

Human Error Reduction Tool: Pre-Job Briefing

Tool Description:



- Informal tool, that is predictable but flexible
- Developed by those performing the task
- Emphasizes use of the SOP
- Reviews key points of the task and who will do what
- Highlights any new information and special precautions

When To Use:



- Tasks not performed daily or weekly
- Critical tasks with high risk of error
- Short term, critical, complex projects
- Tasks that may be impacted by external factors like visitors or non-routine activities.

How to Use:



- Perform at a planned time, before the task
- Avoid unplanned or times immediately before task as instinct is to rush when pressed for time
- All staff involved in the task are present
- Team jointly agree that people, equipment, materials, etc. are ready & task can begin

Template: Pre-Job Briefing Check List

What is the Job? <ul style="list-style-type: none"><input type="checkbox"/> Discuss objective of task. e.g. Complete product transfer<input type="checkbox"/> Verify any pre-requisites have been completed. e.g. equipment and materials checklist completed
Documentation <ul style="list-style-type: none"><input type="checkbox"/> Discuss relevant SOPs and any recent changes, including any supporting SOPs like operation and maintenance documents<input type="checkbox"/> Verify necessary documentation for recording event is ready e.g. printed batch records<input type="checkbox"/> Ensure any supporting electronic devices, like tablets, are charged and ready
Roles & Responsibilities <ul style="list-style-type: none"><input type="checkbox"/> Verify all are appropriately trained/qualified. Pay special attention if training or documents were recently revised<input type="checkbox"/> Discuss who is responsible for what part of the task e.g. primary and secondary operators.<input type="checkbox"/> Discuss any notification requirements e.g. supervisors, QA<input type="checkbox"/> Identify who is available from support staff e.g. engineering/maintenance, QA, cleaning<input type="checkbox"/> Identify hand off points and who will be taking over
Critical Steps <ul style="list-style-type: none"><input type="checkbox"/> Discuss critical steps of the task<input type="checkbox"/> Discuss safety risk and mitigations<input type="checkbox"/> Indicator of issues or potential issues to watch out for
Human Factors <ul style="list-style-type: none"><input type="checkbox"/> Discuss most likely sources of error and mitigations<input type="checkbox"/> Ask for any input from the team on potential issues e.g. fatigue<input type="checkbox"/> Discuss possible external factors e.g. visitors, observers, non-routine activities in the area<input type="checkbox"/> Share any tips or techniques to support best outcomes
Trouble Shooting, Work Stop <ul style="list-style-type: none"><input type="checkbox"/> What troubleshooting is okay e.g. re-standardization can be performed twice<input type="checkbox"/> Actions to take if anyone is unsure of next step, has concerns or questions e.g. contact supervisor or lead<input type="checkbox"/> Actions to take if unexpected result occurs
Ready to Begin? <ul style="list-style-type: none"><input type="checkbox"/> Given discussion, do all agree work is ready to start?

Brief Case Study #1 – Part 1

Event Summary

Product AlphaDelta requires filtration through a 0.2 micron filter. This is performed approximately once every 4-5 weeks. The process is performed in an LFH, requires a single use filter, filter integrity tester and autoclaved small parts and containers. If not performed correctly, entire batch is likely to be rejected.

Things to know:

- Operation requires a primary and secondary operator and one support person in the area
 - The filter integrity testing is described in the filtration procedure
 - Trouble shooting for the filter integrity tester is described in the filter integrity tester operation and maintenance procedure
 - The last time this was performed an incorrect container was loaded into the hood so there was not enough containers to hold the filtered product
 - The procedure was revised and became effective two weeks prior to the next scheduled filtering event
 - High particulate recoveries occurred during last operation because IPA was sprayed near particulate counter
 - Company VIPs are touring the area
 - Two new operators will be involved in the task
 - One, experienced operator, just returned from paternity leave
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Discussion

What would you do?

What would you include in a pre-job briefing to help prepare for the operation?

What would you ask of the team performing the work?

Do you see any potential human factors that need to be addressed?

When would you plan to have the pre-job briefing?

Brief Case Study #1 – Part 2

Pre-Job Briefing Example for Filtration Process of Product AlphaDelta

What is the Job?

- Goal is to complete product filtration.
- Small parts and correct size containers autoclave and in staging area?

