Reducing Product Safety Risks

(Build a customized risk management automation for ICU Medical DAE Team)

Presented by Jerry Xiao

CQE, CQA, CSSBB, CRE

June, 2021

Building Devices Together

icumedical

human connections

DAE Risk Management Webpage (Demo)

https://ww.icumed.com/risk-management

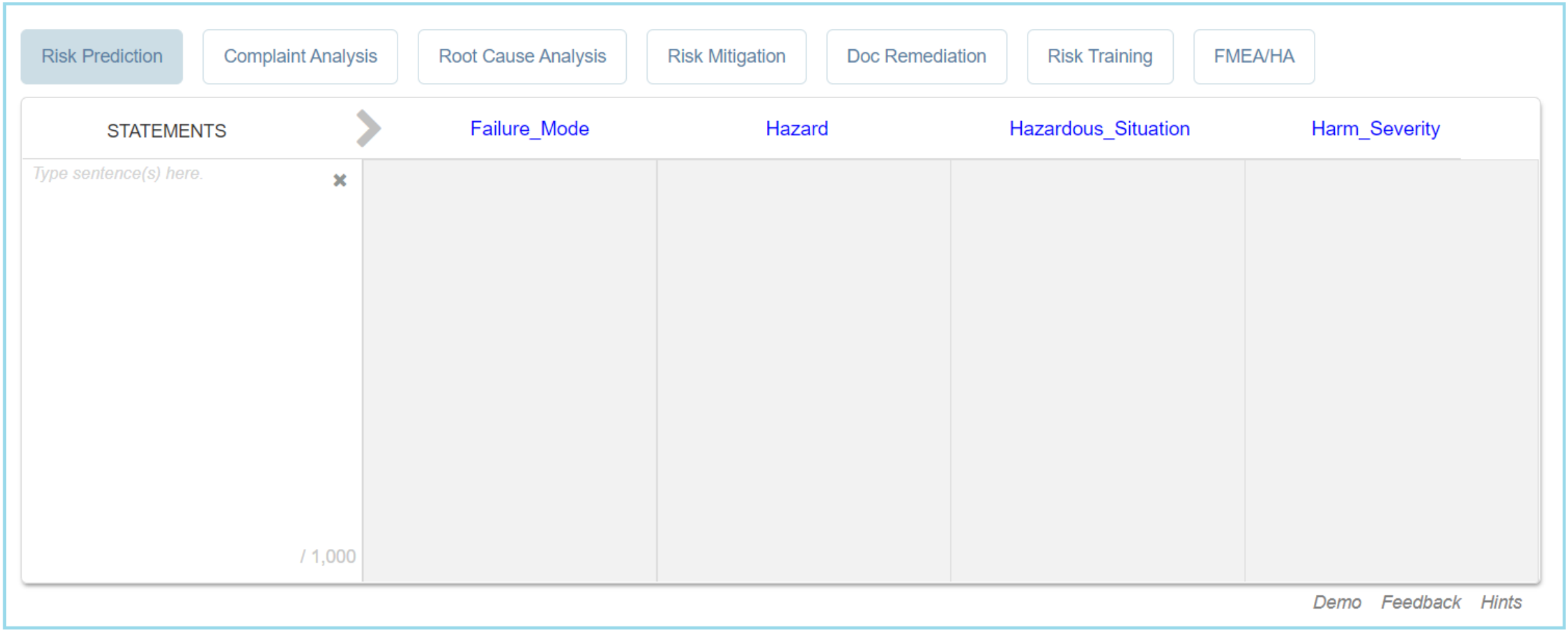
Goals:

Develop a customized risk management system for ICU Medical to provide automation solutions in the fields of:

- **Risk predication**: *identify potential failure modes, hazards*
- **Complaint analysis**: *analyze FDA Maude data*
- **Root cause analysis**: *discern potential failure causes*
- **Risk mitigation**: *discovery potential mitigation actions*
- **Doc remediation**: *convert legacy docs to new template*
- **Risk training**: *randomly create question and score answers*
- **FMEA/PHA**: *electronical FMEA and Hazard Analysis worksheets*

