

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

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International Center
for Computational Logic

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Federal Ministry
of Research, Technology
and Space

Big Picture: RMFs

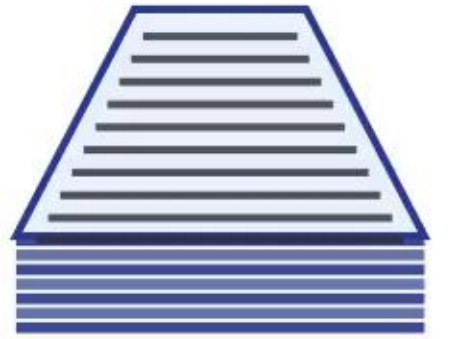
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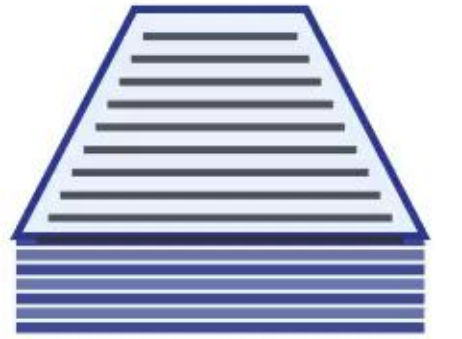


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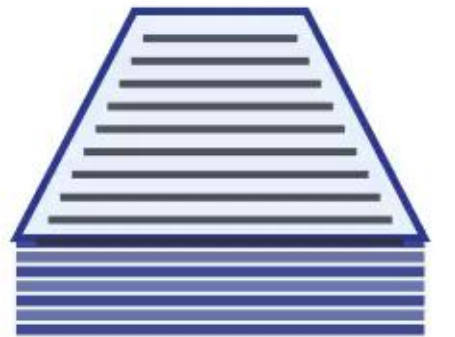
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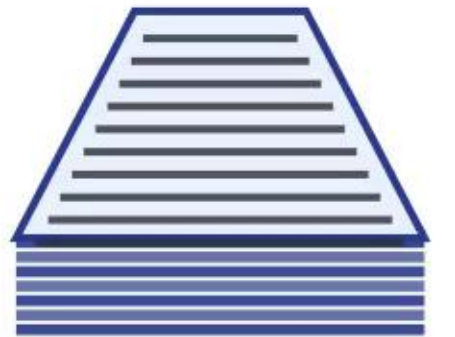
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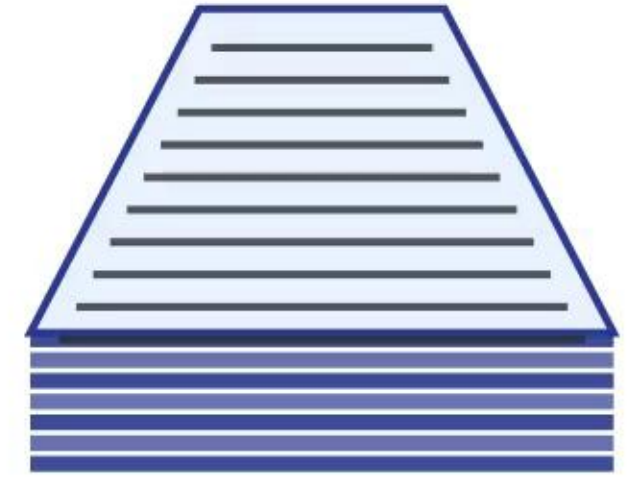
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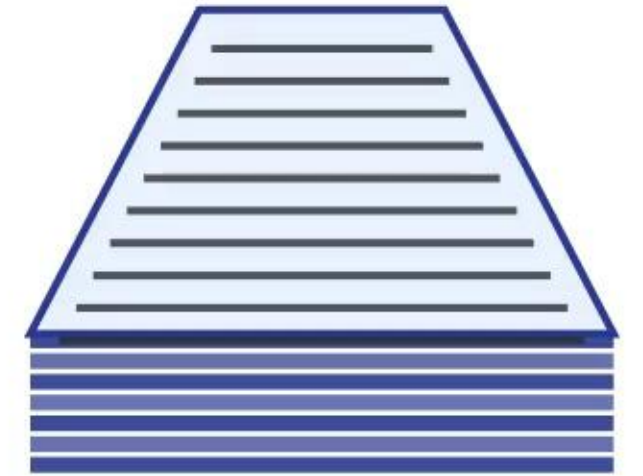
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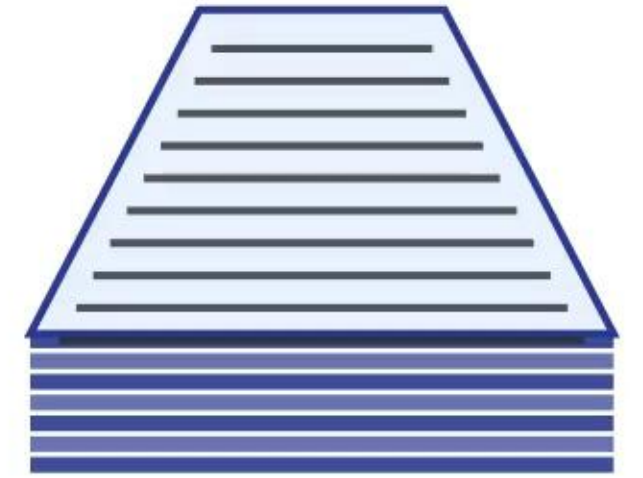


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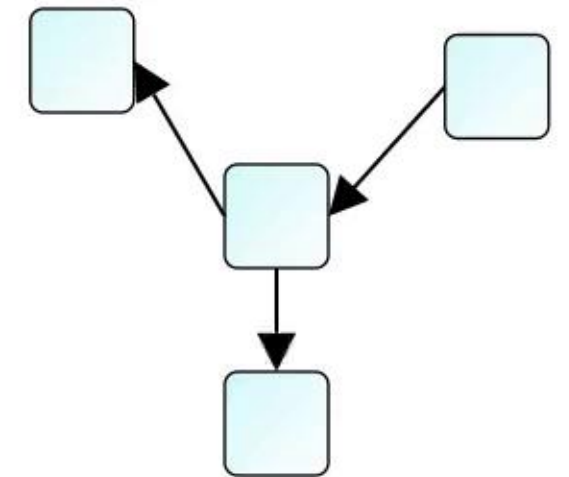
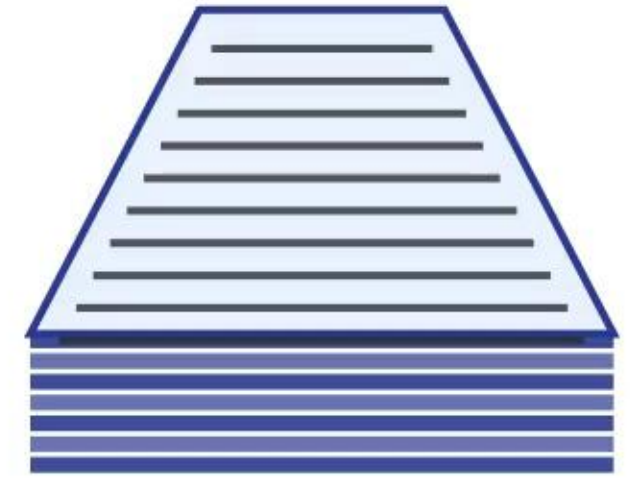


