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DAE Risk Management Webpage (Demo)

https://ww.risk-seek.com

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Goals:

Develop a platform based on RdPDM™ Machine Learning Technology to provide solutions for ICU Medical needs in the fields of:

- Risk analysis (e.g., DFMEA, PFMEA, UFMEA, Hazard Analysis)
- Complaint data risk analysis (e.g., FDA Maude)
- Root cause analysis
- Periodic risk file review
- Remediation on the legacy risk files (QSR Harmonization plan)
- Risk knowledge training
- Provide supports for Audits
- Others

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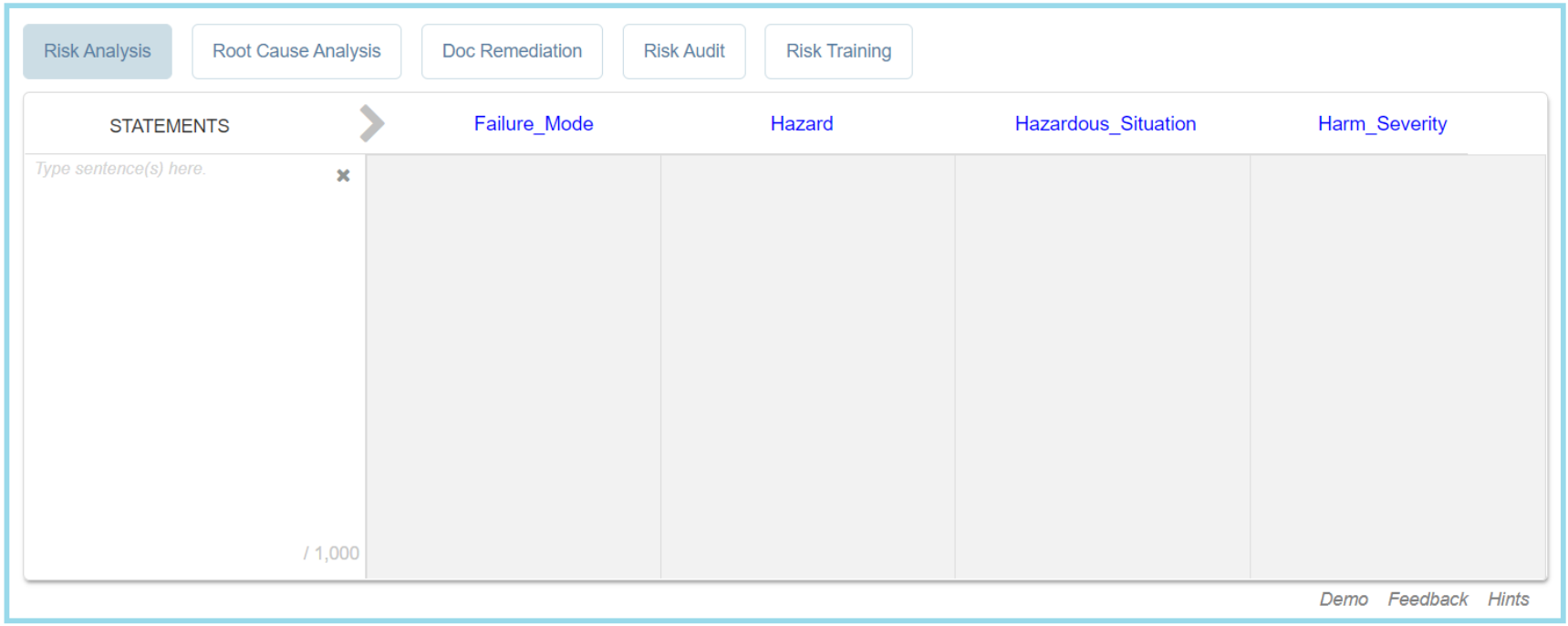
Webpage Layout

