LABORATORY RISK ASSESSMENT

WHAT, WHY, AND HOW

Risk Assessment in the Infectious Disease Laboratory

Study Booklet

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Accompanies the
Videotape of the July 23, 1998, Satellite Broadcast

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INTRODUCTION

All workers in the United States are entitled to a safe and healthy working environment.* It is to this purpose that this program, Laboratory Risk Assessment: What, Why, and How, has been developed.

As new technologies and tests are introduced into the complicated arena of laboratory testing, it becomes increasingly difficult for regulatory and advisory agencies to provide specific safety regulations and guidelines for each new situation. It is, therefore, the responsibility of the laboratory itself to develop its own guidelines and work practices to ensure a safe work environment for all employees.

To develop effective strategies that continually guarantee employees a safe work environment, the performance of risk assessments must be an integral and on-going part of laboratory operation.

"Risk assessment" is a relatively new term, but one that is appearing more frequently in literature and in presentations dealing with laboratory safety. Although the term is used freely, many in the laboratory community are uncertain of (1) what the term means in reference to laboratory safety, (2) when and what kind of assessment should be performed, and (3) how to perform an assessment.

The satellite broadcast, Laboratory Risk Assessment: What, Why, and How, *Risk Assessment in the Infectious Disease Laboratory,* and the contents of this booklet are designed to provide you with tools for performing risk assessments in your facility.

**The Occupational Safety and Health Act of 1970, Executive Order Number 12196*

SPONSORS

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PROGRAM DESCRIPTION

This training program consists of a videotape of the interactive satellite broadcast, *Laboratory Risk Assessment: What, Why, and How,* and a study booklet. Its purpose is to provide the learner with tools for performing risk assessments in infectious disease laboratories. The program provides learners with the opportunity to perform a risk assessment in a simulated mycobacteriology laboratory under the guidance of experts. Although a mycobacteriology laboratory is used for the training exercise, the principles and practices illustrated are applicable to other specialties as well.

TARGET AUDIENCE

This program is for infectious disease personnel working in public health, hospital, physician office, and research laboratories. Types of personnel include laboratory directors, supervisors, technologists, technicians, and researchers, as well as laboratory safety officers, trainers, laboratory designers and engineers, and administrators.

LEARNING OBJECTIVES

After viewing the videotape program, the learner will be able to--

- define risk and risk assessment
- list reasons for performing risk assessments in infectious disease laboratories
- define the selection and use of containment equipment
- perform a risk assessment of a simulated mycobacteriology laboratory
- identify resources for information on risk assessments and laboratory safety.

By applying the principles and practices detailed in the videotape program, study booklet, and suggested resources, you will be able to perform risk assessments effectively in your laboratory.

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RISK ASSESSMENT--THE *WHAT*

What is a risk assessment?

Performing a risk assessment of the workplace is the first step toward ensuring that all workers have safe and healthy working environments. Unfortunately, everyone in the laboratory community does not have the same understanding of what is meant by "risk" or "risk assessment." The following are selected definitions that will be used in this program:

> ***Risk*** is the <u>chance</u> of injury, damage, or loss.
>
> ***Chance*** means the <u>probability</u> of something happening.
>
> A ***Hazard*** is something that is <u>dangerous</u>--an object, a chemical, an infectious agent, or a situation. Hazards are categorized into three groups: ***Physical*** hazards**,** ***Chemical*** hazards, and ***Biological*** hazards. Here are some examples of hazards and the risks associated with each hazard.

Hazard	**Risk of that Hazard**
Careless handling of sharps such as needles	Sticking yourself (*physical*) Sticking and infecting yourself (*biological*)
Pouring hazardous chemicals while working on an open bench	Burning yourself with splashing chemicals (*chemical*)
Eating or drinking in the laboratory	Swallowing infectious material and getting sick (*biological*)

> ***Risk assessment*** is an <u>action</u> or a series of actions taken to recognize or <u>identify hazards</u> and to <u>measure</u> the risk or probability that something will happen because of that hazard. In evaluating risk, the <u>severity</u> of the consequences is also taken into account.

