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Implementing a resource management program for accreditation process at the medical laboratory

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Abstract

Objectives: To plan for and provide adequate resources to meet the mission and goals of a medical laboratory in compliance with the requirements for laboratory accreditation by Joint Commission International.

Design and methods: The related policies and procedures were developed based on standard requirements for resource management.

Results: Competency assessment provided continuing education and performance feedback to laboratory employees. Laboratory areas were designed for the efficient and safe performance of laboratory work. A physical environment was built up where hazards were controlled and personnel activities were managed to reduce the risk of injuries. An Employees Occupational Safety and Health Program (EOSHP) was developed to address all types of hazardous materials and wastes. Guidelines were defined to verify that the methods would produce accurate and reliable results.

Conclusions: An active resource management program will be an effective way of assuring that systems are in control and continuous improvement is in progress.

Keywords: Laboratory accreditation; Resource management; Competency assessment; Method validation; Laboratory safety; Hazard management; Biosafety

Introduction

The Laboratory Accreditation Program from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is one of the most widely used CMS-approved accreditation program. Since 1995, clinical laboratories surveyed using JCAHO standards have been deemed to be certifiable under CLIA '88 requirements. The purpose of CLIA '88 is to ensure that all laboratory testing, wherever performed, is done accurately and according to good scientific practices and to provide assurance to the public that access to safe, accurate laboratory testing is available [1]. The current JCAHO laboratory standards include resource provision and management and mandate that the laboratory leaders plan for and provide adequate resources to meet the mission and goals of the laboratory (Joint Commission on Accreditation of Health Care Organizations, 2003, 2004 Laboratory Standards: http://www.jcaho.org). 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 planning process by lab leaders needs to address the ability to provide these and other resources, as required. There should also be adequate education to appropriate staff about the quality management system plan and implementation. This communication delineates an execution of resource management (RSM) program and some quality assurance tools that have been developed in our laboratory to comply with the requirements for laboratory accreditation by Joint Commission International (JCI) [2].

Methods

The objectives of this work were developed in accordance with the mission of the hospital, the objectives of our laboratory, any

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applicable laws or regulations and all relevant accreditation standards. The related policies and procedures were developed to provide guidance for workers when implementing the process. The policies were generated based on standard requirements for resource provision and management by JCI [2]. Table 1 outlines the descriptions and intents of those pertinent standards.

Results

RSM.1 — RSM.1.1

The qualifications and responsibilities of laboratory personnel included the requirements of CLIA relating to competency assessments in the clinical laboratory [3–5]. Table 2 summarizes the requirements for laboratory director.

RSM.2 — RSM.2.1, 2.2, 2.3, 2.4

Employee orientation and competency assessment activities were accomplished through a number of training and measurement of performance once a year [6,7]. Trainings included department policies, job-related tasks, patient safety and

Table 2
Summary of responsibilities of laboratory director [a]

Ensure that prior to testing patient's specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.
Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical, and post-analytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.
Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the pre-analytical, analytical, and post-analytical phases of testing. This should identify which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results."

[a] Qualifications are described in CLIA'88 under Subpart M – Personnel for Nonwaived Testing §493.1351-§493.1495. A complete description of the requirement is located at http://www.cms.hhs.gov/clia or http://www.phppo.cdc/clia.

