SUNRISE
LABS

Risk Management for Medical Devices

How to get Everyone Speaking the Same Language

N. Christopher Perry

What is Risk Management

Per subclass 3.24 of ISO 14971: 2019

[The] systematic application of management polices, procedures and practices to the task of analyzing, evaluating, controlling and monitoring risk.

Why do we need Risk Management?

Central to FDA Approval Process and EU MDR

- 21 CFR Part 820.30(g)

- MDR Article 10, 2

Key aspect of IEC 60601 / IEC 61010 / ISO 14708-1

Why Implement Risk Management?

> Identifies problems early

> Triages problems

> Builds consensus on how to fix problems

> Communicates how problems are managed

> Focuses testing effort

> Helps you knows when you've done enough

Frequent issues in this process include getting everyone to understand the terminology and the structure of the analysis

Central to the process are the steps of **analyzing**, **evaluating**, and **controlling**

Risk

Combination of the probability of occurrence of harm and the severity of that harm

Harm

Injury or damage to health of people, or damage to property or the environment

Severity

Measure of the possible consequence of a hazard

Per subclauses 3.18, 3.3, 3.27 of ISO 14971: 2019,

Hazard

Potential source of Harm

Hazardous Situation

Circumstance in which people, property or the environment is/are exposed to one or more hazards

Risk Control

Process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels

Residual Risk

Risk remaining after risk control measures have been implemented

Safety

Freedom from unacceptable risk

Per subclauses 3.5, 3. 21, 3.17, & 3.26 of ISO 14971: 2019, respectively
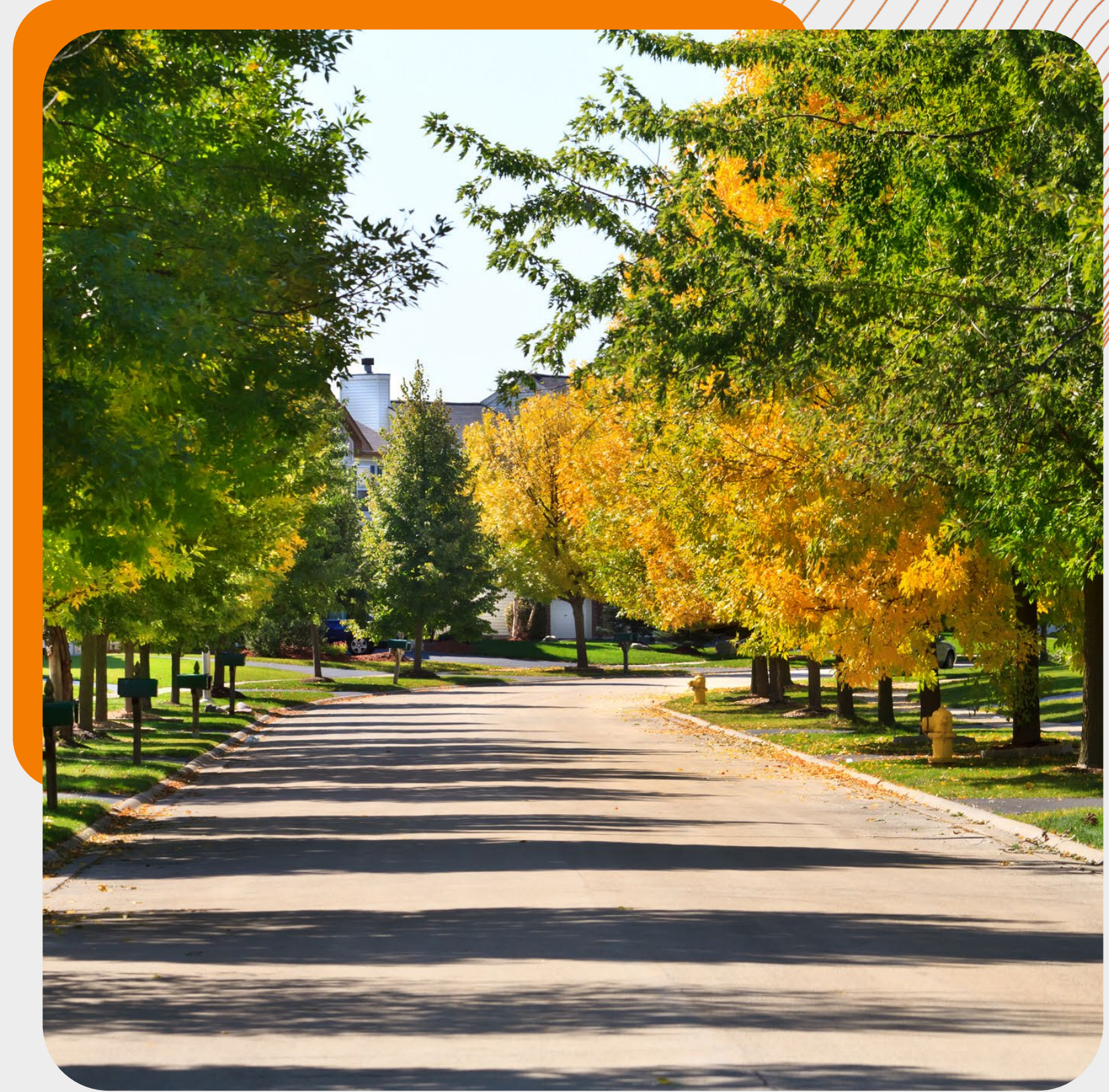
What does it mean?

