

FMEA Facilitator “Thought-Starter” Questions

As an aid for the FMEA facilitator, the following are possible questions to ask as part of the FMEA procedure. These questions are only thought-starters and are not meant to limit in any way the skill of the FMEA facilitator and team in establishing the content of the FMEA.

Functions

When identifying functions for System or Design FMEAs, the team can be asked questions, such as:

- “What are the primary purposes of this item?”
- “What is the item supposed to do? What must the item not do?”
- “What is the standard of performance?”
- “What functions occur at the interfaces?”
- “What safety-related functions are important for this item?”
- Any other questions that ensure all of the primary functions are determined (reference “checklist of function types” in chapter 6, section 6.2-2B)

When identifying functions for Process FMEAs, the team can be asked questions, such as:

- “Is the process function described in the form: do this [operation] to this [part or assembly] with this [tooling]?”
- “What is the primary purpose of the operation?”
- “What is the standard of performance of the operation?”
- “What is the operation intended to do? What must the operation not do?”
- Any other questions that ensure all of the primary process functions are determined (reference “checklist of function” types in chapter 6, section 6.4)

Failure Modes

When identifying failures modes for System or Design FMEAs, the team can be asked questions, such as:

- “In what way could the item fail to perform its intended function?”
- “In what way could the item perform an unintended function?”
- “What could go wrong with this item?”
- “What could go wrong at the interfaces?”
- “What has gone wrong with this item in the past?”
- “How could the item be abused or misused?”
- “What concerns do you have with this design?”
- Use the “failure conditions” in chapter 6, section 6.2-3, to be sure no failure modes are missed

When identifying failure modes for Process FMEAs, the team can be asked questions, such as:

- “In what way could the operation fail to perform its intended function?”
- “In what way could the operation perform an unintended function?”
- “What significant product characteristics from the PFD worksheet can be potential failure modes?”
- “Why would a part be rejected at this operation?”
- “What could go wrong with this operation?”
- “What has gone wrong with this operation in the past?”
- “What concerns do you have with this operation?”
- Use the “failure conditions” in chapter 6, section 6.2-3, to be sure no failure modes are missed

Effects

When identifying effects for System or Design FMEAs, the team can be asked questions such as:

- “What is the consequence of the failure?”
- “If the item fails, what will be the consequences at the local level? At the next higher level? At the system level? At the end user?”
- “If the item fails, what will the customer see, feel or experience?”
- “Will the failure cause potential harm to the end users?”
- “Will the failure cause potential violation of regulations?”
- “What would a failure mean to adjacent parts/subsystems?”
- Any other questions that ensure the effects of failure are fully understood at the local level, the next level and system and/or end user.

When identifying effects for Process FMEAs, the team can be asked questions such as:

- “What is the consequence of the failure?”
- “If the operation fails, what will be the consequences at the local operation? At the next stage of operations? On downstream processing? At the plant level? At the system level? At the end user?”
- “Will the failure cause potential harm to equipment or operators?”
- “Will the failure cause potential violation of regulations?”
- “What would a failure mean to the system or the end user?”
- Any other questions that ensure the effects of failure are fully understood at the manufacturing level, and at the system or end user.

Causes

When identifying causes for System or Design FMEAs, the team can be asked questions such as:

- “How can the failure occur?”
- “What could cause the item to fail in this manner?”
- “What circumstances could cause the item to fail to perform its intended function?”
- “Why could the failure occur?”

- “What is the mechanism of failure?”
- “Are there possible system interactions, degradations, operating environments, customer usages or design-for-manufacturing/assembly issues that could cause the failure?”
- For each cause identified, ask further “whys” in the direction of isolating root cause.

When identifying causes for Process FMEAs, the team can be asked questions such as:

- “How can the failure occur?”
- “What could cause the operation to fail in this manner?”
- “What significant process characteristics from the PFD worksheet could be potential causes?”
- “What circumstances could cause the operation to fail to perform its intended function?”
- “Why could the failure occur?”
- “Are there possible equipment, methods, material, supplier parts, operator, or environment issues that could cause the failure?”
- For each cause identified, ask further “whys” in the direction of isolating root cause.

Controls

When identifying prevention-type design controls for System or Design FMEAS, the team can be asked questions such as:

- “What is already in place that could possibly prevent the cause?”
- “What is not in place yet but is currently planned that could possibly prevent the cause?”
- “What design guidelines, design standards, use of field lessons learned, or other prevention-type tasks are planned or already in place that could prevent the cause?”

When identifying detection-type design controls for System or Design FMEAS, the team can be asked questions such as:

- “What is already in place that could possibly detect the cause?”
- “What is not in place yet but is currently planned that could possibly detect the cause?”
- “What tests, analyses or other analytical or physical tasks are already in place or currently planned that could detect the cause before launch?”

When identifying prevention-type process controls for Process FMEAS, the team can be asked questions such as:

- “What is already in place that could possibly prevent the cause?”
- “What is not in place yet but is currently planned that could possibly prevent the cause?”
- “What design error proofing, process error proofing, operator instructions, equipment controls, preventive maintenance, or other prevention-type tasks are planned or already in place that could prevent the cause?”

When identifying detection-type process controls for Process FMEAs, the team can be asked questions such as:

- “What is already in place that could possibly detect the cause?”
- “What is not in place yet but is currently planned that could possibly detect the cause?”
- “What operator inspections, in-station error detection, end-of-line testing, measuring, gauging or other detection-type tasks are already in place or currently planned that could detect the cause before the product leaves the plant?”

Recommended Actions

When identifying recommended actions for System or Design FMEAs, the team can be asked questions such as:

- “What can be done to reduce severity to a safe level by modifying the design?”
- “Which of the ‘Action Strategies to Reduce *Severity* Risk’ should be recommended?”
- “How can the current design be made safer?”
- “If the product fails, how can the user be protected from potential harm or injury?”
- “What can be done to reduce likelihood of occurrence to a very low level?”
- “Which of the ‘Action Strategies to Reduce *Occurrence* Risk’ should be recommended?”
- “How can the current design be made more robust?”
- “What can be done to reduce likelihood of detection to a very low level?”
- “Which of the ‘Action Strategies to Reduce *Detection* Risk’ should be recommended?”
- “What tests or evaluation techniques need to be added or modified to improve detection capability?”
- “Are there any other actions that are needed to reduce risk to an acceptable level?”
- “If the recommended actions are implemented, will that be sufficient to address all high-severity and high-RPN risk?”

When identifying recommended actions for Process FMEAs, the team can be asked questions such as:

- “What can be done to reduce severity to a safe level by modifying the process?”
- “Which of the ‘Action Strategies to Reduce *Severity* Risk’ should be recommended?”
- “How can the current process be made safer?”
- “If the manufacturing or assembly operation fails, how can the operator be protected from potential harm or injury?”
- “What can be done to reduce likelihood of occurrence to a very low level?”
- “Which of the ‘Action Strategies to Reduce *Occurrence* Risk’ should be recommended?”
- “How can the current operation be made more successful?”
- “What can be done to reduce likelihood of detection to a very low level?”
- “Which of the ‘Action Strategies to Reduce *Detection* Risk’ should be recommended?”
- “What process controls need to be added or modified to improve detection capability?”

- “Are there any other actions that are needed to reduce risk to an acceptable level?”
- “If the recommended actions are implemented, will that be sufficient to address all high-severity and high-RPN risk?”