Table 1
Joint Commission International standards regarding resource management

Standard no.	Standard	Explanation
RSM.1	The leaders determine and provide adequate resources, support laboratory employees and to implement, maintain and improve the quality management program.	After planning for the services provided, the laboratory leaders are responsible for providing adequate, appropriately trained staff and other resources to meet the goals of the laboratory and to meet customer needs. In addition, appropriate resources are provided for the maintenance and improvement of the quality management system. These include the following: • Staff trained to participate in the program • Adequate time is allotted for staff to participate in the various aspects of the quality management system, as required by their job responsibilities. • Information system and data management processes required for the quality management system.
RSM.2	The clinical director (or leaders) of the laboratory provides an adequate number of qualified staff.	The number and qualifications of all staff, including the director and managers are appropriate to the laboratory's services. Required job qualifications are defined for all laboratory staff positions, as well as job expectations. Required qualifications are at least as stringent as applicable law and regulation. An adequate number of technical and support staff are provided for all required functions. There is also provision for an adequate number of supervisory staff with training and experience to oversee laboratory testing and reporting activities.
RSM.3	Basic facilities, including adequate space, utilities, and equipment are sufficient for the efficient and safe performance of laboratory work.	The laboratory can provide consistent test results of acceptable quality only when there is provision of appropriate facilities the laboratory environment. These include adequate buildings, space within the laboratory, appropriate utilities, and supplies and equipment for performance of laboratory tests. In addition, communication systems within the laboratory and between the laboratory and customers are adequate for the size and complexity of the organization, and for the efficient transfer of information and messages.
RSM.4	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, examination, and storage, such as • Laboratory instruments; • Reagents; • Consumables; and • Analytical systems.	Adequate resources must be provided for the laboratory to meet goals and customer requirements. The laboratory director is responsible for defining the process of selecting and using equipment, reagents, and other supplies that affect the quality of services. As part of this process, the director defines performance criteria for test methodologies, equipment, and quality control. Criteria are also defined for the inspection, acceptability, and storage of consumable materials.
RSM.5	The laboratory designs a safe, accessible, effective, and efficient environment consistent with its mission, services, and law and regulation.	Laboratory leaders address safety. Adequate safety devices are provided.

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 [8–15]. Fig. 1 shows a checklist developed in our laboratory to assess the competency of a medical laboratory technician who performs point of care (POC) urinalysis.

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.		

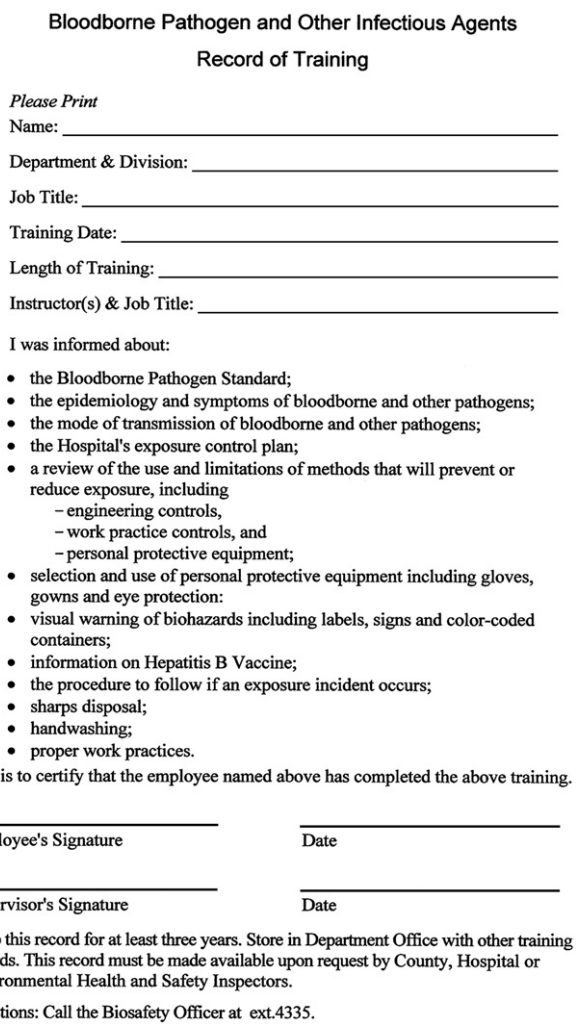
Fig. 1. An employee competency and assessment checklist to assess the competency of a medical laboratory technician who performs point of care (POC) urinalysis.

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.