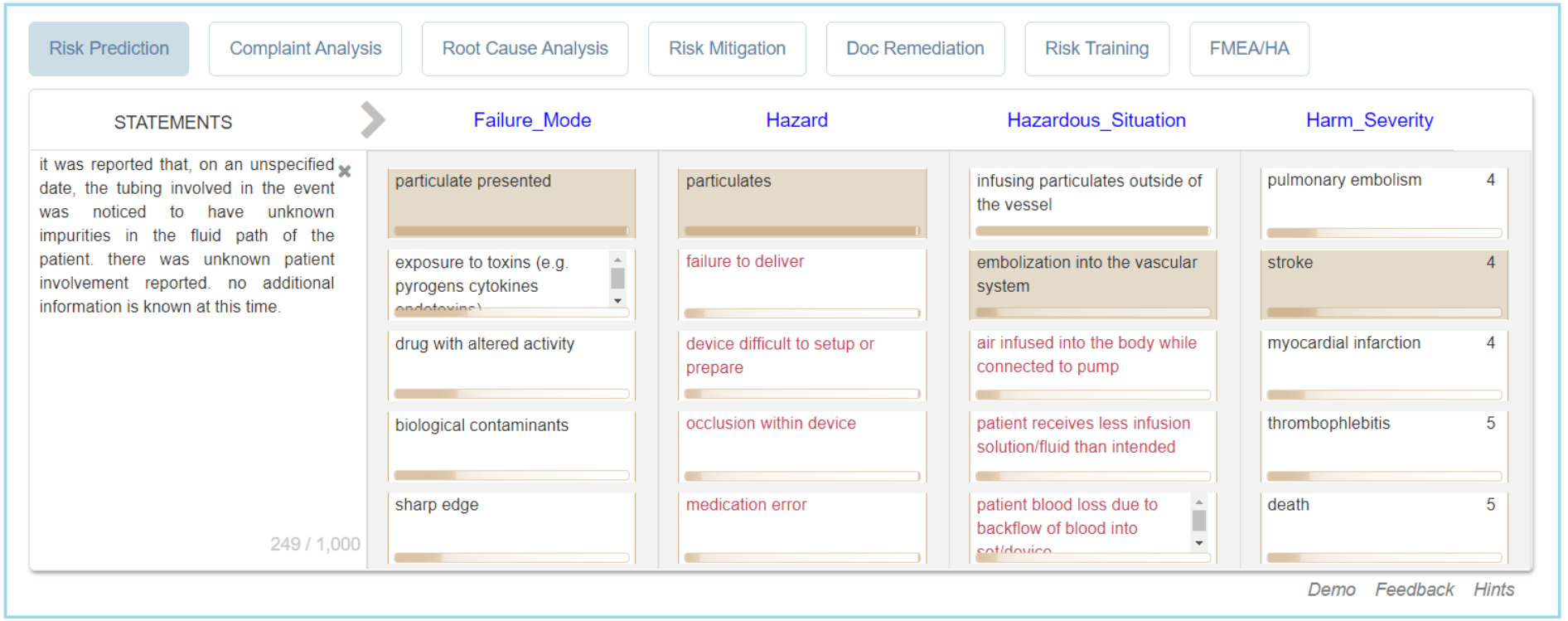
Webpage Layout

https://*youwebpage*.com/risk-management



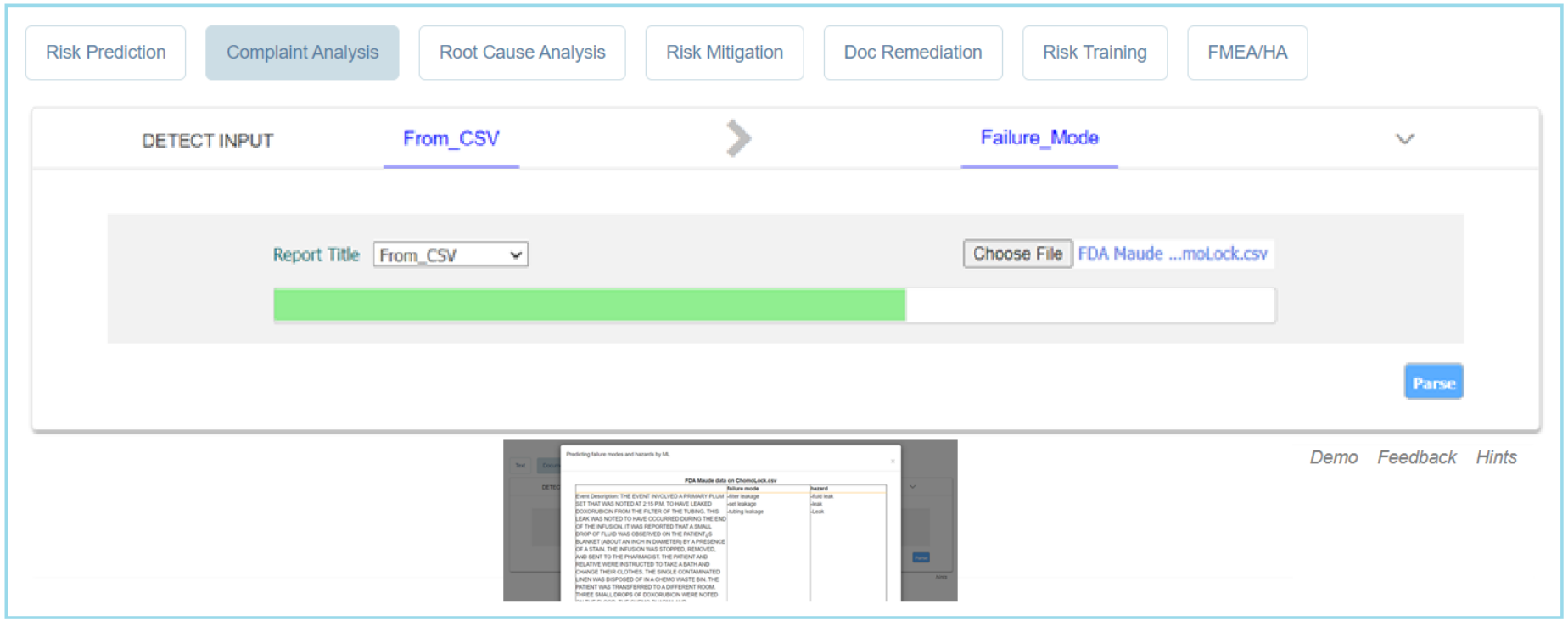
Section 1: Risk Predication

- Use scenario: when working on FMEA worksheets, users need to predict potential failure modes, hazards, hazardous situations, harms, and severity levels.
- Operation: user only need to copy a requirement/function from FMEA/HA, paste to the left below, and pick up potential results.



