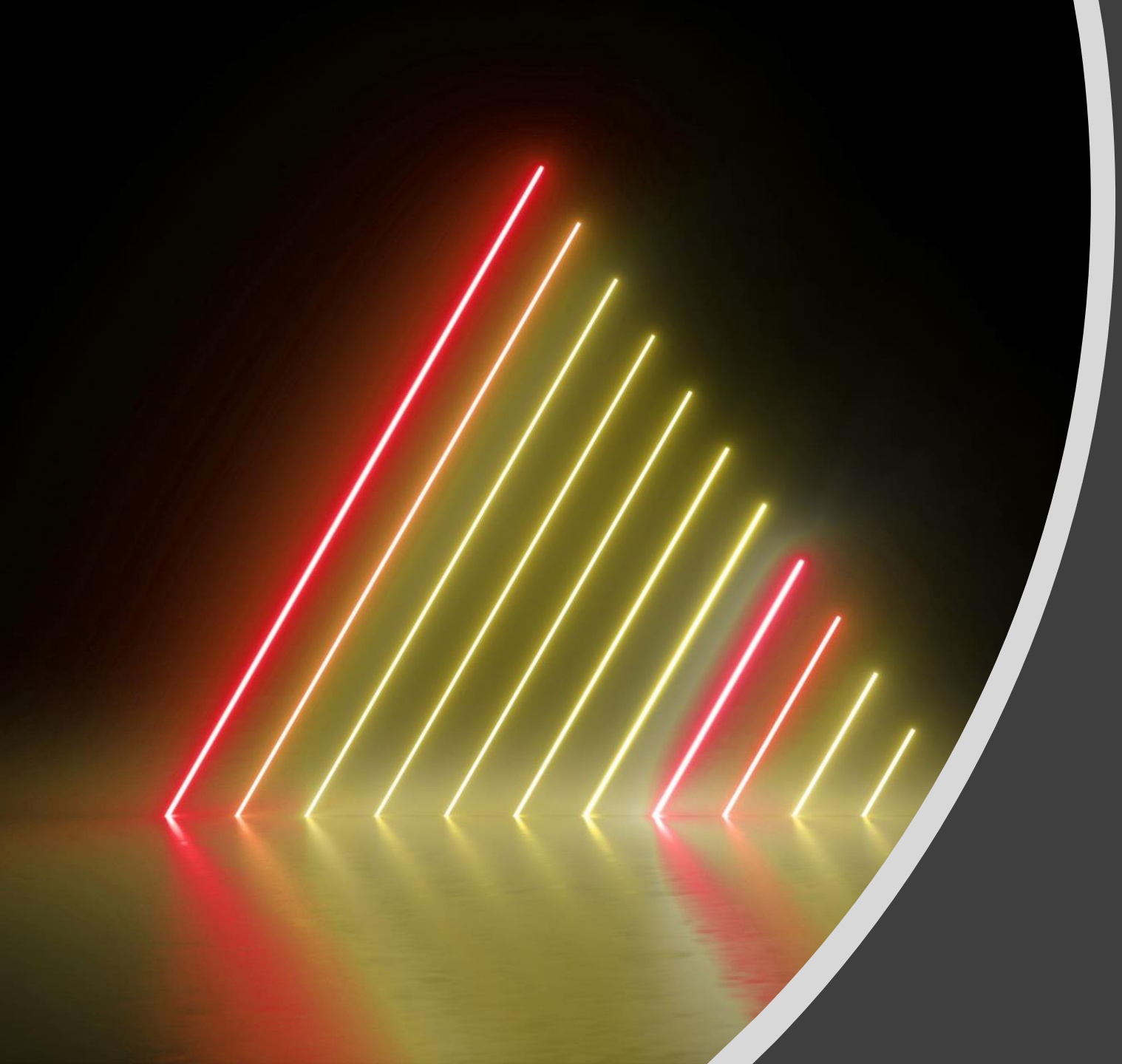


Pharma Forum 2023

Pharmaceutical Occupational Hygiene Practice and Standards of Care

"What We Do, Not Just What We Know"

Nancy M. McClellan, MPH, CIH, CHMM

- AIHA Executive Board of Directors Treasurer
- Occupational Health Management, PLLC Consultancy Principal
- University of Michigan COHSE External Advisory Board Chair

Today's Goals

1. Standards of Care Expectations Defined – Gone are the days of accepting exposure judgement guesses
2. What does a Pharma Mercedes Benz Look Like?
   - Exposure and Control Banding
   - Risk Assessment Tools
3. OH Program Development & Management Tools – Free, Free, Free
   - AIHA Exposure Judgements Course
   - OHTA Pharma Module
   - IH Data Analyst and ExpoStats
   - AIHA Exposure Modeling Tools
4. Emerging Control Technologies

