RESOURCE MANAGEMENT

A Requirement of Accreditation Process

SEDEF YENİCE

Association of Clinical Biochemists
The First International Symposium on
Quality & Accreditation in Laboratory Medicine
April 15 – 18, 2008 , Istanbul, The Marmara Hotel

Joint Commission International (JCI) Accreditation Standards for Clinical Laboratories

- Was created in 1998 as a major division of the Joint Commission's subsidiary, Joint Commission Resources.
- They were formulated with extensive international input, and they reflect, in content and organization, the most comprehensive, state-of-the-art expectations for quality clinical laboratory services.
- The standards are grouped by fundemantals of quality management systems and include very specific quality control requirements that pertain uniquely to clinical laboratories, and are necessary to assure excellence in the provision of laboratory services.

Joint Commission International Accreditation Standards for Clinical Laboratories, 1st ed. Oak Brook Terrace, IL. 2002.

Resource Management is one of the fundamentals of quality management system in the clinical laboratory

This group requires laboratory leaders to plan for and provide adequate resources to meet the mission and goals of the laboratory. The areas of resource provision and management include:

- appropriately trained staff;
- space, utilities, and safety and environmental controls;
- appropriate equipment and supplies; and
- adequate systems to handle required information.

The chapter of resource provision and management include

- Five major standards
  - RSM.1 Provision of Resources
  - RSM.2 Human Resources
  - RSM.3 Infrastructure - Basic Facilities
  - RSM.4 Laboratory Equipment and Other Materials
  - RSM.5 Work Environment - Laboratory Safety
- Their intents and measurable elements

What are the measurable elements of a standard?

- Those requirements of the standard and its intent statement that will be reviewed and assigned a score during the accreditation survey process. The measurable elements simply list what is required to be in full compliance with the standard.

OUR APPROACH

- Implementation a resource management program in accordance with the mission of our hospital, the objectives of our laboratories, any applicable laws or regulations and all relevant JCI standards.
- Policies and procedures were generated based on standard requirements for resource provision and management by JCI.

“ The way to get started is to quit talking and begin doing. ”

Walt Disney

RSM.1 - PROVISION OF RESOURCES

- **The leaders determine and provide adequate resources, support laboratory employees and to implement, maintain and improve the quality management program.**

www.cap.org

Revised: 09/27/2007

Advancing Excellence

COMMISSION ON LABORATORY ACCREDITATION

Laboratory Accreditation Program

TEAM LEADER ASSESSMENT OF DIRECTOR & QUALITY CHECKLIST

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If a Checklist has been updated since receiving your packet, you will be inspected based upon the Checklists that were mailed. If you have any questions about the use of Checklists in the inspection process, please e-mail the CAP (accred@cap.org), or call (800) 323-4040, ext. 6065.

RSM.1.1 - The qualifications required for the position of laboratory director

- **Provides consultations about the medical significance of clinical laboratory data. Interpret, correlate, and communicate laboratory data to clinical requestors.**
- **Provides consultations to physicians regarding the medical significance of laboratory findings as appropriate.**
- **As applicable, serves as an active member of the medical staff for those facilities served.**
- **Relates and functions effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the medical community, the medical device industry, and the patient population served.**
- **Defines, implements, and monitors standards of performance in quality control, quality improvement, and cost-effectiveness of the pathology and clinical laboratory service(s).**
- **Monitors all work performed in the laboratory to determine that medically reliable data are being generated; correlate laboratory data for diagnosis and patient management.**
- **Assumes responsibility for implementation of the quality management plan. The director and professional laboratory personnel must participate as members of the various quality improvement committees of the institution.**

RSM.1.1 - The qualifications required for the position of laboratory director

- **Ensures that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory.**
- **Performs planning for setting goals and developing and allocating resources appropriate to the medical environment.**
- **Provides effective and efficient administration of the laboratory service including budget planning and control with responsible financial management, in accordance with institutional assignment of such responsibilities.**
- **Provides educational programs for the medical and laboratory staff, and participate in educational programs of the institution.**
- **Plans and directs research and development appropriate to the facility.**
- **Implements a safe laboratory environment in compliance with good practice and applicable regulations.**

RSM.2 – HUMAN RESOURCES

- **The clinical director (or leaders) of the laboratory provides an adequate number of qualified staff.**

“ If there is no worker involvement, there is no quality system. ”

Lloyd Dobyns and
Clare Crawford -Mason,
T*hinking About Quality*

RSM.2.1, 2.2, 2.3, 2.4 – HUMAN RESOURCES

- Employee orientation and competency assessment activities were accomplished through a number of training and measurement of performance once a year.
- Trainings included department policies, job-related tasks, patient safety and Employees Occupational Safety and Health Program (EOSHP). During the first year that an individual is performing such patient testing, competency have been assessed every six months.
- Records of documented personnel information including certification or licensure, summary of training and experience, references from previous employers, job description, initial orientation and any retraining, continuing education and achievement, competence evaluations, applicable health records such as immunization status, monitoring for exposure to hazardous chemicals and radiation and untoward incident or accident reports were also maintained for each staff member.

Position: Laboratory Technician

Primary Objective:

- To perform duties associated with all processes and procedures performed within the designated laboratory under the appropriate level of direction of a supervising Scientist and/or Team Leader.
- To ensure that all services are consistently and reliably provided in a manner which satisfies recognised quality standards and customer demand.

Core Competencies

- Assesses and responds effectively to the needs of diverse customers both internal and external, making excellent customer service the first priority. **(Customer Service)**
- Treats others with respect; fosters a cooperative environment where differences and similarities in opinions are encouraged and communicated. **(Diversity)**
- Actively participates in identifying, communicating, and supporting quality improvements that ensure attainment of quality service. **(Performance Improvement)**
- Effectively responds to an emergency that demonstrates proper safety, emergency preparedness, and infection control standards established by CC policy. **(Emergency Procedures)**
- Demonstrates integrity and adheres to Government-wide and HHS Standards of Ethical Conduct, including but not limited to, avoiding conflict of interest, participation in outside activities, political activity, financial disclosure, and use of government resources and equipment. **(Ethics)**
- Positively effects team performance goals by completing his or her fair share of the work. Complies with team ground rules which include assisting other team members in completing assignments, as necessary or as requested, and fills in where and when needed. **(Teamwork)**
- Completes all mandatory training within the proscribed time frame.

Performance Management Competencies

- Manages own self-development plan for continuing education and professional growth to maintain required competencies and licensure.

- Participates with supervisor in establishing performance plans and provides self-assessment if required.

CLINICAL CHEMISTRY LABORATORY
EMPLOYEE ORIENTATION/COMPETENCY ASSESSMENT CHECKLIST

Part 1: Identifying Information (Typed) DATE:

1. Employee's Name:
2. Position Title: Medical Laboratory Technician
3. Job Description : POC test : UA Multistix/ Chemstrip
4. Organizational Location (Dept/Office/Section): Urinanalysis

Part 2: Signatures

	Rater's Signature/Date	Reviewing Official's Signature/Date	Employee Signature/Date
a. Competencies & Plan Discussed & Developed by Rater & Employee*			
b. Initial Competencies Assessed			
c. Progress Review**			
d. Final Review**			

* Signatures Indicate That Expectations Are Understood
**Discussion and Signatures are Required - Narrative is Optional Except When Performance is Unacceptable

I - INITIAL ORIENTATION (NEW EMPLOYEES)

A- New Employee Orientation program : The New Employee Orientation program is designed to familiarize new staff members with their jobs, the hospital and work-site environment before an employee begin laboratory work and related other activities. This is a mandatory training requirement for all new employees.

	DATE	Training Method	Assessment Method
1. Date attended new employee orientation			
2. Date completed departmental orientation			
3. On the job orientation and training			
4. Evaluate and establish initial competencies			

B- Position/Job Specific Orientation: Supervisor or designated staff member (preceptor) provides new employee orientation and initial training to his/her job responsibilities, reviews position description, establishes and discusses performance standards, competencies, behavioral indicators, training requirements, and the performance evaluation process.

Competency Assessment :	**EMPLOYEE ACK (INITIALS)**	**VALIDATOR CHECK**
1. For initial validation, reads entire Policy/Procedure (SOP)		
2. Completes and passes written test (Passing criteria is 100%)		
3. Performs ONE unknown (patient specimens from Clinical Chemistry)		
a. Observes universal precautions		
b. Checks expiration date of strips		
c. Closes vial of strips after removal of strip for test		
d. Mixes specimen 10 times by inversion		
e. Dips appropriately, blots off excess		
f. Matches up strip to reagent pads successfully		
g. Differentiates between positive vs negative test results		
h. Reads reagent pads correctly - achieves passing grade on unknown		
4. Knows storage requirements of specimen if not immediately dipped and read		
5. Understands quality control requirements		
! CRITICAL POINTS — STAFF PLACES INITIALS BY EACH ONE		
a. Interfering substances: Glucose- High oncentrations of Vitamin C (ascorbic acid) and moderately high amounts of ketones (40 mg/dl) may cause false negatives for specimens containing small amounts of glucose (100 mg/dl).		
b. QC: Two levels of liquid QC must be run and documented every day.		
c. Reading results: Must read pads within indicated times, else blood and glucose may give false positives.		

