

Failure Modes and Effects Analysis (FMEA) Worksheet – SAMPLE

FMEA Process Steps

Step 1: Define the scope and the process to be studied (select a high-risk process):

Include your rationale for the high-risk topic and your completed decision tree analysis:

Check all that apply:

- ☐ Near misses have identified the potential for risk issues that may impact patient safety
- ☐ Internal data and/or occurrences reveal frequency or severity for topic chosen
- ☐ External data indicate frequency or severity for topic chosen
- ☐ A new system, process, procedure and/or technology is being introduced

Other – explain: _____

Note: Attach data (run charts, control charts, etc.) that support the rationale for the high-risk topic selection (as applicable).

Conduct the FMEA under the quality oversight process and document the FMEA information in the quality committee minutes.

STATEMENT OF CONFIDENTIALITY: [Consult with counsel regarding the wording of an appropriate statement of confidentiality for insertion on each page of this document.]

COPYRIGHTED

1

This document is a work product of Coverys' Risk Management Department. This information is intended to provide general guidelines for risk management. It is not intended and should not be construed as legal or medical advice. Your organization should add to and modify this tool to address the compliance standards and regulations applicable in your state or organization.

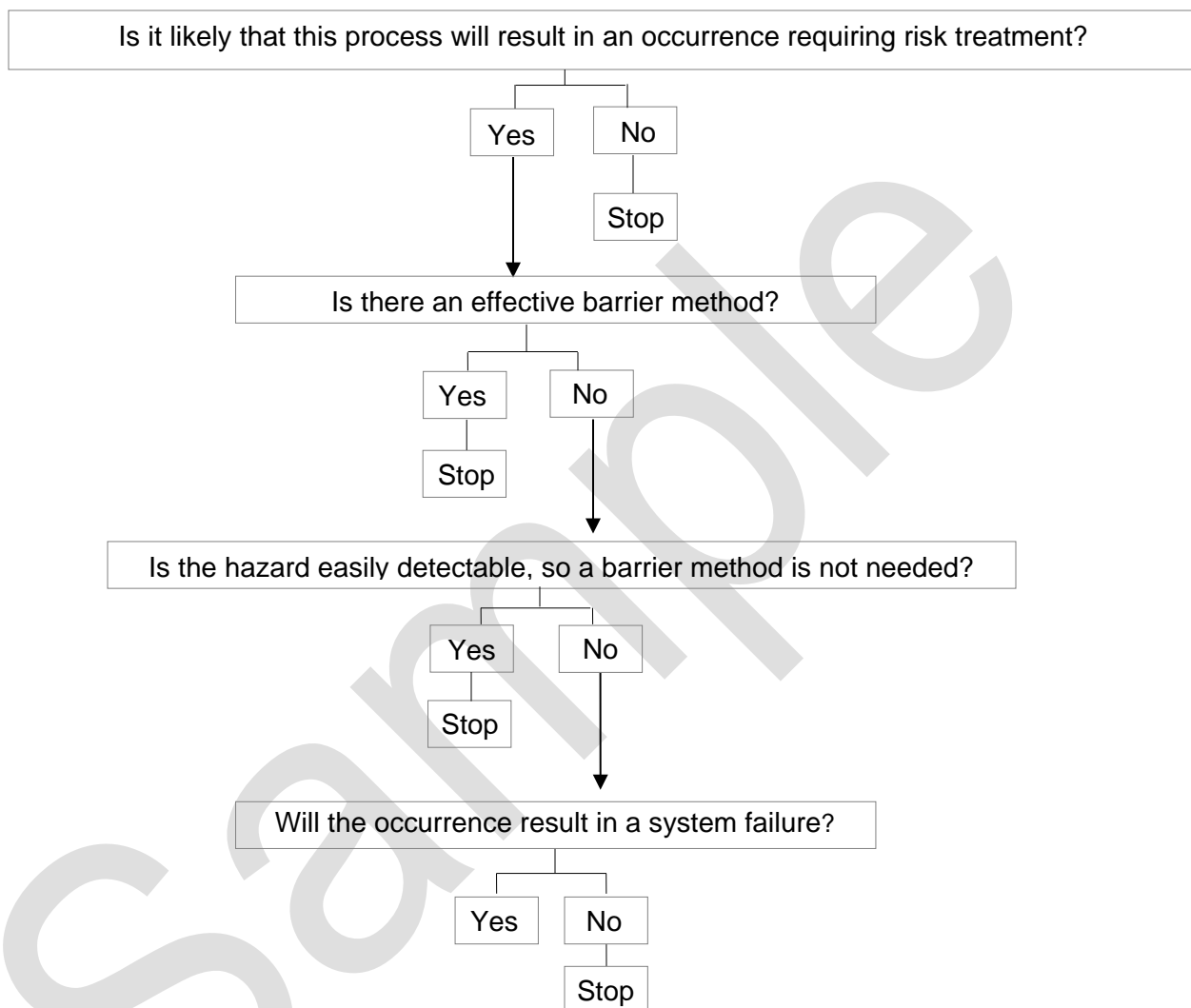
The links included in this document are being provided as a convenience and for informational purposes only; they are not intended and should not be construed as legal or medical advice. Coverys Risk Management bears no responsibility for the accuracy, legality or content of the external site or for that of subsequent links. Contact the external site for answers to questions regarding its content.

