

# Supporting Risk Management for Medical Devices via the **RISKMAN** Ontology & Shapes

---

**Piotr Gorczyca**, Dörthe Arndt, Martin Diller, Jochen Hampe, Georg Heidenreich, Pascal Kettmann, Markus Krötzsch, Stephan Mennicke, Sebastian Rudolph, Hannes Straß

SEMANTiCS 2025, Vienna – 4th September 2025



International Center  
for Computational Logic

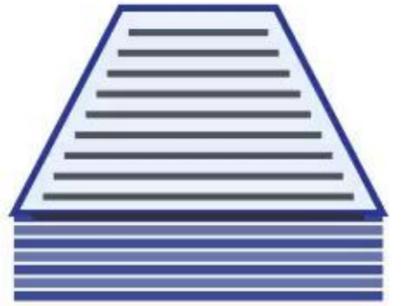
With funding from the:



Federal Ministry  
of Research, Technology  
and Space

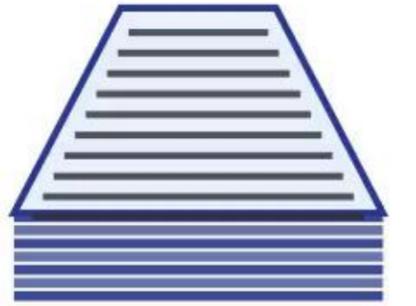
# Big Picture: RMFs

**Risk management files:** hundreds of rows, dozens of pages



# Big Picture: RMFs

**Risk management files:** hundreds of rows, dozens of pages  
**Manual review:** slow, error-prone, inconsistent, tedious...



# Big Picture: RMFs

**Risk management files:** hundreds of rows, dozens of pages

**Manual review:** slow, error-prone, inconsistent, tedious...

**Objective:** automate checks → ensure consistency, speed the process up



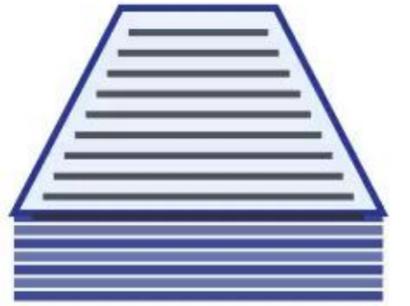
# Big Picture: RMFs

**Risk management files:** hundreds of rows, dozens of pages

**Manual review:** slow, error-prone, inconsistent, tedious...

**Objective:** automate checks → ensure consistency, speed the process up

**Notified bodies need:** quick, objective validation



# Big Picture: RMFs

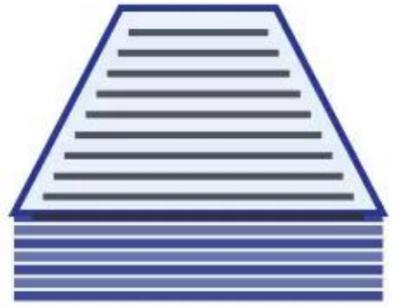
**Risk management files:** hundreds of rows, dozens of pages

**Manual review:** slow, error-prone, inconsistent, tedious...

**Objective:** automate checks → ensure consistency, speed the process up

**Notified bodies need:** quick, objective validation

**Manufacturers need:** instant feedback before submission



# Big Picture: RMFs

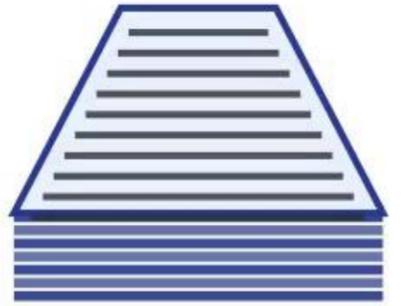
**Risk management files:** hundreds of rows, dozens of pages

**Manual review:** slow, error-prone, inconsistent, tedious...

**Objective:** automate checks → ensure consistency, speed the process up

**Notified bodies need:** quick, objective validation

**Manufacturers need:** instant feedback before submission



# Current Practices

Ctr. risk	Analysed risk	Hazard	Init. P1	Foreseeable sequence of events	Hazardous situation	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	(1) Vibration mechanism fails, (2) Vibration cannot be felt	No insulin delivered	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...
2.	Overdelivery of insulin due to stuck motor	Motor control failure	II	(1) Motor does not stop, (2) Continuous insulin infusion	Overdose	IV	Hypoglycemia leading to seizure	V	Dual motor monitoring, automatic shutoff	II	III	...
3.	Underdelivery of insulin due to occlusion	Catheter blockage	III	(1) Kinked tubing, (2) Insulin flow obstructed	Underdose	III	Hyperglycemia, risk of ketoacidosis	IV	Pressure sensor with alarm and backup injection option	II	III	...
4.	Loss of therapy due to empty reservoir not detected	Reservoir sensor failure	II	(1) User forgets to refill, (2) Sensor fails to alarm	Underdose	III	Severe hyperglycemia	IV	Dual sensing, mandatory periodic checks	II	III	...
5.	...	...	...	...	...	...	...	...	...	...	...	...

# Current Practices

Ctr. risk	Analysed risk	Hazard	Init. P1	Foreseeable sequence of events	Hazardous situation	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	(1) Vibration mechanism fails, (2) Vibration cannot be felt	No insulin delivered	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...
2.	Overdelivery of insulin due to stuck motor	Motor control failure	II	(1) Motor does not stop, (2) Continuous insulin infusion	Overdose	IV	Hypoglycemia leading to seizure	V	Dual motor monitoring, automatic shutoff	II	III	...
3.	Underdelivery of insulin due to occlusion	Catheter blockage	III	(1) Kinked tubing, (2) Insulin flow obstructed	Underdose	III	Hyperglycemia, risk of ketoacidosis	IV	Pressure sensor with alarm and backup injection option	II	III	...
4.	Loss of therapy due to empty reservoir not detected	Reservoir sensor failure	II	(1) User forgets to refill, (2) Sensor fails to alarm	Underdose	III	Severe hyperglycemia	IV	Dual sensing, mandatory periodic checks	II	III	...
5.	...	...	...	...	...	...	...	...	...	...	...	...

# Current Practices

Ctr. risk	Analysed risk	Hazard	Init. P1	Foreseeable sequence of events	Hazardous situation	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	(1) Vibration mechanism fails, (2) Vibration cannot be felt	No insulin delivered	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...
2.	Overdelivery of insulin due to stuck motor	Motor control failure	II	(1) Motor does not stop, (2) Continuous insulin infusion	Overdose	IV	Hypoglycemia leading to seizure	V	Dual motor monitoring, automatic shutoff	II	III	...
3.	Underdelivery of insulin due to occlusion	Catheter blockage	III	(1) Kinked tubing, (2) Insulin flow obstructed	Underdose	III	Hyperglycemia, risk of ketoacidosis	IV	Pressure sensor with alarm and backup injection option	II	III	...
4.	Loss of therapy due to empty reservoir not detected	Reservoir sensor failure	II	(1) User forgets to refill, (2) Sensor fails to alarm	Underdose	III	Severe hyperglycemia	IV	Dual sensing, mandatory periodic checks	II	III	...
5.	...	...	...	...	...	...	...	...	...	...	...	...

# Current Practices

Ctr. risk	Analysed risk	Hazard	Init. P1	Foreseeable sequence of events	Hazardous situation	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	(1) Vibration mechanism fails, (2) Vibration cannot be felt	No insulin delivered	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...
2.	Overdelivery of insulin due to stuck motor	Motor control failure	II	(1) Motor does not stop, (2) Continuous insulin infusion	Overdose	IV	Hypoglycemia leading to seizure	V	Dual motor monitoring, automatic shutoff	II	III	...
3.	Underdelivery of insulin due to occlusion	Catheter blockage	III	(1) Kinked tubing, (2) Insulin flow obstructed	Underdose	III	Hyperglycemia, risk of ketoacidosis	IV	Pressure sensor with alarm and backup injection option	II	III	...
4.	Loss of therapy due to empty reservoir not detected	Reservoir sensor failure	II	(1) User forgets to refill, (2) Sensor fails to alarm	Underdose	III	Severe hyperglycemia	IV	Dual sensing, mandatory periodic checks	II	III	...
5.	...	...	...	...	...	...	...	...	...	...	...	...

# Current Practices

Ctr. risk	Analysed risk	Hazard	Init. P1	Foreseeable sequence of events	Hazardous situation	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	(1) Vibration mechanism fails, (2) Vibration cannot be felt	No insulin delivered	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...
2.	Overdelivery of insulin due to stuck motor	Motor control failure	II	(1) Motor does not stop, (2) Continuous insulin infusion	Overdose	IV	Hypoglycemia leading to seizure	V	Dual motor monitoring, automatic shutoff	II	III	...
3.	Underdelivery of insulin due to occlusion	Catheter blockage	III	(1) Kinked tubing, (2) Insulin flow obstructed	Underdose	III	Hyperglycemia, risk of ketoacidosis	IV	Pressure sensor with alarm and backup injection option	II	III	...
4.	Loss of therapy due to empty reservoir not detected	Reservoir sensor failure	II	(1) User forgets to refill, (2) Sensor fails to alarm	Underdose	III	Severe hyperglycemia	IV	Dual sensing, mandatory periodic checks	II	III	...
5.	...	...	...	...	...	...	...	...	...	...	...	...

# Current Practices

Ctr. risk	Analysed risk	Hazard	Init. P1	Foreseeable sequence of events	Hazardous situation	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	(1) Vibration mechanism fails, (2) Vibration cannot be felt	No insulin delivered	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...
2.	Overdelivery of insulin due to stuck motor	Motor control failure	II	(1) Motor does not stop, (2) Continuous insulin infusion	Overdose	IV	Hypoglycemia leading to seizure	V	Dual motor monitoring, automatic shutoff	II	III	...
3.	Underdelivery of insulin due to occlusion	Catheter blockage	III	(1) Kinked tubing, (2) Insulin flow obstructed	Underdose	III	Hyperglycemia, risk of ketoacidosis	IV	Pressure sensor with alarm and backup injection option	II	III	...
4.	Loss of therapy due to empty reservoir not detected	Reservoir sensor failure	II	(1) User forgets to refill, (2) Sensor fails to alarm	Underdose	III	Severe hyperglycemia	IV	Dual sensing, mandatory periodic checks	II	III	...
5.	...	...	...	...	...	...	...	...	...	...	...	...

# Current Practices

Ctr. risk	Analysed risk	Hazard	Init. P1	Foreseeable sequence of events	Hazardous situation	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	(1) Vibration mechanism fails, (2) Vibration cannot be felt	No insulin delivered	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...
2.	Overdelivery of insulin due to stuck motor	Motor control failure	II	(1) Motor does not stop, (2) Continuous insulin infusion	Overdose	IV	Hypoglycemia leading to seizure	V	Dual motor monitoring, automatic shutoff	II	III	...
3.	Underdelivery of insulin due to occlusion	Catheter blockage	III	(1) Kinked tubing, (2) Insulin flow obstructed	Underdose	III	Hyperglycemia, risk of ketoacidosis	IV	Pressure sensor with alarm and backup injection option	II	III	...
4.	Loss of therapy due to empty reservoir not detected	Reservoir sensor failure	II	(1) User forgets to refill, (2) Sensor fails to alarm	Underdose	III	Severe hyperglycemia	IV	Dual sensing, mandatory periodic checks	II	III	...
5.	...	...	...	...	...	...	...	...	...	...	...	...

# Current Practices

Ctr. risk	Analysed risk	Hazard	Init. P1	Foreseeable sequence of events	Hazardous situation	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	(1) Vibration mechanism fails, (2) Vibration cannot be felt	No insulin delivered	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...
2.	Overdelivery of insulin due to stuck motor	Motor control failure	II	(1) Motor does not stop, (2) Continuous insulin infusion	Overdose	IV	Hypoglycemia leading to seizure	V	Dual motor monitoring, automatic shutoff	II	III	...
3.	Underdelivery of insulin due to occlusion	Catheter blockage	III	(1) Kinked tubing, (2) Insulin flow obstructed	Underdose	III	Hyperglycemia, risk of ketoacidosis	IV	Pressure sensor with alarm and backup injection option	II	III	...
4.	Loss of therapy due to empty reservoir not detected	Reservoir sensor failure	II	(1) User forgets to refill, (2) Sensor fails to alarm	Underdose	III	Severe hyperglycemia	IV	Dual sensing, mandatory periodic checks	II	III	...
5.	...	...	...	...	...	...	...	...	...	...	...	...

# Current Practices

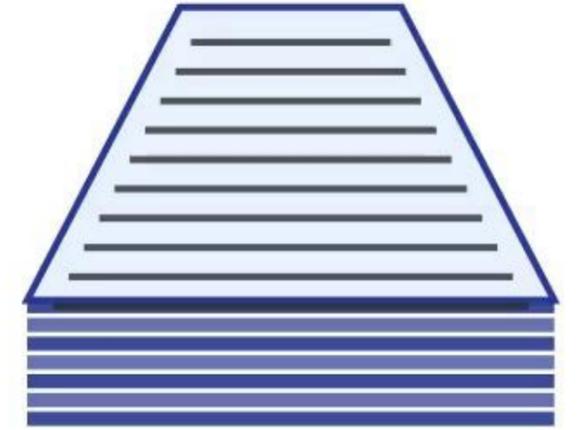
Ctr. risk	Analysed risk	Hazard	Init. P1	Foreseeable sequence of events	Hazardous situation	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	(1) Vibration mechanism fails, (2) Vibration cannot be felt	No insulin delivered	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...
2.	Overdelivery of insulin due to stuck motor	Motor control failure	II	(1) Motor does not stop, (2) Continuous insulin infusion	Overdose	IV	Hypoglycemia leading to seizure	V	Dual motor monitoring, automatic shutoff	II	III	...
3.	Underdelivery of insulin due to occlusion	Catheter blockage	III	(1) Kinked tubing, (2) Insulin flow obstructed	Underdose	III	Hyperglycemia, risk of ketoacidosis	IV	Pressure sensor with alarm and backup injection option	II	III	...
4.	Loss of therapy due to empty reservoir not detected	Reservoir sensor failure	II	(1) User forgets to refill, (2) Sensor fails to alarm	Underdose	III	Severe hyperglycemia	IV	Dual sensing, mandatory periodic checks	II	III	...
5.	...	...	...	...	...	...	...	...	...	...	...	...

# Current Practices

Ctr. risk	Analysed risk	Hazard	Init. P1	Foreseeable sequence of events	Hazardous situation	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	(1) Vibration mechanism fails, (2) Vibration cannot be felt	No insulin delivered	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...
2.	Overdelivery of insulin due to stuck motor	Motor control failure	II	(1) Motor does not stop, (2) Continuous insulin infusion	Overdose	IV	Hypoglycemia leading to seizure	V	Dual motor monitoring, automatic shutoff	II	III	...
3.	Underdelivery of insulin due to occlusion	Catheter blockage	III	(1) Kinked tubing, (2) Insulin flow obstructed	Underdose	III	Hyperglycemia, risk of ketoacidosis	IV	Pressure sensor with alarm and backup injection option	II	III	...
4.	Loss of therapy due to empty reservoir not detected	Reservoir sensor failure	II	(1) User forgets to refill, (2) Sensor fails to alarm	Underdose	III	Severe hyperglycemia	IV	Dual sensing, mandatory periodic checks	II	III	...
5.	...	...	...	...	...	...	...	...	...	...	...	...

# Our Proposal

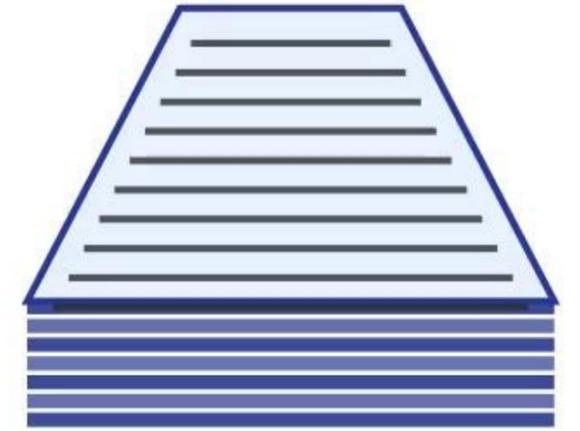
**Assumption:** RMFs should be digitized



# Our Proposal

**Assumption:** RMFs should be digitized

**Requirement:** RMFs must be human- and machine-readable

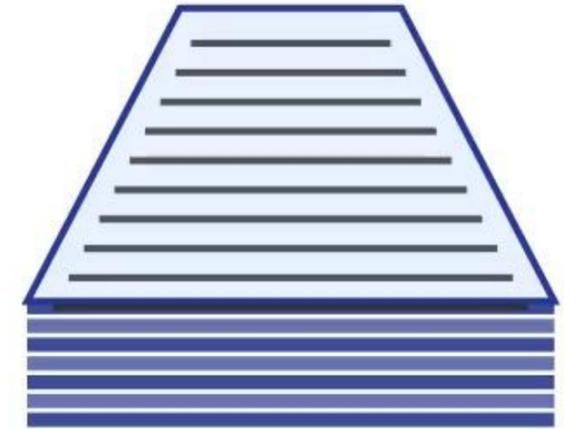


# Our Proposal

**Assumption:** RMFs should be digitized

**Requirement:** RMFs must be human- and machine-readable

**Approach:** encode them in a logic-based language:  $\text{RDFa} = \text{HTML} + \text{RDF}$

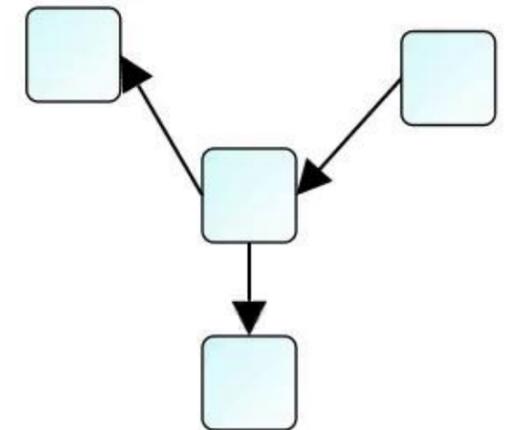
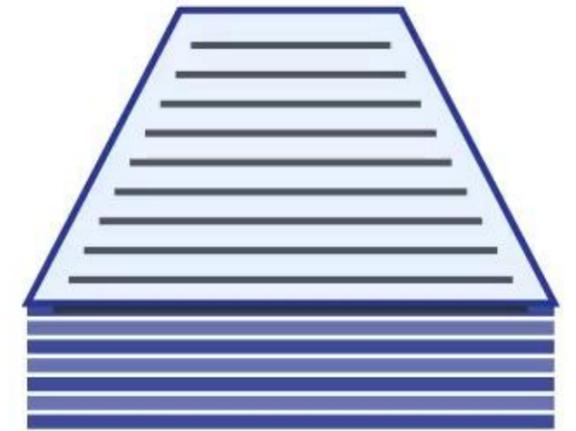


# Our Proposal

**Assumption:** RMFs should be digitized

**Requirement:** RMFs must be human- and machine-readable

**Approach:** encode them in a logic-based language:  $\text{RDFa} = \text{HTML} + \text{RDF}$



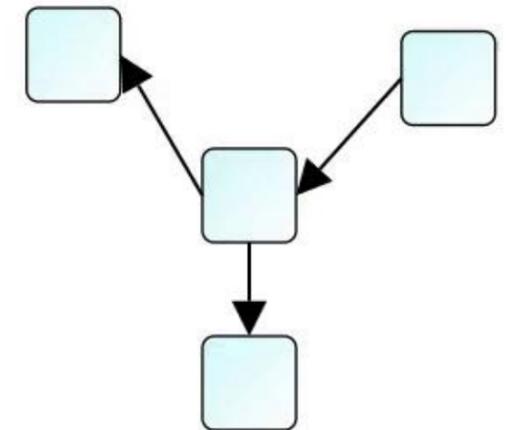
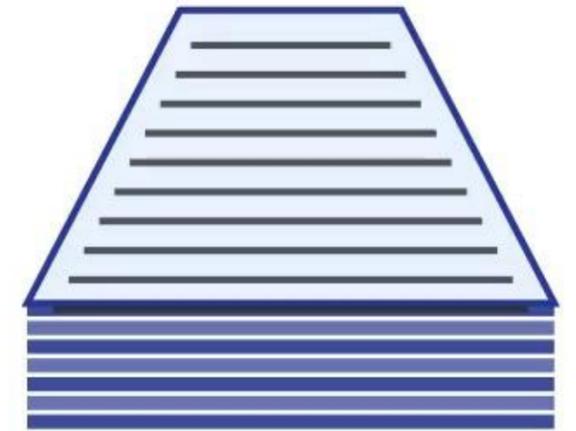
# Our Proposal