Is there a documented program to ensure that each person performing POCT maintains satisfactory levels of competence?

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing

2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results

3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records

4. Direct observation of performance of instrument maintenance and function checks, as applicable

5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

6. Evaluation of problem-solving skills

- *Competency must be reassessed at least annually. During the first year that an individual is performing such patient testing, competency must be assessed every six months. It may not be necessary to assess all of the above elements for each individual on an annual basis. The Program Director should identify and incorporate the elements most pertinent to the testing being performed.*
- REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register. 2003(Oct 1):1065-66 [42CFR493.1453] and 1053-4 [42CFR493.1413]; 2) Zaloga GP, et al. Near-patient blood gas and electrolyte analyses are accurate when performed by non-laboratory-trained personnel. J Clin Monit. 1993;9:341-346; 3) Kilgore ML, et al. Continuous quality improvement for point-of-care*

Duties and Responsibilities:

COMPETENCY	KEY OUTPUTS
1. Participate in an ancillary capacity in all processes and procedures performed within the designated Laboratory	Under the appropriate level of supervision and direction as determined by the individuals competency: • Perform functions related to the processing, storage and distribution of donated blood within assessed skill competencies **(Blood Processing Laboratory)** • Perform functions related to the testing of donation and tissue specimens for accreditation purposes within assessed skill competencies **(Donation Accreditation Laboratory)** • Perform functions related to pre-transfusion, antenatal and diagnostic testing and the issue of blood and blood products for clinical purposes within assessed skill competencies **(Blood Bank and Reference Laboratories)** • Perform functions related to transplantation, clinical and diagnostic testing within assessed skill competencies **(Tissue Typing Laboratory)** • Where practical, operate in and move between the various departments of the Laboratory and Manufacturing Services if necessary
2. Develop, provide and maintain a consumer and customer focussed approach to all aspects of the service	• Ensure all services are provided in a consistent and timely fashion to all customers • Ensure all results and products are produced within the appropriate timeframes and reports are authorised where applicable

CLINICAL MICROBIOLOGY REVIEWS, July 2004, p. 681–694

Competency Assessment in the Clinical Microbiology Laboratory

Susan E. Sharp[1]* and B. Laurel Elder[2]

Microbiology COMPETENCY FORM

Bacteriology = Performs/Documents procedures

Competency Assessment documentation form

PLEASE PRINT **Annual** ☐ **Initial** ☐

EMPLOYEE: **EE #:**			**TITLE: Medical Technologist**	**DEPT #:**
VALIDATOR: **EE #:**			**TITLE: Supervisor**	**DEPT #:**
NOTE: This is a representative sampling of the competencies necessary for safe, effective performance.				
K E Y	**HOW COMPETENCY MEASURED:** A. Policy Review B. Direct Observation C. Document Review D. Unknown specimen		**Employee Signature** **Date** **POSSESSES AND DEMONSTRATES THE ABILITIES NECESSARY FOR THE QUALITY PERFORMANCE OF THIS JOB.**	**LEVEL OF COMPETENCE** 1. Little or no experience 2. Some experience (may require practice or assistance) 3. Competent and can perform independently 4. Competent and can perform independently and is able to assess the competency of others.
DATE	**HOW MEASURED**	**VALIDATOR INITIALS**	**COMPETENCIES**	**LEVEL OF COMPETENCE** 1, 2, 3, or 4 **Comments:**
	B or D		• Gram stains from plate and broth	
	B		• Enzymatic tests	
	B		• Chemical tests	
	B or D		• Latex agglutination tests for staphylococcal and streptococcal identification	
	B		• Motility	
	A, B, C or D		• Identification procedures	
	A, B, C or D		• Susceptibility procedures	
	C		• Computer entry and result reporting	
	C		• Stat reporting/calling/documentation	
	C		• Appropriate documentation of all testing	
	A		• Age specific competencies – FQ not reported on children < 16 years old	
	A, B or C		• Can determine when organisms are identified/reported/sensitivity testing done using provided procedures and algorithms.	
	B		• Plate reading	
	C		• Problem solving skill – see attached example provided by employee	

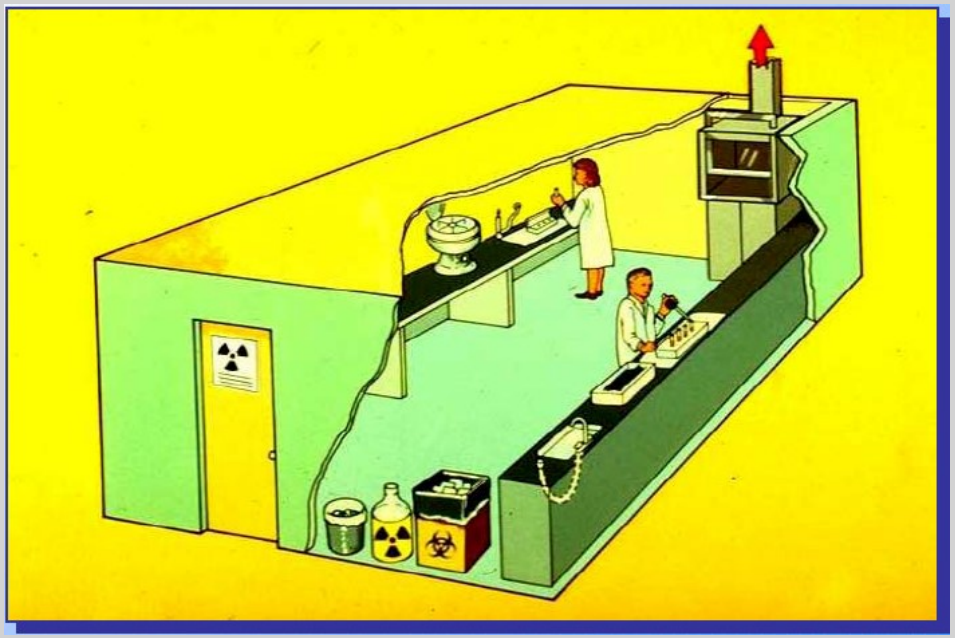
FIG. 1. Example of how the six areas of required CLIA competency assessment can be addressed and documented. FQ, fluoroquinolones.

Date	HOW MEASURED	VALIDATOR INITIALS	COMPETENCIES	LEVEL OF COMPETENCE 1, 2, 3, or 4 Comments:
11/2/03	B or D	JG	• Gram stains from plate and broth	4. Observed tech prepare, stain & read 5 Gram stains from plated media and 3 Gram stains from BHI broths. Stains reviewed = All acceptable.
9/23/03	B	KW	• Enzymatic tests	4. Observed tech perform beta-lactamase, catalase, slide coagulase, oxidase, & PYR test. Asked tech to perform patient and +/- QC. All acceptable.
9/23/03	B	KW	• Chemical tests	4. Observed tech perform bile esculin, bile solubility, 6.5% NaCl, sugar fermentations, hippurate, indole, MIL, & TSI. All acceptable.
7/1/03	B or D	CAS	• Latex agglutination tests for staphylococcal and streptococcal identification	3. Tech worked up 4 lab unknown organisms (S.aureus, coagulase-negative Staphylococcus, Group A Streptococcus; Group G Streptococcus). All acceptable. See attached documentation.
9/23/03	B	KW	• Motility	***2. Observed tech performing mot deep & wet prep motility: deep=acceptable. Didn't do hanging drop wet prep procedure and got a false negative result. Retraining necessary. KW 9/12/03.*** ***3. See attached completed remedial action form. Remedial action acceptable, allowed to perform independent motility testing. KW 10/11/03.***
12/1/03	A, B, C or D	DSL	• Identification procedures	4. Tech reviewed spot identification test policy & signed off. Review of 20 workcards = acceptable IDs performed in each case. Tech also performed 2 CAP unknowns = S.marcescens & N.meningitidis = acceptable. See attached documentation of CAP work up.

FIG. 2. Example of how the assessment form can be used for documentation of competency.