> These terms and the process can certainly seem cryptic

> Having a mental model helps everyone understand the terms and the process better

Crossing the Street

All aspects of risk management can be explored by analyzing the risks of crossing a residential street.

Harm

The injury received by being struck by a car, e.g. blunt force trauma

Severity

How bad is the injury received by being struck by a car, e.g. cuts/bruises, broken bones, etc.

Hazard

Moving objects*

*Derived from examples in Table C.1 of ISO 14971

Hazardous Situation

Pedestrian in the path of on -coming traffic

Risk

Everyone would agree blindly stepping into the street is 'risky', i.e. not **Safe** (not free from unacceptable risk)

*Derived from examples in Table C.1 of ISO 14971

Risk Control Measures

- Looking both ways prior to stepping into the street
- Waiting for an approaching car to pass when one is approaching
- Requiring drivers to yield to pedestrians in the street
- Speed limits
- Zoning rules for visibility
- Streetlights

Residual Risk

If the previous Risk Control Measures are applied, most would agree the risk of crossing the street is acceptable, i.e., **Safe** (free from unacceptable risk)

Probability of Occurrence

> How likely will **HARM** Occur?

> Can be broken down into two Probabilities:

  (As discussed in C.1 of ISO 14971: 2019)

> P1 - Probability that a **HAZARDOUS SITUATION** occurs

> P2 - Probability of **HAZARDOUS SITUATION** leading to **HARM**

> Overall Probability, P, is P1 * P2

P1- Probability that a **HAZARDOUS SITUATION** Occurs

From our 'crossing a residential street' example:

≫ **How probable is it that there will be an oncoming car when the pedestrian steps into the street?**

- Occasionally there is a car driving down the street
- Guess: 10 cars / day

P2 - Probability of **HAZARDOUS SITUATION** leading to **HARM**

From our 'crossing a residential street' example:

> **How probable is the type of injury to occur if the pedestrian is struck by an on-coming car, in increasing levels of SEVERITY?**

