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

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SEMANTiCS 2025, Vienna – 4th September 2025

TECHNISCHE UNIVERSITÄT DRESDEN

KIMEDS

International Center for Computational Logic

With funding from the:

Federal Ministry of Research, Technology and Space

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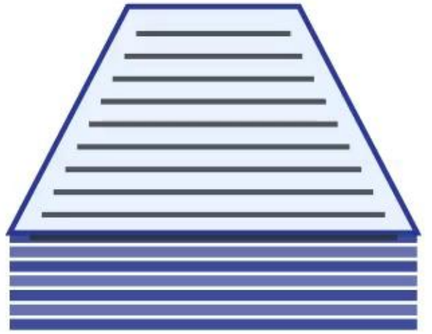
Assumption: RMFs should be digitized



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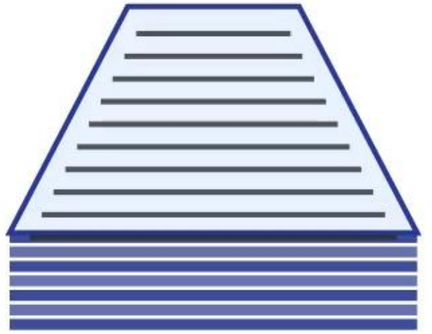

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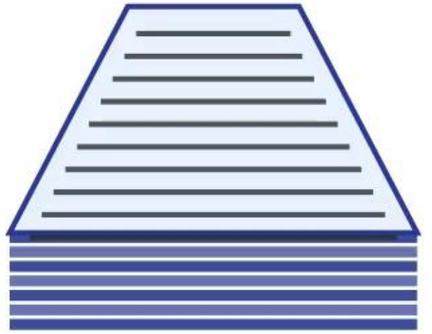

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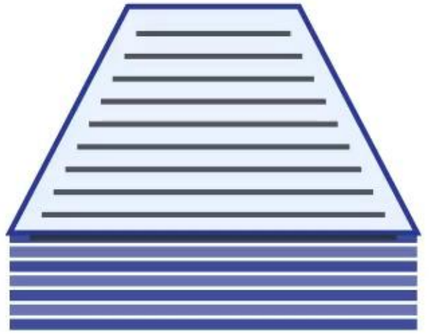

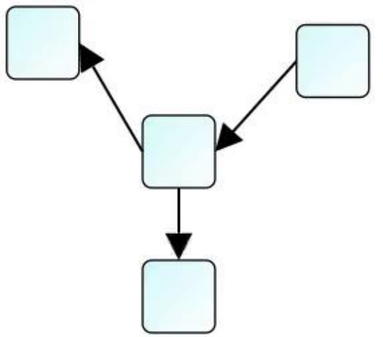

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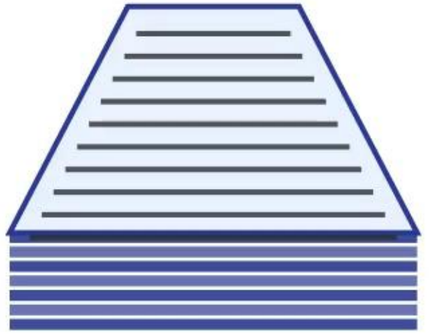

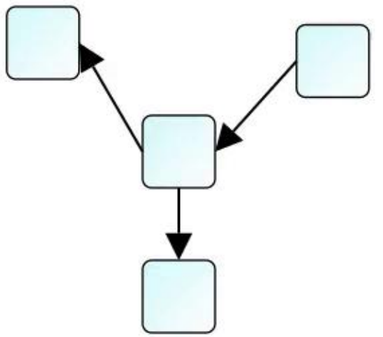

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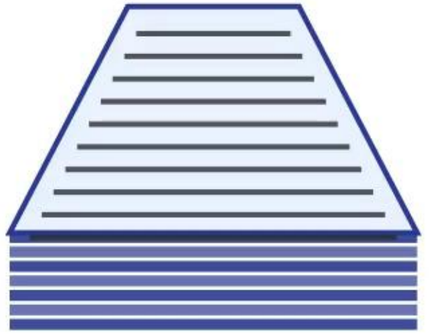

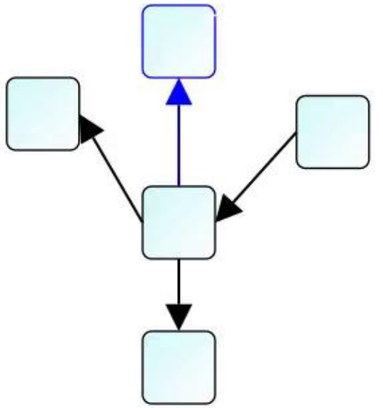

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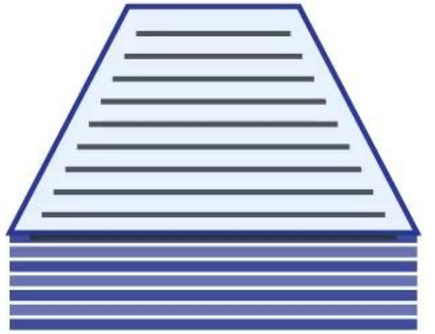

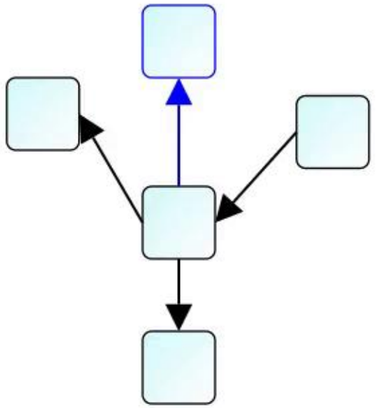

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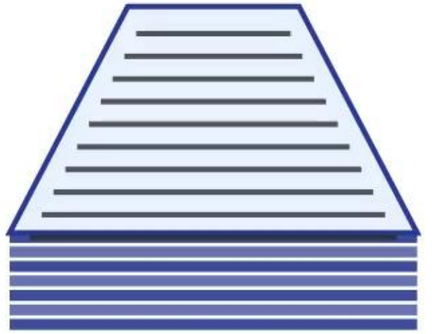

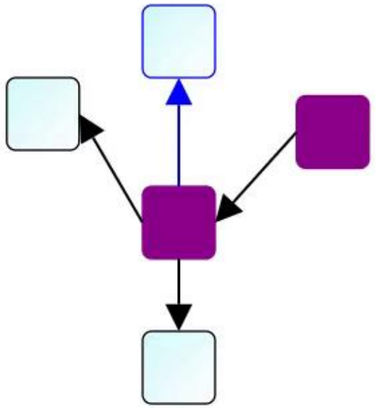

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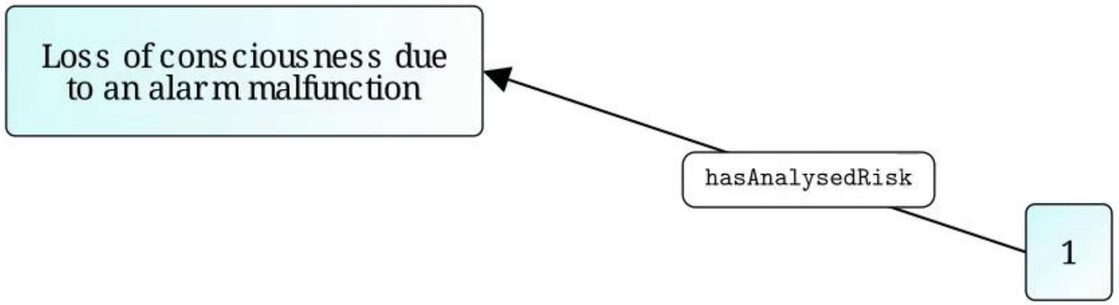

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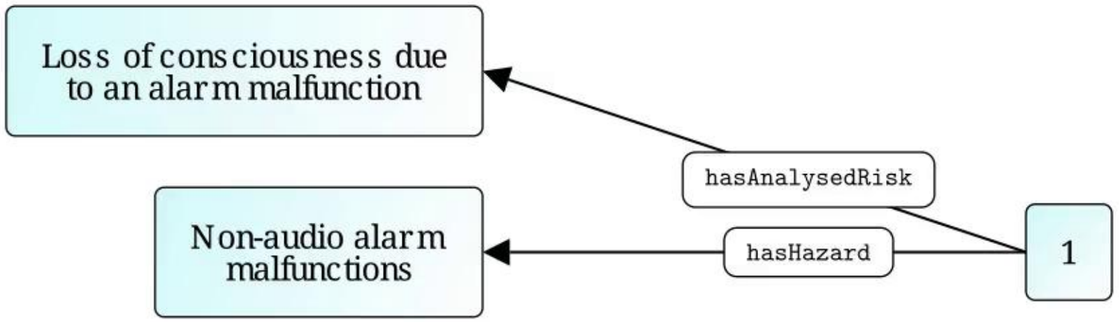

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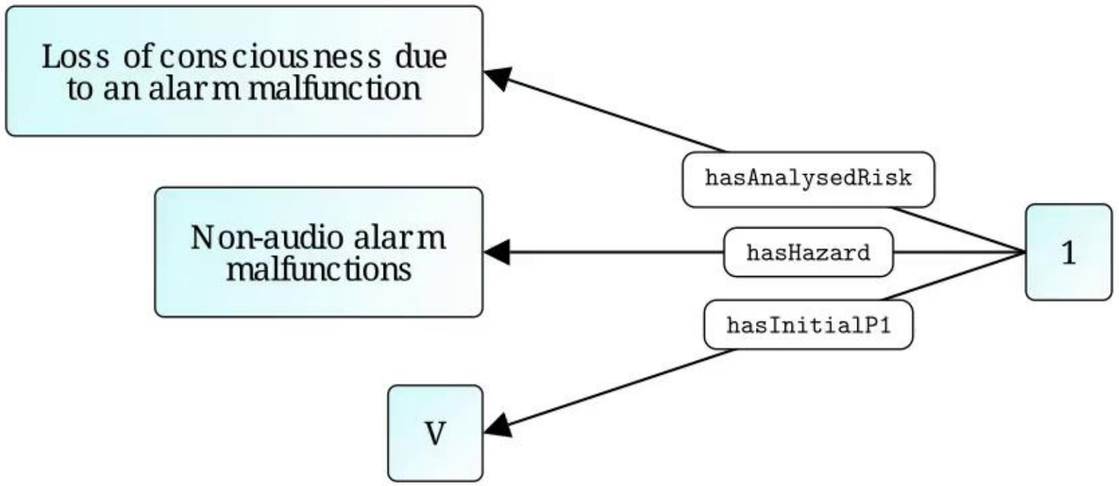

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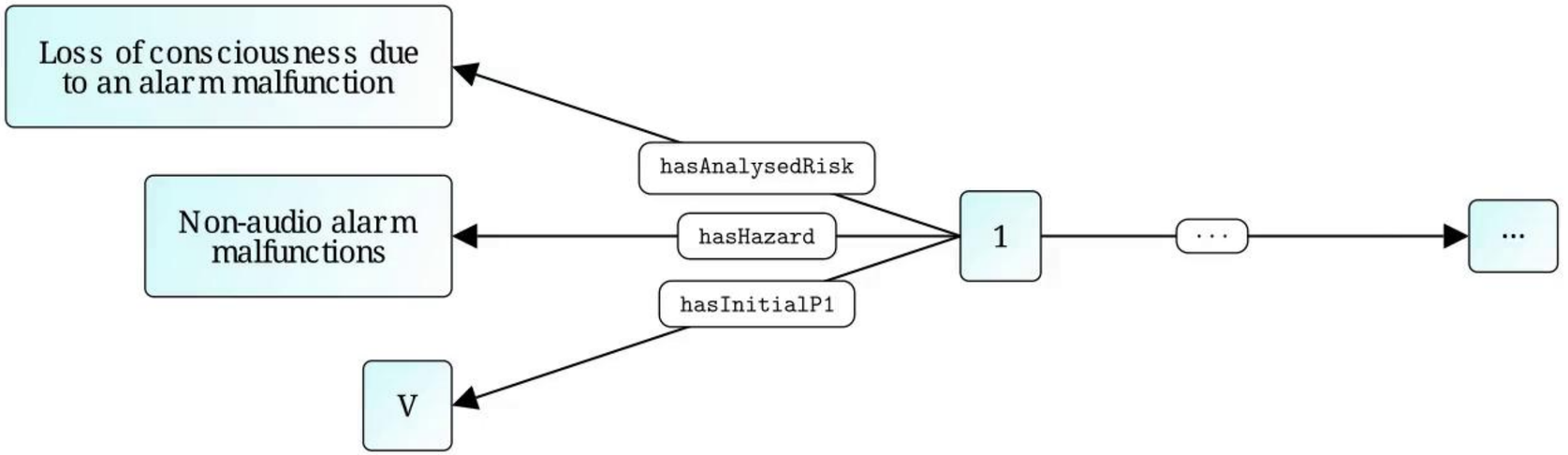

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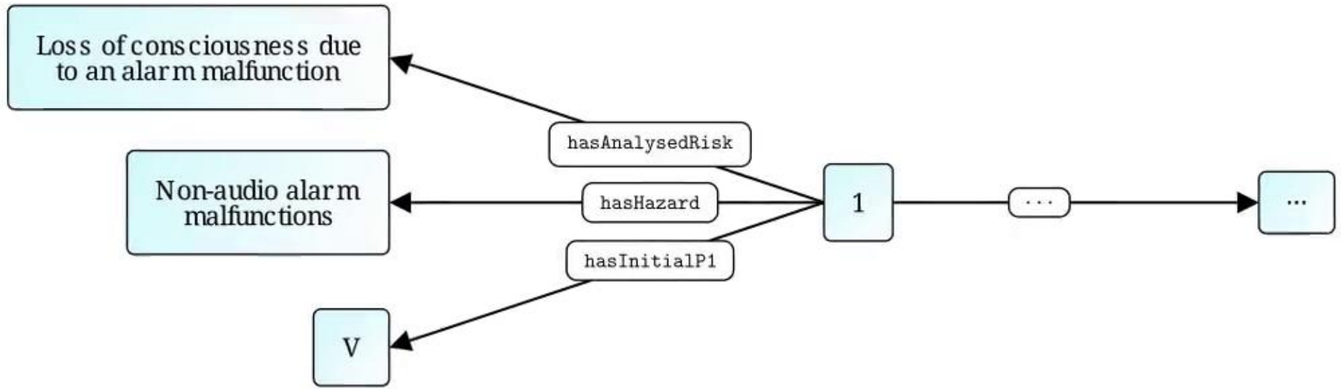

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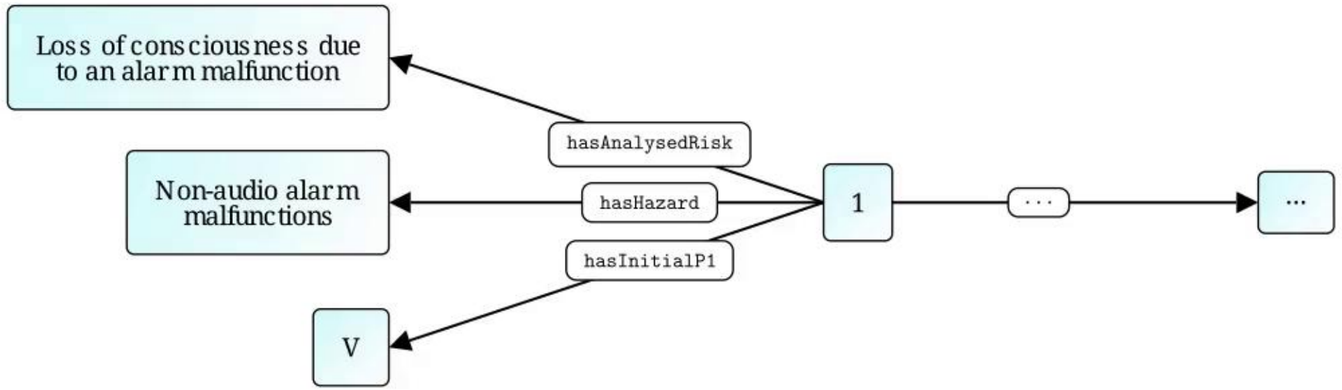


```
@prefix : <https://w3id.org/riskman/ontology> .
@prefix rdfs: <http://www.w3.org/2000/01/rdf-schema#> .


_:1 :hasAnalysedRisk [
        rdfs:comment "Loss of consciousness..."
    ] ;
    :hasHazard [
        rdfs:comment "Non-audio alarm..."

    ] ;
    :hasInitialP1 :II ;
    ...
.
```

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Combination of probability and severity.