A world where all workers and their communities are healthy and safe

The Importance of Occupational Hygiene

The World Health Organization estimates that globally there are:

- **2,400,000 work-related deaths per year due to chemical exposures!! (Compared to 300,000 safety fatalities per year)**

A Story: Low Standards and Ambulances

- Chemical Exposure not **anticipated** – Fire
  - Ambulance to the hospital with 12 people
- Chemical Exposure not **recognized** – Manufacturing (Mfg.)
  - Ambulance to the hospital with 7 people – 3 later to OH Clinic
- Chemical Exposure not **evaluated** properly – Mfg. & Cleaning process
  - Ambulance to the hospital with 5 people – 4 later to OH Clinic
- Chemical Exposure not **controlled -** Ventilation
  - >4 Employees with chronic health effects

AIHA Initiatives

Initiative	Purpose
AIHA – ACGIH Defining the Science	Advance our science to improve the ability of practitioners to protect workers and communities.
State of the Art vs. Practice	Implement a continuous improvement strategy to close gaps between current practice and the state of the art and minimum standards of care.
AIHA – ACGIH Improving Exposure Judgements	Accelerate adoption of the use of IH statistical and other tools to improve the accuracy of worker exposure assessments.
Standards of Care	Define minimum practice performance expectations for ensuring acceptable worker protection.

Learn More Here

Initiative
AIHA – ACGIH Defining the Science
State of the Art vs. Practice
AIHA – ACGIH Improving Exposure Judgements
Standards of Care

AIHA Guideline Foundation (GF) Standards of Care (SOC)

- The protection of workers and communities depends on the performance of risk management programs.
- As currently implemented, the effectiveness of those risk protection programs is highly variable, resulting in excessive risk for many workers and communities.
- The SOC initiative seeks to inspire continuous improvement activities that increase the effectiveness of risk management programs and thereby accelerate progress toward our shared vision for healthy and safe workers and communities around the world.

A WORLD WHERE ALL WORKERS AND THEIR COMMUNITIES ARE HEALTHY AND SAFE

Initiative
AIHA – ACGIH Defining the Science
State of the Art vs. Practice
AIHA – ACGIH Improving Exposure Judgements
Standards of Care

AIHA GF SOC

Definitions

- The minimum expected standards of practice and performance established for a particular profession or function.
- Specific to the OEHS profession, standards of care are practical, proven, and available practices that provide robust and reliable performance to effectively protect workers and communities from unacceptable risks.

Standards of Care – How do we apply standard of care in industrial arena?

Standard of Care Are:

Expected standards of practice and performance (<u>What one does</u>)

Are <u>Not</u>:

Competencies (What one knows)

AIHA GF SOC

Round 1:

- Noise and Hearing Conservation
  IN PROCESS

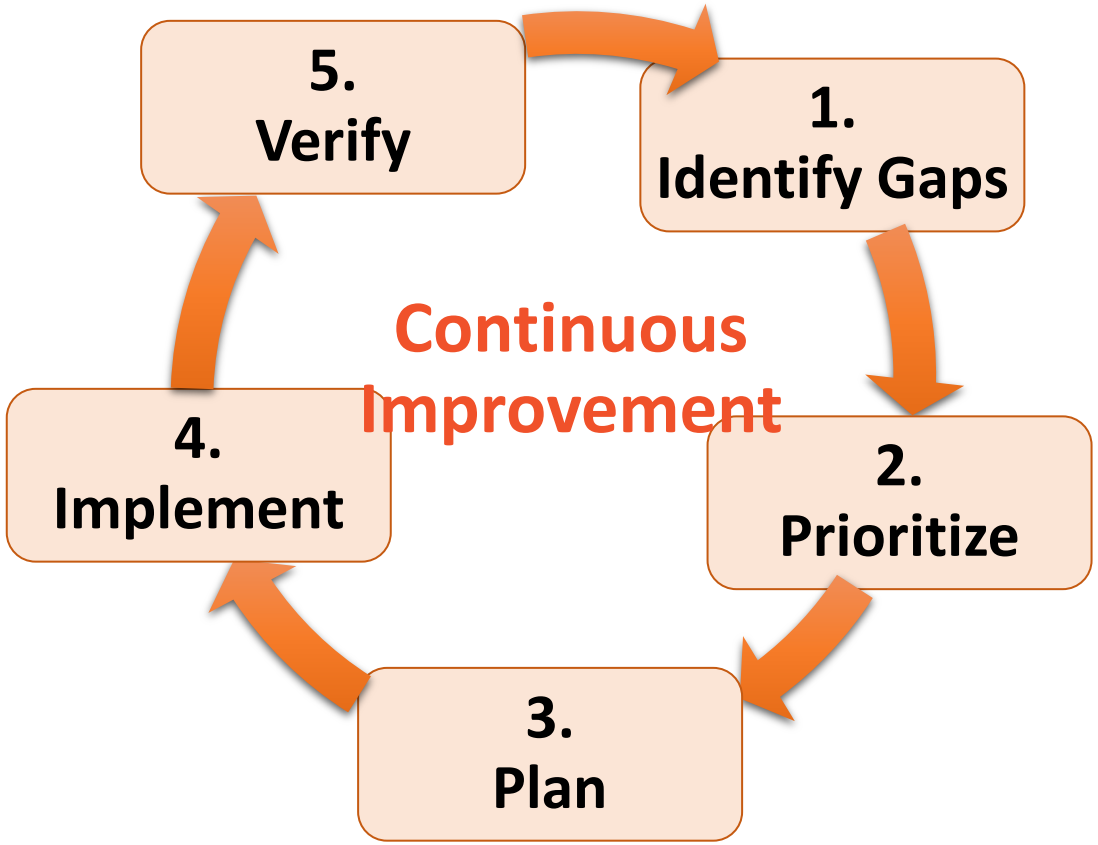
Round 2:

- Exposure Assessment **COMPLETE!**
- Respiratory Protection Program
- Control Banding
- Management

Download the Latest SOC Version:

HERE

AIHA SOC SUGGESTED IMPLEMENTATION STRATEGY



Integration Into Existing Management Systems
(e.g. ISO 45001, ISO 14001)

OCCUPATIONAL EXPOSURE ASSESSMENT SOC

Selected SOC Section	Selected Key Content
Scope & Objectives	• Assess and control all chemical, physical and biological exposures for all workers across all workdays
Program Management	• Written program • Under direction of an industrial hygienist experienced and trained in exposure assessment
Basic Characterization	• Critical information for characterizing exposures is documented for the workplace
Occupational Exposure Limits	• Authoritative or internal OELs are used for exposure judgments • Regulatory OELs are used if lower than authoritative or internal OELs
SEGs	• The workforce is stratified into similar exposure groups (SEG).
Exposure Judgments	• Exposure are acceptable if the 95th percentile is less than the OEL with 70% confidence (95% confidence best practice) • An AIHA Exposure Control Category (ECC) and certainty rating are selected for each air contaminant and noise SEG • The exposure profile for each SEG is judged acceptable or unacceptable

SOC DECISION STATISTIC:

SOC: At least 70% confident that the true 95th percentile exposure is less than the OEL

Best Practice: Strive to be at least 95% confident that the true 95th percentile exposure is less than the OEL

AIHA GF SOC Next Steps

1. Complete and Publish SOC

- **Round 1 Areas of Practice**
  - Noise and Hearing Conservation
- **Round 2 Areas of Practice**
  - Exposure Assessment **Published!**
  - Respiratory Protection Program
  - Control Banding
  - Management

2. Initiate Next Rounds

Potential Next Round Areas of Practice

- Biological Agents
- Community Exposure Assessment
- Confined Spaces
- Education, Training & Communications
- Epidemiology
- Ergonomics
- Evaluation and Management of Hazard Controls
- Incident Preparedness and Response
- Indoor Environmental Quality
- Ionizing Radiation
- Laboratory Health and Safety
- Non-Ionizing Radiation
- Personal Protective Equipment
- Product Stewardship
- Thermal Stress
- Total Worker Health
- Vibration