Documentation

- Filtration is described in SOP AD-0123. Note that new revision requires a 1 minute hold during testing that was not there before. This is highlighted by red “new step” before step in SOP.
- Verify that integrity tester has been re-programmed with new hold time
- Supporting integrity tester SOP is AD-0567
- Filtration batch record has been issued by QA doc control and is in staging area

Roles & Responsibilities

- Everyone has trained on new revisions of document
- Newer operators have completed signoff on qualification and all training documentation is in order
- John is primary operator, Sue is secondary operator and Sam is support. Joe is available as back up if needed
- If notification is required, Mark is available for production supervisor and Jane has QA on-call phone.
- Ben is on call for engineering if maintenance issues occur

Critical Steps

- Filter Integrity test must be completed before product is capped and moved out of LFH
- Sanitization of equipment and operators' hands is key, but take care to avoid spraying near particulate counter to avoid false hits
- A decrease in flow may indicate a potentially clogged filter. Refer to SOP for trouble shooting if this occurs

Human Factors

- New operators may be nervous, take it slow, check in, don't be afraid to ask questions.
- Any concerns for the team? Anyone uncomfortable with their assigned role?
- Visitors are likely to be touring area. Do not disturb signs can be displayed during operation and they have been instructed not to interrupt an operator while a task is being performed.

Trouble Shooting, Work Stop

- A filter may be retested twice if failure occurs, refer to O&M for trouble shooting. After second failure notify supervisor and on-call QA for next step.
- Verify there are no questions or concerns before moving onto next step.

Ready to Begin?

- Given discussion do all agree work is ready to start?

Human Error Reduction Tool: Root Cause Decision Tree

Tool Description

- Systematic approach to digging deeper into suspected “manpower” root cause
- Guiding questions to find the true root cause (s) of an event if manpower is suspected.

When to Use

- During root cause analysis, before determining CAPA
- When human factors contributed to an event and identifying the true root cause is key. This can be every event or using a risk-based approach.

How to Use

- Don’t assume a single cause
 - Perform interviews in the place where the event occurred
 - Include supervisor, personnel involved in event and SMEs (as appropriate).
 - Methodically evaluate all possible system causes
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Interview Questions to Assess Underlying Cause(s) of Human Error

MATERIALS

- Are the material handling and storage procedures clearly defined?
- Are materials labeled in a human friendly manner?

MACHINE/MAINTENANCE

- Is the equipment appropriate and designed properly for the task?
- Are the buttons, valves, switches on the equipment easily identified and accessible for the operation?
- Was the equipment in good working order at the time of the event?
- Are failure response process and troubleshooting decisions for the equipment clearly defined?

MEASUREMENT

- Do tools for measuring provide appropriate units and needed accuracy? Is on-the-fly unit conversion required?
- Are calculations performed manually? Are tools or job aids available to help with manual calculations?

ENVIRONMENT

- Is the work area set up appropriately for task? (e.g. lighting, temperature, tools/materials in easy reach)
- Are attention activators present to promote recognition of correct action?
- Is the workspace organized in a logical way to support task?
- Are there external pressures (e.g. time limits) that impacted the task?

METHOD

- Are instructions clear and concise, in the order in which the steps must be performed?
- Are procedures written in paragraphs, steps or bullets?
- Are pictures provided where words are ambiguous? (e.g. equipment set up, color change indicators)
- Are recent procedure changes highlighted by attention activators?

TRAINING

- Do training materials provide motivation, ability and support to form new habits?
- Does training include ways situations could go wrong to support decision making under stress?
- Is learning material presented in brain friendly format?
- How long was the gap between training and performing the activity?
- Does training on changes support creation of new habits?

Brief Case Study #2 – Part 1

Event Summary

Product AlphaDelta is sensitive to degradation when exposed to oxygen, particularly at certain in process steps. Therefore, it is key that a nitrogen overlay is used in the process. Release testing of lot # AD78910 identified degradant commonly seen after exposure to oxygen.

This result was confirmed and a laboratory investigation ruled out any potential errors during analysis, including sample handling. A manufacturing investigation determined that compressed air, instead of nitrogen was used as the overlay during one of the critical in-process steps. This was confirmed by reviewing compressed gas usage, which is tracked via the utility monitoring system.

The investigation concluded that the operator inadvertently used compressed air for the overlay instead of nitrogen.

CAPA: Re-training of the operator was documented. The procedure and batch record were revised to require verification of the gas used by a second operator. The batch was rejected.

Things to know:

- All investigational activities were performed either via phone, in conference rooms or at the investigator's desk
 - Compressed gases are controlled from a single utility panel in the rooms where they are used
 - Compressed gasses are controlled manually by operators
 - Compressed air is routinely used for other processes in the area
 - The operations that day were running behind due to an earlier maintenance issue and operators were pressed for time
 - Qualification of operators is well defined and provides opportunity to practice activities
 - Operators understand the process, the product and the consequences of using the wrong gas at the wrong time
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Discussion

What would you do?

Do you think the true root cause was reached? Will the CAPA be effective?

How could you use a Root Cause Decision Tree to assess the human factors involved?

What questions would you ask in an interview?

Would you do anything differently?

Brief Case Study #2 – Part 2

New Information Revealed

Materials – All Materials were appropriate, well labeled and handled correctly. Operators understand the importance of each step and the effects on the product.