RSM.3 — RSM.3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.3, 3.4, 3.4.1, 3.4.2, 3.4.3

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. Manufacturer or other authoritative storage requirements were met, such as for temperature, ventilation and humidity. Storage areas were kept clean and well maintained. A policy covering security issues concerning patients, visitors, other customers, personnel, and property was established.

An Employees Occupational Safety and Health Program (EOSHP) was developed to address all types of hazardous materials and wastes [16]. This project was introduced as a reference case and published in the source book entitled "Understanding Health Care Facility Safety" by Joint Commission [17]. The EOSHP has put a system in place that lets employees know about the hazards they are exposed to while working and the identities of the chemicals that pose the hazard. It is the right and the need of employees to know these things. It is essential to communicate the hazard information and protective measures required to use these chemicals safely to exposed or potentially exposed employees who may use the chemicals. The implementation of EOSHP is comprised of the establishment of a Chemical Hygiene Plan, description of a Hazard Communication Quality Standard (HCQS), development of 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, preparation of an inventory of all hazardous chemicals used in the laboratory and a written list comprising the hazard descriptions of chemicals. Hazard symbols and classifications were delineated based on the guidelines of NFPA (National Fire Protection Association, USA) [18]. In compliance with the EOSHP HCQS, the Material Safety Data Sheets (MSDS) for the specific hazardous products or chemicals were provided. A guide was published to explain the terms and definitions in the MSDS. Appropriate signs and labels were prepared as hazard warnings to convey the hazardous effects of the materials. Labeling guidelines were published. Storage conditions and groups were identified for chemical substances. Special areas and cabinets were designated based on the hazard identifications. Safety equipments were acquired to ensure the protection of laboratory staff [19]. Guidelines were determined in the event of a chemical spill, incident, or leak from a sealed container. Initial and refresher trainings were provided to all laboratory staff. A copy of the Employee's Guide to Handle the Hazardous Chemicals was handed out as training source document. The primary policies for managing biological hazards defined the mechanisms for controlling exposures to biological materials in the workplace and included the bloodborne pathogens and exposure plan (Fig. 2) [20–24]. The related policies and procedures for handling biohazardous materials were developed to provide guidance for worker safety when handling or being exposed to biological agents and included in the new employee orientation and annual update training programs [25,26]. The administration and oversight of patient exposures to and infection with biological agents is the primary responsibility of our Hospital Infection Control Unit. Assessments of risk for the biological safety management activities were accomplished through a number of audits and data collections on a semi-annual basis. All occupational exposures to or injuries from biological materials were to be reported by employees to the



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.

Fig. 2. Record of training for bloodborne pathogen and other infectious agent.

EOSHP coordinator. Biological safety posters including the information, reporting and reduction of exposures to blood-borne pathogens and tuberculosis [27] were posted in all major areas of the laboratory 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 (Fig. 3). Chemical waste was characterized as non-hazardous or hazardous in accordance with the rules and regulations specified by OSHA (The federal *O*ccupational *S*afety and *H*ealth *A*dministration, USA) [28,29]. In 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 (Fig. 4).

Policies and procedures for managing and handling radioactive materials and waste were well defined. The ALARA program [30] and associated work practices were put in practice to reduce risks to workers by keeping doses well below the limits. All procedures and practices for radiation safety complied with law and regulations by Turkish Atomic Energy Authority [31].

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.

Fig. 3. Hazardous waste generator record of training.