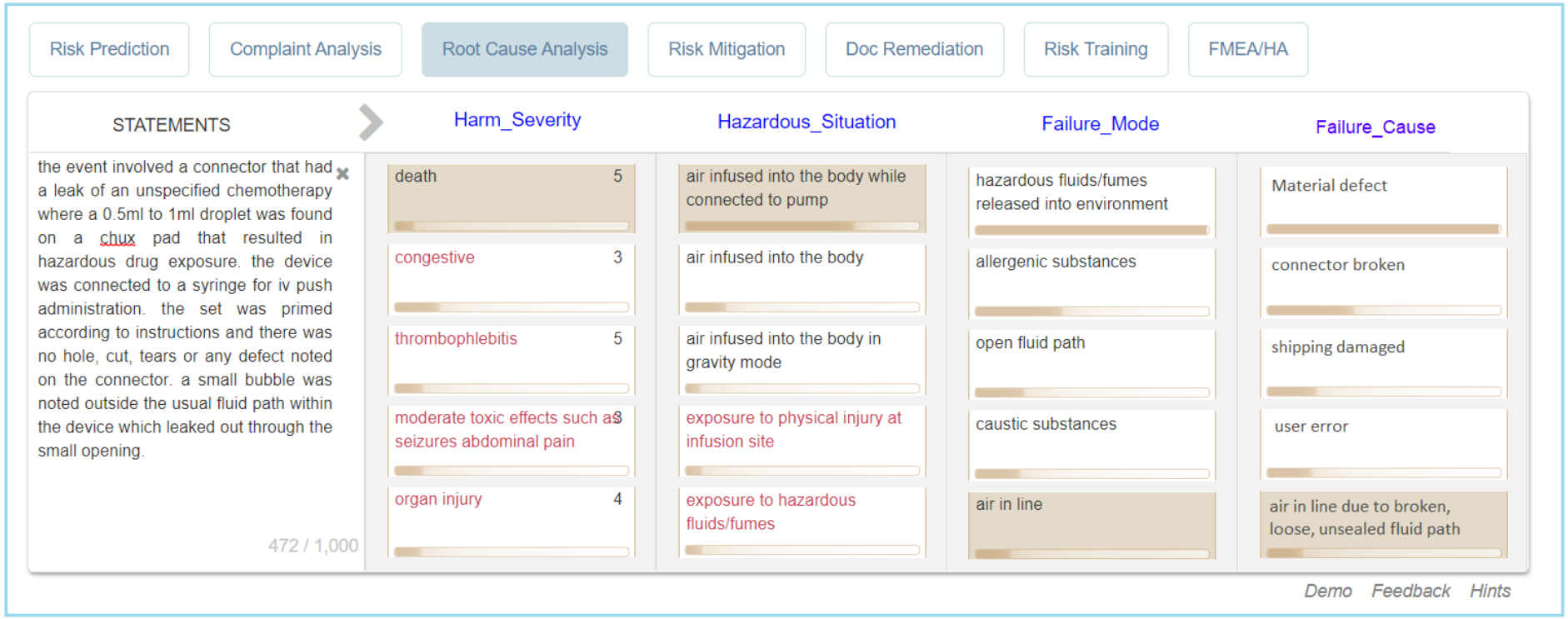
Section 2: Complaint Analysis

- Use scenario: when working on periodic risk file review, users need to predict potential failure modes, hazards, hazardous situations, harms from FDA Maude database.
- Operation: users collect event statements in a excel file and upload to system, and final results shall be popup to screen and able to save to desktop.