In the video is a scenario that focuses on a "wet spot" on the floor in a mycobacteriology laboratory. This scenario illustrates the progression in severity of the potential consequences that can result from broken test tubes. Crucial in determining the severity of risk due to the broken tubes are the contents of the tubes--from sterile media to cultures of *Mycobacterium tuberculosis.* For example:

> Breaking tubes of liquid media is more hazardous than breaking tubes of solid media because splashing liquid media can generate aerosols.

Breaking tubes of liquid media containing infectious agents is more hazardous than breaking tubes of sterile media because of the potential for becoming infected.

Breaking tubes of liquid media containing infectious agents that are transmitted by inhalation is more hazardous than breaking tubes of liquid media containing infectious agents that are transmitted by other means, such as ingestion, because of the potential for inhaling infectious aerosols.

Other factors to consider when doing a risk assessment of a spill include--

- the amount of material spilled
- the presence and number of infectious particles or the concentration of a hazardous chemical
- the nature of the ventilation in the room
- the personal protection equipment, such as a respirator, being worn by those in the room

Evaluations of risk may be only partly quantitative; complete assessment also requires--

- background information
- experience
- common sense
- ability to visualize potential outcomes

Tools useful in performing laboratory risk assessments are--

Reviewing laboratory records

Injury, illness, and surveillance reports
Equipment maintenance records
Employee training records
Environmental monitoring records

Inspecting the laboratory

Daily monitoring by employees
Periodic walk-throughs
Formal inspections by certifying agencies

Reviewing published materials

Equipment manuals
Manufacturers' bulletins and newsletters
Product inserts
Scientific journals
Published safety manuals and guidelines

Observing laboratory operation *(requires a knowledge of relevant literature and experience with similar activities)*

New procedures
New employees
New equipment
Work-flow

RISK ASSESSMENT--THE *WHY*

Why do risk assessments?

Risk assessments provide us with the information we need **to keep people safe**--people in the ***immediate laboratory***, people in the entire ***facility***, and people in the ***external environment***, i.e., the community.

Some ***additional benefits*** that can be derived from performing risk assessments include--

- Effective use of resources
- Identification of training needs and supervision
- Advance planning for renovations
- Evaluation of procedural changes
- Prevention of biohazard transmission to family members of employees
- Ensure compliance with governmental regulations
- Justification for space and equipment needs
- Cost effective laboratory operation
- Evaluation of emergency plans

RISK ASSESSMENT--THE *WHEN*

When should risk assessments be done?

Risk assessments should be done at ***regular intervals***, at least annually, but more frequently if problems are discovered.

A risk assessment should be done whenever ***a change occurs*** in the laboratory such as a--

- move or renovation
- new employee
- new infectious agent or new reagent
- new piece of equipment

RISK ASSESSMENT--THE *HOW*

How does one do risk assessments?

Maintaining a safe laboratory is the ***shared responsibility*** of both managers and employees; likewise, risk assessments are also a shared responsibility.

In an individual laboratory, the ***best assessors*** of risk are usually those who work in the laboratory, the first line supervisors, and others close to the situation.

Certain ***prerequisites*** are required before attempting to perform a risk assessment. These prerequisites include--

- A knowledge of biological, chemical, and physical hazards
- An understanding of the principles of biological, chemical, and physical safety
- A knowledge of the modes of transmission for the various infectious agents encountered in the laboratory

- An understanding of the importance of aerosols in the laboratory
  - *How aerosols act as modes of transmission for infectious agents and chemical vapors*
  - *What procedures are likely to generate aerosols*
  - *What methods can be used to reduce or contain aerosols*

- A knowledge of essential safety features of your facility
  - *The air handling system*
  - *The safety equipment available*
  - *The adequacy and limitations for decontaminating waste*

- A knowledge of the type of medical surveillance needed for each employee's job

- An understanding of how the facility, the equipment, the personnel, the procedures, and the hazardous materials must be integrated to create a safe working environment

- A knowledge of the local, state, and federal regulations under which the laboratory operates

Risk assessments must be done **systematically**. Before doing a risk assessment, you should make a check-list customized for your laboratory so that essential items are not overlooked.