https://www.risk-seek.com



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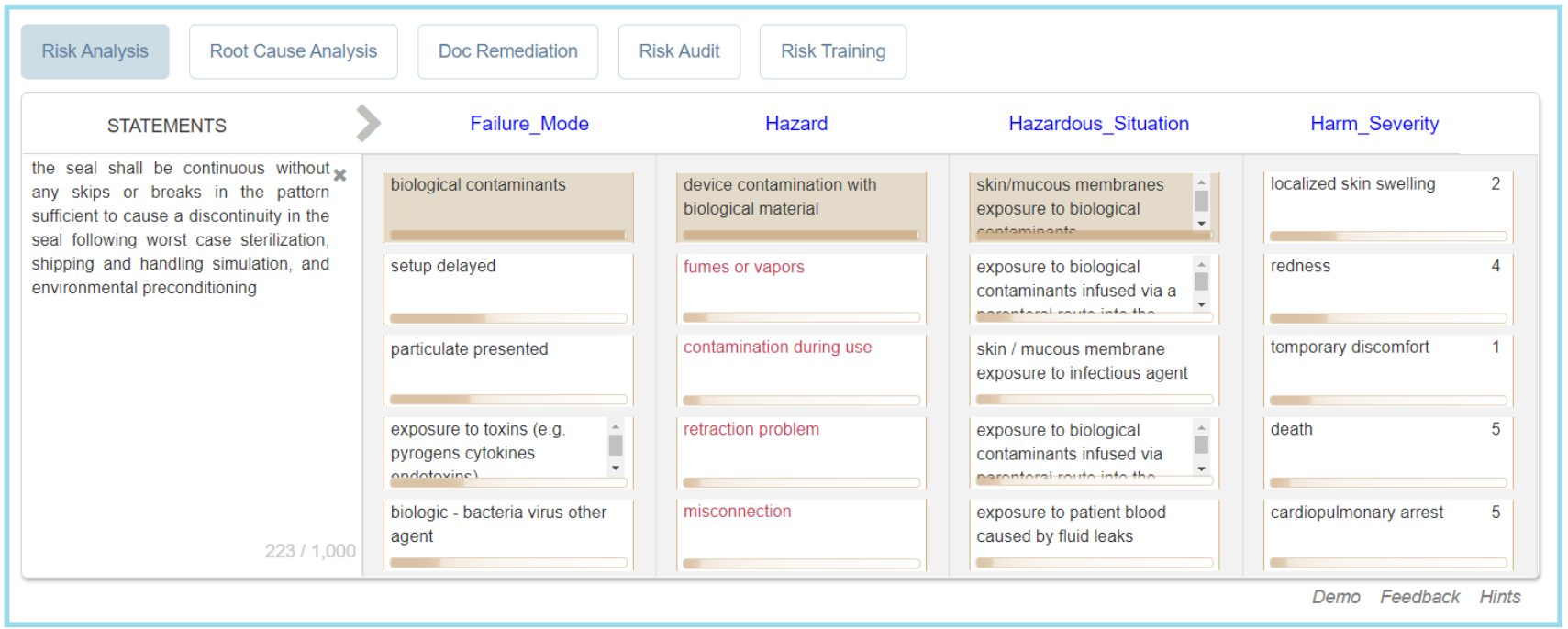
Section 1 Risk Analysis

- Use scenario: when working on FMEA worksheet, DAE needs to predict failure modes, failure causes, hazards, hazardous situations, harms, severity level, mitigation actions.
- How to use this tool: user only need to copy a requirement/function from FMEA/HA, paste to the left below, and pick up potential results.



