Because
"Read & Understood" Isn't Good Enough

How to Build an Effective OJT Program

NE PDA Meeting
September 8, 2010
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How to Build an Effective OJT Program

- Topics
  - Characteristics of a Universal, Effective OJT Program
  - OJT Content
  - How to Build an OJT Program

Characteristics of a Universal, Effective OJT Program

- Performance/competency based, confirming both knowledge & performance – not R&U!
- Structured, in a curriculum, with progression built on prior competencies
- Standardized content/format
- Owned & delivered by area personnel
- Defined for specific job responsibilities, ensuring consistency across the group/site
- Thoroughly defines performance expectations at training completion

Characteristics of a Universal, Effective OJT Program

- Competence assessed by OJT trainers and area management

- SOPs documented as "complete" at signoff of OJT – no separate "R&U" entry needed!

- Employs periodic requalification as appropriate

    - Utilize operational checks in place of requals

- Ties training to production needs, but retains structure and planned nature

- Time budgeted for training

Characteristics of a Universal, Effective OJT Program

- Delivered by trainers who:
  - Possess expertise with & ability to perform the task
  - Are qualified/certified & designated by area management to train others on that task
  - Have their performance periodically assessed through:
    - Performance reviews/evaluations, including feedback from trainees
    - Data on instructor performance (deviations, metrics, etc.)
    - Annual observation (by the area manager/supervisor or another qualified trainer) as they perform training

So what should be in an OJT?

Element	What Is It	Rationale
Format	Structure & required elements	Consistency
Prerequisites	Items to complete prior to beginning training	Structured training plan, progression of skills
Related Items	SOPs utilized in the task	Demonstrated ability to utilize the procedures
Learning Objectives	What the trainee will be able to do at the completion of training	Scope of the task & required level of competence
Background/ Rationale	Non-SOP information related to the task (the why's)	Knowledge of operation
Checklists	Signoff of successful completion of defined operational components	Demonstrated competence against assessment criteria
Signoffs	Trainee, trainer, supervisor acknowledgement of completion	Approval of readiness to perform independently

How to Build an OJT Program

- Identify the tasks done in the area
  - Defines what OJTs are needed
- Identify what people need to do as part of each task
  - Defines Learning Objectives & Related Items
  - Use [Bloom's Taxonomy](#)!
- Create a [training plan](#), ordering tasks by "level"
  - Defines [Structured Training Progression](#) & Prerequisites

How to Build an OJT Program

- Define task components & performance criteria (use SOPs & SMEs!)
  - Defines competencies & assessment criteria, creates Checklist (training documentation)
  - Use Bloom's Taxonomy!
- Document big picture, why's, tips/techniques
  - Provides Background & Rationale on operation
- Define signoffs (who, when, meaning)
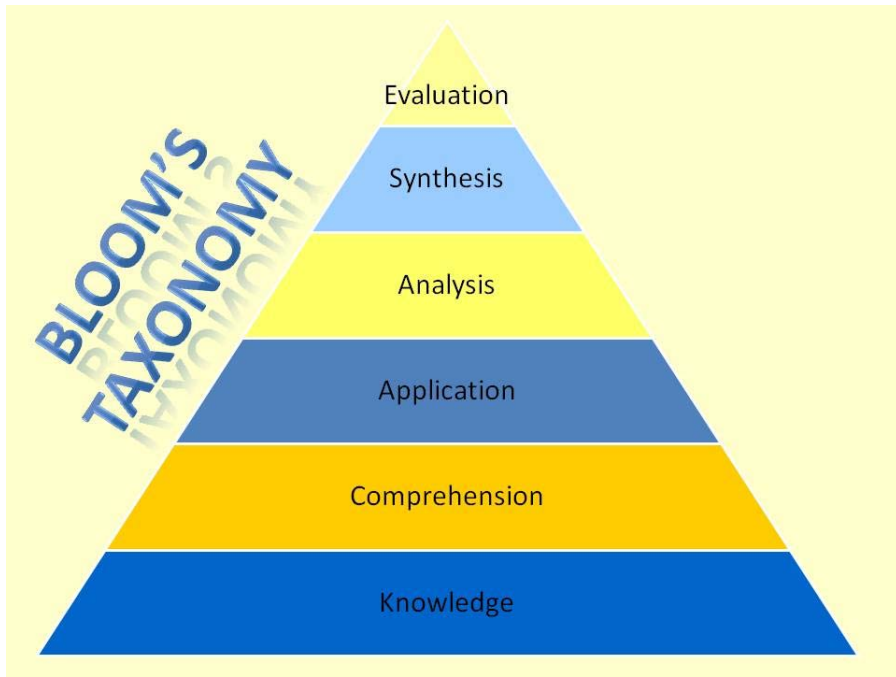 - Documents authorized level of performance

What's the Key to Success?