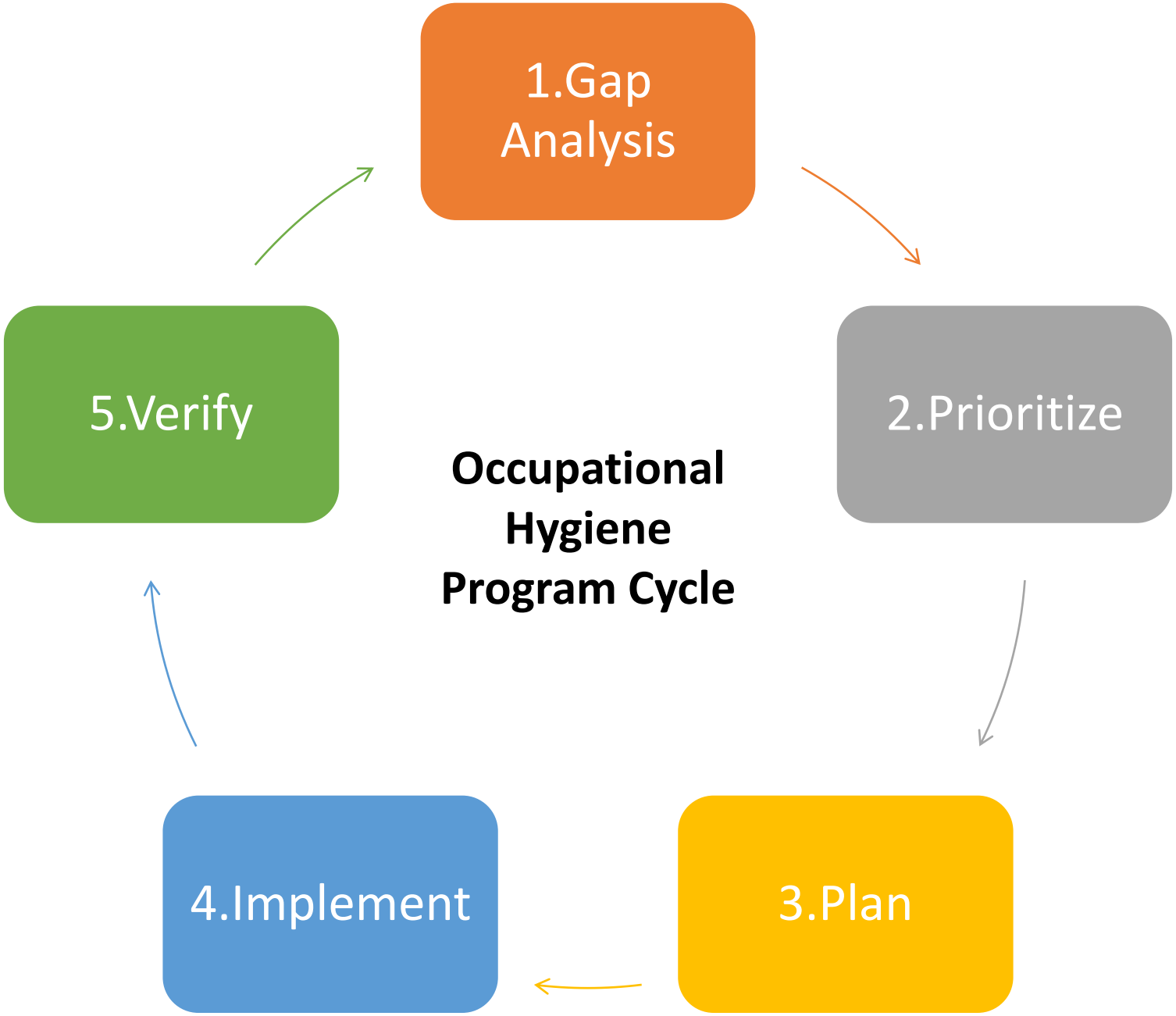
The implementation of a standard of care

- What is the required approach to standards of care?
  - Legally/Regulatory
  - Liability
  - Company Policy
- As an OEHS professional, what is our ultimate goal?

To incorporate the best risk management practices whenever feasible to implement effective work health protection practices

The implementation of a standard of care – continuous improvement

- Standard of care is not a “one & done” process, but rather an ongoing practice of comprehensive program assessment and implementation.
- SOCs are not equivalent to “minimum acceptable,” nor are they necessarily “state of the art”.
- Standards of care should be practical, proven, and available.
- Each OEHS practitioner is responsible for acting with integrity, in conformance with professional ethics, and within the limitations of their capabilities to ensure that the level of risk protection is equivalent or better than that provided by the SOC.


1.Gap Analysis
2.Prioritize
3.Plan
4.Implement
5.Verify
Occupational Hygiene Program Cycle

Example – OEHS Professions “A” & “B”