Containment Equipment

The use of containment equipment is the primary mechanism for protecting employees from hazardous (*infectious or toxic*) aerosols. The two types of containment equipment most frequently used in the infectious disease laboratory are the biological safety cabinet (BSC) and aerosol-free centrifuge cups.

Other types of cabinets or hoods (as they are frequently called in the laboratory) are also available in addition to the BSC. Each type of cabinet, however, is designed for particular functions. The type of cabinet selected for use must match the type of hazardous material being manipulated. It is, therefore, essential that those who perform risk assessments in laboratories requiring containment equipment have a basic understanding of the types and functions of the various types of containment cabinets.

<u>Biological Safety Cabinets</u>

The BSC is the most important piece of equipment for containing infectious aerosols. Three kinds of BSCs have been developed to meet various needs. These have been designated Class I, II, and III. Class I cabinets protect the worker but not the product. Class III cabinets provide the maximum protection. They are tightly sealed, the front opening is closed, and a glove port provides access to the inside of the cabinet. Class III cabinets are typically used when working with highly infectious agents, such as Ebola virus or with an unknown pathogenic agent.

The most commonly used cabinet, the Class II, is further subdivided into types A, B1, B2, and B3. These variations reflect cabinet design, air flow, and installation mode. Most clinical laboratories use a Class II, Type A BSC. In a Class II, Type A BSC, room air enters the cabinet, mixes with filtered cabinet air, and passes through the intake grilles at the front of the cabinet. The air mixture is drawn up in an enclosed area (the plenum) behind the work space to the top of the cabinet. Seventy percent of the air mixture is pushed through the high-efficiency particulate air (HEPA) supply filters into the cabinet work area; the remaining 30% of the mixture is pushed through the exhaust HEPA filters. Class II type A cabinets are not suitable for working with chemicals.

Class II BSCs protect--

- the ***worker*** because the air flows into the cabinet
- the ***product*** because particulates have been removed from the air by the HEPA filters before flowing into the cabinet
- the ***environment*** because infectious particles have been removed from the air by HEPA filters before it is exhausted

BSCs are protective only if 1) they have been properly installed, 2) the appropriate air velocity is maintained during use, and 3) proper procedures are used when working in them. If any of these requirements are lacking, the BSC will not provide the intended protection. Performing a risk assessment should detect if any of these faulty conditions exist.

<u>Chemical Fume Hoods</u>

Chemical fume hoods are designed for working with chemicals that produce toxic fumes. Air enters through the front opening of the hood and exits through an exhaust duct without being filtered.

Chemical fume hoods protect--

- only the ***worker*** because the air flow is inward
- ***neither*** the product ***nor*** the environment because the exhaust air is not filtered

<u>Clean Benches *(Vertical and horizontal laminar-flow cabinets)*</u>

In clean benches, HEPA-filtered air moves across the work area either from the top- (vertical-flow) or from the back (horizontal-flow) of the cabinet. Clean benches are not suitable for work with infectious or toxic material. They are used primarily for working with or preparing sterile non-toxic media and reagents.

Clean benches protect--

- only the ***product*** because the air flowing over the work area is HEPA filtered
- ***neither*** the worker ***nor*** the environment because the air does not flow away from the worker nor is it filtered before it is exhausted

Performing a Risk Assessment

Risk assessments are a two-part process--first, identifying the hazards, and second, determining the degree of risk associated with each hazard. Only after these two steps have been completed can risk be effectively managed.

Performing risk assessments should not be limited to the immediate laboratory area. All parts of a facility must be a safe environment in which to work. As in the video walk-through, risk assessments begin with the arrival of the specimen at the facility. Below are some of the hazards or potential hazards seen in the video during the laboratory walk-through; you may have seen others as well.

- Confusion caused by a poor work flow creates conditions that could lead to workers ***colliding*** with other workers or with an object, resulting in the dropping, spilling, or breaking of potentially infectious material.

- Opening primary shipping containers which contain the specimen tube (or other receptacle) without using any barrier protection places workers at risk. If the specimen tube breaks, ***infectious aerosols*** could be generated. In addition, the worker's hands could become ***contaminated*** with infectious materials or ***cut*** with the sharp edges of the broken container.

