Massachusetts Department of Public Health
Bureau of Infectious Disease and Laboratory Sciences

Safety Risk Assessment Process

Shoolah H. Escott, MS, MT(ASCP)
Biosafety Manager
Massachusetts State Public Health Laboratory

Risk Assessment Is Not New

- We conduct risk assessments all the time…

Objectives

- Explain the goal of the risk assessment process
- Describe the biosafety risk assessment process
- Utilize the risk assessment template to the exercise

Why Do Risk Assessments?

Approximately 500,000 US laboratorians work with or handle hazardous materials and/or processes every day.

Because of where you work and what you do…

Why Do Risk Assessments?

- To *identify* and *minimize* all potential risks that may adversely affect
  - the health and safety of laboratory and non-laboratory staff,
  - the health and safety of the community,
  - the environment, and
  - the quality of work being performed.
- But remember:

Risk is never zero!

Why Do Risk Assessments?

- Prevent laboratory-acquired infections (LAIs) from:
  - Direct contact to mucous membranes
  - Inhalation of aerosols
  - Percutaneous inoculation
  - Ingestion
  - Indirect contact (contamination from fomites*)
- Prevent exposure to:
  - Chemicals
  - Physical Hazards
  - Radiological Hazards

*Fomite - an inanimate object (e.g., computer, doorknob, phone) that may be contaminated with infectious agent(s)

What is a Risk Assessment?

- **Risk Assessment (RA)** is a process that involves hazard identification and hazard control
- Risk assessment requires
  - Knowledge of the hazards
  - An understanding of the work, the environment, and the staff
  - Management involvement and support

Overall Risk Assessment Process

1. Identify hazards
   - What may happen?
   - How may it happen?
2. Evaluate risks
   - How likely, how severe?
3. Determine controls to mitigate risk
   - To reduce risk if it is not acceptable
   - Evaluate whether the controls are technically and economically feasible
4. Implement controls
5. Review effectiveness of controls and adjust

RA Process

Who Does Risk Assessments?

- *Ideally,* a multidisciplinary team
  - Laboratory staff
  - Management/supervisors
  - Health and safety specialists (biosafety, EH&S, occupational health …)
  - Facility staff
  - Scientists with unique expertise & experience
    - Microbiologists, molecular biologists, chemists
    - Veterinarians
    - Others

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When?

***Ideally,* at regular intervals**

- When a recurring problem is identified
- When there is an incident, accident or exposure
- When changes occur
  - Move, renovation or new facility
  - New infectious agent or reagent
  - New piece of equipment, technique or procedure
  - New scientific information available

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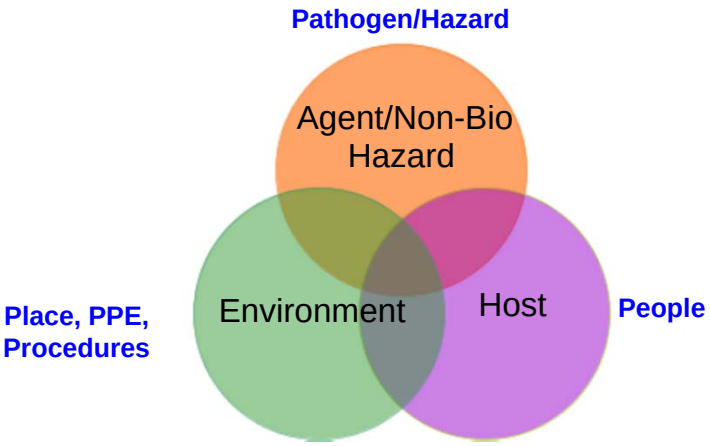
Steps of RA

1. Gather information and identify the potential hazard
2. Evaluate and prioritize the risk (likelihood and consequence)
3. Determine what additional safety precautions (controls) are needed to reduce the risk (mitigation)
4. Implement controls
5. Review and evaluate effectiveness, adjust

Risk Assessment: Interaction of Factors



Source: B. Johnson, Anthology of Biosafety, IV, 2001

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REMEMBER!