**Assumption:** RMFs should be digitized

**Requirement:** RMFs must be human- and machine-readable

**Approach:** encode them in a logic-based language:  $RDFa = HTML + RDF$

**Benefit:** supports **inference** (implicit knowledge completion)



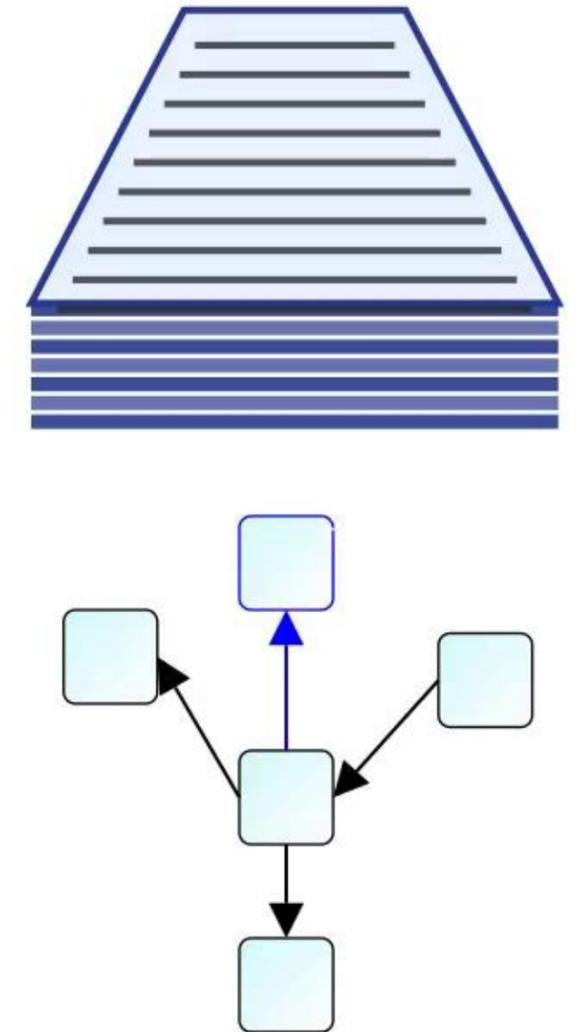
# Our Proposal

**Assumption:** RMFs should be digitized

**Requirement:** RMFs must be human- and machine-readable

**Approach:** encode them in a logic-based language:  $RDFa=HTML+RDF$

**Benefit:** supports *inference* (implicit knowledge completion)



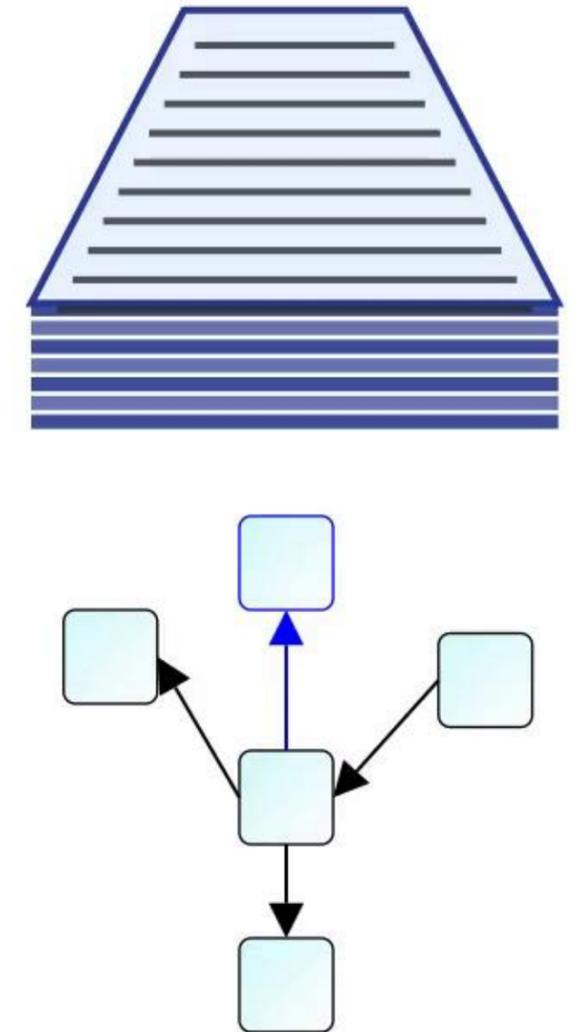
# Our Proposal

**Assumption:** RMFs should be digitized

**Requirement:** RMFs must be human- and machine-readable

**Approach:** encode them in a logic-based language:  $RDFa = HTML + RDF$

**Benefit:** supports **inference** (implicit knowledge completion)  
and **validation** (constraints checking)



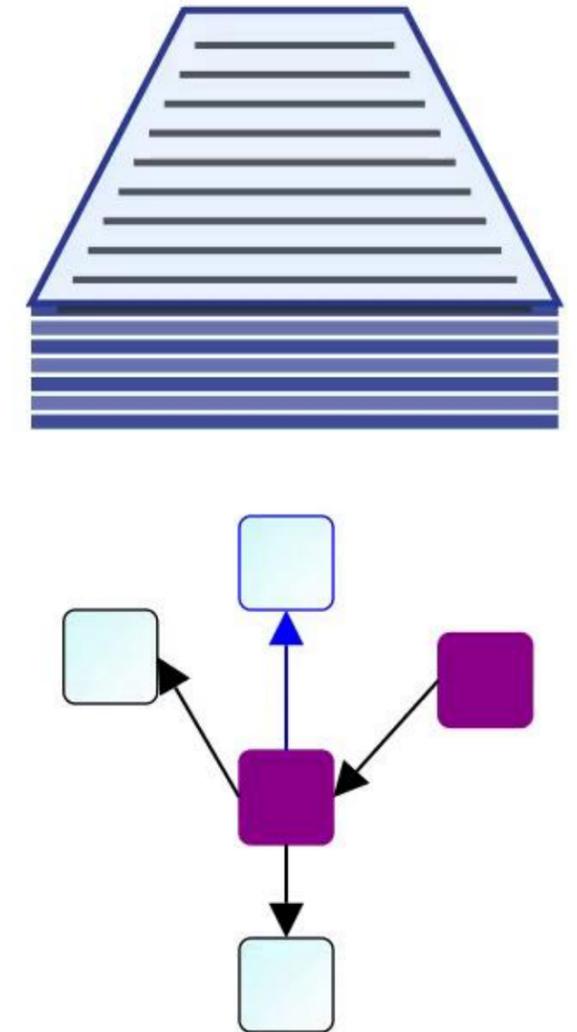
# Our Proposal

**Assumption:** RMFs should be digitized

**Requirement:** RMFs must be human- and machine-readable

**Approach:** encode them in a logic-based language:  $RDFa = HTML + RDF$

**Benefit:** supports **inference** (implicit knowledge completion)  
and **validation** (constraints checking)



# Risk Management File – RDF Graph encoding

Ctr. risk	Analysed risk	Hazard	Init. P1	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	...

# Risk Management File – RDF Graph encoding

Ctr. risk	Analysed risk	Hazard	Init. P1	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	...

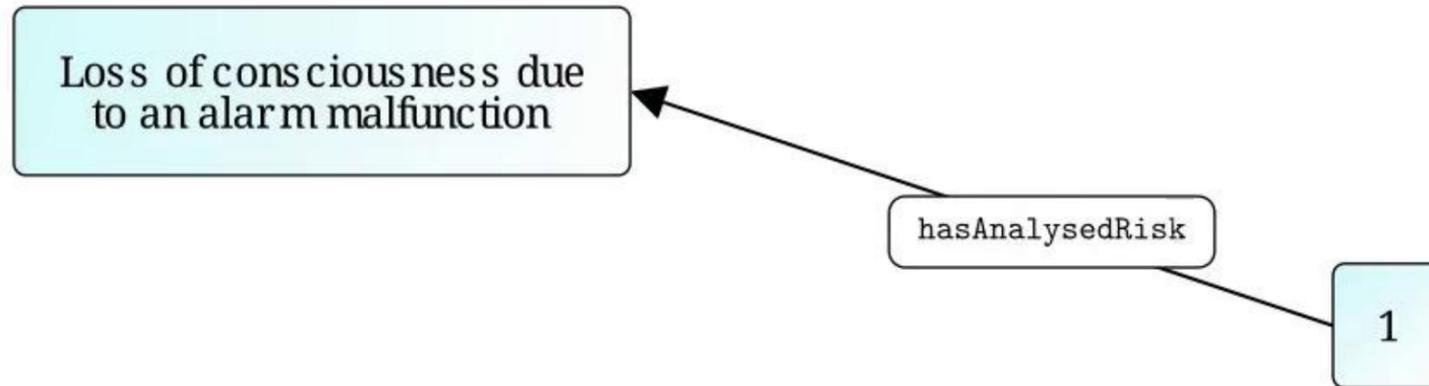
# Risk Management File – RDF Graph encoding

Ctr. risk	Analysed risk	Hazard	Init. P1	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	...

1

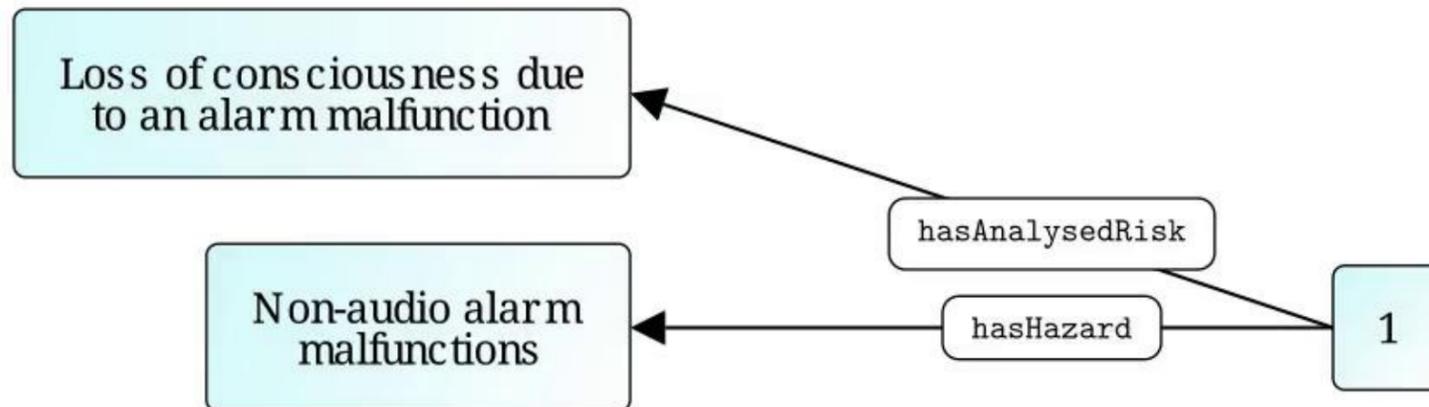
# Risk Management File – RDF Graph encoding

Ctr. risk	Analysed risk	Hazard	Init. P1	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	...



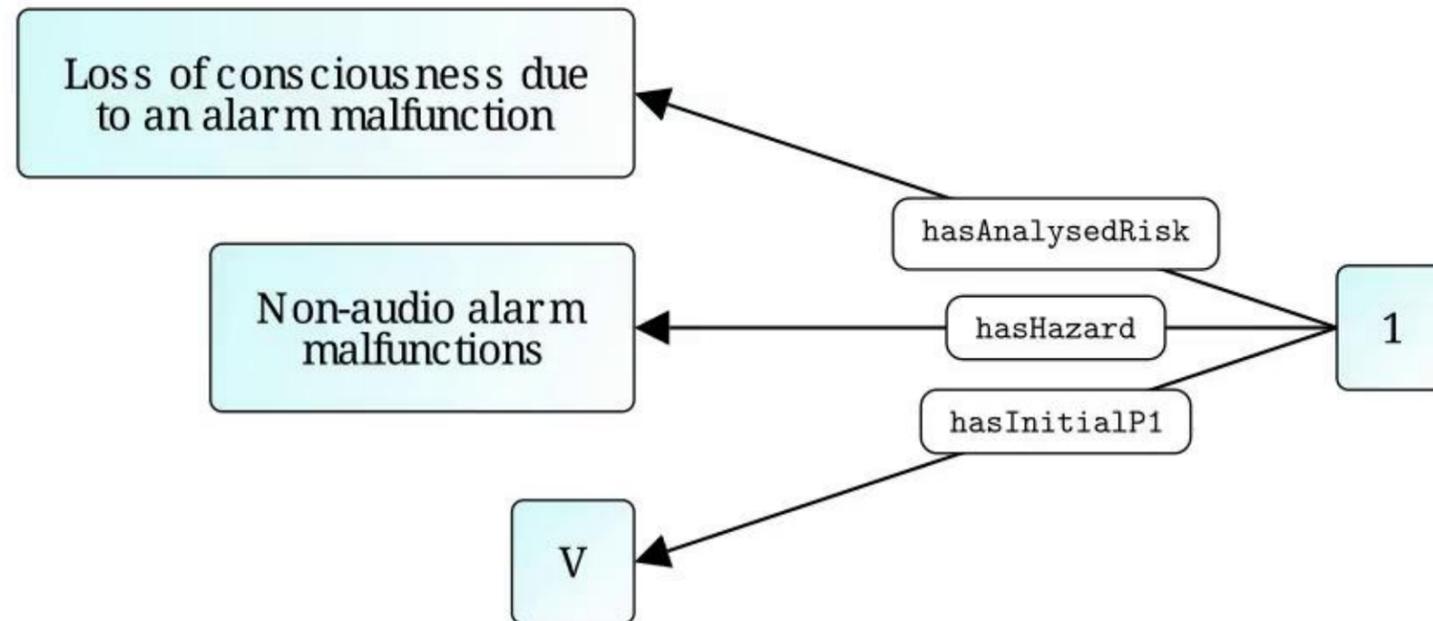
# Risk Management File – RDF Graph encoding

Ctr. risk	Analysed risk	Hazard	Init. P1	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	...



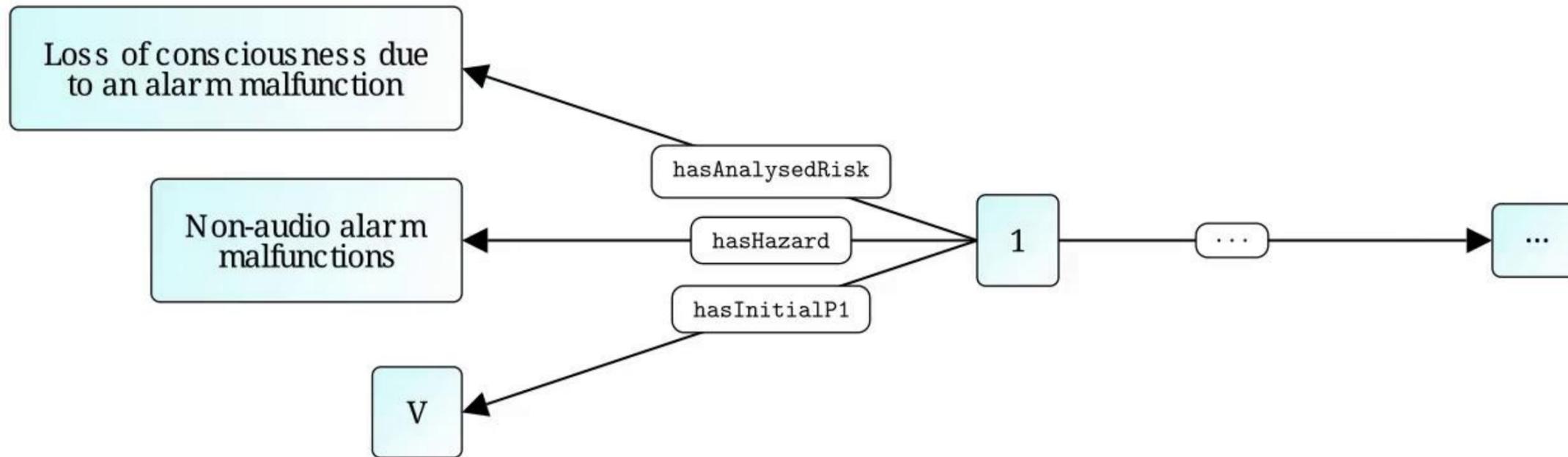
# Risk Management File – RDF Graph encoding

Ctr. risk	Analysed risk	Hazard	Init. P1	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	...



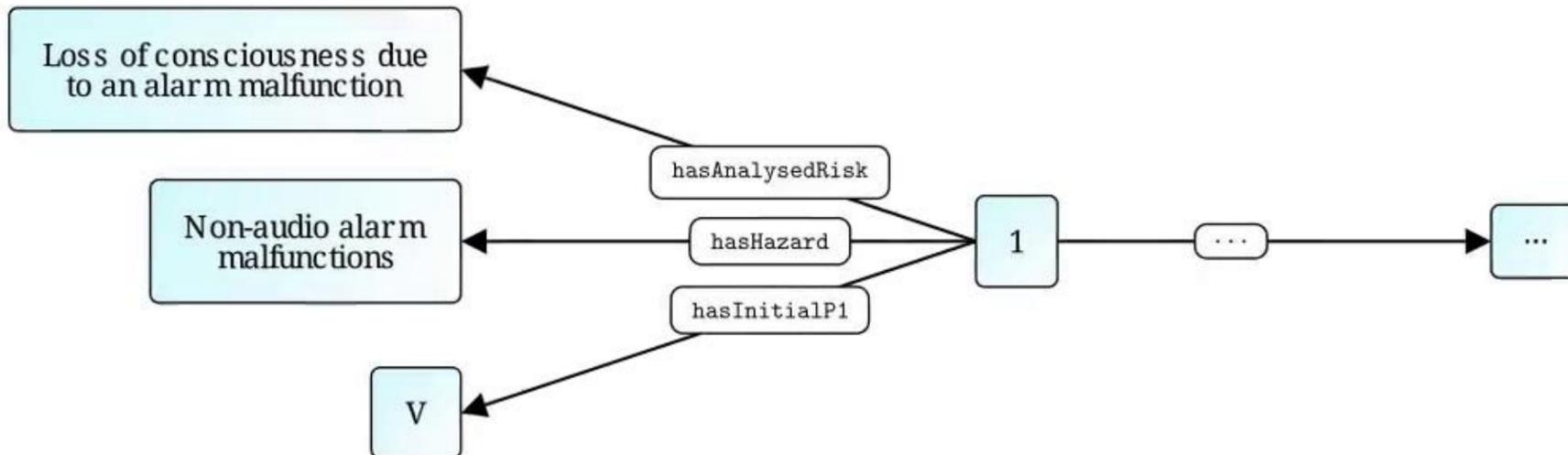
# Risk Management File – RDF Graph encoding

Ctr. risk	Analysed risk	Hazard	Init. P1	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	...



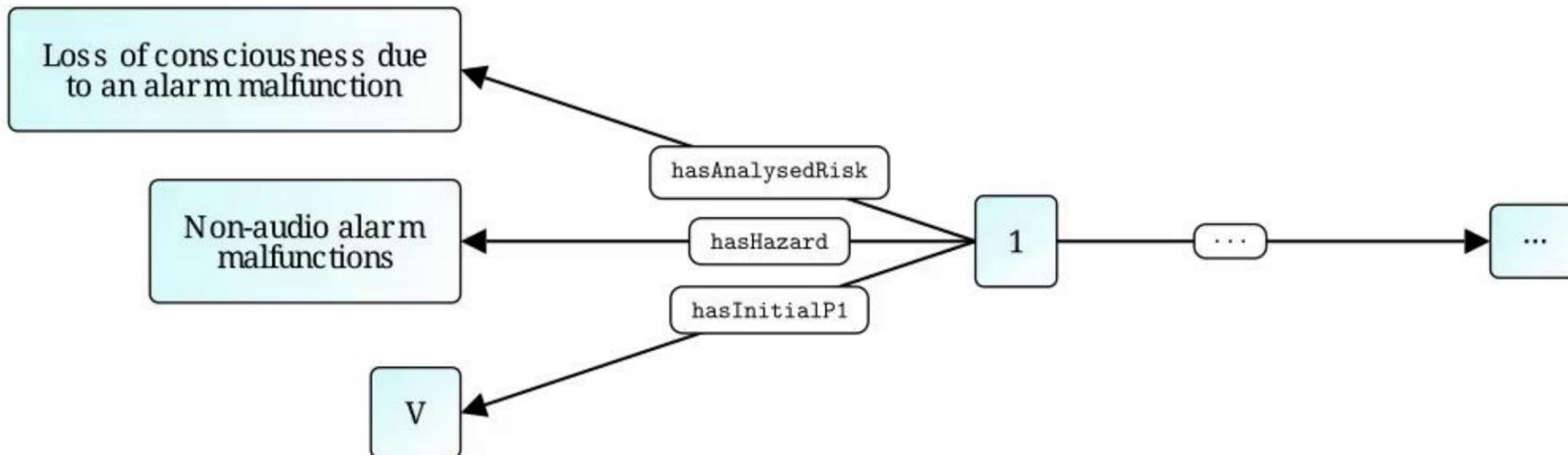
# Risk Management File – RDF Graph encoding

Ctr. risk	Analysed risk	Hazard	Init. P1	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	...