- Cuts & Bruises: Pretty high, ~100% of the time

- Sprains & Broken Bones: Slightly less likely, easily 50% of the time

- Internal Injuries Requiring Hospitalization: Less likely, maybe 10%

Probability of Occurrence
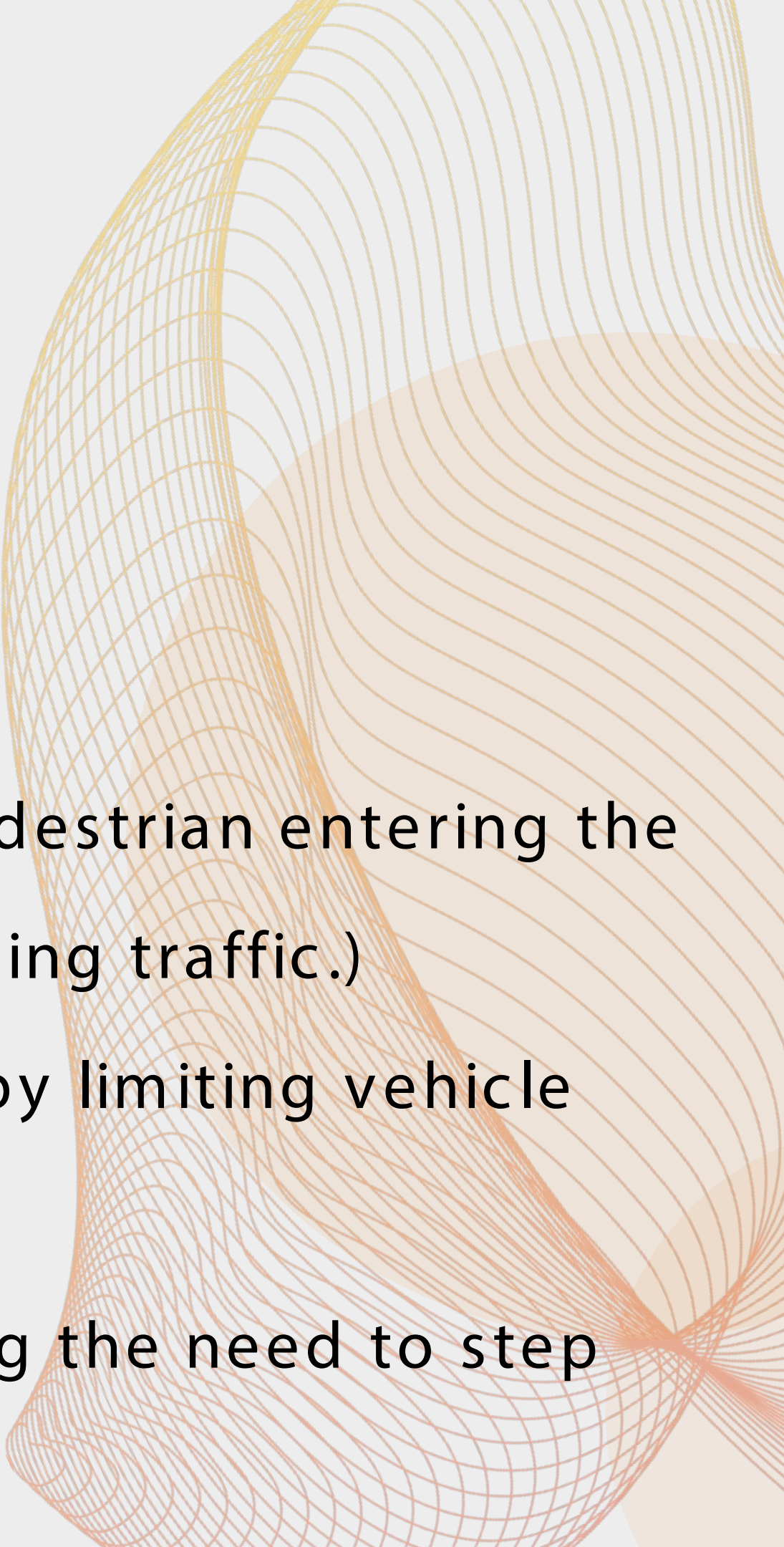
> **Combining P1 & P2:**

- Cuts & Bruises: ~10 times / day.

- Sprain & Broken Bones: ~5 times / day.

- Internal Injuries requiring hospitalization: ~1 time / day

How Risk Controls Work

> Risk Controls work in one of three ways:

- Reducing P1(e.g. Reducing the Probability of a Pedestrian entering the Hazardous Situation of being in the path of oncoming traffic.)

- Reducing P2 (e.g. Reducing the Severity of Harm by limiting vehicle speed.)

- Interrupting the sequence of events (e.g. Removing the need to step into the street.)

How do we start a Risk Management File?