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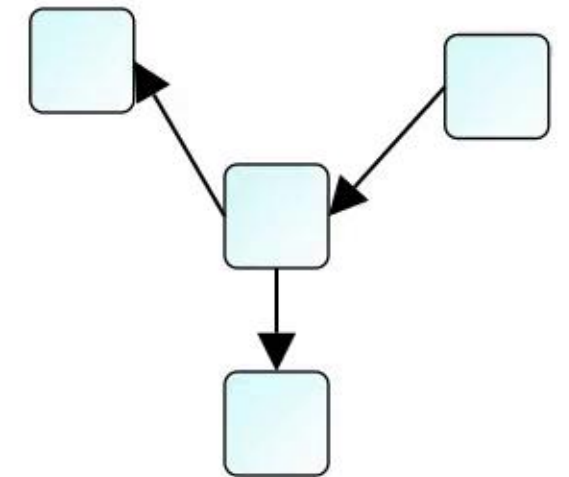
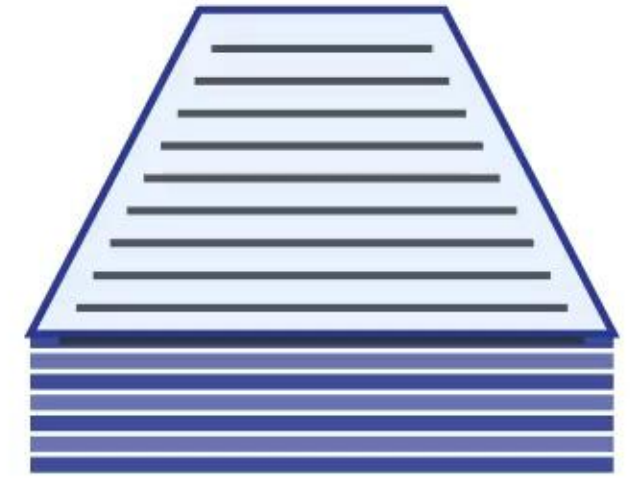
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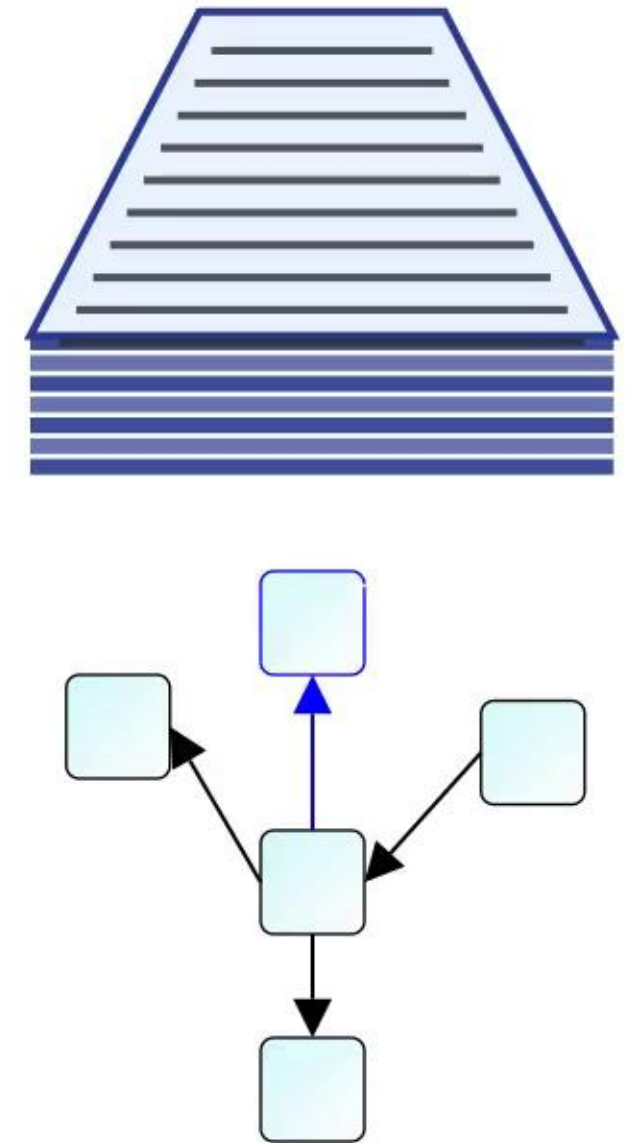
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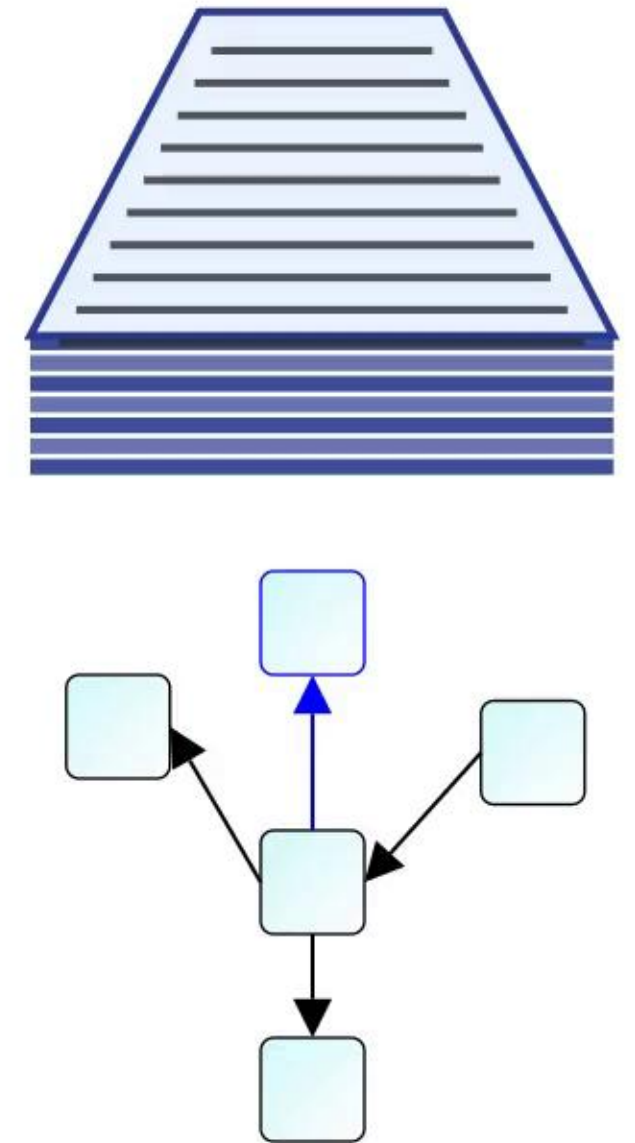
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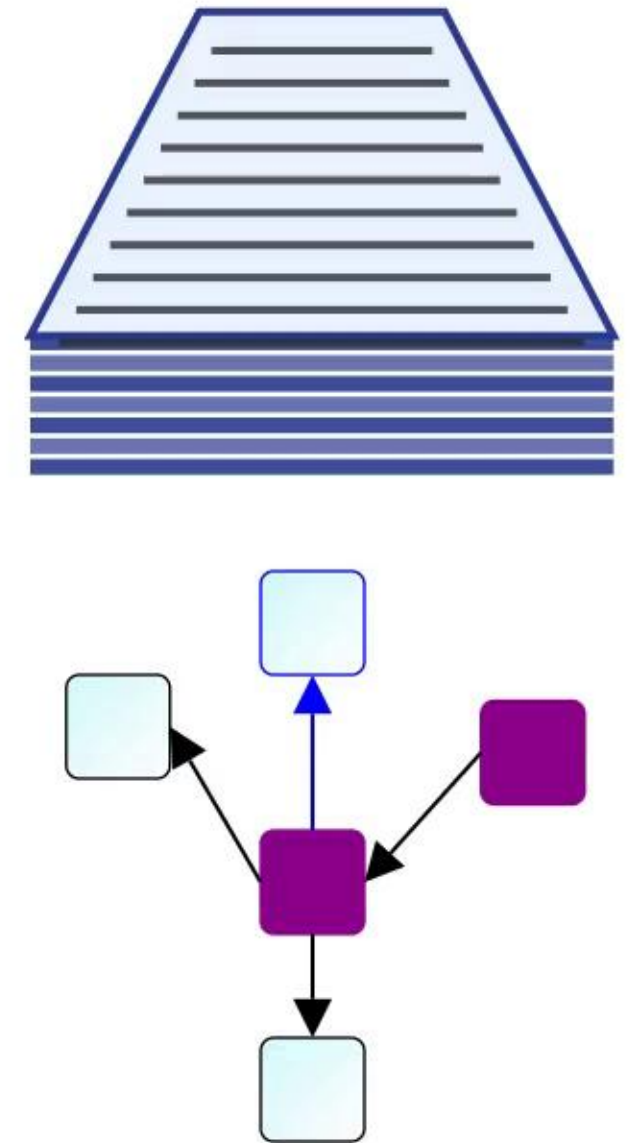
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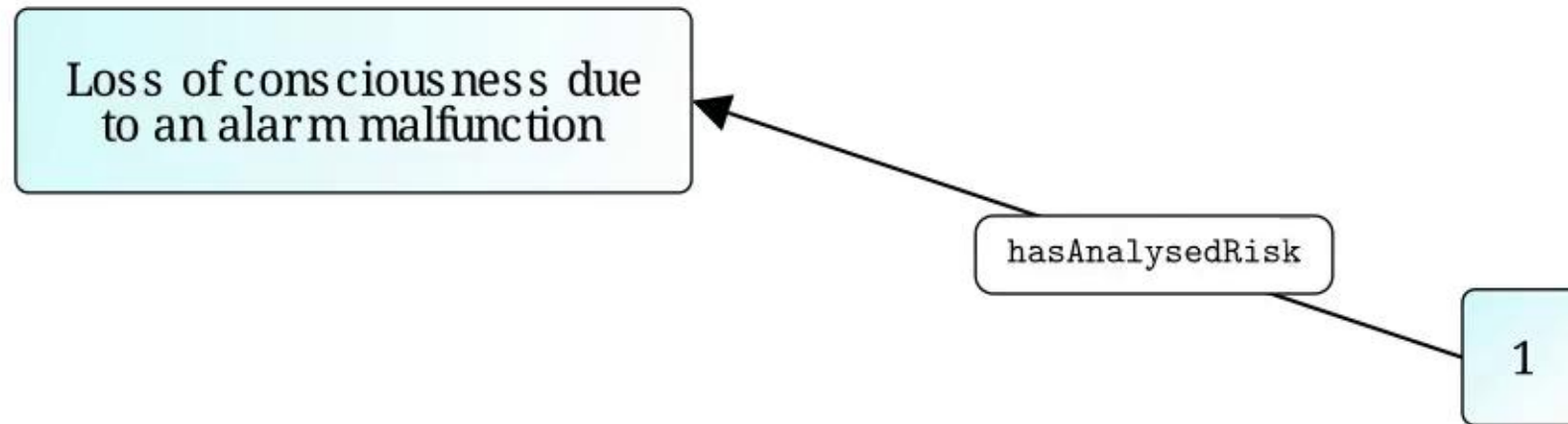
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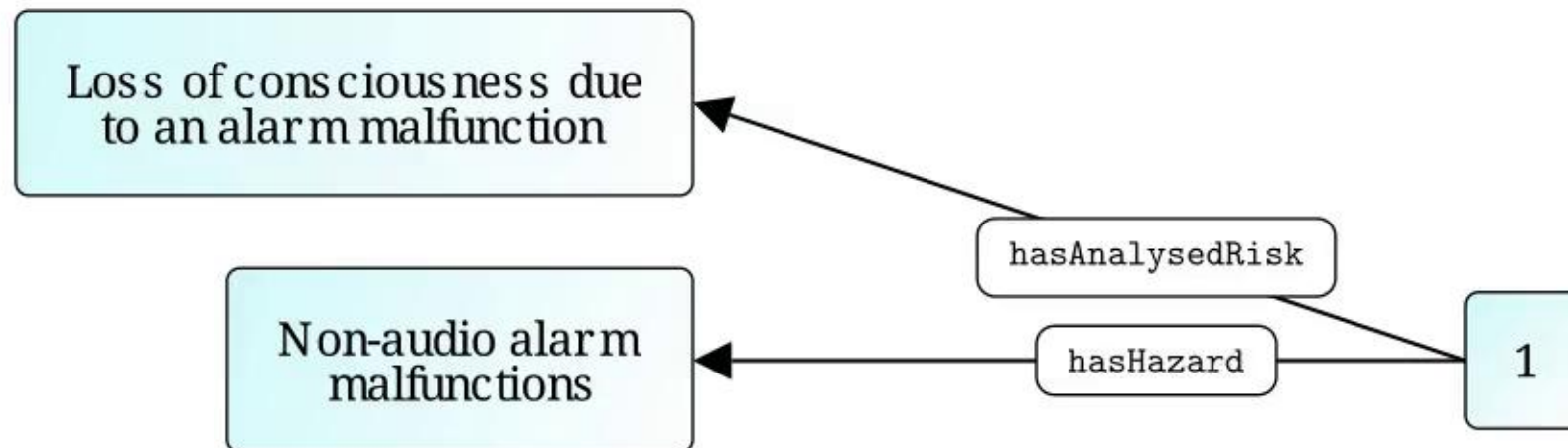
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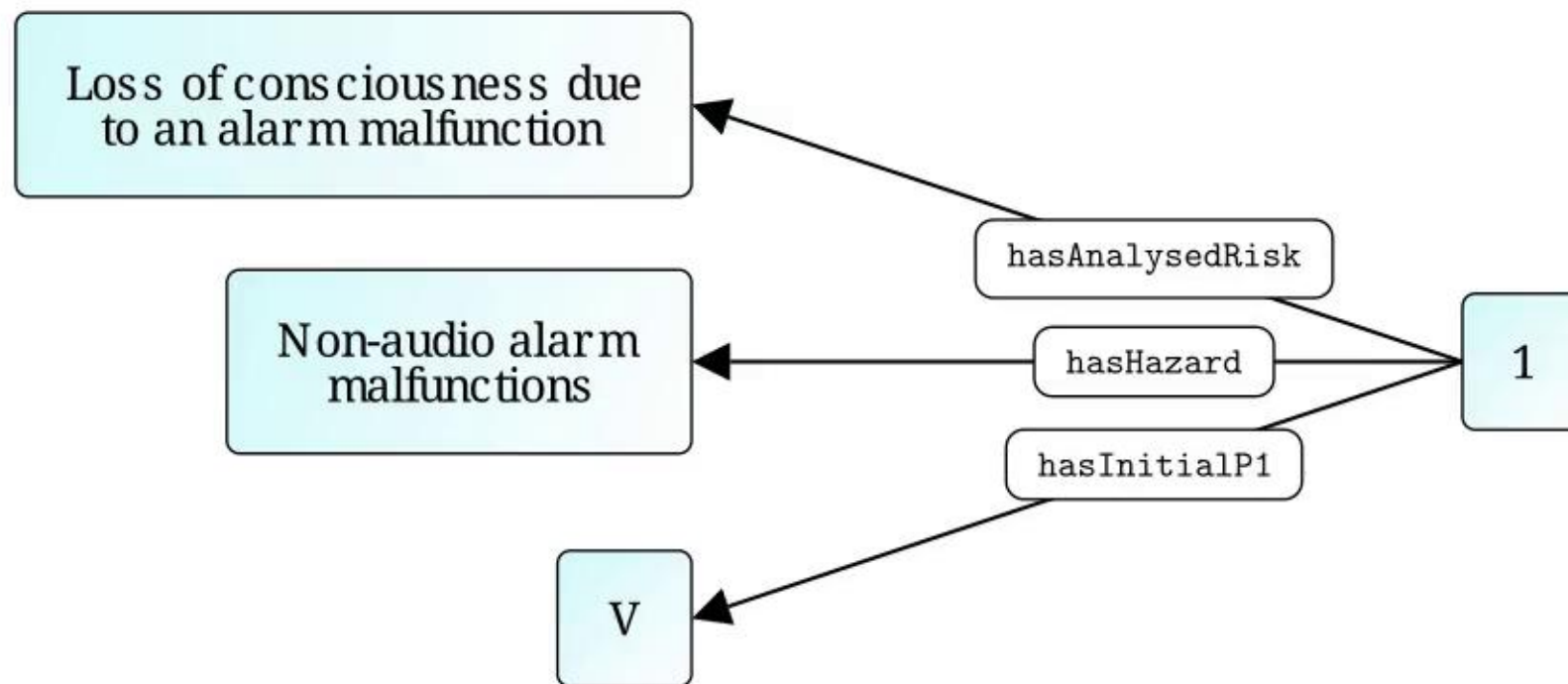
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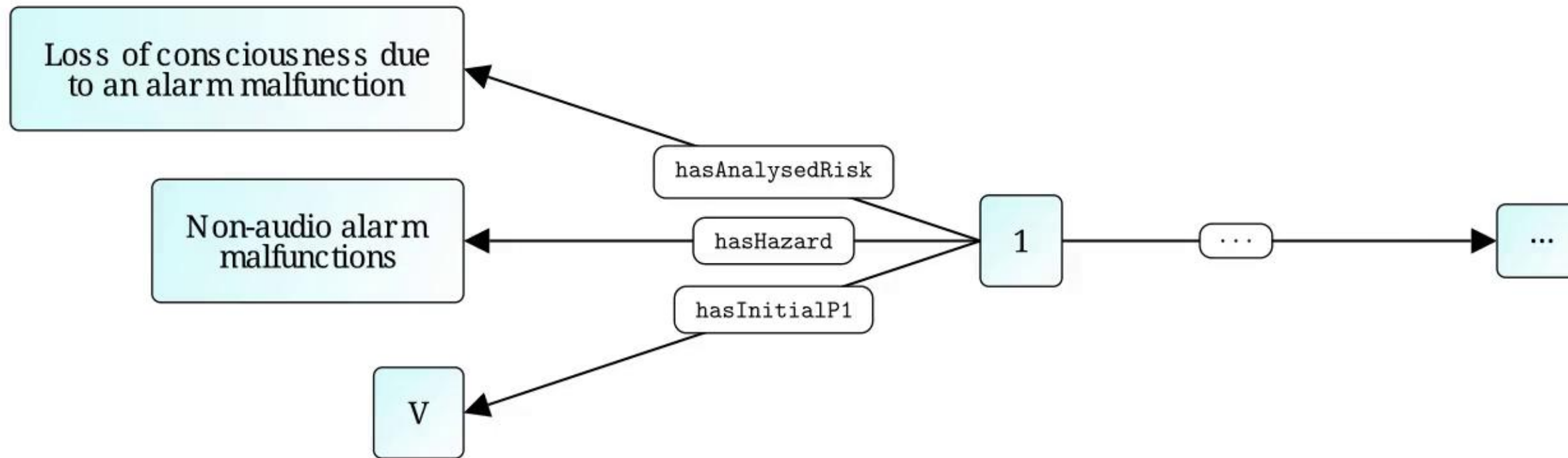
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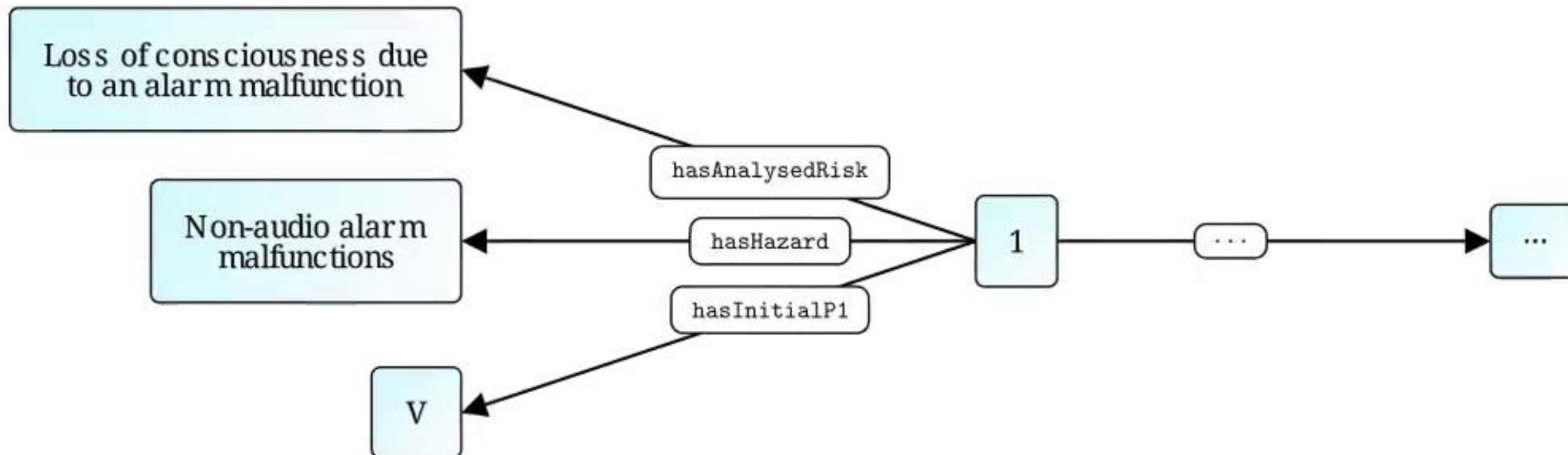
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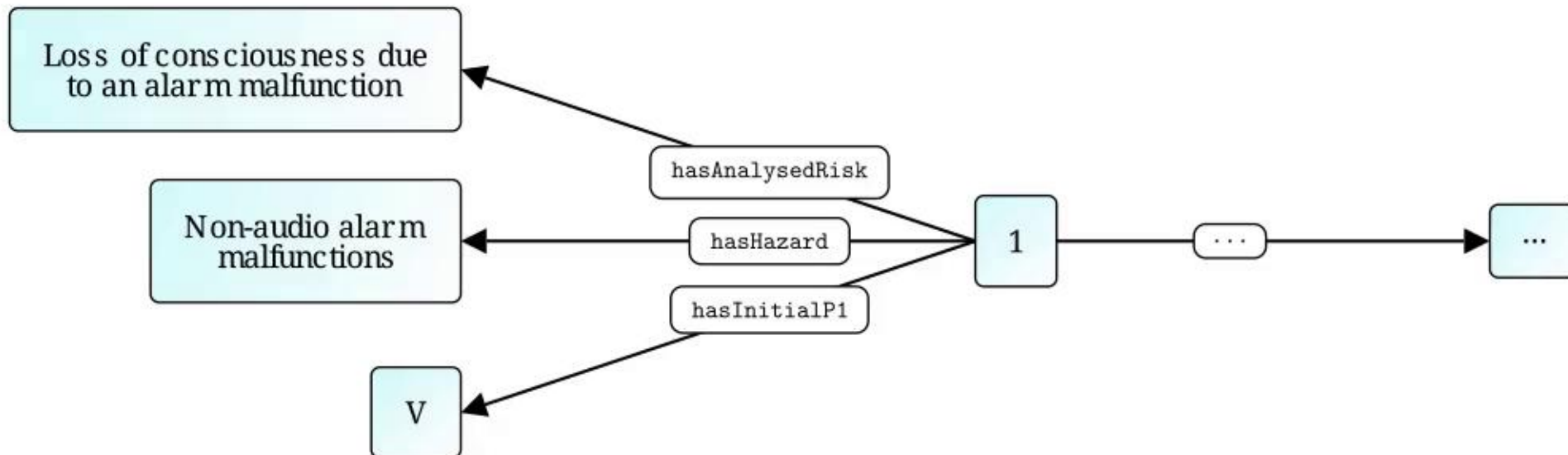
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```
1 @prefix : <https://w3id.org/riskman/ontology> .
2 @prefix rdfs: <http://www.w3.org/2000/01/rdf-schema#> .
3
4
5 _:1 :hasAnalysedRisk [
6   rdfs:comment "Loss of consciousness..."
7 ] ;
8 :hasHazard [
9   rdfs:comment "Non-audio alarm..."
10 ]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

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Combination of probability and severity.

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Ontology (TBox)