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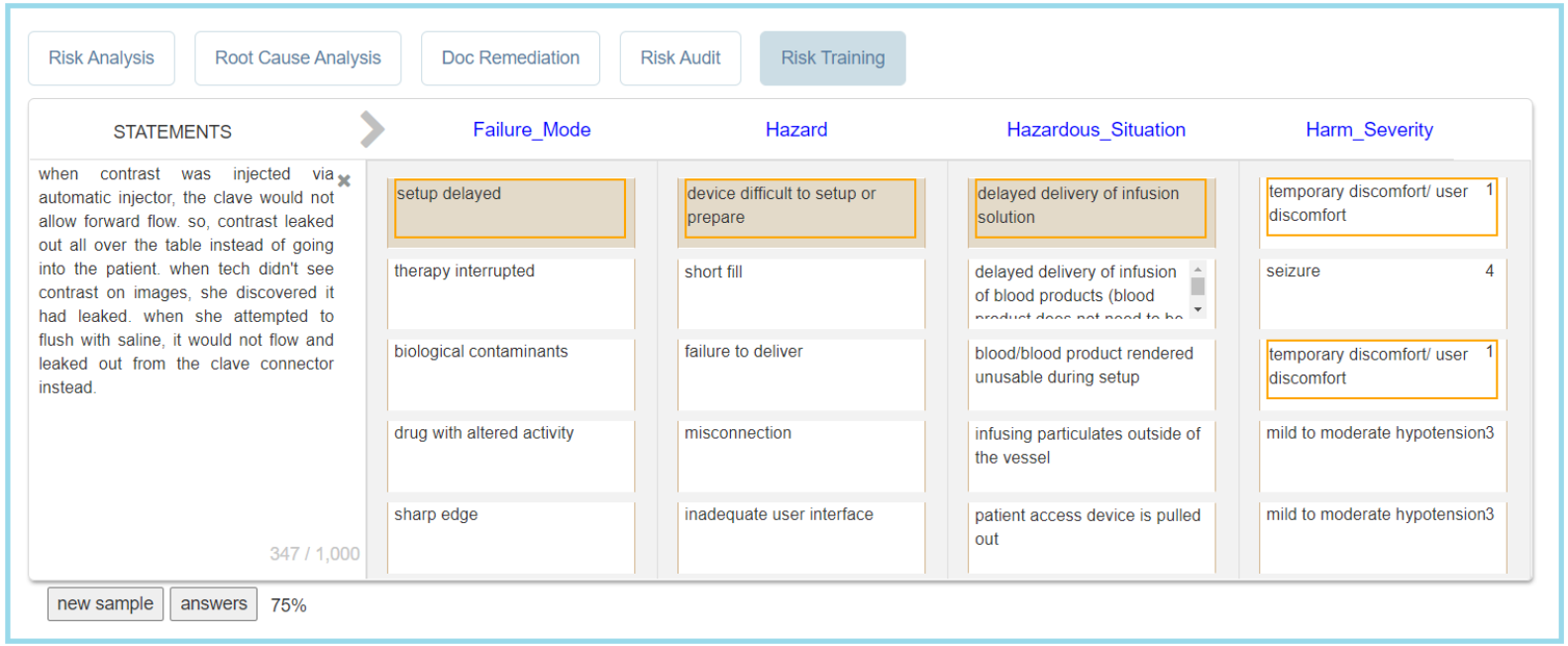
Section 2 Risk Knowledge Training

- Use scenario: DAE may need to update their risk management skills and knowledge routinely.
- How to use this tool: the tool shall randomly generate questions, provide lists of selections on each step (e.g. failure modes, hazards, hazardous situations, harms, severity levels), score, and demo the corrections.