# Risk Management File – RDF Graph encoding

Ctr. risk	Analysed risk	Hazard	Init. P1	...
1.	Loss of consciousness due to an alarm malfunction	Non-audio alarm malfunctions	V	...



```
1 @prefix : <https://w3id.org/riskman/ontology> .
2 @prefix rdfs: <http://www.w3.org/2000/01/rdf-schema#> .
3
4
5 _:1 :hasAnalysedRisk [
6     rdfs:comment "Loss of consciousness..."
7 ];
8 :hasHazard [
9     rdfs:comment "Non-audio alarm..."
10 ];
11 ];
12 :hasInitialP1 :II ;
13 ...
14 .
```

# The RISKMAN Ontology: Encoding Rules (1)

# The RISKMAN Ontology: Encoding Rules (1)

**risk level**

Combination of probability and severity.

# The RISKMAN Ontology: Encoding Rules (1)

**risk level**

Combination of probability and severity.

Ontology (TBox)

Data (ABox)

---

# The RISKMAN Ontology: Encoding Rules (1)

## **risk level**

Combination of probability and severity.

Ontology (TBox)

Data (ABox)

---

$\exists \text{hasProbability.} \top \sqcap$   
 $\exists \text{hasSeverity.} \top \sqsubseteq \textit{RiskLevel}$

# The RISKMAN Ontology: Encoding Rules (1)

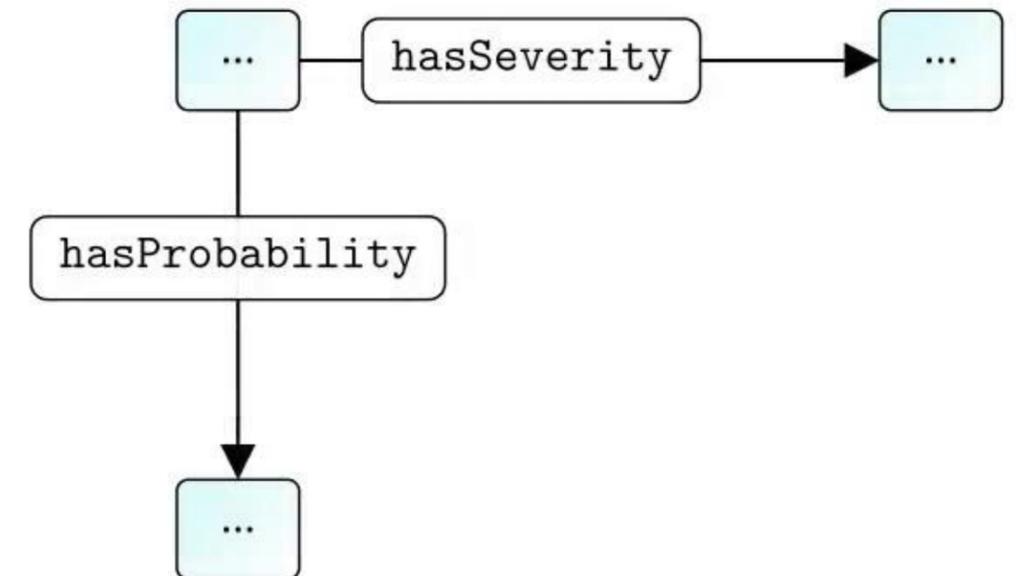
## **risk level**

Combination of probability and severity.

Ontology (TBox)

Data (ABox)

$\exists \text{hasProbability.} \top \sqcap$   
 $\exists \text{hasSeverity.} \top \sqsubseteq \textit{RiskLevel}$



# The RISKMAN Ontology: Encoding Rules (1)

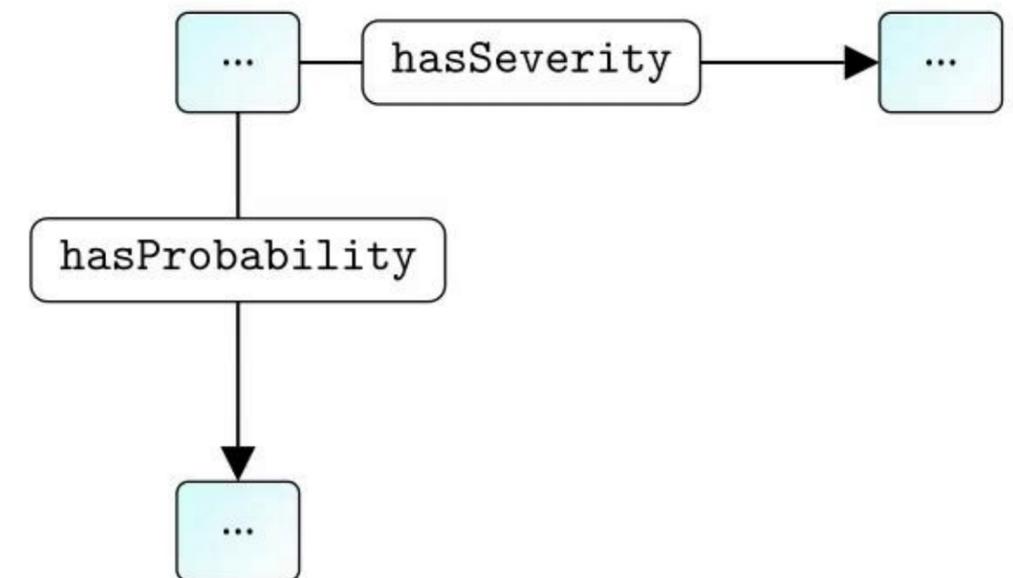
## **risk level**

Combination of probability and severity.

Ontology (TBox)

Data (ABox)

$\exists \text{hasProbability.} \top \sqcap$   
 $\exists \text{hasSeverity.} \top \sqsubseteq \textit{RiskLevel}$



# The RISKMAN Ontology: Encoding Rules (1)

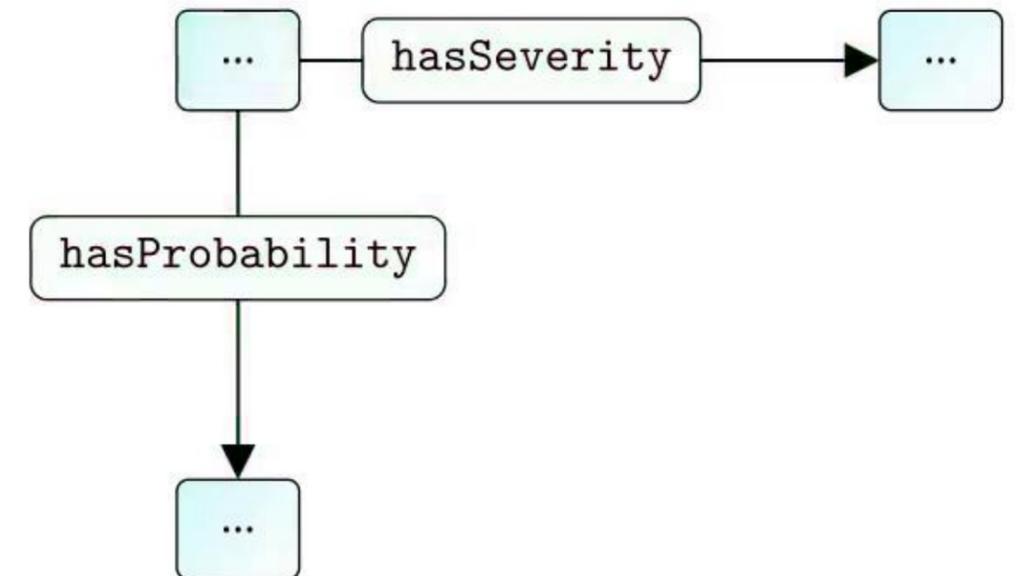
## **risk level**

Combination of probability and severity.

Ontology (TBox)

Data (ABox)

$\exists \text{hasProbability.} \top \sqcap$   
 $\exists \text{hasSeverity.} \top \sqsubseteq \textit{RiskLevel}$



# The RISKMAN Ontology: Encoding Rules (1)

## **risk level**

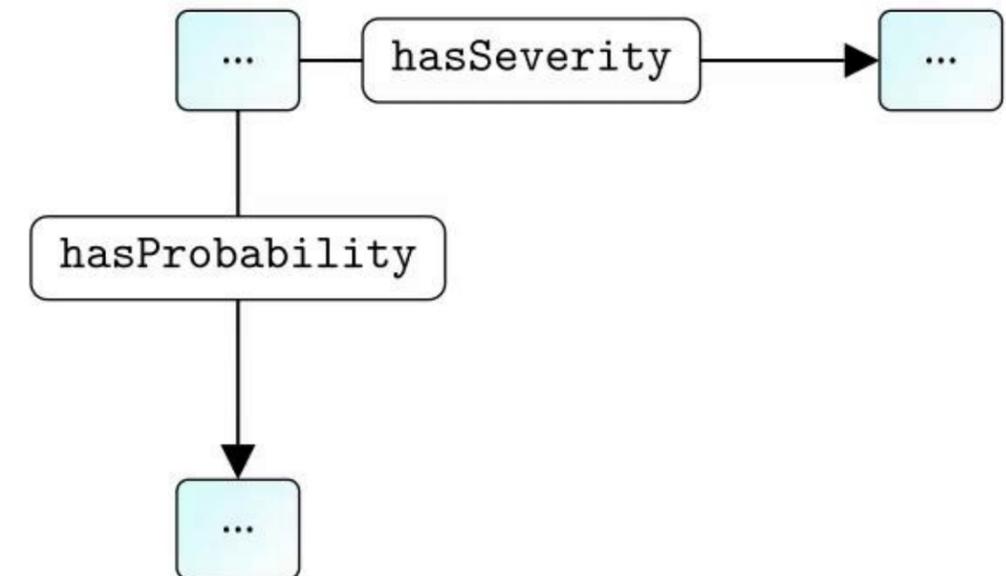
Combination of probability and severity.

Ontology (TBox)

Data (ABox)

$\exists \text{hasProbability.} \top \sqcap$   
 $\exists \text{hasSeverity.} \top \sqsubseteq \textit{RiskLevel}$

*RiskLevel*



# The RISKMAN Ontology: Encoding Rules (2)

According to ISO 14971 [3.18]:

**risk**

Combination of probability of occurrence of harm and severity.

# The RISKMAN Ontology: Encoding Rules (2)

According to ISO 14971 [3.18]:

**risk**

Combination of probability of occurrence of harm and severity.

Ontology (TBox)

Data (ABox)

---

# The RISKMAN Ontology: Encoding Rules (2)

According to ISO 14971 [3.18]:

**risk**

Combination of probability of occurrence of harm and severity.

Ontology (TBox)

Data (ABox)

---

$\exists \text{hasRiskLevel.} \top \sqcap$   
 $\exists \text{hasHarm.} \top \sqsubseteq \textit{Risk}$

# The RISKMAN Ontology: Encoding Rules (2)

According to ISO 14971 [3.18]:

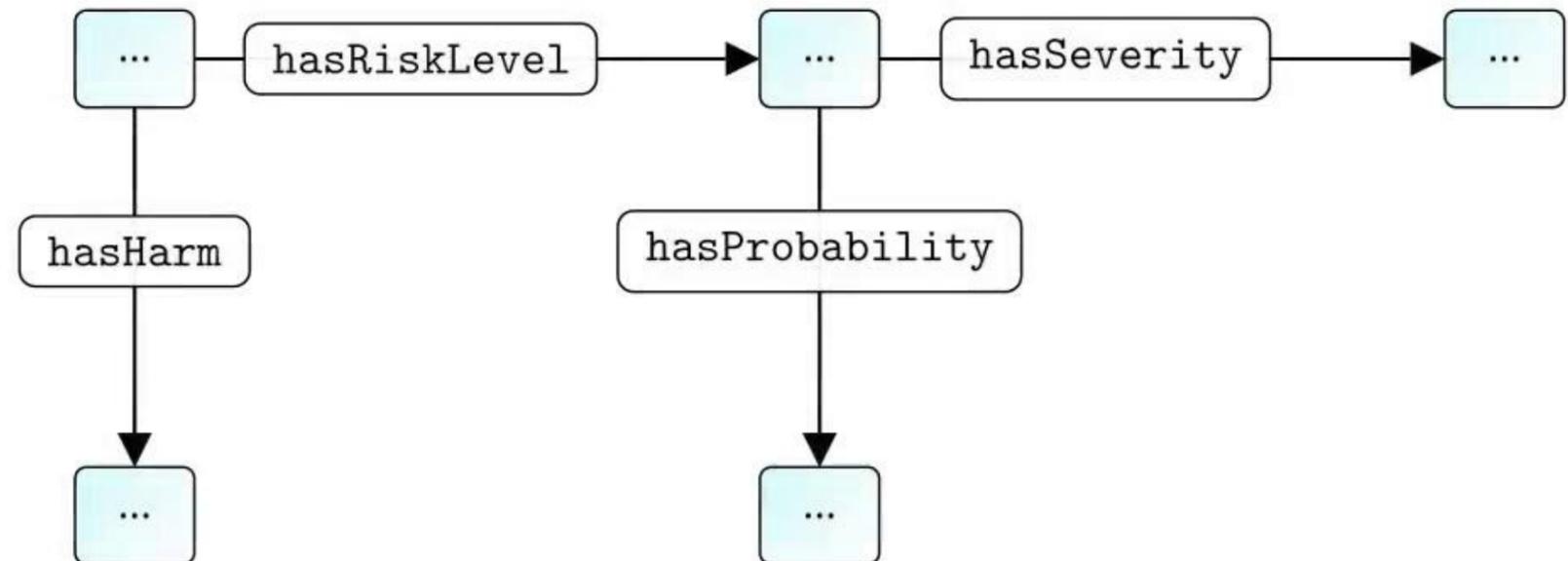
**risk**

Combination of probability of occurrence of harm and severity.

Ontology (TBox)

Data (ABox)

$\exists \text{hasRiskLevel}.\top \sqcap$   
 $\exists \text{hasHarm}.\top \sqsubseteq \textit{Risk}$



# The RISKMAN Ontology: Encoding Rules (2)

According to ISO 14971 [3.18]:

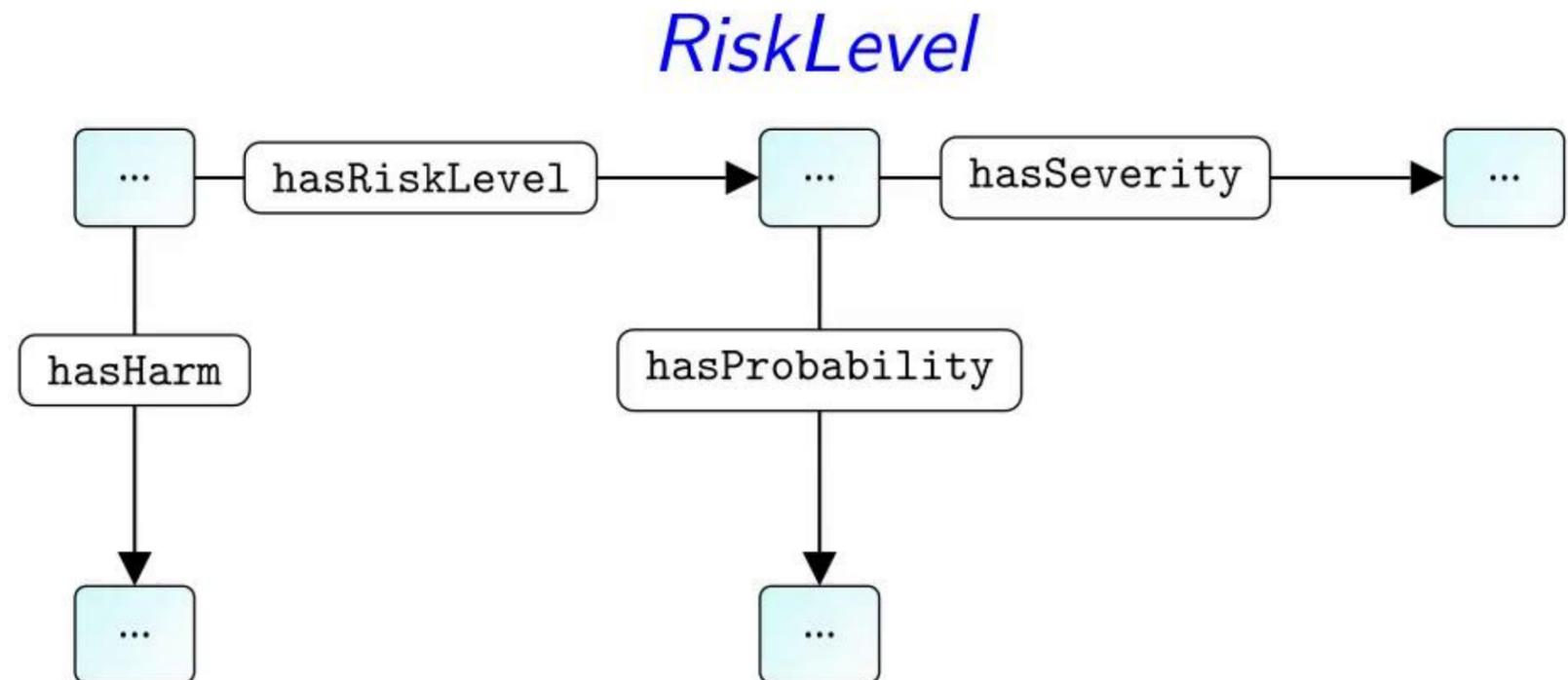
**risk**

Combination of probability of occurrence of harm and severity.

Ontology (TBox)

Data (ABox)

$\exists \text{hasRiskLevel}.\top \sqcap$   
 $\exists \text{hasHarm}.\top \sqsubseteq \textit{Risk}$



# The RISKMAN Ontology: Encoding Rules (2)

According to ISO 14971 [3.18]:

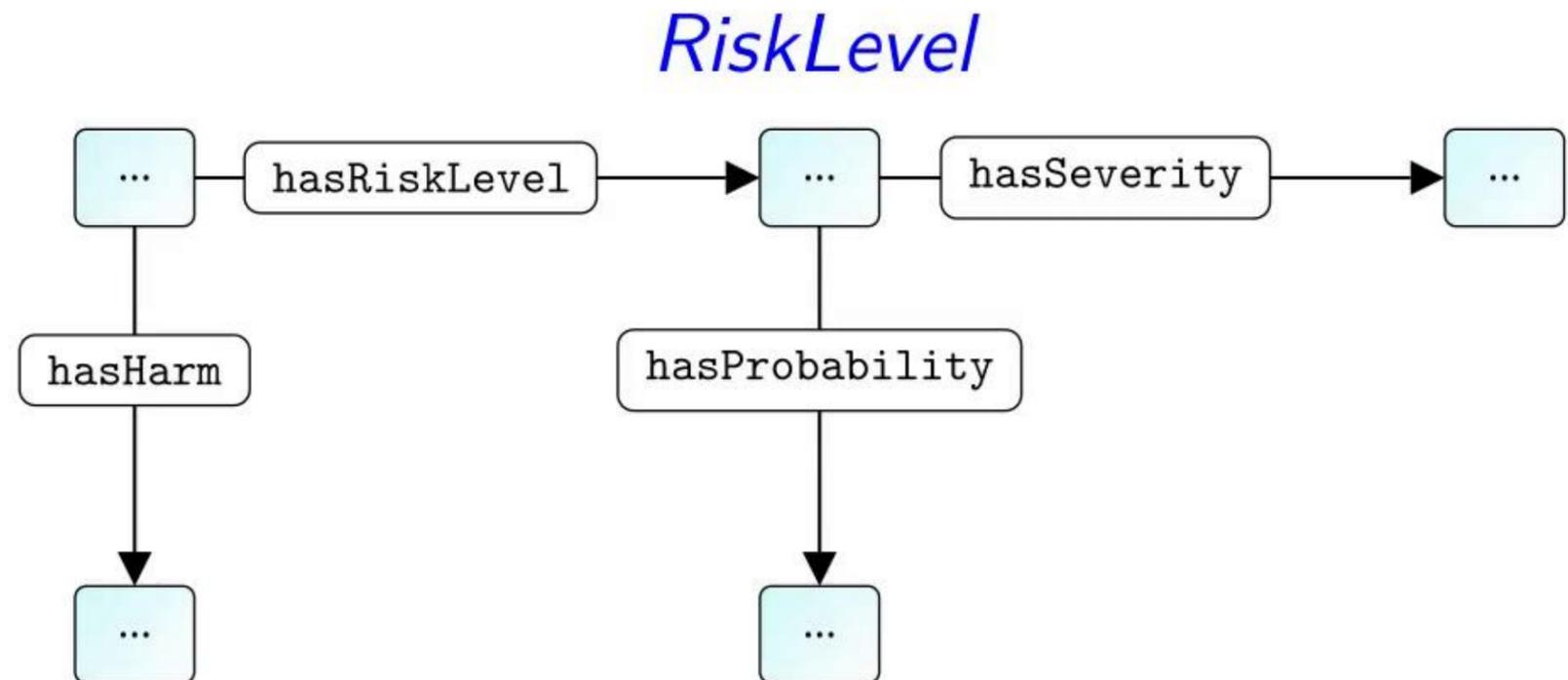
**risk**

Combination of probability of occurrence of harm and severity.

