Risk Basics For Medical Devices

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Learning Objectives

- Define basic terms
- Review an example of events and their relationships to determine risk
- Discuss risk-based decisions and risk analysis
- Describe the concept of risk management as it relates to the ISO 14971 Standard

Basic Definitions

The Importance of Definitions

- Understanding these basic terms helps to ensure that everyone is talking about the same thing during risk discussions
- Definitions come mostly from the International Organization for Standardization, or ISO, 14971:2019 standard

Disclaimer when looking at definitions of risk terms:

- Understand context and nuance as they relate to the specific guidance documents or standards etc. and where they are used

Definitions: The Three H's

- **Hazard:** potential source of harm
- **Hazardous Situation:** circumstances in which people, property or environment is/are exposed to one or more hazards
- **Harm:** Injury or damage to health of people, or damage to property or environment

ISO 14971: 2019

Definitions: Probability and Severity

- **Probability of Occurrence** – chance that given event will occur, the likelihood something will happen
- **Severity** – measure of possible consequences of a hazard

Probability of Occurrence-Merriam/Webster
Severity-ISO 14971: 2019

Definition: Risk

- CDRH has no statutory or regulatory definition for the term "**Risk**"

- **Starting Point:**
  - Potential harm of a medical device's use to patients, end users and environment, which includes the harm of the device if it were to fail in normal and fault conditions, i.e., not operate as intended

- **International Organization for Standardization (ISO) 14971:2019 3.18:**
  - Combination of the probability of occurrence of harm and severity of that harm

Definition: Benefit

CDRH has no statutory or regulatory definition for the term “Benefit”

ISO 14971:2019 3.2:

- Positive impact or desirable outcome of the use of a medical device on the health of an individual, or
- Positive impact on patient management or public health

Risk Analysis in the Quality System 1996 Preamble, Comment #83

Risk Analysis includes:

(1) Identification of possible hazards, including [user] error

(2) Risk Calculation/estimation, normal and fault conditions

(3) Risk Acceptability Determination

(4) Risk Reduced to Acceptable Level

(5) Evaluation of changes for introduction of new hazards

Definition: Risk Analysis in ISO 14971:2019

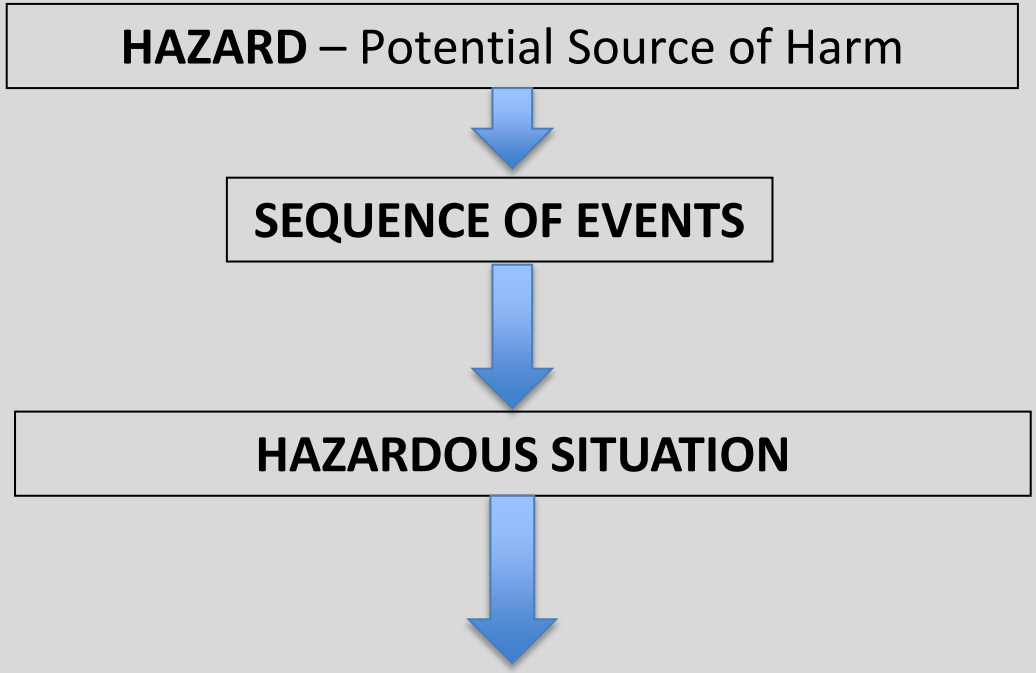
3.19 Risk Analysis

Systematic use of available information to identify hazards and to estimate the risk