> **Intended Use / Purpose defined** (*See 5.2 of ISO 14971*):

- What it's for?
    - Crossing Example: Safe transit of Pedestrians and Vehicles on local streets
- Who it's for?
    - Crossing Example: All ambulatory individuals, including wheelchair users
- What's the environment?
    - Crossing Example: Outside environment, day / night, all seasons

> **Basic description of device / system** (*See 5.3 of ISO 14971*)

- Crossing Example: Typical paved residential street, with sidewalks, lined with single family homes, in a municipality that provides services and enforces laws / regulations

> **Criteria for Risk Acceptability** (*See 6 of ISO 14971*), typically a Risk Acceptability Matrix

How do we organize a Risk Management File?

⟩⟩ **Hazard Analysis: What Hazards are inherent in use of the device is the intended application?**

- Crossing Example: What can go wrong when crossing the street?

⟩⟩ **Design FMEA(s): What about the device / system can go wrong?**

- Crossing Example: What can go wrong with the car, e.g. cracked windshield, worn tires, faulty brakes? What can go wrong on street / in neighborhood that can cause Harm, e.g. streetlights failing, overgrown bushes?

⟩⟩ **Use FMEA: What mistakes can the Patient / Caregiver / Operator commit?**

- Crossing Example: What errors can the vehicle driver / pedestrian make?

Reasonably Foreseeable Misuse

Use of a product or system in a way not intended by the manufacturer (3.9), but which can result from readily predictable human behavior.

..includes the behavior of …. lay and professional users.
..can be intentional or unintentional.

Not necessarily malicious misuse.

Per subclauses 3.15 of ISO 14971: 2019, respectively

Hazard Analysis Structure

Here are a couple of lines for a 'Crossing the Street' Hazard Analysis:

HAZARD	CAUSE	SEQUENCE OF EVENTS	HAZARDOUS SITUATION	HARM	SEVERITY	PROBABILITY	RISK	RISK CONTROL MEASURES	RESIDUAL PROBABILITY	RESIDUAL RISK	NOTES
Moving Objects	Pedestrian and vehicle fail to avoid contact	- Pedestrian steps into a street when a vehicle is approaching - Vehicle fails to stop and hits Pedestrian	Pedestrian in the path of on-coming vehicle	Blunt trauma	High	Once / Day	Not Acceptable	- Looking both ways before stepping into street - Waiting for an approaching car to pass - Speed limits - Drivers to yield to pedestrians - Streetlights - Setback zoning rules	<<Once / Day	Acceptable	Speed limits serve to ensure that a vehicle has enough stopping distance if the Pedestrian misjudges the separation distance/fails to see the vehicle
Falling	Pedestrian losses balance	Pedestrian trips while stepping up curb, leading to a fall	Pedestrian fall	Blunt trauma	Medium	<Once / Day	Acceptable				

Design FMEA Structure

Here are a couple of lines for a 'Crossing the Street' Design FMEA:

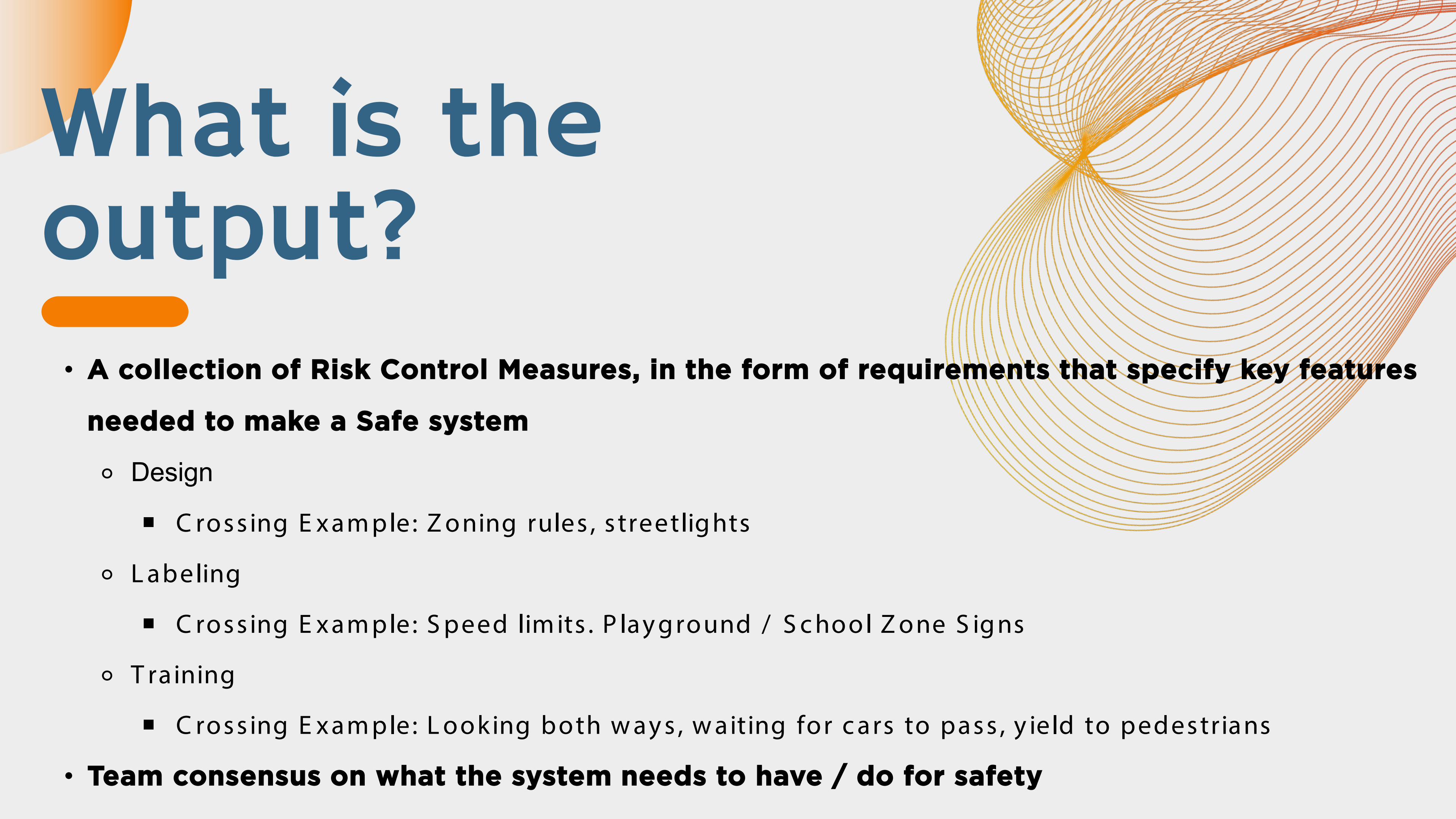| COMPONENT	FAILURE MODE	CAUSE	SEQUENCE OF EVENTS	HAZARDOUS SITUATION	HARM	SEVERITY	PROBABILITY	RISK	RISK CONTROL MEASURES	RESIDUAL PROBABILITY	RESIDUAL RISK	NOTES
Street	Pedestrian / Driver view blocked	Overgrowth of foliage	- Vehicle Operator / Pedestrian unable to see each other in time for operator to stop - Pedestrian is hit	Pedestrian in the path of on-coming vehicle	Blunt trauma	High	Once / Day	Not Acceptable	- City / state to keep foliage trimmed - Extra care in looking both ways when view is obstructed - Speed limits	<<Once / Day	Acceptable	Speed limits serve to ensure that a vehicle has enough stopping distance if the Pedestrian misjudges the separation distance/fails to see the vehicle
Vehicle	Pedestrian / Driver view blocked	Scratched / cracked windshield	- Vehicle Operator / Pedestrian unable to see each other in time for operator to stop - Pedestrian is hit	Pedestrian in the path of on-coming vehicle	Blunt trauma	Medium	<Once / Day	Not Acceptable	- Annual vehicle inspection - Looking both ways prior to stepping into the street - Waiting for an approaching car to pass - Speed limits	<<Once / Day	Acceptable	- Probability assumes most windshields are intact - Vehicle inspection includes windshield check

