the team makes is with the various departments who do audits. At Environment, Health, and Safety (EH&S), the training team talked with Frank, a senior auditor. He told the team that the last audit uncovered a performance gap in an aseptic filling area of the facility (Filling Area A) that needed action. "Yea, it looks like the fill area technicians have forgotten their aseptic procedures. There's a group you can train," Frank said. Sandy, the training team lead, asked Frank to clarify what his audit team had found. "The environmental monitoring data from one of the aseptic filling areas (AX02) showed a trend toward increasing particulate (nonviable) and microbial (viable) counts. We tested uniforms as employees entered the area to rule out contamination coming into the area. The uniforms were free of contamination. So it seems clear to the audit team that the contamination is being generated by poor aseptic technique as practiced by the employees in this area. Also, the other fill areas are doing just fine. Based on the trend we observed, production management determined that the corrective action would be to conduct a refresher training course on proper aseptic technique, covering topics such as frequently sanitizing hands with an alcohol solution or similar agents; avoiding sweeping, fast movements in the room; minimizing time in the 'critical zone'; and similar behaviors." Sandy confirmed Frank's report of the production management's assessment. Management was convinced that the cause of contamination was poor execution of aseptic techniques by the fill area operators.

Sandy then asked whether anyone had done an observation of the fill area operators as they worked to test the conclusion. "No, not needed. This seems pretty cut and dry. No contamination going in on the uniforms. Contamination has got to be introduced by them while doing their jobs." Sandy noted the gap and asked whether Frank's audit group would be open to other ideas if the training team uncovered anything different. "Sure, break a leg. We'll listen," said Frank. "But remember people are the source of most contamination." The team recorded the performance gap it uncovered.

Exhibit 1. Performance Gap Reported by the Environmental Audit Team

Job: Aseptic Fill Room Technicians			
Who	Task	Current Status	Required Status
All Incumbents in Fill Area AX02	Sustain sterile work environment	<ul style="list-style-type: none">Observed particulate counts at .005 parts per million and .004 log₁₀ cfus per mL of air.Count rising over time	<ul style="list-style-type: none">Observed particulate counts at or below .001 parts per million and .001 log₁₀ cfus per mL of airCount stable or declining over time

Analyzing Possible Causes

The training team began its cause analysis by reviewing the three categories of reasons why a gap might exist. Mike, a team member, pointed out that the team would need to rule out the design of the work itself first. "If work design is flawed, then the technicians will fail no matter how well they do their jobs. Hey, they'd be contaminating the area by *doing the job right!*"

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“Then we need to look at support issues,” Carol added. “The setting, especially inside the clean room, has to provide the right resources, at the right time for any work process to succeed. After that, we can look into technician issues. I doubt there is a capacity concern. I know that job and while it demands a disciplined focus on details and methods, they keep the shift cycles reasonable. I have never seen a person in that area who could not sustain the attentiveness that’s needed.”

“People do forget and leave steps out over time, however.” Mike interjected. “So we will need to look at the competency issue. Also, let’s not forget motivation. You need a keen interest in doing the job right to stick to the techniques policy lays out.”

Work Process and Work Setting Issues

The team looked first into the issue of work design. Was there anything in the procedures governing how technicians worked that might be causing the contamination? The team reviewed the information it had. Only one fill area was exhibiting a performance gap. “Well,” Mike observed, “I guess that means the work process is fine. After all, it’s doing the job in the other fill areas.” Sandy responded, “Not so fast. I think your right to consider the good performance elsewhere as it could mean the work design is fine, but remember how often we have been on the floor and asked people to show us an operation and their first question to us is ‘Which way? By the book or how we really do it?’ What about us making sure that people are operating by the book everywhere?” Mike and the other team members agreed. So, the team decided to talk with some technicians. “Why not at lunch?” Carol asked. “We can eat together and get their ideas about what’s happening?” Everyone agreed it was a quick way to move the analysis forward.

In the cafeteria, the team spotted several aseptic fill area technicians from different fill areas, including the one having the contamination problem. They sat down together to chat. What they learned was really interesting. First, they all the operators in Fill Area AX02 knew about the problem. The technicians in the AX02 area, as the others, regularly checked their individual monitoring results and saw the problem first hand. All seemed puzzled by it. All the technicians agreed that they were following the same procedure without work-arounds. Sam, an AX02 technician, made the point very clearly: “You do not improvise in sterile environments period! Hey, we are paid a premium for working in the aseptic areas; we won’t jeopardize it by improvising. We are expected to do the job by the book, and by the book is the way we do it!”

We ask the AX02 technicians present whether they had the tools and other resources they expected to have when doing the job. They reported no problems. Then we asked whether they observed anything unusual about their fill room and we got an interesting piece of information. Jack, one of the AX02 technicians who also had worked in the AX01 fill area, said that the AX02 room seems to run warmer than the other rooms. “The room temperature for our area goes up from 65 F to 75 F when it is in use. The other filling rooms increase only two degrees or so. It got so uncomfortable that we asked our supervisor if we could shed the white uniforms we were wearing under our sterile gowns. She said fine that there was no

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specification requiring that we wear them. So now most of us only wear our underclothes under our gowns.”

Mike asked whether the room had always run warm. Jack answered “No.” He reflected a bit and then added, “I think it began around the time we upgraded our equipment about a year ago. We are—or were—the lead area, so they were using our area to introduce new equipment.”

As a follow-up, Carol asked Jack when he had moved over to AX02 and whether there had been other personnel changes recently. Jack said that he had moved over two years ago and that the team has been stable since then.

As lunch ended, Sandy asked whether there were any other differences between the AX02 fill area and the other areas. Alice responded that most often we work with four people in the room. We use to work with just two, like the other fill areas do.