Training – Operators had the ability and motivation to take the right actions. The involved personnel were qualified and the qualification process was appropriate

Measurement – No measurements were taken and no calculation were performed at the step where the error occurred

Equipment – All gasses are controlled from a single panel in the room. When interviewing the operators in the space where the event occurred it was observed that the compressed air control and the nitrogen control are located on the same panel, immediately next to each other and are identical. Operators stated that labels were there at one time, but they had worn off due to cleaning. Now they just “knew” which one to use.

Method – The procedure was not very clear. It states to “overlay with nitrogen” but does not provide instruction on how to perform that task. Operators stated that when labels had worn off of the panel they referenced the SOP but since it didn’t have pictures or any indication of which control was which it wasn’t helpful. They stated that they asked Jack if they were confused or forgot since he was here the longest and always knew what to do.

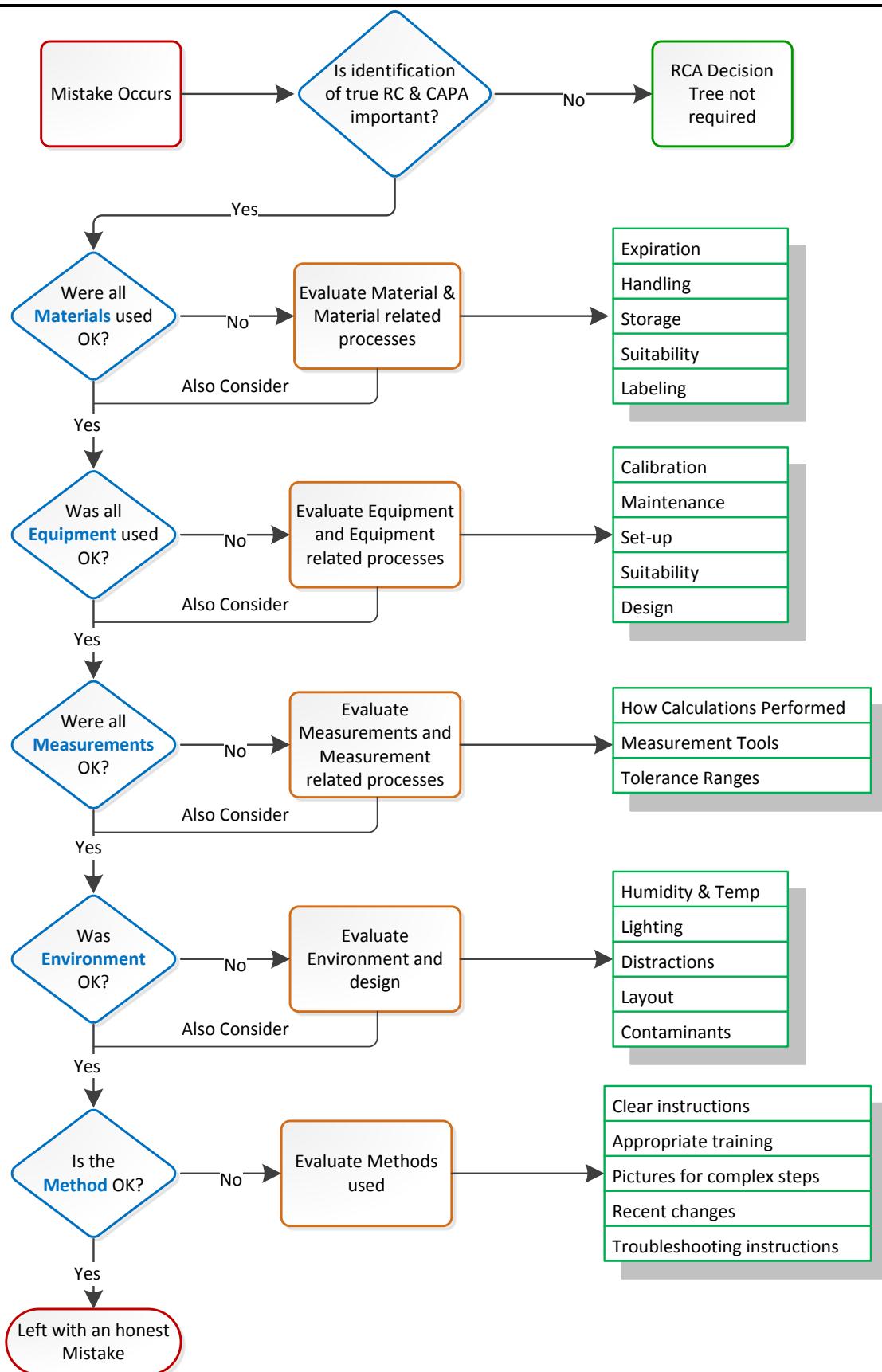
Discussion

What do you think now?

Does this information change your perspective of the event and associated causal factors?

How would you classify the root cause of this event? What CAPA would you put in place?

Example: Root Cause Decision Tree



Example: Root Cause Decision Tree