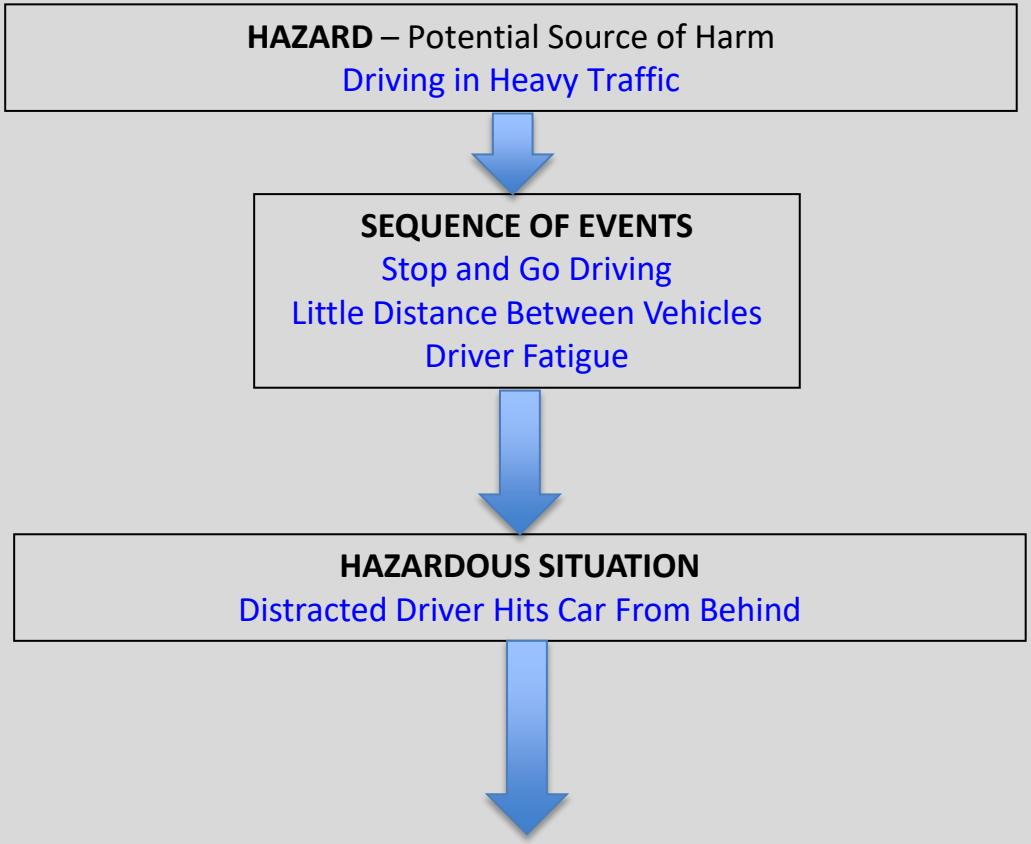
An Example:

Relationships, Circumstances and Sequence of Events involving Risk

ISO 14971:2019 Annex C Figure C.1

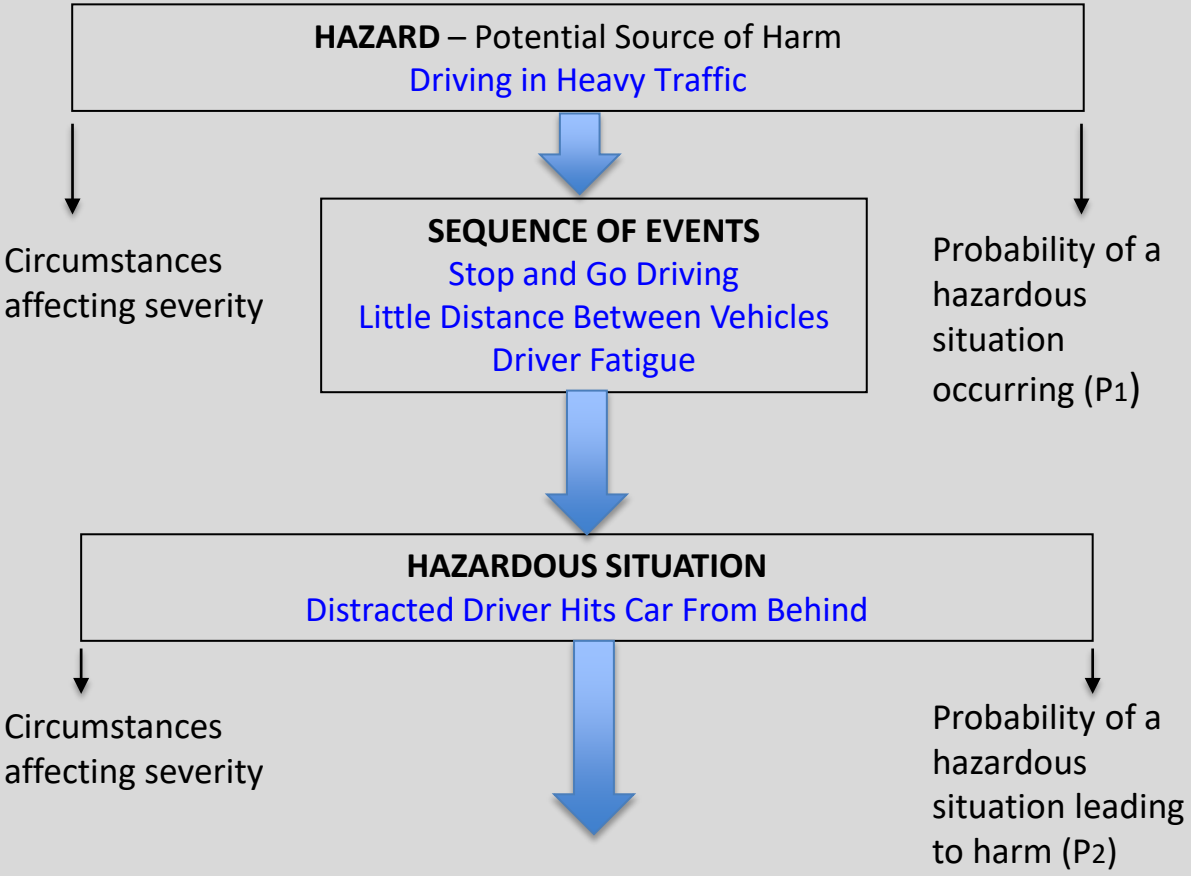


Example: Driving



ISO 14971:2019 Annex C Figure C.1

Example: Driving



ISO 14971:2019 Annex C Figure C.1

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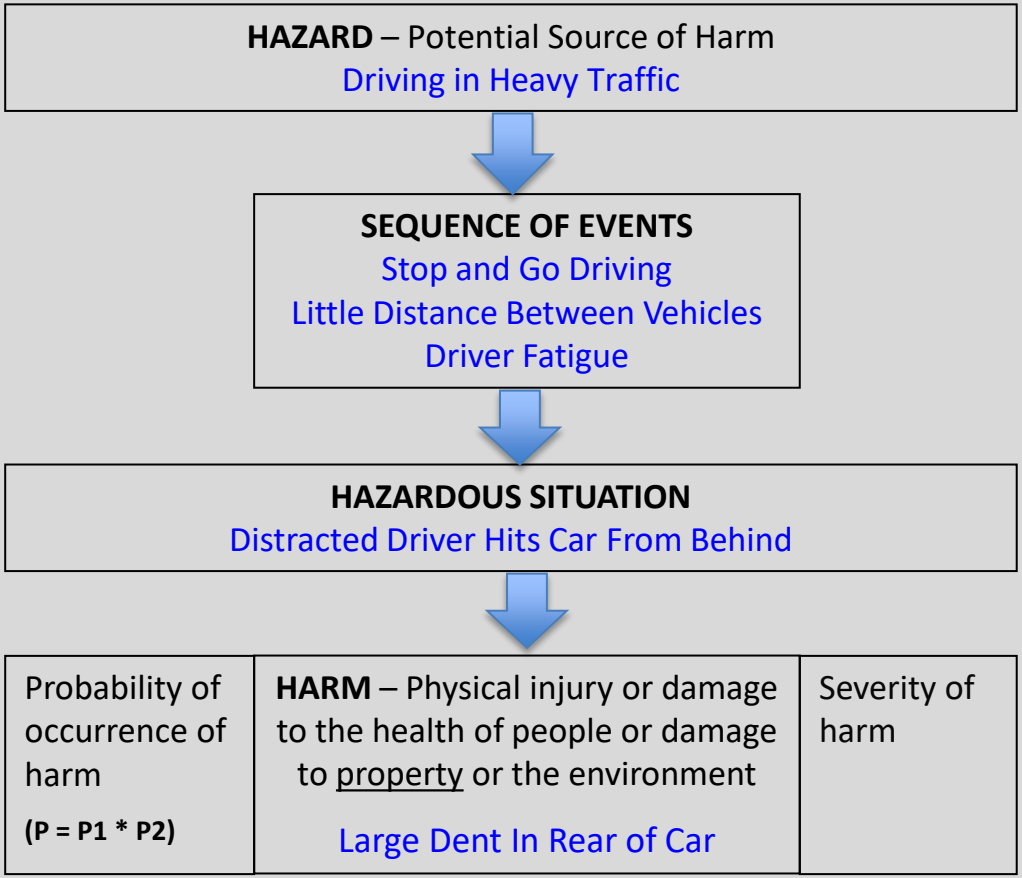