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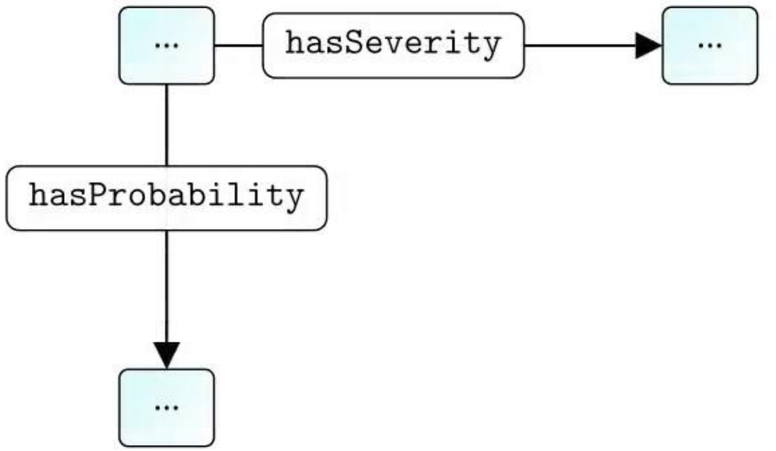

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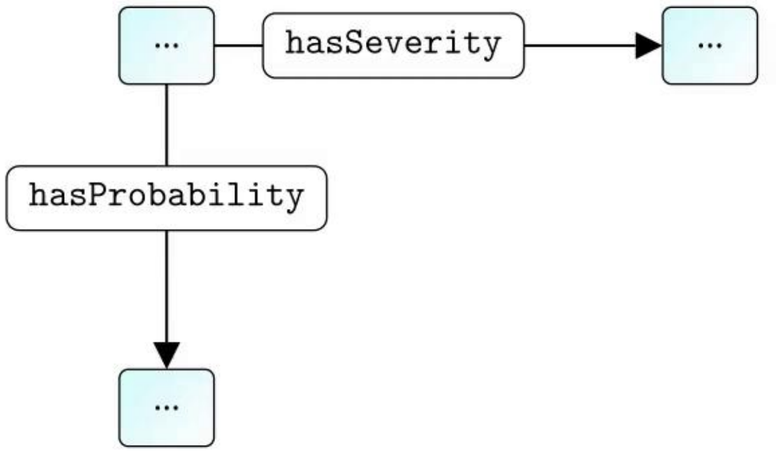

The RISKMAN Ontology: Encoding Rules (1)

risk level

Combination of probability and severity.

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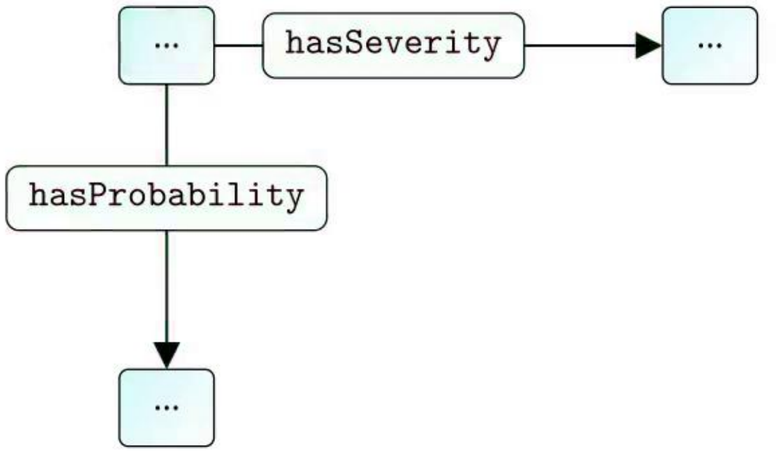

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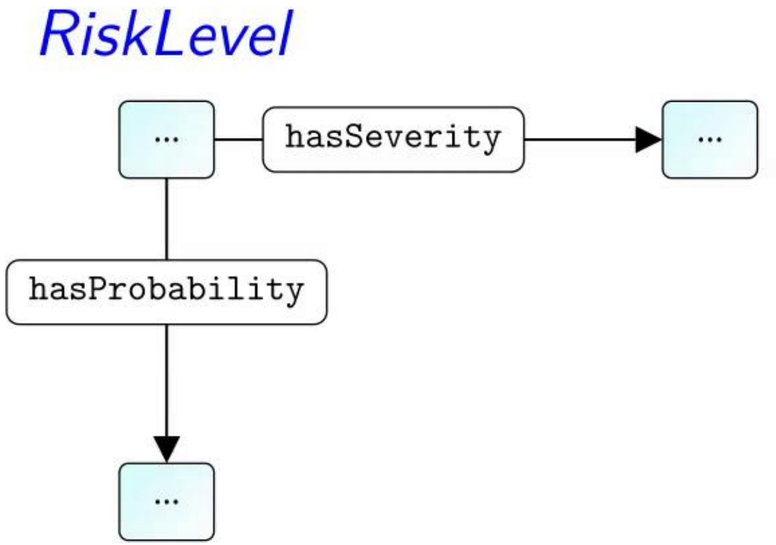

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According to ISO 14971 [3.18]:

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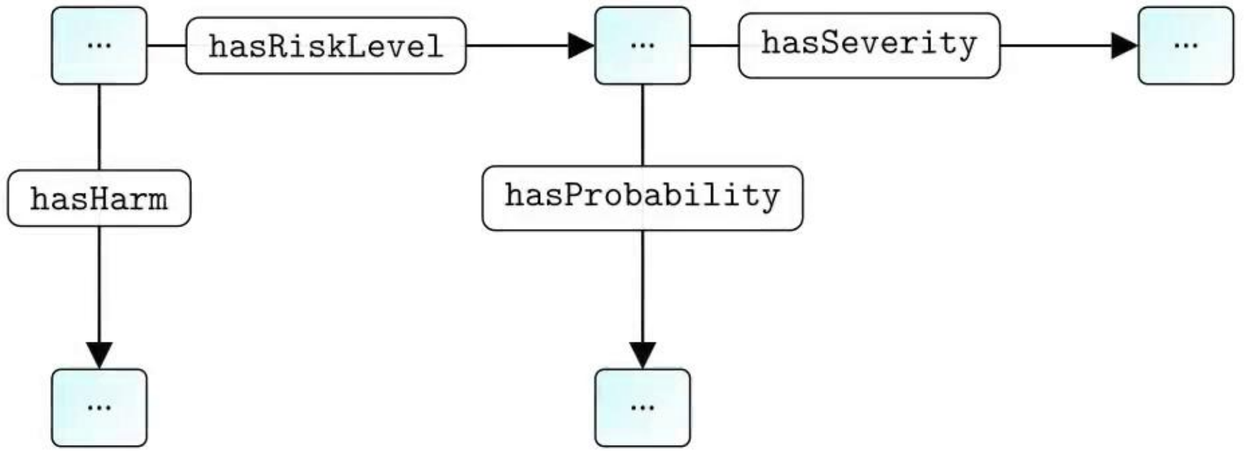

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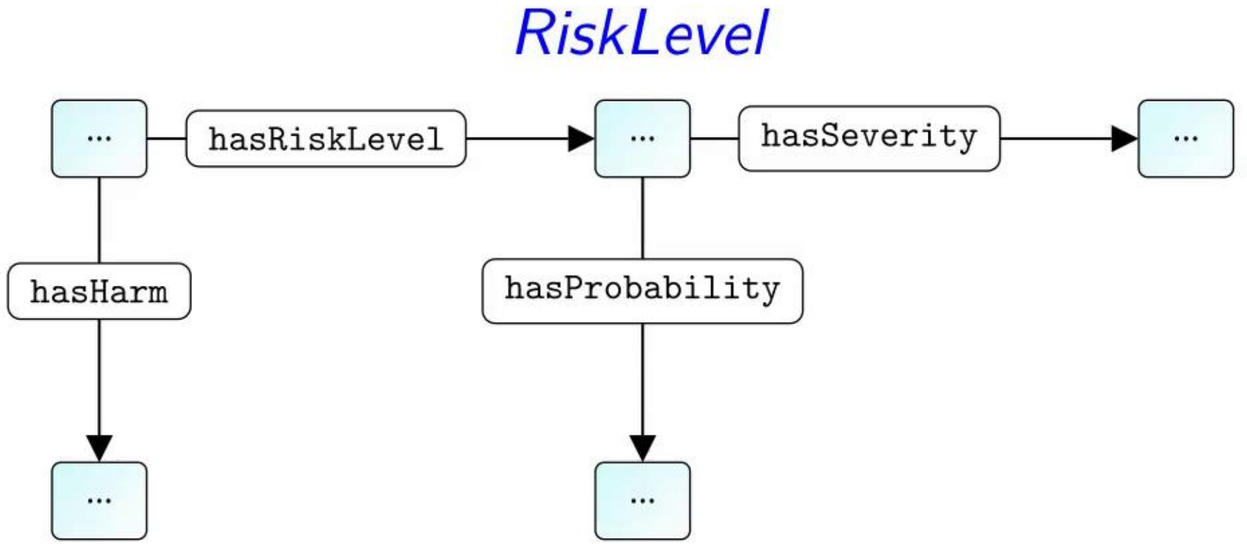

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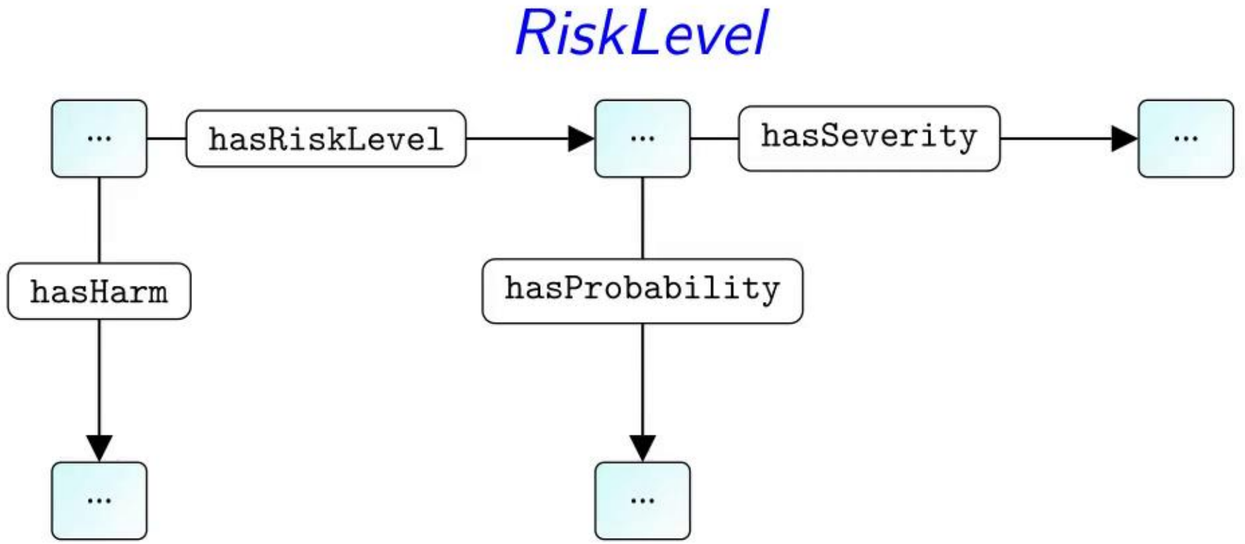

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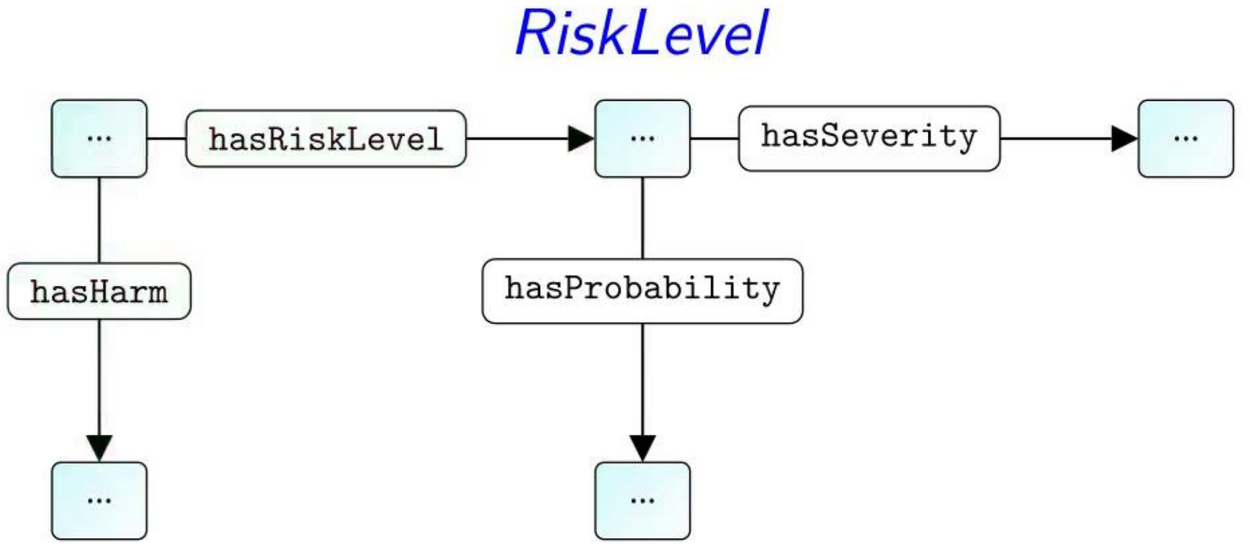

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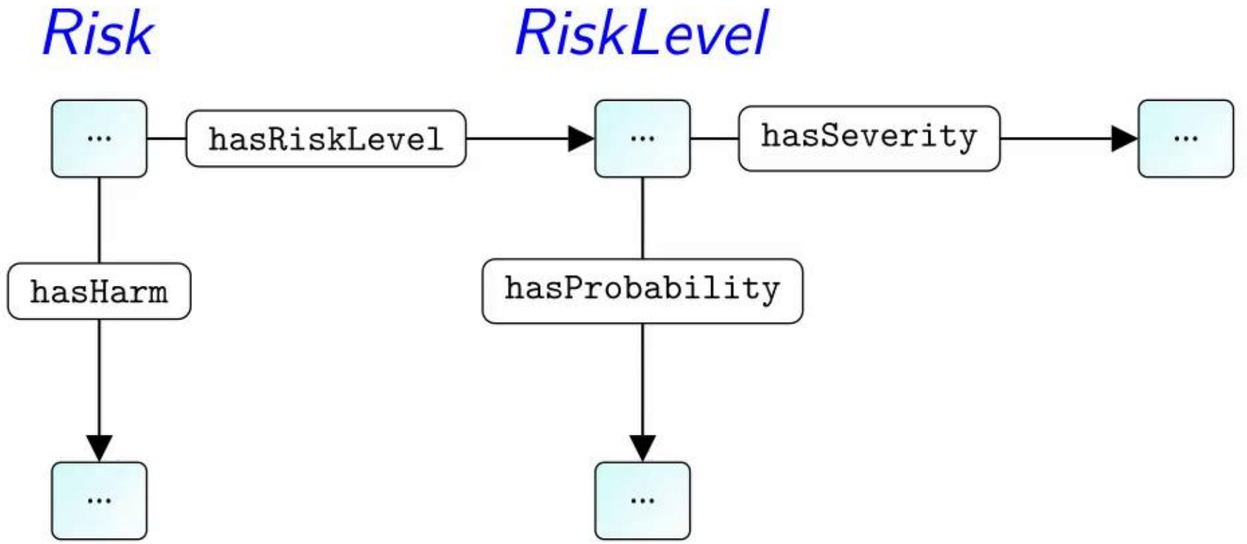
$\exists \mathsf{hasRiskLevel}.\top \sqcap \exists \mathsf{hasHarm}.\top \sqsubseteq \mathit{Risk}$	