"Biosafety is an inexact science, and the interacting system of agents and activities and the people performing them are constantly changing."[1]

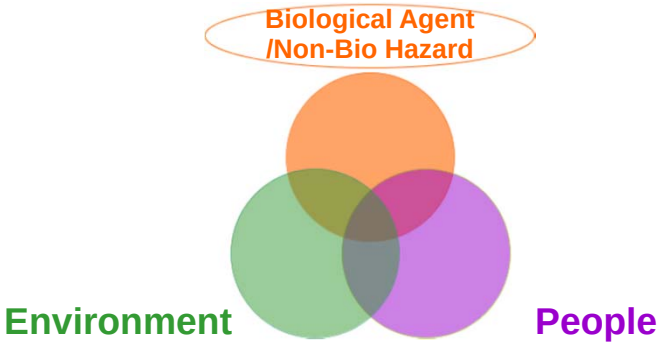
Every etiologic agent is different

Every laboratory is different

Every person is different

[1] Biological Safety: Principles and Practices, 4th Ed. Fleming DO, Hunt DL, eds., p. 81. Washington, DC. American Society for Microbiology, 2006

Risk Assessment Considerations



Bacteria, fungi, viruses, protozoa, algae, prions, recombinant organisms, cell lines, cell cultures, human/animal specimens, toxins…

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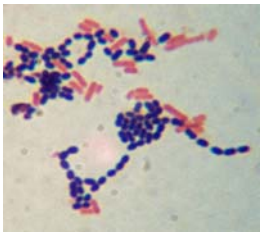
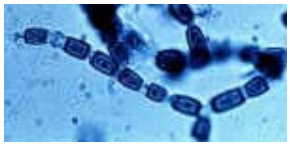
Some Agent Factors to Consider



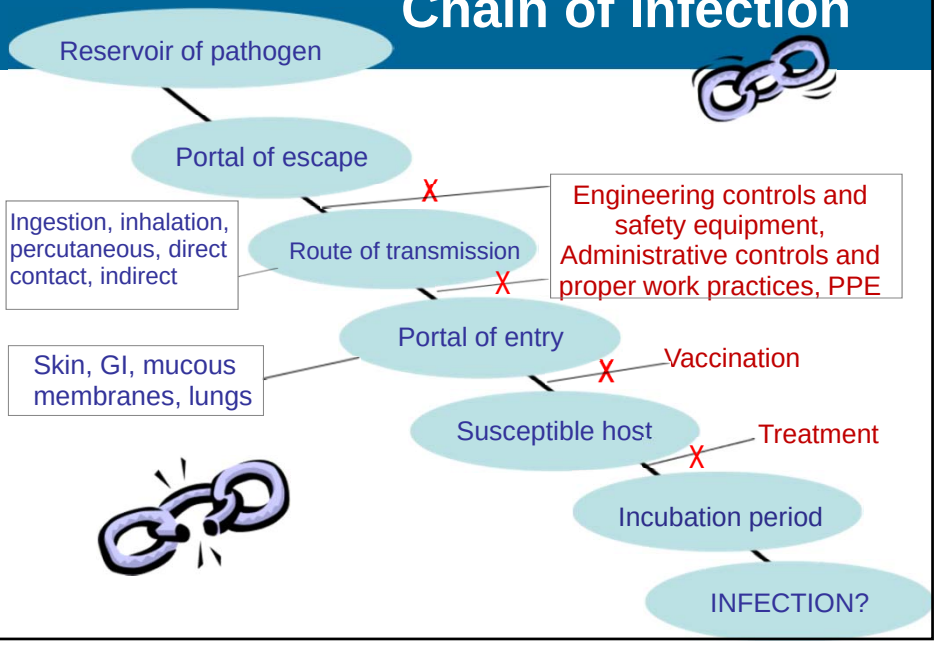
- Pathogenicity
- Virulence
- Transmissibility/communicability
- Stability in the environment
- Infectious dose
- Route of transmission
- Indigenous or rare
- Host range (humans, animals, plants)
- Availability of vaccine/treatment
- Antibiotic resistance
- Resistance to disinfection
- Availability of data



Agent: Route of Transmission

- Inhalation, ingestion, percutaneous, direct contact, indirect contact (fomites)
- Infection/disease can differ based on the route of transmission
  - *B. anthracis*
    - Inhalational anthrax
    - Cutaneous anthrax
    - Gastrointestinal anthrax