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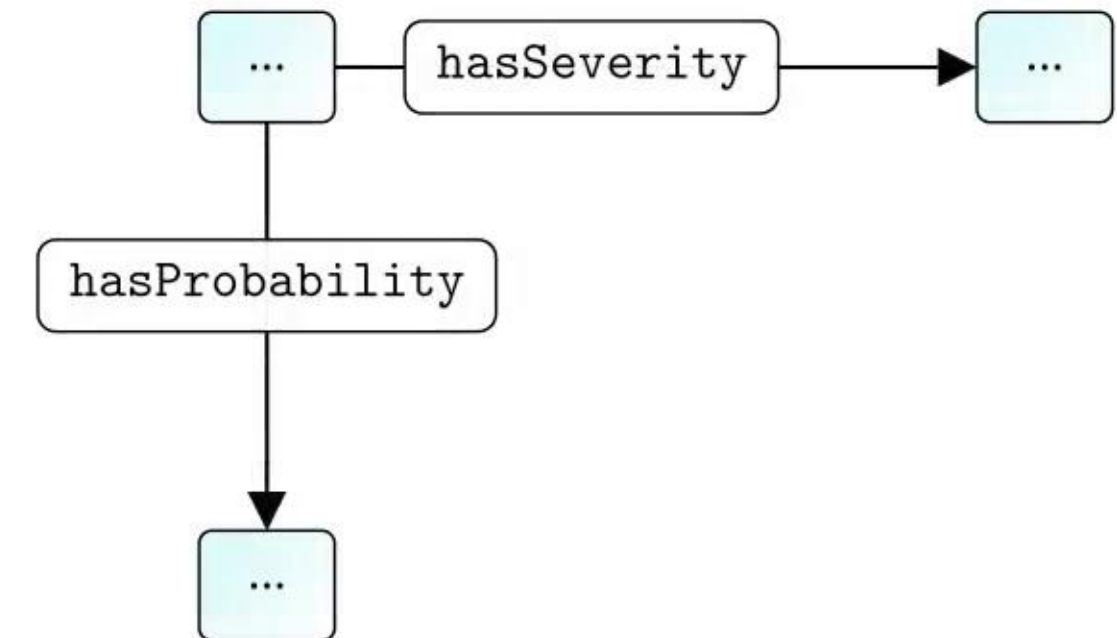
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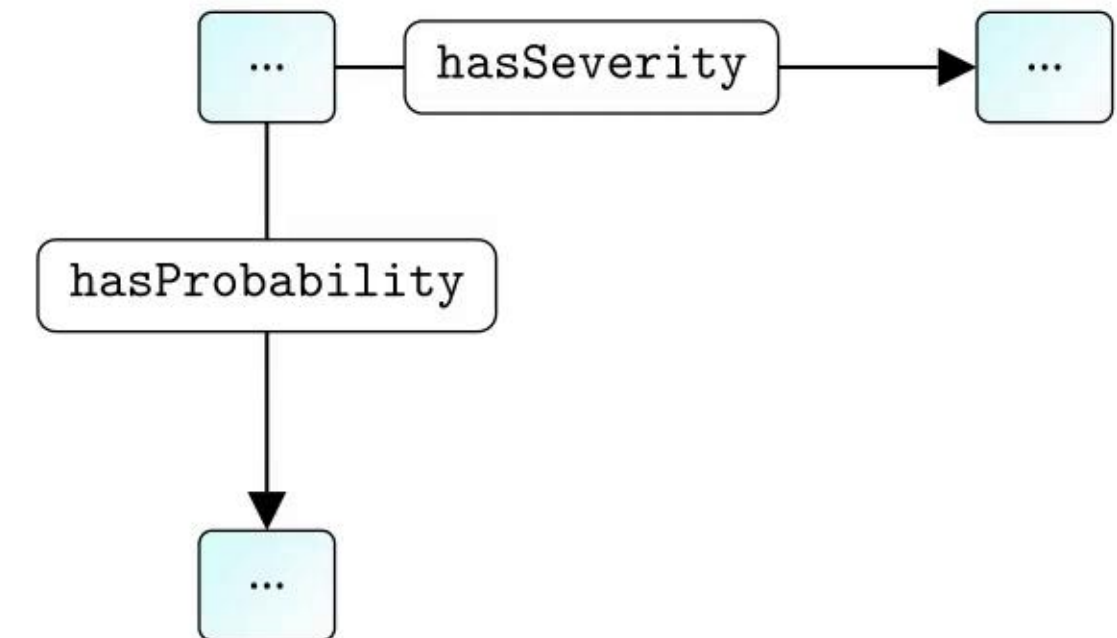
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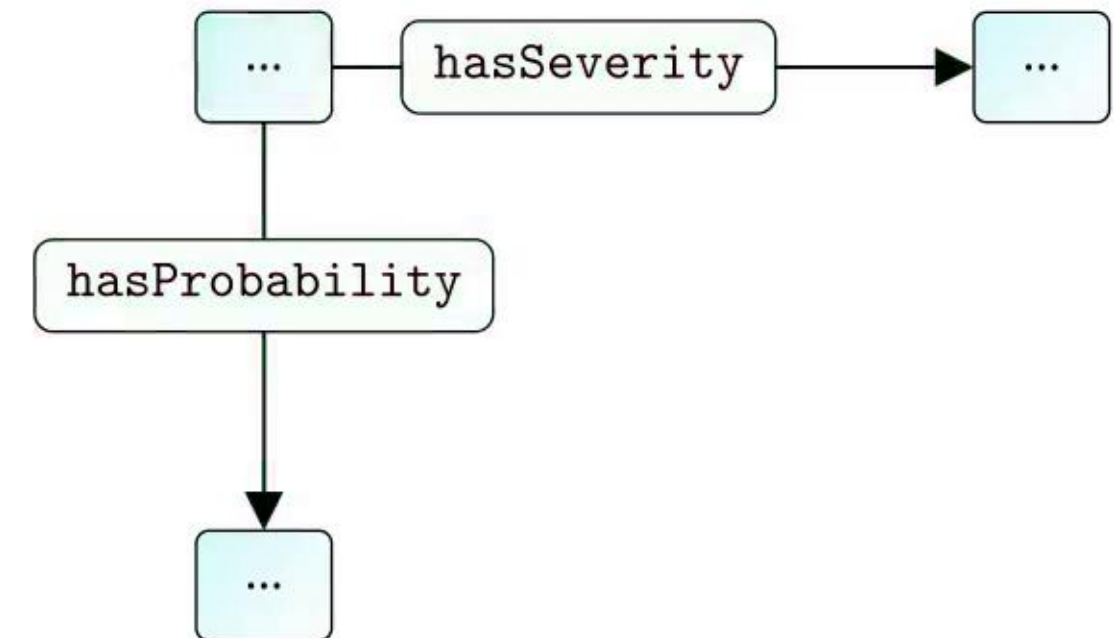
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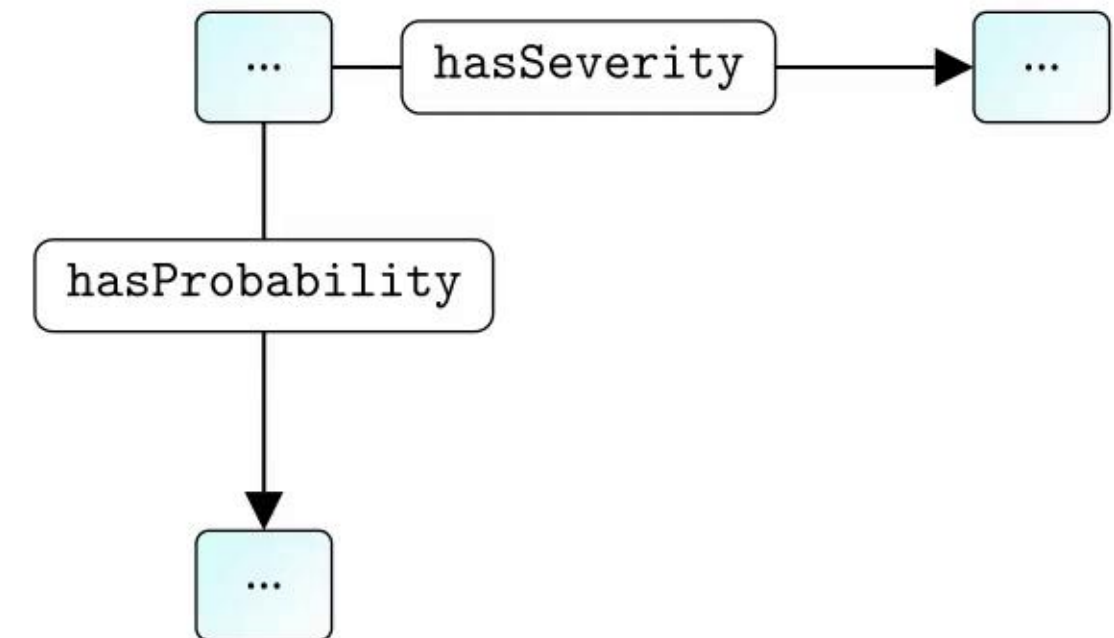
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According to ISO 14971 [3.18]:

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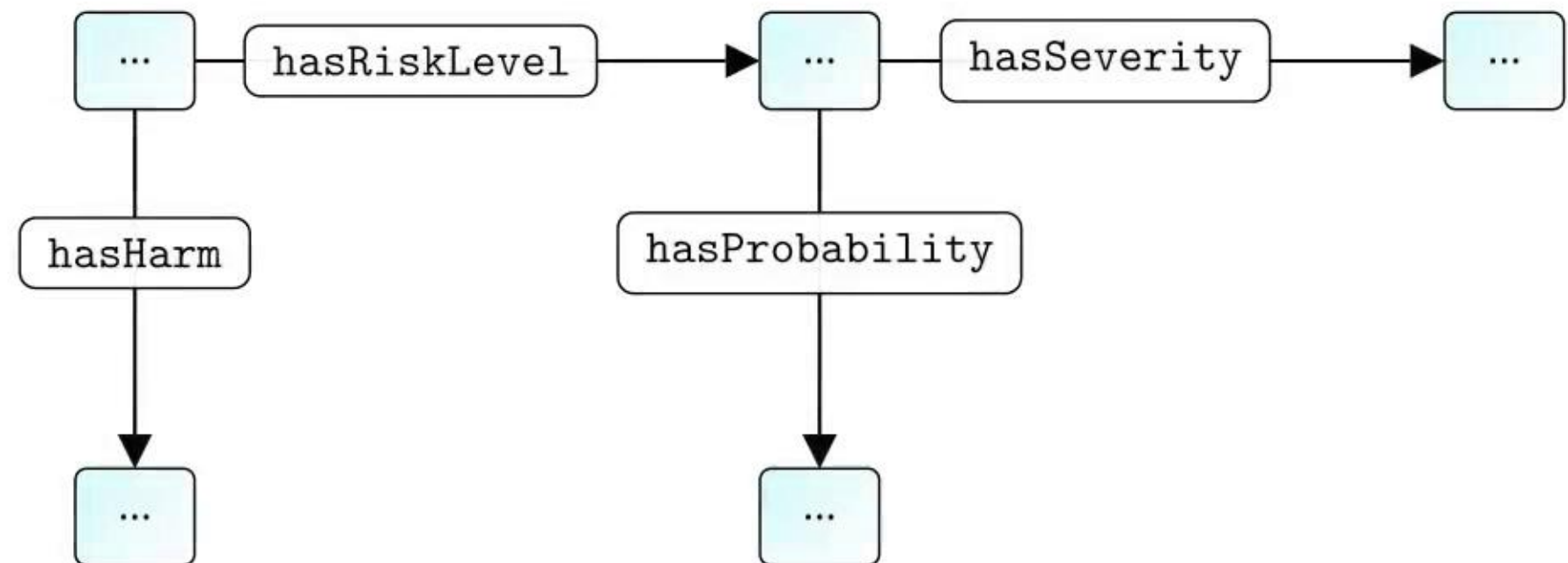
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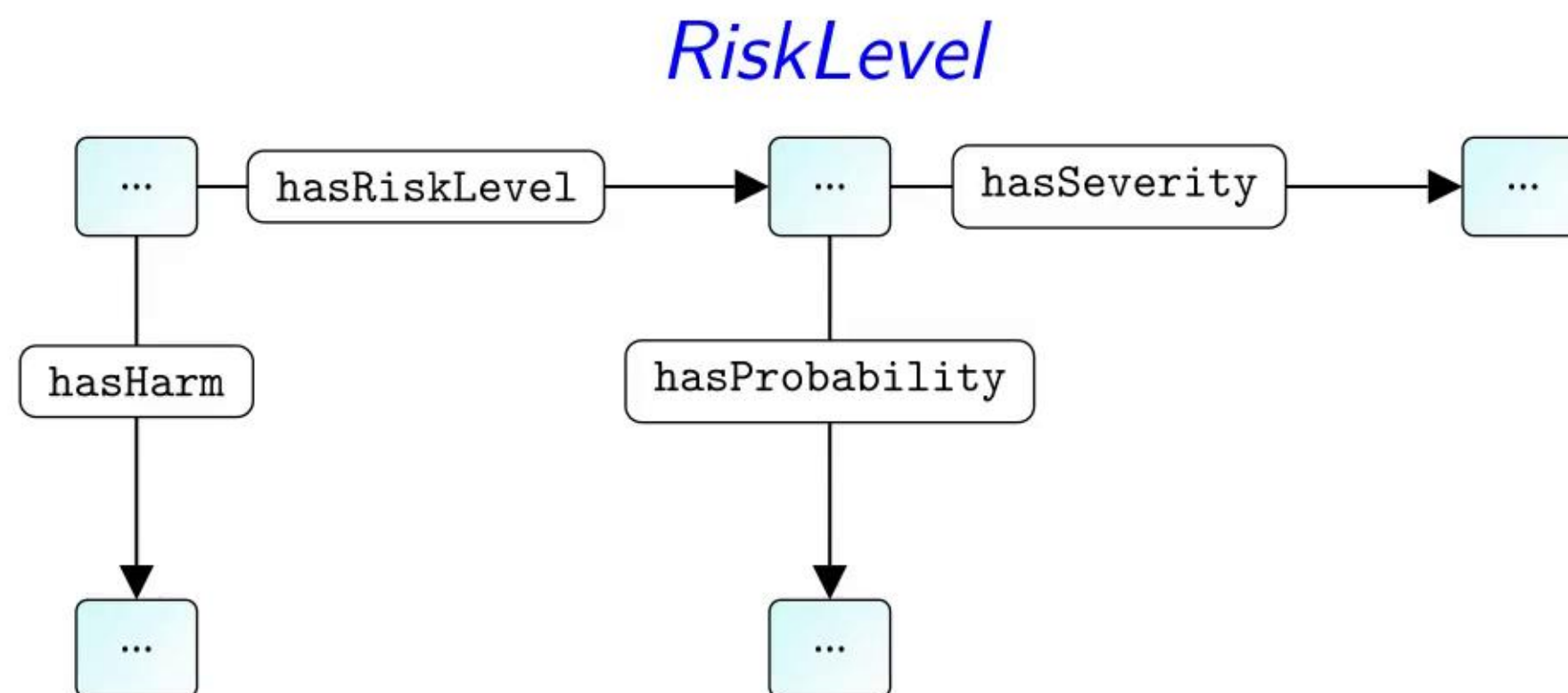
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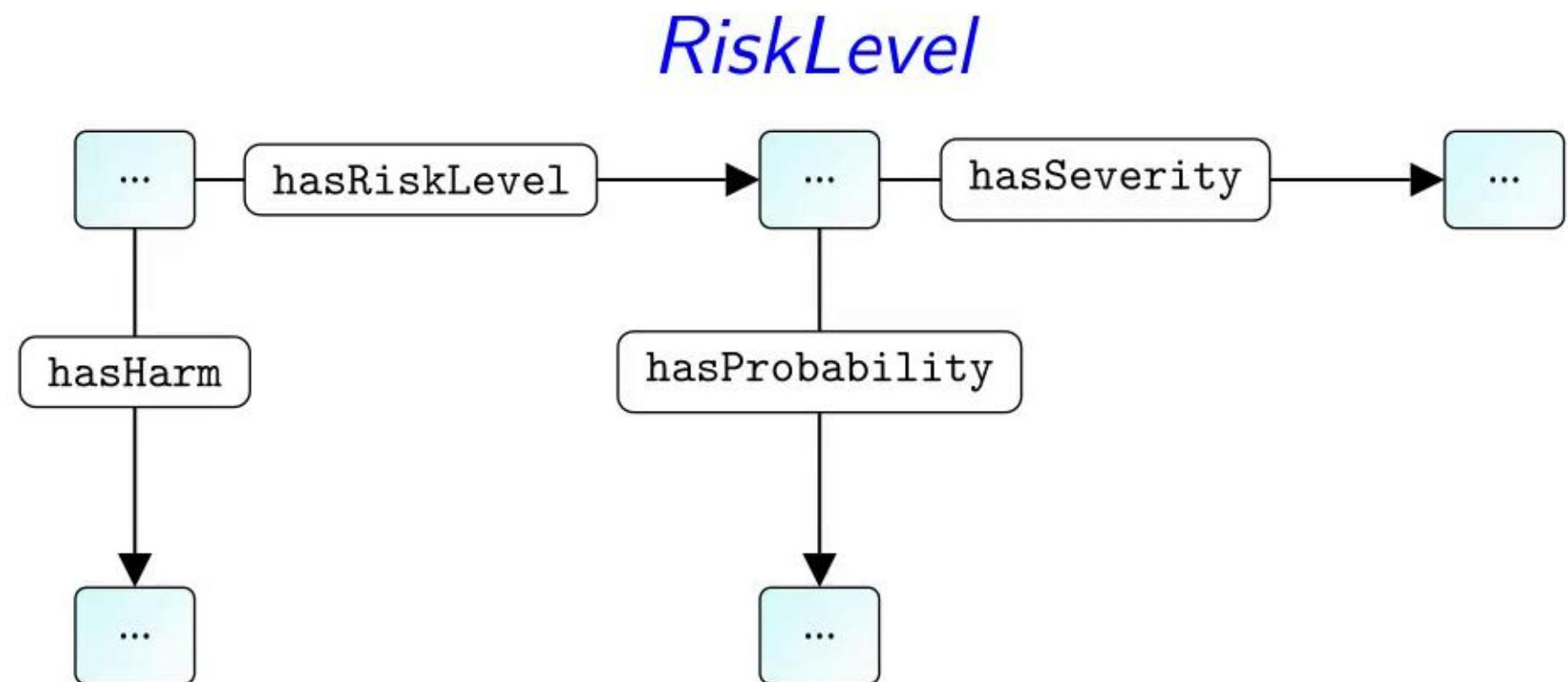
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 $\exists \text{hasHarm}.\top \sqsubseteq \textit{Risk}$



The RISKMAN Ontology: Encoding Rules (2)

According to ISO 14971 [3.18]:

