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## "Read and Understand" vs. "A Competency-Based Approach" to Designing, Evaluating, and Validating SOP Training

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*The Road to Performance Excellence*

## "Read and Understand" vs. "A Competency-Based Approach" to Designing, Evaluating, and Validating SOP Training

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*Each person engaged in the manufacture, processing, packaging or holding of a drug product shall have education, training, and experience, or any combination thereof to enable that person to perform the assigned function. (CFR 211.25, Personnel Qualifications)*

Manufacturers typically use several systems to prepare personnel to perform their jobs. These systems include establishing job descriptions, formulating Standard Operating Procedures (SOPs), setting performance guidelines, providing leadership and supervision, and training employees. The goal of these systems is to enable employees to perform their assigned functions competently. Such systems are considered to be "working" to the extent to which they prepare employees to do their jobs effectively.

What differentiates successful systems from not-so-successful ones? Most people would agree that factors such as strong organizational commitment to adhering to performance guidelines and providing solid leadership play important roles in ensuring success. Another key factor involves establishing a method for conveying and assessing employee competencies. In fact, systems that do not include this critical element, no matter how well-intentioned they may be, are likely to be less successful in achieving their goals than those that include this key component.

Although many organizations have adopted a competency-based approach to training and qualifying employees, others have not abandoned practices that involve methods that do not conform to a competency-

based approach to training. One of these is the still-popular "read and understand" method of conveying job-related skills and knowledge through SOPs. The problems inherent in this approach are discussed below.

### "Read and Understand" vs. Establishing Competencies

The "read and understand" method of SOP training requires employees to read SOPs and to sign a form stating that they have read and understood the information. Although many organizations use this approach, the method has a number of pitfalls. First, consider the use of the word "understand." Trainers developing performance objectives avoid this word for good reason. What exactly does "understand" mean? For example, if an SOP involves performing certain tasks, does "understand" suggest that the employee can do the tasks correctly after reading the SOP? Or does it simply mean that the employee understands that the job requires certain tasks to be performed? And how does this understanding translate into performance, the only true measure of "understanding" in performance-based organizations?

A second problem is that this approach can place undue pressure on employees to sign the "read and understand" statement regardless of any questions they may have about what they have read. How many new employees will speak up if they are not clear about an SOP? How many incumbents are comfortable expressing their uncertainty about a vaguely worded or ambiguous procedure? The truth is that many employees sign the "read and understand" form as a matter of course, without expressing the concerns they may have about an SOP.

Still another difficulty involves questions around employee reading level and English as a second language. Employees may not be reading on the level in which SOPs are written, or they may be unfamiliar with words

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or terms in SOPS. And learning styles vary in almost any audience. Employees who learn best by seeing or doing will derive little benefit from reading SOPS. Regardless of learning style, few employees can truly learn a job simply by reading an SOP.

As to this the problem of poorly written and confusing SOPS and you can see why the "read and understand" approach to SOP training presents difficulties. Indeed, employees and managers alike will benefit from adopting a systematic approach to SOP training that is based on demonstrating true competency in skill and knowledge areas.

#### Valid and Reliable Training: What Is It?

The terms "valid" and "reliable" are used often in training today. Simply stated, training is valid when it is tied directly to the requirements of the job and when it includes evaluations that are linked to the skills and knowledge stated in the objectives. Say, for example, that a job requires an operator to calibrate a piece of equipment to  $\pm$  a certain range. This requirement would be stated in the training program objectives, trained on, and tested in a performance demonstration.

Reliability means the test clearly differentiates between those who can perform the task and those who cannot. It also means that similar results will be achieved over time. Training programs conducted many times with similar employee populations under the same conditions should produce the same results. If results vary, the training program is not reliable.

Consider the "read and understand" method of conveying knowledge against a "valid and reliable training" approach. Clearly the "read and understand" method does not meet the criteria set out for validity or reliability. Since "read and understand" does not involve performance testing against specified, job-related objectives, managers have no way to measure whether or not employees can do the job set out in the SOP. Similarly, "read and understand" does not include a testing component that differentiates between those who can and cannot do the job, nor does it measure results over time.