Person Issues

After lunch, the team addressed the last possible set of causes—worker factors. The team had four factors to consider: capacity, competence, motivation, and distractions. EH&S has concluded that training was the solution. That meant that they thought there was a competency issue—some lack of knowledge or skills or proficiency levels on the part of the AX02 technicians. One quick test of whether a competency issue was whether the technicians had ever performed to expectation. Well, EH&S’ own data indicates that the answer is “Yes.” As Frank reported, the impurities were on the rise, but they had been at acceptable levels previously. There had been no team changes, so the same people were operating the area when it was doing well as now. Also, the team checked the training records to see whether all people in that area were trained previously on aseptic technique and were involved in successful media-fill validations (the performance test that regulatory inspectors ask for as evidence that the training was successful). They were. If they were not applying what they learned, it probably was not due to lack of knowledge or skills. As our conversations with technicians indicated, motivation did not seem to be an issue either. They all spontaneously indicated that priority number one was maintaining a sterile workplace. They all checked their individual monitoring results that are available to each person. And they all seem to value the premium pay they received for working in aseptic fill areas.

Thinking Through the Possible Causes

The training needs team settled in to pull together what they had learned. Sandy put up a flip chart page with the performance spelled out on top and the possible causes below (Exhibit 2, next page). “Let’s walk through what we learned,” she said.

Mike led off. “Well, the work design seems fine. People report using it as specified and it produces good results in all the fill rooms except AX02 and even in AX02 it produced good results up to a year or so ago.”

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Exhibit 2. Team Flip Chart Analysis				
Performance Gap				
Job: Aseptic Fill Room Technicians				
Who	Task	Current Status	Required Status	Likely Cause
All Incumbents in Fill Area AX02	Sustain sterile work environment	<ul style="list-style-type: none"> Observed particulate counts at .005 parts per million and .004 log₁₀ cfus per mL of air. Count rising over time 	<ul style="list-style-type: none"> Observed particulate counts at or below .001 parts per million and .001 log₁₀ cfus per mL of air Count stable or declining over time 	?
Possible Causes				
Work Process		Work Setting	Person	
<ul style="list-style-type: none"> Work process is performed as defined. Work process produces expected results in all but one aseptic fill area. Work process produced good results in the problematic fill area up to a year ago. 		<ul style="list-style-type: none"> Tools and materials are fine. Feedback on performance individualized, accurate, and regular. Incentives reward good performance. Temperature of AX02 fill area is elevated. Use of cotton-blend under garments suspended due to heat. Workers are four to room, not two to room as in other aseptic fill areas. 	<ul style="list-style-type: none"> Capacity of workers seems to match requirement. Knowledge and skills were trained and mastery has been demonstrated. Transfer of skills to job was also demonstrated by prior performance. Motivation seems high. Work to standard seems the strong norm. None seem distracted by external issues 	

Carol added, “We seem to have mixed information about the setting. On the plus side, tools and materials seem fine. Feedback on performance is provided in a timely manner too. The incentive system seems straight—do well and hold a premium-paying job. Something does seem to be going on with the workspace, though. First the temperature is out of line with other fill areas. We know that people shed more particulates as their body temperature increases, especially viable particulates (cells capable of growing and proliferating). They came up with a possible way to control that by shedding under clothing. That solution they are trying might be a problem. It doesn’t violate any existing policy but those undergarments they shed are made of a cotton-blend. One of their functions is to provide a barrier and help to absorb skin cells and bacteria that get sloughed off with perspiration. The workers in the other fill areas wear the undergarments.”

Sandy closed by summarizing what was learned about the technicians. “Well, there seems to be no capacity issues. All the technicians have previously performed their tasks as expected. Nothing has changed with respect to their capacity to do the work. None seem distracted by any external issues. All are very much concerned about improving their performance. The current information suggests that the technicians are performing their tasks according to the work standard. I guess we could confirm that with an observation, if there is any doubt. But, they have been trained and validated in their work. They’ve done it right before. They do all elements of their jobs each day, so there is no lack of practice. And they

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certainly seem motivated to get their jobs done correctly, by the book.” When she finished, Sandy asked the team for their summary judgment about the causes for the gap. “What do you think? Is it a learning need or something else?”

Everyone spoke in unison, “Something else.”

Carol put it together. “No learning need based on the information we have. No work design problem either. The likely sources for the problem are the way the setting is a supporting work. The fill room’s temperature is not being controlled effectively. It’s too high and that raises the likelihood of contamination. The clothing decision adds to it. It might tie back into when they changed out equipment. I wonder if anyone has checked to see if the new equipment is running hotter than old equipment which, I believe, the other rooms still use.” Mike added, “Let’s not forget that they also have more people working in their room at one time. That might place a demand on the cooling equipment it cannot handle.”

Sandy recorded the team’s judgment on the flip chart (Exhibit 3).

Exhibit 3. Cause Analysis Results				
Performance Gap				
Job: Aseptic Fill Room Technicians				
Who	Task	Current Status	Required Status	Likely Cause(s)
All Incumbents in Fill Area AX02	Sustain sterile work environment	<ul style="list-style-type: none">■ Observed particulate counts at .005 parts per million and .004 log10 cfus per mL of air.■ Count rising over time	<ul style="list-style-type: none">■ Observed particulate counts at or below .001 parts per million and .001 log10 cfus per mL of air■ Count stable or declining over time	<ul style="list-style-type: none">■ Work place support<ul style="list-style-type: none">▪ Excess heat in room▪ Garment change may permit more shedding of viables▪ Possible issue with recently installed equipment upgrade - it may run temperature up■ Possible contributor may also be having added workers in room (4 vs. 2) making an extra demand on the cooling system it can’t handle