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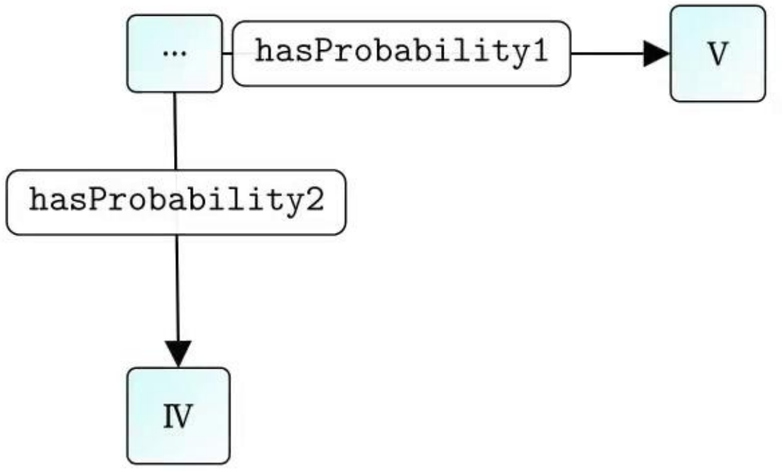

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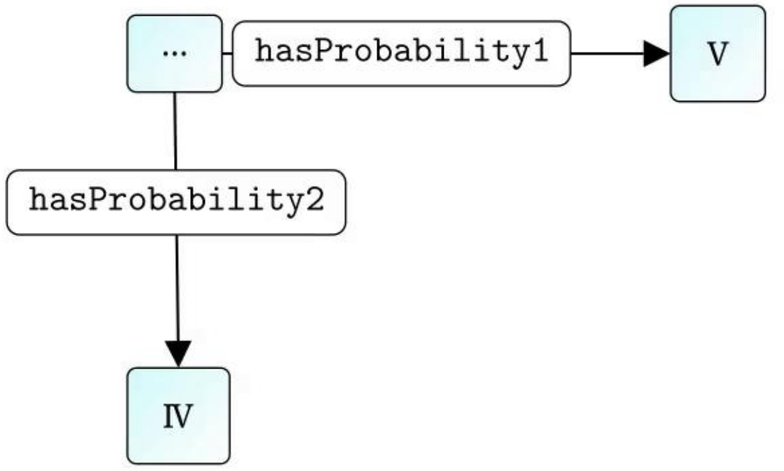

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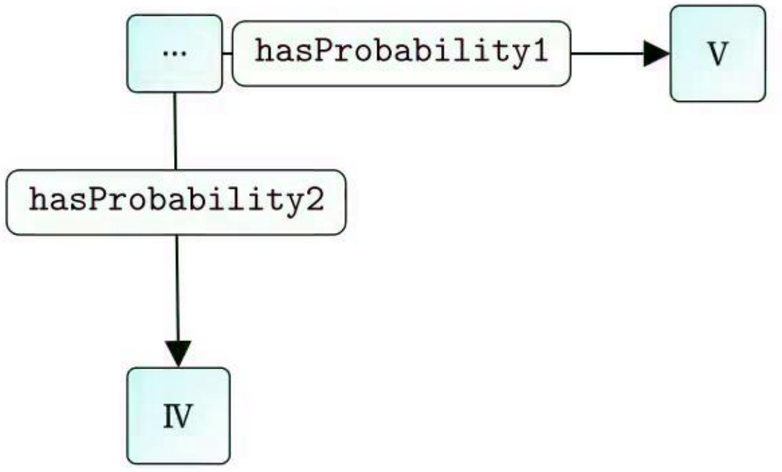
$\exists \mathsf{hasProbability1}.\{\mathsf{V}\} \sqcap$	
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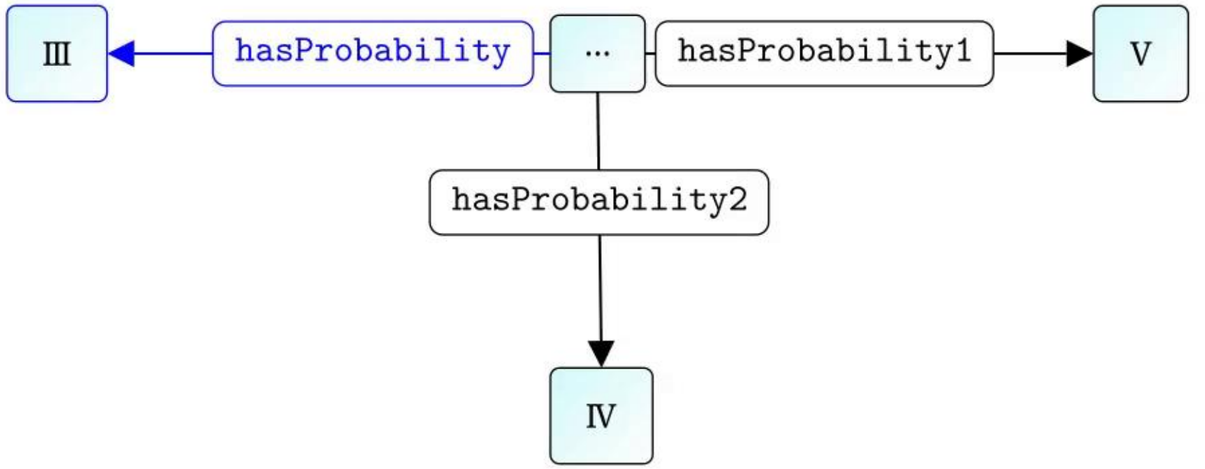

RISKMAN: Reasoning & Validation

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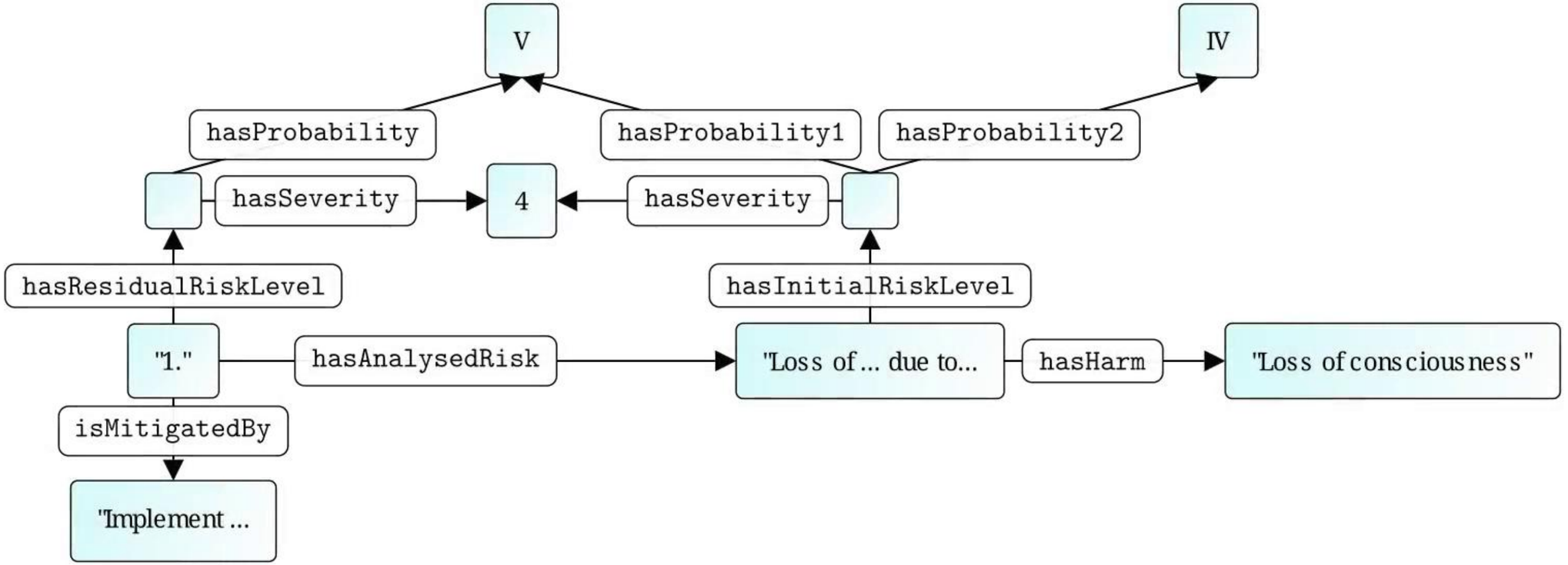

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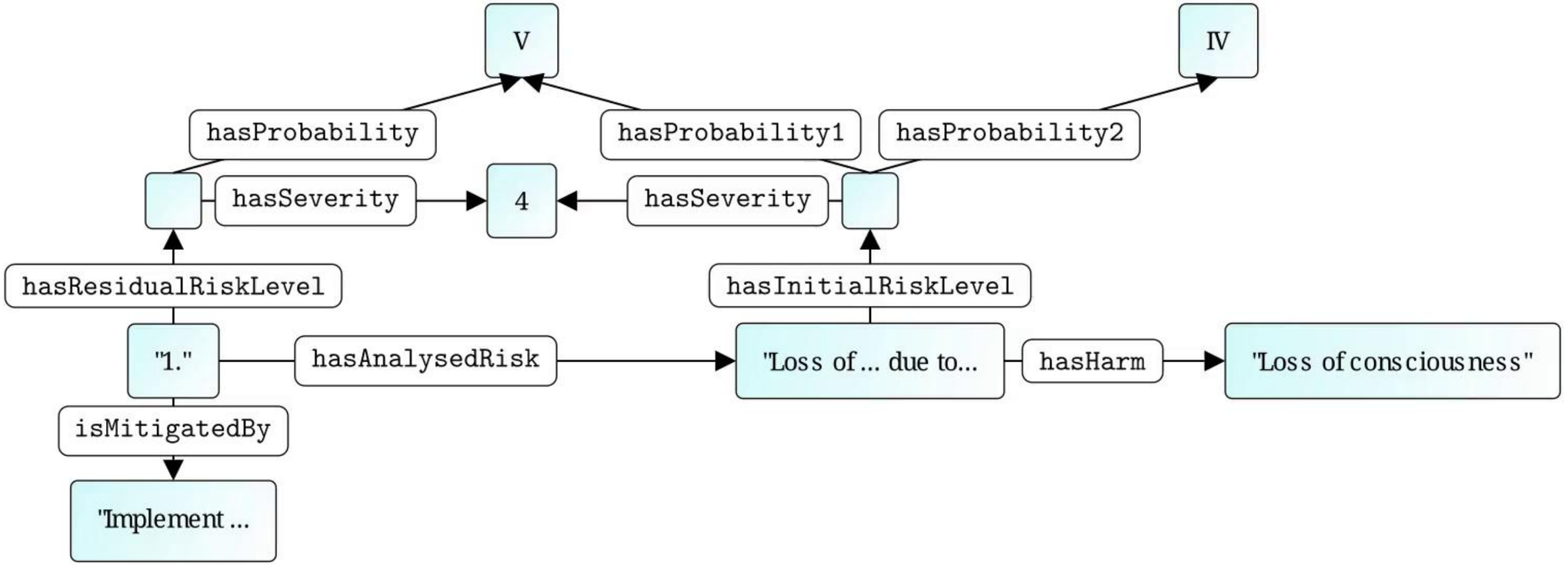

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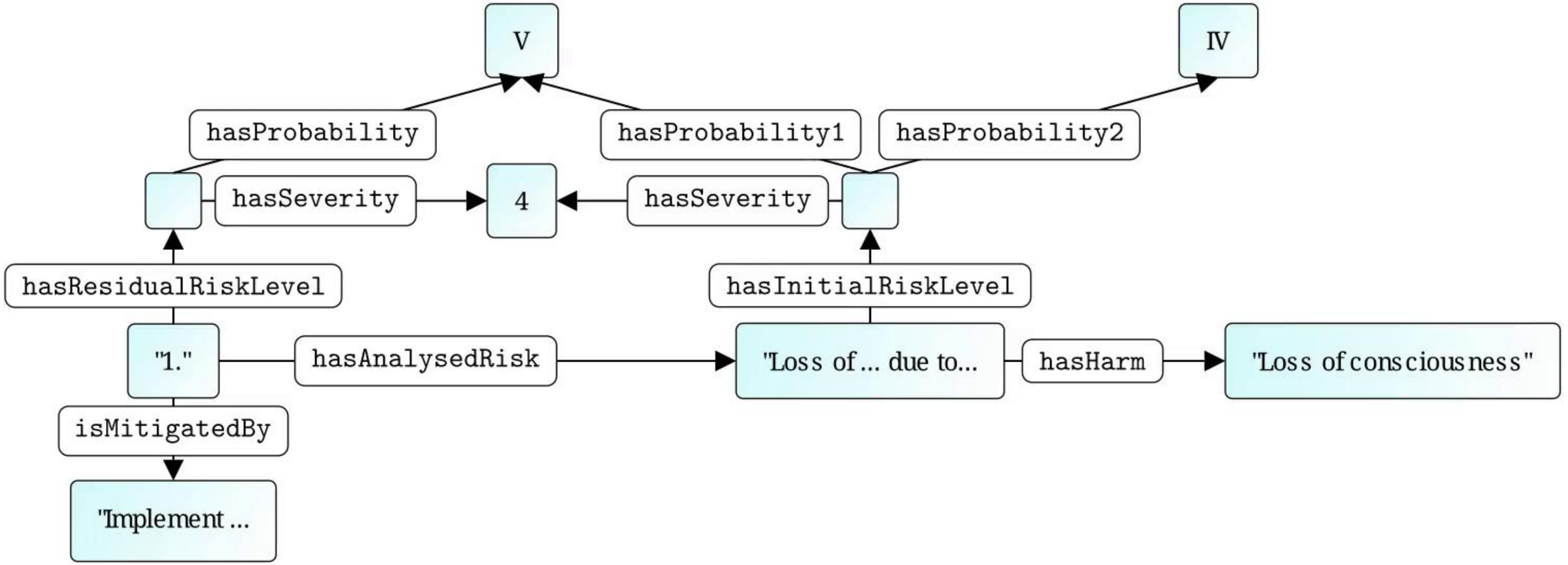