Ontology (TBox)

Data (ABox)

$\exists \text{hasRiskLevel.} \top \sqcap$   
 $\exists \text{hasHarm.} \top \sqsubseteq \textit{Risk}$



# The RISKMAN Ontology: Encoding Rules (2)

According to ISO 14971 [3.18]:

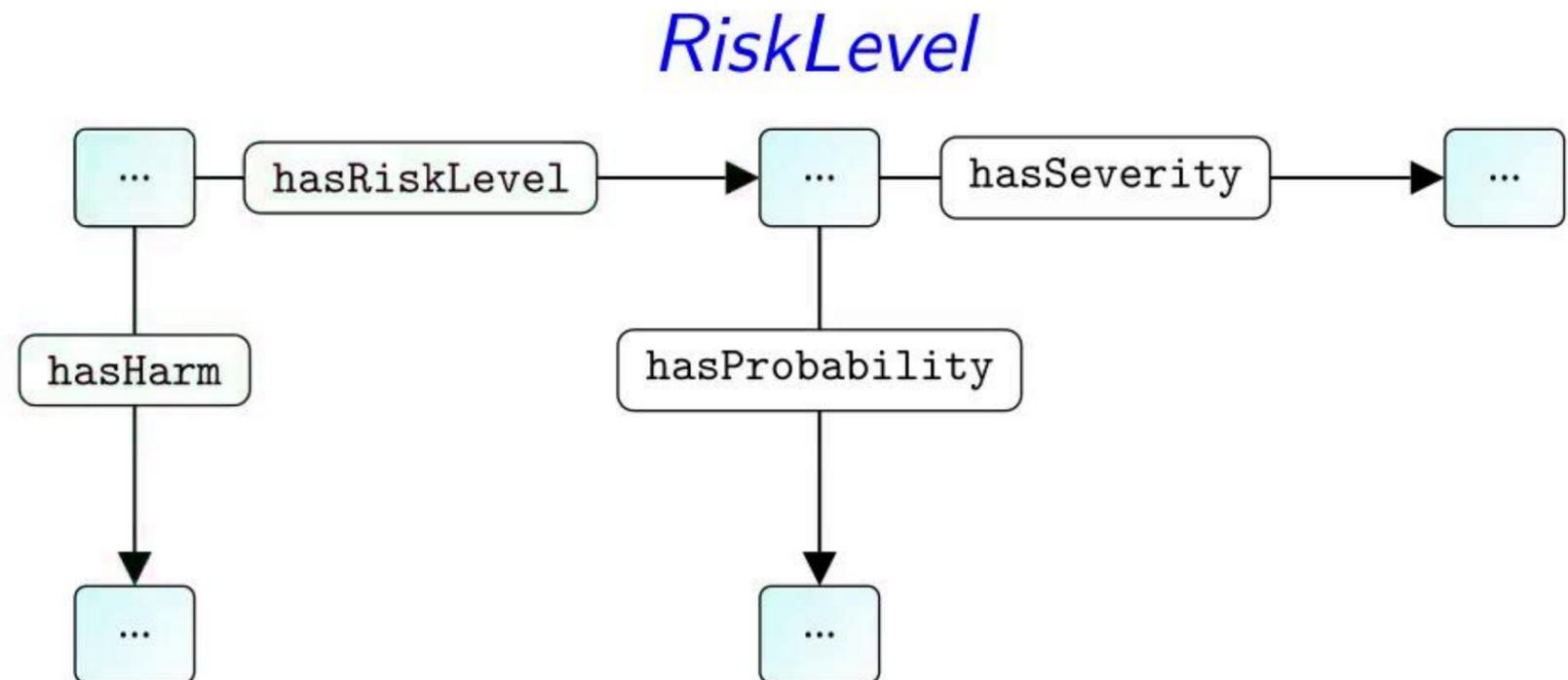
**risk**

Combination of probability of occurrence of harm and severity.

Ontology (TBox)

Data (ABox)

$\exists \text{hasRiskLevel}.\top \sqcap$   
 $\exists \text{hasHarm}.\top \sqsubseteq \textit{Risk}$



# The RISKMAN Ontology: Encoding Rules (2)

According to ISO 14971 [3.18]:

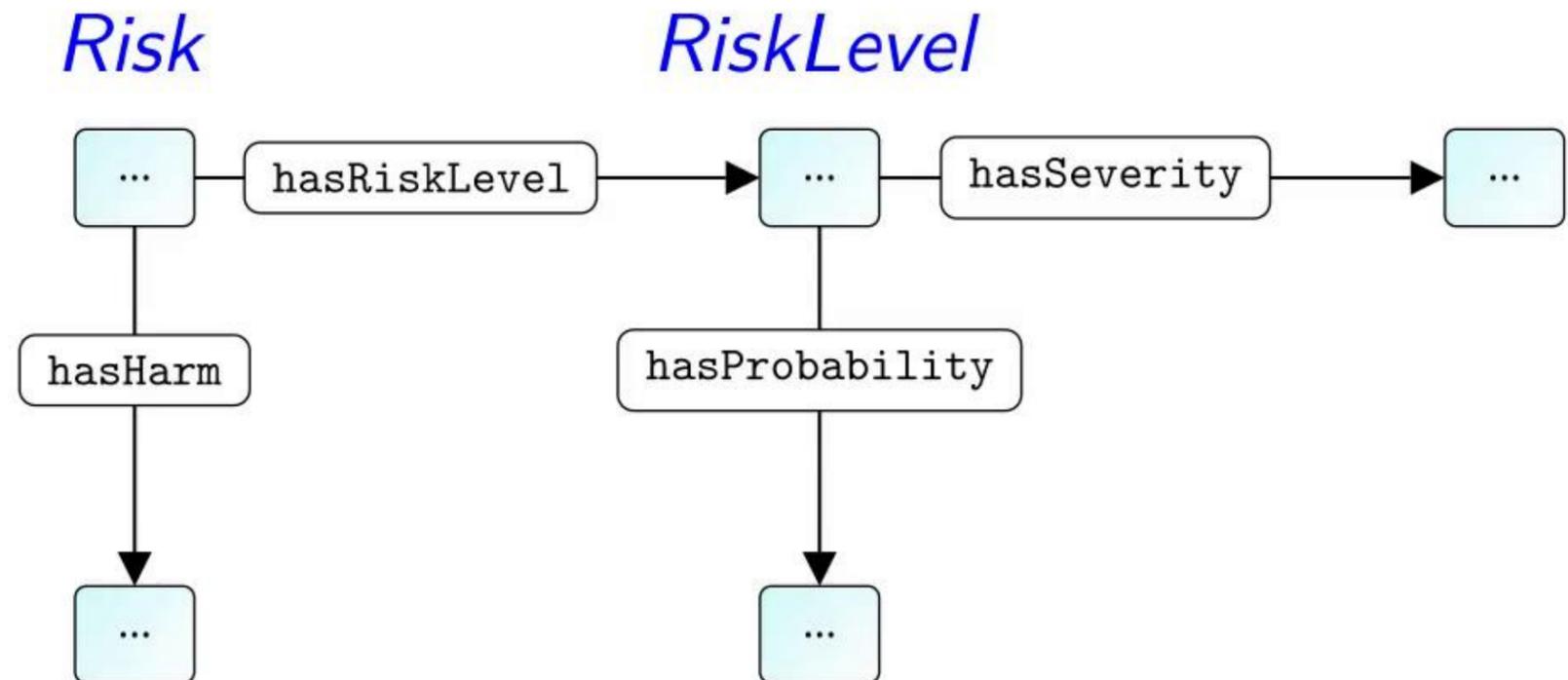
**risk**

Combination of probability of occurrence of harm and severity.

Ontology (TBox)

Data (ABox)

$\exists \text{hasRiskLevel}.\top \sqcap$   
 $\exists \text{hasHarm}.\top \sqsubseteq \textit{Risk}$



# The RISKMAN Ontology: Encoding Rules (3)

According to ISO 14971:

$P_1$  – probability of a hazardous situation occurring

$P_2$  – probability that the hazardous situation leads to harm

$P = P_1 \times P_2$  – overall probability of harm

# The RISKMAN Ontology: Encoding Rules (3)

According to ISO 14971:

$P_1$  – probability of a hazardous situation occurring

$P_2$  – probability that the hazardous situation leads to harm

$P = P_1 \times P_2$  – overall probability of harm

Ontology (TBox)

Data (ABox)

---

# The RISKMAN Ontology: Encoding Rules (3)

According to ISO 14971:

$P_1$  – probability of a hazardous situation occurring

$P_2$  – probability that the hazardous situation leads to harm

$P = P_1 \times P_2$  – overall probability of harm

Ontology (TBox)

Data (ABox)

---

$\exists \text{hasProbability1.}\{V\} \sqcap$

$\exists \text{hasProbability.}\{IV\} \sqsubseteq$

$\exists \text{hasProbability.}\{III\}$

# The RISKMAN Ontology: Encoding Rules (3)

According to ISO 14971:

$P_1$  – probability of a hazardous situation occurring

$P_2$  – probability that the hazardous situation leads to harm

$P = P_1 \times P_2$  – overall probability of harm

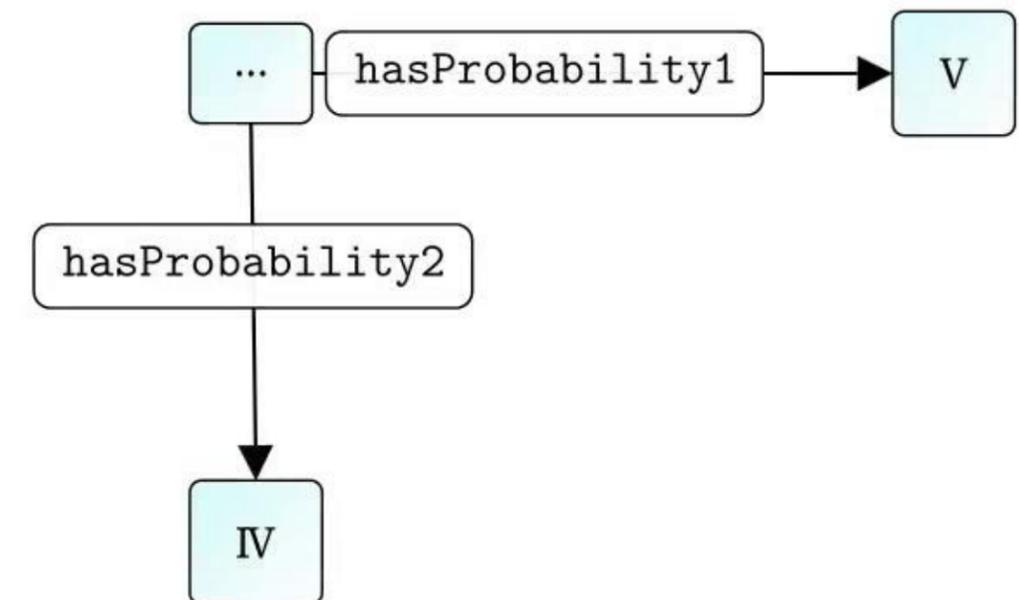
Ontology (TBox)

$\exists \text{hasProbability1}.\{V\} \sqcap$

$\exists \text{hasProbability}.\{IV\} \sqsubseteq$

$\exists \text{hasProbability}.\{III\}$

Data (ABox)



# The RISKMAN Ontology: Encoding Rules (3)

According to ISO 14971:

$P_1$  – probability of a hazardous situation occurring

$P_2$  – probability that the hazardous situation leads to harm

$P = P_1 \times P_2$  – overall probability of harm

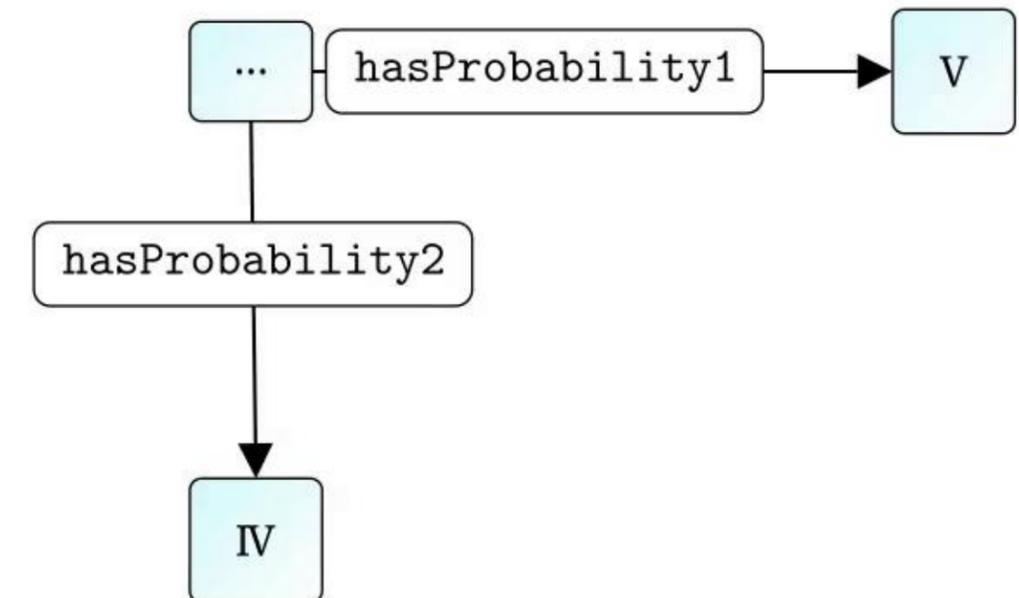
Ontology (TBox)

$\exists \text{hasProbability1}.\{V\} \sqcap$

$\exists \text{hasProbability}.\{IV\} \sqsubseteq$

$\exists \text{hasProbability}.\{III\}$

Data (ABox)



# The RISKMAN Ontology: Encoding Rules (3)

According to ISO 14971:

$P_1$  – probability of a hazardous situation occurring

$P_2$  – probability that the hazardous situation leads to harm

$P = P_1 \times P_2$  – overall probability of harm

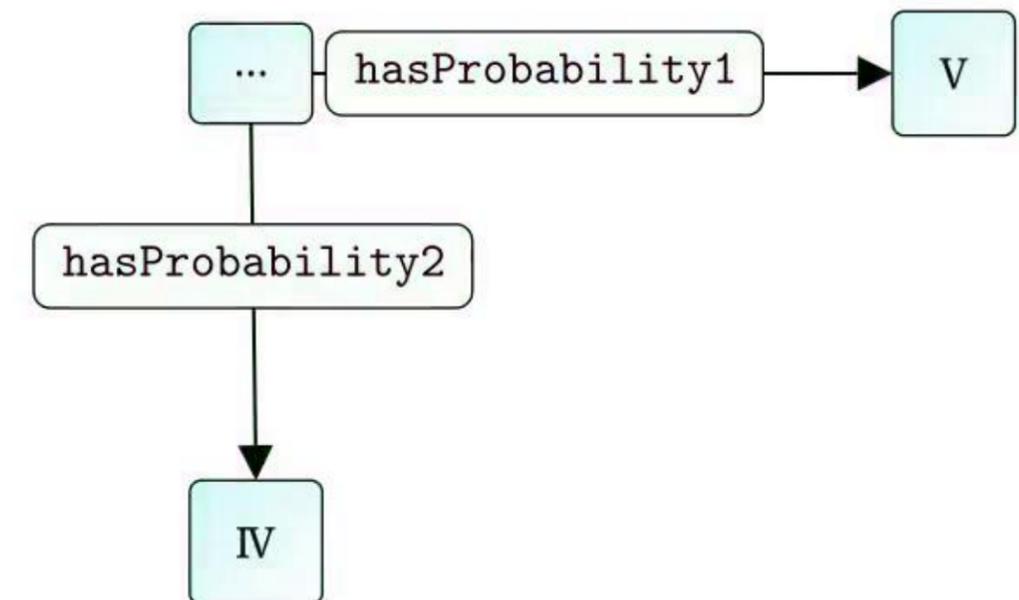
Ontology (TBox)

$\exists \text{hasProbability1}.\{V\} \sqcap$

$\exists \text{hasProbability}.\{IV\} \sqsubseteq$

$\exists \text{hasProbability}.\{III\}$

Data (ABox)



# The RISKMAN Ontology: Encoding Rules (3)

According to ISO 14971:

$P_1$  – probability of a hazardous situation occurring

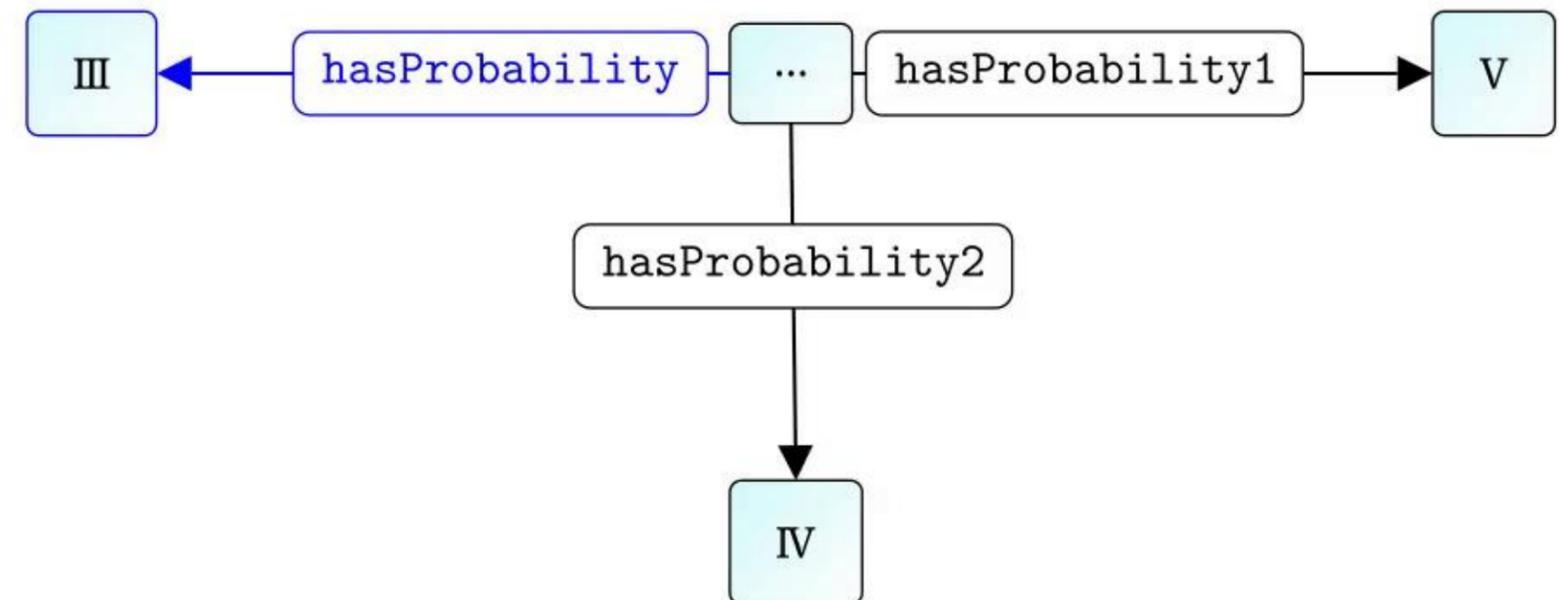
$P_2$  – probability that the hazardous situation leads to harm

$P = P_1 \times P_2$  – overall probability of harm

Ontology (TBox)

Data (ABox)

$\exists \text{hasProbability1}.\{V\} \sqcap$   
 $\exists \text{hasProbability}.\{IV\} \sqsubseteq$   
 $\exists \text{hasProbability}.\{III\}$