RSM.3 – INFRASTRUCTURE – BASIC FACILITIES

- **Basic facilities, including adequate space, utilities, and equipment are sufficient for the efficient and safe performance of laboratory work.**

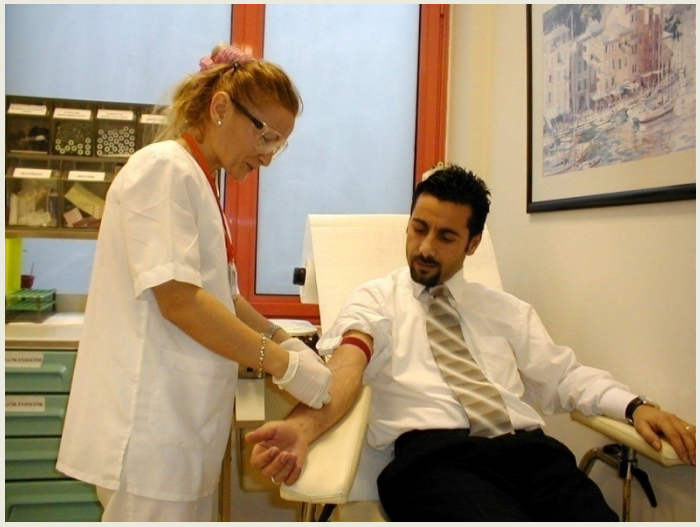


Quality is never an accident; it is always the result of intelligent effort. ”

John Ruskin, English critic, essayist , & reformer

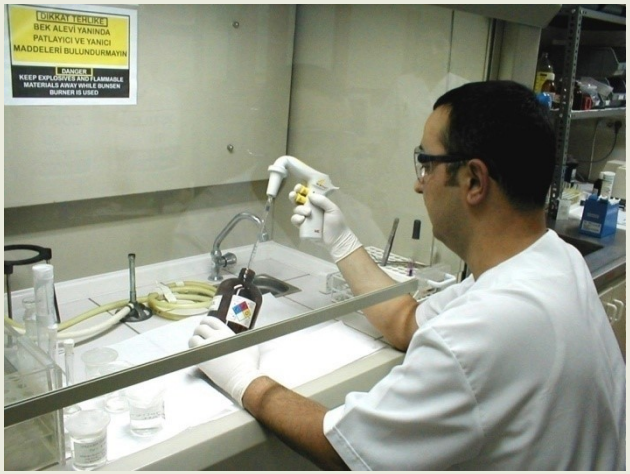
(1819 – 1900)

RSM.3.1, 3.1.1, 3.1.2, 3.1.3
INFRASTRUCTURE – BASIC FACILITIES



- The laboratory facilities were designed and organized to provide adequate space and allow personnel to perform required work with optimal accuracy, precision, efficiency, timeliness and safety.
- Specimen collection facilities were designated to respect patient's privacy, security, comfort, and disabilities.
- Sufficient and appropriate storage space was provided for specimens, reagents, control materials, equipment, laboratory supplies, manuals, slides, histology blocks, and files.
- A policy covering security issues concerning patients, visitors, other customers, personnel, and property. was established.

RSM.3.1.4 – INFRASTRUCTURE – BASIC FACILITIES



•Manufacturer or other authoritative storage requirements were met, such as for temperature, ventilation and humidity.

•Storage areas were kept clean and well maintained. Utilities and environmental conditions were adequate for the types of procedures and workload of the laboratory.

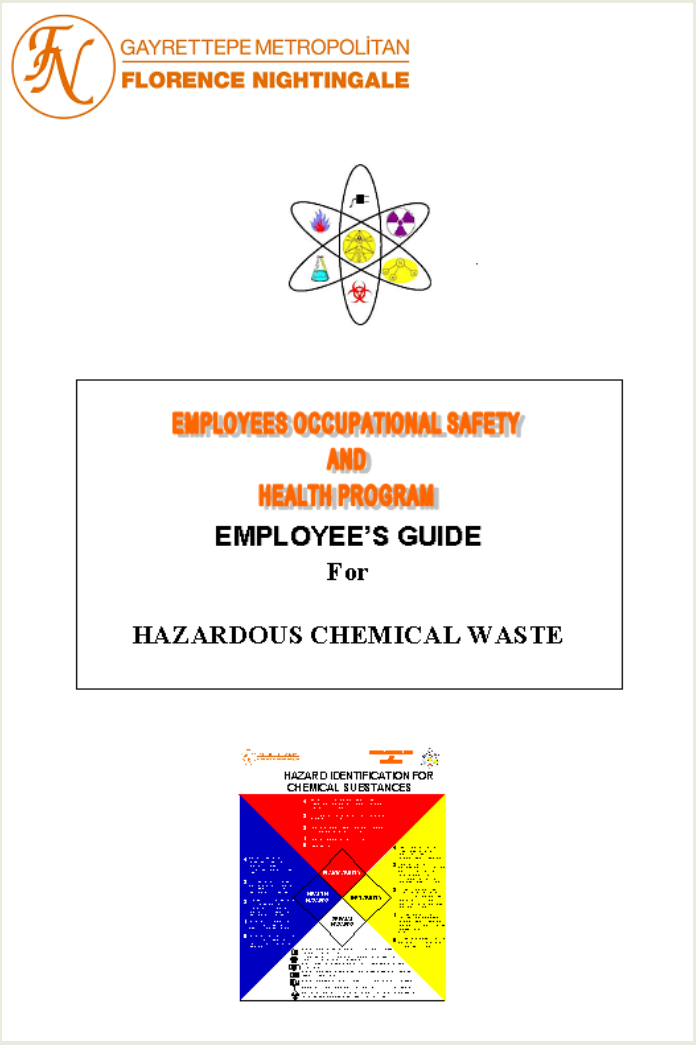
•The following were provided, and were adequate:

Biological safety cabinets and chemical fume hoods;
Water taps, sinks, and drains;
Stable electrical power;
Grounded electrical outlets;
Control of ventilation;
Temperature control;
Appropriate humidity; and
Telephones.

RSM.3.2, 3.3 – INFRASTRUCTURE – BASIC FACILITIES

- Emergency power, when required for the services provided to supply electricity to the critical areas (including the following) when there is interruption in the normal power supply:
  - blood, bone, and tissue storage units;
  - essential refrigeration and heating (for example, designated refrigerators, freezers, and incubators); and
  - essential equipment, for example stat equipment such as a blood gas instrument.
- Emergency lighting for safe evacuation of the laboratory;
- Suction; and
- Gas supplies.
- The laboratory has a system in place to monitor, control, record and maintain environmental conditions and supporting utilities in order to reduce adverse effects on testing accuracy, efficiency, and timeliness, as well as personnel and patient comfort.
- There is a plan to provide security for laboratory services and facilities. The plan includes controlling access to and use of areas affecting the quality of test results, and safeguarding specimens and resources from unauthorized access. The plan addresses security issues concerning patients, visitors, other customers, personnel, and property. Equipment (software and hardware), reference materials, consumables, reagents, and analytical systems are safeguarded from adjustments or tampering which would invalidate test results.

RSM.3.4 – INFRASTRUCTURE – BASIC FACILITIES

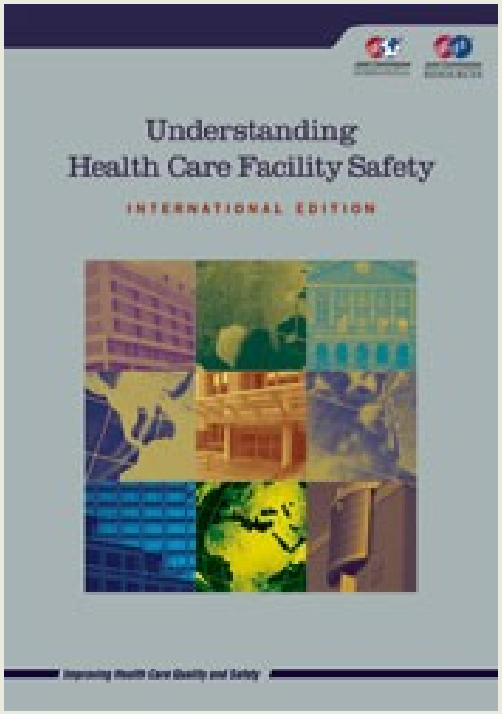


- An Employees Occupational Safety and Health Program (EOSHP) was developed to address inventory, handling, storage, and use of hazardous materials, and the control and disposal of hazardous wastes. Safety policies and procedures has been in place for the following:
- Biohazardous or infectious waste, including sharps;
- Hazardous chemicals and waste;
- Chemotherapeutic materials and waste;
- Radioactive materials and waste; and
- Hazardous gases and vapors.

