Breaking Down Risk for Medical Device Hazard Analyses

Taylor Dieringer
Sr. Staff Quality Engineer – Risk Management
iRhythm Technologies, Inc.

In medical device risk management, the structure of a hazard analysis greatly impacts both product development and post-market surveillance. A clear, intentional structure supports traceability, aligns with ISO 14971:2019, and enables effective risk control. This article explores three common structures for hazard analysis and highlights a flexible, practical option that aligns well with real-world data and regulatory expectations.

Three Common Approaches to Structuring Hazard Analyses

Hazard analyses are typically structured in one of the following ways:

1. Detailed line items based on sequences of events

   This method breaks down risks by individual event chains. While comprehensive, it becomes difficult to maintain and nearly impossible to link to post-market complaints, which rarely provide such detailed sequences. See the example in Figure 1 below, showing each line with the same hazard, hazardous situation and harm. The only thing that differs from each line item is the sequence of events.

ID	Hazard	Sequence of Events	Hazardous Situation	Harm	Acts to	Pre			
						S	P	R	
R-03	Energy / Thermal Energy	Inadequate insulation design >> Device surface overheats during use	Patient exposed to excessive thermal energy	Burn	Patient	3	3	MED	1. ISD maxim 122F (SR 2. PM: A devic (SR p app
R-04	Energy / Thermal Energy	Defective temperature sensors used during assembly >> temperature regulation fails >> Device surface overheats during use	Patient exposed to excessive thermal energy	Burn	Patient	2	4	MED	1. PM: device in (SREQ-00 2. IFS: "V potent appli
R-05	Energy / Thermal Energy	User applies device for an excessive amount of time due to unclear instruction >> Patient exposed to excessive thermal energy during use	Patient exposed to excessive thermal energy	Burn	Patient	3	1	LOW	1. IF poten applied

Figure 1. Example of a Hazard Analysis with Risk Line Items with unique sequence of events.

2. Limiting potential harm to a single severity level per hazardous situation

   This simplifies documentation but can underrepresent common, lower-severity harms. It also creates challenges in designing and verifying risk controls targeted at specific severities.

ID	Hazard	Hazardous Situation	Harm	Acts to	Pre			Risk Controls	Post		
					S	P	R		S	P	R
R-07	Energy / Thermal Energy	Patient exposed to excessive thermal energy	Burn	Patient	3	3	MED	ISD: Insulated Design (SREQ-001)	3	1	LOW

Figure 2. Example of a Hazard Analysis only identifying highest severity harm.

3. Hazardous situation/harm combinations *(Recommended Approach)*

   This structure defines each line item as a specific combination of a hazardous situation and a severity of harm. It offers clearer traceability, better alignment with post-market data, and improved support for targeted risk control strategies.

Line-Item Definition Based on Hazardous Situation/Harm Combinations

This approach defines each risk line item by pairing a hazardous situation with a specific severity of harm. It enables better alignment with both pre- and post-market information and avoids oversimplifications that can hinder effective risk management.

ID	Hazard	Hazardous Situation	Harm	Acts to	Pre			
					S	P	R	
R-07	Energy / Thermal Energy	Patient exposed to excessive thermal energy	Burn (major)	Patient	3	3	MED	1. (SF 2. po > 2
R-08			Burn (minor)	Patient	2	4	MED	1. (SF 2. ter cal 3. po > 2
R-09			No Harm	Patient	1	4	LOW	1. po > 2

Figure 3. Example of Hazard Analysis demonstrating hazardous situation/harm combinations.

A key strength of this method is its ability to reflect that the same hazardous situation may result in varying harm severities, each with different probabilities. Rather than bundling all outcomes into a worst-case or mapping them to complex event trees, each combination is treated individually.

Structuring Risk Estimates for Clarity and Control

To ensure traceability and avoid overlap in risk assessment, it's important that each hazardous situation is defined with mutual exclusivity. This allows for clear association between a hazardous situation and each potential harm it may cause — particularly when those harms vary in severity.

When estimating risk for each of these situation/harm combinations, it's helpful to use a structure that reflects the real-world relationship between severity and probability. A practical

approach is to treat the probability as conditional on the severity of harm, allowing manufacturers to more precisely define and target risk controls.

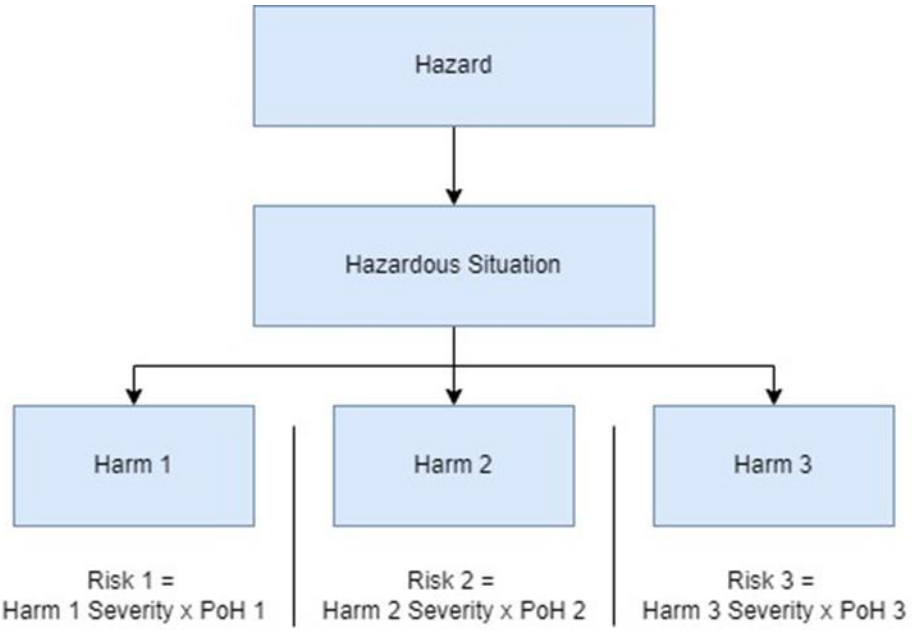

Figure 4. Flow chart showing how to extract risk line items from potential harms as a result of a hazardous situation.

Risk Expression Model

$R(x) = s(x) \times p(x \mid s(x))$

This formula expresses risk as a function of:

- **s(x)**: the severity of a specific harm, and
- **p(x | s(x))**: the probability of that harm occurring given the hazardous situation

By modeling probability this way, each severity level can be assessed on its own terms — leading to better decision-making, stronger justification for controls, and improved post-market alignment.

Example:

If a device exposes a patient to excessive heat, the hazard analysis might include multiple risks:

- Exposure → First-degree burn
- Exposure → Second-degree burn

Each with its own probability, controls, and post-market tracking. This avoids the pitfall of assuming a single outcome (e.g., only a second-degree burn) and instead gives visibility into the more likely but less severe events.

Conclusion

The structure of a hazard analysis influences not just design control but how effectively a manufacturer can respond to field data. While other methods offer value, defining line items based on hazardous situation/harm combinations provides the clearest path for traceability, verification, and continuous improvement. By focusing on reducing the probability of each specific harm, manufacturers can better meet both regulatory expectations and real-world safety goals.