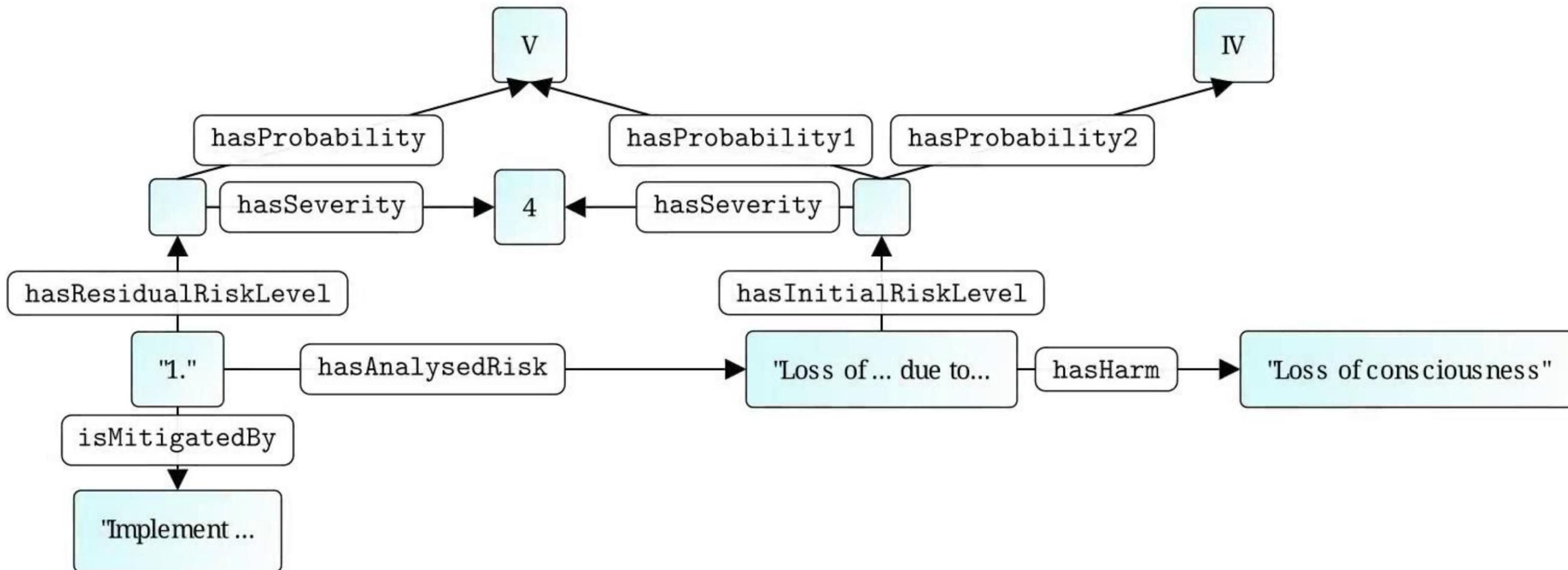


# RISKMAN: Reasoning & Validation

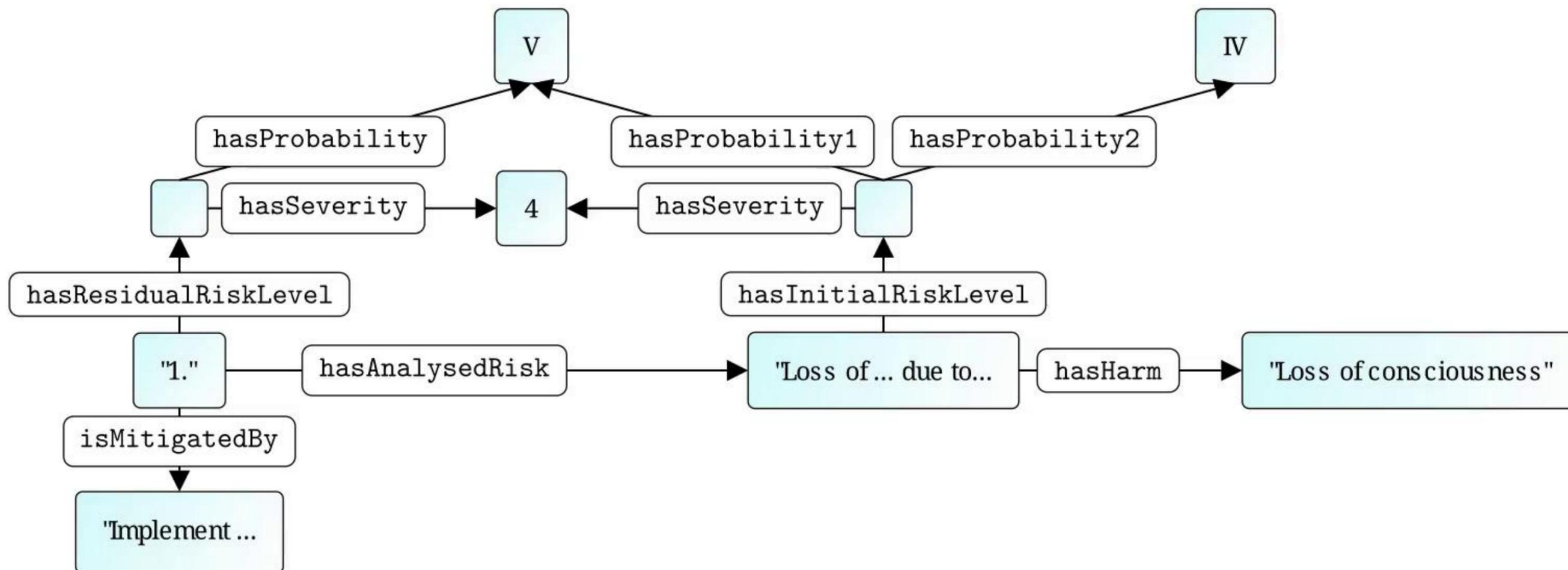
Ctr. risk	Analysed risk	...	Init. P1	...	...	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev	...
1.	Loss of consciousness due to an alarm malfunction	...	V	...	...	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...

# RISKMAN: Reasoning & Validation

Ctr. risk	Analysed risk	...	Init. P1	...	...	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev.	...
1.	Loss of consciousness due to an alarm malfunction	...	V	...	...	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...

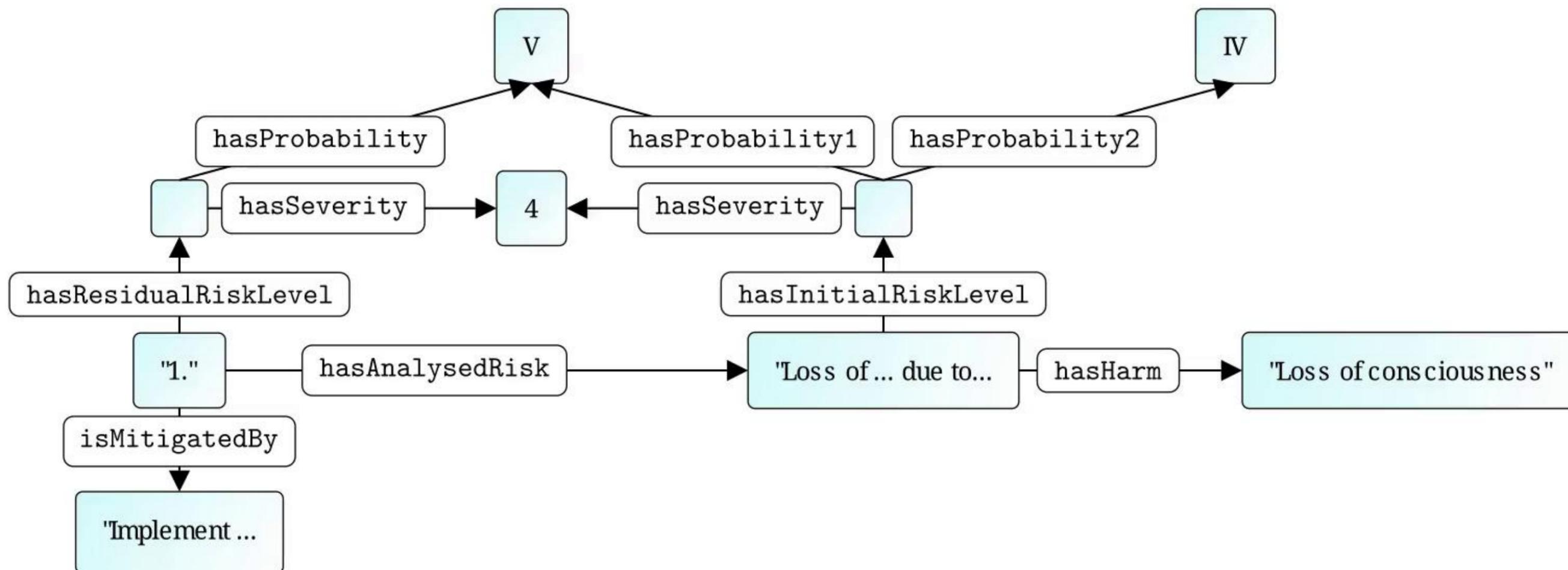


# RISKMAN: Reasoning & Validation



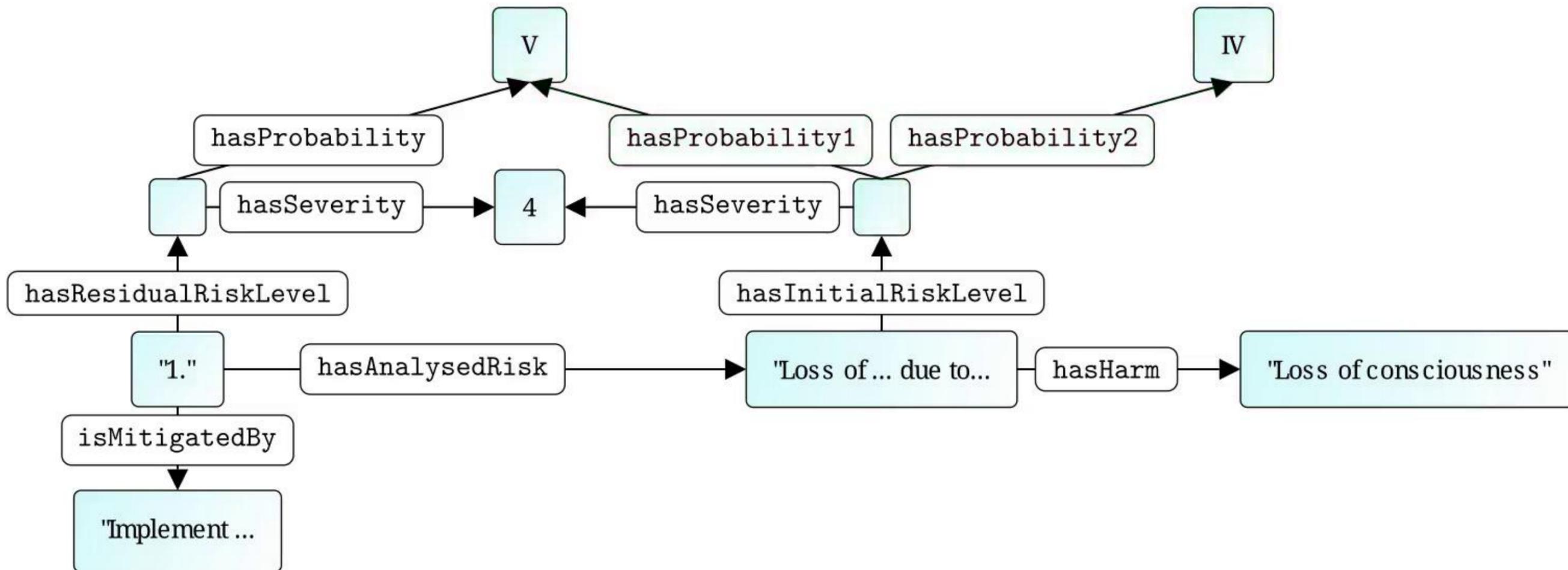
# RISKMAN: Reasoning & Validation

$\exists \text{hasProbability1}.\{V\} \sqcap$   
 $\exists \text{hasProbability}.\{IV\} \sqsubseteq$   
 $\exists \text{hasProbability}.\{III\}$



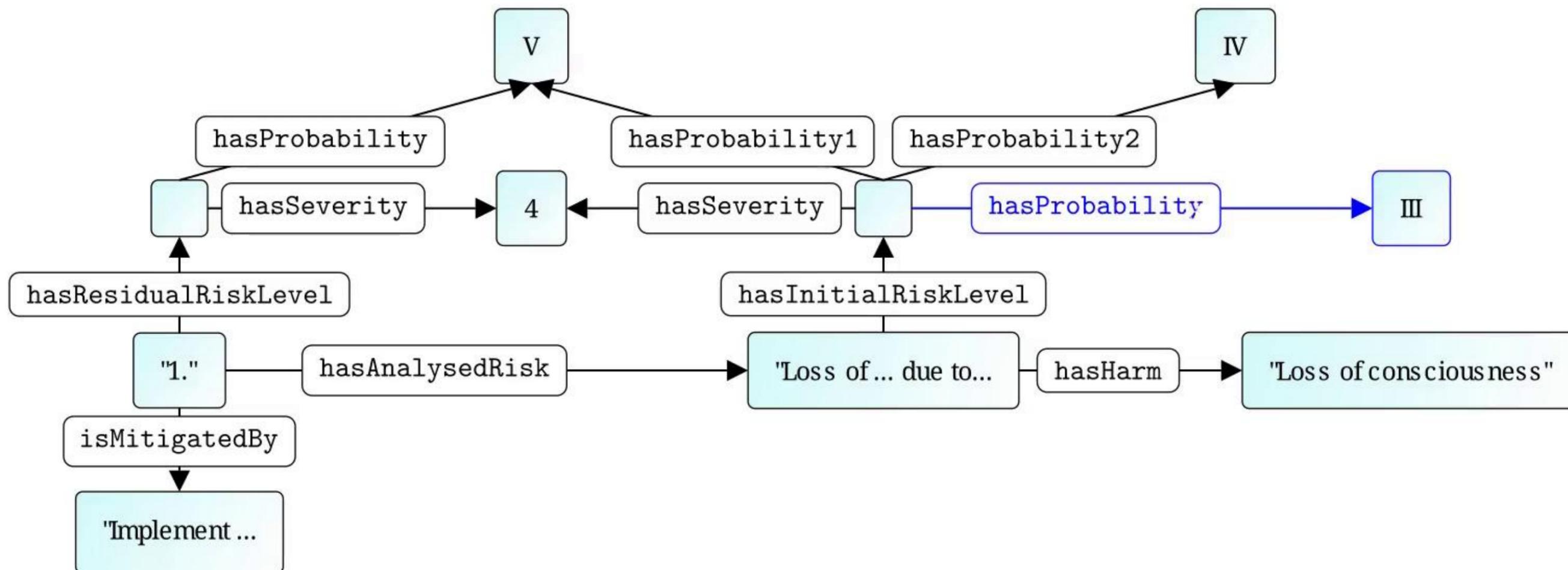
# RISKMAN: Reasoning & Validation

$\exists \text{hasProbability1}.\{V\} \sqcap$   
 $\exists \text{hasProbability}.\{IV\} \sqsubseteq$   
 $\exists \text{hasProbability}.\{III\}$



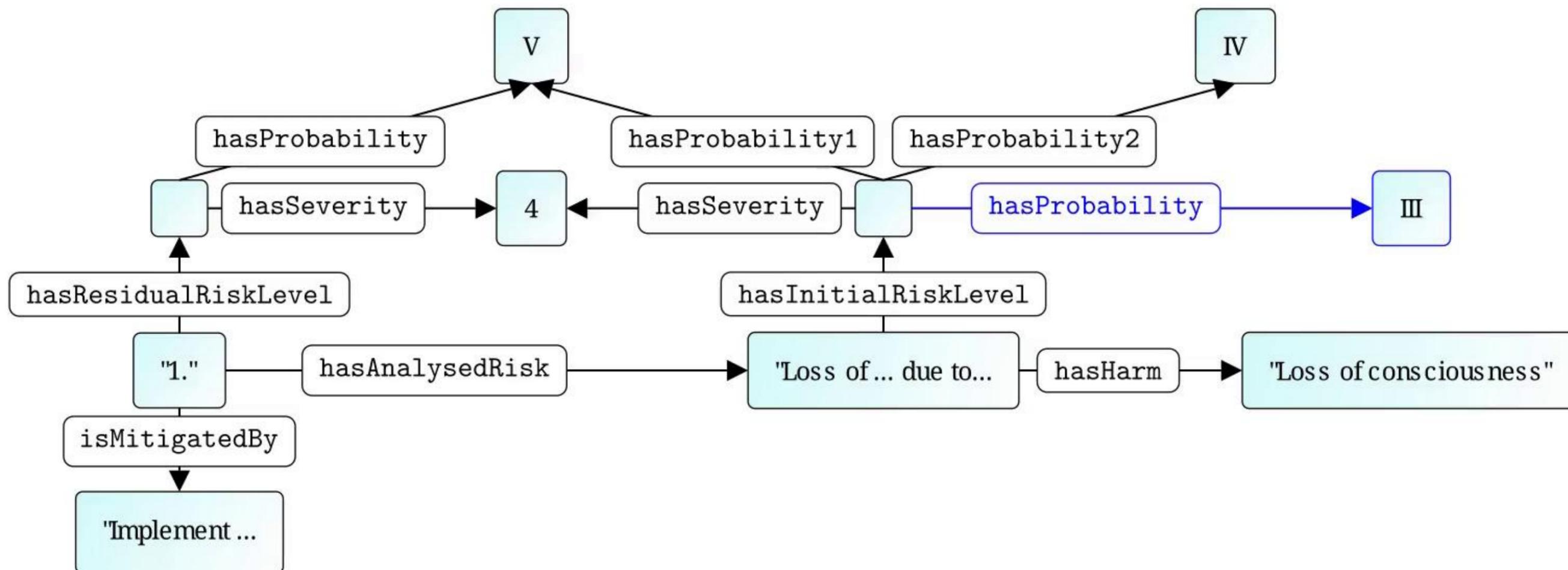
# RISKMAN: Reasoning & Validation

$\exists \text{hasProbability1}.\{V\} \sqcap$   
 $\exists \text{hasProbability}.\{IV\} \sqsubseteq$   
 $\exists \text{hasProbability}.\{III\}$



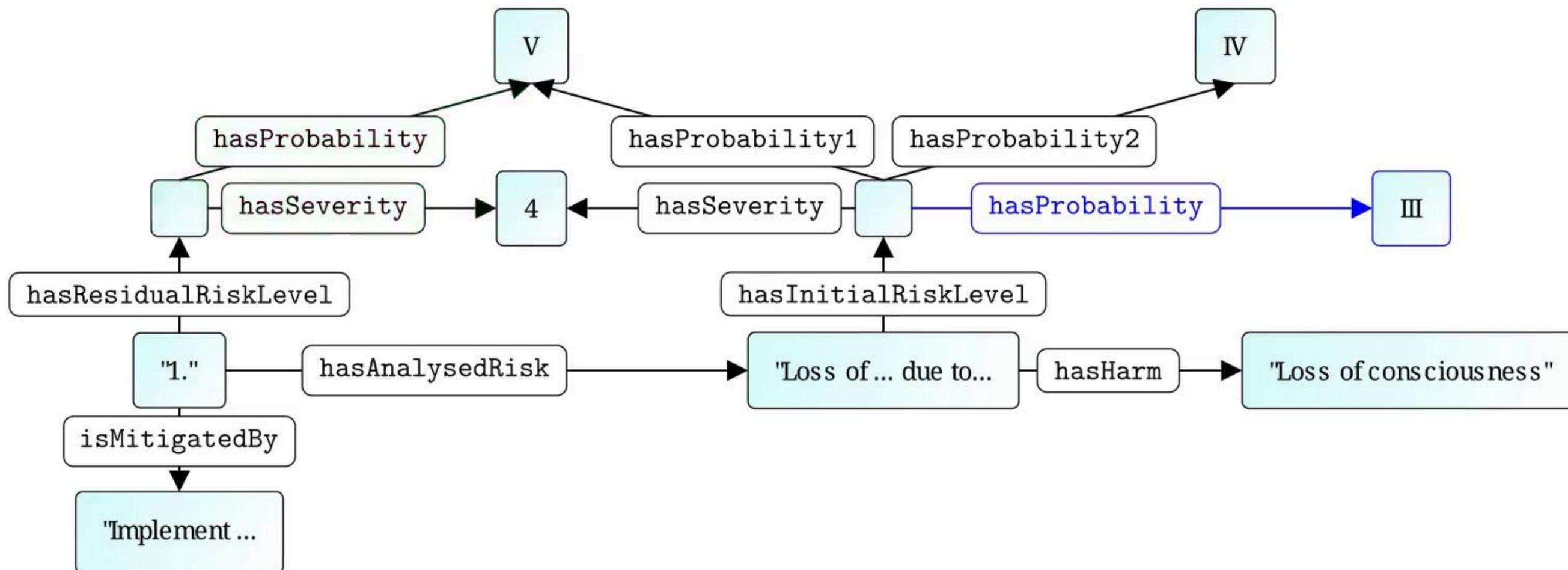
# RISKMAN: Reasoning & Validation

$\exists \text{hasProbability}.\top \sqcap$   
 $\exists \text{hasSeverity}.\top \sqsubseteq \textit{RiskLevel}$



