

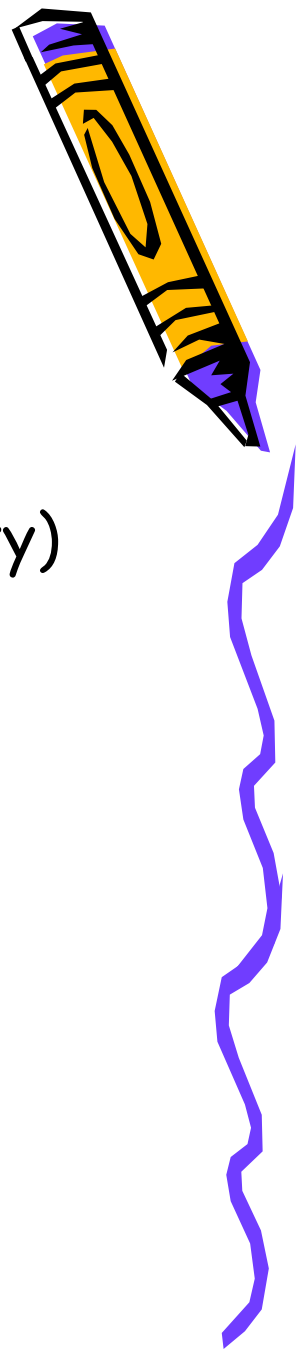


Internal Auditor Training

"How to write a better Observation"

C.L. "Chuck" Landis
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ASQ 1302



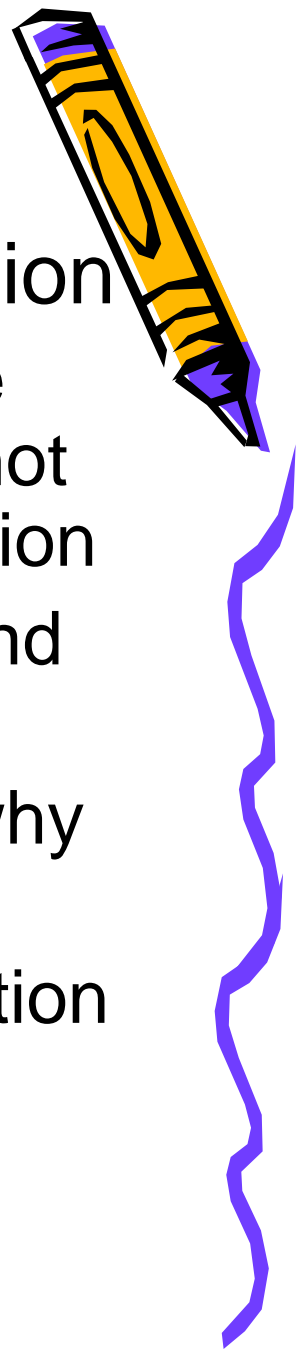


Internal Auditor Training

- C. L. "Chuck" Landis
 - MS Engineering Mgt. (Quality and Reliability)
 - ASQ Certified Quality Engineer
 - ASQ Certified Quality Auditor
 - ASQ Certified Quality Manager
 - ASQ Certified Quality Biomedical Auditor
 - Juran Institute 6 Sigma Black Belt



Internal Audit Training



- Why should I write a better observation
 - After the audit is complete and you are reviewing your notes later, you might not remember why you wrote the observation
 - Your customer/client doesn't understand the observation.
 - Your Registrar might not understand why you wrote what you wrote.
 - Can help you decide if it is an observation or a comment!



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- What does a better observation look like?
 - It begins with a reference to the criteria that you are writing the observation against. Such as, ISO9001-2000, 6.4, The company shall determine and manage the work environment.
 - Then the text of the citation. Such as, ISO9001-2000, 6.4 requires that the facility be painted purple in manufacturing areas.



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- Then you say what the auditee is or is not doing that is in nonconformance with the criteria.
 - On June 31, 2006 during the audit of the Widget manufacturing area, it was observed to be painted white.



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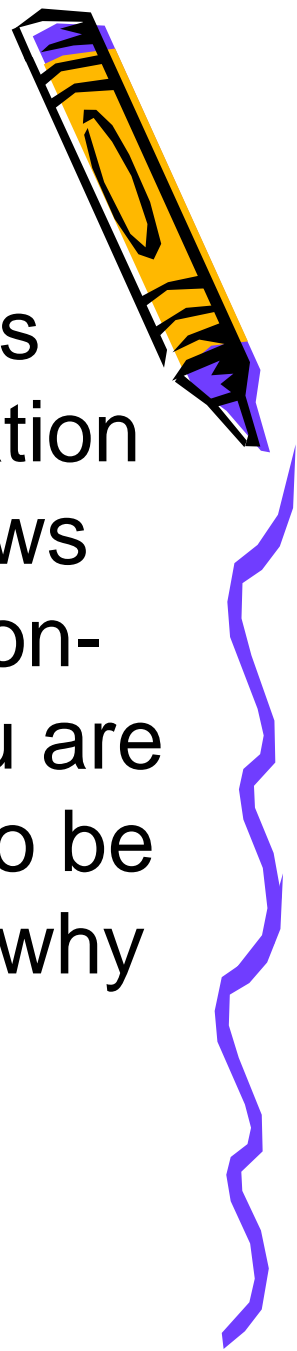


- Thus, the entire observation would look like this:
- ISO9001-2000, 6.4 requires that the facility be painted purple in manufacturing. On June 31, 2006 during the audit of the Widget Manufacturing area it was observed to be painted white.