RSM.3.4.1 – INFRASTRUCTURE – BASIC FACILITIES

- The EOSHP has put a system in place that employees have both the right and the need to know about the hazards they are exposed to while working and the identities of the chemicals that pose the hazard.
- The implementation of EOSHP comprised:
  - the establishment of a Chemical Hygiene Plan,
  - description of a Hazard Communication Quality Standard (HCQS),
  - development an Employee's Guide to Handle the Hazardous Chemicals to assist the laboratory staff in complying with the EOSHP HCQS,
  - identification of the Staff who will be responsible for the initial set up of the EOSHP and the day-to-day activities necessary to comply with each aspect of the HCQS,
  - construction an inventory of all hazardous chemicals used in the laboratory and
  - a written list comprising the hazard descriptions of chemicals.

- Our project was introduced as a reference case and published in the source book entitled "Understanding Health Care Facility Safety" by Joint Commission



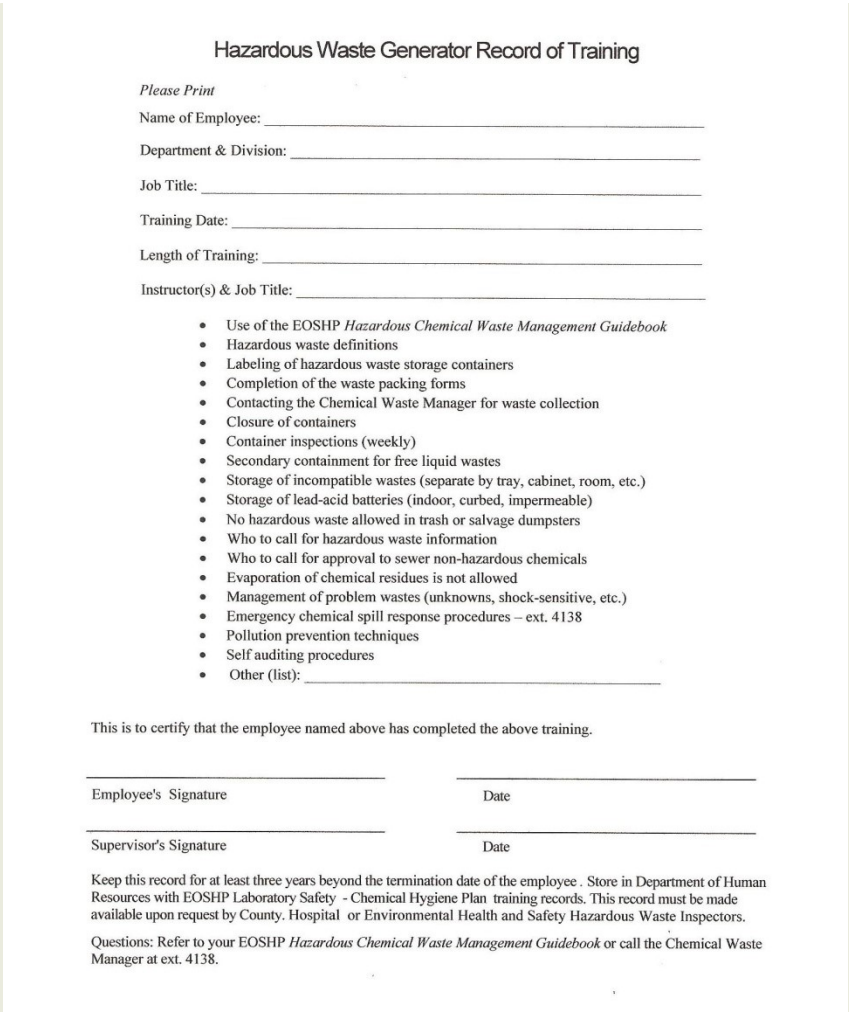
http://store.jcrinc.com/JCRStore/DetailsAction.do

Lab Safety Training

- Lab Safety Training to meet requirements for those working with chemicals, hazardous waste, and bloodborne pathogens. This training has been offered regularly.
  - Chemical Safety and Hazardous Waste
  - Biological Materials
- Biological material training is required for work with:
  - human blood;
  - human body fluids (such as spinal fluid, synovial fluid, vaginal fluid, sperm);
  - human cells;
  - and/or infectious agents (such as viruses, bacteria, fungi, rickettsia)
- Lab Safety Training is a comprehensive course that covers the following topics:
  - understanding and planning for chemical safety;
  - the proper handling of hazardous waste;
  - and safely working with biological materials.

RSM.3.4.2 – INFRASTRUCTURE – BASIC FACILITIES

- A Laboratory Waste Management program was established to safely control hazardous chemical and biological waste from receipt or generation through use or final disposal in the laboratory.
- Orientation training included hazardous waste management .



Hazardous Waste Generator Record of Training

Please Print

Name of Employee: _____

Department & Division: _____

Job Title: _____

Training Date: _____

Length of Training: _____

Instructor(s) & Job Title: _____

- Use of the EOSHP *Hazardous Chemical Waste Management Guidebook*
- Hazardous waste definitions
- Labeling of hazardous waste storage containers
- Completion of the waste packing forms
- Contacting the Chemical Waste Manager for waste collection
- Closure of containers
- Container inspections (weekly)
- Secondary containment for free liquid wastes
- Storage of incompatible wastes (separate by tray, cabinet, room, etc.)
- Storage of lead-acid batteries (indoor, curbed, impermeable)
- No hazardous waste allowed in trash or salvage dumpsters
- Who to call for hazardous waste information
- Who to call for approval to sewer non-hazardous chemicals
- Evaporation of chemical residues is not allowed
- Management of problem wastes (unknowns, shock-sensitive, etc.)
- Emergency chemical spill response procedures – ext. 4138
- Pollution prevention techniques
- Self auditing procedures
- Other (list): _____

This is to certify that the employee named above has completed the above training.

_____ _____

Employee's Signature Date

_____ _____

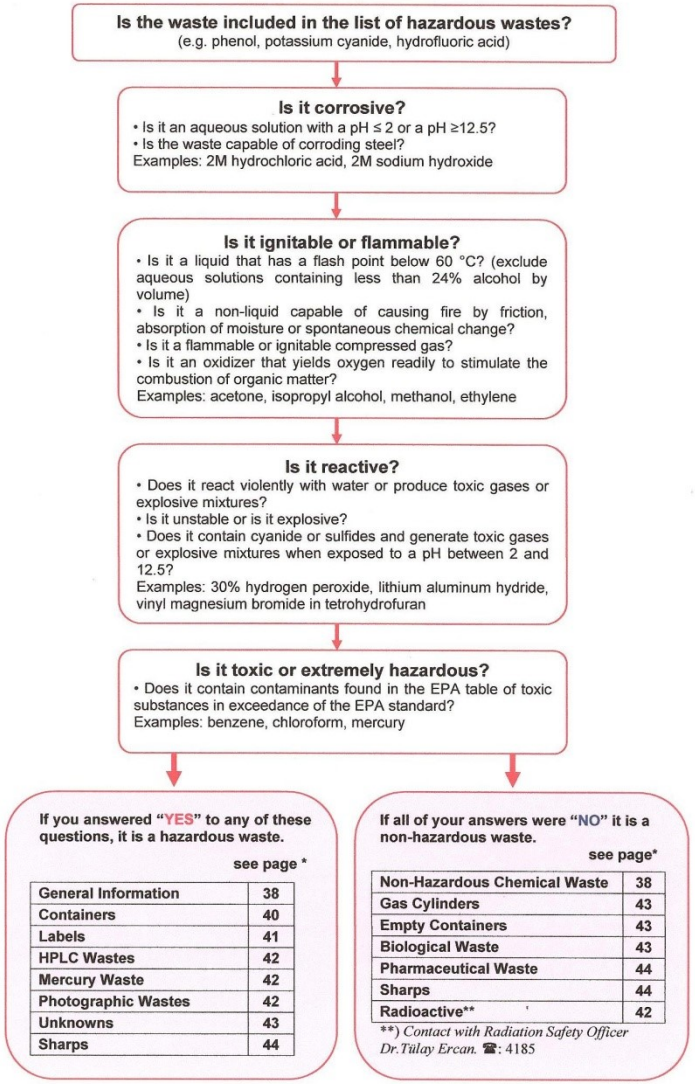
Supervisor's Signature Date

Keep this record for at least three years beyond the termination date of the employee . Store in Department of Human Resources with EOSHP Laboratory Safety - Chemical Hygiene Plan training records. This record must be made available upon request by County. Hospital or Environmental Health and Safety Hazardous Waste Inspectors.

Questions: Refer to your EOSHP *Hazardous Chemical Waste Management Guidebook* or call the Chemical Waste Manager at ext. 4138.