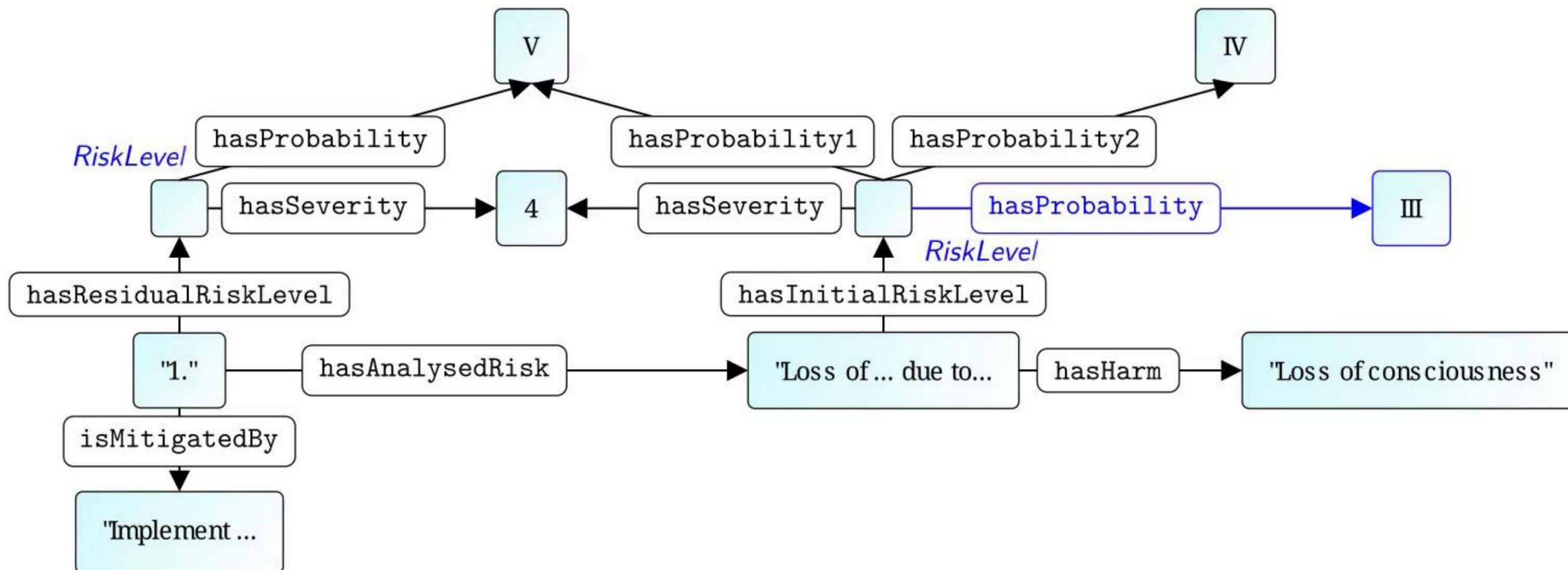
# RISKMAN: Reasoning & Validation

$\exists \text{hasProbability}.\top \sqcap$   
 $\exists \text{hasSeverity}.\top \sqsubseteq \textit{RiskLevel}$



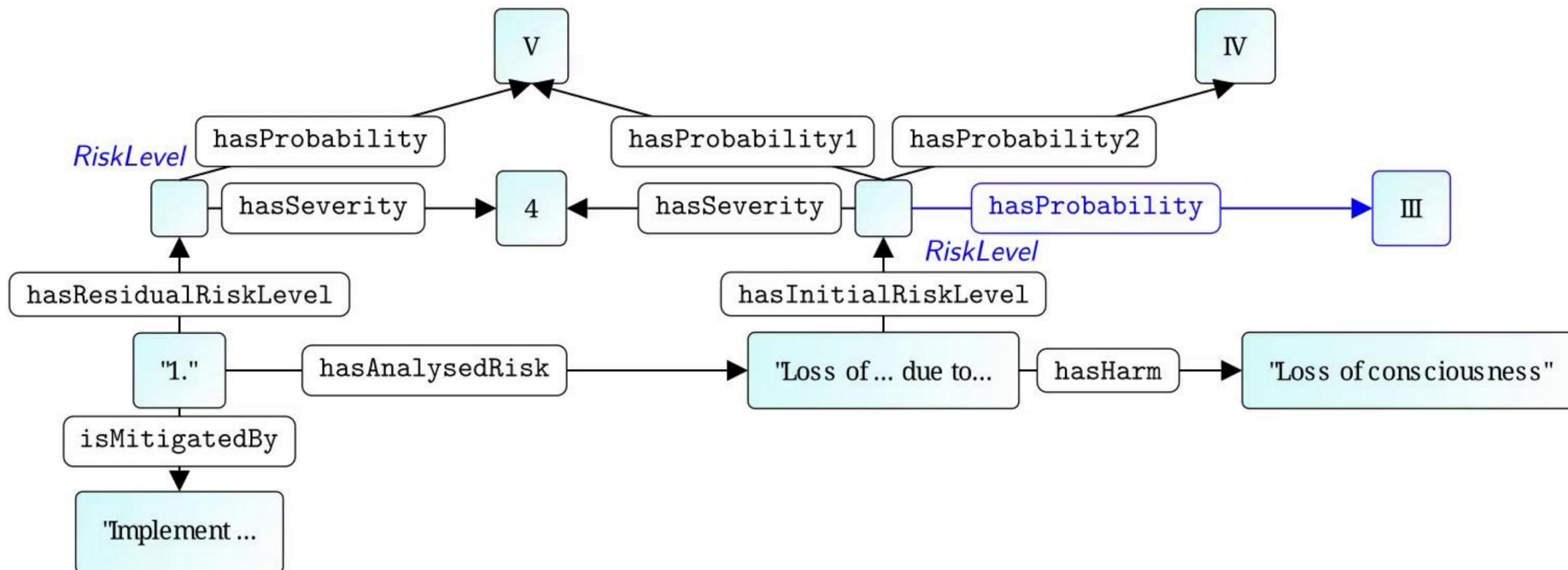
# RISKMAN: Reasoning & Validation

$\exists \text{hasProbability}.\top \sqcap$   
 $\exists \text{hasSeverity}.\top \sqsubseteq \textit{RiskLevel}$



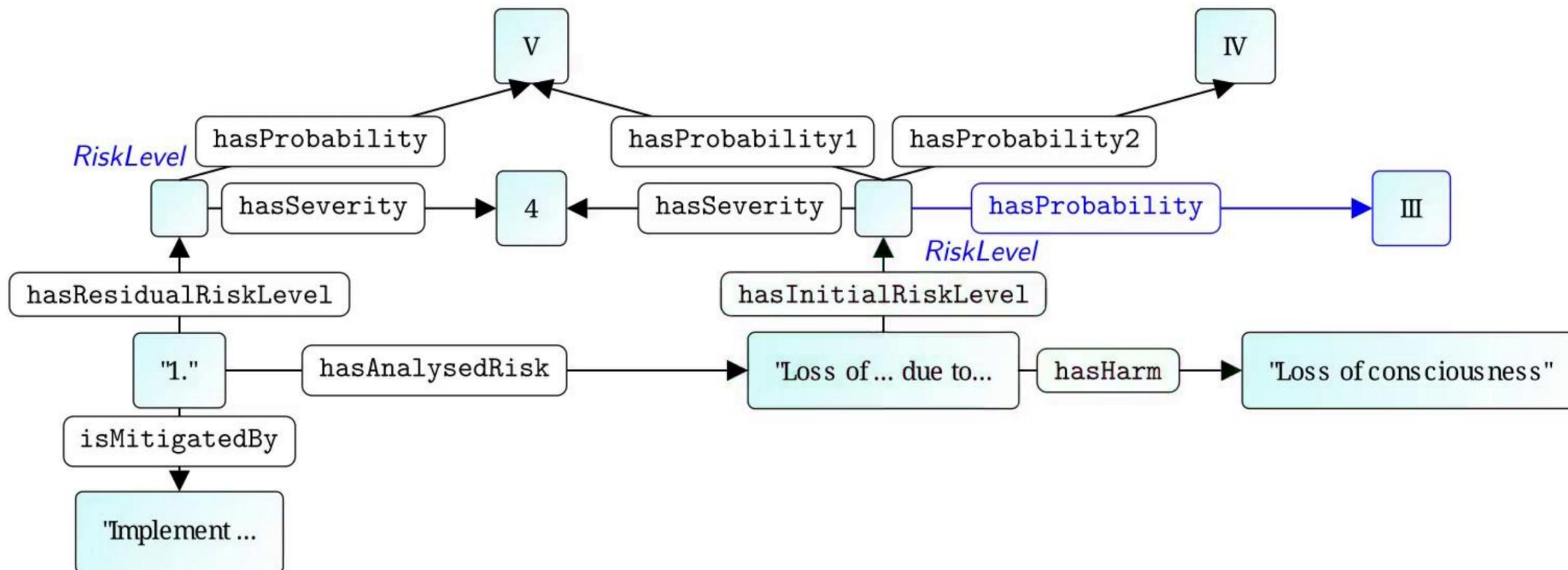
# RISKMAN: Reasoning & Validation

$\exists \text{hasRiskLevel}.\top \sqcap$   
 $\exists \text{hasHarm}.\top \sqsubseteq \textit{Risk}$



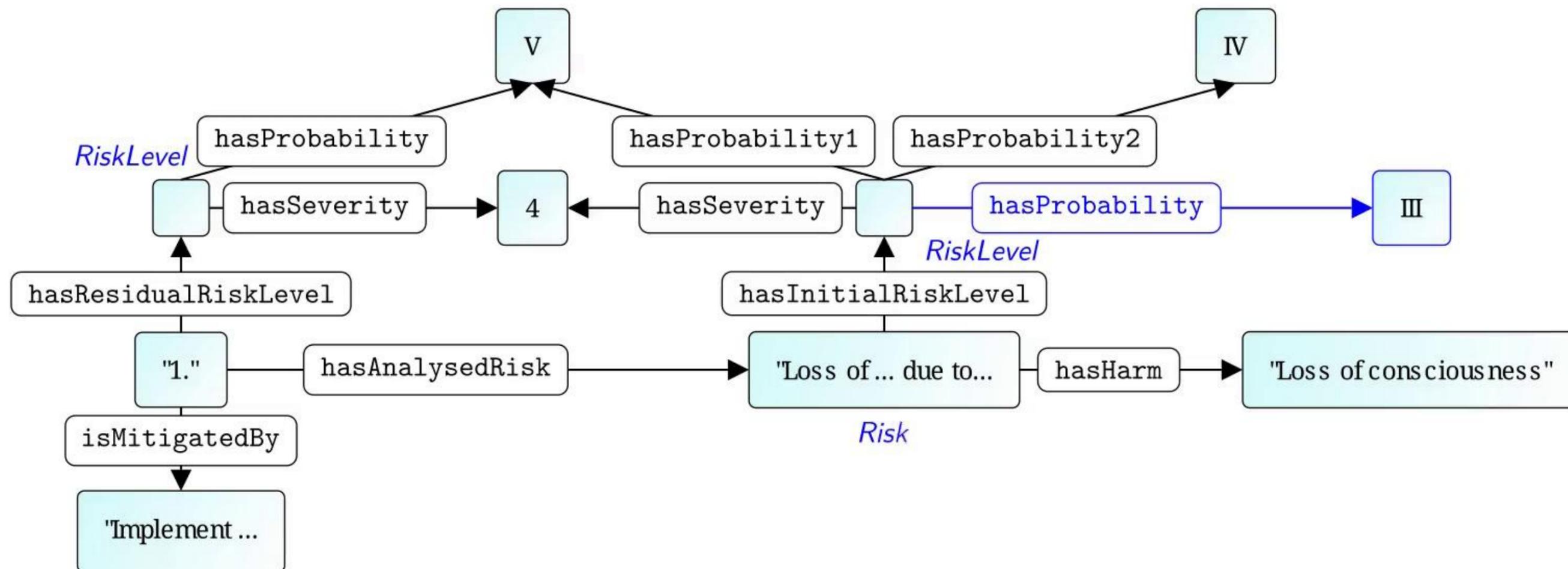
# RISKMAN: Reasoning & Validation

$\exists \text{hasRiskLevel}.\top \sqcap$   
 $\exists \text{hasHarm}.\top \sqsubseteq \textit{Risk}$

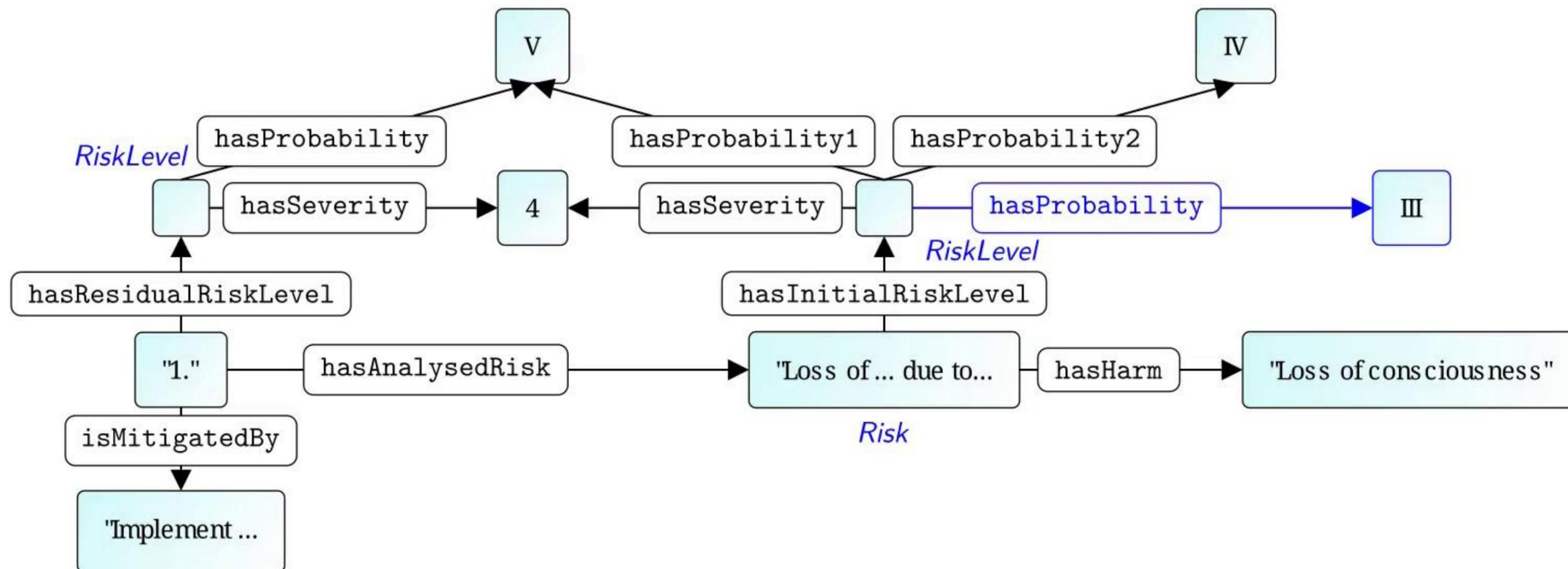


# RISKMAN: Reasoning & Validation

$\exists \text{hasRiskLevel}.\top \sqcap$   
 $\exists \text{hasHarm}.\top \sqsubseteq \textit{Risk}$



# RISKMAN: Reasoning & Validation

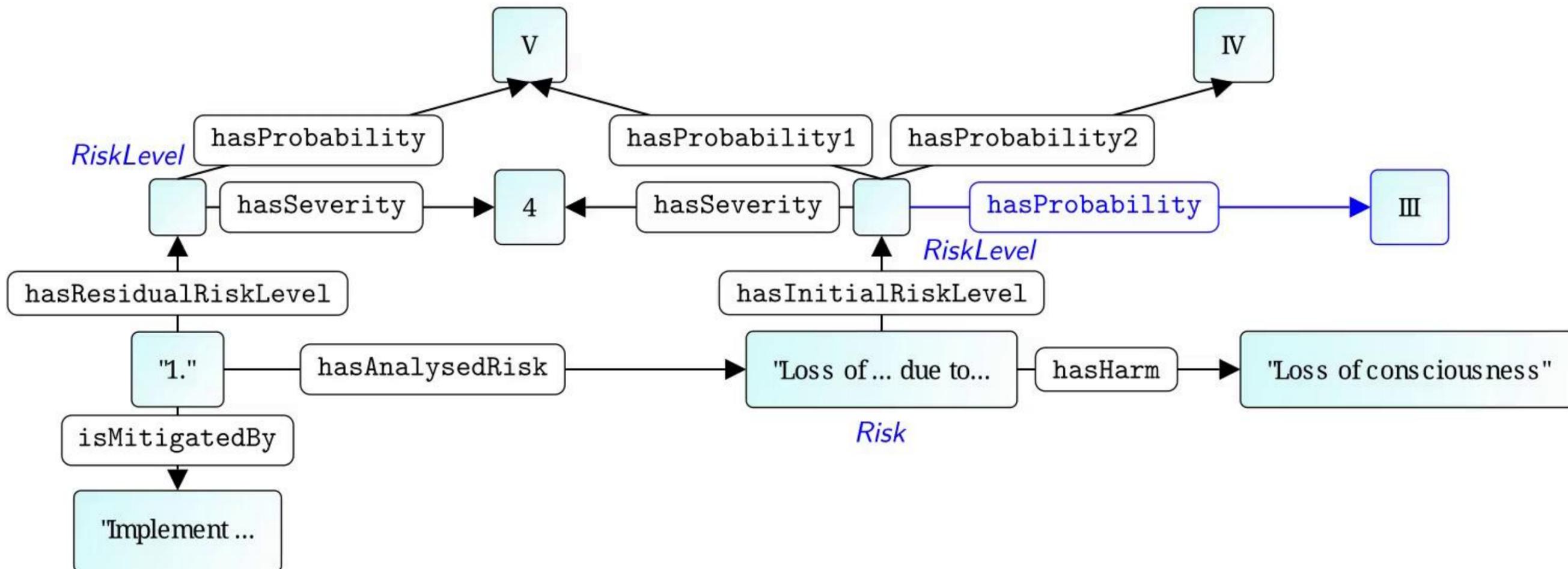


# RISKMAN: Reasoning & Validation

SHACL

$\text{Risk} \Rightarrow \exists \text{hasInitialRiskLevel} \cdot \text{hasProbability} \cdot \text{gt}^- \cdot \text{hasProbability}^- \neq \cdot \text{hasAnalysedRisk}^- \cdot \text{hasResidualRiskLevel}$

*"Residual probability should not be higher than initial probability."*

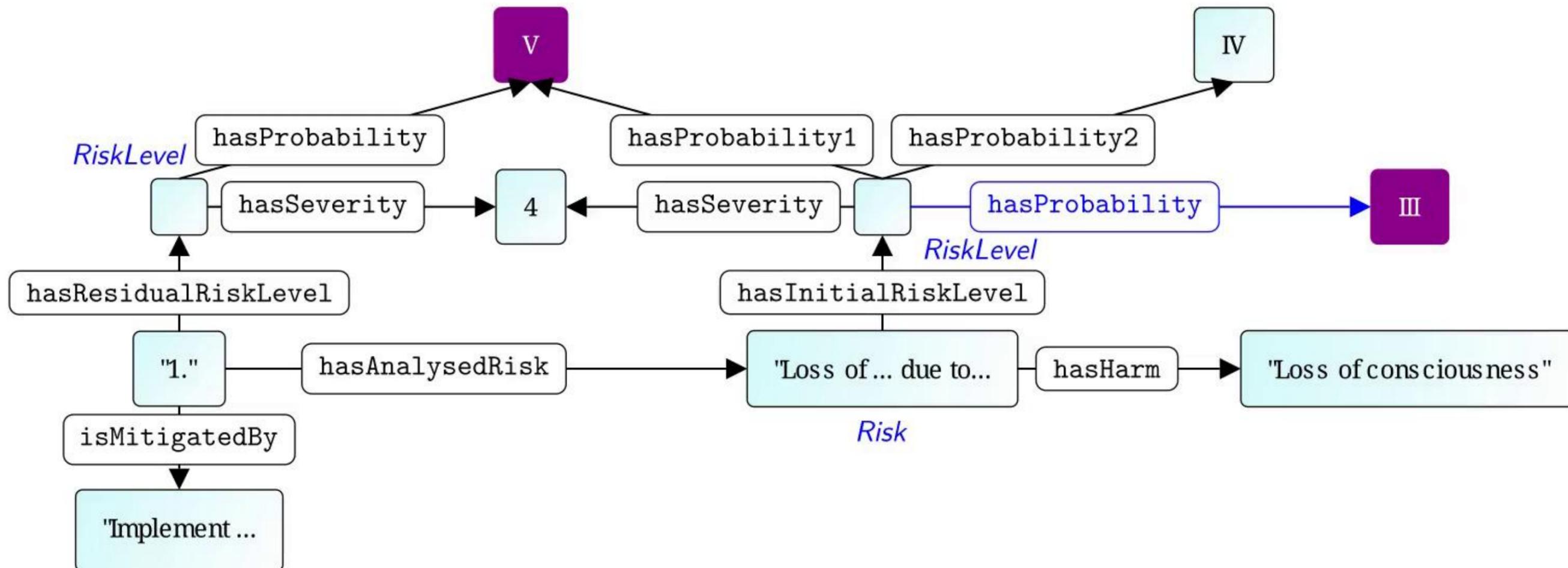


# RISKMAN: Reasoning & Validation

SHACL

$\text{Risk} \Rightarrow \exists \text{hasInitialRiskLevel} \cdot \text{hasProbability} \cdot \text{gt}^- \cdot \text{hasProbability}^- \neq \cdot \text{hasAnalysedRisk}^- \cdot \text{hasResidualRiskLevel}$

*"Residual probability should not be higher than initial probability."*



# RISKMAN: SHACL Shapes

# RISKMAN: SHACL Shapes

ControlledRisk  $\Rightarrow$   $=_1$  isMitigatedBy.T

*"Every controlled risk must be mitigated."*

# RISKMAN: SHACL Shapes

$\text{ControlledRisk} \Rightarrow =_1 \text{isMitigatedBy.T}$

*"Every controlled risk must be mitigated."*

$\text{SDA} \Rightarrow \exists \text{hasSubSDA} \cdot \text{hasImplementationManifest.T}$

*"Every SDA needs a final mitigation (which has the implementation manifest)."*

# RISKMAN: SHACL Shapes

ControlledRisk  $\Rightarrow =_1$  isMitigatedBy. $\top$   
*"Every controlled risk must be mitigated."*

SDA  $\Rightarrow \exists$ hasSubSDA · hasImplementationManifest. $\top$   
*"Every SDA needs a final mitigation (which has the implementation manifest)."*

...