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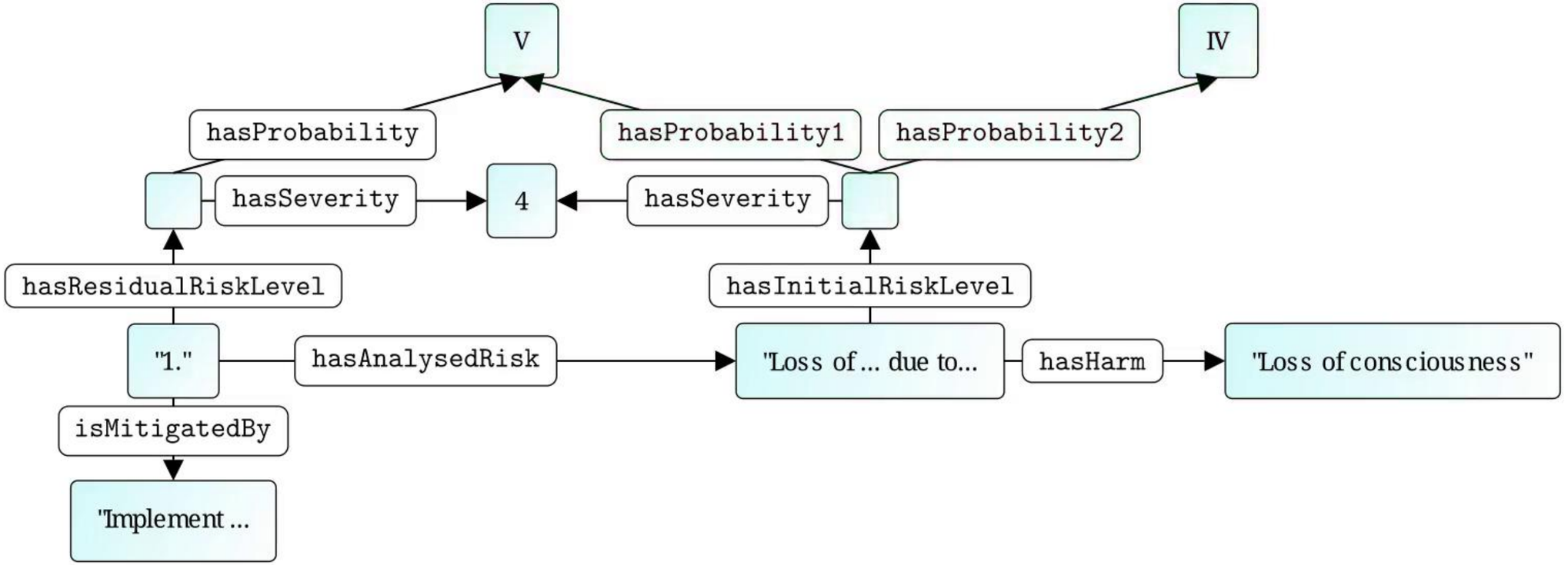

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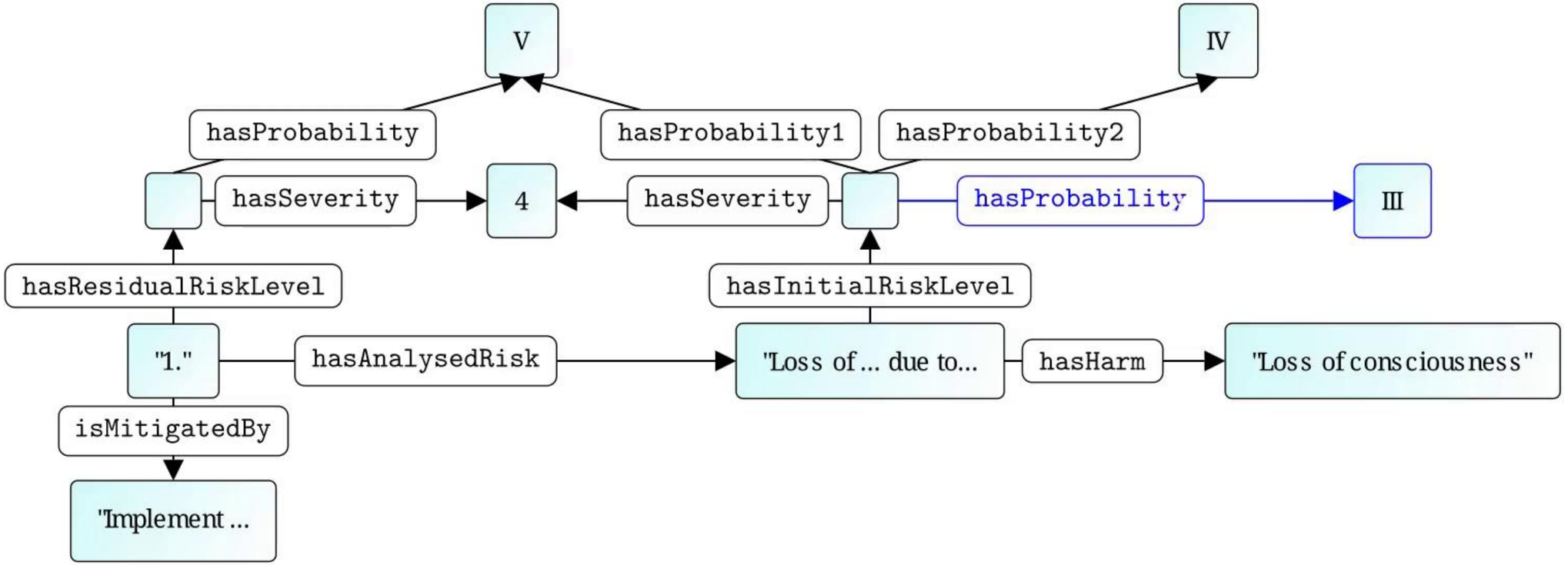

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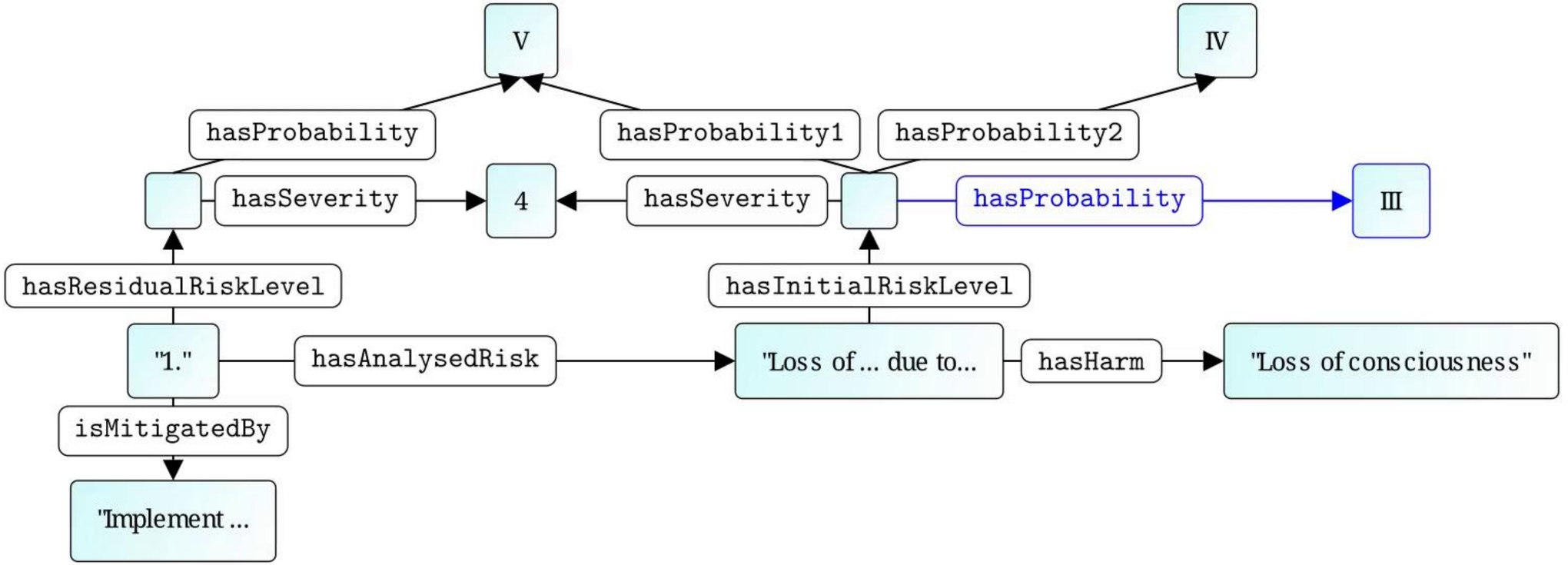

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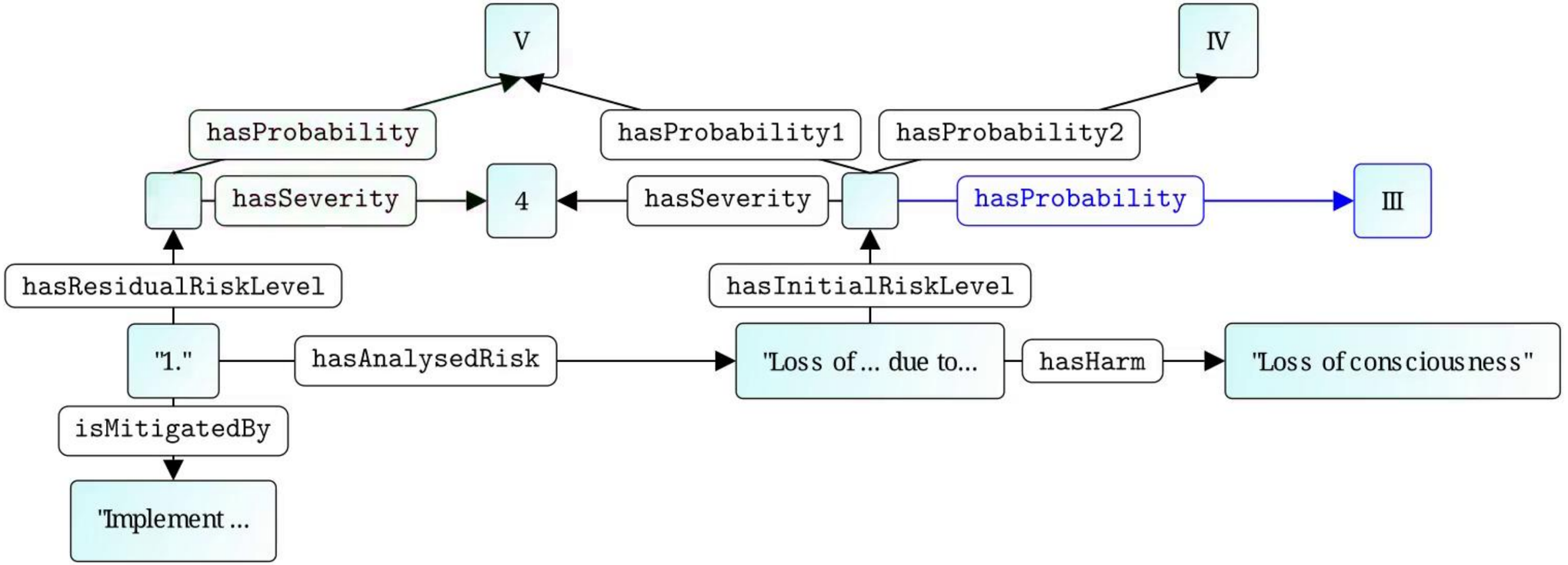

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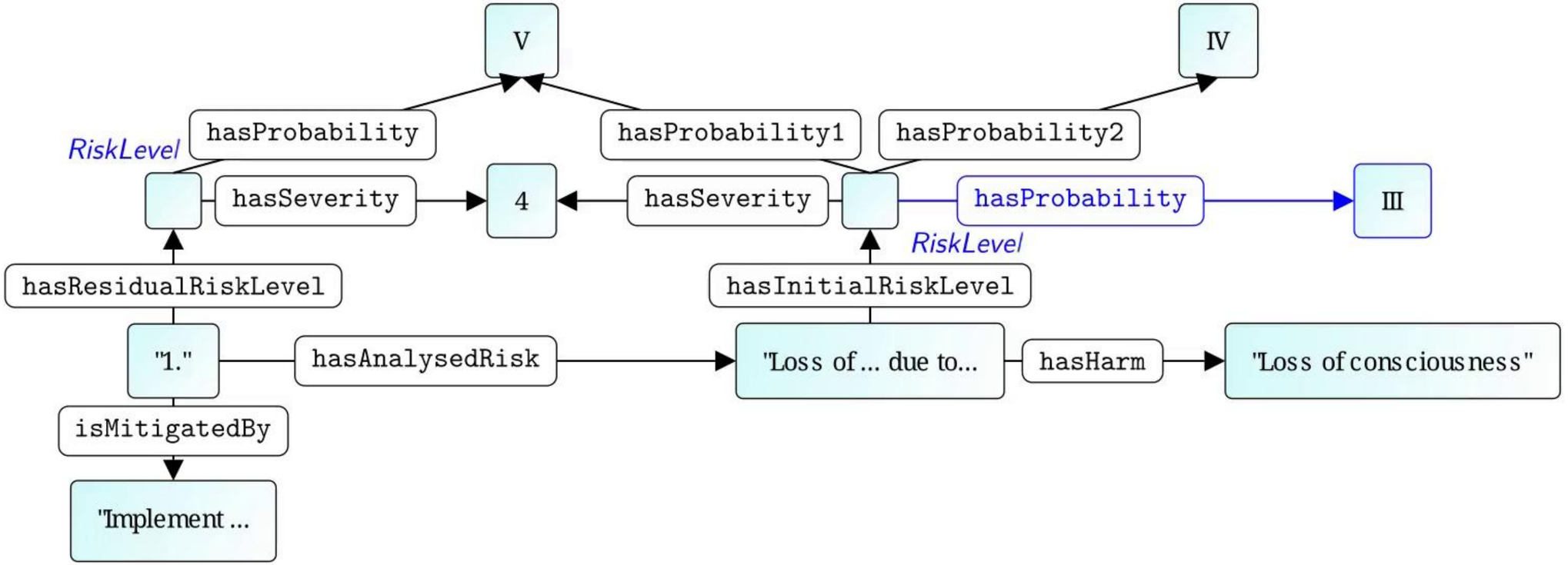

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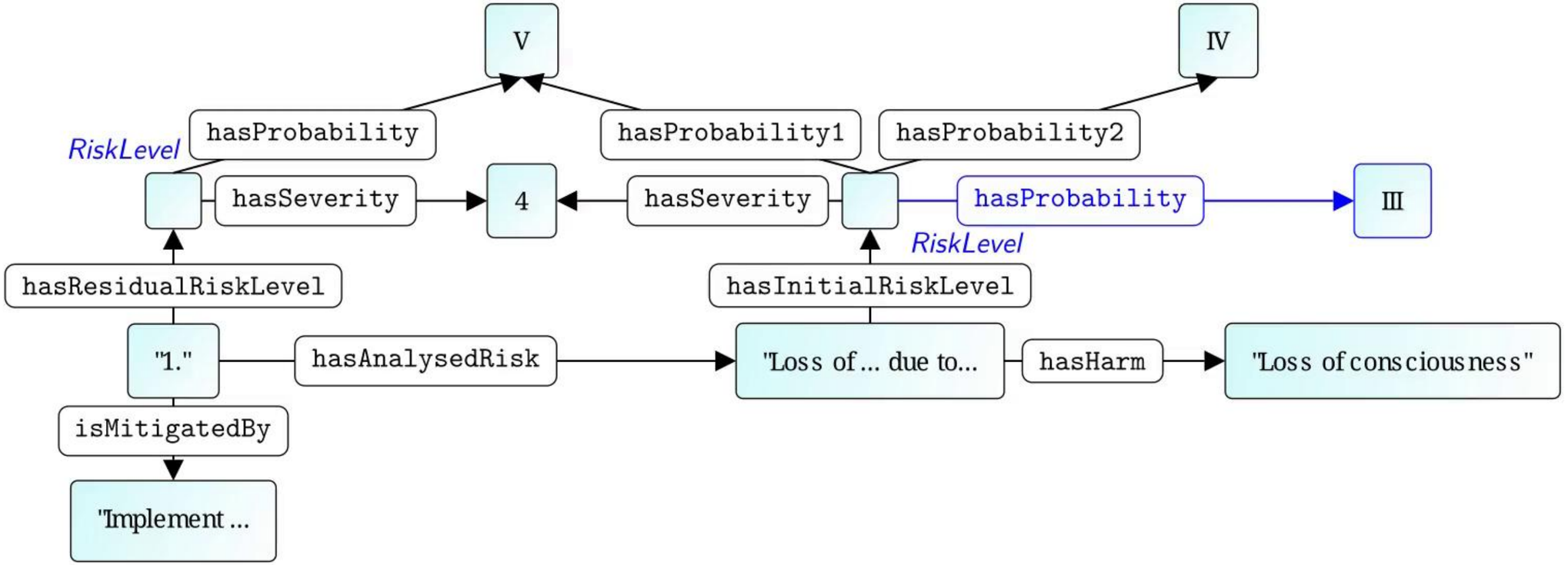