Chain of Infection



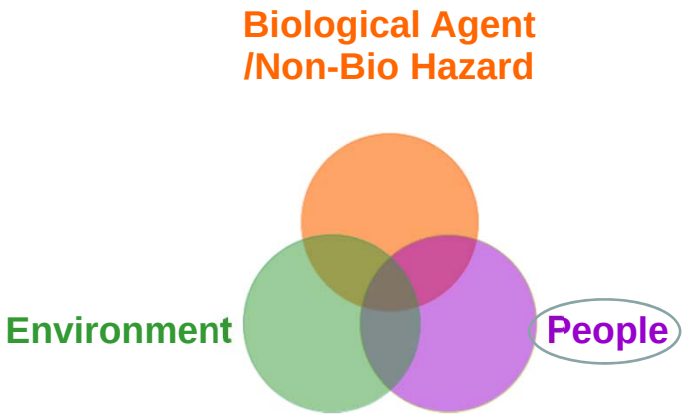
Infectious Dose- The number of microorganisms required *to* initiate infection can vary greatly with the specific organism and the route of transmission

Organism	Route	Dose
E. coli	**ingestion**	**~10^8**
***E. coli* O157:H7**	**ingestion**	**~10**
N. meningitidis	**inhalation, direct contact**	**unknown**
***Salmonella* spp.**	**ingestion**	**~100-1000**
***Shigella* spp.**	**ingestion**	**~10-180**
***Brucella* spp.**	**inhalation, direct contact, ingestion**	**10-100*** **By aerosol and subcutaneous routes in laboratory animals*

Non-Bio Hazards

- Chemical:
  - Explosives
  - Flammable gases
  - Oxidizing gases
  - Flammable liquids
  - Selfreactive chemicals
- Physical
  - Electrical
  - Compressed Gas Tanks
  - Sharps
- Radiological

Risk Assessment Considerations



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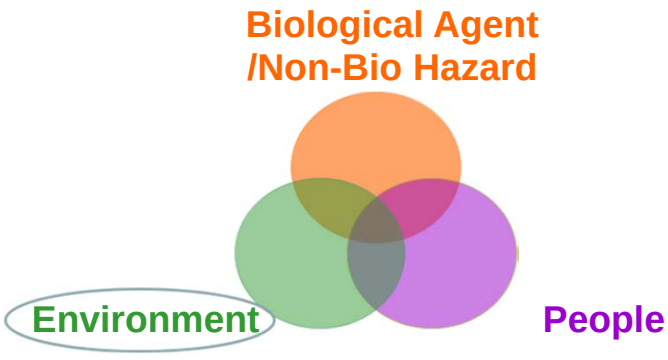
Host: Health Factors

- Age or life-stage
- Pre-existing conditions/medical status (autoimmune disease, chemotherapy, non-intact skin, allergies, medications, infections/disease, antibiotics)
- Stress and fatigue
- Pregnancy (Cytomegalovirus, HIV, HSV)
- Nutrition, diet
- Immunizations (HBV, Meningococcus)

Host: Behavioral Factors

- Stress, fatigue, mental status
- Cultural differences, age, habits
- **Perception** of risk
- **Attitude** toward safety
  - Follow procedures? Take shortcuts?
  - Use equipment/PPE as designed?
- Competency
  - Education and experience
  - Trained?
  - Students, language barriers
- Dexterity or reaction time affected by medications or PPE?

Risk Assessment Considerations



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Environmental Factors

Place (facility)

- BSL-2/3
- Workflow-is the lab crowded/cluttered?
- Lab equipment (biosafety cabinet [BSC], sharps, centrifuges, vortex, autoclaves …)
    - Is it available?
    - Does it protect or is it a hazard by itself?
    - Air exchange rate

PPE (hazard or protection?)

- Appropriate PPE available?
- Is it used?
- Are people trained?