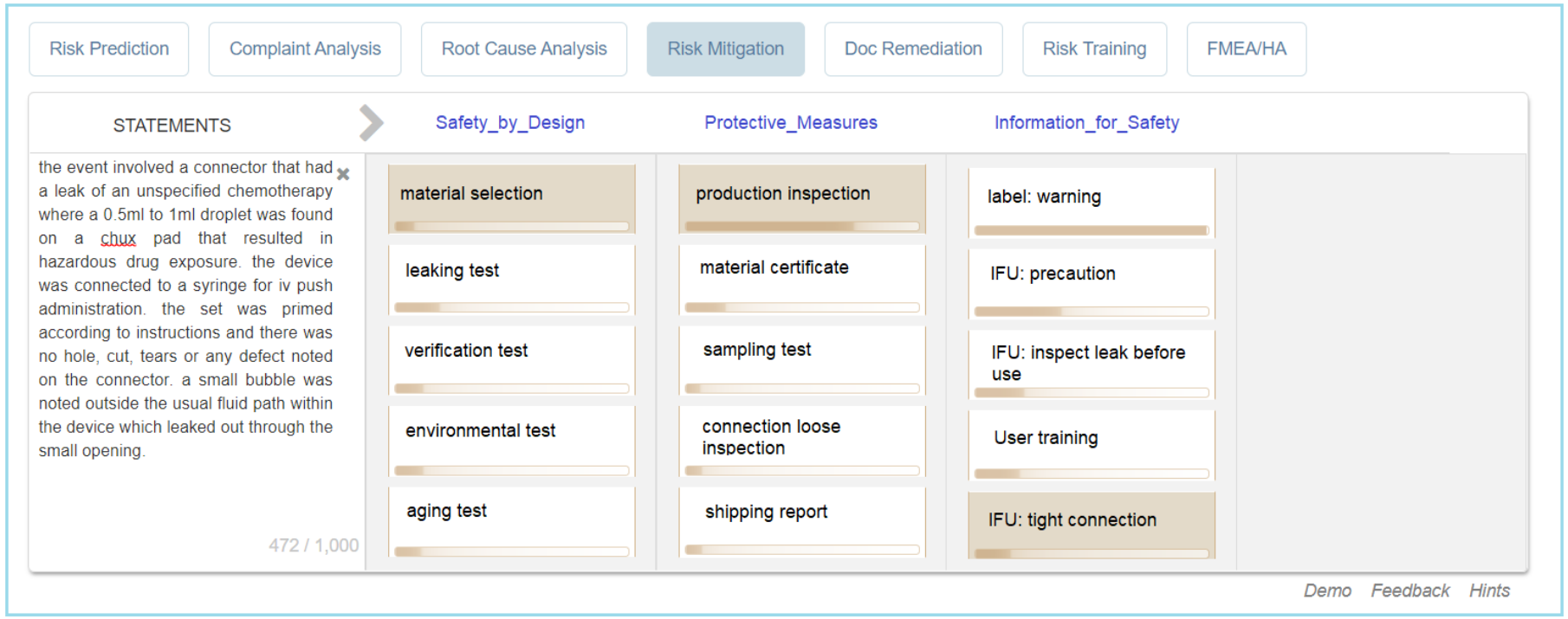
Section 3: Root Cause Analysis

- Use scenario: when working on product failure analysis, users need to dig out potential failure causes on specific customer complaints.
- Operation: users copy complaint statement on the left table, system direct users to predict potent failure causes along the path of harm->hazardous situation->failure mode.