ISO 14971:2019 Annex C Figure C.1

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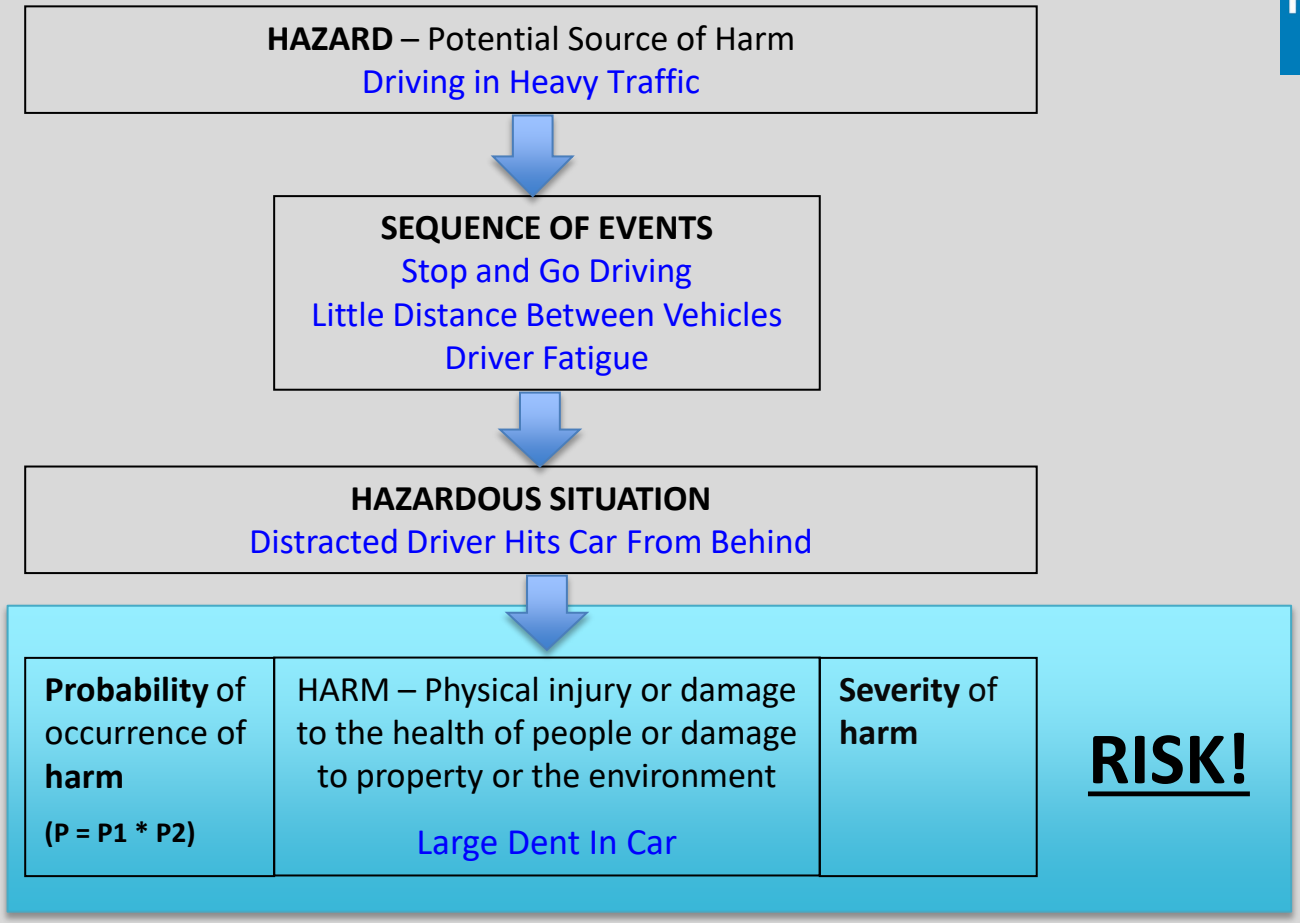