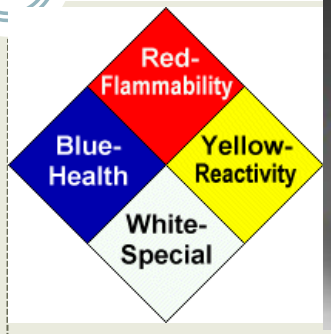
RSM.3.4.2 – INFRASTRUCTURE – BASIC FACILITIES

- Chemical waste was characterized as non-hazardous or hazardous in accordance with the rules and regulations specified by OSHA (The federal Occupational Safety and Health Administration, USA) . With this regard, a substance, which exhibits one of the four hazardous characteristics (corrosivity, ignitability, reactivity, toxicity), was delineated as Hazardous Chemical Waste. Chemical waste that does not exhibit any of the hazardous characteristics as defined above was considered non-hazardous chemical waste (TOKA, in Turkish). Any waste that is potentially biohazardous, infectious, or pathological was described as Biological Waste. A Waste Characterization Checklist was developed to determine whether the waste is hazardous or non-hazardous.

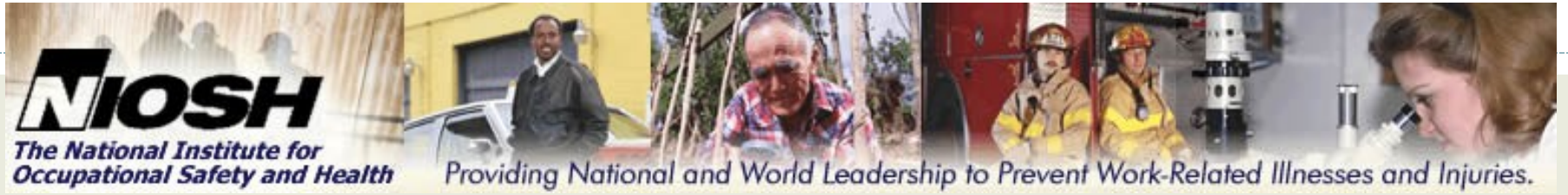


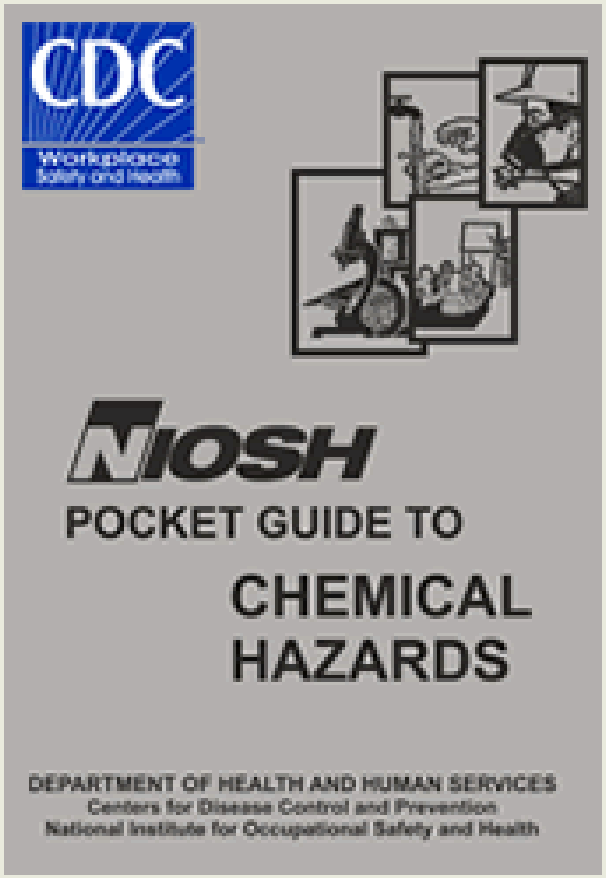
RSM.3.4.2 – INFRASTRUCTURE – BASIC FACILITIES

- Hazard symbols and classifications were delineated based on the guidelines of NFPA (National Fire Protection Association, USA).
- In compliance with the EOSHP HCQS, the Material Safety Data Sheets (MSDS) for the specific hazardous products or chemicals were provided.
- Appropriate signs and labels were prepared as hazard warnings to convey the hazardous effects of the materials.
- Safety equipments were acquired to ensure the protection of laboratory staff .
- Guidelines were determined in the event of a chemical spill, incident, or leak from a sealed container.



Department of Health and Human Services
Centers for Disease Control & Prevention





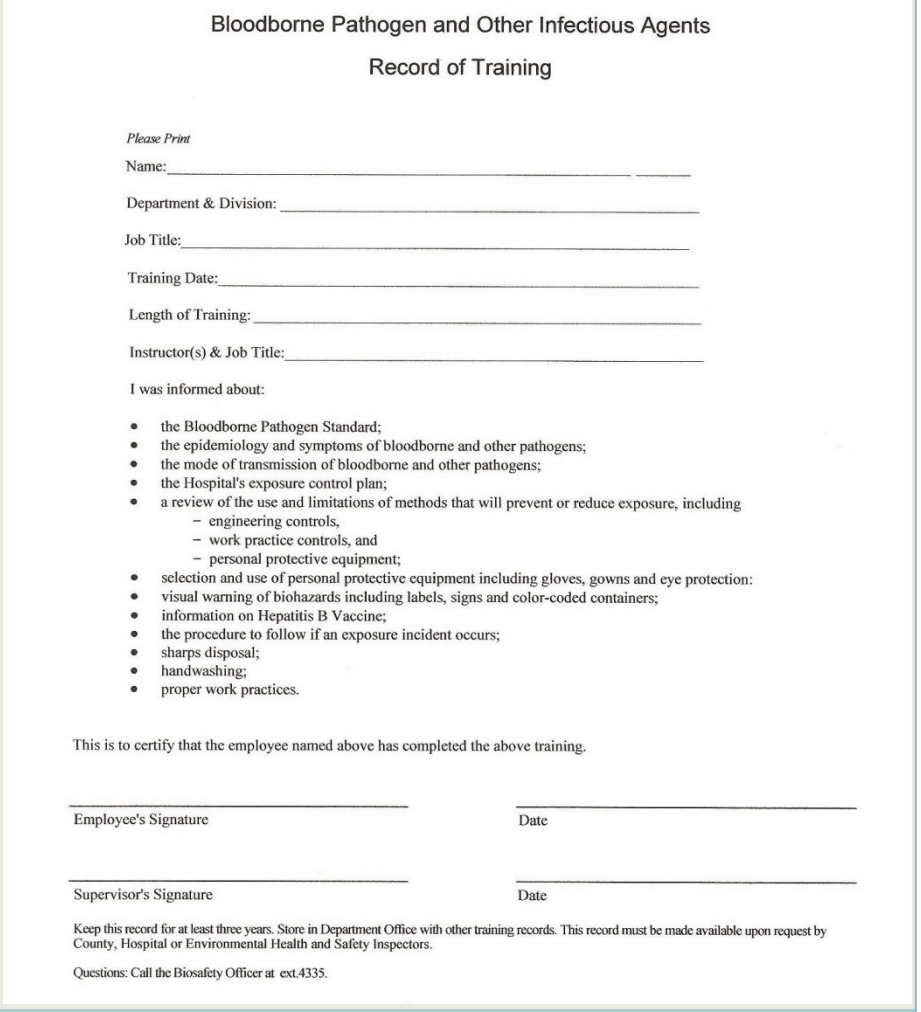
The *NIOSH Pocket Guide to Chemical Hazards provides a concise source of general industrial hygiene information for workers, employers, and occupational health professionals. The Pocket Guide presents key information and data in abbreviated tabular form for 677 chemicals or substance groupings commonly found in the work environment (e.g., manganese compounds, tellurium compounds, inorganic tin compounds, etc.). The industrial hygiene information found in the Pocket Guide assists users to recognize and control occupational chemical hazards. The chemicals or substances contained in this revision include all substances for which the National Institute for Occupational Safety and Health (NIOSH) has recommended exposure limits (RELs) and those with permissible exposure limits (PELs) as found in the Occupational Safety and Health Administration (OSHA) Occupational Safety and Health Standards (29 CFR 1910.1000 – 1052).*

Material Safety Data Sheets

- Canadian Center for Occupational Health and Safety For University of Minnesota staff and students only. Access to MSDS, FTSS, NIOSHTIC, CHEMINFO, HSELINE, and RTECS.
- Chemfinder Sponsored by CambridgeSoft Corp.
- Cornell MSDS Database
- Envirofacts Warehouse Chemical References
- ExToxNet: the Extension Toxicology Network Database of pesticide toxicology information
- Interactive Learning Paradigms Incorporated Internet Resources for MSDS
- Integrated Risk Information System (IRIS) A chemical database maintained by the U.S. Environmental Protection Agency
- Laboratory Chemical Safety Summaries (Prudent Practices)
- MSDS-SEARCH Envirocare International Inc. site
- National Toxicology Program Chemical Health and Safety Data
- New Jersey Right to Know Hazardous Substance Fact Sheets
- Sigma-Aldrich MSDS Requires registration. No fee.
- Oxford University MSDS
- TOXNET TOXNET is a cluster of databases on toxicology, hazardous chemicals, and related areas maintained by the National Library of Medicine.
- Vermont SIRI MSDS collection
- Household Product Database - National Institute of Health

RSM.3.4.2 – INFRASTRUCTURE – BASIC FACILITIES
Preventing Employee Exposure to Bloodborne and Other Pathogens

- Policies, procedures and practices implemented to reduce the hazards of exposure to biohazardous materials. Infections acquired in the laboratory have been reported internally and, when appropriate, to public health agencies.