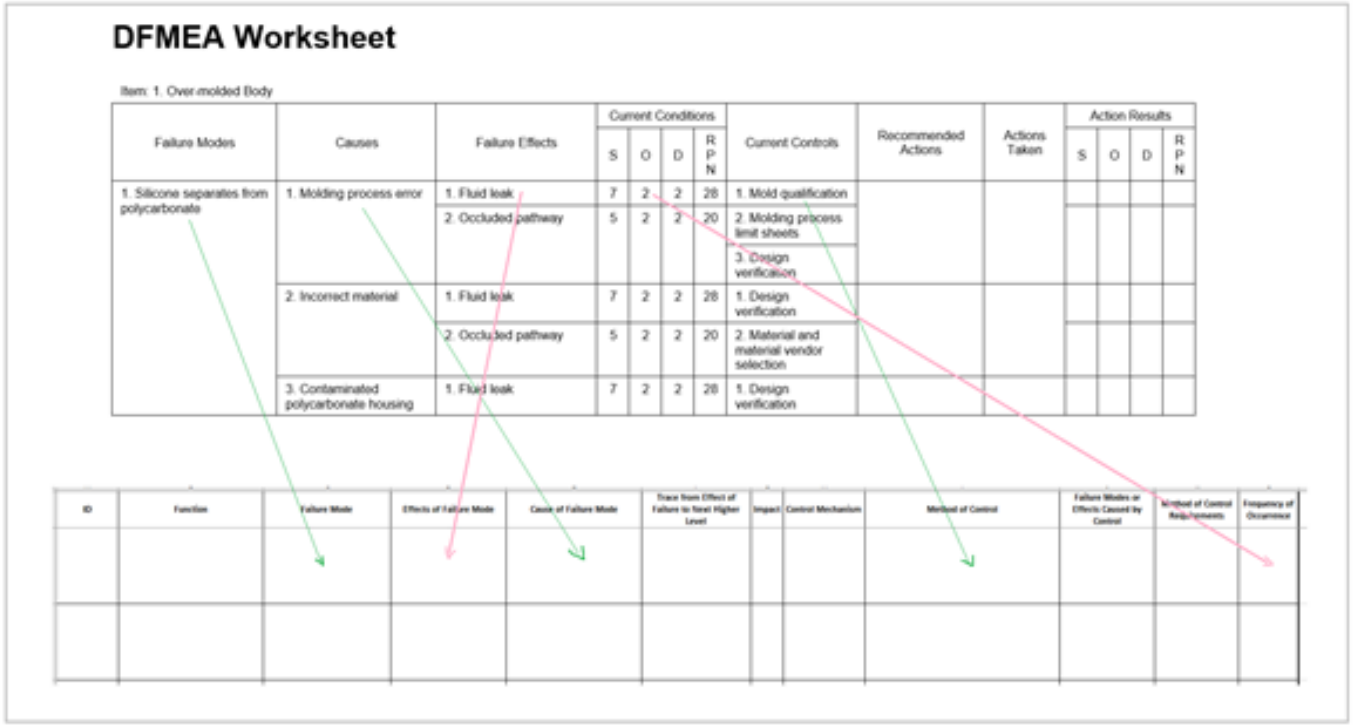
Section 4: Risk Mitigation

- Use scenario: when working on FMEA worksheet, users need to define different levels of risk mitigations for those unacceptable risk items.
- Operation: users input any statement (require./spec./complaint), system provides potential lists of ‘safety by design’, ‘ protective measures’, ‘info for safety’ at one time.



Section 5: Document Remediation

- Use scenario: when working on FMEA remediation, users need to convert legacy risk files into new templates due to standard new revision, EU MDR, audit action.
- Operation: users upload the legacy risk files (e.g. Excel, word) to system, data will be dumped accordingly.