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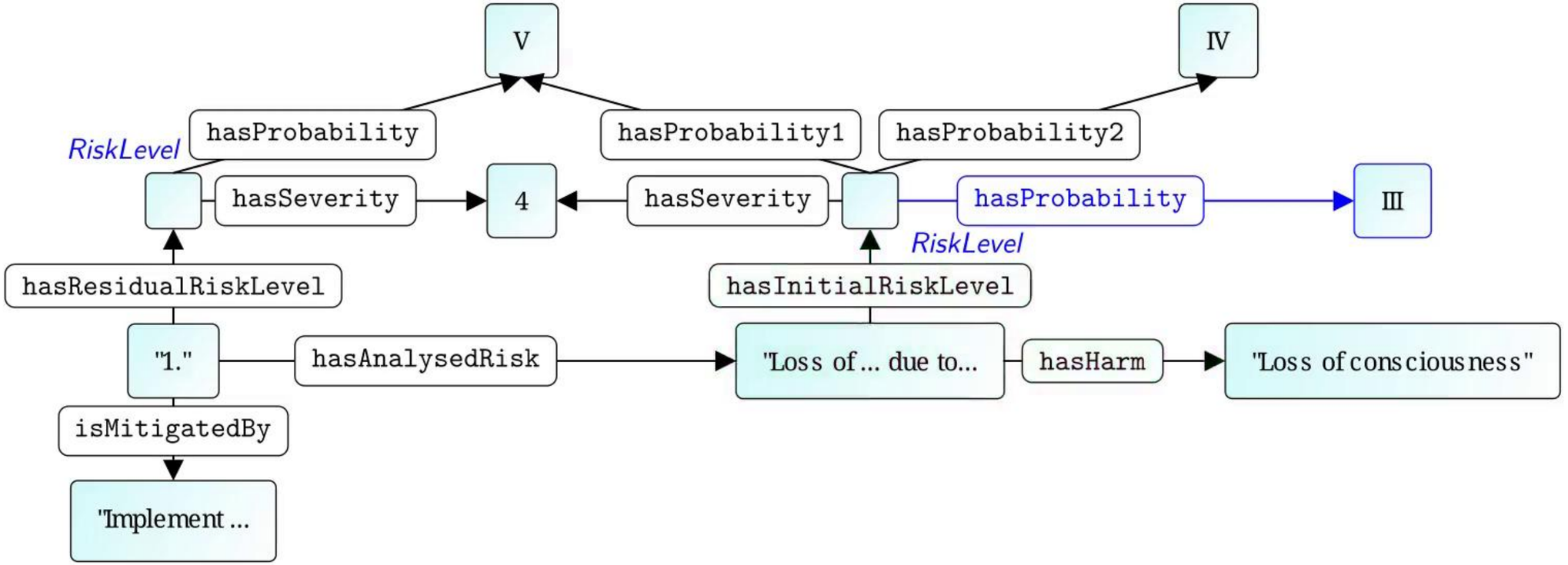

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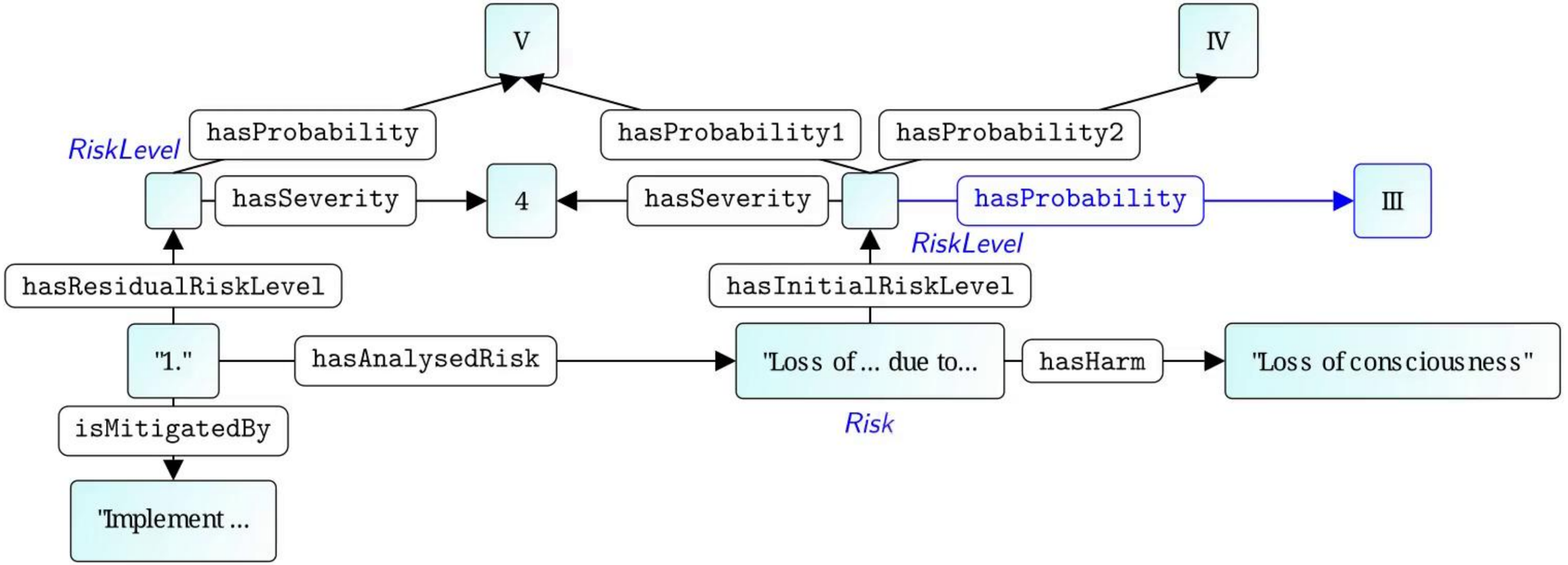

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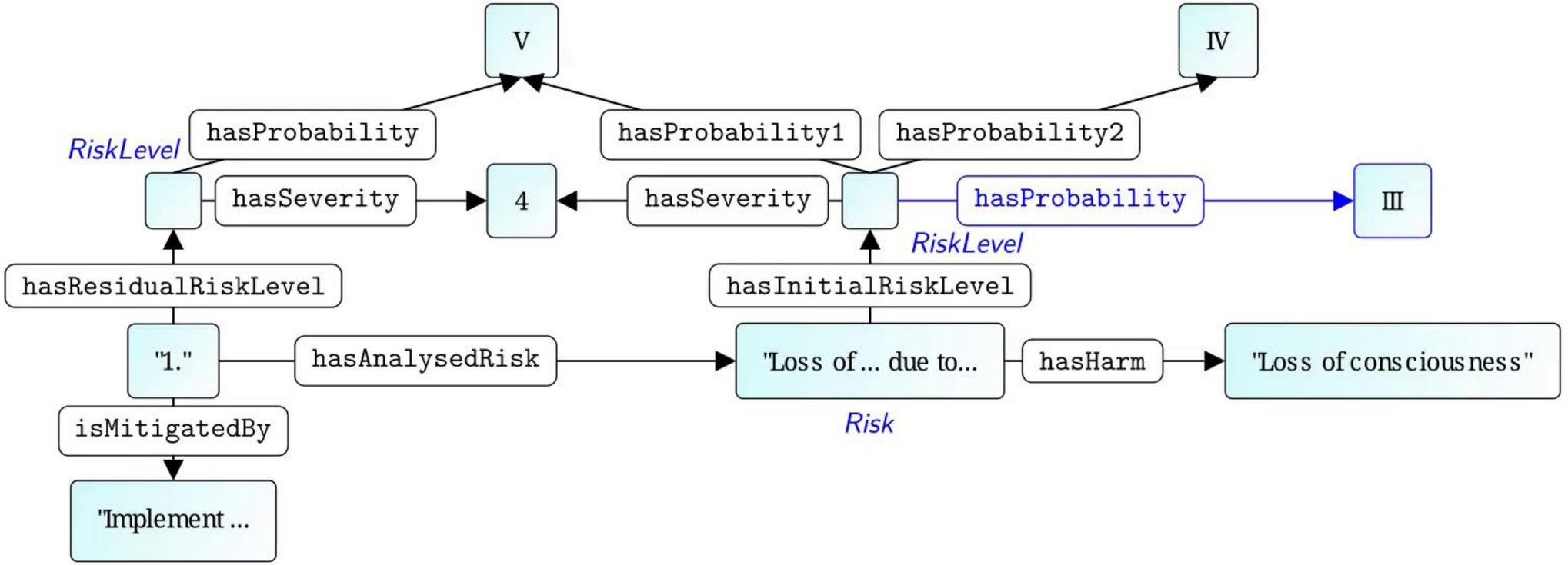

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Risk $\Rightarrow \exists$hasInitialRiskLevel $\cdot$ hasProbability $\cdot$ gt^{-} $\cdot$ hasProbability^{-} $\not\equiv$ $\cdot$hasAnalysedRisk^{-} $\cdot$ hasResidualRiskLevel

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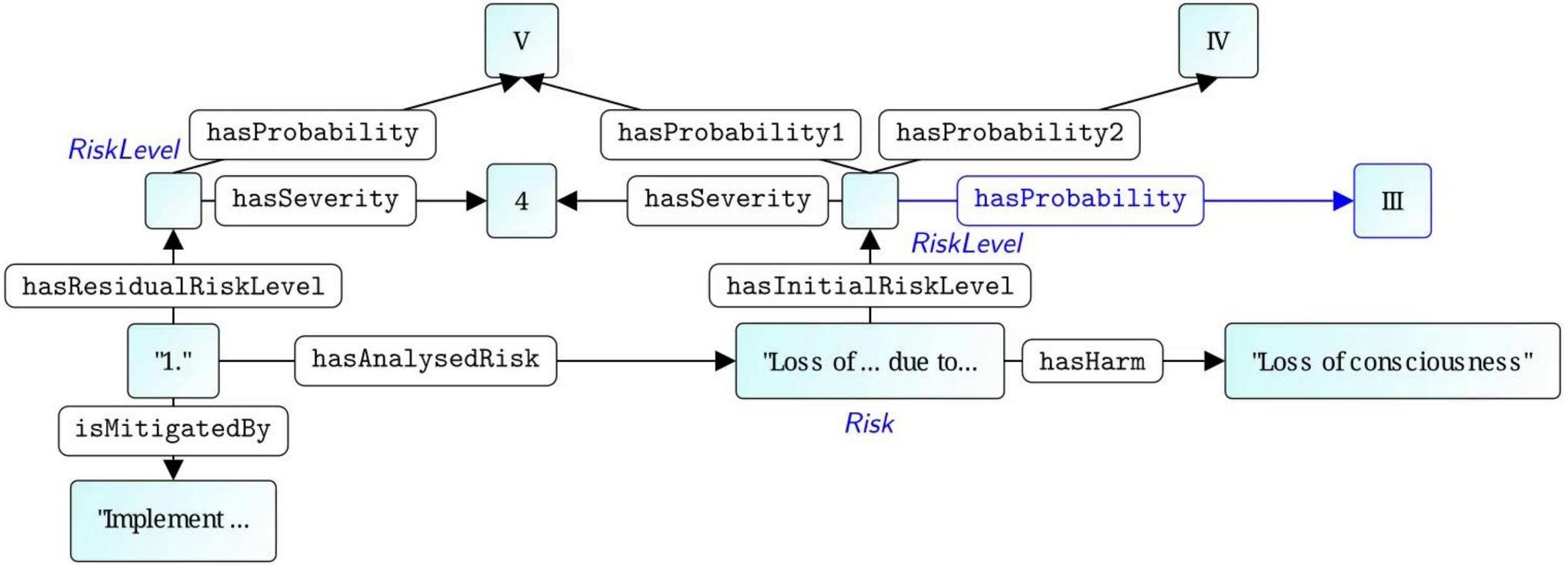

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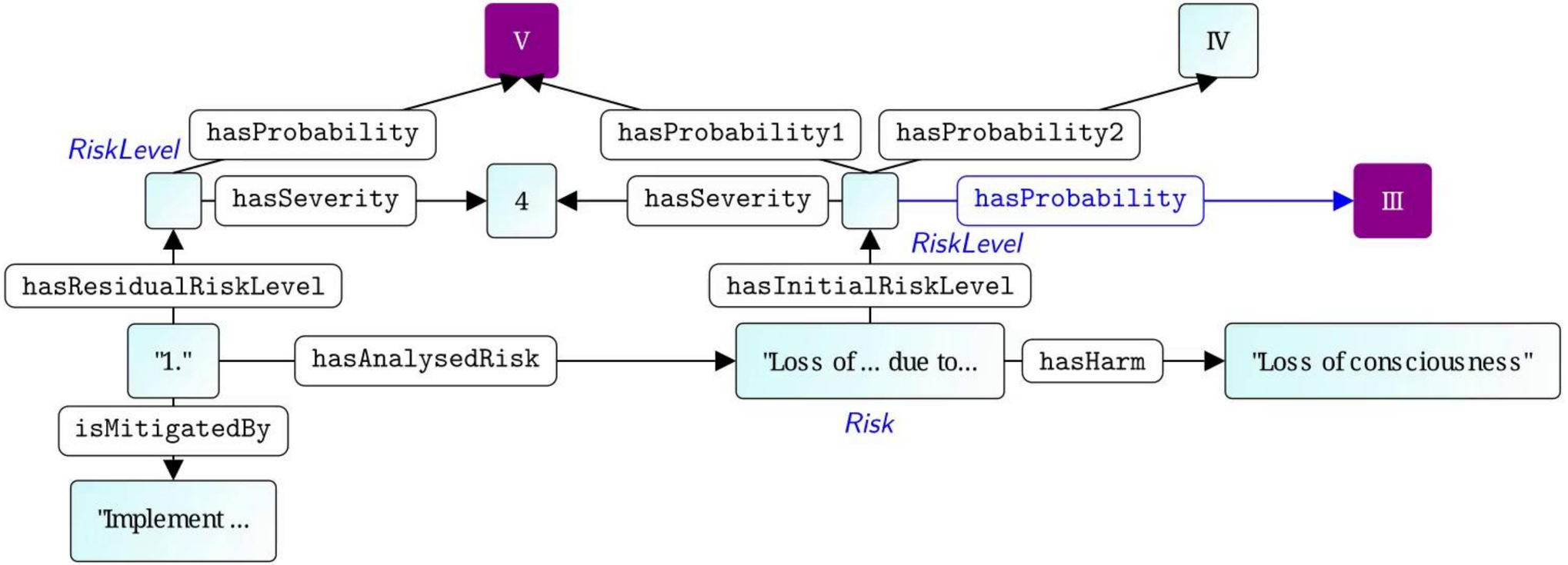