Bloodborne Pathogen and Other Infectious Agents

Record of Training

Please Print

Name:_____

Department & Division: _____

Job Title:_____

Training Date:_____

Length of Training: _____

Instructor(s) & Job Title:_____

I was informed about:

- the Bloodborne Pathogen Standard;
- the epidemiology and symptoms of bloodborne and other pathogens;
- the mode of transmission of bloodborne and other pathogens;
- the Hospital's exposure control plan;
- a review of the use and limitations of methods that will prevent or reduce exposure, including
  - engineering controls,
  - work practice controls, and
  - personal protective equipment;
- selection and use of personal protective equipment including gloves, gowns and eye protection:
- visual warning of biohazards including labels, signs and color-coded containers;
- information on Hepatitis B Vaccine;
- the procedure to follow if an exposure incident occurs;
- sharps disposal;
- handwashing;
- proper work practices.

This is to certify that the employee named above has completed the above training.

_____ _____

Employee's Signature Date

_____ _____

Supervisor's Signature Date

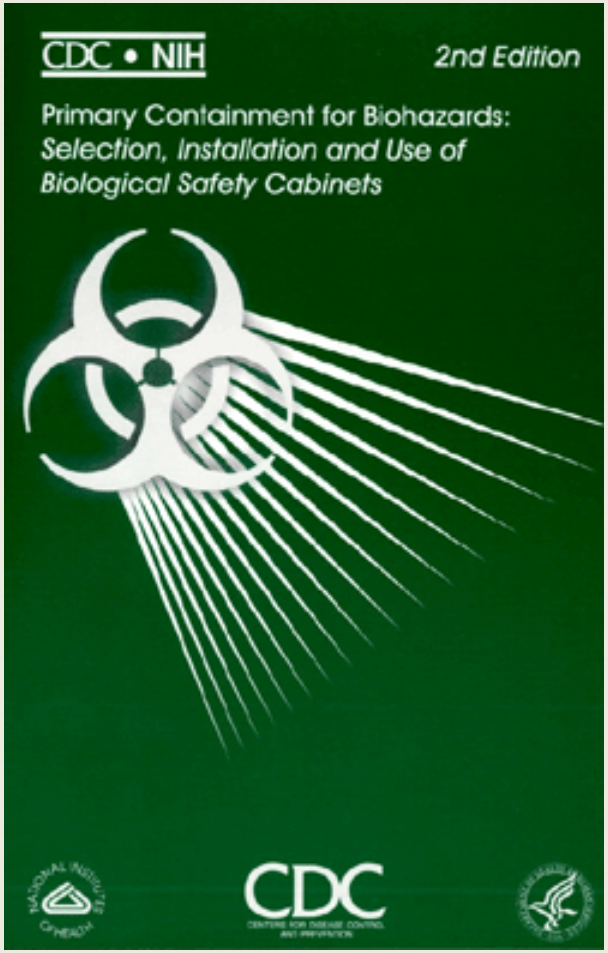
Keep this record for at least three years. Store in Department Office with other training records. This record must be made available upon request by County, Hospital or Environmental Health and Safety Inspectors.

Questions: Call the Biosafety Officer at ext.4335.

Biosafety Resource Links
Biosafety Resources

- Biosafety in Microbiological and Biomedical Laboratories (BMBL)
  CDC/NIH web site provides information on Biosafety Levels 1-4 and the appropriate practices and equipment to use in order to work safely in the laboratory.
  http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm
- Material Safety Data sheets for Biological Materials
  Health Canada provides these MSDS sheets for workers in the life sciences to use as a safety reference for work with infectious microorganisms. To be used in conjunction with the above risk group classifications to determine appropriate biosafety levels and safety precautions.
- Risk Group Classification for Infectious Agents
  This searchable database of international risk group classifications for bacteria, viruses, fungi, and parasites provide information to be used as a starting point for the risk assessment and the determination of the biosafety level to be used when working in the laboratory. For printable version, see American Biological Safety Association web site,
  http://www.absa.org/resriskgroup.html
- Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets
  CDC/NIH publication provides everything you need to know about biological safety cabinets. For information on how to use biological safety cabinets, go to Section 5.
  http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm
- The World Health Organization Laboratory Biosafety Manual, Second Edition 2003
  This document is a good resource for lab safety questions and procedures to incorporate into SOPs. Topics include risk assessment, biosafety cabinets, equipment designed to reduce biological hazards, good microbiological techniques and many more.
- NIH Guidelines for Research Involving Recombinant DNA Molecules
  Responsibilities of the principal investigator can be found in Section IV-B-7. Appendix B contains the Classification of Human Etiologic Agents on the Basis of Hazard (Risk Group Classification). http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

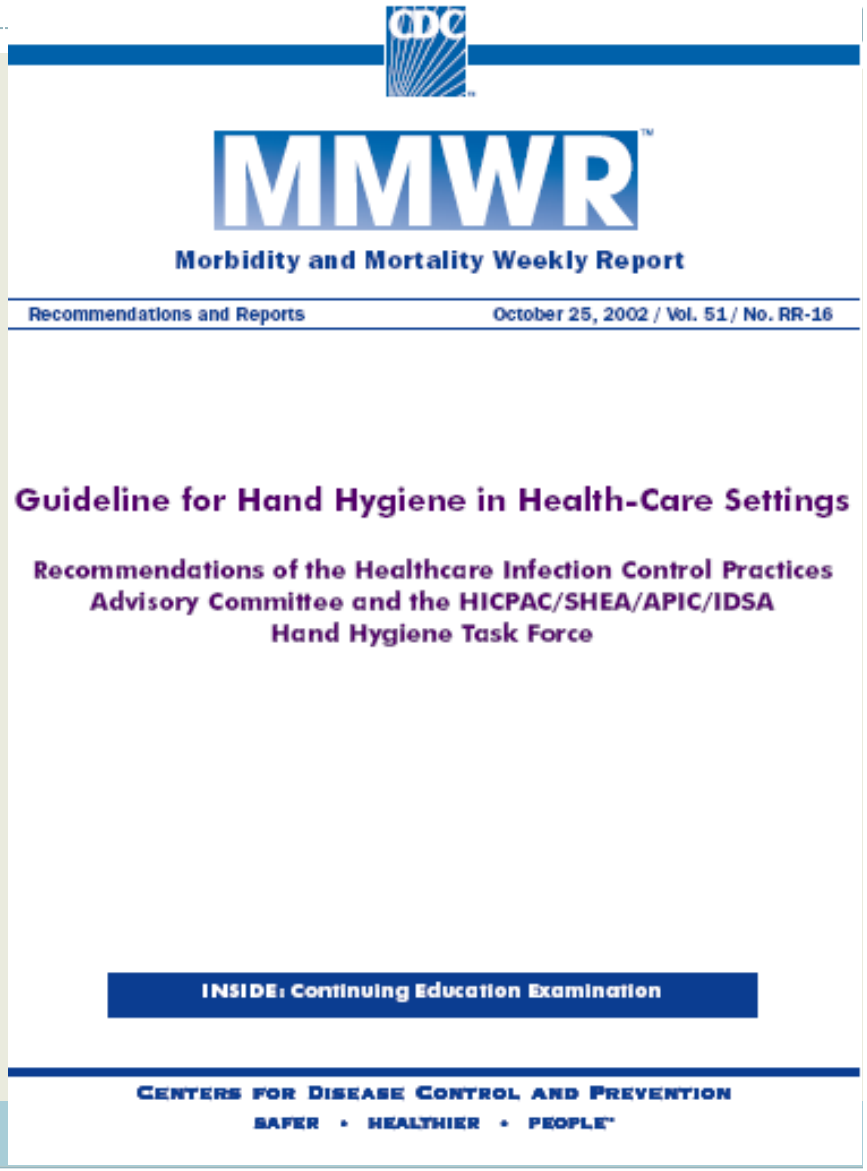
http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm