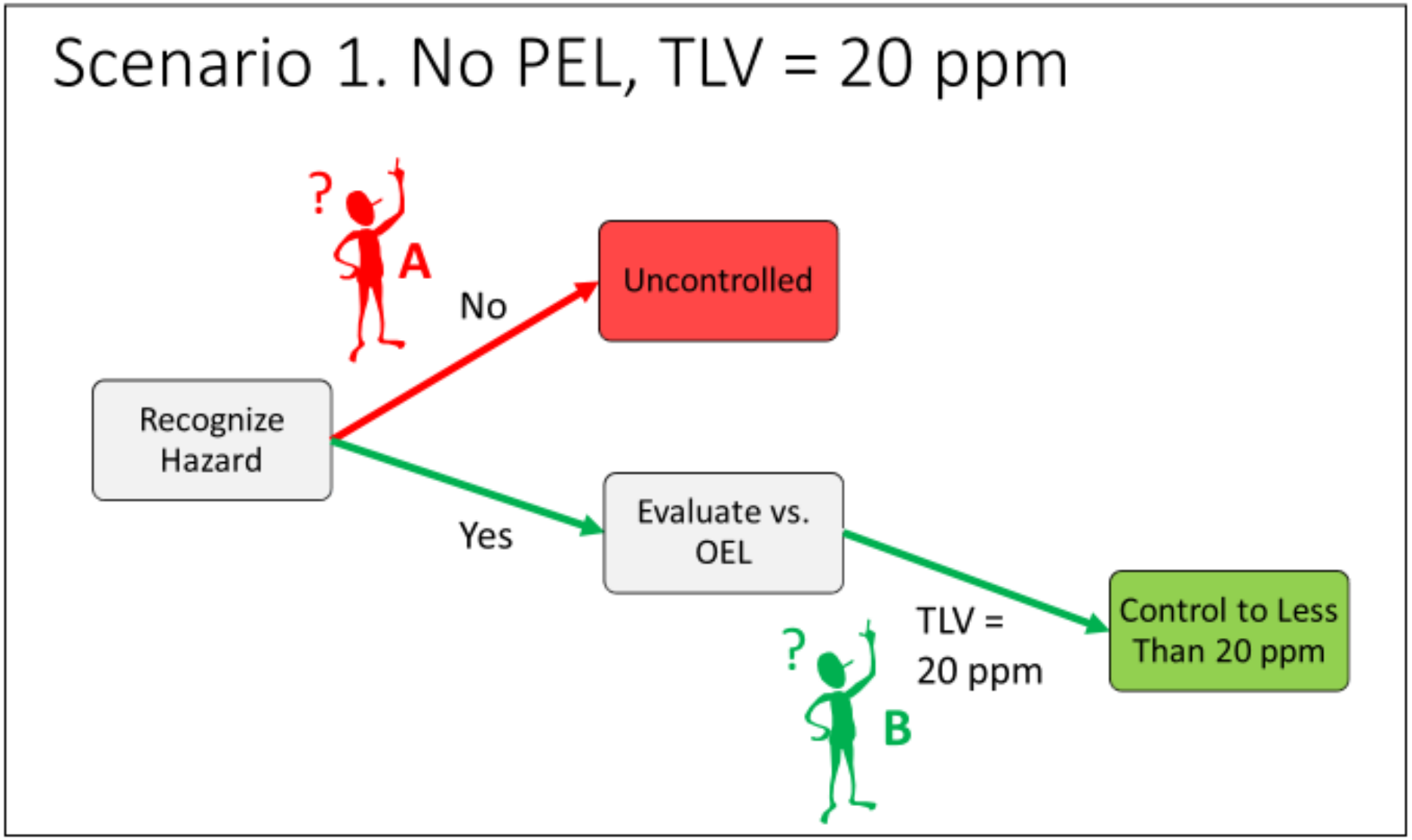
OEHS Professional A:

- Practice based solely on basic regulatory compliance.
- Uses OSHA PELs exclusively

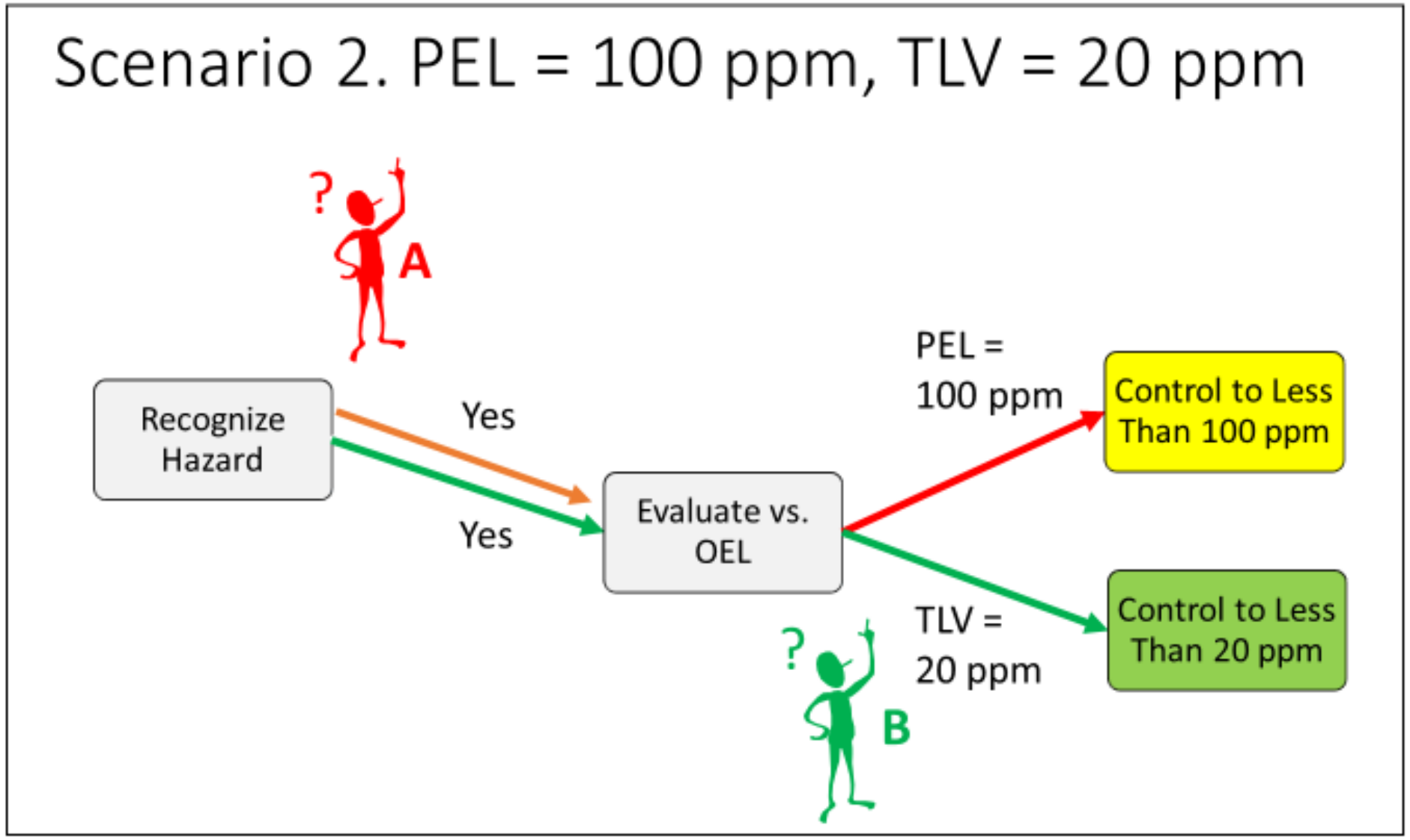
OEHS Professional B:

- Takes a comprehensive approach, considering all potential hazards, whether regulated or not.
- Uses lower of PEL or ACGIH TLV

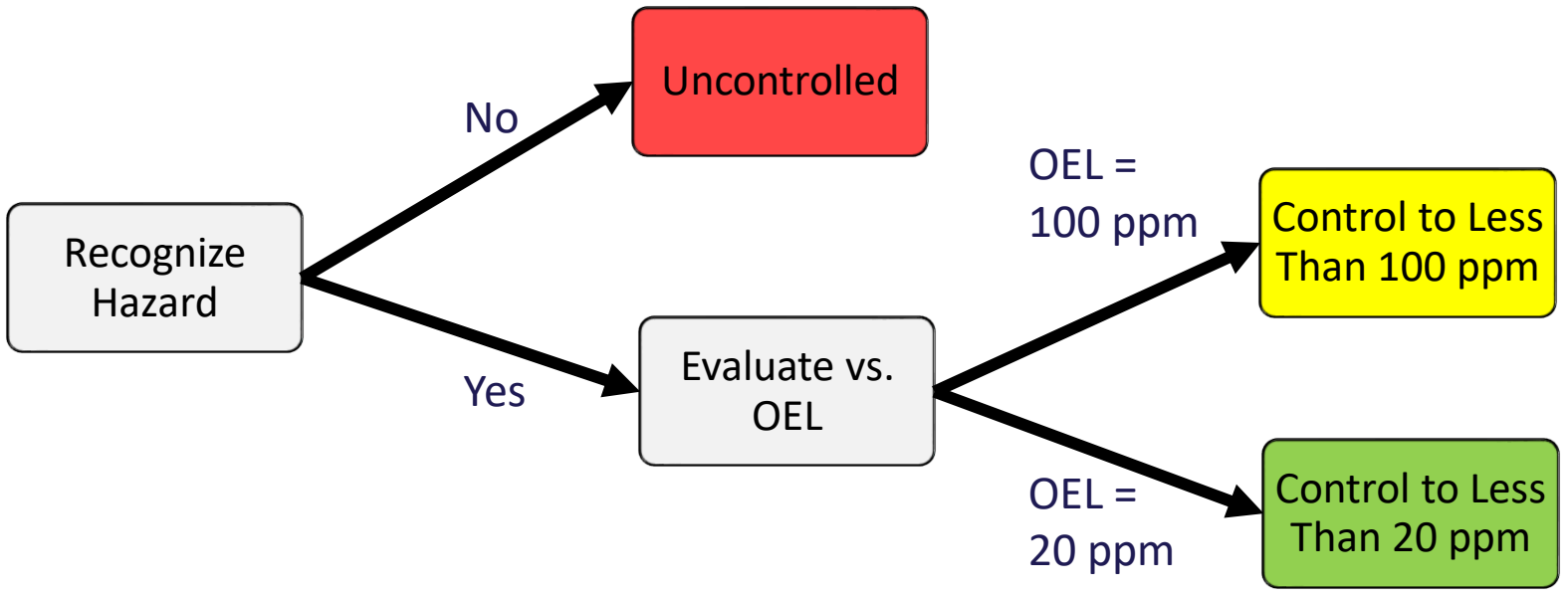
Example – OEHS Professions “A” & “B”