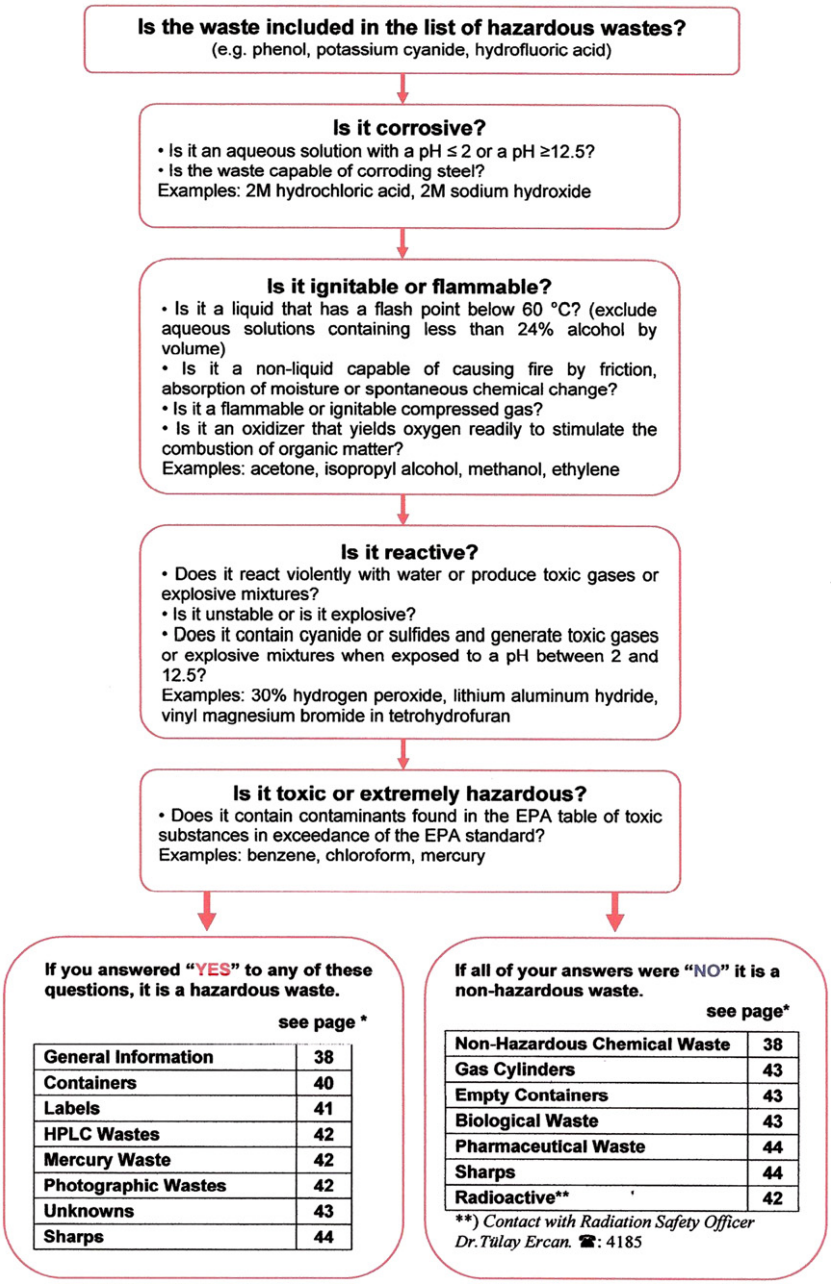


Fig. 4. Waste characterization checklist. Adapted from http://www.uri.edu/safety/old_website/data/LabWasteGuide.pdf.

RSM.4 — RSM.4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9

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 [32–34]. 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 the 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 [35]. A maintenance log for the instruments and analytical systems was kept up to date. The historical records were maintained for each instrument. Detailed records identifying daily, weekly, or monthly performance tests and function checks were retained for at least two years. Records of major repairs, parts replacement, and semiannual or annual calibration checks and preventive maintenance were retained for the life of the instrument. 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.

RSM.5 — RSM.5.1, 5.2, 5.3

Policies and procedures were developed to provide a safe physical environment where hazards are controlled and personnel activities are managed to reduce the risk of injuries [36]. The laboratory's safety processes included adequate fire detection and prevention policies (Fig. 5). Adequate safety devices such as emergency eyewash, safety cans, puncture-resistant containers for discarding all waste sharps [37], fire extinguishers and blankets were made available and training as 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 : _____

Fig. 5. Laboratory safety self-audit checklist.

Discussion

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.

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