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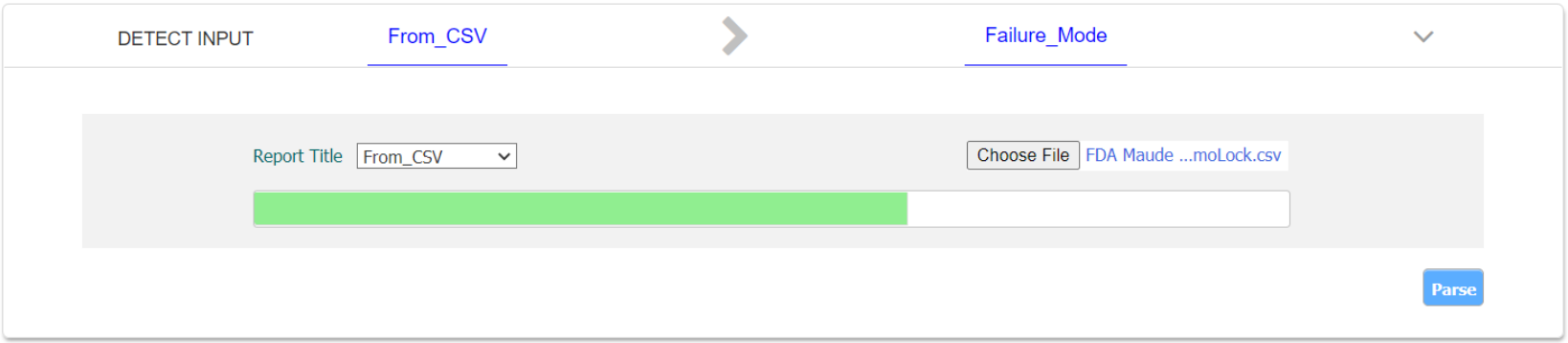
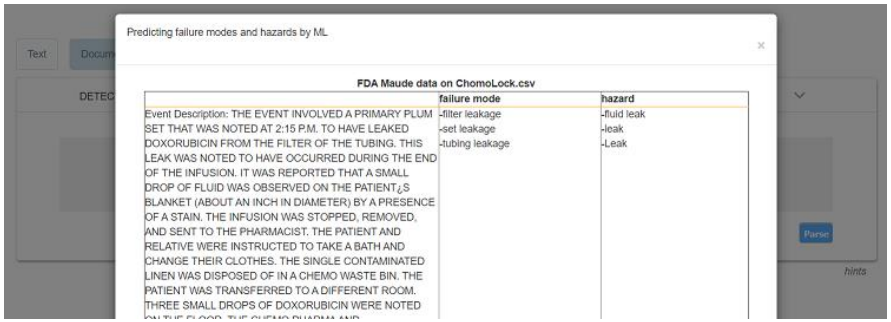
Section 3 FDA Maude Data Analysis

(under construction)

- Use scenario: when working on periodic risk file review, DAE needs to predict failure modes and hazards on individual complaint from FDA Maude database (this is a time consuming process due to big data).
- How to use this tool: user only need to upload the complaint raw data as one file, and automatically obtain an output file with all failure modes and hazards in short period times.





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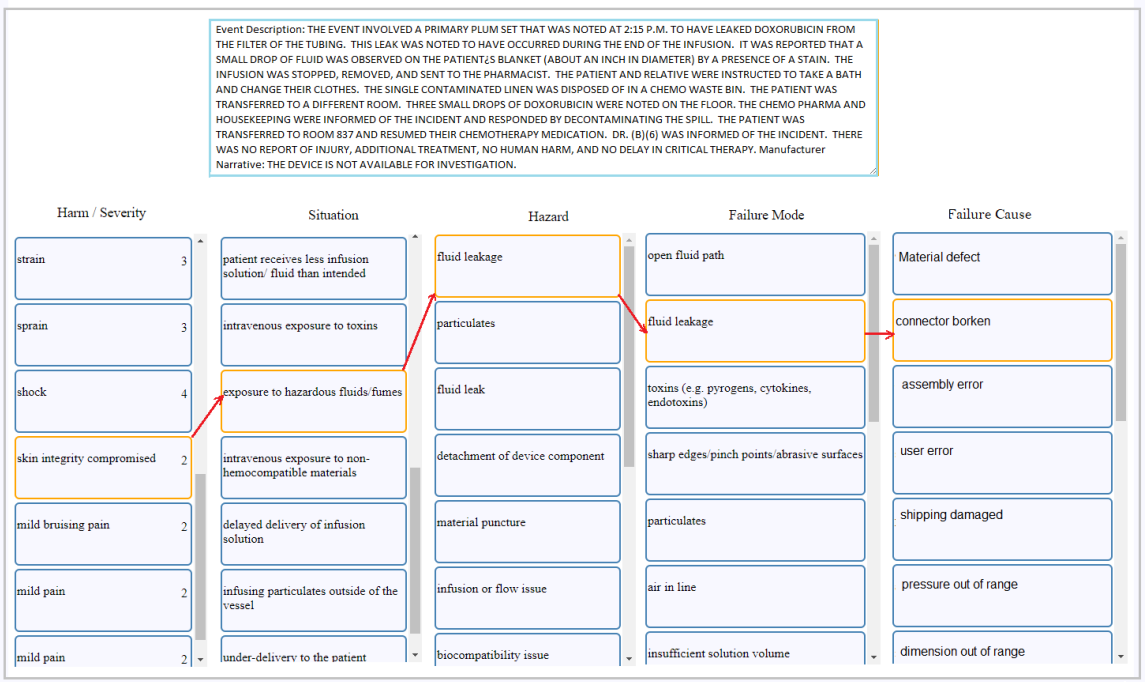
Section 4 Root Cause Analysis
(under construction)