- Have a vision – take the time to figure out what you want and understand what the end result should look like.

  - *It may not be what you're doing now!*

BLOOM'S TAXONOMY

- Evaluation
- Synthesis
- Analysis
- Application
- Comprehension
- Knowledge

Beware of vague verbs

- Know
- Comprehend
- Understand
- Appreciate
- Familiarize
- Study
- Be aware
- Become acquainted with
- Gain knowledge of
- Cover
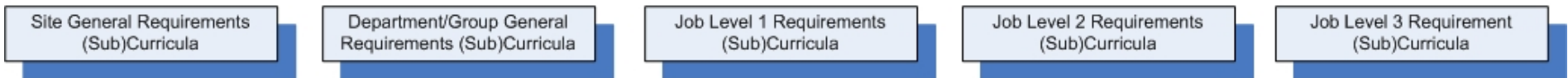- Learn
- Realize

How can these be measured?

Knowledge	Comprehension	Application	Analysis	Synthesis	Evaluation
List, name, identify, define, state, etc.	Summarize, explain, interpret, describe, compare, classify, etc.	Solve, calculate, demonstrate, apply, modify, perform, etc.	Analyze, organize, compare, contrast, etc.	Design, write, report, justify, support, etc.	Evaluate, choose, estimate, judge, defend, critique, etc.

Job Level 3 Curricula

Job Level 2 Curricula

Job Level 1 Curricula

Site General Requirements (Sub)Curricula	Department/Group General Requirements (Sub)Curricula	Job Level 1 Requirements (Sub)Curricula	Job Level 2 Requirements (Sub)Curricula	Job Level 3 Requirement (Sub)Curricula

Site General Requirements (Sub)Curricula

Sitewide, basic SOPs, such as:
- Documentation system
- GDP
- Site Quality Manual
- Documentation of Training
- etc...

Sitewide, basic courses, such as:
- New Hire Orientation
- cGMP Training
- etc...

Department/Group General Requirements (Sub)Curricula

Functional SOPs applicable to entire group
- Auditing SOPs

Courses required for entire group, i.e.:
- Auditing (external source), within 3 months

Any other department level requirements, i.e.:
- Safety requirements
- Annual certification
- etc...

Curricula for Department Systems

Job Level 1 Requirements (Sub)Curricula

Curricula defining specific, <u>basic</u> tasks to be performed, containing related SOPs & OJTs, i.e.:

Curricula for gowning:
- SOP 1
- SOP 2
- SOP 3
- Gowning OJT

Curricula for aseptic task:
- SOP 1
- SOP 2
- Aseptic task OJT
- Prereq: Gowning OJT

May include additional tasks, courses, soft skills training, etc...

Job Level 2 Requirements (Sub)Curricula

Curricula defining specific, <u>more advanced</u> tasks to be performed, containing related SOPs & OJTs, (may include additional tasks, courses, soft skills training, supervisory training, etc.):
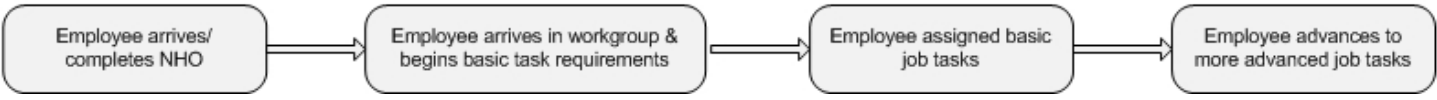
Curricula for performing investigations:
- SOP 1
- SOP 2
- RCA & Critical Thinking Course
- Interviewing skills course
- Deviation Management System curricula
- Investigation OJT
etc.

Job Level 3 Requirement (Sub)Curricula

Curricula defining specific tasks assigned to the most senior levels

Begin working towards Level 2 requirements

Begin working towards Level 3 requirements

Employee arrives/ completes NHO → Employee arrives in workgroup & begins basic task requirements → Employee assigned basic job tasks → Employee advances to more advanced job tasks

Identify Job Tasks &
Requirements

Task 1

Task 1 Requirement 1
Task 1 Requirement 2
Task 1 Requirement 3

Task 2

Task 2 Requirement 1
Task 2 Requirement 2
Task 2 Requirement 3

Task 3

Task 3 Requirement 1
Task 3 Requirement 2
Task 3 Requirement 3