Environmental Factors (Procedures)

- hand washing-cracked skin?
- large volume, high agent concentration
- centrifuging, autoclaving
- sharps
- generating aerosols-anything that imparts energy to a suspension
- waste management
- inoculating biochemicals
- PPE doffing procedures
- not using or improper use of BSC/Chemical Fume Hood (CFH)

Steps of RA

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Risk Assessment

Very seldom is risk assessment a black and white issue

- Involves personal and social value judgments
- Everyone has different perceptions of risk and what is “acceptable”

Old woman or young girl?

Evaluate and Prioritize Risk-Example

Likelihood (probability) of occurrence

- Rare: Will only occur in exceptional circumstances
- Unlikely: Not likely to occur within the foreseeable future
- Possible: May occur within the foreseeable future, sporadic exposure is possible
- Likely: Likely to occur within the foreseeable future, routine exposure is likely
- Highly Likely: Almost certain to occur within the foreseeable future, consistent exposure is highly likely

Evaluate and Prioritize Risk-Example

Consequence (severity) of exposure

- Insignificant: No treatment required
- Minor: Minor injury requiring First Aid treatment (e.g. minor cuts, bruises) or possibly colonization
- Moderate: Injury requiring medical treatment or lost time
- Major: Serious injury (injuries) requiring specialist medical treatment or hospitalization (infection and recovery)
- Critical: Loss of life, permanent disability or multiple serious injuries (disease and sequelae)

Risk Matrix

Risk Assessment Matrix		Hazard Consequence				
		Insignificant	Minor	Moderate	Major	Critical
Hazard Likelihood	Highly likely	Medium	Medium	High	Extreme	Extreme
	Likely	Low	Medium	High	High	Extreme
	Possible	Low	Medium	High	High	High
	Unlikely	Low	Low	Medium	Medium	High
	Rare	Low	Low	Low	Medium	Medium

Red = HIGH/EXTREME RISK
Yellow = Medium Risk
Green = low risk

Evaluate and Prioritize Risk-Example

- **Performing Gram stain:**
  - Potential Hazards:
    - Aerosols from making/flaming slides — mucous membrane exposure
    - Others - Exposure to chemicals and sharps
  - Likelihood: Possible
  - Consequence: Colonization; medical treatment (minor/moderate)
  - Risk: **Medium/High**
- **AFB culture work-up (includes smear):**
    - Potential Hazard: Aerosols — inhalation
    - Others - Exposure to chemicals and sharps
  - Likelihood: Likely
  - Consequence: Infection; medical treatment; disease (mod/major)
  - Risk: **High**

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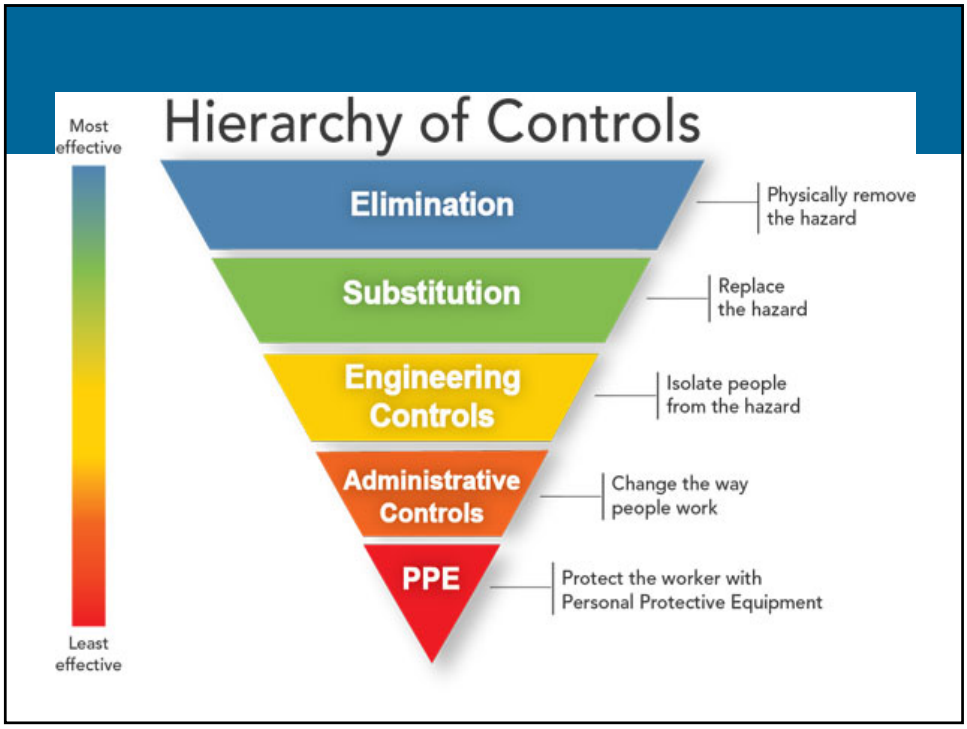
Determine Additional Control Measures