ISO 14971:2019 Annex C Figure C.1

Risk-Based Decisions, Risk Analysis and Risk Management of Medical Devices

Where You May Consider "Risk"

Throughout Total Product Life Cycle

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Throughout Total Product Life Cycle

Where You May Consider "Risk"

Throughout Total Product Life Cycle

Risk-Based Decisions

- CDRH has no statutory or regulatory definition for “risk-based decision”.
- However, risk-based decision making is essential to CDRH’s approach.
- It is incorporated into how FDA determines the safety and effectiveness of a device. See 21 CFR 860.7 (d)(1)
- Other regulatory documents, including guidance, provide additional discussion and examples of risk-based decisions.

Examples of Risk-Based Decisions in the Preamble of the Final Rule for 21 CFR 820

- "…gives the manufacturer the flexibility to determine the controls that are necessary and commensurate with risk."
- "The extent of the documentation necessary to meet the regulation requirements may vary with …, and the risk associated with the failure of the device, among other factors."

CFR = Code of Federal Regulations

www.govinfo.gov/content/pkg/FR-1996-10-07/html/96-25720.htm

Examples of Risk-Based Decisions in the Preamble of the Final Rule for 21 CFR 820

- "… the degree of corrective and preventive action taken to eliminate or minimize actual or potential nonconformities must be appropriate to the magnitude of the problem and commensurate with the risks encountered."

www.govinfo.gov/content/pkg/FR-1996-10-07/html/96-25720.htm

Where Does FDA Use Risk-Based Decisions?

- Medical Device Classification
- Medical Device Premarket Submissions
- Scheduling of Inspections
- Recalls
- Enforcement Actions

Commonly Used Risk Analysis Techniques

- Preliminary Hazard Analysis (PHA)
- Fault Tree Analysis (FTA)
- Failure Mode and Effects Analysis (FMEA)

➢ See ISO/TR 24971 for guidance on selected risk analysis techniques, including those for in-vitro diagnostic medical devices.

Risk Management Standard

- AAMI/ANSI/ISO 14971:2019 Medical devices-Application of risk management to medical devices (ISO 14971)
  - Systematic approach to conducting risk management activities
- AAMI/ISO TR 24971:2020-Medical devices-guidance on the application of ISO 14971
  - Guidance on the application of ISO 14971

Summary

- Risk basics involves some foundational key terms and definitions
- Determination of risk involves relationships, circumstances and sequences of events
- Risk, risk analysis and risk management spans the full total product lifecycle of medical devices
- Concepts of risk are included in FDA regulations and international standards

Resources

Slide Number	Cited Resource	URL
5-13, 22	ANSI/AAMI/ISO 14971:2019 Medical devices – Applications of risk management to medical devices	www.iso.org/standard/72704.html (for purchase from standards organization)
17-18	21 CFR 820 Quality System Regulation and Preamble	www.govinfo.gov/content/pkg/FR-1996-10-07/pdf/96-25720.pdf
20, 21	ISO/TR 24971:2020 Medical devices — Guidance on the application of ISO 14971	www.iso.org/standard/74437.html (for purchase from standards organization)

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   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: **www.fda.gov/DICE**

Your Call to Action

1. Become familiar with risk
2. Determine the risk of your medical device
3. Build a culture that values the importance of understanding risk
4. Use the resources available to help you comply with your responsibilities


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