- Use scenario: when working on complaint data, DAE may need to dig out potential failure causes on individual customer compliant.
- How to use this tool: user copies the complaint statement and picks up the best of predicting options through entire which are provided by ML



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Section 5 Periodic Risk File Review
(under construction)

- Use scenario: users need to update risk files periodically for addressing new failure modes, hazards, or P1 increasing from complaint data in a period of times per ISO 14971.
- Webpage operation: users may upload complaint data (e.g. FDA Maude) and target risk files (e.g. FMEA); the webpage shall provide lists of new failure modes and lists of increased P1 value

	A	B
1	Failure_Modes from the FDA Complaints	Chemolock_connector (UFMEA/DFMEA/PFMEA) RSK00-00205
2	balloon detached ✓	UFMEA
3	cap detached ✓	Doesn't connect
4	chamber leakage	No fluid flow
5	closed male luer leakage	No click when connectors pushed together
6	closed system transfer device leakage	Units don't come apart when required
7	connection leakage	Unable to connect device to a luer
8	connector adaptor leakage	Chemo Lock accidentally disconnects at the ISO luer
9	connector detached	Leak at connection point
10	connector falling apart ✓	Fluid residue at connection point
11	connector housing leakage	DFMEA
12	connector leakage	Leaks
13	connector port leakage	Stick-down, silicone fails to return after activation
14	foreign material inside	Difficult to activate
15	loose connection	Fails to latch on to the poppet body
16	medication sprayed	Fails to unlatch from the poppet body
17	particles in the fluid path	Fails to latch on to the poppet body
18	Port blocked ✓	Fails to unlatch from the poppet body
19	port leakage	Post fails to seal on Silicone or Main Seal
20		Post fails to seal on Poppet