Use FMEA Structure

Here are a couple of lines for a 'Crossing the Street' Use FMEA:

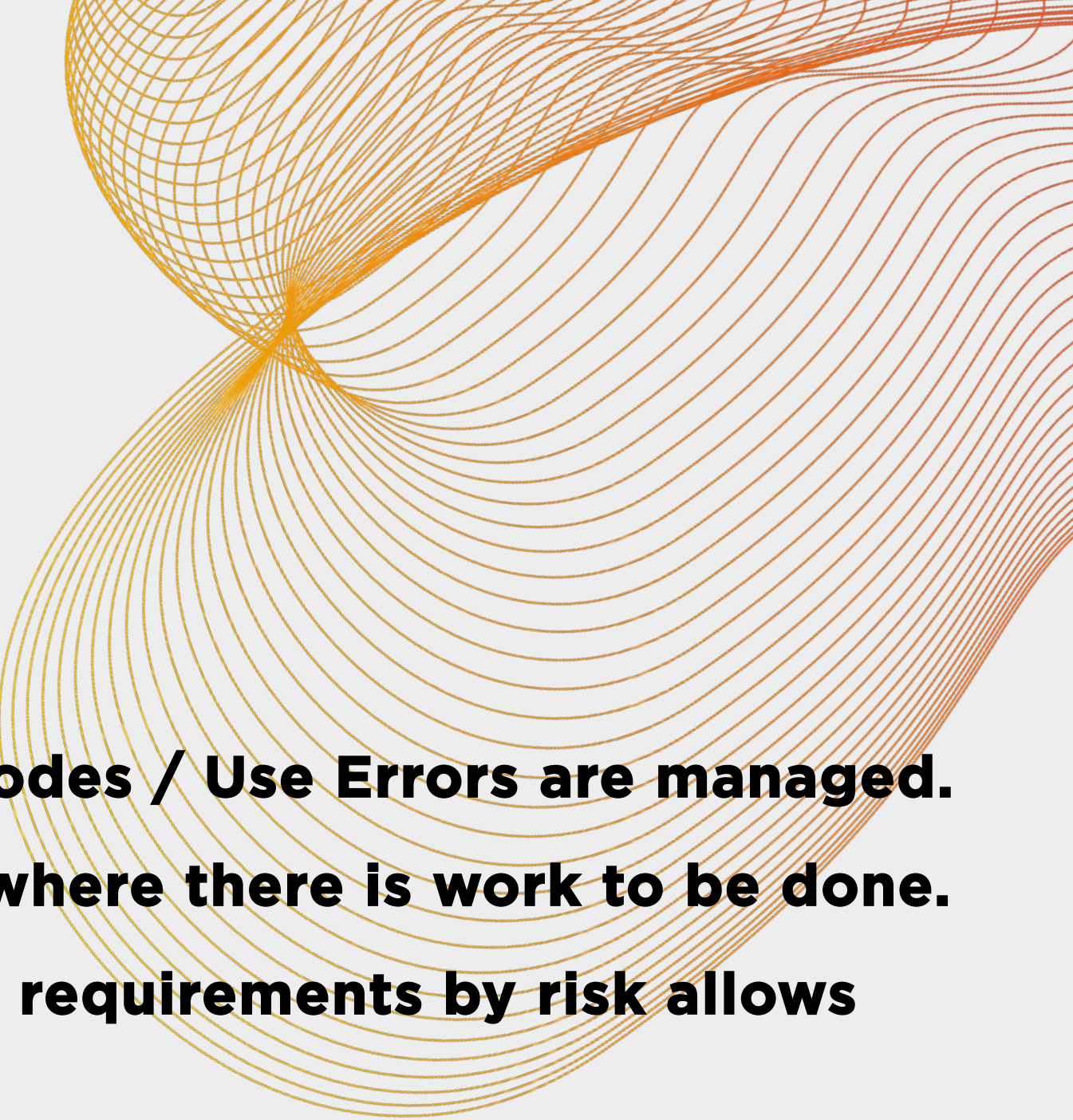| TASK	USE ERROR	SEQUENCE OF EVENTS	HAZARDOUS SITUATION	HARM	SEVERITY	PROBABILITY	RISK	RISK CONTROL MEASURES	RESIDUAL PROBABILITY	RESIDUAL RISK	NOTES
Operation of vehicle	Operator distracted by telephone	Vehicle Operator doesn't see Pedestrian in time for operator to stop and hits Pedestrian	Pedestrian in the path of on-coming vehicle	Blunt trauma	High	<Once / Day	Not Acceptable	-Use of Handheld Devices Prohibited - Looking both ways prior to stepping into street - Waiting for an approaching car to pass - Speed limits	<<Once / Day	Acceptable	
Staying clear of street	Entering street when a vehicle is approaching	Child chasing a ball that enters the street while a vehicle is approaching. Operator unable to stop before striking Child	Pedestrian in the path of on-coming vehicle	Blunt trauma	Medium	Once / Day	Not Acceptable	- Speed limits - Driver training to watch for children. - Signage	<<Once / Day	Acceptable	- This is relevant to schools / daycare centers - Probability is assessed based on increased Probability of high Severity of Harm for children.