Example – OEHS Professions “A” & “B”



Identify Risk-Critical Practices and Standards of Care

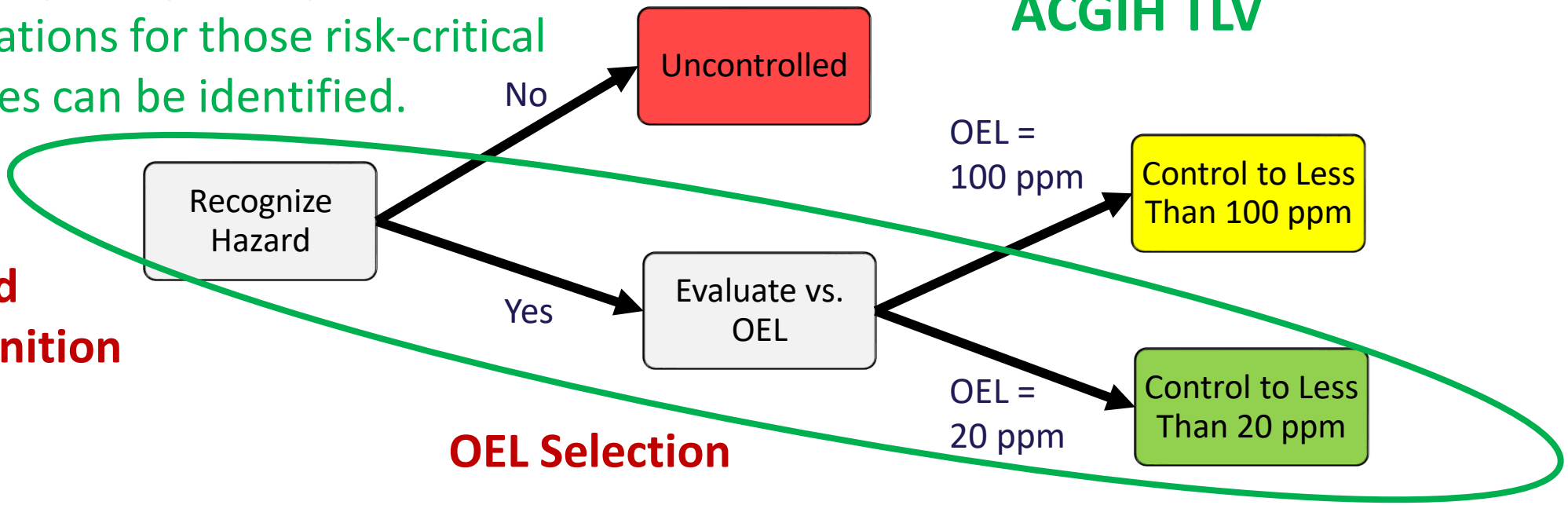


Identify Risk-Critical Practices and Standards of Care

1. Risk-critical practices can be defined for OEHS risk management processes and programs.
2. Minimally acceptable professional expectations for those risk-critical practices can be identified.

Standards of Care:

- **Comprehensive Approach**
- **Use Lower of PEL or ACGIH TLV**



Example of Pharma Structured Deterministic Model (SDM)

(From the OHTA Pharmaceutical Module)

Step #1 – Choose the Potential For Exposure (PFE)

		Dustiness Potential				
		Low (Tablets, Capsules, Lentils)	Medium (Granular)	High (Powders)		
Quantity of Material Handled	Small (g) to Medium(kg)	PFE-1	PFE-1	PFE-2	Minutes	**Duration of the Task**
		PFE-1	PFE-2	PFE-3	Hours	
	Medium (kg) to High (ton)	PFE-1	PFE-2	PFE-3	Minutes	
		PFE-2	PFE-3	PFE-4	Hours	
	High (ton)	PFE-3	PFE-3	PFE-4	Minutes	
		PFE-3	PFE-4	PFE-4	Hours	

Step #2 – Choose the Control Band

		Potential For Exposure (PFE)			
		PFE-1	PFE-2	PFE-3	PFE-4
Exposure Band	1. OEL is >100 mcg/m3	1	1	2	3
	2. OEL is 10-100 mcg/m3	2	3	3	4
	3. OEL is 1-10 mcg/m3	3	3	4	5
	4. OEL is 0.1-1 mcg/m3	4	4	5	5
	5. OEL is <0.1 mcg/m3	5	5	5	5

$$$ Decisions

Step #3 – Choose the Control Strategy

	Control Band 1	Control Band 2	Control Band 3	Control Band 4	Control Band 5
Control Strategy Examples	• Open transfers • General room ventilation	• Independent Powder Enclosures • Downflow Booths • Open transfer w/ LEV • Sleeve covered transfers	• Flexible Containment • Wet-in- place (WIP) or Clean-in- place (CIP) process • Closed transfer with LEV • Downflow booth with glove port shield	• Split butterfly valve • Closed transfer • Wet-in- place or Clean-in-place process • Glovebox with RTPs	• Glovebox isolator with RTPs • Split butterfly valves with extraction • Closed transfer systems • WIP or CIP in process