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```
 1 <tr>
 2   <td>
 3      1.
 4   </td>
 5 <tr>
 6   <td>
 7      Loss of consciousness...
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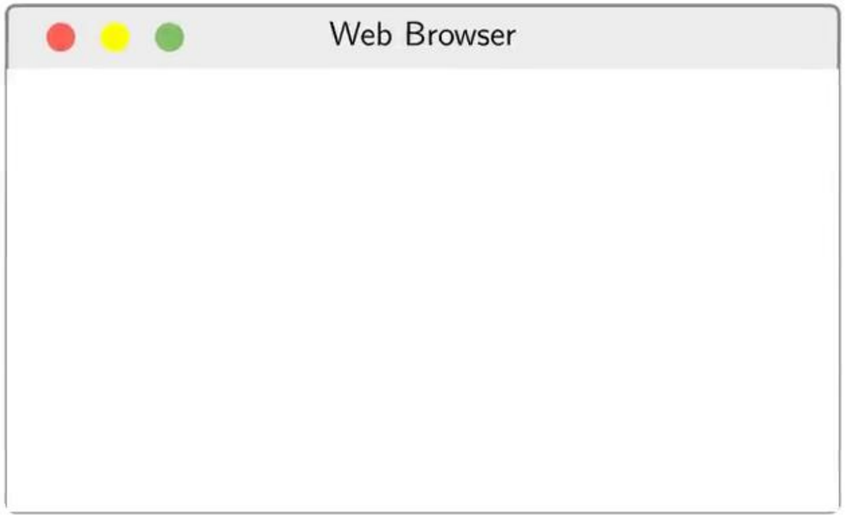

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Web Browser

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">
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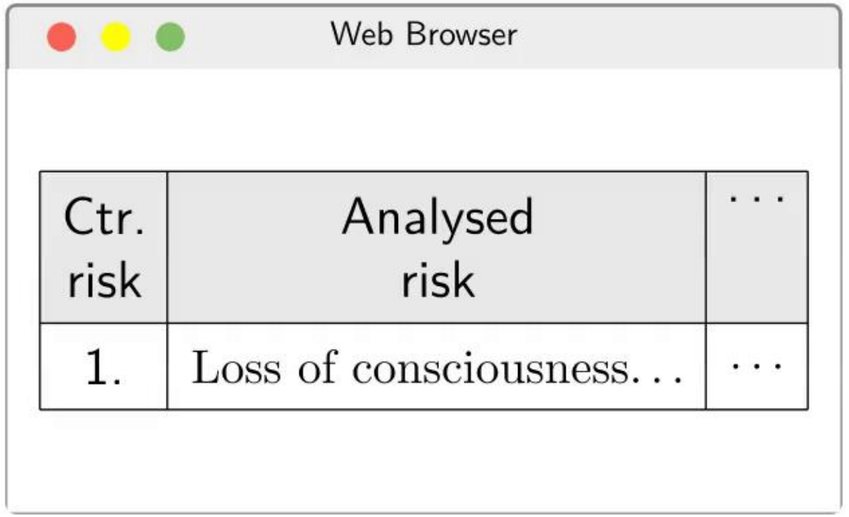
```



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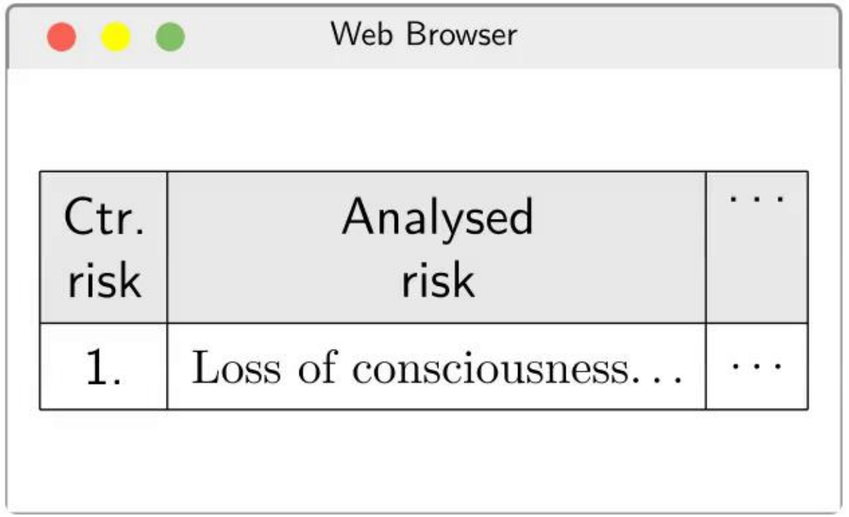
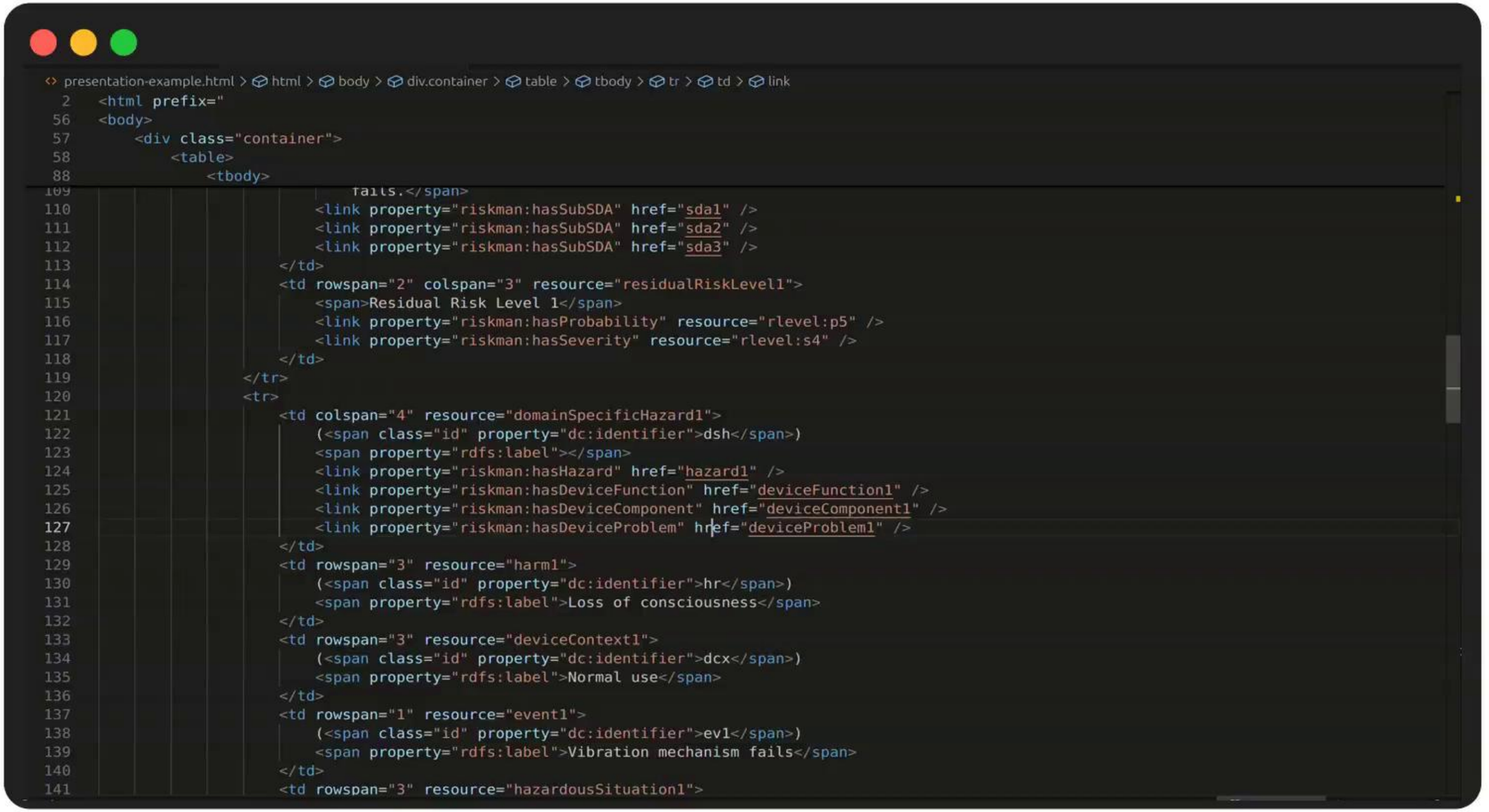



```
@prefix : <https://w3id.org/riskman/ontology> .
@prefix rdfs: <http://www.w3.org/2000/01/rdf-schema#> .