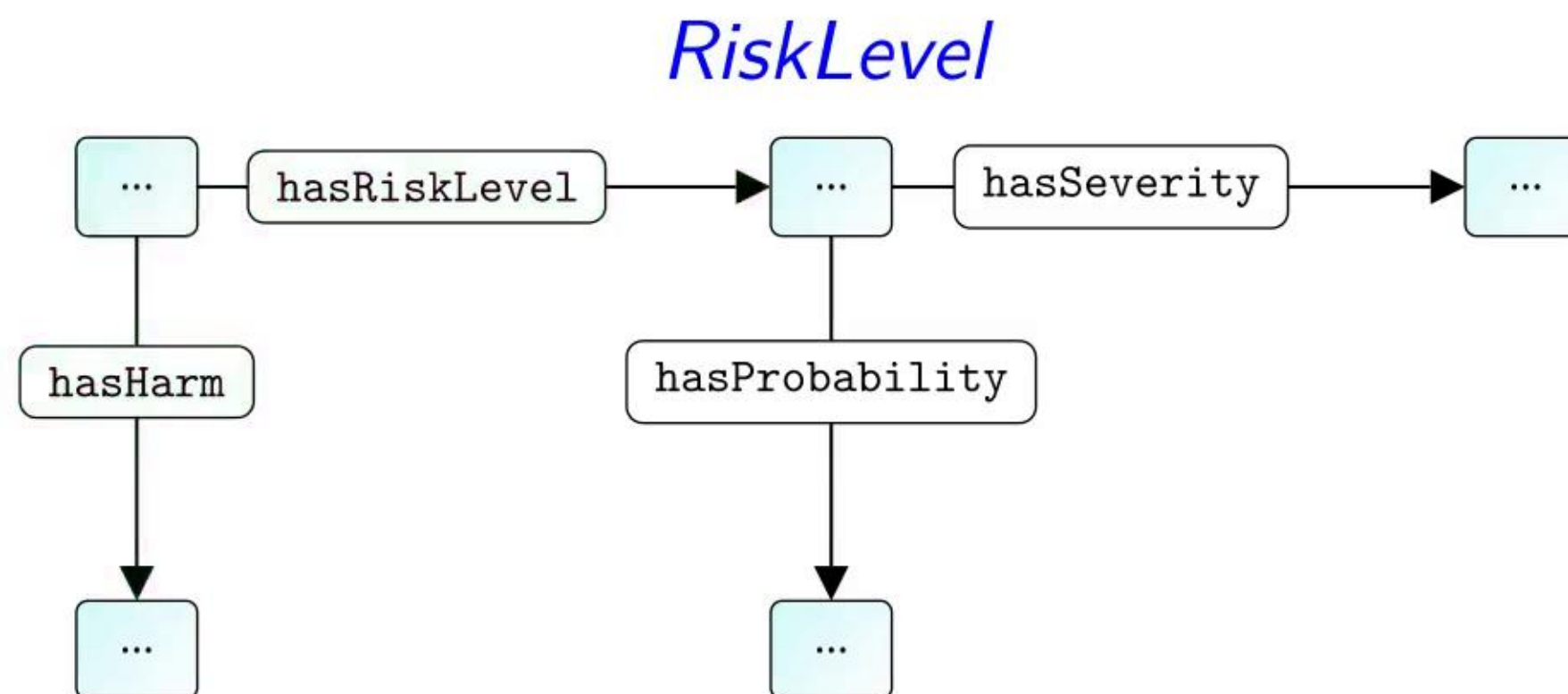
risk

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

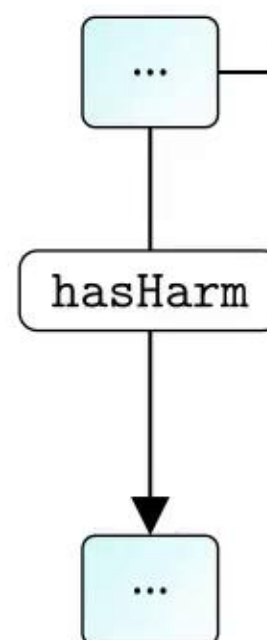
Combination of probability of occurrence of harm and severity.

Ontology (TBox)

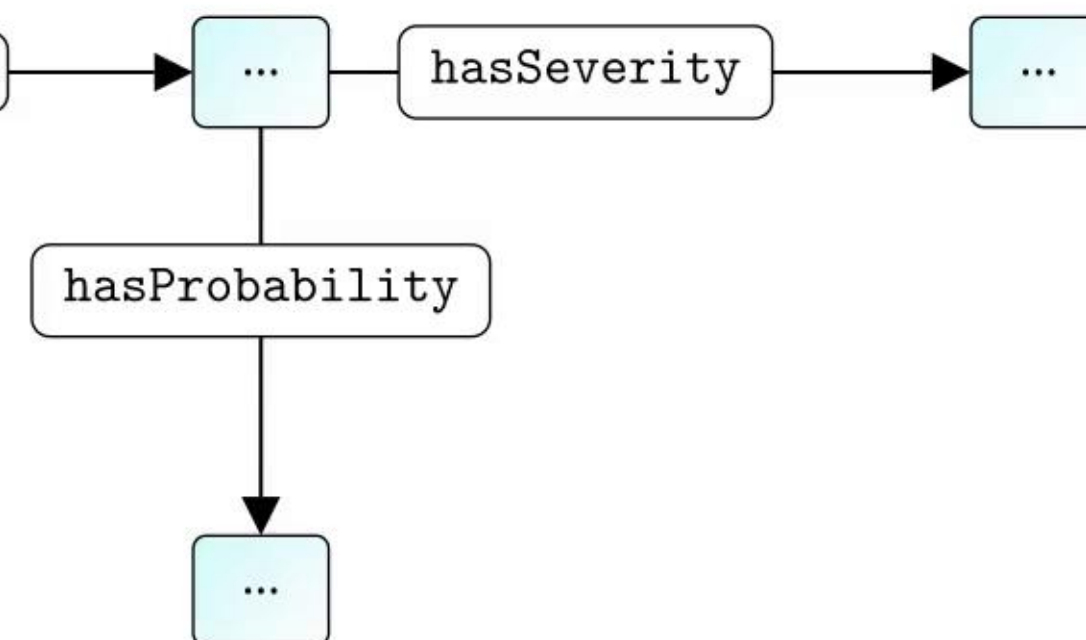
Data (ABox)

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

Risk



RiskLevel



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

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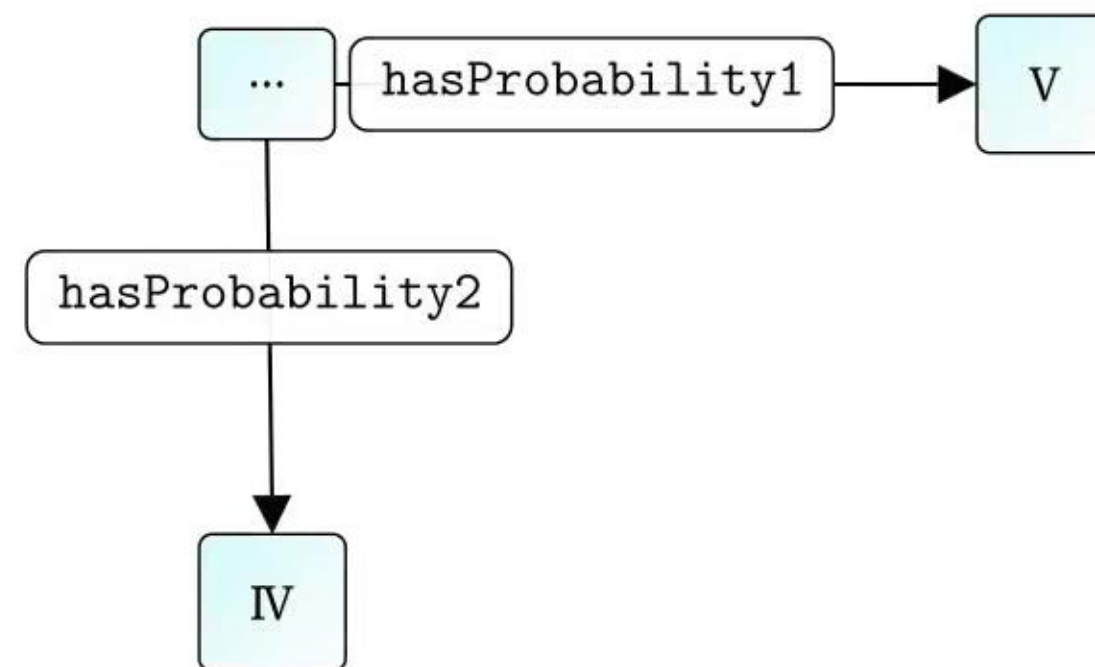
Ontology (TBox)

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

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

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

Data (ABox)



The RISKMAN Ontology: Encoding Rules (3)

According to ISO 14971:

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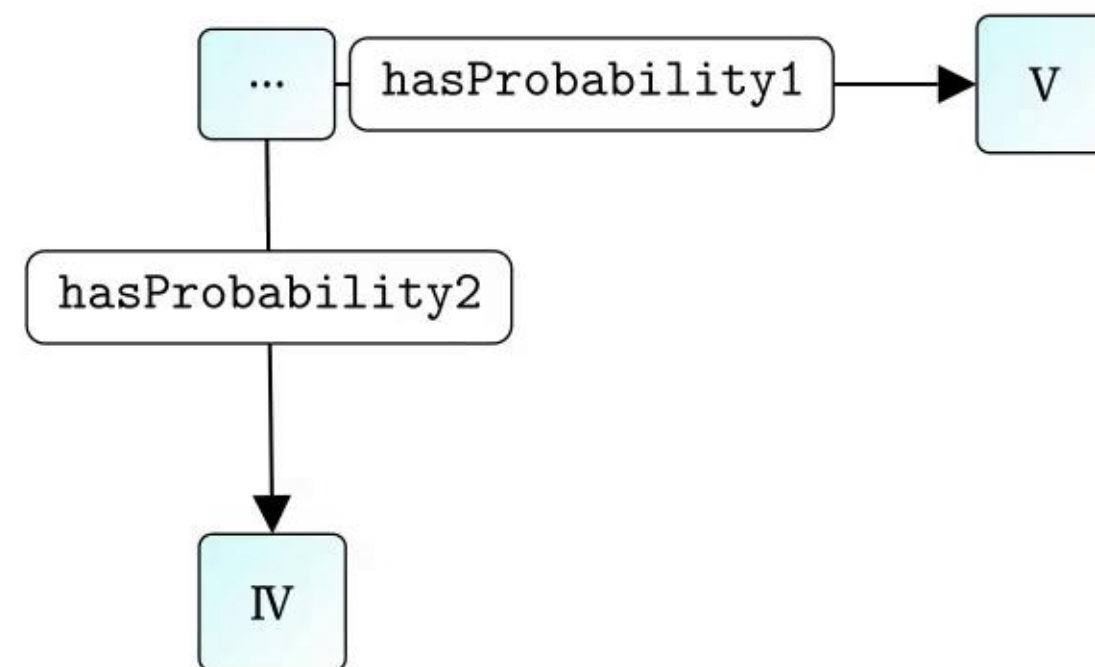
Ontology (TBox)

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

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

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

Data (ABox)



The RISKMAN Ontology: Encoding Rules (3)

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

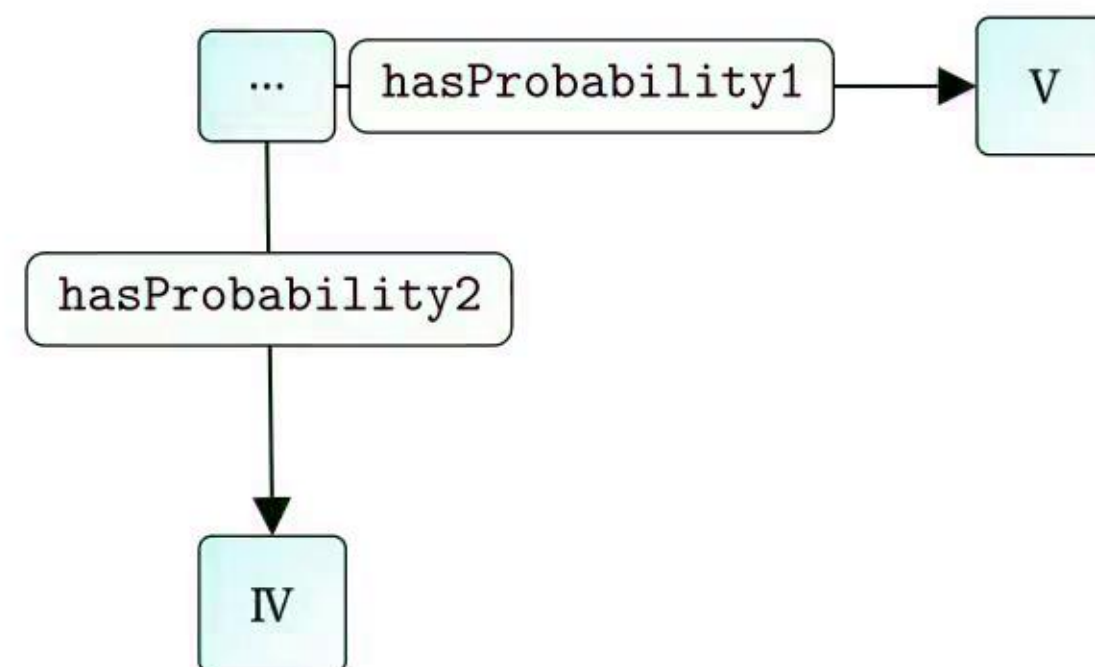
Ontology (TBox)

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

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

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

Data (ABox)



The RISKMAN Ontology: Encoding Rules (3)

According to ISO 14971:

P_1 – probability of a hazardous situation occurring

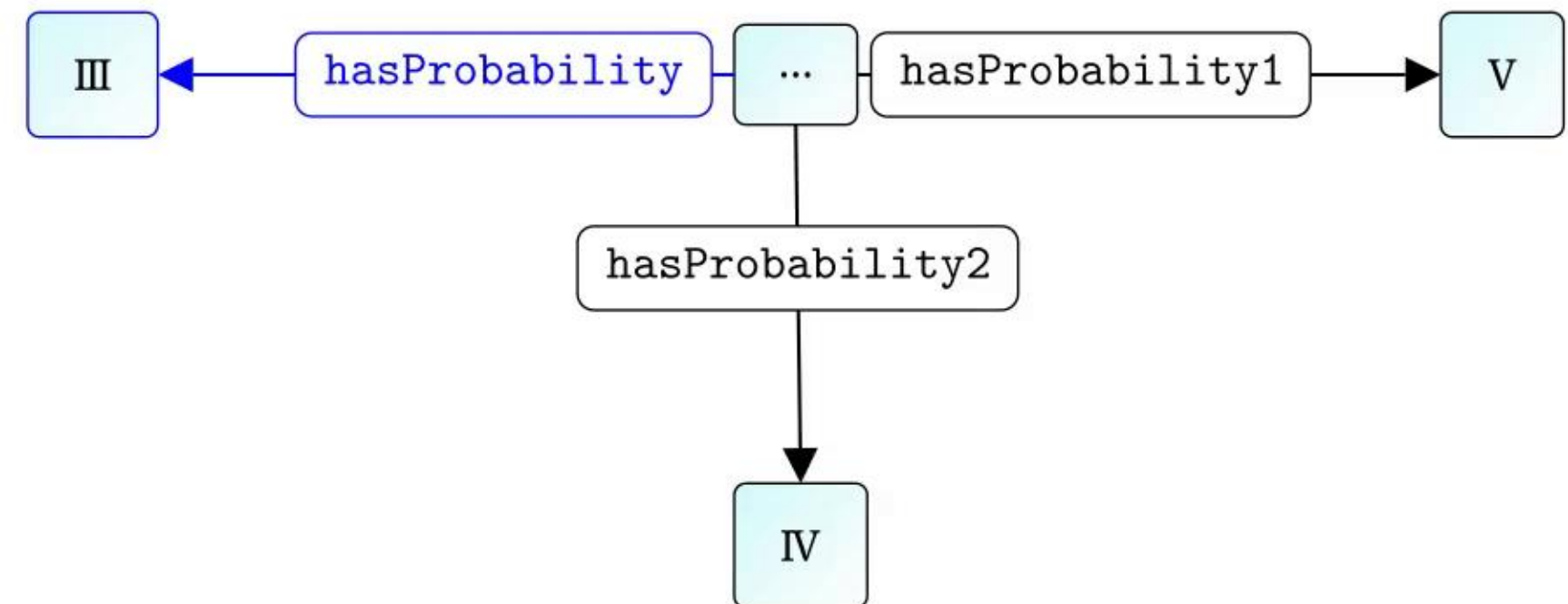
P_2 – probability that the hazardous situation leads to harm

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

Ontology (TBox)

Data (ABox)