# The RISKMAN Ontology & Shapes: Overview

- formulated in the lightweight OWL EL



# The RISKMAN Ontology & Shapes: Overview

- formulated in the lightweight OWL EL
- 24 classes



# The RISKMAN Ontology & Shapes: Overview

- formulated in the lightweight OWL EL
- 24 classes
- 27 object properties (each with domain and range)



# The RISKMAN Ontology & Shapes: Overview

- formulated in the lightweight OWL EL
- 24 classes
- 27 object properties (each with domain and range)
- 15 concept and role inclusion axioms



# The RISKMAN Ontology & Shapes: Overview

- formulated in the lightweight OWL EL
- 24 classes
- 27 object properties (each with domain and range)
- 15 concept and role inclusion axioms
- 10 SHACL shapes



# The RISKMAN Ontology & Shapes: Overview

- formulated in the lightweight OWL EL
- 24 classes
- 27 object properties (each with domain and range)
- 15 concept and role inclusion axioms
- 10 SHACL shapes
- registered under stable URI <https://w3id.org/riskman>



# The RISKMAN Ontology & Shapes: Overview

- formulated in the lightweight OWL EL
- 24 classes
- 27 object properties (each with domain and range)
- 15 concept and role inclusion axioms
- 10 SHACL shapes
- registered under stable URI <https://w3id.org/riskman>

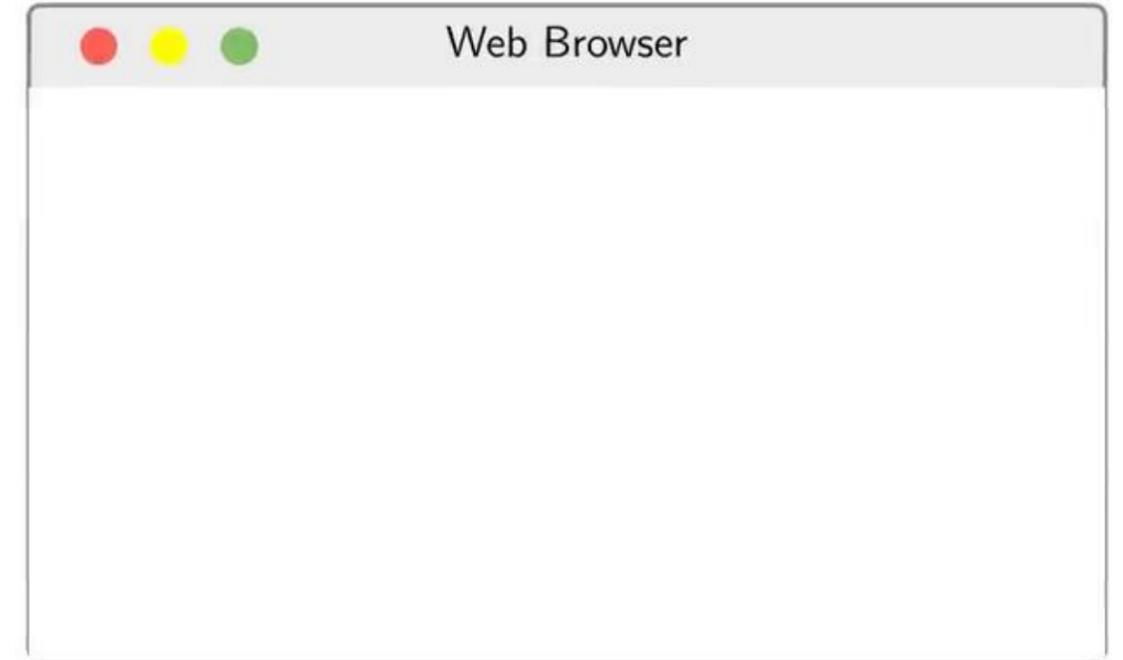


# The RISKMAN Ontology: Human Readability

```
1 <tr>
2   <td>
3     1.
4   </td>
5 <tr>
6   <td>
7     Loss of consciousness...
8   </td>
9   ...
10 </tr>
```

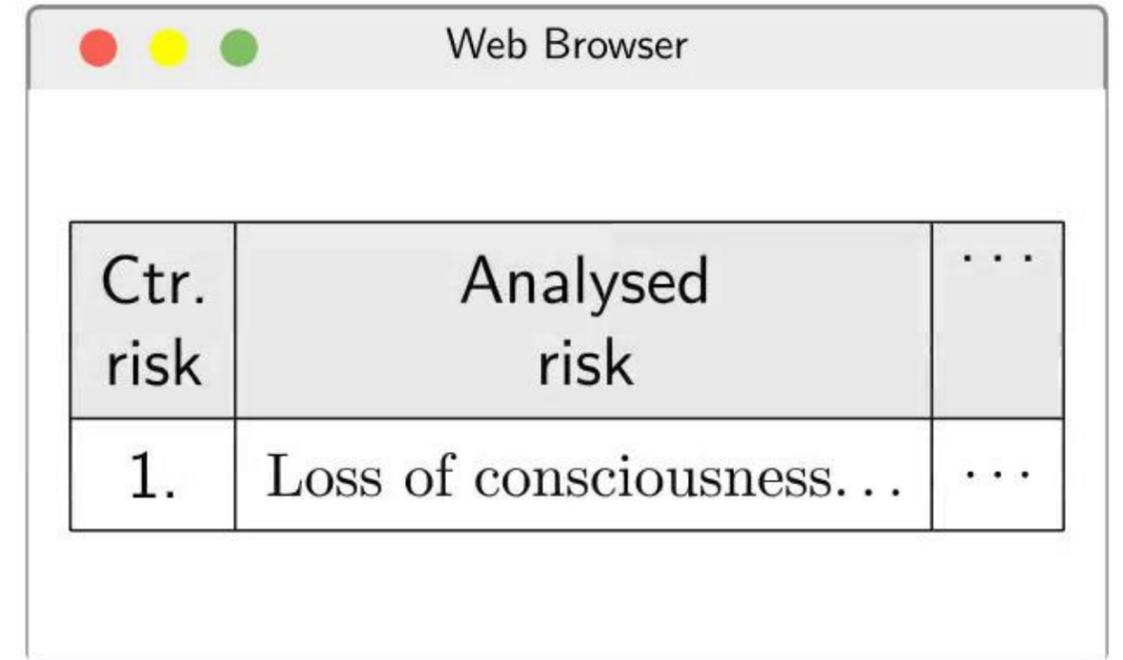
# The RISKMAN Ontology: Human Readability

```
1 <tr>
2   <td>
3     1.
4   </td>
5 <tr>
6   <td>
7     Loss of consciousness...
8   </td>
9   ...
10 </tr>
```



# The RISKMAN Ontology: Human Readability

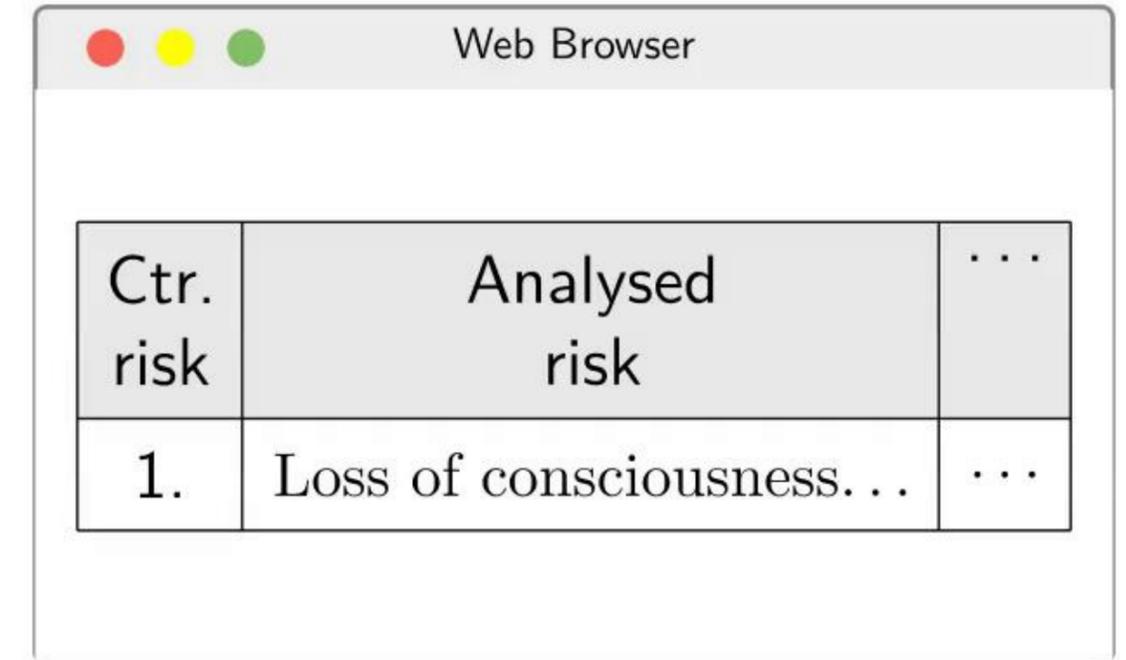
```
1 <tr>
2   <td>
3     1.
4   </td>
5 <tr>
6   <td>
7     Loss of consciousness...
8   </td>
9   ...
10 </tr>
```



Ctr. risk	Analysed risk	...
1.	Loss of consciousness...	...

# The RISKMAN Ontology: Human Readability

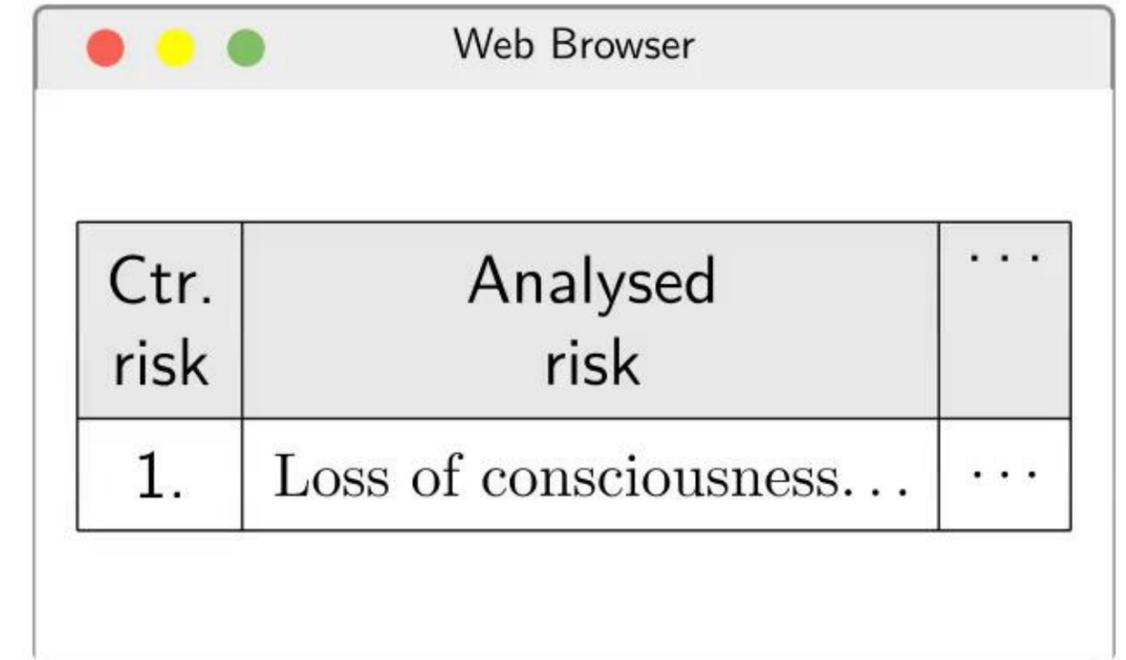
```
1 <tr prefix="">
2   <td resource="cr1">
3     1.
4     <link property="riskman:hasAnalysedRisk" href="ar1"/>
5   </td>
6   <td resource="ar1">
7     <span property="rdfs:comment">
8       Loss of consiousness...</span>
9     </span>
10  </td>
11  ...
12 </tr>
```



Ctr. risk	Analysed risk	...
1.	Loss of consciousness...	...

# The RISKMAN Ontology: Human Readability

```
1 <tr prefix="">
2   <td resource="cr1">
3     1.
4     <link property="riskman:hasAnalysedRisk" href="ar1"/>
5   </td>
6   <td resource="ar1">
7     <span property="rdfs:comment">
8       Loss of consiousness...</span>
9     </span>
10  </td>
11  ...
12 </tr>
```



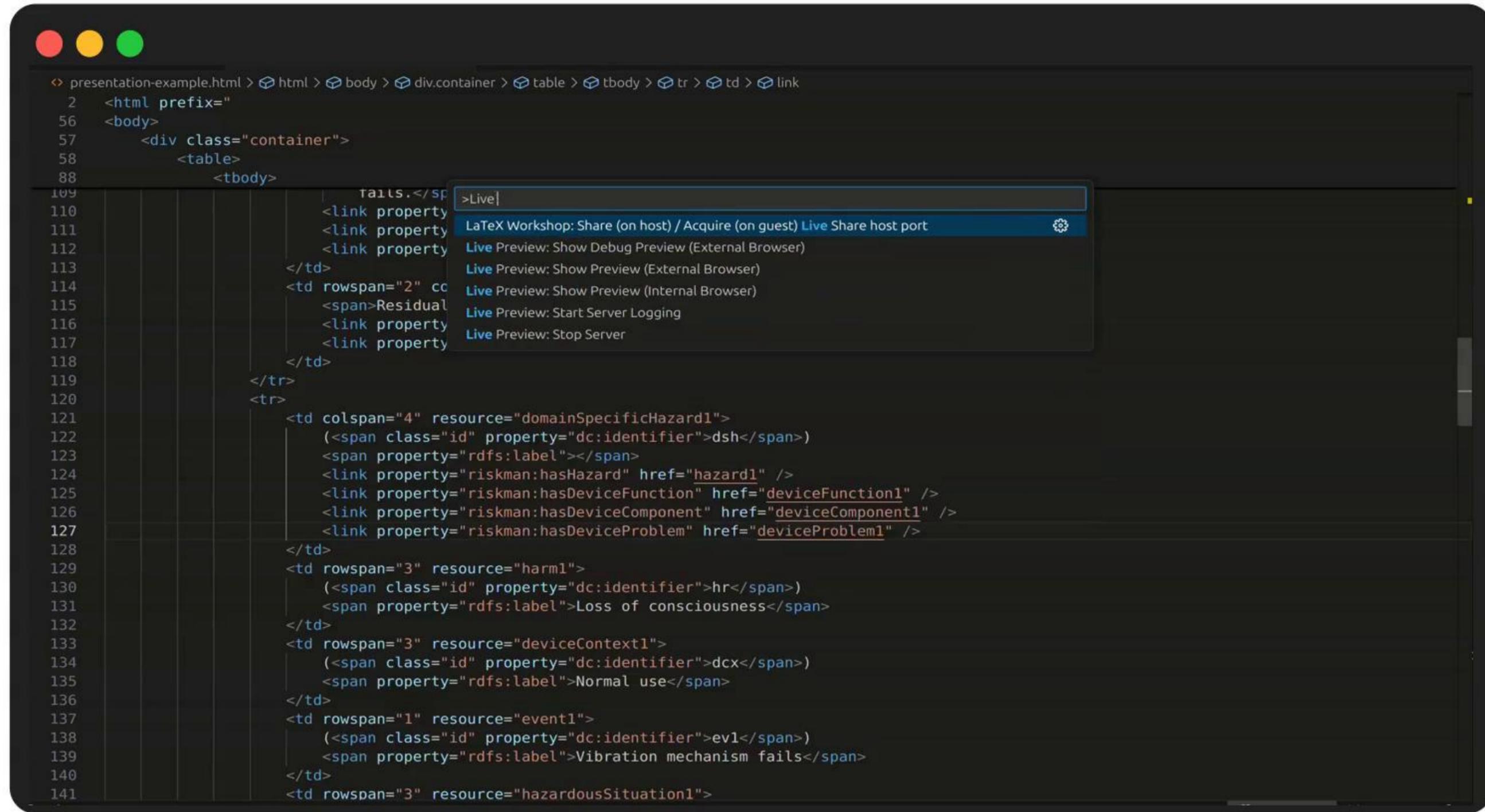
Ctr. risk	Analysed risk	...
1.	Loss of consciousness...	...

```
1 @prefix : <https://w3id.org/riskman/ontology> .
2 @prefix rdfs: <http://www.w3.org/2000/01/rdf-schema#> .
3
4 :cr1 :hasAnalysedRisk [
5     rdfs:comment "Loss of consciousness..."
6 ] ;
7 ...
8 .
```

# The RISKMAN Workflow: Demo

```
presentation-example.html > html > body > div.container > table > tbody > tr > td > link
  2  <html prefix="
 56  <body>
 57    <div class="container">
 58      <table>
 88        <tbody>
109          <td colspan="4" resource="failure1">
110            <span>Failure 1</span>
111            <link property="riskman:hasSubSDA" href="sda1" />
112            <link property="riskman:hasSubSDA" href="sda2" />
113            <link property="riskman:hasSubSDA" href="sda3" />
114          </td>
115          <td rowspan="2" colspan="3" resource="residualRiskLevel1">
116            <span>Residual Risk Level 1</span>
117            <link property="riskman:hasProbability" resource="rlevel:p5" />
118            <link property="riskman:hasSeverity" resource="rlevel:s4" />
119          </td>
120        </tr>
121        <tr>
122          <td colspan="4" resource="domainSpecificHazard1">
123            (<span class="id" property="dc:identifier">dsh</span>)
124            <span property="rdfs:label"></span>
125            <link property="riskman:hasHazard" href="hazard1" />
126            <link property="riskman:hasDeviceFunction" href="deviceFunction1" />
127            <link property="riskman:hasDeviceComponent" href="deviceComponent1" />
128            <link property="riskman:hasDeviceProblem" href="deviceProblem1" />
129          </td>
130          <td rowspan="3" resource="harm1">
131            (<span class="id" property="dc:identifier">hr</span>)
132            <span property="rdfs:label">Loss of consciousness</span>
133          </td>
134          <td rowspan="3" resource="deviceContext1">
135            (<span class="id" property="dc:identifier">dcx</span>)
136            <span property="rdfs:label">Normal use</span>
137          </td>
138          <td rowspan="1" resource="event1">
139            (<span class="id" property="dc:identifier">ev1</span>)
140            <span property="rdfs:label">Vibration mechanism fails</span>
141          </td>
142        </tr>
143        <tr>
144          <td colspan="4" resource="hazardousSituation1">
145            (<span class="id" property="dc:identifier">hs1</span>)
146            <span property="rdfs:label">Vibration mechanism fails</span>
147            <link property="riskman:hasDeviceProblem" href="deviceProblem1" />
148          </td>
149          <td rowspan="2" resource="harm1">
150            (<span class="id" property="dc:identifier">hr</span>)
151            <span property="rdfs:label">Loss of consciousness</span>
152          </td>
153          <td rowspan="2" resource="deviceContext1">
154            (<span class="id" property="dc:identifier">dcx</span>)
155            <span property="rdfs:label">Normal use</span>
156          </td>
157          <td rowspan="1" resource="event1">
158            (<span class="id" property="dc:identifier">ev1</span>)
159            <span property="rdfs:label">Vibration mechanism fails</span>
160          </td>
161        </tr>
162        <tr>
163          <td colspan="4" resource="hazardousSituation1">
164            (<span class="id" property="dc:identifier">hs1</span>)
165            <span property="rdfs:label">Vibration mechanism fails</span>
166            <link property="riskman:hasDeviceProblem" href="deviceProblem1" />
167          </td>
168          <td rowspan="1" resource="harm1">
169            (<span class="id" property="dc:identifier">hr</span>)
170            <span property="rdfs:label">Loss of consciousness</span>
171          </td>
172          <td rowspan="1" resource="deviceContext1">
173            (<span class="id" property="dc:identifier">dcx</span>)
174            <span property="rdfs:label">Normal use</span>
175          </td>
176          <td rowspan="1" resource="event1">
177            (<span class="id" property="dc:identifier">ev1</span>)
178            <span property="rdfs:label">Vibration mechanism fails</span>
179          </td>
180        </tr>
181      </tbody>
182    </table>
183  </div>
184 </body>
185 </html>
```

# The RISKMAN Workflow: Demo



The screenshot shows a code editor window with a dark theme. The breadcrumb navigation at the top reads: presentation-example.html > html > body > div.container > table > tbody > tr > td > link. The code is an HTML document with a table structure. A context menu is open over a `<link>` element, displaying several options: `>Live|`, `LaTeX Workshop: Share (on host) / Acquire (on guest) Live Share host port` (with a gear icon), `Live Preview: Show Debug Preview (External Browser)`, `Live Preview: Show Preview (External Browser)`, `Live Preview: Show Preview (Internal Browser)`, `Live Preview: Start Server Logging`, and `Live Preview: Stop Server`. The code in the background includes various HTML tags like `<html>`, `<body>`, `<div class="container">`, `<table>`, `<tbody>`, `<tr>`, `<td>`, `<td colspan="4">`, `<td rowspan="3">`, and `<td rowspan="1">`. It also contains `<span>` and `<link property="riskman:hasHazard" href="hazard1" />` tags.