:cr1 :hasAnalysedRisk [
        rdfs:comment "Loss of consciousness..."
    ] ;
    ...
.
```

The RISKMAN Workflow: Demo



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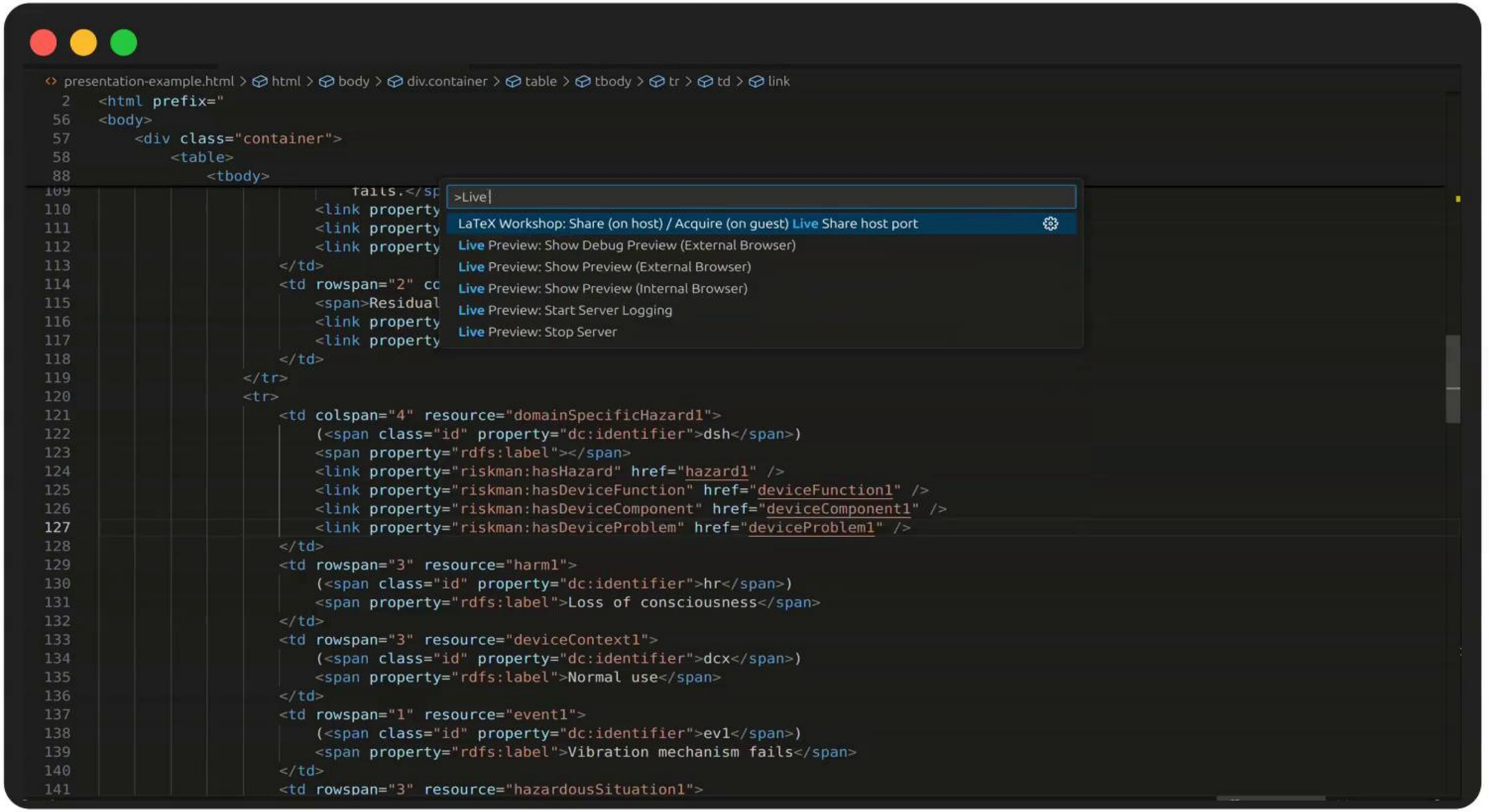

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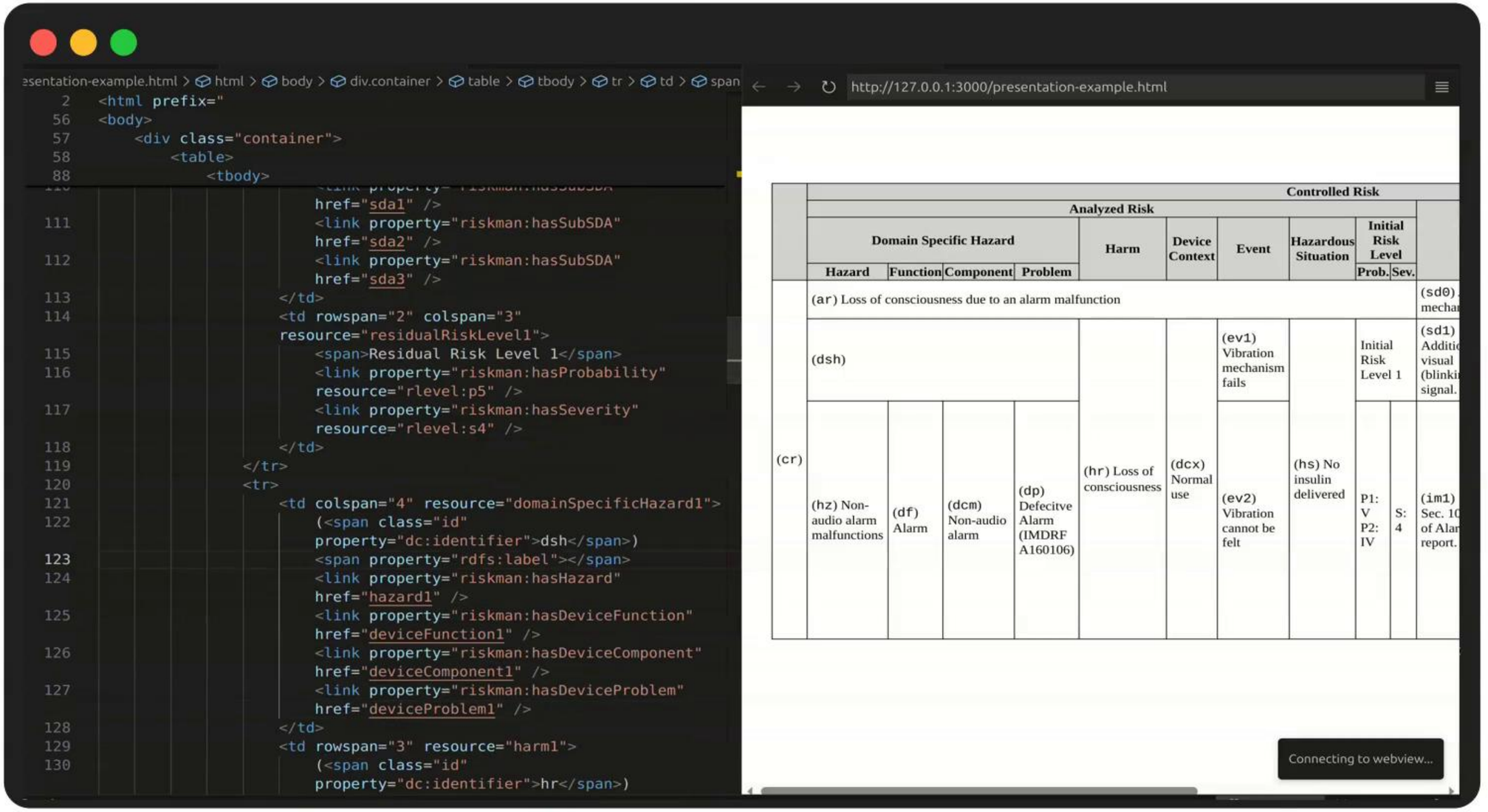

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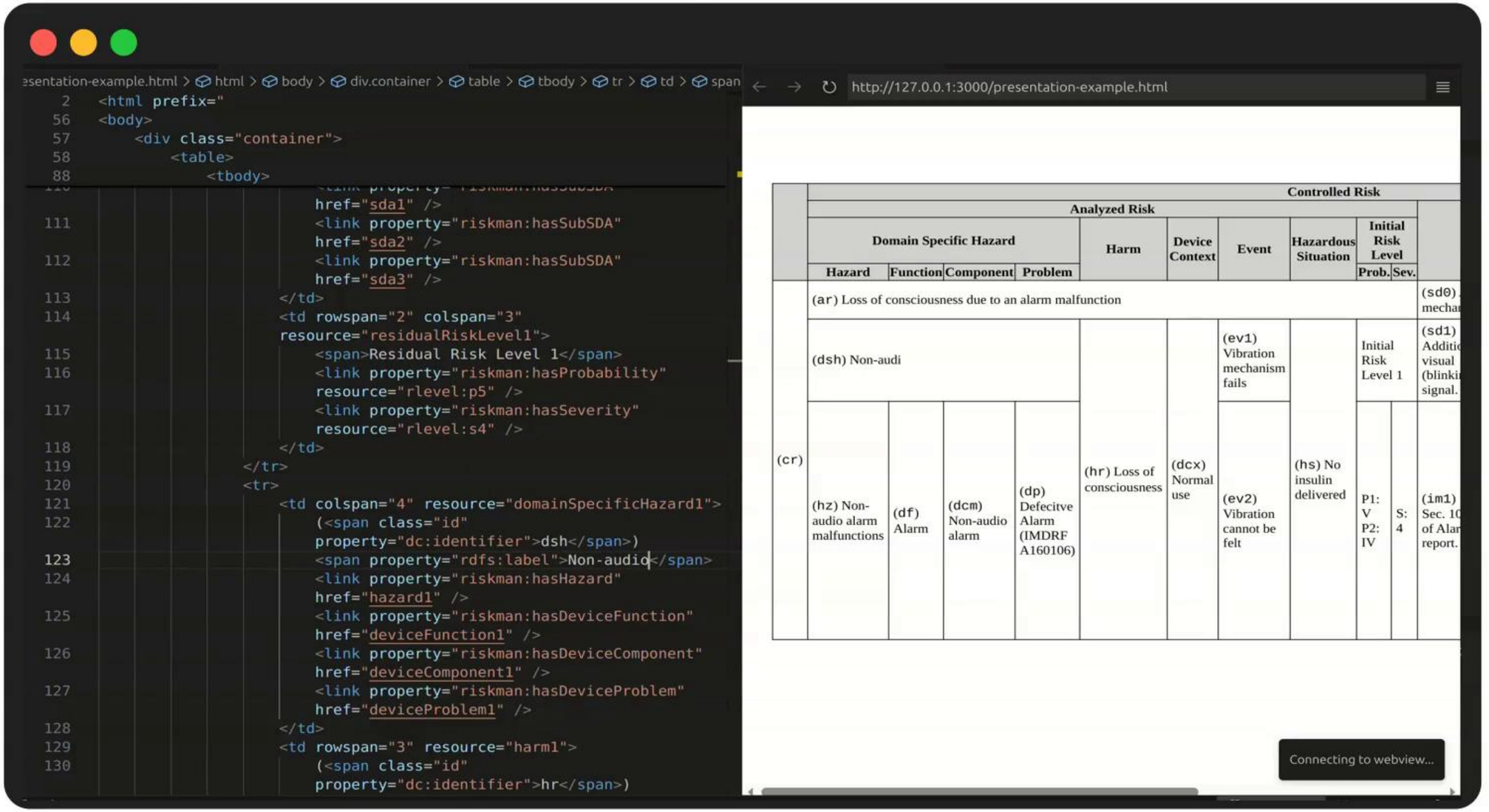

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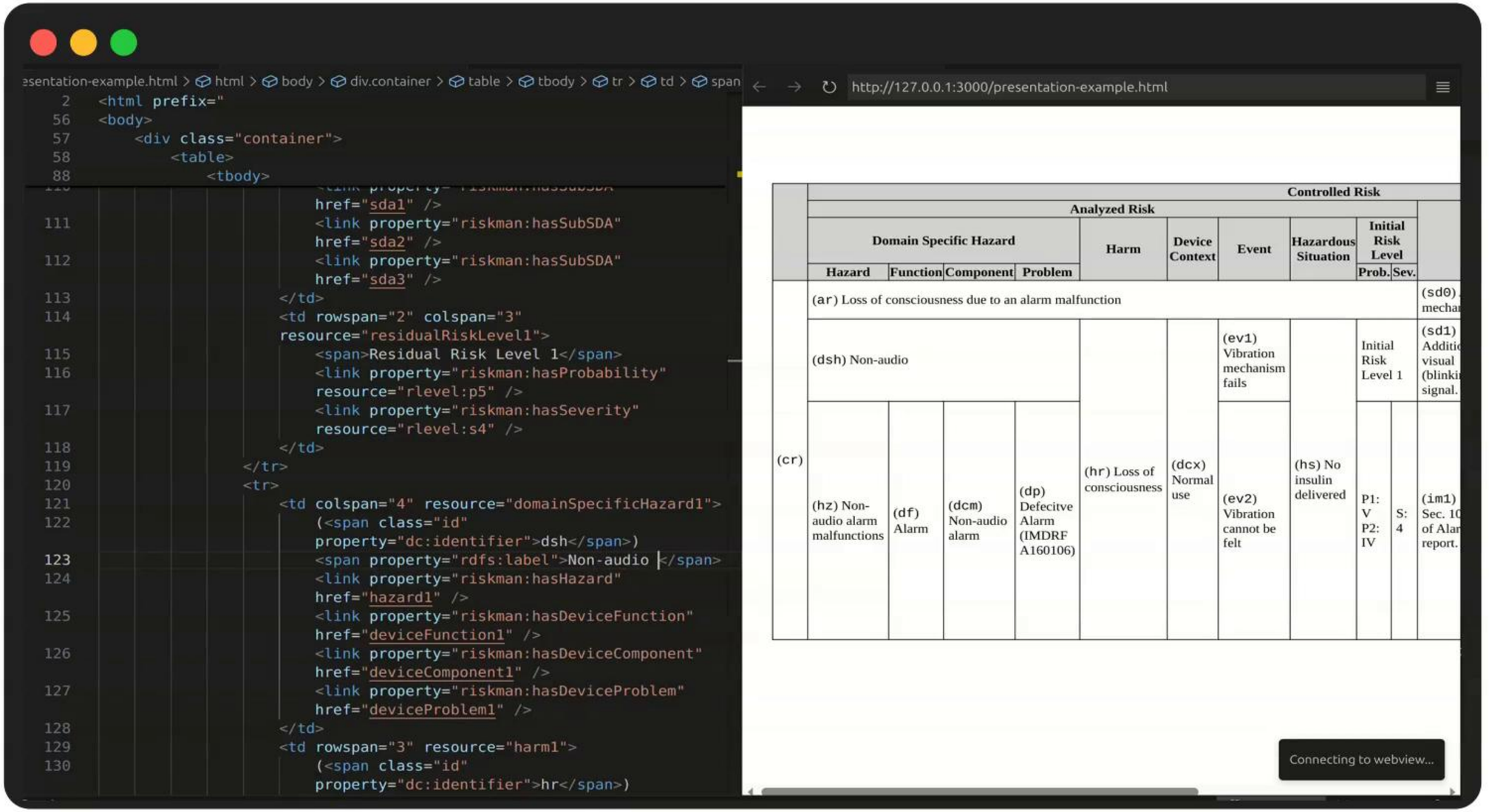

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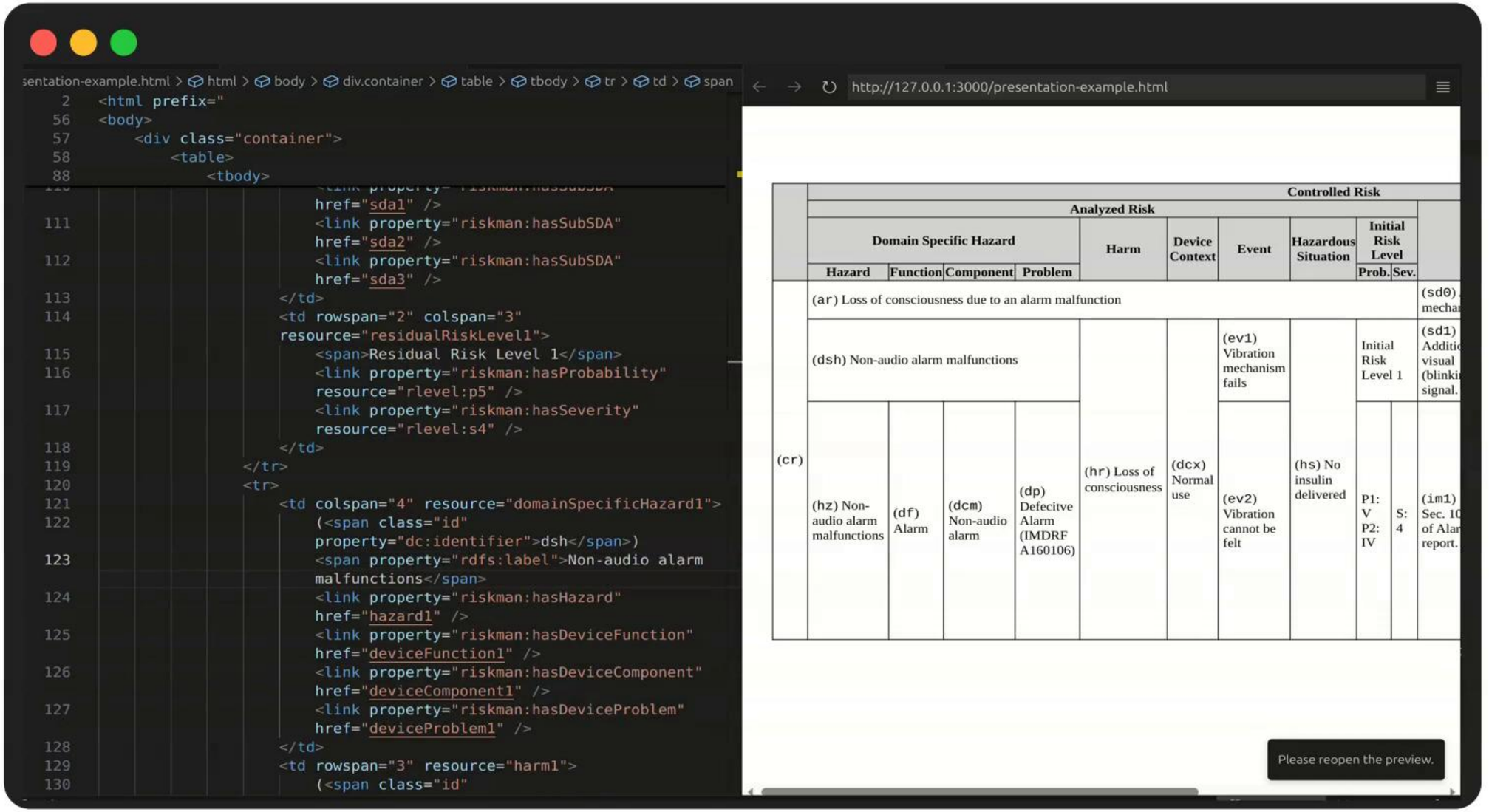