2nd Edition
Primary Containment for Biohazards:
Selection, Installation and Use of Biological Safety Cabinets

U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention
and
National Institutes of Health
September 2000

http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf



MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports — October 25, 2002 / Vol. 51 / No. RR-16

Guideline for Hand Hygiene in Health-Care Settings

Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force

INSIDE: Continuing Education Examination

CENTERS FOR DISEASE CONTROL AND PREVENTION

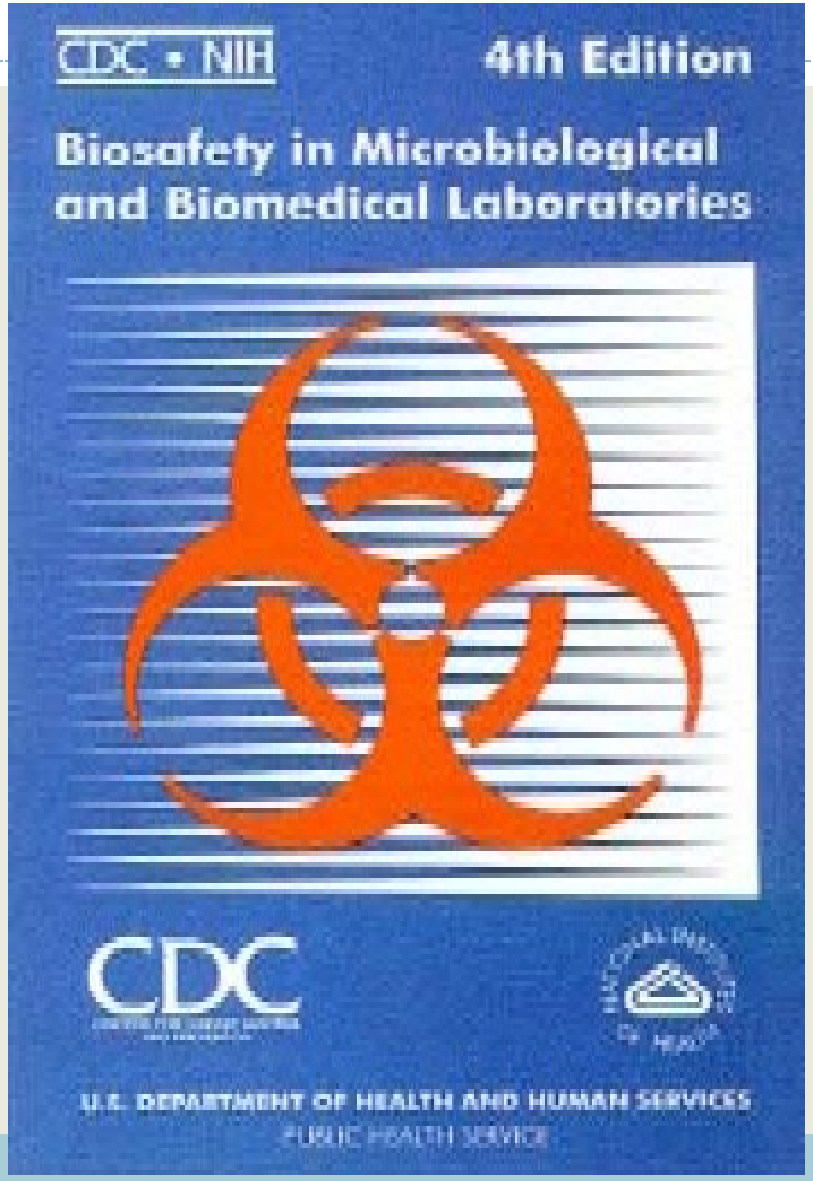
SAFER • HEALTHIER • PEOPLE™

The *MMWR* series of publications is published by the Epidemiology Program Office, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30333.

SUGGESTED CITATION
Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51(No. RR-16):[inclusive page numbers].

CONTENTS

http://www.cdc.gov/



MYCOBACTERIUM TUBERCULOSIS:
ASSESSING YOUR LABORATORY

Developed by
The Association of State and Territorial Public Health Laboratory Directors
and
Public Health Practice Program Office
Division of Laboratory Systems
Centers for Disease Control and Prevention

Technical Reviews by

National Center for Infectious Diseases
National Center for Prevention Services
National Institute for Occupational Safety and Health
Office of Health and Safety
Centers for Disease Control and Prevention

March 1995

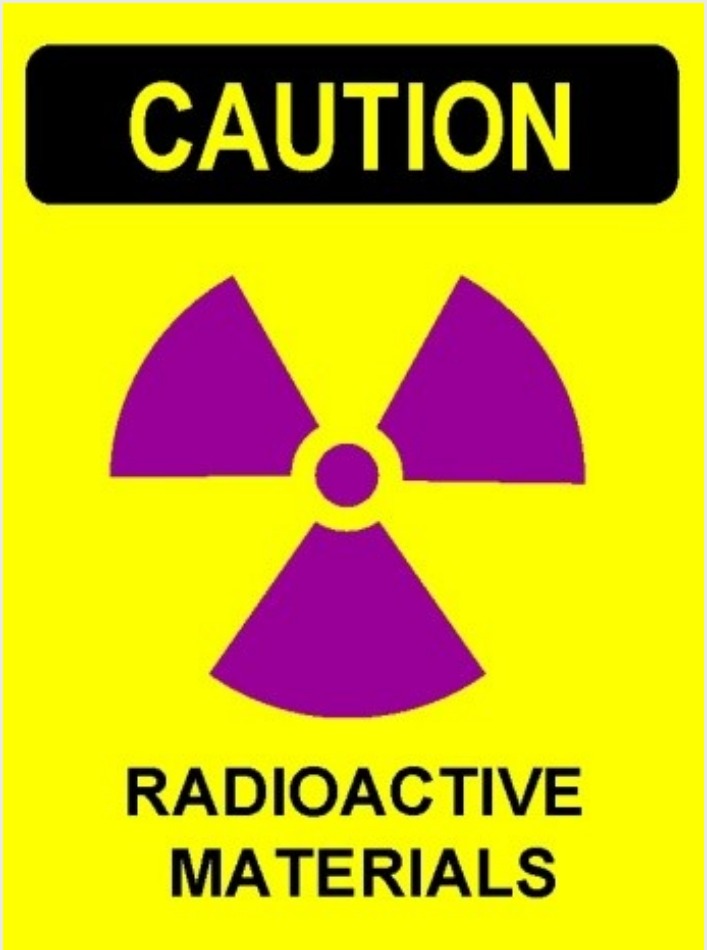
THE ASSOCIATION OF STATE AND TERRITORIAL PUBLIC HEALTH LABORATORY DIRECTORS
AND
U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
Atlanta, Georgia 30333

CDC

•The laboratory has also a plan to control exposure to tuberculosis.

RSM.3.4.3 – INFRASTRUCTURE – BASIC FACILITIES
Radioactive Waste Management in the Lab

- Radioactive waste requires the same security considerations given to other radioactive materials. To achieve these responsibilities, this storage was done within a secured, posted radioactive materials lab. Technical staff have been trained that the volume of radioactive waste generated must be kept to a minimum, and items that are known not to be contaminated with radioactive material should not be placed into a radioactive waste container.
- All procedures and practices for radiation safety complied with law and regulations by Turkish Atomic Energy Authority .



RSM.4 – LABORATORY EQUIPMENT AND OTHER MATERIALS

- Laboratory leaders assure that resources required for the provision of services are adequate and available.
- Such resources include materials required for specimen collection, preparation and processing, testing, reporting, and storage, as well as standardization and quality control of tests.

RSM.4.1 - 4.9 – LABORATORY EQUIPMENT AND OTHER MATERIALS

- The guidelines were generated to perform initial validation for new instruments and analytical systems to verify that the method(s) will produce accurate and reliable results.
- All required verification checks were documented, along with remedial action when instruments or test methods did not meet performance expectations.
- Calibration, calibration verification, function checks, and preventive maintenance were performed on instruments and analytical systems, as needed, and at least according to manufacturers' recommendations.
- Criteria for calibration verification included at changes of reagent lots; when indicated by quality control data; after major maintenance or service; as recommended by the manufacturer and at least every six months.
- A maintenance log for the instruments and analytical systems was kept up to date.
- Procedures were determined to check the validity and quality of reagents and water quality used in laboratory testing.
- Labeling protocols were defined for all reagents, controls, kits, and solutions.
- Processes were defined for validating and maintaining computer software and information.

Are criteria established for calibration verification, and is compliance documented?