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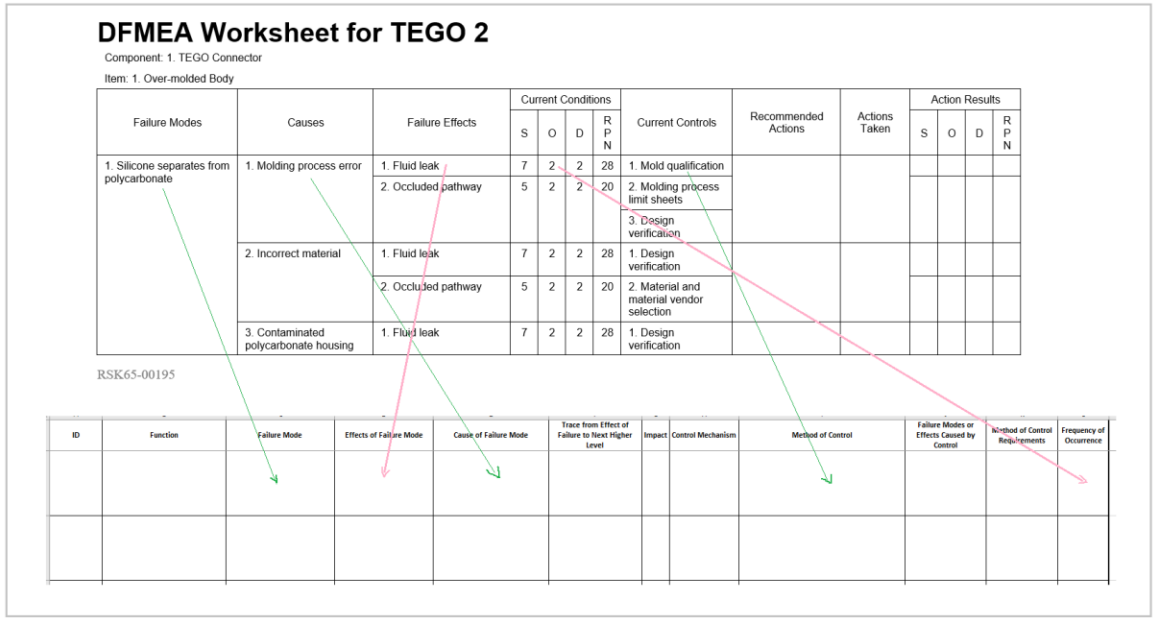
Section 6 Remediation on Legacy Risk Files (under construction)

- Use scenario: users need to convert legacy risk files into new templates due to requirements from ISO 14971 new version, Eu MDR, audit remediation actions, or company QMS integration.
- Webpage operation: users need to upload the legacy risk files to webpage and all history data will be dumped into new template efficiently and accurately. Furthermore, more data can be filled as needs (e.g. ID, S, RR)



DFMEA Worksheet for TEGO 2

Component: 1. TEGO Connector

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						

RSK65-00195

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

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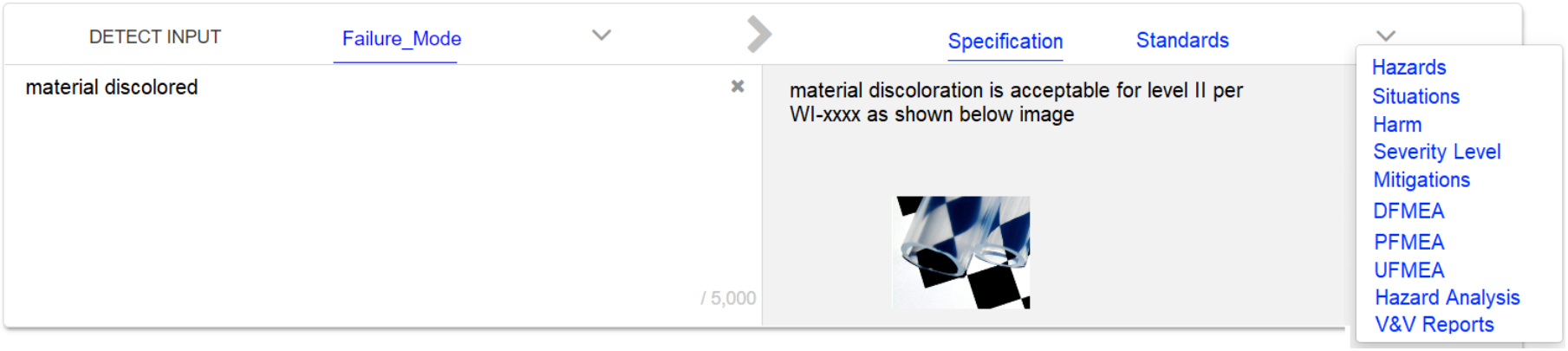
Section 7 Support Risk Management Audit (under construction)

- Use scenario: auditor wants to quickly know how the failure mode ‘material discolored’ is managed (Auditor’s question).
- Webpage operation: the system shall direct to associated engineering specifications, hazards, hazardous situations, harms, severity levels, mitigation actions, risk files (DFMEA, PFMEA, UFMEA, Hazard analysis), test reports, etc.



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Section 8: Others

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