

Examples

- Corrective And Preventive Action (CAPA)
- Yield issue
- Field issue
- Recall
- Development
 - Design
 - Manufacturing

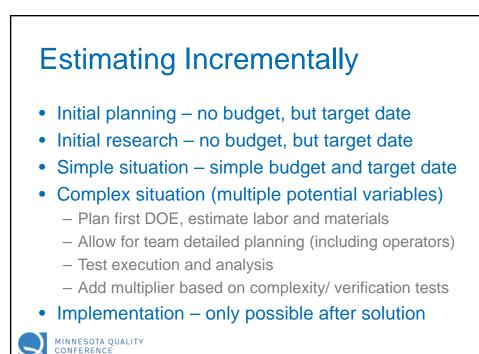
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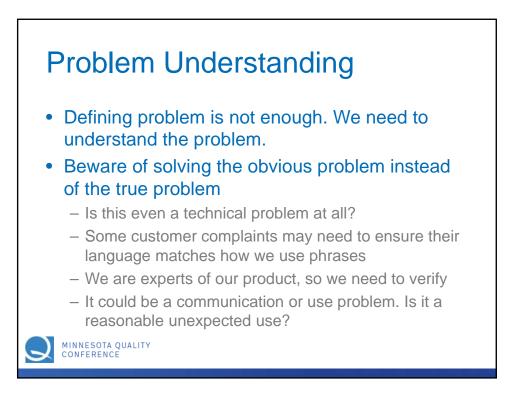
Challenges

- Verify problem exists we often assume customer is right
- Uncertainty of when problem will be resolved
 - How big is it?
 - Could be resolved tomorrow
 - Could take months
- Impact of changes does it even matter?
- Simple fixes versus complex fixes

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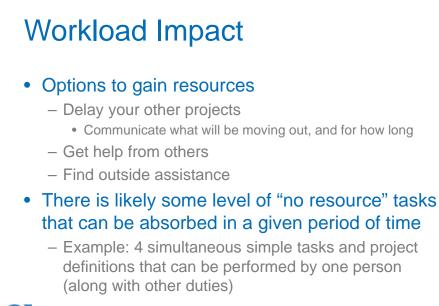


Estimating Basis For Complex

- Detailed bottoms up
- Similarity
- Comparative (twice as much as project A)
- Parametric model
- Expert opinion
- Combination
 - Remember effort and duration

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Implementation Risk

Consider technical risks of solution being achieved

- How complex is the situation
- Do we have the skills
- Knowledge
- Resources

Also consider business risk

- Will customers accept our short term solution
- Should we only provide the long term option
- Can they temporarily handle the current condition

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Manufacturing Options

- · Consider short and long term solutions
- Short term solutions may be less than ideal
 - Several options always exist
 - May not be efficient, or may cost too much
- Long term solutions may take too long
 - Several options always exist
 - Is there enough life remaining to justify investment?
- This means we want to estimate the short and long term solution, and be clear what is included

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instead?

Take-aways

- Verify problem exists (first increment)
- Uncertainty of when problem will be resolved (define after short period of time versus day 1 or some standard time)
- Impact of changes (is this worth our time and should it be done now)
- Simple fixes versus complex fixes (allowing for this option positions our
- discussions for follow up)