NOTE: Criteria typically include:

1. *At changes of reagent lots, unless the user can demonstrate that the use of different lots does not affect the accuracy of patient test results and the range used to report patient test data, or the control value*

2. *When indicated by quality control data*

3. *After major maintenance or service*

4. *As recommended by the manufacturer*

5. *At least every six months*

- REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register. 2003(Jan 24):3707 [42CFR493.1255]; 2) Miller WG. Quality control, In Professional practice in clinical chemistry: a companion text, ed DR Dufour. Washington, DC: AACC Press, 1999:12-1 to 12-22.*

RSM.5 – WORK ENVIRONMENT – LABORATORY SAFETY

- **The laboratory designs a safe, accessible, effective, and efficient environment consistent with its mission, services, and law and regulation.**

RSM.5.1, 5.2, 5.3 – WORK ENVIRONMENT – LABORATORY SAFETY

- The laboratory's safety processes included adequate fire detection and prevention policies.
- Adequate safety devices such as emergency eyewash, safety cans, puncture-resistant containers for discarding all waste sharps, fire extinguishers and blankets were made available and training were provided to all laboratory staff.

Laboratory Safety - Self-Audit

Laboratory Name : _____ Date of Inspection: _____

Department : _____ Inspector/Auditor Name: _____

Responsible party : _____

Y or N	ITEM
	1. LAB SIGNS
	a. Primary & second contracts posted with phones
	b. Warning & restriction signs (rad, carcinogen, biohaz -if needed)
	c. Emergency phone numbers posted in lab
	d. Emergency action plan/procedures - available & up to date
	2. SAFETY EQUIPMENT
	a. Fire extinguisher available (within max 20 m)
	1. Unobstructed & mounted at designated location (1 m top)
	2. Extinguisher has annual inspection, sealed, and charged
	3. Appropriate extinguisher for hazard (Class A, B, C, or D)
	b. MSDS's available in lab or other central location
	c. Eyewash present (within 15 m or 10 sec travel)
	1. Unobstructed
	2. Checked/tested within past month (record tag)
	d. First Aid kit available & marked
	1. Stocked, up to date
	e. Exit signs & emergency lighting operating (if needed)
	3. PROTECTIVE CLOTHING (PPE)
	a. PPE (eyewear, gloves, smock) readily available in lab
	b. Proper eye protection use (safety glasses/goggles/face shield)
	c. Visitor glasses readily available
	d. Proper chemical resistant/heat resistant/cryogenic gloves
	e. No shorts/skirts/sandals/cosmetics (when chems in use)
	f. Rubber apron available (if concentrated acid/base)
	4. GENERAL HAZARDS
	a. Walkways & doors unobstructed
	b. Adequate lighting and switches
	c. Excess trash, boxes, & paper removed promptly
	d. No eating, drinking, smoking or food storage in lab
	5. SPILL PROCEDURE
	a. Spill kit available - proper size & type
	b. Spill procedures established - written & available
	6. ELECTRICAL
	a. Proper power cord use (good housekeeping, no trip hazard)
	1. Extension cords- temp, use, single only (no daisy chains)
	2. Powerstrips (w/surge protection)- computer equip, only
	3. No cording through walls, floors or ceiling
	b. Electrical cords not frayed & good insulation
	c. 3-pronged plugs not altered
	d. GFCI (Ground Fault Circuit Interrupter) near sinks / rubber mats on floors in wet areas
	e. Electrical panels and disconnects unobstructed
	7. GAS CYLINDERS
	a. Properly secured (individual chain/cable recommended)
	b. Storage bottle with empty or full labels
	c. Cylinder labeled as to contents
	d. Caps on cylinders not in use

Y or N	ITEM
	8. REFRIGERATOR/FREEZER
	a. "No Food or Drink" sign
	b. Food/drink not stored in unit
	c. Flammables stored in approved flammables refrigerator
	d. "Food or Drink Only" sign in separate refrigerator
	9. CHEMICAL STORAGE
	a. Chemicals stored by reactive class (flamm, acids, bases, etc.)
	b. Incompatible chemicals physically separated
	c. Chemicals properly labeled (original or secondary label inplace)
	1. Secondary containers w/ NFPA labels (filled in correctly)
	2. Storage areas labeled with hazard &/or NFPA placard
	e. Special labels & storage (carcinogens, biohaz or acute toxics)
	f. Acids/corrosives/solvents stored in compatible trays
	g. No excess chems on bench tops/in fiime hoods/under sinks
	h. Flammable &/or corrosive cabinets available (if needed)
	10. UNSTABLES/EXPLOSIVES
	a. Marked with receipt & open dates
	b. Peroxide formers have required disposal date
	11. WASTE CHEMICALS
	a. Waste form complete & located on container
	b. Containers closed (second containment if needed)
	12. VENTILATION - HOODS
	a. Exhaust hood & alarm (if approp.) working
	1. Annual inspection sticker within year (80-120 fpm)
	2. Sash kept 2/3 closed except for adjustment
	b. Cert, biosafety hood in use for BSL2 (Laboratory Biosafety Level 2)
	c. Hood housekeeping - properly maintained, no excess storage
	13. MECHANICAL
	a. Belts, pulley drives, rotating parts guarded
	b. Stop switch is easily accessible
	c. Equipment is secured (i.e., bolted to floor)
	d. Electrical disconnect unobstructed
	e. Unattended operating equipment labeled
	14. CHEMICAL INVENTORY
	a. Annual inventory -available at EOSHP* office
	1. Up to date and complete
	2. Copy to EOSHP* coordinator within year
	b. MSDS readily available for all chemicals (within 10 minutes)
	15. TRAINING
	a. HazCom Training - training docs & users understand regs.
	b. Lab Standard - training docs & users understand CHP (Chemical Hygiene Plan)
	1. Departmental Chemical Hygiene Officer (designated)
	2. Chemical Hygiene Plan (available, current)
	c. Annual Bloodborne Training (if approp.) - documentation
	1. Exposure control plan (available, up to date)
	d. Hazardous waste training (if regular waste stream)
	e. Radiation, Laser, & other training as appropriate

*) Employees Occupational Safety and Health Program

NOTES : _____

RSM.5.1, 5.2, 5.3 – WORK ENVIRONMENT – LABORATORY SAFETY

The laboratory's safety processes provide a physical environment where hazards are controlled and personnel activities are managed to reduce the risk of injuries.

There is provision for:

- Conducting risk assessment that proactively evaluates the impact of buildings, grounds, equipment, occupants, and internal physical systems on patient and personnel safety.

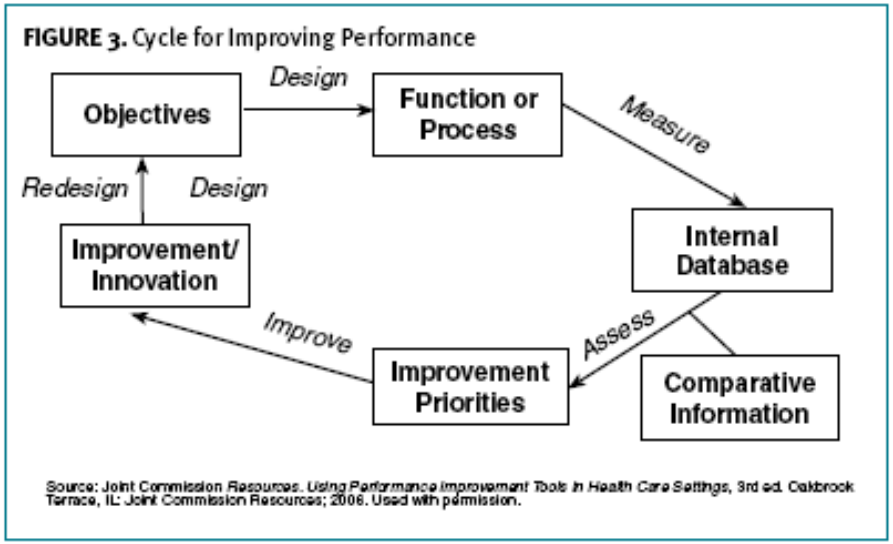
2008 LABORATORY ACCREDITATION STANDARDS (LAS)

- **Item: LSM08**
- **Description:** 2008. 464 pages. ISBN: 978-1-59940-132-4

  Now includes scoring information!
- The *2008 Laboratory Accreditation Standards (LAS)* is an easy-to use guide to all the lab standards, rationales, and elements of performance.

CONCLUSIONS

- Resource management by JCI applies to many aspects of quality management including personnel, basic facilities, equipment, security and safety.
- Preparation is key to the success of a resource management program. A program that includes management commitment, effective training, regular audits of critical functions to identify potential problems, implementation of corrective action and establishment of priorities for improvement benefits the laboratory in many ways.



“ Quality is the result of a carefully constructed cultural environment. It has to be the fabric of the organization, not part of the fabric. ”

Philip Crosby ,
Reflections on Quality