SOC Expects Innovation: Advanced Manufacturing Approaches

A. IoT systems that monitor chemical and biological contamination real-time, provide automatic feedback to building management systems, improve energy conservation and can reduce carbon emissions.

B. New UV-C systems that can continuously reduce airborne and surface biological contamination in pharma environments by more than 85% and 65%, respectively, add over 4 effective air changes per hour, potentially reduce suite downtime for cleaning, reduce product contamination, and reduce operational energy costs.

C. Novel carbon dioxide neutralization technology based on polymer science that converts CO2 to limestone (a desired, reusable product), reduces indoor airborne CO2 and particulate concentrations, environmental emissions, and energy costs.

AIHA – “Disclaimer”

- These SOC are not intended as legal expectations, “requirements of practice,” or “standards” along the lines of ANSI or ISO standards. It is hoped that they will influence standard setting organizations, but the ultimate intention is that the SOC will drive continuous improvement in OEHS practices and program performance to better protect workers and communities.
- These SOC are not equivalent to “minimum acceptable practice,” which is primarily driven by regulatory requirements. Such requirements often, but not always, deliver lower risk protection than the SOC and must always be followed. Nor are the SOC necessarily state of the art, which May 24, 2023be more theoretical or experimental and not yet able to meet the criteria of being practical, proven, and widely available.
- Under certain circumstances, alternate approaches May 24, 2023be more efficient and effective than those in the SOC. When making adjustments in those circumstances, each OEHS practitioner is responsible for acting with integrity, in conformance with professional ethics, and within the limitations of their capabilities to ensure that the level of risk protection is equivalent or better than that provided by the SOC.

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Discussions Re: Legal Issues and Liabilities

Recognizing Reliable Expert Methodology Under Daubert

Factors include:

- Whether the theory or technique in question can be and has been tested.
- Whether the theory or technique has been subjected to peer review and publication.
- Its known or potential error rate.
- Whether there exist standards to control its operation, and if so, how these standards are maintained.
- Whether the theory or technique has received broad acceptance within the relevant scientific, technical, or professional community.

- Dani Alexis Ryskamp, J.D. "How to Make Sure Your Expert Methodology is Reliable". Expert Institute. Updated on June 8, 2022.

NOTE: THIS INITIATIVE DOES NOT DEFINE OR ESTABLISH A LEGAL OR COMMUNITY STANDARD, NOR IS IT INTENDED TO CREATE A PRESUMPTION OF A BREACH OF A LEGAL DUTY OR FORM THE BASIS FOR CIVIL LIABILITY.

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Standard of Care: The Legal View

Neil A. Feldscher, CIH, CSP, Esq., FAIHA

Standard of Care in the Legal Arena?

- Why do we care?

- It is how our conduct is measured and compared in regulatory actions, and civil and criminal litigation
  - i.e., It is our “protection” in litigation
  - Or the nail in our coffin…

Regulatory Actions

- What does the law require?

- Did you violate the letter of the law?
- Did you violate the intent of the law?

Civil Litigation

- Negligence (or Professional Malpractice)
  - Duty – contract or otherwise owing an obligation
  - Breach – YOUR CONDUCT
  - Cause – act or omission
  - Harm – injury or impact

The Legal View of Standard of Care

- Act or Omission
- Negligence
  - “Reasonable Person” standard
- Malpractice
  - In the professional environment interpreted similar to “degree of care and skill of the average similar professional working in the same field

How do we measure? - Industry

- General Rule: How would 1) similar professionals performing 2) similar work in a 3) similar industry have performed?

BUT

- Don’t forget about the *minimums*:
  - Regulations
  - Policies/Requirements
- What about:
  - Industry Standards?

How do we measure? - Contracts

- You can set a higher level of Standard of Care through your contracting!

"shall meet the highest standards prevalent in the industry or business most closely involved in providing the Services…"

Vs.

"shall exercise the degree of skill, care, and diligence normally exercised by members of the profession performing services similar…"

Expert Witnesses

- Some of the factors of FRE 702:
  - The testimony is based on sufficient facts or data
  - The testimony is the product of reliable principles and methods
  - The expert's opinion reflects a reliable application of the principles and methods to the facts of the case*

* Includes language of the upcoming FRE 702 amendments