Assessed Risk Level		Description of Risk Level	Actions
☐	Low	If an incident were to occur, there would be little likelihood that an injury would result.	Undertake the activity with the existing controls in place.
☐	Medium	If an incident were to occur, there would be some chance that an injury requiring First Aid would result.	Additional controls are advised.
☐	High	If an incident were to occur, it would be likely that an injury requiring medical treatment would result.	Control will need to be in place before the activity is undertaken.
☐	Extreme	If an incident were to occur, it would be likely that a permanent, debilitating injury or death would result.	Consider alternatives to doing the activity. Significant control measures will need to be implemented to ensure safety.



Some Engineering Controls

- Safety Equipment (BSC, CFH, glovebox, sharps containers, centrifuge safety cups, eyewash, sealed rotors)

-Facility Design (directional airflow, air exchange rate, lockable doors, hands-free faucets)

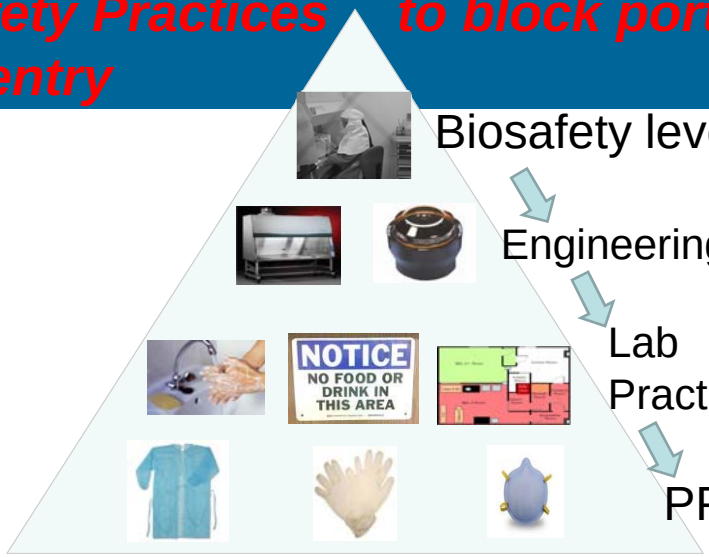
Some Administrative Controls and Work Practices

- Training
- Signage
- SOP's and site-specific safety manuals
- Medical surveillance program (including a process to address unusual absences, sickness, and injury)
- Frequent hand washing
- Appropriate use of PPE
- No mouth pipetting
- Limiting use of needles and sharps
- Minimizing aerosols

PPE

- PPE is your *last* resort, after all other mitigation steps have been taken
- Proper technique for donning and doffing PPE is as important as having the correct PPE-staff must be trained!
- *More PPE is not always better* (decreased dexterity and sensitivity, uncomfortable, hot)
- PPE can vary on what you are doing and where you are doing it-depends on risk assessment!
- Institutions must establish policies for adherence

Safety Practices to block portal of entry



Select, implement, and evaluate appropriate controls that minimize the risk for exposure

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Routes of Transmission	Mitigation Strategies
inhalation	BSC, CFH, glovebox, respiratory protection, centrifuge safety cups
ingestion	No mouth pipetting, gloves, hand washing
percutaneous	Safer sharps, sharps containers, cover compromised skin
direct contact with mucous membranes	Gloves, hand washing, face protection
indirect (fomites)	Disinfecting surfaces, spill procedures, designated clean and dirty areas

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Review and Evaluate Effectiveness

- Review incidents, accidents, illnesses
  - Encourage and support non-punitive reporting
- Identify causes/problems, make changes, follow-up training
  - Document and maintain records
- Conduct routine lab inspections
- Repeat RA when incidents or changes occur
- Do Hotwash 1-3 months after performing work with the implemented control measures identified in Step 3.