- Using poor practices and techniques when working in the BSC can cause ***disruption of the air barrier*** allowing infectious aerosols to escape into the room.

- ***Failure to check the condition*** of the containment equipment before it is used may lead to working with equipment that is not safe. Safety equipment to be effective must not only be used properly, but must function properly as well.

- Use of the Bunsen burner in the BSC can ***disrupt the air flow,*** allowing escape of infectious material.

- Flaming wet smears can create potentially ***infectious aerosols***.

- Skin can be burned or damaged if not protected from possible ***carcinogens*** or other hazardous chemicals.

- Hazards associated with the use of the fluorescence microscope must be avoided or minimized--burns from contact with ***hot surfaces***; inhalation of ***mercury vapors*** from an exploding lamp; and ocular burns from exposure to ***ultraviolet light***.

- Overfilled sharps container creates the risk of being ***stuck with a contaminated needle*** and becoming infected with a pathogen.

- The ***spread of hazardous material*** via contaminated gloves to uncontaminated surfaces outside the BSC endangers all in the laboratory.

- ***Unfamiliar hazards*** may be associated with new procedures, new equipment, or new reagents.

- ***Improper use of chemical fume hoods*** can lead to escape of toxic vapors into the room.

- ***Pregnant women (or those that might be pregnant) should not be exposed*** to hazardous chemicals that might endanger the fetus.

- ***Improperly stored materials/supplies*** create unnecessary hazards for workers who might be injured if an objects falls on them or they collide with an object while moving about the laboratory.

- ***Wet spots*** on floors could cause someone to slip and possibly fall.

- ***Drinking, eating,*** or ***smoking in the laboratory*** provides a mechanism for ingesting infectious or toxic material.

- If ***emergency supplies are blocked***, they will be of little use if no one can get to them quickly.

- ***Improper disposal of waste*** endangers all in the laboratory--laboratory and non-laboratory staff.

- A ***malfunctioning door closure*** causes a disruption in all air-flow patterns and may allow laboratory air to escape into the hallway.

Once potential hazards are identified, the degree of risk must be determined for each hazard. Determining risks requires the integration of knowledge about the facility, the containment equipment, the personnel, and the infectious agents, chemicals, and other materials that are used in the laboratory. Following are some suggestions for laboratory features to be evaluated when performing risk assessments.

<u>Laboratory Features to be Evaluated</u>

- Physical facility (laboratory design, engineering controls)
  Air-flow
  Laboratory access
  Composition of ceiling, walls, and floors

- Containment equipment
  Biological safety cabinets
  Fume hoods
  Aerosol-free centrifuge cups/carriers

- Personnel

  Experience and training
  Physical handicaps
  Attitude
  Immune status

- Agents worked with in the laboratory

  Pathogenicity
  Mode of transmission, e.g., inhalation, blood, ingestion, unknown
  Information available, e.g., limited information on a new agent

- Types of procedures performed

  Aerosol generating
  Requiring use of syringes and needles
  Requiring temperature extremes, e.g., ultra hot or ultra cold
  Requiring dexterity and use of sterile techniques

<u>Some Factors that Influence Risk</u>

- Mode of transmission, e.g., inhalation vs. ingestion

- Procedures that produce aerosols vs. procedures that do not produce aerosols

- Severity of the consequences of exposure, e.g., nontoxic/nonpathogenic vs. pathogenic/lethal

- Concentration of the pathogen or chemical, e.g., <10 (<1 log) infectious particles per milliliter vs. >1000 (>3 logs) infectious particles per milliliter

- Volume, e.g., <1ml vs. >10ml

- State or form of the agent, e.g., suspended in liquid vs. colonies on solid medium, lyophilized, or dried/fixed to a slide; clinical specimen vs. purified/concentrated suspension, etc.

A P P E N D I X

OBSERVATION WORKSHEET

PERFORMING A RISK ASSESSMENT

As you look at the video showing a walk through a simulated mycobacteriology laboratory, use this worksheet to indicate each time you identify a hazardous or potentially hazardous situation. Make note of any poor practices you might observe. In a second walk-through of the laboratory, the important hazards and poor practices will be identified and the risks of each discussed.