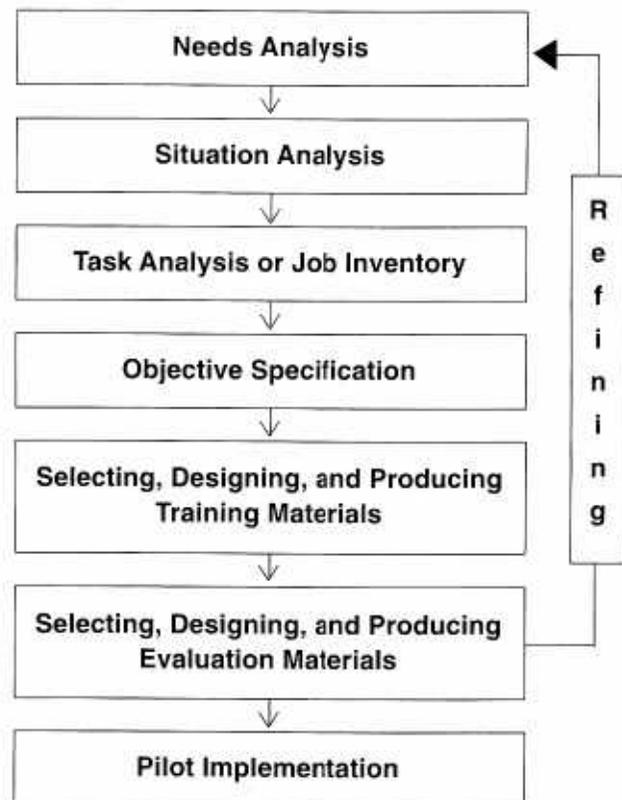
What kind of training does satisfy these criteria? Developed properly, competency-based training programs help ensure both validity and reliability.

#### Developing Competency-based Training

How can employees and managers know whether employees are able to perform their jobs? A competency-based approach to training and qualifying personnel addresses the true training needs of the employee. It includes these components:

1. Identifying competencies required to do a job
2. Stating objectives describing the competencies employees will exhibit after completing training
3. Developing and delivering training that conveys competencies
4. Evaluating a representative group of trainees against the stated competencies

A model that helps ensure valid and reliable training is shown below.



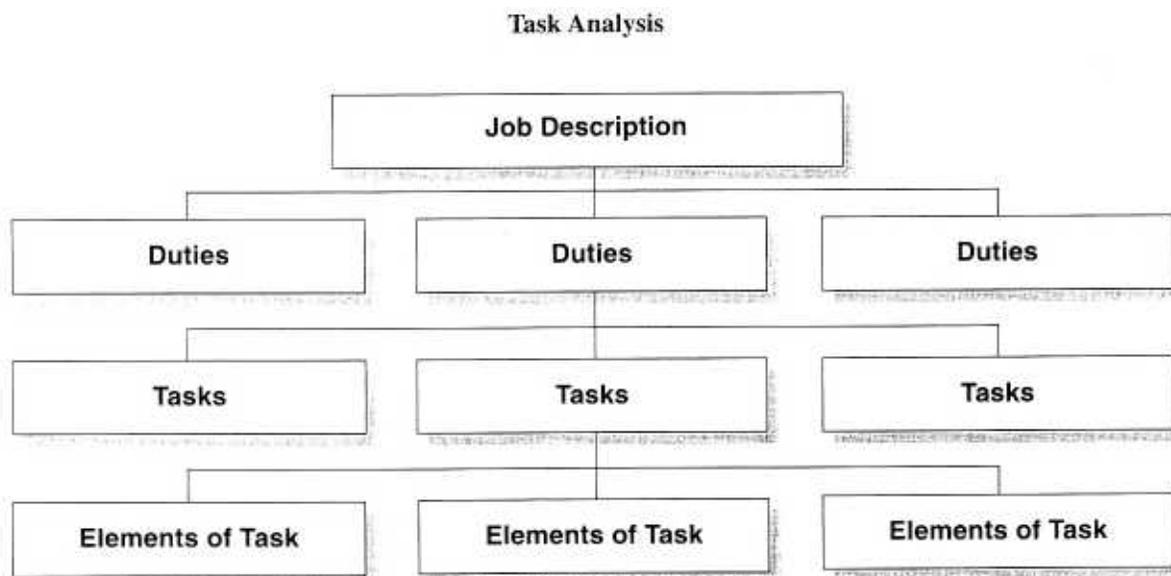
## The First Steps: Needs Analysis, Situation Analysis, and Task Analysis

How do we know whether a performance issue is related to a training need or to some other area, such as unclear communication, conflicting directions, and so on? The needs analysis establishes whether training is needed and, if so, areas which need to be addressed in the training. During the needs analysis step, gaps in desired vs. actual performance are identified and provide the basis for developing training. For example, suppose a supervisor wants her employees to be able to use a new piece of equipment properly. In that case the desired performance (using the equipment) and the actual performance (inability to use the equipment) can be addressed by training.