Updated: December 2018

FMEA Worksheet – SAMPLE

Decision Tree

Use the decision tree to ensure that the high-risk area is proper selection for an FMEA topic.



Adapted from: VA National Center for Patient Safety (NCPS), "The Basics of Healthcare Failure Mode and Effect Analysis." Available at <http://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp>, 06/17/2016.

STATEMENT OF CONFIDENTIALITY: [Consult with counsel regarding the wording of an appropriate statement of confidentiality to be inserted on each page of this document.]

COPYRIGHTED

2

This document is a work product of Coverys' Risk Management Department. This information is intended to provide general guidelines for risk management. It is not intended and should not be construed as legal or medical advice. Your organization should add to and modify this tool to address the compliance standards and regulations applicable in your state or organization.

The links included in this document are being provided as a convenience and for informational purposes only; they are not intended and should not be construed as legal or medical advice. Coverys Risk Management bears no responsibility for the accuracy, legality or content of the external site or for that of subsequent links. Contact the external site for answers to questions regarding its content.

Updated: December 2018

FMEA Worksheet – SAMPLE

Step 2: Identify the multidisciplinary team members (maximum of 10-12 team members).

Area of Expertise	Unit/Dept/Company	Person's Name
1. Subject matter expert		
2. FMEA leader		
3. FMEA facilitator		
4. FMEA recorder		
5.		
6.		
7.		
8.		
9.		
10.		

Step 3: List the information needed to conduct the FMEA process.

- a. List the internal procedures, guidelines and protocols specific to the subject matter.

- b. List the external procedures, guidelines and protocols specific to the subject matter.

STATEMENT OF CONFIDENTIALITY: [Consult with counsel regarding the wording of an appropriate statement of confidentiality to be inserted on each page of this document.]

COPYRIGHTED

3

This document is a work product of Coverys' Risk Management Department. This information is intended to provide general guidelines for risk management. It is not intended and should not be construed as legal or medical advice. Your organization should add to and modify this tool to address the compliance standards and regulations applicable in your state or organization.

The links included in this document are being provided as a convenience and for informational purposes only; they are not intended and should not be construed as legal or medical advice. Coverys Risk Management bears no responsibility for the accuracy, legality or content of the external site or for that of subsequent links. Contact the external site for answers to questions regarding its content.

Updated: December 2018

- c. List results of literature searches for standards/best practices.

- d. List the professional organizations/societies for resources.

- e. Staff members/department personnel to interview regarding the process.

Step 4: Process Map – Identify area/process to be mapped out.

Map current practice

Map standard practice according to “best practice/comparative practice”

Map practice in accordance with your internal procedures

(Attach maps)

STATEMENT OF CONFIDENTIALITY: [Consult with counsel regarding the wording of an appropriate statement of confidentiality to be inserted on each page of this document.]

COPYRIGHTED

4

This document is a work product of Coverys' Risk Management Department. This information is intended to provide general guidelines for risk management. It is not intended and should not be construed as legal or medical advice. Your organization should add to and modify this tool to address the compliance standards and regulations applicable in your state or organization.

The links included in this document are being provided as a convenience and for informational purposes only; they are not intended and should not be construed as legal or medical advice. Coverys Risk Management bears no responsibility for the accuracy, legality or content of the external site or for that of subsequent links. Contact the external site for answers to questions regarding its content.

Updated: December 2018

FMEA Worksheet – SAMPLE

Step 5: Hazard Analysis – List the failure modes for the process steps and sub-process steps under study. Assess failure modes and identify causes and effects.

(Attach FMEA table)

5a) Determine hazard analysis score: severity x probability = criticality

5b) Determine detectability: Use decision tree on failure modes.

Step 6: Prioritize failure modes for action based on criticality score.

Step 7: Identify risk treatment, actions, follow-up measures and person accountable; include a timeline.

Step 8: Test the redesigned process and implement, if effective.

Step 9: Monitor the effectiveness of the redesigned process.

Step 10: Maintain the effectiveness through spot checks.

Step 11: Report activity and results to the quality oversight committee.

STATEMENT OF CONFIDENTIALITY: [Consult with counsel regarding the wording of an appropriate statement of confidentiality to be inserted on each page of this document.]

COPYRIGHTED

5

This document is a work product of Coverys' Risk Management Department. This information is intended to provide general guidelines for risk management. It is not intended and should not be construed as legal or medical advice. Your organization should add to and modify this tool to address the compliance standards and regulations applicable in your state or organization.

The links included in this document are being provided as a convenience and for informational purposes only; they are not intended and should not be construed as legal or medical advice. Coverys Risk Management bears no responsibility for the accuracy, legality or content of the external site or for that of subsequent links. Contact the external site for answers to questions regarding its content.

Updated: December 2018