Perform a Risk Assessment

- In order to simplify the entire process and make it more practical for laboratorians, a **Job Hazard Analysis** framework can be used to break down a complex process into individual steps.
- Each step is then evaluated separately, and mitigation controls can be determined and implemented at each step of the process.

OSHA Job Hazard Analysis

- “A technique that focuses on job tasks as a way to identify hazards before they occur.
- Ideally, after you identify uncontrolled hazards, you will take steps to eliminate or reduce them to an acceptable risk level.”
- https://www.osha.gov/Publications/osha3071.html

Job Hazard Analysis Steps

- Break procedure down into individual components
- Determine hazard(s) associated with individual component* (hazard ID)
- Determine initial risk
- Identify way to deal with each hazard (hazard control)
- Determine residual risk

*5 P's: pathogen/non-biohazard, people, place, PPE, procedures

Name of Process – General Precautions

Pathogen(s): There is a potential to be exposed to _____ during _____process dependent on _____.

Infectious Dose: Dependent on the pathogen.

Routes of Transmission: List any that are appropriate for example:

- Parenteral inoculation from a needle stick or other sharps
- Ingestion from spill or splash into mouth
- Contact from touching, or from a spill or splash onto a mucous membrane or non-intact skin
- Inhalation of infectious aerosol

Current Requirement(s):

Process Assessment

Pre-analytic

☐ **Process Name**

Process Step	Potential Hazards	Initial Risk Level	Control (Mitigation)	Residual Risk Level
			Required: ☐ Optimal: ☐	

Comments:

Screening Cultures - General Precautions

Pathogen(s): There is a potential to be exposed to pathogens that may be isolated on screening media dependent on the patient's health, the type of specimen that is being screened and the screening media that is used.

Infectious Dose: Dependent on the pathogen.

Routes of Transmission:

- Parenteral inoculation from a needle stick or other sharps
- Ingestion from spill or splash into mouth
- Contact from touching, or a spill or splash onto mucous membrane or non-intact skin
- Inhalation of infectious aerosol

Screening Cultures – Catalase Test Assessment

☐ **Perform Screening Cultures. Please select any of the following cultures types:** ☐ Urine ☐ Throat ☐ MRSA ☐ Other (be specific)

Process Step	Potential Hazards	Initial Risk Level	Control (Mitigation)	Residual Risk Level
1) Examine culture media for growth, or screening media for growth of the specific pathogen being screened for. 2) If suspicious colonies are growing, proceed to catalase test. 3) Touch colony with stick or plastic loop. 4) Smear on glass slide. 5) Add drop of Hydrogen peroxide. 6) Observe for bubbles. 7) Discard slide and proceed to other tests as needed. 8) Clean bench with appropriate disinfectant.	• An aerosol may be created opening the plate and performing catalase test. • Risk of contamination by touching growth. • Chemical hazard: Hydrogen peroxide - Causes skin irritation. Causes serious eye damage. • Chemical hazard – disinfectant – look up SDS. • Sharps hazard – glass slide.	Medium	**Required:** ☐ Follow written procedures (trained and competent). ☐ Perform test in a tube or petri dish. ☐ Wear PPE: lab coat ☐ Sharps container ☐ Disinfectant **Preferred:** ☐ Wear gloves and additional eye protection when there is a risk of a splash or spray. ☐ Examine screening media for growth in a Class II BSC. ☐ Perform catalase test on suspicious growth in a Class II BSC. ☐ Use additional BSL-3 practices if patient is known or suspected to have a highly infectious disease transmitted by aerosols, or droplets (i.e. MERS, SARS, avian influenza, mumps, measles, etc.). **Alternative:** ☐ Work behind a full safety shield/face shield and wear eye protection.	Low

Comments:

Don't Forget:

- There is some risk in everything we do-we can reduce it, but not eliminate it
- To ask questions
- Your staff, their training and competency
- To evaluate, review and adjust