Specimen Path	Hazards/Poor Practices Identified	Discussion
Accession Area		
Laboratory: Specimen Processing Readying the BSC Processing the specimen		
Laboratory: Acid-Fast Microscopy Preparing smears Staining smears Examining smears		*continued next page*

Specimen Path	Hazards/Poor Practices Identified	Discussion
Laboratory: Inoculation of Culture Media (Isolation) Inoculation Incubation of Cultures Exiting the Laboratory		
Laboratory: Identification of Isolates (HPLC)		
Exiting the Laboratory		

Additional Notes:____

The National Laboratory Training Network

The videotape of the July 23, 1998 satellite broadcast, "Laboratory Risk Assessment:What, Why, and How" is available for loan from the National Laboratory Training Network (NLTN). While on loan the videotape may be copied, but the original must be returned to the office from which it was borrowed.

Calling **1-800-536-NLTN** will automatically connect you with the office serving your state. Visit the NLTN web site @ http://www.cdc.gov/phppo/dls/nltn.htm

SUGGESTED RESOURCES

General Laboratory Safety

CRC Handbook of Laboratory Safety. Furr A.K. (ed.). CRC Press, Boca Raton. 1995. pp. 412-473.

Laboratory Safety: Principles and Practices, 2nd ed. Fleming DO, Richardson JH, Tulis JJ, Vesley D, eds., Washington, DC. American Society for Microbiology, 1994.

Physical and Biological Hazards of the Workplace. Wald, Peter H, Stave, Gregg M eds. Van Nostrand Reinhold, New York, 1994.

Preventing Occupational Disease and Injury. American Public Health Association, Washington, DC, 1991.

Biological Safety

AHIA - Biosafety Reference Manual. Heinsohn PA, Jacobs RR, Concoby BA eds. American Industrial Hygiene Association, Fairfax, 1995, pp 51-99.

Biohazards Management Handbook. Lieberman DF, ed. New York: Marcel Dekker, 1995; 173-192.

CDC/National Institutes of Health Biosafety in Microbiological and Biomedical Laboratories, 3rd ed. Atlanta: U.S. Department of Health and Human Services, Public Health Service, CDC and NIH, 1993; DHHS publication no. (CDC)93-8395.

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Sewell DL. Laboratory-Associated Infections and Biosafety. Clin Microbiol Rev 1995;8:389-405.

Stern E, Johnson JW, Vesley D, Halbert MM, Williams IE, Blume P. Aerosol production associated with clinical laboratory procedures. Am J Clin Pathol 1974;62:591-600.

Mycobacteriology (TB) Laboratory Safety

CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities, 1994. MMWR 1994;43(No. RR-13).

Heifets LB, Good RC. Current laboratory methods for the diagnosis of tuberculosis. In: Bloom BR, ed. Tuberculosis: pathogenesis, protection and control. Washington, DC: American Society for Microbiology Press, 1994:85-110.

Kent PT, Kubica GP. Public Health Mycobacteriology. A Guide for the Level III Laboratory. Atlanta: U.S. Department of Health and Human Services, Public Health Service, CDC, 1985.

Kubica GP, Dye WE. Laboratory Methods for Clinical and Public Health Mycobacteriology. Public Health Service Publication No. 1547. Washington, D.C. U.S. Department of Health , Education, and Welfare. United States Government Printing Office, 1967.

Richmond JY, Knudsen RC, Good RC. Biosafety in the Clinical Mycobacteriology Laboratory. Clinics in Laboratory Medicine 1996;16:527-550.

Chemical Safety

NIOSH/OSHA Pocket Guide to Chemical Hazards. NIOSH Publication No. 97-140, Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402,1997.

Prudent Practices in the Laboratory - Handling and Disposal of Chemicals. National Research Council, National Academy Press, Washington DC, 1995.

Physical Safety

Safe Handling of Compressed Gas in Containers. Compressed Gas Association, Inc., Publication No. P-I, 8th ed., 2235 Jefferson Davis Highway. Arlington. VA., 22207, 1991.

Ventilation and Safety Cabinets

American National Standards Institute. Laboratory Ventilation Standard, ANSI NO. Z9.5. 1992. American Industrial Hygiene Association, Fairfax, VA 1993.