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

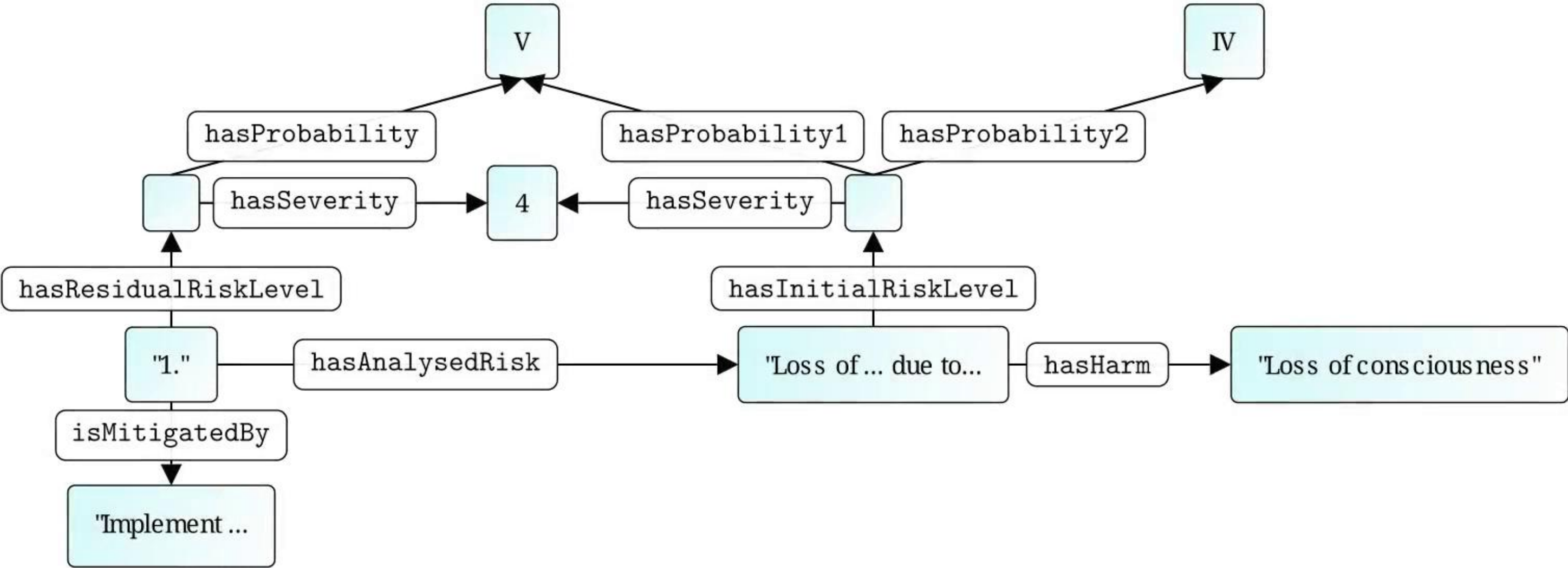


RISKMAN: Reasoning & Validation

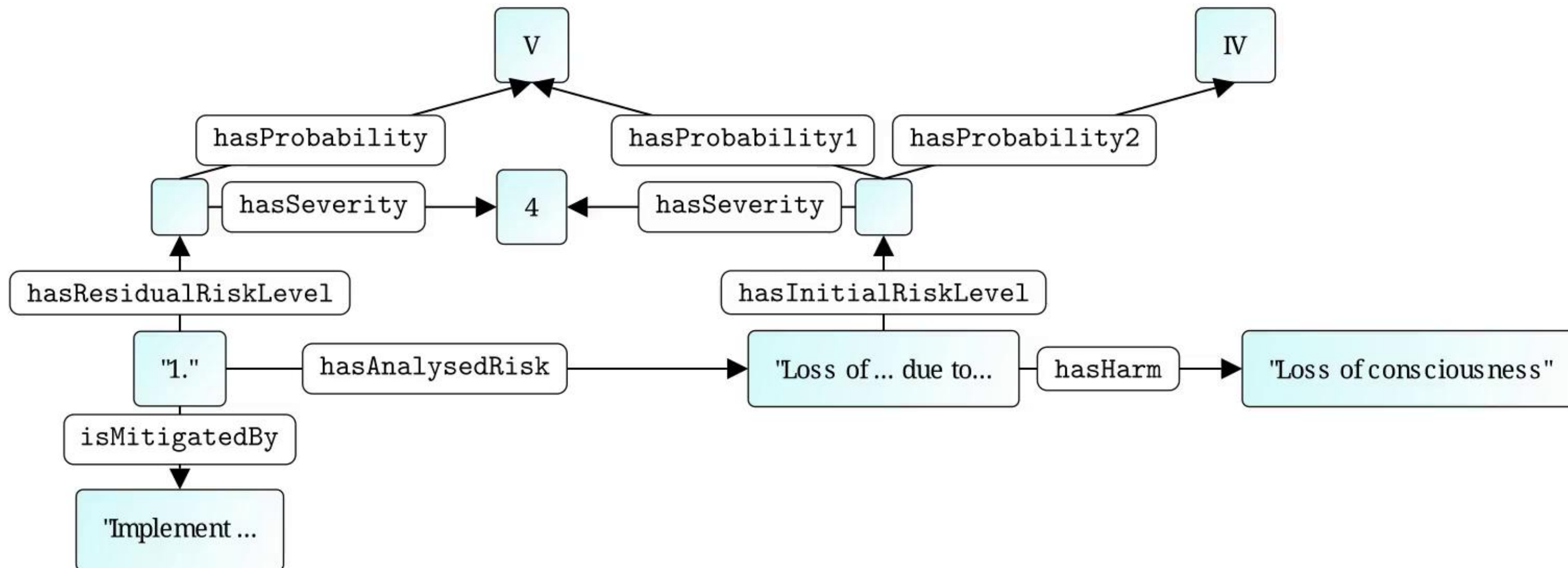
Ctr. risk	Analysed risk	...	Init. P1	Init. P2	Harm	Init. Sev.	Mitigation	Res. P	Res. Sev	...
1.	Loss of consciousness due to an alarm malfunction	...	V	IV	Loss of consciousness	4	Implement an alternative alerting system	V	4	...

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	...

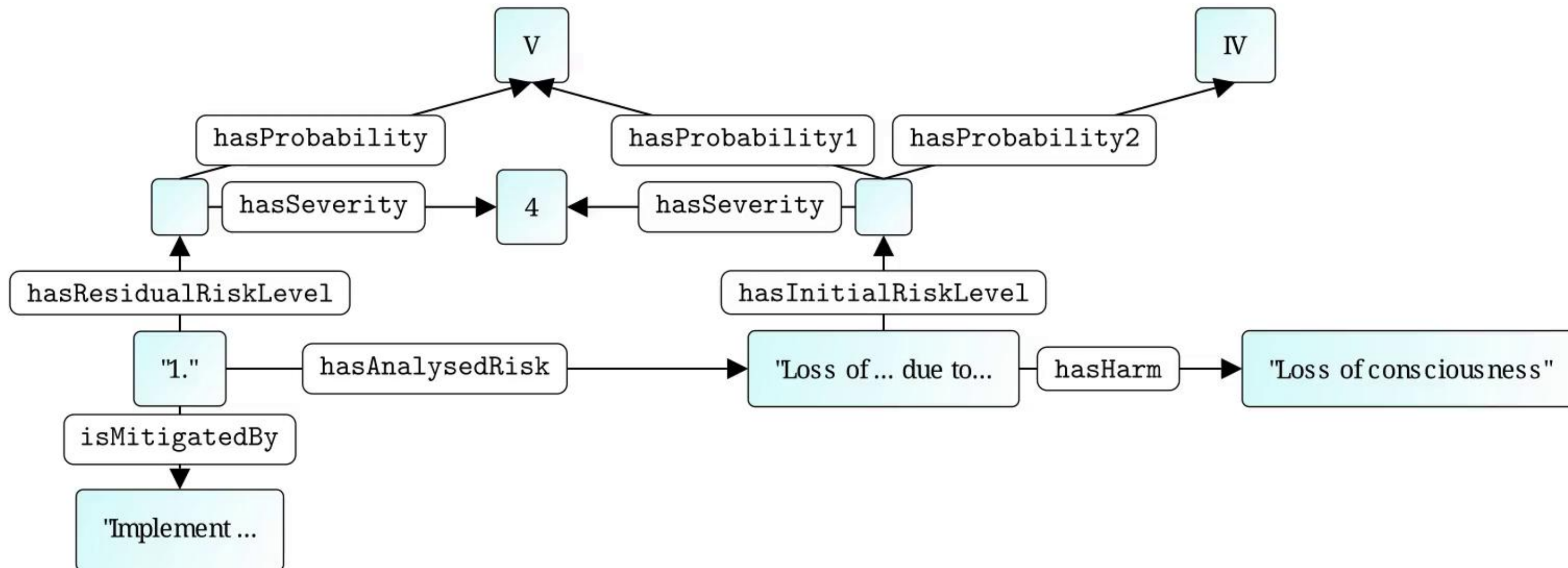


RISKMAN: Reasoning & Validation



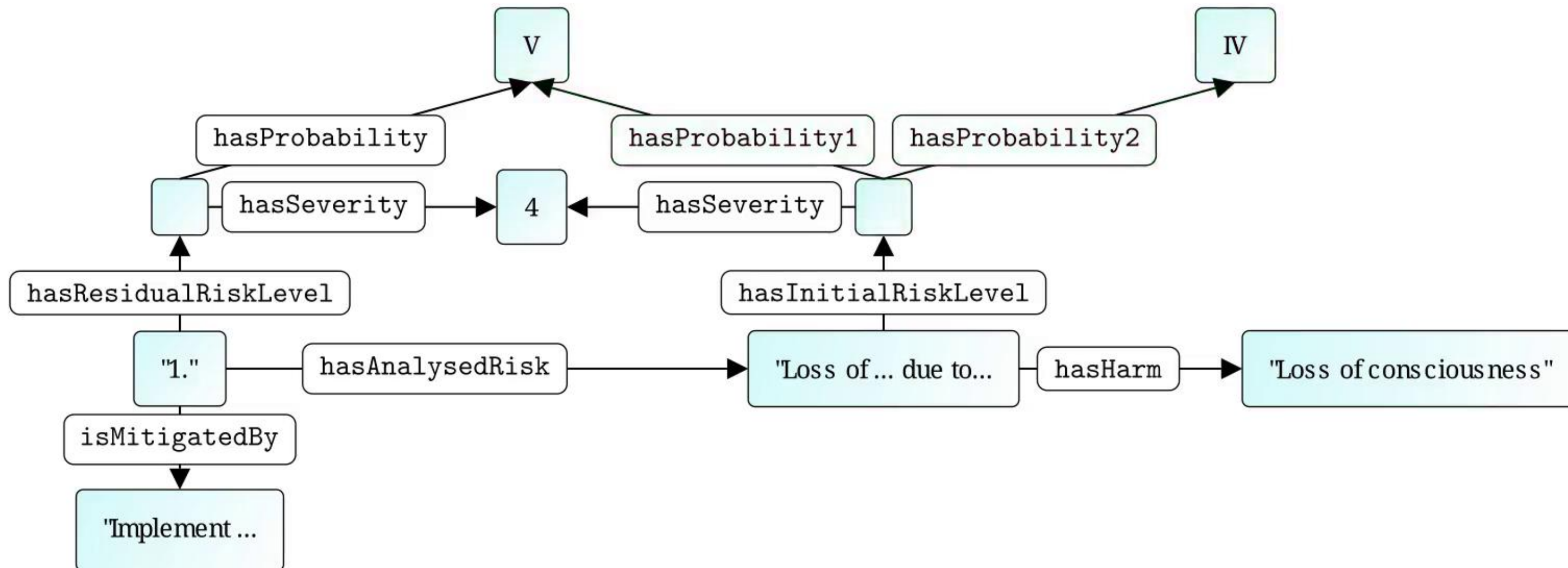
RISKMAN: Reasoning & Validation

$\exists \text{hasProbability1}.\{V\} \sqcap$
 $\exists \text{hasProbability}.\{IV\} \sqsubseteq$
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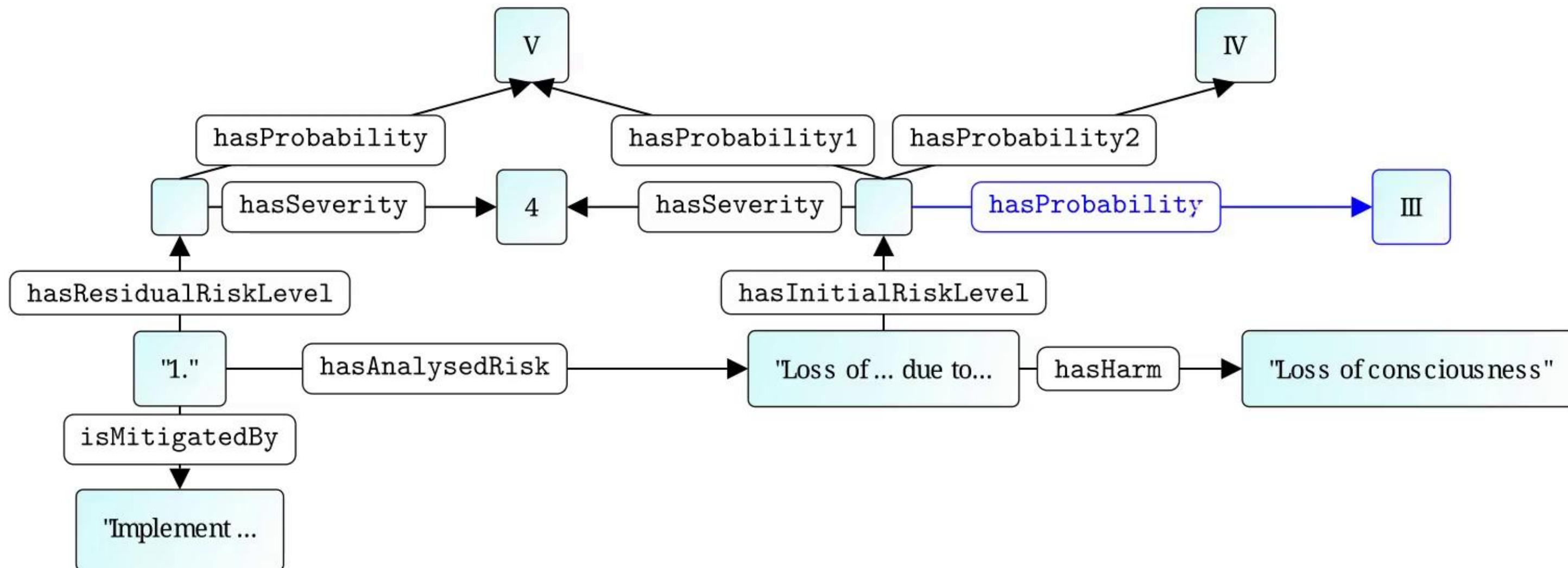
RISKMAN: Reasoning & Validation

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 $\exists \text{hasProbability}.\{IV\} \sqsubseteq$
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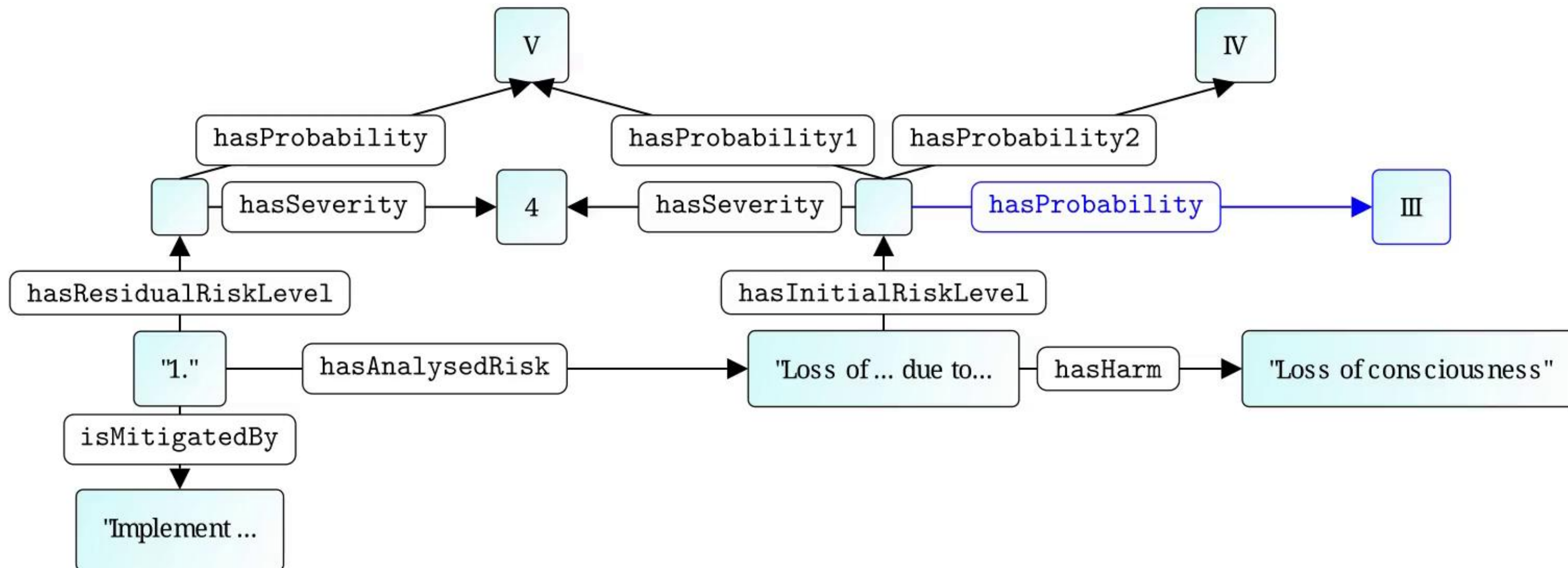
RISKMAN: Reasoning & Validation