# The RISKMAN Workflow: Demo

```

111 <link property="riskman:hasSubSDA"
112 href="sda2" />
113 <link property="riskman:hasSubSDA"
114 href="sda3" />
115 </td>
116 <td rowspan="2" colspan="3"
117 resource="residualRiskLevel1">
118 <span>Residual Risk Level 1</span>
119 <link property="riskman:hasProbability"
120 resource="rlevel:p5" />
121 <link property="riskman:hasSeverity"
122 resource="rlevel:s4" />
123 </td>
124 </tr>
125 <tr>
126 <td colspan="4" resource="domainSpecificHazard1">
127 <span class="id"
128 property="dc:identifier">dsh</span>
129 <span property="rdfs:label"></span>
130 <link property="riskman:hasHazard"
131 href="hazard1" />
132 <link property="riskman:hasDeviceFunction"
133 href="deviceFunction1" />
134 <link property="riskman:hasDeviceComponent"
135 href="deviceComponent1" />
136 <link property="riskman:hasDeviceProblem"
137 href="deviceProblem1" />
138 </td>
139 <td rowspan="3" resource="harm1">
140 <span class="id"
141 property="dc:identifier">hr</span>

```

http://127.0.0.1:3000/presentation-example.html

Controlled Risk											
Analyzed Risk										Initial Risk Level	
Domain Specific Hazard				Harm	Device Context	Event	Hazardous Situation	Initial Risk Level			Additional Information
Hazard	Function	Component	Problem					Prob.	Sev.		
(ar) Loss of consciousness due to an alarm malfunction										(sd0) mechan	
(dsh)				(hr) Loss of consciousness	(dcx) Normal use	(ev1) Vibration mechanism fails	(hs) No insulin delivered	Initial Risk Level 1		(sd1) Additional visual (blinking) signal.	
(hz) Non-audio alarm malfunctions	(df) Alarm	(dcm) Non-audio alarm	(dp) Defecitve Alarm (IMDRF A160106)			(ev2) Vibration cannot be felt		P1: V P2: IV	S: 4	(im1) Sec. 10 of Alarm report.	

Connecting to webview...

# The RISKMAN Workflow: Demo

```

111 <link property="riskman:hasSubSDA"
112 href="sda2" />
113 <link property="riskman:hasSubSDA"
114 href="sda3" />
115 </td>
116 <td rowspan="2" colspan="3"
117 resource="residualRiskLevel1">
118 <span>Residual Risk Level 1</span>
119 <link property="riskman:hasProbability"
120 resource="rlevel:p5" />
121 <link property="riskman:hasSeverity"
122 resource="rlevel:s4" />
123 </td>
124 </tr>
125 <tr>
126 <td colspan="4" resource="domainSpecificHazard1">
127 <span class="id"
128 property="dc:identifier">dsh</span>
129 <span property="rdfs:label">Non-audio</span>
130 <link property="riskman:hasHazard"
131 href="hazard1" />
132 <link property="riskman:hasDeviceFunction"
133 href="deviceFunction1" />
134 <link property="riskman:hasDeviceComponent"
135 href="deviceComponent1" />
136 <link property="riskman:hasDeviceProblem"
137 href="deviceProblem1" />
138 </td>
139 <td rowspan="3" resource="harm1">
140 <span class="id"
141 property="dc:identifier">hr</span>

```

http://127.0.0.1:3000/presentation-example.html

Controlled Risk											
Analyzed Risk										Initial Risk Level	
Domain Specific Hazard				Harm	Device Context	Event	Hazardous Situation	Initial Risk Level			Additional Information
Hazard	Function	Component	Problem					Prob.	Sev.		
(ar) Loss of consciousness due to an alarm malfunction										(sd0) mechan	
(dsh) Non-audio				(hr) Loss of consciousness	(dcx) Normal use	(ev1) Vibration mechanism fails	(hs) No insulin delivered	Initial Risk Level 1		(sd1) Additional visual (blinking) signal.	
(hz) Non-audio alarm malfunctions	(df) Alarm	(dcm) Non-audio alarm	(dp) Defective Alarm (IMDRF A160106)					(ev2) Vibration cannot be felt	P1: V P2: IV	S: 4	(im1) Sec. 10 of Alarm report.

Connecting to webview...

# The RISKMAN Workflow: Demo

```

111 <link property="riskman:hasSubSDA"
112 href="sda2" />
113 <link property="riskman:hasSubSDA"
114 href="sda3" />
115 </td>
116 <td rowspan="2" colspan="3"
117 resource="residualRiskLevel1">
118 <span>Residual Risk Level 1</span>
119 <link property="riskman:hasProbability"
120 resource="rlevel:p5" />
121 <link property="riskman:hasSeverity"
122 resource="rlevel:s4" />
123 </td>
124 </tr>
125 <tr>
126 <td colspan="4" resource="domainSpecificHazard1">
127 <span class="id"
128 property="dc:identifier">dsh</span>
129 <span property="rdfs:label">Non-audio </span>
130 <link property="riskman:hasHazard"
131 href="hazard1" />
132 <link property="riskman:hasDeviceFunction"
133 href="deviceFunction1" />
134 <link property="riskman:hasDeviceComponent"
135 href="deviceComponent1" />
136 <link property="riskman:hasDeviceProblem"
137 href="deviceProblem1" />
138 </td>
139 <td rowspan="3" resource="harm1">
140 <span class="id"
141 property="dc:identifier">hr</span>

```

Controlled Risk

Analyzed Risk										Initial Risk Level	Prob. Sev.	
Domain Specific Hazard				Harm	Device Context	Event	Hazardous Situation	Initial Risk Level				Prob. Sev.
Hazard	Function	Component	Problem					Prob.	Sev.			
(ar) Loss of consciousness due to an alarm malfunction										(sd0)	mecha	
(dsh) Non-audio				(hr) Loss of consciousness	(dcx) Normal use	(ev1) Vibration mechanism fails	(hs) No insulin delivered	Initial Risk Level 1		(sd1) Additional visual (blinking) signal.		
(hz) Non-audio alarm malfunctions	(df) Alarm	(dcm) Non-audio alarm	(dp) Defecitve Alarm (IMDRF A160106)			(ev2) Vibration cannot be felt		P1: V P2: IV	S: 4	(im1) Sec. 10 of Alar report.		

Connecting to webview...

# The RISKMAN Workflow: Demo

```

2 <html prefix="
56 <body>
57 <div class="container">
58 <table>
88 <tbody>
111 <td colspan="4" resource="domainSpecificHazard1">
112 <span class="id" property="dc:identifier">dsh</span>
113 <span property="rdfs:label">Non-audio alarm
114 malfunctions</span>
115 <link property="riskman:hasHazard"
116 href="hazard1" />
117 <link property="riskman:hasDeviceFunction"
118 href="deviceFunction1" />
119 <link property="riskman:hasDeviceComponent"
120 href="deviceComponent1" />
121 <link property="riskman:hasDeviceProblem"
122 href="deviceProblem1" />
123 </td>
124 <td rowspan="3" resource="harm1">
125 <span class="id" property="dc:identifier">hr</span>
126 <span property="rdfs:label">Loss of consciousness</span>
127 <link property="riskman:hasHarm" href="harm1" />
128 </td>
129 <td colspan="2" resource="deviceContext1">
130 <span class="id" property="dc:identifier">dcx</span>
131 <span property="rdfs:label">Normal use</span>
132 <link property="riskman:hasDeviceContext" href="deviceContext1" />
133 </td>
134 <td colspan="2" resource="event1">
135 <span class="id" property="dc:identifier">ev1</span>
136 <span property="rdfs:label">Vibration mechanism fails</span>
137 <link property="riskman:hasEvent" href="event1" />
138 </td>
139 <td colspan="2" resource="hazardousSituation1">
140 <span class="id" property="dc:identifier">hs</span>
141 <span property="rdfs:label">No insulin delivered</span>
142 <link property="riskman:hasHazardousSituation" href="hazardousSituation1" />
143 </td>
144 <td colspan="2" resource="initialRiskLevel1">
145 <span class="id" property="dc:identifier">ir</span>
146 <span property="rdfs:label">Initial Risk Level 1</span>
147 <link property="riskman:hasInitialRiskLevel" href="initialRiskLevel1" />
148 </td>
149 <td colspan="2" resource="probSev">
150 <span class="id" property="dc:identifier">ps</span>
151 <span property="rdfs:label">Prob. Sev.</span>
152 <link property="riskman:hasProbSev" href="probSev" />
153 </td>
154 </tr>
155 <tr>
156 <td colspan="4" rowspan="2" resource="residualRiskLevel1">
157 <span>Residual Risk Level 1</span>
158 <link property="riskman:hasProbability" resource="rlevel:p5" />
159 <link property="riskman:hasSeverity" resource="rlevel:s4" />
160 </td>
161 <td colspan="2" rowspan="2" resource="sd0">
162 <span class="id" property="dc:identifier">sd0</span>
163 <span property="rdfs:label">mechanism</span>
164 <link property="riskman:hasSubSDA" href="sd0" />
165 </td>
166 </tr>
167 <tr>
168 <td colspan="2" resource="sd1">
169 <span class="id" property="dc:identifier">sd1</span>
170 <span property="rdfs:label">Additional visual signal</span>
171 <link property="riskman:hasSubSDA" href="sd1" />
172 </td>
173 </tr>
174 </tbody>
175 </table>
176 </div>
177 </body>
178 </html>

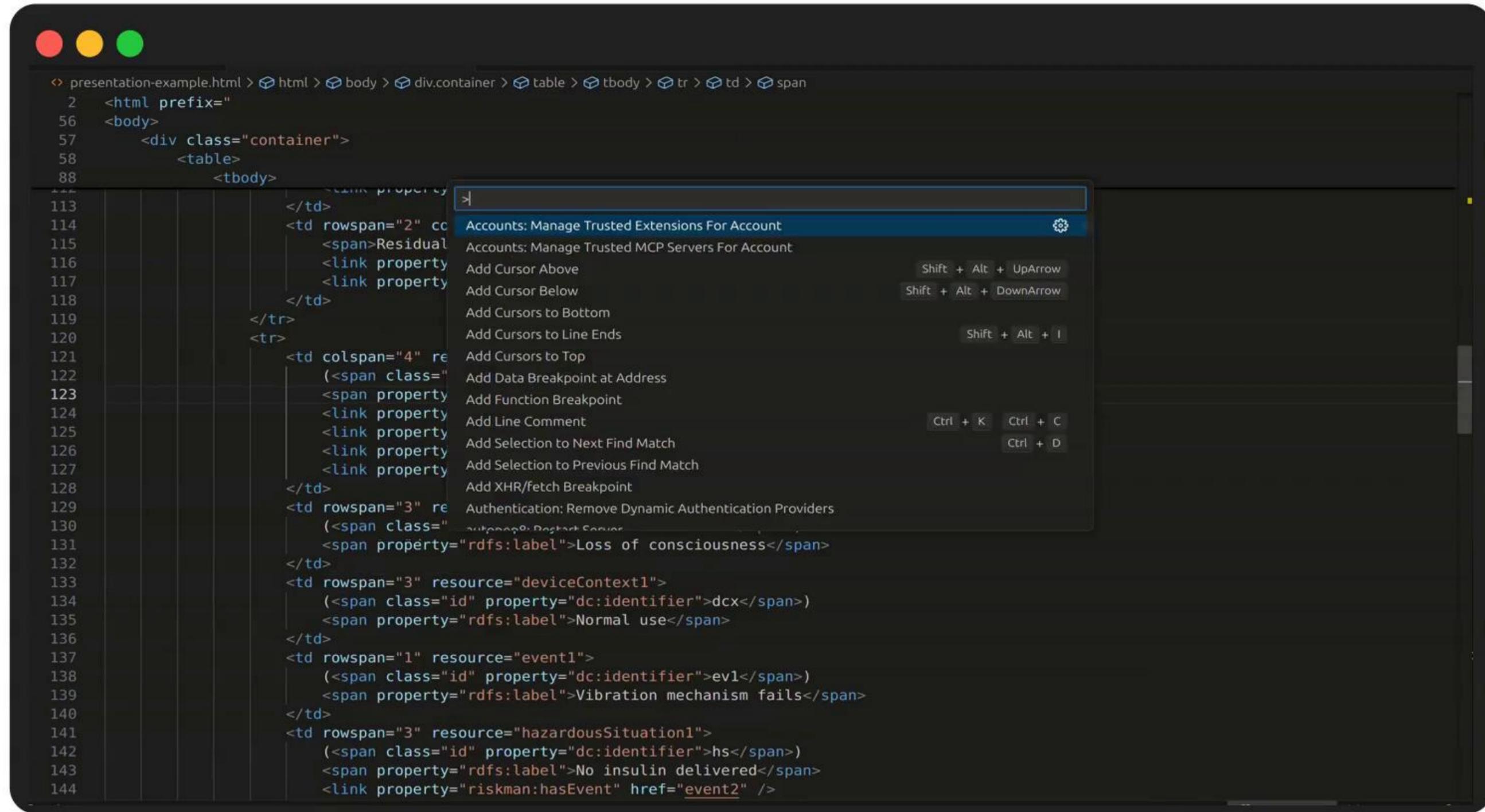
```

http://127.0.0.1:3000/presentation-example.html

Controlled Risk											
	Analyzed Risk							Initial Risk Level			
	Domain Specific Hazard				Harm	Device Context	Event				Hazardous Situation
	Hazard	Function	Component	Problem				Prob.	Sev.		
(ar)	Loss of consciousness due to an alarm malfunction									(sd0) mechan	
(dsh)	Non-audio alarm malfunctions						(ev1) Vibration mechanism fails		Initial Risk Level 1		(sd1) Additional visual signal.
(cr)	(hz) Non-audio alarm malfunctions	(df) Alarm	(dcm) Non-audio alarm	(dp) Defective Alarm (IMDRF A160106)	(hr) Loss of consciousness	(dcx) Normal use	(ev2) Vibration cannot be felt	(hs) No insulin delivered	P1: V P2: IV	S: 4	(im1) Sec. 10 of Alarm report.

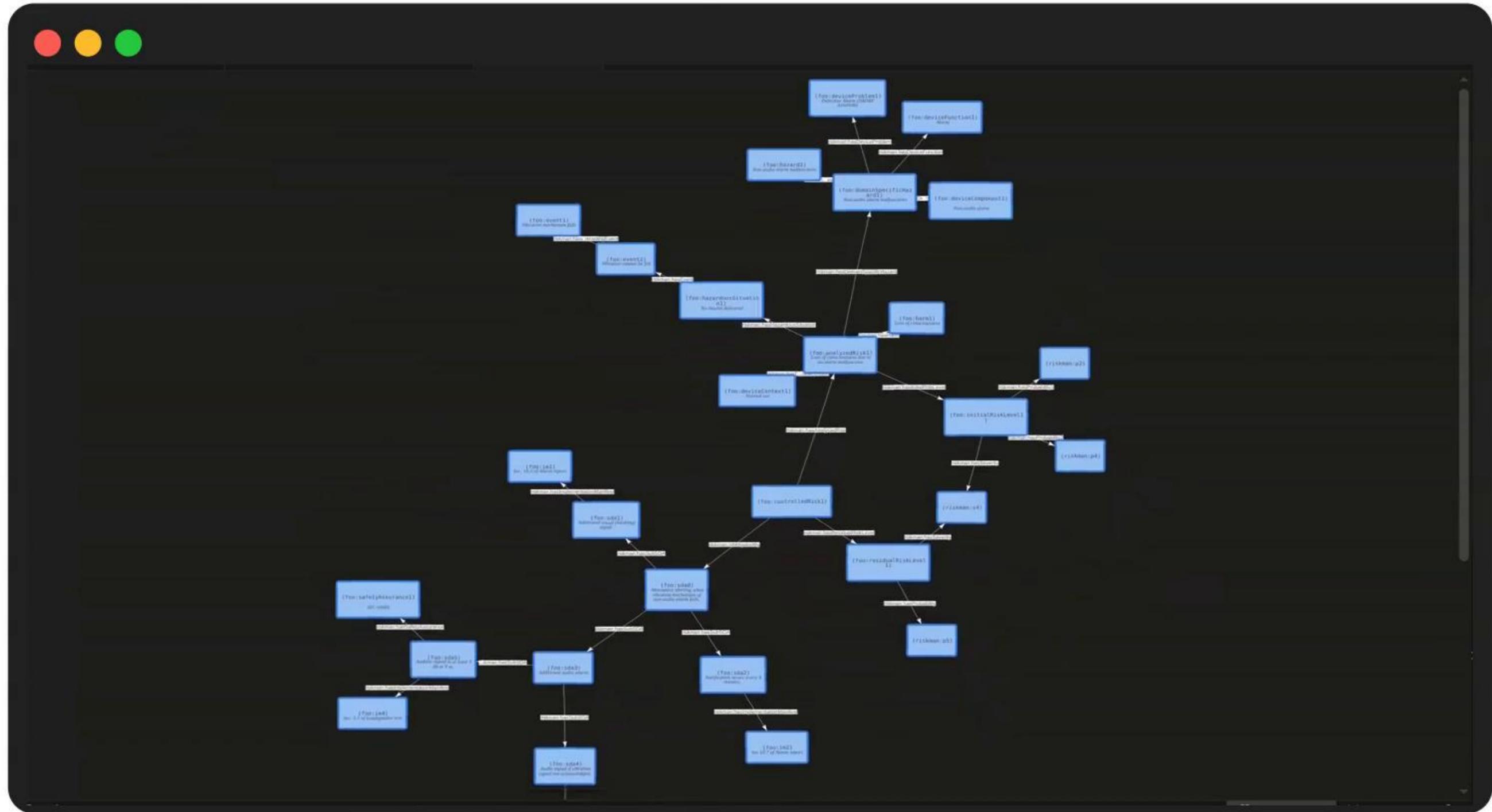
Please reopen the preview.

# The RISKMAN Workflow: Demo





# The RISKMAN Workflow: Demo





# The RISKMAN Workflow: Demo







# The RISKMAN Workflow: Demo



Wrap-up

Conclusions



# Wrap-up

## Conclusions

**Riskman:** OWL EL ontology + SHACL constraints



# Wrap-up

## Conclusions

**Riskman:** OWL EL ontology + SHACL constraints

**Digitization:** RMFs encoded as a RDFa files



# Wrap-up

## Conclusions

**Riskman:** OWL EL ontology + SHACL constraints

**Digitization:** RMFs encoded as a RDFa files

**Readability:** human- and machine-readable RMFs are ensured



# Wrap-up

## Conclusions

**Riskman:** OWL EL ontology + SHACL constraints

**Digitization:** RMFs encoded as a RDFa files

**Readability:** human- and machine-readable RMFs are ensured

**Two pillars:** reasoning derives implicit knowledge; SHACL validates compliance



# Wrap-up

## Conclusions

**Riskman:** OWL EL ontology + SHACL constraints

**Digitization:** RMFs encoded as a RDFa files

**Readability:** human- and machine-readable RMFs are ensured

**Two pillars:** reasoning derives implicit knowledge; SHACL validates compliance



## Future Work

# Wrap-up

## Conclusions

**Riskman:** OWL EL ontology + SHACL constraints

**Digitization:** RMFs encoded as a RDFa files

**Readability:** human- and machine-readable RMFs are ensured

**Two pillars:** reasoning derives implicit knowledge; SHACL validates compliance



## Future Work

**Integration:** AIRO (AI Act), NCIt, SNOMED

# Wrap-up

## Conclusions

**Riskman:** OWL EL ontology + SHACL constraints

**Digitization:** RMFs encoded as a RDFa files

**Readability:** human- and machine-readable RMFs are ensured

**Two pillars:** reasoning derives implicit knowledge; SHACL validates compliance



## Future Work

**Integration:** AIRO (AI Act), NCIt, SNOMED

**Beyond completeness:** assess assurance quality

# Wrap-up

## Conclusions

**Riskman:** OWL EL ontology + SHACL constraints

**Digitization:** RMFs encoded as a RDFa files

**Readability:** human- and machine-readable RMFs are ensured

**Two pillars:** reasoning derives implicit knowledge; SHACL validates compliance



## Future Work

**Integration:** AIRO (AI Act), NCIt, SNOMED

**Beyond completeness:** assess assurance quality

**Usability:** explain SHACL violations and suggest fixes

# Wrap-up

## Conclusions

**Riskman:** OWL EL ontology + SHACL constraints

**Digitization:** RMFs encoded as a RDFa files

**Readability:** human- and machine-readable RMFs are ensured

**Two pillars:** reasoning derives implicit knowledge; SHACL validates compliance



## Future Work

**Integration:** AIRO (AI Act), NCIt, SNOMED

**Beyond completeness:** assess assurance quality

**Usability:** explain SHACL violations and suggest fixes