What is the output?

- **A collection of Risk Control Measures, in the form of requirements that specify key features needed to make a Safe system**
  - Design
    - Crossing Example: Zoning rules, streetlights
  - Labeling
    - Crossing Example: Speed limits. Playground / School Zone Signs
  - Training
    - Crossing Example: Looking both ways, waiting for cars to pass, yield to pedestrians
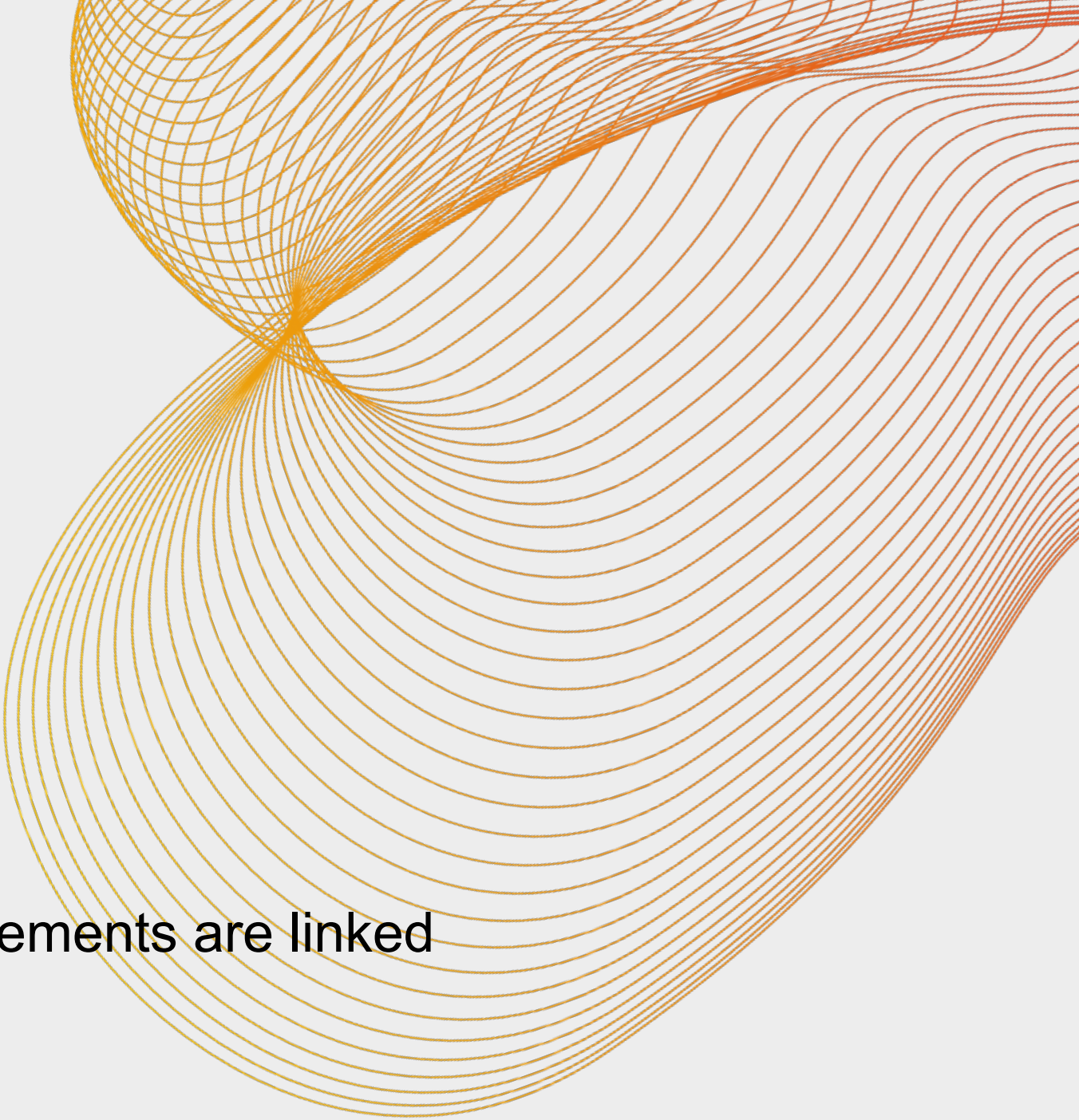- **Team consensus on what the system needs to have / do for safety**