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



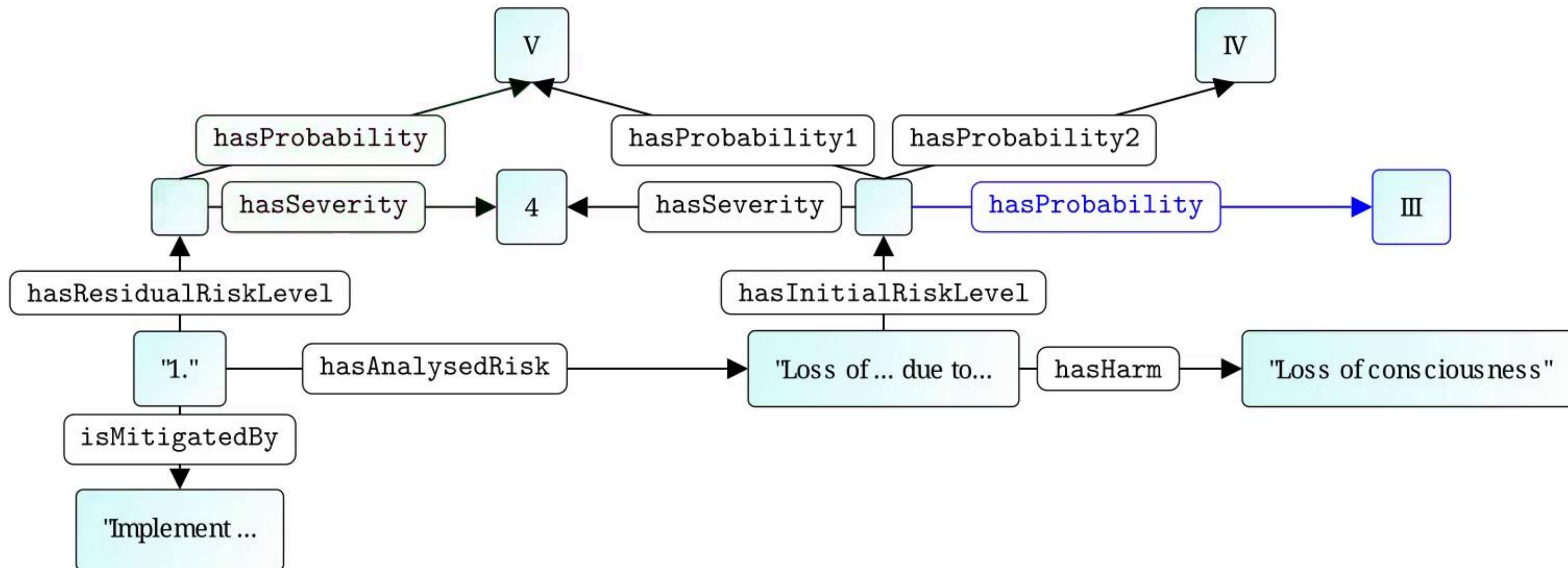
RISKMAN: Reasoning & Validation

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



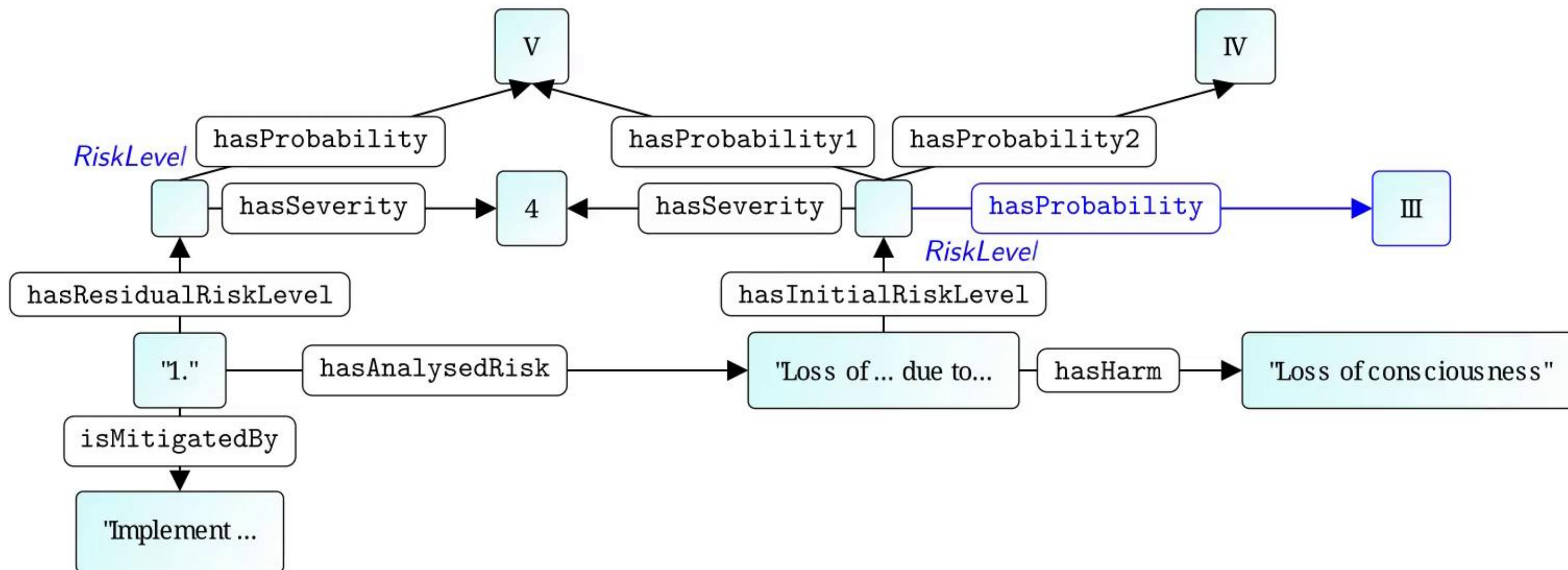
RISKMAN: Reasoning & Validation

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

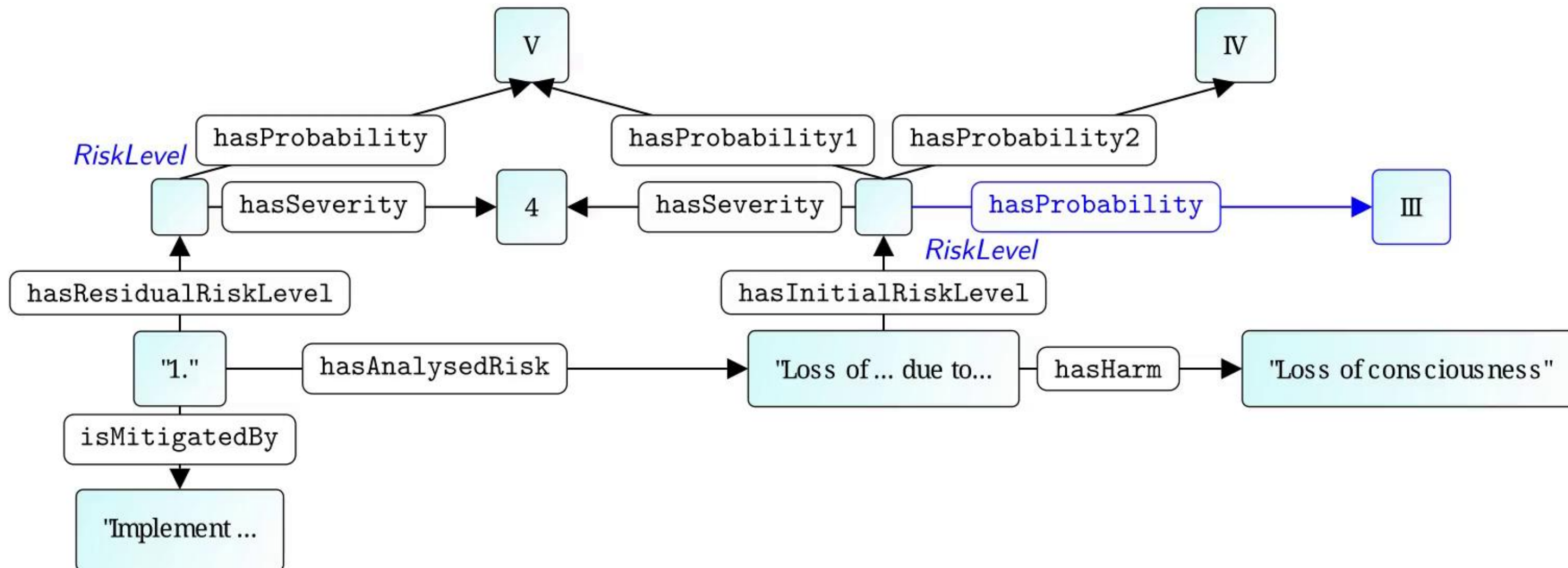


RISKMAN: Reasoning & Validation

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

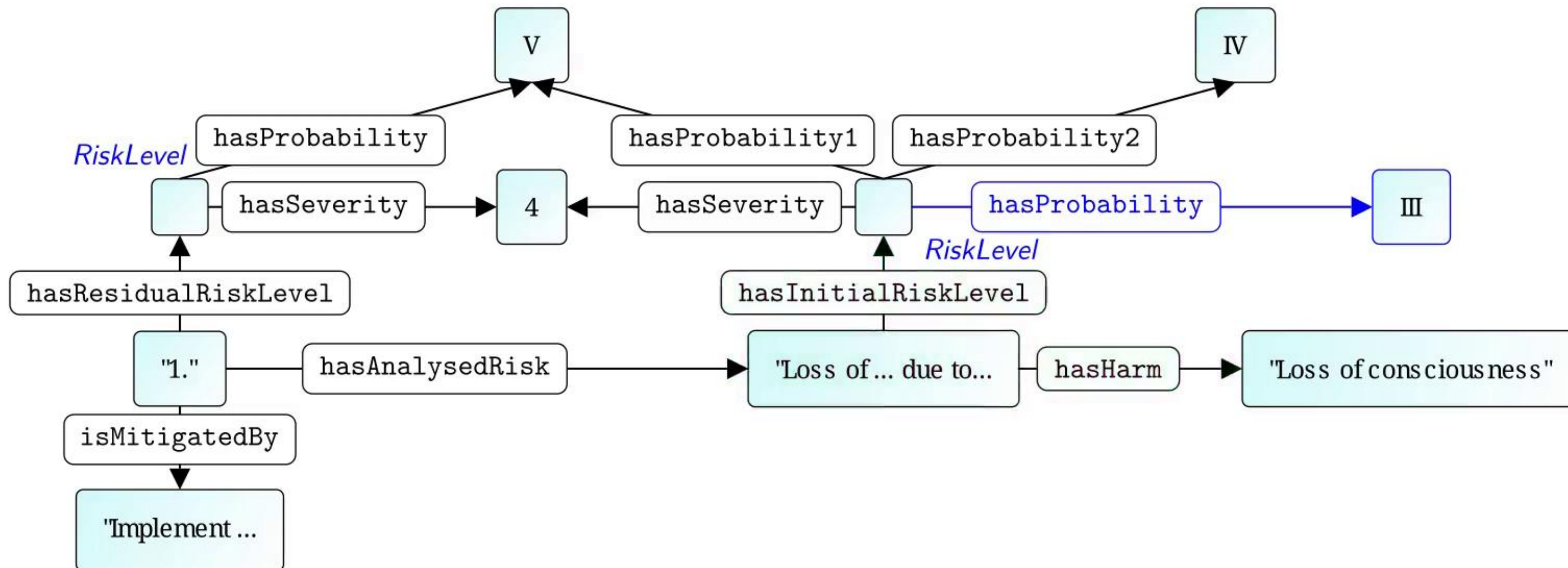


RISKMAN: Reasoning & Validation

$$\begin{aligned} &\exists \text{hasRiskLevel}.\top \sqcap \\ &\exists \text{hasHarm}.\top \sqsubseteq \textit{Risk} \end{aligned}$$


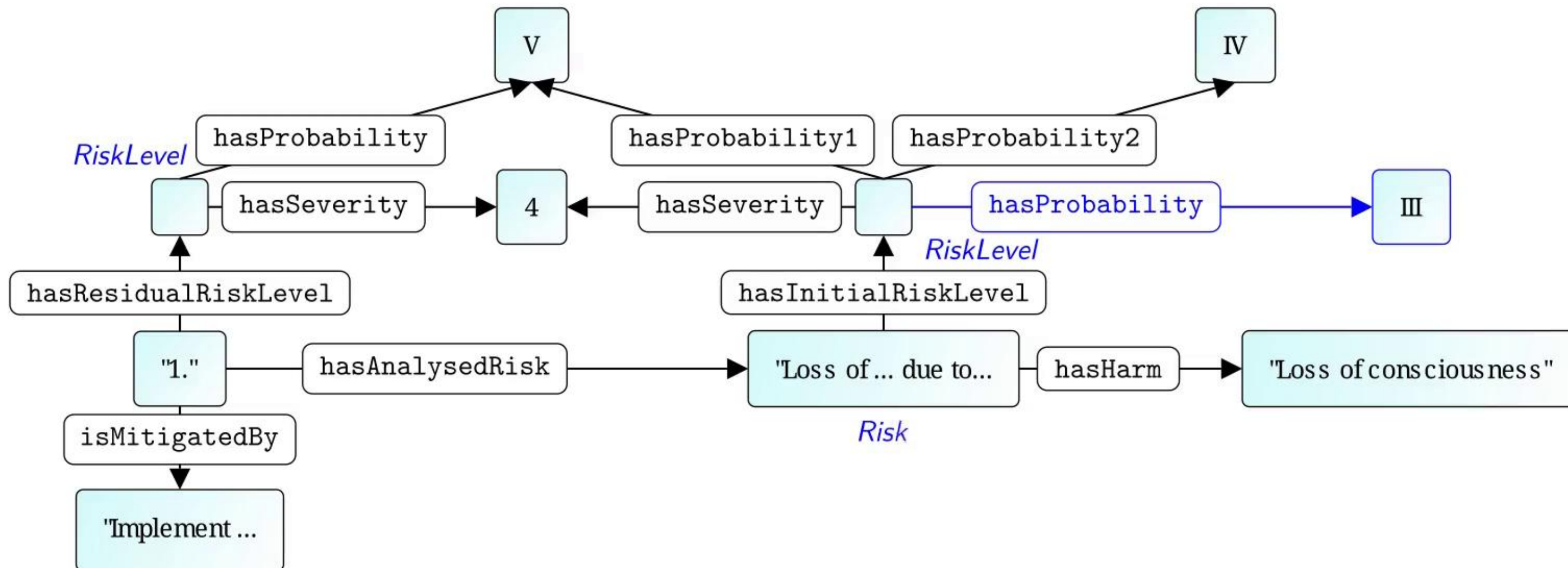
RISKMAN: Reasoning & Validation

$\exists \text{hasRiskLevel}.\top \sqcap$
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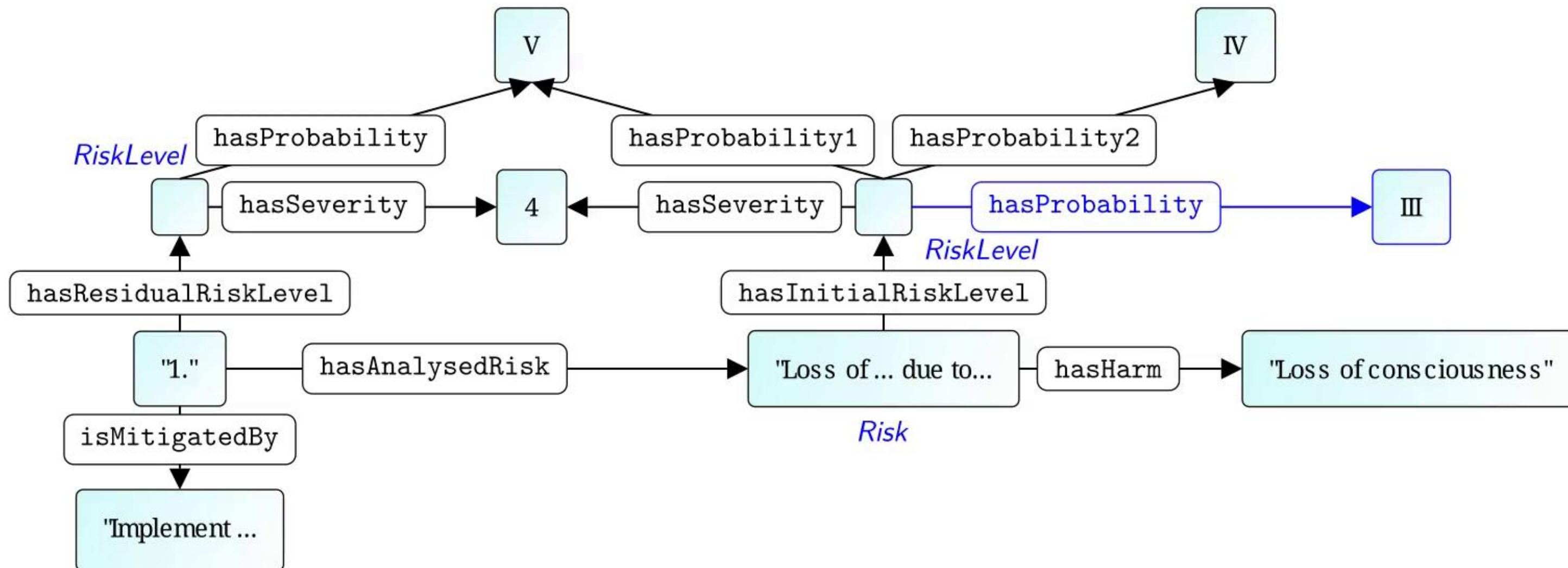