American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE). 1995 Handbook - HVAC Applications. ASHRAE, Atlanta, GA 1995.

CDC/NIH. Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets. U.S. Department of Health and Human Services, Public Health Service, CDC, 1995.

Kruse RH, Puckett WH, Richardson JH. Biological Safety Cabinetry. Clin Microbiol Rev 1991;4:207-41.

National Sanitation Foundation (NSF). Standard 49, Class II (Laminar Flow) Biohazard Cabinetry. Ann Arbor: 1992.

Web Sites

CDC Office of Health and Safety
http://www.cdc.gov/od/ohs/

APHL (*formerly, ASTPHLD*)
http://www.aphl.org

CDC Home Page
http://www.cdc.gov

Eagleson Institute
http://www.eagleson.org

HPLC Standardized Method Manual
http://www.cdc.gov/ncidod/publications/hplc.pdf

You will need an Acrobat Reader 3.0 to print the document. Acrobat Reader can be downloaded for free from http://www.adobe.com

List of Approved Respirators
http://www.cdc.gov/niosh/respinfo.html

National Laboratory Training Network (NLTN)
http://www.cdc.gov/phppo/dls/dlshome.htm

National Tuberculosis Center Homepage
http://www.umdnj.edu/%7entbcweb/ntbchome.htm

Self-Assessment Manual for the *Mycobacterium tuberculosis* Laboratory
http://www.cdc.gov/phppo/dls/ltapubs.htm

World Health Organization Homepage
http://www.who.ch/

Answers to Quiz

The quiz is on page 19. The answers are as follows: 1=D; 2=B; 3=C; 4=F; 5=B; 6=C; 7=A; 8=C; 9=B; 10=C; 11=B; 12=C.

QUIZ

Select the single best answer for each question. Answers are on page 18. If you do not score 100%, that is, answer all questions correctly, it is suggested that you view the video again.

1. Which of the following could be considered hazards?
   A. Carelessly handled sharps
   B. Dangerous chemicals on an open bench
   C. Eating or drinking in the laboratory
   D. All of the above
   E. None of the above

2. A complete risk assessment requires all of the following EXCEPT:
   A. Background information
   B. A substantial budget
   C. Experience
   D. Common sense
   E. The ability to visualize potential accidents

3. What is the primary reason for doing risk assessments?
   A. To analyze the cost-effectiveness of laboratory operations
   B. To save time when performing routine procedures
   C. To ensure the safety of laboratory personnel and protection of the environment

4. Risk assessments should be done—
   A. At regular intervals
   B. Whenever problems occur
   C. Anytime there is a change in the laboratory, e.g., new equipment
   D. Only before an inspection
   E. All of the above
   F. A, B, and C only

For questions 5 - 7, choose the most appropriate containment equipment from one of the following responses:

A = Class II, type A or B biological safety cabinet (BSC)
B = Fume hood
C = Clean bench

5. ______ Protects only personnel against toxic fumes

6. ______Protects only products from contamination

7. ______Protects personnel, products, and the environment against biohazards

8. In the laboratory walk-through, what color were the laboratory coats and gowns worn by the laboratorians performing the diagnostic tests?
   A. White
   B. Yellow
   C. Blue
   D. Green
   E. All of the above
   F. None of the above

9. Product information such as package insets and Material Safety Data Sheets (MSDS) should be kept in--
   A. The administrative area or office so they will not get damaged in the lab
   B. A central location in the lab so that everyone can find them quickly and easily
   C. Each lab worker's desk drawer

10. Which of the following is **NOT** a source for more information about risk assessments?
   A. Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual
   B. Internet
   C. Newspapers
   D. Peer-reviewed scientific journals
   E. Scientific meetings

11. The first time new equipment is used in the laboratory, actual testing samples should be used to see if the equipment is working properly.
   A. True
   B. False

12. Which of the following is **NOT** a tool to use when performing risk assessments?
   A. Reviewing equipment maintenance records
   B. Reviewing employee training records
   C. Wiping lab surfaces
   D. Reviewing published materials such as equipment manuals and package inserts
   E. Observing laboratory operations
   F. Reviewing injury and illness reports