Once the needs analysis is completed, the situation analysis focuses on the audience, resources, and constraints to conducting the training. For instance, the

training may need to be facilitated during equipment downtime, on three shifts, and under the leadership of a Subject Matter Expert (SME). In this case the training would probably be conducted on-the-job by an SME.

Next is the process of task analysis, which begins with a review of the job description and duties, tasks and subtasks it entails. Typically, training program designers conduct task analyses by observing and interviewing operators, reviewing current SOPS and equipment manuals, and consulting other source materials. Drafts are reviewed by operators designated as reviewers, usually those considered most knowledgeable and experienced by managers and co-workers. Drafts may also be reviewed by team leaders or supervisors serving as SMEs. The development process also involves reaching consensus on best practices when disagreement arises among SMEs-or when SOPS are too vague to be a deciding factor.

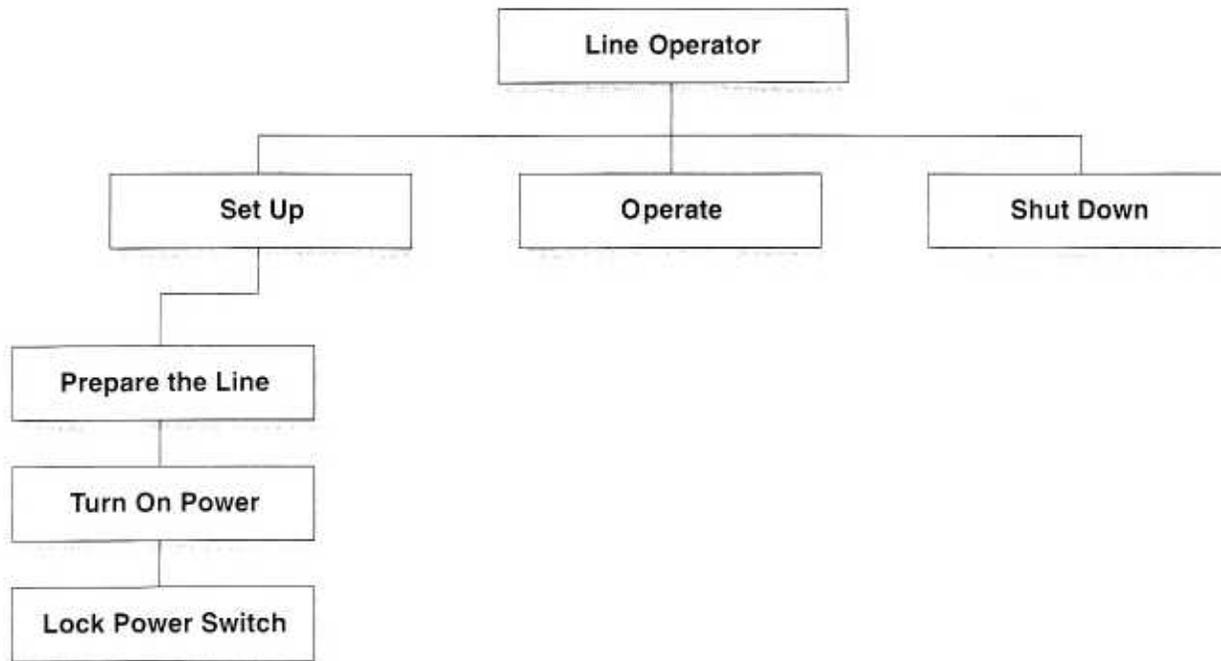


Suppose, for example, that a line operator's job description contained three major components: the operator is required to set up, operate, and shut down a piece of equipment properly. This will be the starting point for our training program development.

Next, we break down the major components into duties. For instance, a duty associated with setting up the

equipment might be to prepare the line for operation. To execute this duty, the operator first has to turn on power to the line. This task may be further divided into elements or subtasks. In this case the first element is to locate the power switch.

Following this protocol, each part of the job is identified and broken down into manageable units for training.



#### Objective Specification and Material/Method Selection

One way we can ensure training is valid is to develop objectives that reflect the actual tasks, duties, and subtasks required in the job. For example, if one duty of the operator's job involves shutting down the equipment, an objective for training might read "after completing the process the operator will be able to shut down the equipment according to standard procedure."