RISKMAN: Reasoning & Validation

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



RISKMAN: Reasoning & Validation

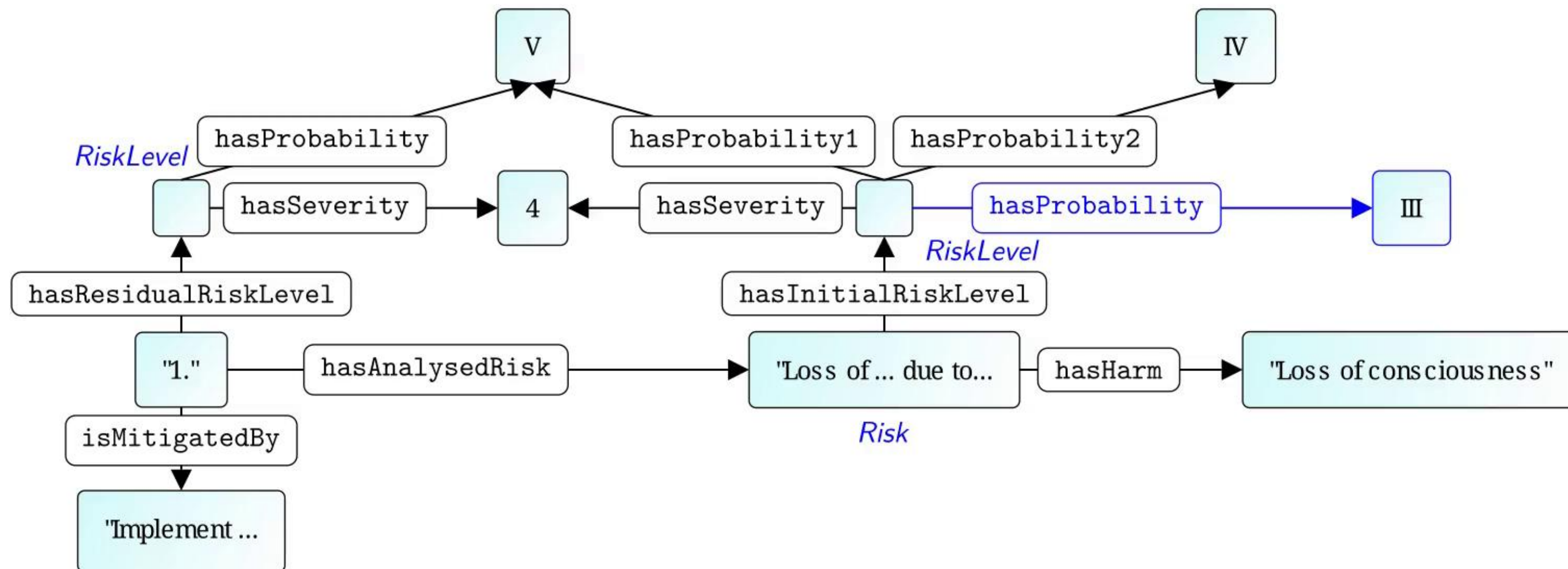


RISKMAN: Reasoning & Validation

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."

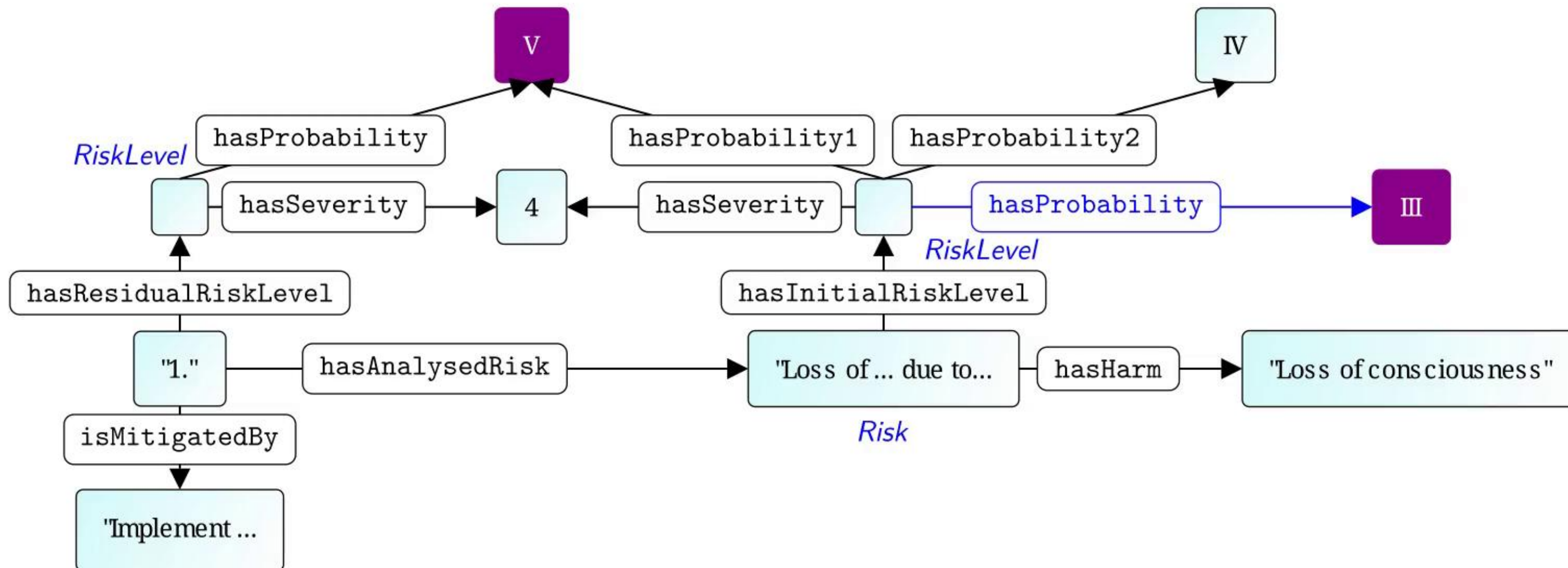


RISKMAN: Reasoning & Validation

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.⊤

"Every controlled risk must be mitigated."

RISKMAN: SHACL Shapes

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

"Every controlled risk must be mitigated."

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

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

RISKMAN: SHACL Shapes

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

$\text{SDA} \Rightarrow \exists \text{hasSubSDA} \cdot \text{hasImplementationManifest}.\top$
"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)



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The RISKMAN Ontology & Shapes: Overview

- formulated in the lightweight OWL EL
- 24 classes
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- 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>

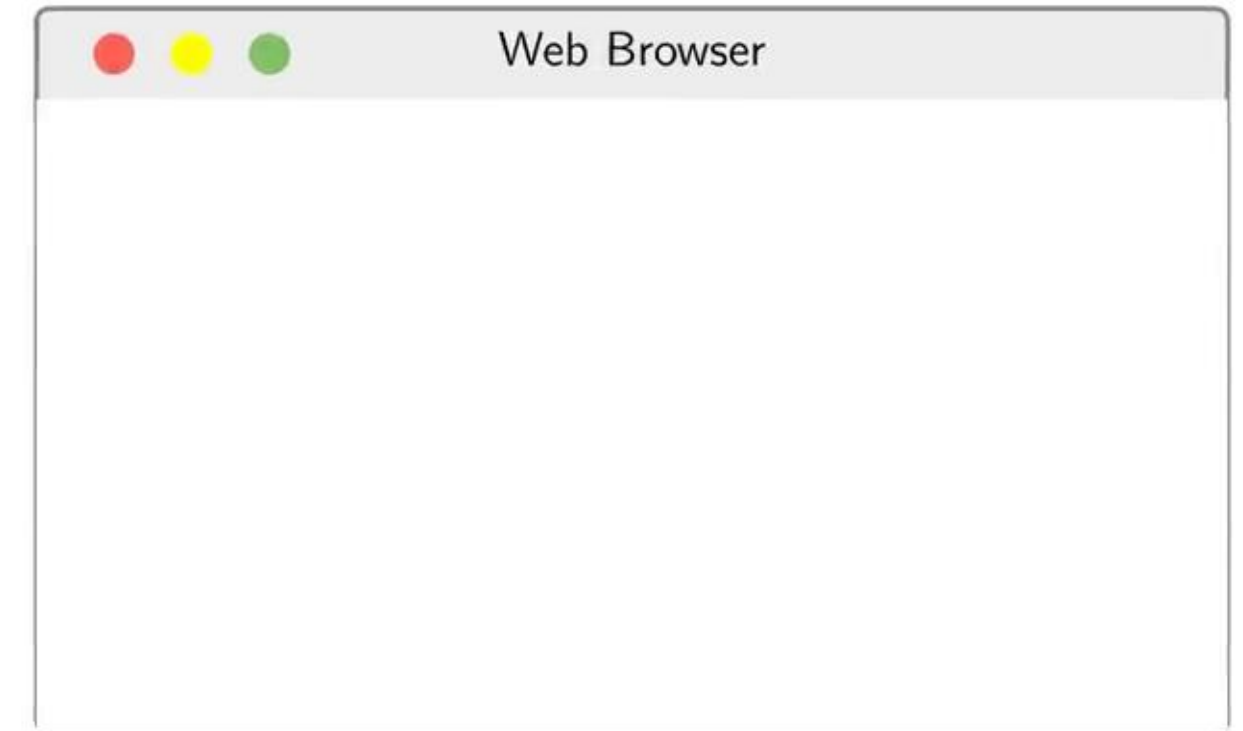


The RISKMAN Ontology: Human Readability

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

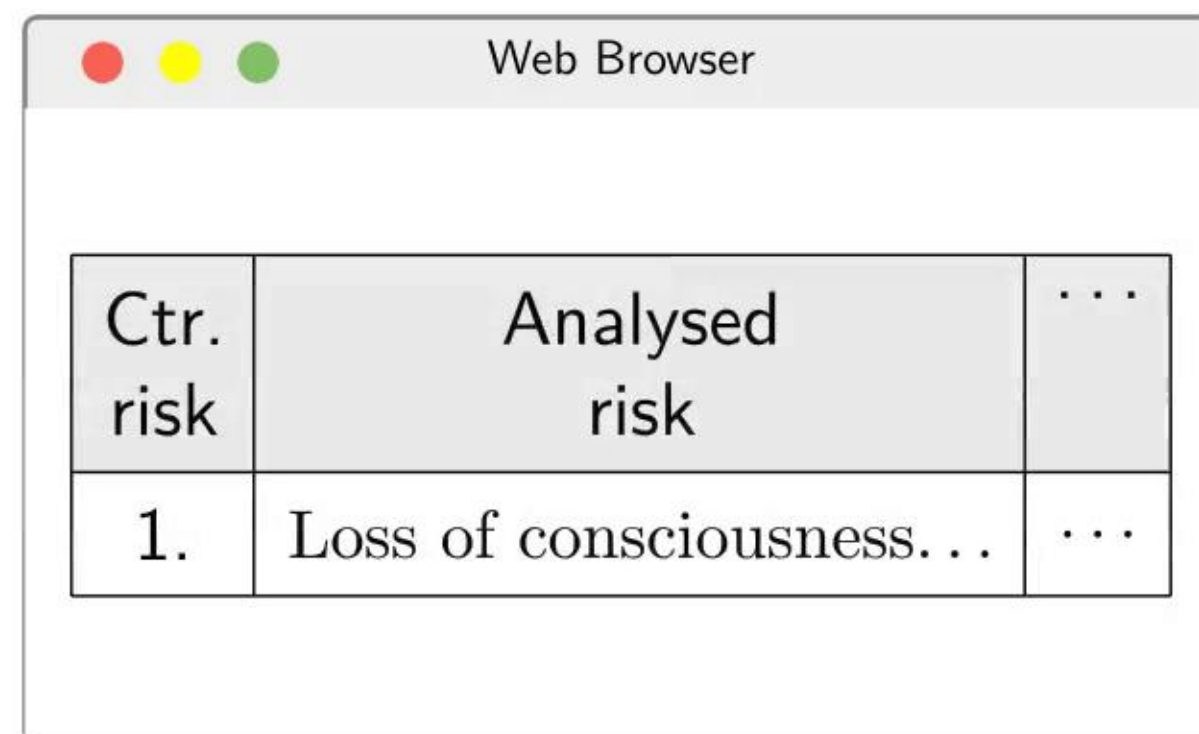
The RISKMAN Ontology: Human Readability

```
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>
```



A web browser window titled "Web Browser" displays a table with three columns: "Ctr. risk", "Analysed risk", and "...". The first row of data shows "1." under "Ctr. risk", "Loss of consciousness..." under "Analysed risk", and "..." under "...".

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>
```

Web Browser		
Ctrl. risk	Analysed risk	...
1.	Loss of consciousness...	...

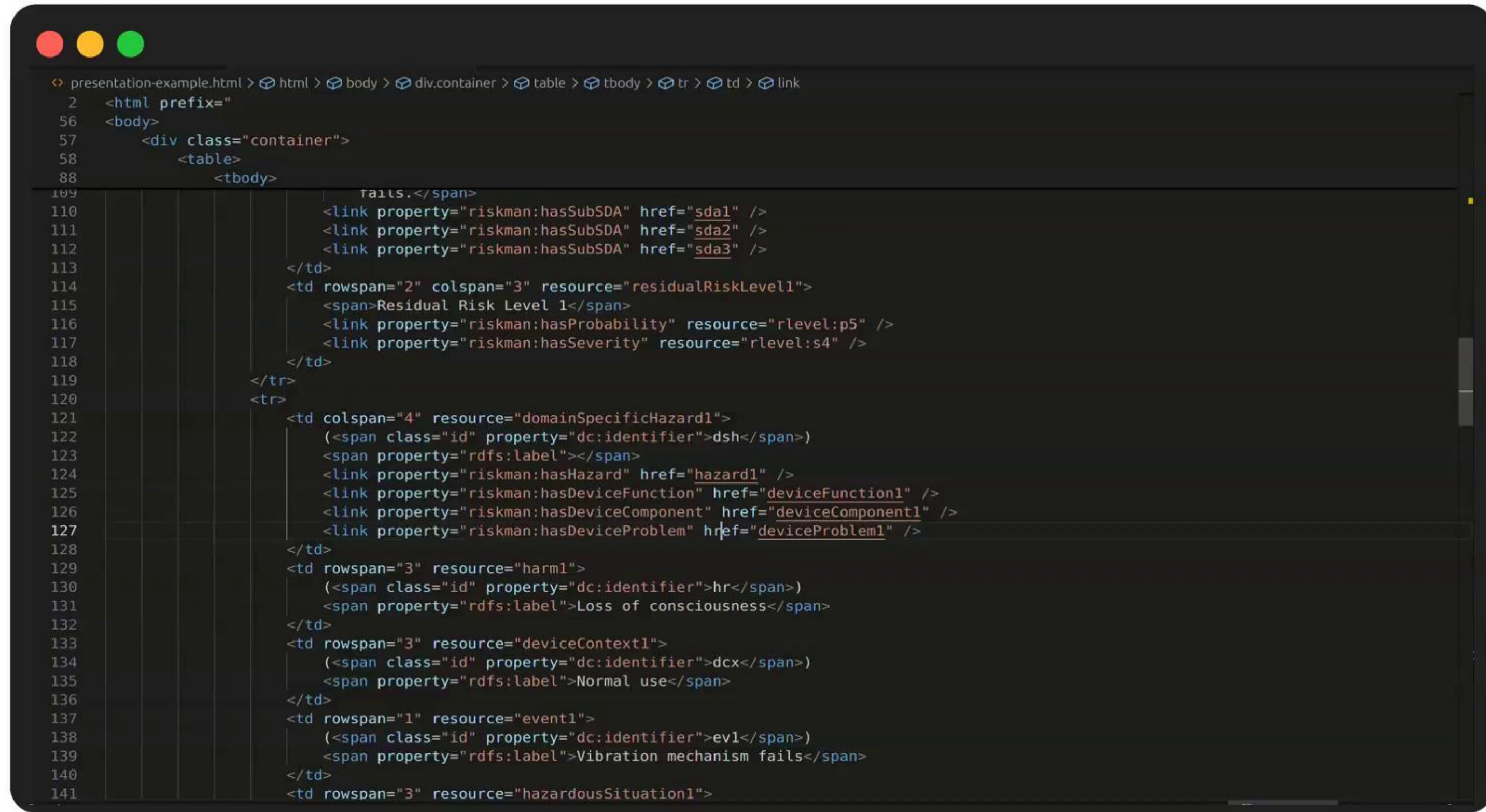
The RISKMAN Ontology: Human Readability