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- This observation can now stand on it's own and needs no additional explanation or clarification. The auditee also knows what they need to do to correct the non-conformance. In 6 months, when you are reviewing the audit report you will also be able to remember what you saw and why it was nonconforming.



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- More examples:
- Training record for associate in Barrel molding does not have signature or date of when training was conducted. Comment has been added below signature line that is not signed or dated.
 - Good audit observation or can it be improved?



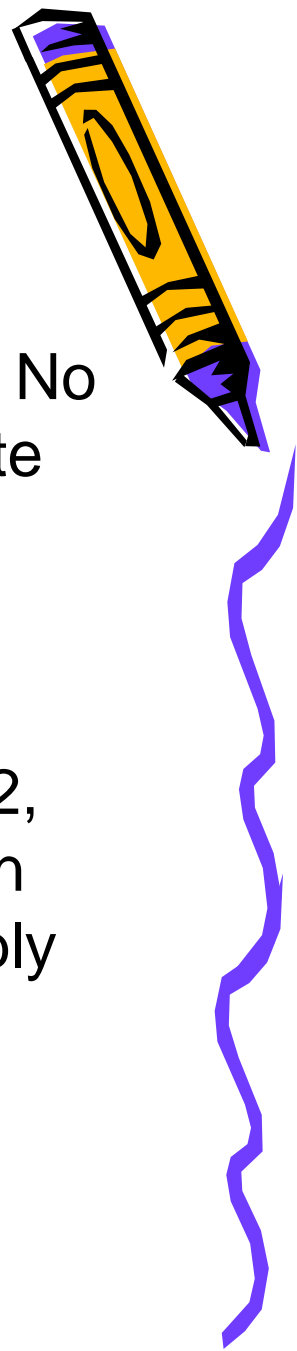
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- HMFG-6 R-3 requires all associates to read all applicable documentation and receive documented training. Training record for molding associate (form 2000-22 r3) has all check boxes checked but does not have the required signature and date on bottom of form. In addition, a statement has been hand written at the bottom of the form without proper signature and date.
 - Better?



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- QC700512 rev. 12. section 5.0, 413-182 rev16. No evidence of written instruction on how to complete this inspection. Associate unsure of action to be taken when an OOS condition occurs.
- Per ISO9001-2000, 7.1, b and QC700512 rev. 12, sec. 5.5, and 413-182 r16. No evidence of written instructions on how to perform the hand assembly inspection and what action to take if an OOS condition is found.



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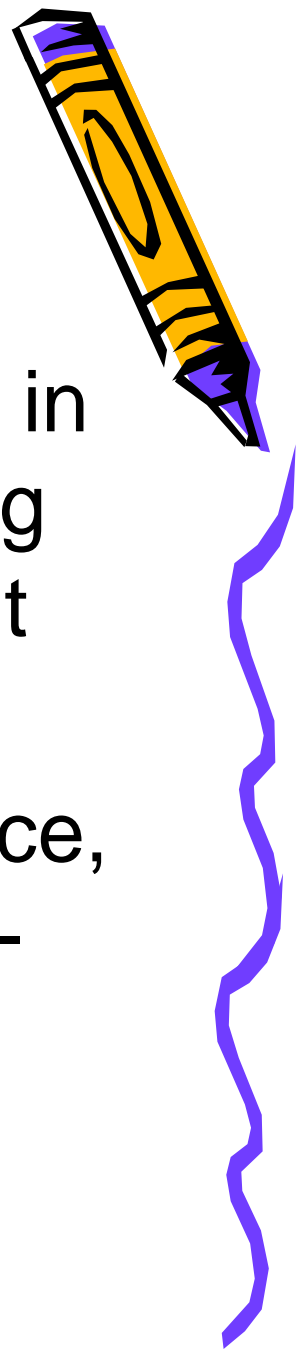


- QC700512 rev. 12. section 6.2 413-183(R22) Tip ID and bow. No documented evidence of inspection at process changes.
- QC700512 rev 12 section 6.2 and form 413-183 rev 22 requires dimension inspection once per shift or at process change. No documented evidence presented that required inspections were completed at process changes.



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- Each of the last 3 examples are from actual audits and reflect the changes in the draft presented at the exit meeting and what was written in the final audit report.
- Each example cites a criteria reference, then what was observed to be in conformance with that criteria.