DFMEA Worksheet

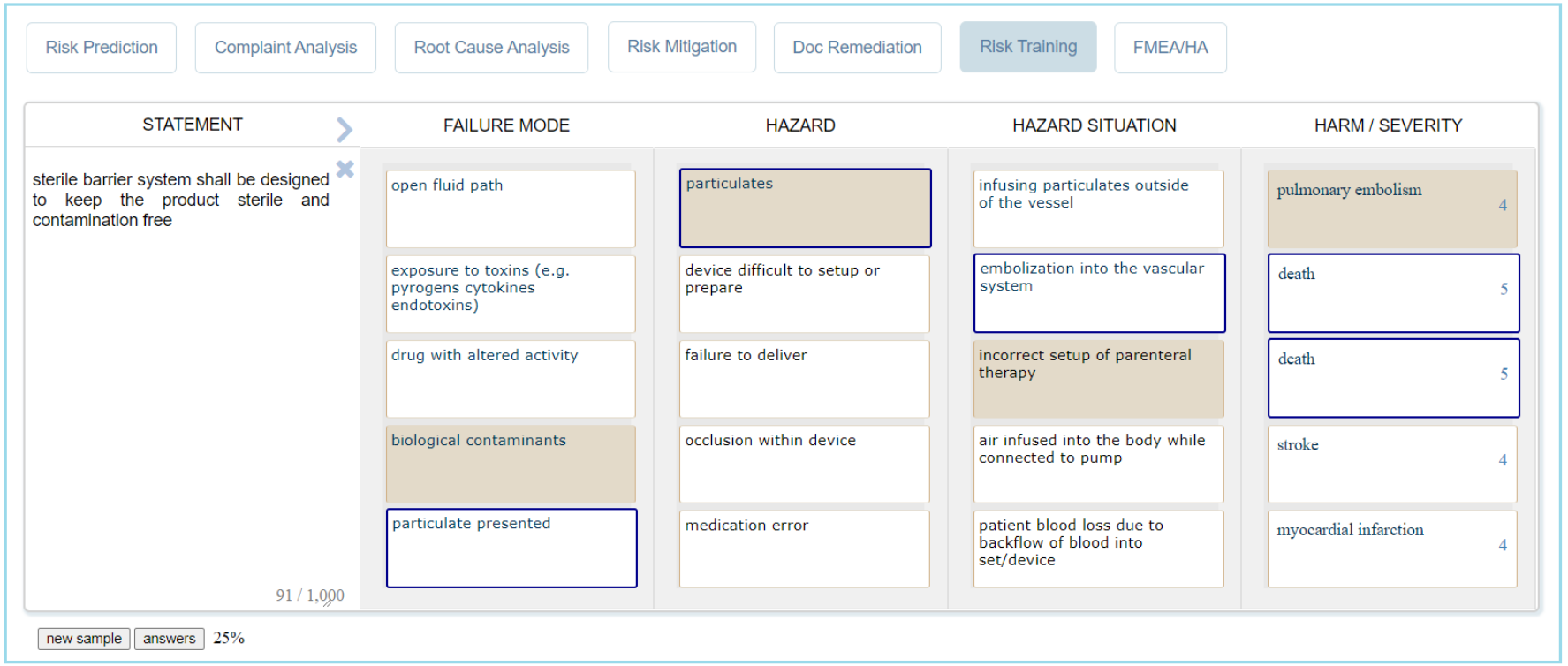
Item: 1. Over-molded Body

Failure Modes	Causes	Failure Effects	Current Conditions				Current Controls	Recommended Actions	Actions Taken	Action Results			
			S	O	D	RPN				S	O	D	RPN
1. Silicone separates from polycarbonate	1. Molding process error	1. Fluid leak	7	2	2	28	1. Mold qualification						
		2. Occluded pathway	5	2	2	20	2. Molding process limit sheets						
							3. Design verification						
	2. Incorrect material	1. Fluid leak	7	2	2	28	1. Design verification						
		2. Occluded pathway	5	2	2	20	2. Material and material vendor selection						
	3. Contaminated polycarbonate housing	1. Fluid leak	7	2	2	28	1. Design verification						

ID	Function	Failure Mode	Effects of Failure Mode	Cause of Failure Mode	Trace from Effect of Failure to Next Higher Level	Impact	Control Mechanism	Method of Control	Failure Modes or Effects Caused by Control	Method of Control Requirements	Frequency of Occurrence