```
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>
```

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

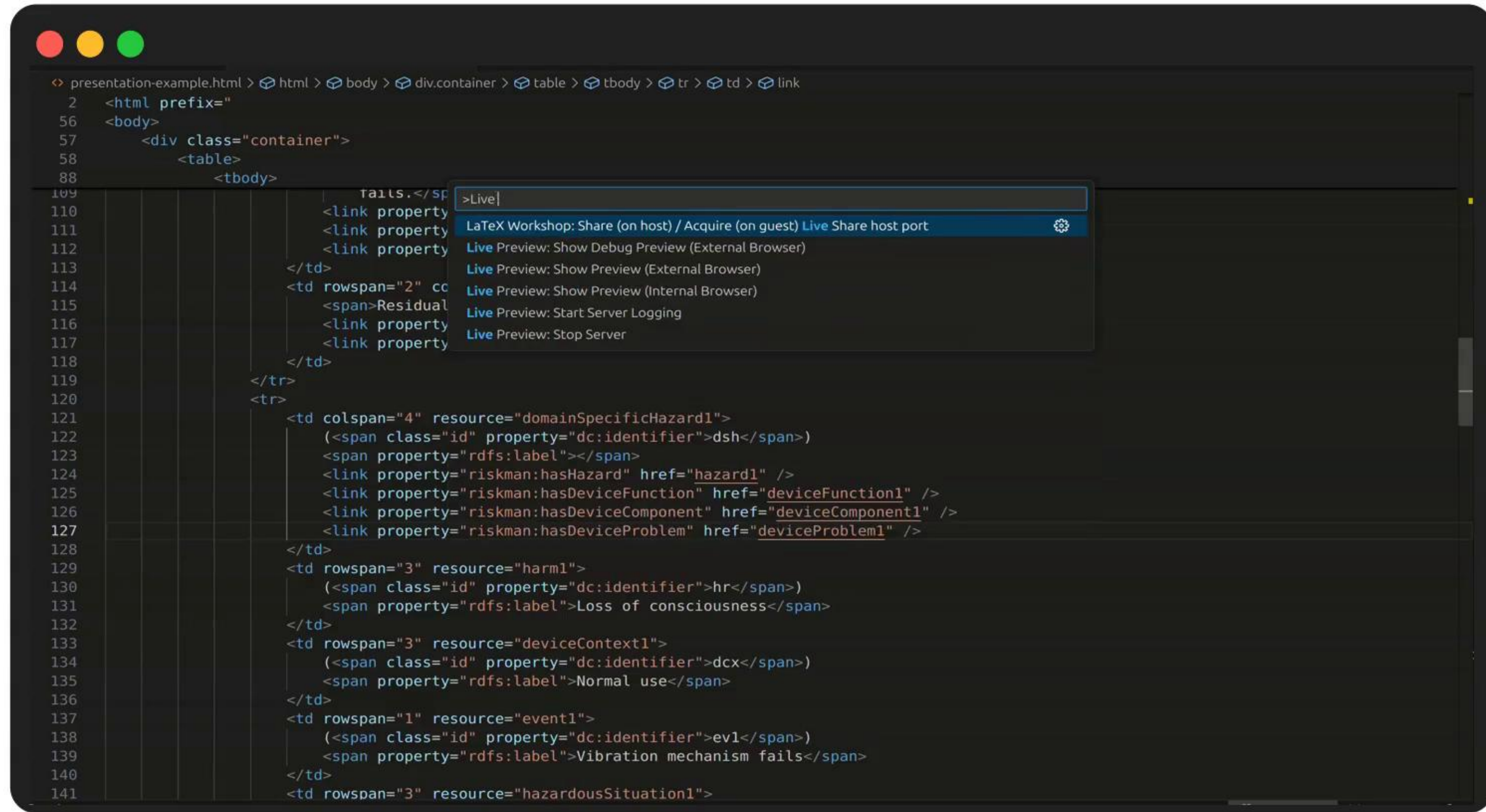
```
1 @prefix : <https://w3id.org/riskman/ontology> .
2 @prefix rdfs: <http://www.w3.org/2000/01/rdf-schema#> .
3
4 :cr1 :hasAnalysedRisk [
5     rdfs:comment "Loss of consciousness..."
6 ] ;
7 ...
8 .
```


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">
110            <span>Failure</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          <td rowspan="3" resource="hazardousSituation1">
```

The RISKMAN Workflow: Demo



The screenshot shows a code editor with a file named 'presentation-example.html'. The breadcrumb navigation at the top indicates the current position: `<html> <body> <div.container> <table> <tbody> <tr> <td> <link>`. The code is an HTML document with a table. A context menu is open over a `<link>` tag, showing options for live preview and server management. The code includes various RDFS and RiskMan properties like `dc:identifier`, `rdfs:label`, `riskman:hasHazard`, `riskman:hasDeviceFunction`, `riskman:hasDeviceComponent`, and `riskman:hasDeviceProblem`.

```
<?xml prefix="
2  <html prefix="
56  <body>
57    <div class="container">
58      <table>
88        <tbody>
109          <tr>
110            <td>
111              <div>
112                <div>
113                  <div>
114                    <div>
115                      <div>
116                        <div>
117                          <div>
118                            <div>
119                              <div>
120                                <div>
121                                  <div>
122                                    <div>
123                                      <div>
124                                        <div>
125                                          <div>
126                                            <div>
127                                              <div>
128                                                <div>
129                                                  <div>
130                                                    <div>
131                                                      <div>
132                                                        <div>
133                                                          <div>
134                                                            <div>
135                                                              <div>
136                                                                <div>
137                                                                  <div>
138                                                                    <div>
139                                                                      <div>
140                                                                        <div>
141                                                                          <div>
```

Live Preview Options:

- >Live|
- LaTeX Workshop: Share (on host) / Acquire (on guest) Live Share host port
- Live Preview: Show Debug Preview (External Browser)
- Live Preview: Show Preview (External Browser)
- Live Preview: Show Preview (Internal Browser)
- Live Preview: Start Server Logging
- Live Preview: Stop Server

The RISKMAN Workflow: Demo

resentation-example.html > html > body > div.container > table > tbody > tr > td > span

2

<html prefix="

56

<body>

57

<div class="container">

58

<table>

88

<tbody>

111

<link property="riskman:hasSubSDA"

112

<link property="riskman:hasSubSDA"

113

</td>

114

<td rowspan="2" colspan="3"

115

Residual Risk Level 1

116

<link property="riskman:hasProbability"

117

<link property="riskman:hasSeverity"

118

</td>

119

</tr>

120

<tr>

121

<td colspan="4" resource="domainSpecificHazard1">

122

(<span class="id"

123

property="dc:identifier">dsh)

124

125

<link property="riskman:hasHazard"

126

<link property="riskman:hasDeviceFunction"

127

<link property="riskman:hasDeviceComponent"

128

<link property="riskman:hasDeviceProblem"

129

</td>

130

<td rowspan="3" resource="harm1">

<span class="id"

property="dc:identifier">hr

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.	
(cr)	(ar) Loss of consciousness due to an alarm malfunction									
	(dsh)				(hr) Loss of consciousness	(dcx) Normal use	(ev1) Vibration mechanism fails	(hs) No insulin delivered	Initial Risk Level 1	
	(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

presentation-example.html > html > body > div.container > table > tbody > tr > td > span

2

<html prefix="

56

<body>

57

<div class="container">

58

<table>

88

<tbody>

111

<link property="riskman:hasSubSDA"

112

<link property="riskman:hasSubSDA"

113

</td>

114

<td rowspan="2" colspan="3"

115

Residual Risk Level 1

116

<link property="riskman:hasProbability"

117

<link property="riskman:hasSeverity"

118

</td>

119

</tr>

120

<tr>

121

<td colspan="4" resource="domainSpecificHazard1">

122

<span class="id"

123

Non-audio

124

<link property="riskman:hasHazard"

125

<link property="riskman:hasDeviceFunction"

126

<link property="riskman:hasDeviceComponent"

127

<link property="riskman:hasDeviceProblem"

128

</td>

129

<td rowspan="3" resource="harm1">

130

<span class="id"

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

Controlled Risk										
Analyzed Risk				Harm	Device Context	Event	Hazardous Situation	Initial Risk Level		
Domain Specific Hazard								Prob.	Sev.	
Hazard	Function	Component	Problem							
(ar) Loss of consciousness due to an alarm malfunction										(sd0) mechan
(dsh) Non-audi						(ev1) Vibration mechanism fails		Initial Risk Level 1		(sd1) Additiona visual (blinking signal.
(cr) (hz) Non-audio alarm malfunctions	(df) Alarm	(dcm) Non-audio alarm	(dp) Defecitve 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 Alar report.

Connecting to webview...

The RISKMAN Workflow: Demo

resentation-example.html > html > body > div.container > table > tbody > tr > td > span

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<html prefix="

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<body>

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111

<link property="riskman:hasSubSDA"

112

<link property="riskman:hasSubSDA"

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Residual Risk Level 1

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<link property="riskman:hasProbability"

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<link property="riskman:hasSeverity"

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</td>

119

</tr>

120

<tr>

121

<td colspan="4" resource="domainSpecificHazard1">

122

<span class="id"

123

Non-audio

124

<link property="riskman:hasHazard"

125

<link property="riskman:hasDeviceFunction"

126

<link property="riskman:hasDeviceComponent"

127

<link property="riskman:hasDeviceProblem"

128

</td>

129

<td rowspan="3" resource="harm1">

130

<span class="id"

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.	
(cr)	(ar) Loss of consciousness due to an alarm malfunction									
	(dsh) Non-audio				(hr) Loss of consciousness	(dcx) Normal use	(ev1) Vibration mechanism fails	(hs) No insulin delivered	Initial Risk Level 1	
	(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

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56

<body>

57

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58

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88

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114

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Residual Risk Level 1

116

<link property="riskman:hasProbability"

117

<link property="riskman:hasSeverity"

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119

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120

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121

<td colspan="4" resource="domainSpecificHazard1">

122

<span class="id"

123

Non-audio alarm

124

<link property="riskman:hasHazard"

125

<link property="riskman:hasDeviceFunction"

126

<link property="riskman:hasDeviceComponent"

127

<link property="riskman:hasDeviceProblem"

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129

<td rowspan="3" resource="harm1">

130

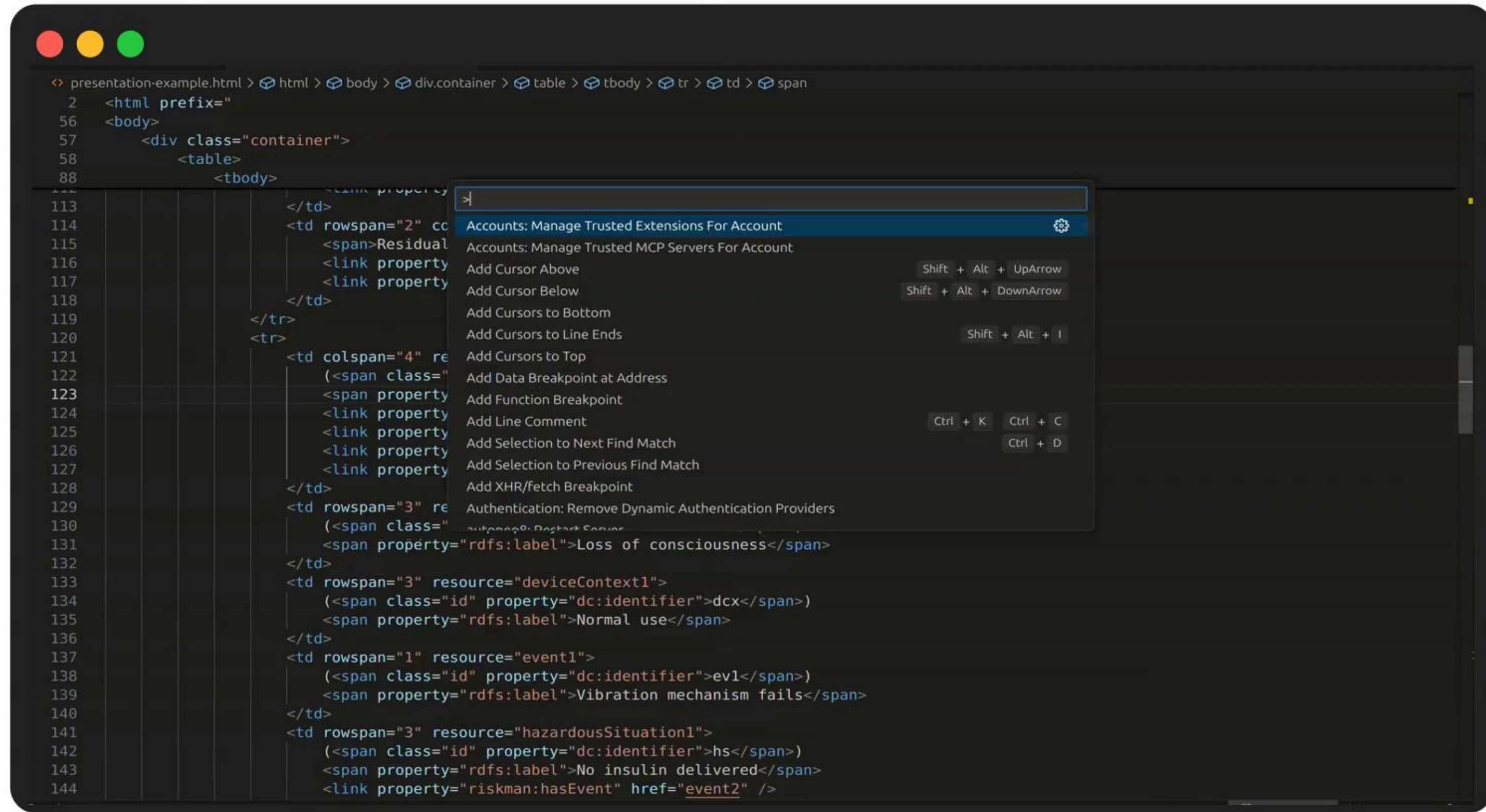
<span class="id"

← → ↺ http://127.0.0.1:3000/presentation-example.html

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

Please reopen the preview.

The RISKMAN Workflow: Demo



The RISKMAN Workflow: Demo



The RISKMAN Workflow: Demo



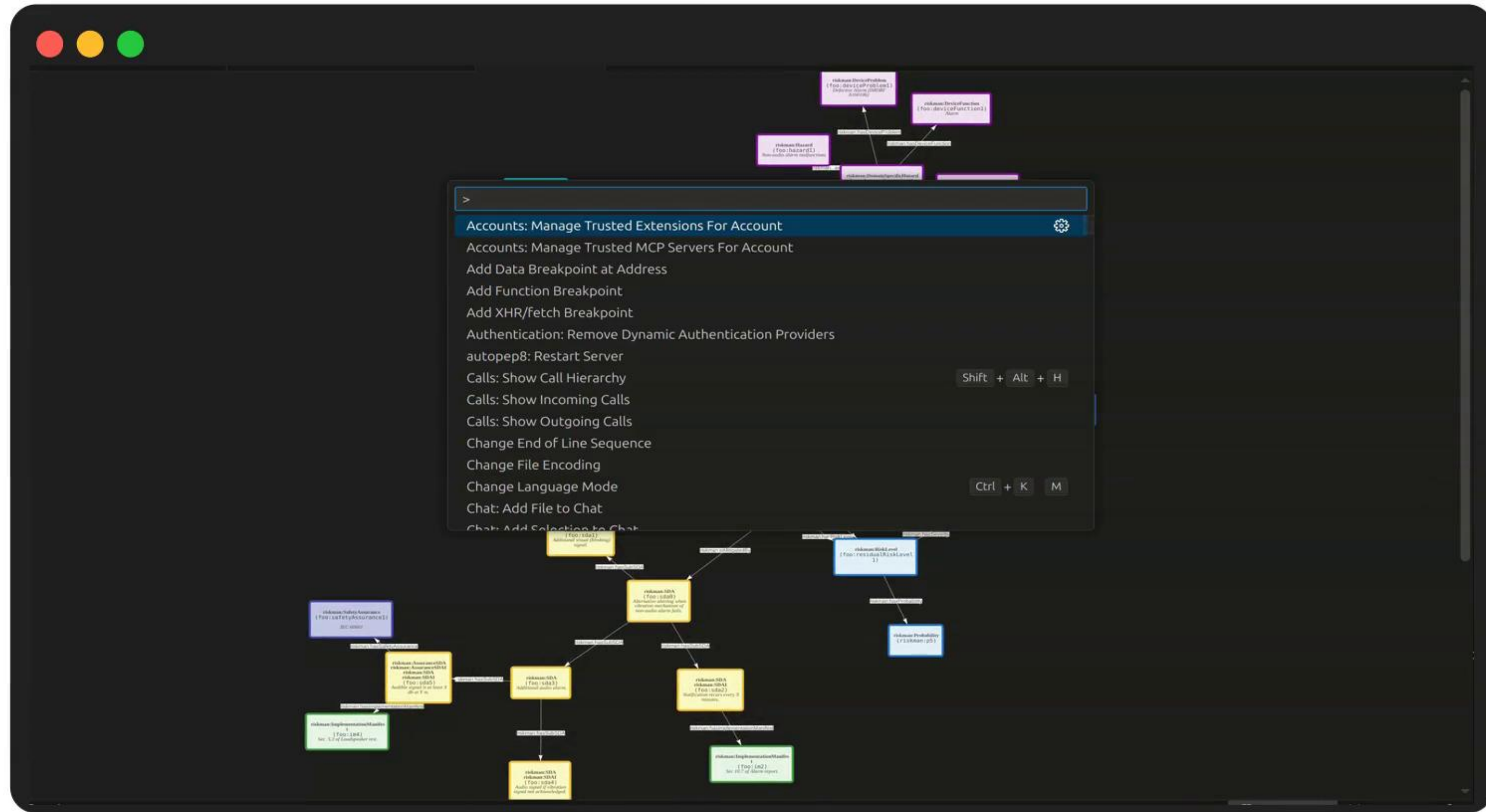
The RISKMAN Workflow: Demo



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The RISKMAN Workflow: Demo



The RISKMAN Workflow: Demo



The RISKMAN Workflow: Demo



Wrap-up

Conclusions



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Riskman: OWL EL ontology + SHACL constraints



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Digitization: RMFs encoded as a RDFa files



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