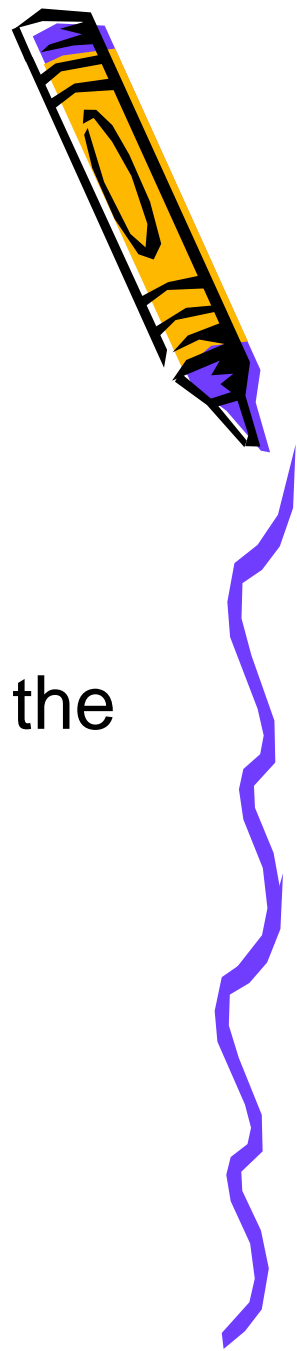
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- In each of the 3 previous examples, each rewritten observation stands by itself and needs no additional explanation. Anyone can now read it and be able to determine what kind of corrective action needs to be taken.



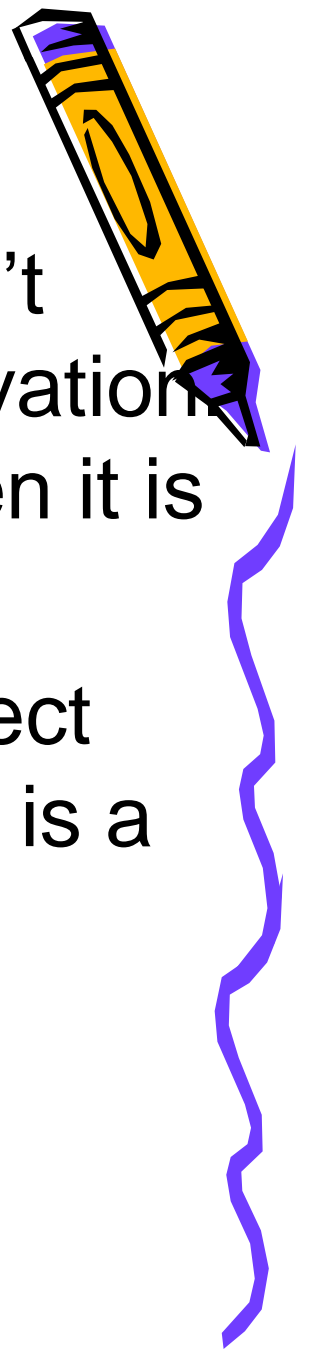
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- Is it a comment or an observation?
 - It is a comment if, as lead auditor, you don't like something that the auditee is doing, but it is in **conformance** with all the criteria or QMS documentation.
 - It is an observation, if it is in **nonconformance** with the criteria.



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- Just because you don't like it, it doesn't automatically mean that it is an observation. If you can't cite a specific criterion, then it is a comment only.
- Some Auditors have a tendency to inject personal opinion into audit findings. It is a finding IF and only IF it is in non-conformance with a requirement.



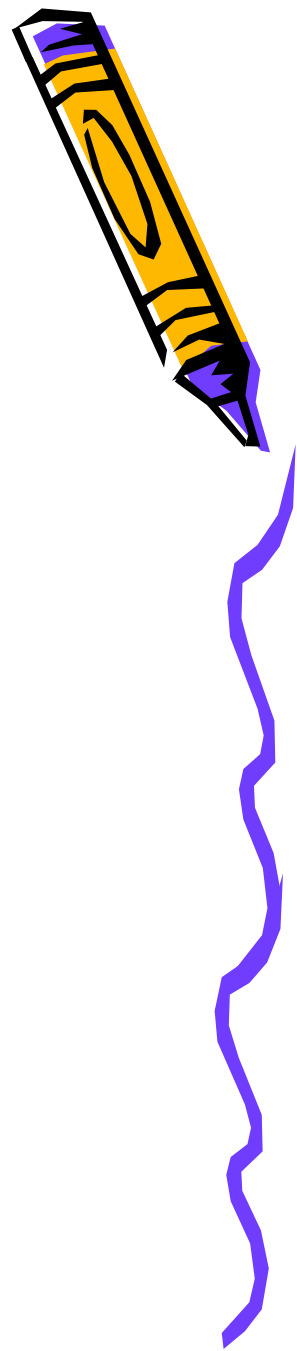
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- How do you get an Auditor to not write an observation for a strong personal opinion?
 - Ask the question- I need to improve my understanding of the standard, so "What criterion is this in non-conformance with?"
 - *If the auditor can't answer the question, they will usually scale it back to a comment or OFI. Make sure you have the standard with you so you can follow along.*



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- Questions?