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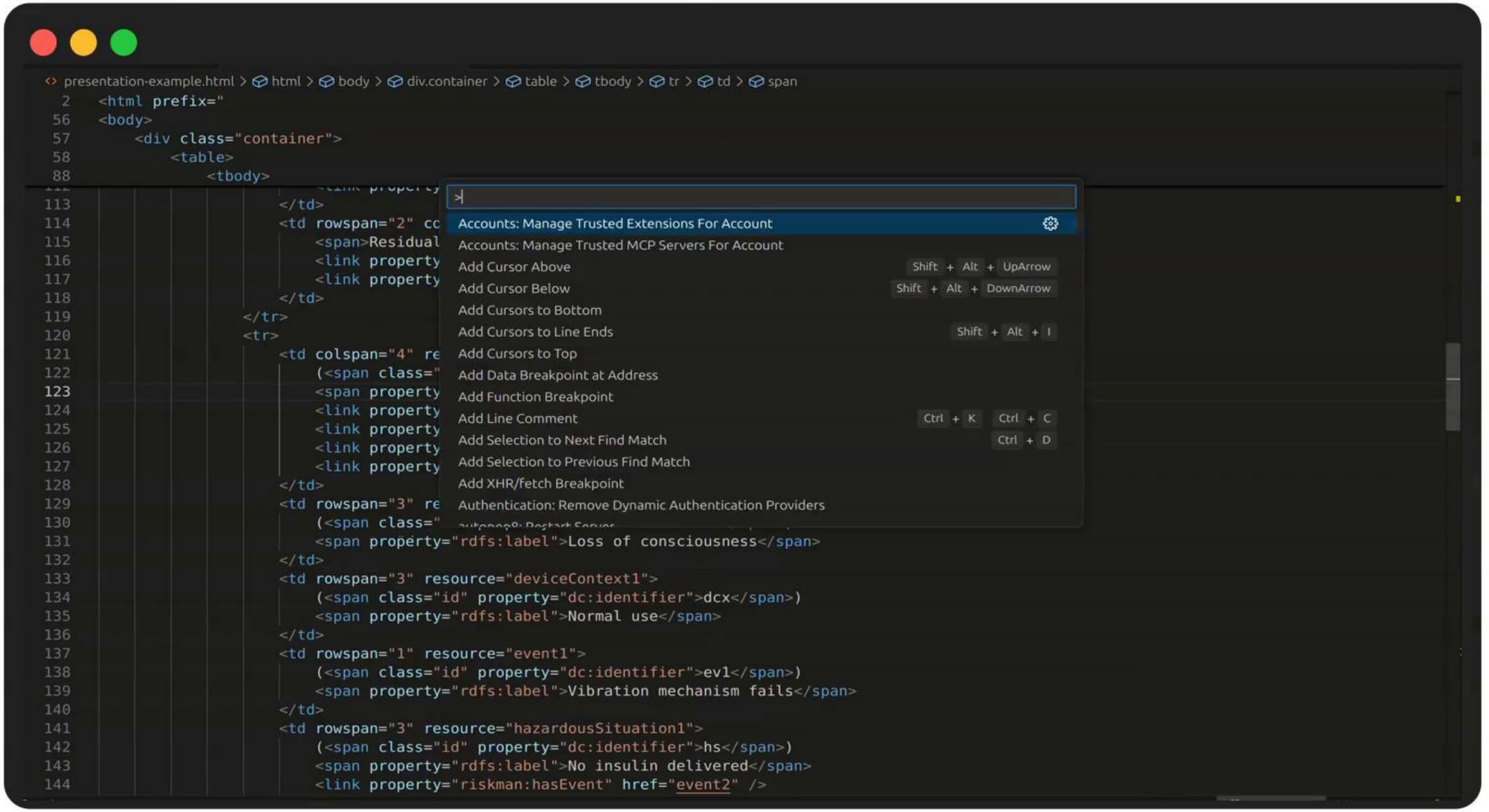

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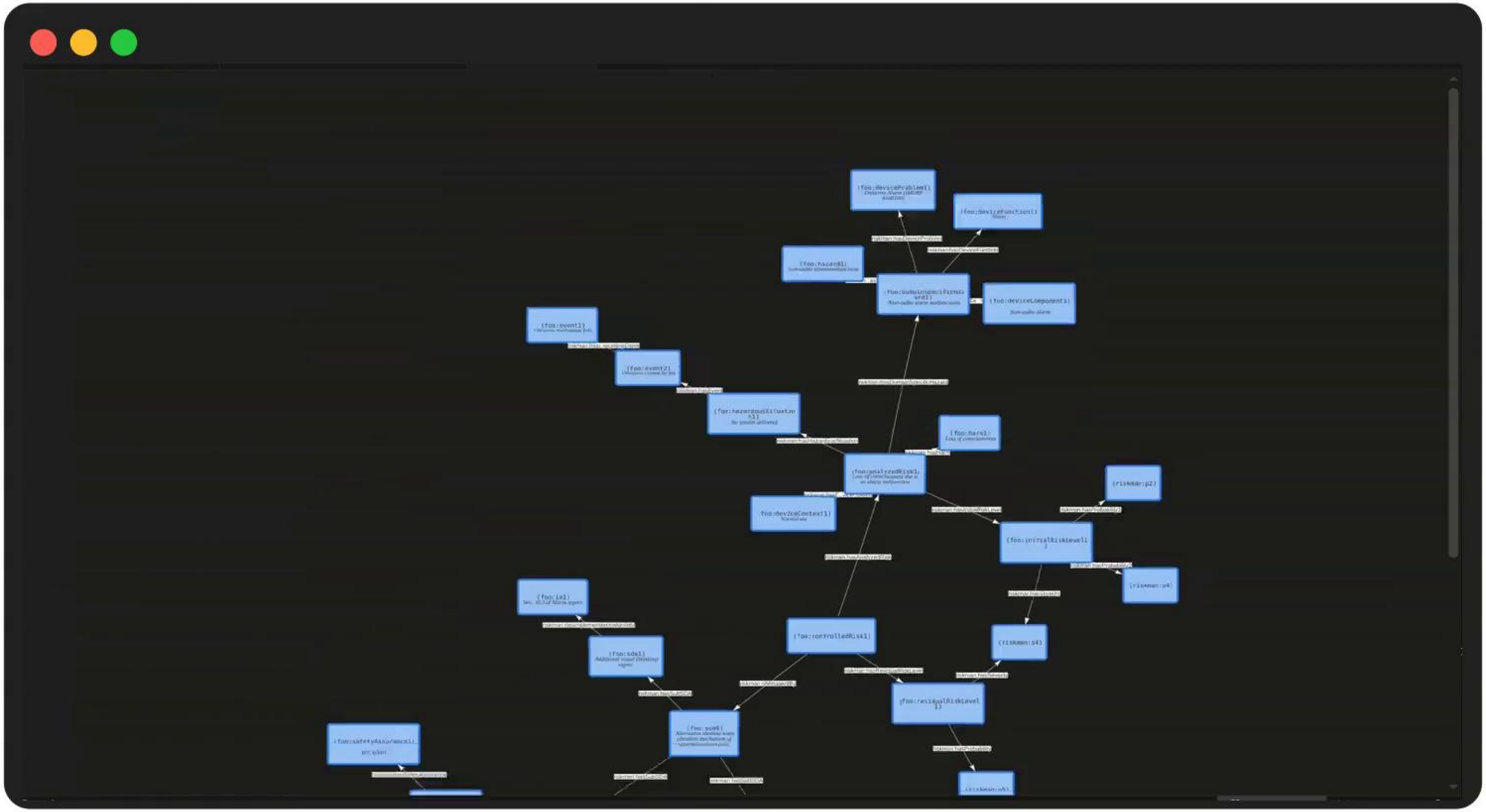

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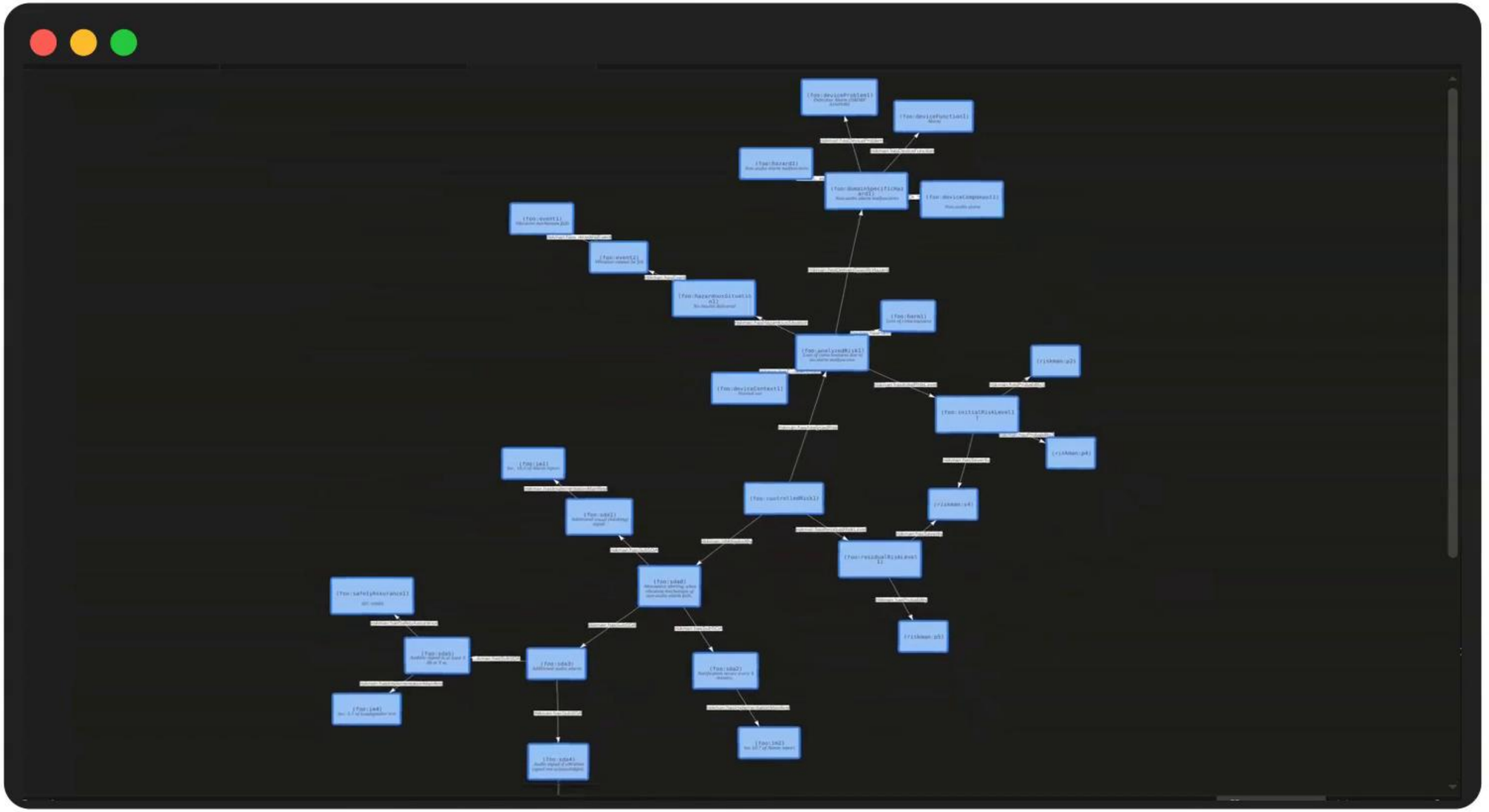

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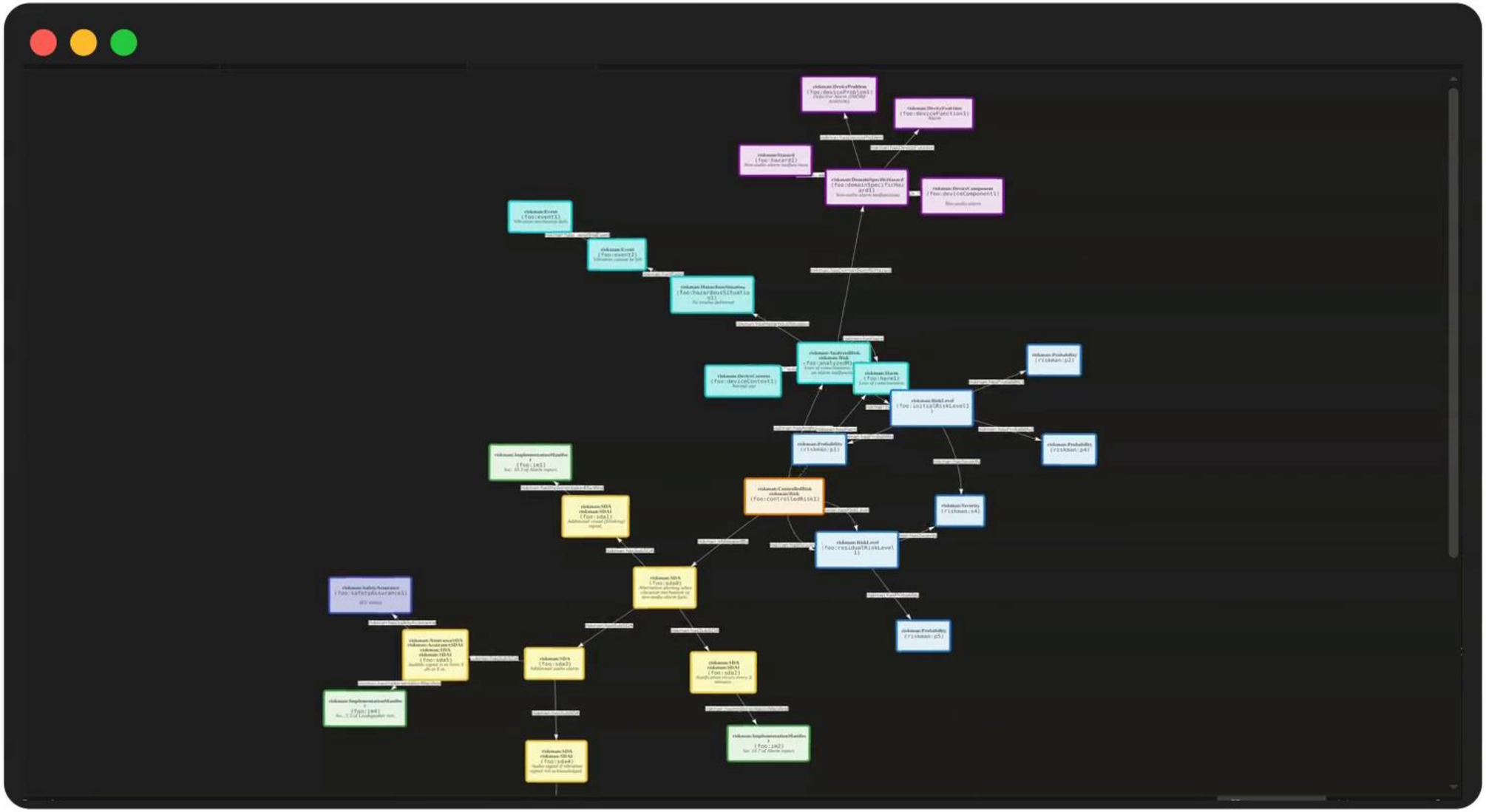

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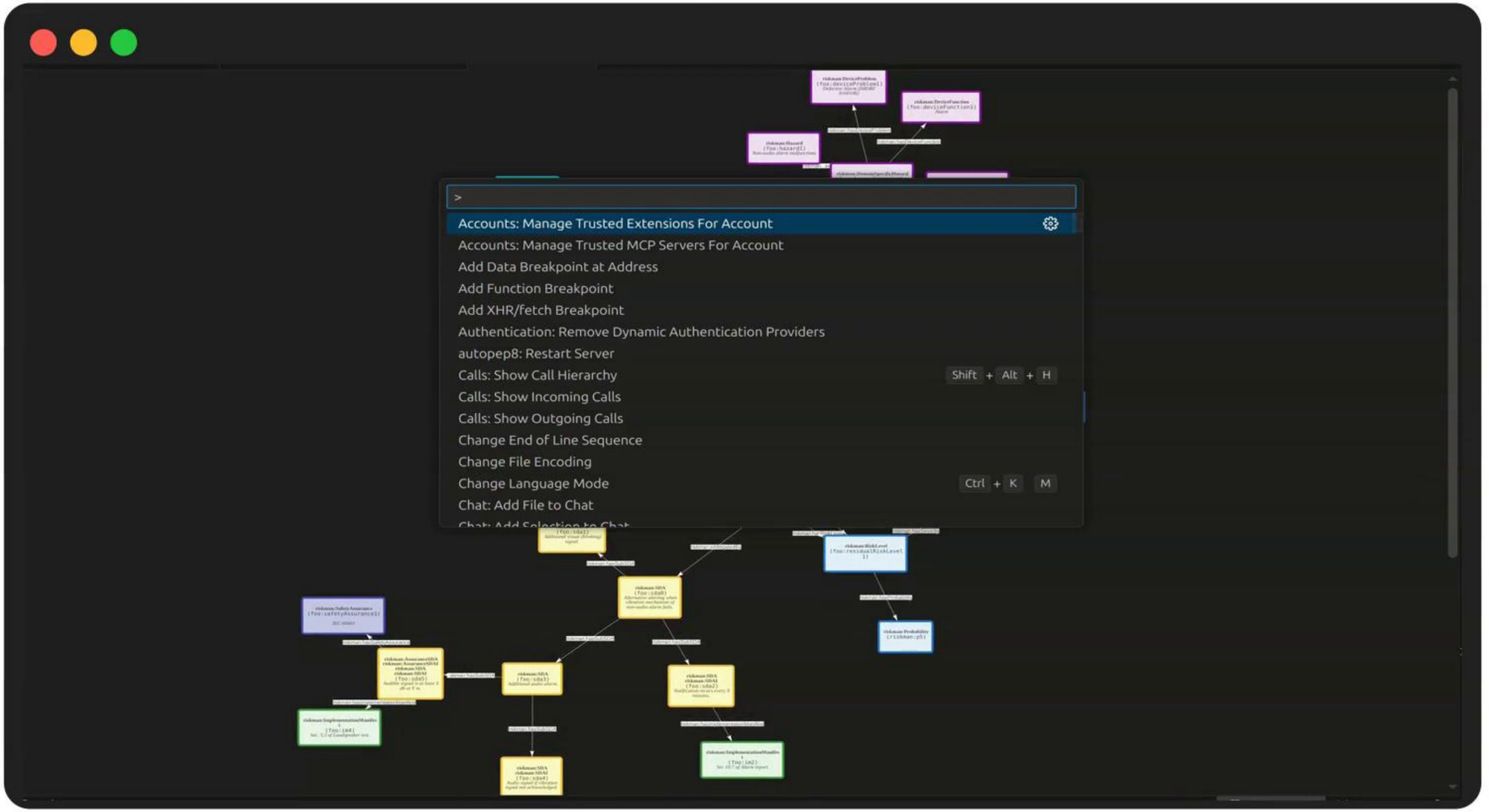

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Wrap-up

Conclusions

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