What is the output?

- **Communicates to all stakeholders how Hazards / Failure Modes / Use Errors are managed.**
- **Comparing concept hardware with requirement list shows where there is work to be done.**
- **Unmet requirements trace to risk items - Organizing unmet requirements by risk allows high-risk items to be prioritized.**
- **When problems come up**
  - If the RMF already captures the issue the team already knows what the risk is and what RCMs address the problem.
  - If not, the RMF will need to be updated with this new information, which will ensure the team knows how we address the new problem.

What is the output?

- **Means to focus test effort**
  - Design requirements tested by simulating Failure Modes where requirements are linked
  - Use FMEA is starting point for Human Factors testing
- **System / device risk profile that communicates if the device acceptable**

When the device meets claims and the risk control requirements,

your product is ready to submit!

Risk Estimation
Defining Levels of Severity

Severity	Criteria
Negligible	No adverse health consequences on patient, User, or other person (possible temporary discomfort) and negligible environment safety concerns.
Minor	Temporary or reversible harm, without medical intervention, on patient, User, or other person. Or temporary environmental safety concerns. Device may operate at reduced functionality or performance
Serious	Harm that is a condition necessitating medical or surgical intervention to prevent Critical or Life-Threatening harm to a patient, User, or other person. Or environment safety concern.
Critical	Harm results in permanent impairment of body function or permanent damage/change to a body structure of a patient, User, or other person.
Catastrophic	Life-Threatening harm (death of a patient, User, or other person could occur)

Risk Estimation
Defining Levels of Probability

Probability	Criteria	Percentage Rate
Improbable	Failure improbable. It may be assumed the failure will not occur during the market life of the product	P < 0.01%
Remote	Relatively few failures. Failure unlikely to occur in the market life of the product	0.01% ≤ P < 0.10%
Occasional	Occasional failures during normal / abnormal use of the product. Failure likely to occur sometime in the market life of the product	0.10% ≤ P < 1%
Probable	Failure is likely to occur, perhaps several times in the market life of the product. Repeated failures likely	1% ≤ P < 50%
Frequent	New application or change in operating conditions with no previous experience.	50% ≤ P

Risk Estimation

An example Risk Acceptability Matrix:

Probability	Severity				
	Negligible	Minor	Serious	Critical	Catastrophic
Improbable	Acceptable	Acceptable	Acceptable	Acceptable	Not Acceptable
Remote	Acceptable	Acceptable	Acceptable	Acceptable	Not Acceptable
Occasional	Acceptable	Acceptable	Acceptable	Not Acceptable	Not Acceptable
Probable	Acceptable	Acceptable	Not Acceptable	Not Acceptable	Not Acceptable
Frequent	Acceptable	Not Acceptable	Not Acceptable	Not Acceptable	Not Acceptable