#### Training Materials

What do the training materials look like in competency based training? The possibilities are virtually unlimited, ranging from leader's guides for classroom-based or on-the-job training to self-instructional programs delivered in computer-based or workbook formats. The materials are dictated in large part by the training situation, which includes the constraints placed on the way in which the training can be delivered.

In most cases, though, job training involving SOPS is delivered by an SME trainer in a combination on-the-job and classroom setting. This entails developing leader's and participants' materials, job aids such as checklists, and appropriate performance demonstrations to ensure competency.

#### Evaluations

What is it exactly that we are evaluating when we collect data about training programs? According to Donald Kirkpatrick, we should evaluate four levels.

##### Level 1: Reaction

What did the trainees feel about the program? Evaluation of trainees' reactions to training is usually conducted by questionnaires administered immediately after the program ends.

This type of evaluation can measure whether the program met its objectives, whether the trainees felt the training could be improved, and how well the program applies to trainees' jobs. It should not be used as the only measurement, though. Level I evaluations are most useful when they are complemented by the other levels of evaluation, which help us measure the trainee's skills and knowledge, and measure the results of the training.

##### Level 2: Learning

Most technical training is aimed at conveying skills and knowledge. To what degree were skills and knowledge

affected by the training? This can be measured by pre- and post-tests administered before and after the training. In most cases tests contain a written component and performance demonstrations to ensure skills as well as knowledge have been conveyed. Reviewing these evaluations over time will help us establish the reliability of the program.

### Level 3: Behavior

Suppose Level 1 and Level 2 evaluations show participants felt positive about the training and scored well on the post-test. Next we need to assess whether this change in behavior transferred to the job. Did participants change their job behavior as a result of the training? In what ways? If the participants did not change their behavior, was it because other factors intervened- for example, a supervisor discouraging the new behavior or a leader who failed to reward it?

### Level 4: Results

Did the training pay off? Did productivity increase? Was improvement in quality or reduction in costs noted? We should never forget that a primary objective of job training is to ensure on-the-job results. Level 4 measures results.

This type of evaluation can be difficult to design and administer, which is why it is still seldom performed in industry-though this will probably change over time. In many cases it involves gathering baseline data before the training and comparing it with post-training results.

Evaluation at this level can involve looking at the cost of time spent in training, the costs of the program, and other factors that many trainers and managers would just as soon forget. But the purpose of industrial training is ultimately to produce results that impact favorably on the bottom line, and Level 4 evaluation can help make the case for training.

### Implementation

The first presentation of the program is usually referred to as the "pilot." This term lets everyone know some program adjustments are expected. For certain programs, however, it is simply too expensive to put the time and effort into such testing. In these cases, you

will be "piloting" the program on the first group to be trained.

### Refining

Even the best training programs can be made more effective if they are revised or modified. The pilot program evaluations will tell you where you can improve the training program.

Revising the training program may mean incorporating new material to help the program meet its objectives, or it may mean revising the objectives themselves, based on input from trainees or managers. In any case, though, you will follow the steps you used to develop the training program as you refine it.

- Make sure the revisions are designed to support specific, measurable objectives.
- Follow the appropriate steps to select, design, or produce training materials to support those revisions.
- Implement, evaluate, and refine the revised program to see if further modifications are necessary.

In a sense, the refining process for competency-based training never ends because we are always looking for ways to update, revise, and modify the training programs we design. Developments in technology, changes in skills and knowledge among trainees, new marketplace demands, and a variety of other factors impact our training programs and make it critical that we improve training on an *ongoing* basis.

It is only by constant evaluation and revision that our training program-and therefore our employees-are the best that they can be.

### Conclusion: **Will Management Buy It?**

Does all this sound like more effort than simply asking employees to sign a "read and understand" statement? Consider this: How much more time and effort are expended to correct problems that arise when employees do not know how to do their jobs effectively? In the long run, the benefits of well-designed competency-based training outweigh the costs in terms of rework, quality, and waste.

But will management buy it? One way to help get the buy-in needed for competency-based training is to establish baseline data around rework, quality, waste, downtime, and other factors. Then ask management whether they would like to see these numbers improve. Our experience has been that when it is developed properly, competency-based training inevitably contributes to the bottom-line and pro-

vides outstanding return-on-investment. Equally important, competency-based training is becoming the industry standard because it is based on a sound model of training program design. The handwriting is on the wall: the "read and understand" method of training-which is really not a training method at all-will eventually be abandoned in favor of competency-based training.