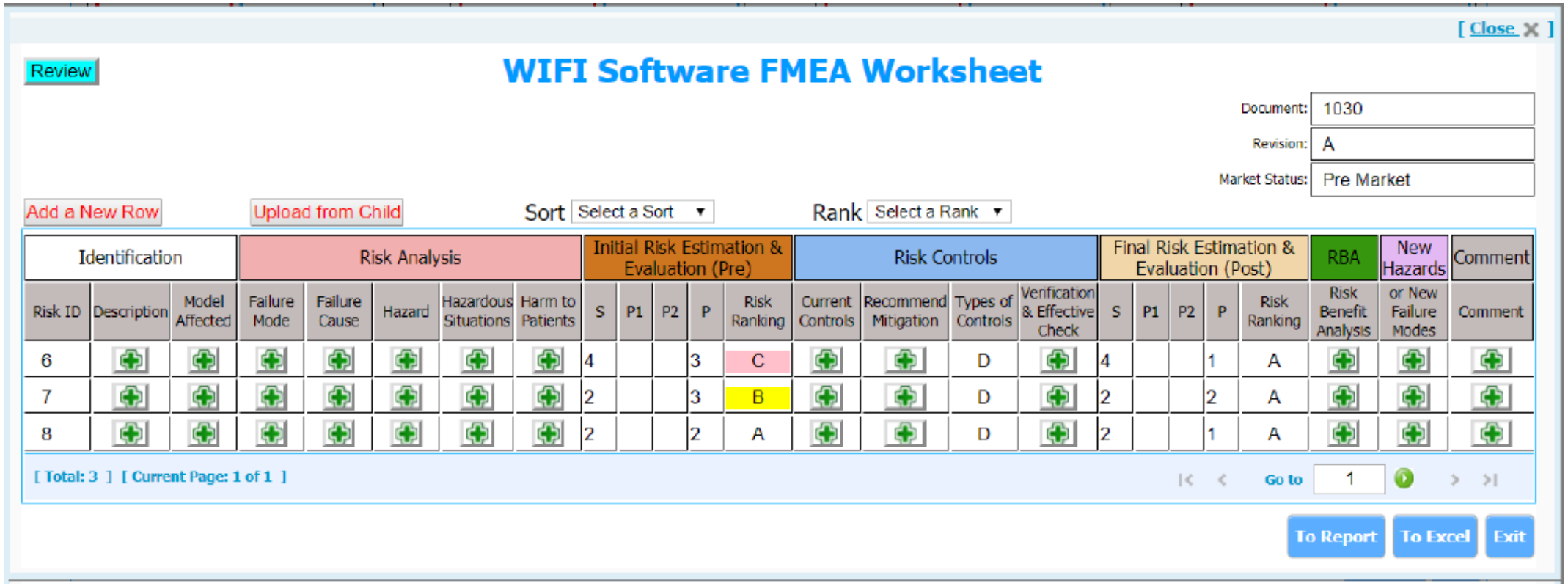
Section 6: Risk Training

- Use scenario: by using the system, users are able to update their risk assessment skills routinely.
- Operation: system randomly generates questions, interacts with users to predict risks, scores the results, and demos the correct answers.



Section 7: FMEA and Hazard Analysis

- Operation: by integrating electronical FMEA worksheet with risk search engine, users are able to run entire risk analysis on one page and save risk results to database.



[Close]

Review

WIFI Software FMEA Worksheet

Document: 1030
Revision: A
Market Status: Pre Market

Add a New Row | Upload from Child | Sort: Select a Sort | Rank: Select a Rank

Identification			Risk Analysis					Initial Risk Estimation & Evaluation (Pre)					Risk Controls				Final Risk Estimation & Evaluation (Post)					RBA	New Hazards	Comment
Risk ID	Description	Model Affected	Failure Mode	Failure Cause	Hazard	Hazardous Situations	Harm to Patients	S	P1	P2	P	Risk Ranking	Current Controls	Recommend Mitigation	Types of Controls	Verification & Effective Check	S	P1	P2	P	Risk Ranking	Risk Benefit Analysis	or New Failure Modes	Comment
6								4			3	C			D		4			1	A			
7								2			3	B			D		2			2	A			
8								2			2	A			D		2			1	A			

[Total: 3] [Current Page: 1 of 1] Go to 1

To Report | To Excel | Exit

Your challenges inspire our solutions,
please let us know how we can help…